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Original Article

Clear film adhesion barrier use at cesarean section: a retrospective analysis

Neha A Deshpande[2], Roberto J Vargas[1,2], Daniela A Carusi[1,2]

[1]Harvard Medical School, Boston, MA, USA; [2]Department of Obstetrics & Gynecology, Brigham and Women's Hospital, Boston, MA, USA

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Abstract: We evaluated the use of a carboxymethylcellulose-hyaluronate adhesion barrier (Seprafilm) at the time of Cesarean section, controlling for severity of adhesions in a racially diverse population. This retrospective cohort study included all women who underwent Cesarean section between the years 2006-2010 and returned for a second pelvic surgical procedure at our tertiary care center. All patients who had a Seprafilm barrier placed at the first (index) Cesarean section were matched on a 2:1 basis to those who received no barrier. Effectiveness and surgical outcomes were compared with Chi Square and Wilcoxon tests. Cofounders were identified and controlled with logistic regression models. The main outcome measures were the location and severity of pelvic adhesions at the follow-up pelvic surgery. Seventy-seven women who had Seprafilm placed at the index delivery were matched to 154 controls who received no barrier. The two groups had similar rates of any dense adhesions (43% and 42% respectively, *P*=.78) and adhesions on the anterior uterus (34% and 31%, *P*=.62) at follow-up. After controlling for all significant confounders, adhesion barrier use did not show a significant decrease in any adhesion formation (aOR=0.79, 95% CI, 0.43-1.45) or anterior uterine dense adhesion formation (aOR=0.88, 95% CI, 0.46-1.65). There were no significant differences in delivery times at follow-up (median 11 minutes in each group, *P*=.54), or in rate of pelvic infection at the index surgery (5% in each group, *P*=1.0). Seprafilm use at Cesarean section was not associated with a significant decrease in dense adhesion formation, operative complications, or delivery time.

Keywords: Surgical adhesions, adhesion barriers, cesarean section

Introduction

One out of three births in the United States is currently performed by Cesarean section, making it the most common surgical procedure in the United States [1]. Like other forms of surgical intervention it can result in the formation of adhesions, with reported incidences ranging from 24-73% [2]. In addition to increased costs to the medical system, adhesions increase the risk of operative complications such as bleeding, accidental enterotomy or cystotomy, and lead to increased operative time [3]. Given these findings, there has been significant interest in the application of synthetic barriers to prevent adhesions.

One such product, the Seprafilm Adhesion Barrier (Genzyme Biosurgery, Framingham, MA) is an absorbent clear film composed of hyaluronate and carboxymethylcellulose. Currently, seprafilm is FDA approved for use at abdominal laparotomy. Its effectiveness in gynecologic surgery was demonstrated by a randomized trial of Seprafilm placement at the time of abdominal uterine myomectomy, which showed an 85% reduction in anterior uterine adhesion formation [4]. More recent data has raised safety concerns regarding the product, with increased rates of bowel anastamosis leak and possibly pelvic abscess [5, 6].

Multiple studies comparing primary and repeat Cesarean sections have documented increased adhesion formation and delayed infant delivery time with repeat delivery, raising the question of whether an adhesion barrier placed at Cesarean section would be efficacious [7, 8]. While the use of Seprafilm at Cesarean section falls within its approved use at laparotomy, its effectiveness and safety remain largely unexplored in this field, and the product's package

insert notes the lack of specific data in pregnancy (http://www.seprafilm.com/SeprafilmPackageInsert.pdf). One recent systematic review reported that using adhesion barriers at Cesarean delivery is currently "ill-advised" due to limited data to support any meaningful clinical benefit [2].

Given the paucity of controlled data for the use of Seprafilm at Cesarean section, this study was designed to evaluate the postoperative course, degree of future adhesive disease, and adhesion-related complications among these patients. We hypothesized that patients receiving Seprafilm would have decreased dense adhesions at the time of future pelvic surgery, similar to the benefit seen with gynecologic surgery.

Materials and methods

This retrospective cohort study was approved by the Institutional Review Boards at Partners Healthcare and Harvard Medical School. Individual informed consent was waived, given anonymous abstraction and removal of identifiers at the conclusion of our data collection.

We identified all patients who had a Seprafilm barrier placed during a Cesarean delivery at Brigham & Women's Hospital between the years 2006-2010, and selected those who returned for a second pelvic surgical procedure. All subjects had a sheet of Seprafilm placed over the anterior uterus. Control subjects were matched to the Seprafilm cohort on a 2:1 basis according to hysterotomy type (low transverse or vertical) and whether the initial surgery was a primary or repeat Cesarean section. We also matched subjects based on the primary attending surgeon. If an exact match by surgeon could not be made within the other two constraints, then a different surgeon from the same practice group was selected. When multiple exact matches were available, we selected controls whose Cesarean section took place in the same year as the Seprafilm subject. Patients who underwent hysterectomy or who had alternative adhesion barriers placed at time of index Cesarean were excluded.

All data were abstracted from operative notes, labor and delivery records, and electronic medical records of patients' first (index) and second surgical procedures. For all subjects, we collected patient demographic data (maternal age, parity, and race) and relevant data from their medical and surgical history. We also collected the basic characteristics of each surgery and complications at the index surgery, including major hemorrhage (blood loss greater than 1200 cc or description of major bleeding requiring operative intervention), visceral organ injury, postoperative ileus or bowel obstruction, infection, and hysterotomy extensions. We also recorded any additional pelvic procedures performed with the index Cesarean section, including any arterial devascularization procedures (uterine artery ligations or embolization). Operative times were obtained from an electronic labor and delivery record.

Our primary outcome of interest was the presence, severity, and location of adhesions at the time of the patient's second surgical procedure. Adhesions at either surgery were characterized based on a previously validated "Adhesion Scoring Data Sheet" as described in Lyell et al [9]. We characterized adhesions as either simple ("filmy", "minimal") or dense ("extensive", "vascular"). Adhesions that altered the surgical approach or required surgical intervention were categorized as dense. The location of the adhesions on the uterus and/or other pelvic structures was noted. Secondary outcomes included occurrence of immediate surgical complications, uterine rupture or scar dehiscence (documented as complete dehiscence, uterine "window", or absent myometrial tissue in the prior uterine scar) at the second surgical procedure, and delivery times with repeat Cesarean section. Delivery time was recorded from the time of initial skin incision. In order to control for individual patient factors that could affect surgical time (such as body habitus or abnormal anatomy), we additionally calculated a "delta-delivery time," defined as the difference (in minutes) between the delivery times at the first and second Cesarean sections.

Statistical analyses were performed using SAS software, Version 9 (Copyright Ó 2002-2008, SAS Institute, Inc). Categorical variables were analyzed with Chi Square or Fisher's Exact tests. Continuous variables were analyzed with Wilcoxon tests for nonparametric data. Univariate analyses were used to define factors associated with adhesion formation and with Seprafilm placement. We then controlled for multiple confounding variables with logistic

Table 1. Patient and operative factors at the time of index surgery

Variable	Seprafilm (n=77)	No barrier (n=154)	*P*-value[a]
Maternal age, years[b]	32.3 (30.2-35.6)	32.9 (30.9-35.6)	.43
Gestational age, weeks[b]	39.1 (38.7-39.6)	39.1 (38.0-40.0)	.89
Nulliparous	43 (56%)	87 (56%)	.92
Number of prior C-sections			.96
0	48 (62%)	95 (62%)	
1	24 (31%)	51 (33%)	
2	4 (5%)	7 (4%)	
3	1 (1%)	1 (1%)	
Race			.12
White	52 (68%)	113 (74%)	.35[c]
Black	16 (21%)	14 (9%)	.01[c]
Hispanic	5 (6%)	11 (7%)	1.0[c]
Asian	4 (5%)	14 (9%)	.43[c]
Not available/Other	0	2 (1%)	
Presence of labor	21 (27%)	63 (41%)	.04
Endometriosis history	3 (4%)	9 (6%)	.76
Fibroid history	16 (21%)	15 (10%)	.02
Type of hysterotomy			.97
Classical	10 (13%)	20 (13%)	
Low vertical	8 (10%)	14 (9%)	
Low transverse	59 (77%)	120 (78%)	
Adhesions present			
None	56 (73%)	127 (83%)	
Any	21 (27%)	27 (18%)	.08
Dense adhesions only	17 (22%)	17 (11%)	.02[d]
Peritoneal closure	16 (21%)	20 (13%)	.12
Estimated blood loss, ml[b]	800 (600-800)	700 (500-800)	.51
Total surgical time, min[b]	50 (42-62)	47 (40-59)	.13
Complications			
Postpartum pelvic Infection	4 (5%)	8 (5%)	1.0
Hysterotomy extensions	12 (16%)	23 (15%)	.90
Major hemorrhage	5 (6%)	10 (6%)	1.0
Vascular or organ injury	1 (1%)	0	.33
Pelvic hematoma	0	1 (1%)	1.0
Devascularization	5 (6%)	0	<.01
Time between surgeries, mos[b]	28.3 (21.9-34.3)	27.6 (21.1-33.3)	.74

[a]Chi Square unless otherwise indicated; [b]Reported as median (25-75% Interquartile range), *P*-value from Wilcoxon test; [c]When compared to all other groups in that category; [d]When compared to those with no adhesions or simple adhesions only.

regression models, excluding subjects with missing data. Variables associated with either the exposure or the outcome was retained in the models if they changed an odds ratio by more than 10%. With the number of Seprafilm subjects available for our analysis (77), a 2:1 ratio of controls to Seprafilm subjects, and an alpha of .05, we had 90% power to detect a 50% reduction in adhesions, using a baseline adhesion rate of 42% [10].

Results

We identified 378 women who had Seprafilm placed at Cesarean section, 77 of whom returned for a second pelvic surgery prior to July 2013. These subjects were matched to 154 control patients who did not have a barrier placed at the index delivery. Controls were matched to the exact surgeon 78% of the time, while the other 22% were matched to a different surgeon in the same practice group.

As shown in **Table 1**, the two groups were highly similar in terms of maternal age, rate of nulliparity, number of prior Cesarean sections, and endometriosis history, while those receiving Seprafilm had a higher rate of current or past fibroids (21% vs. 10% in the control group, *P*=.02). Subjects in the Seprafilm group were also more likely to report their race as black (21% vs. 9%, *P*=.01), while race information was missing for two subjects in the control group.

When evaluating the index Cesarean sections, we found no significant difference between the two groups in relation to gestational age, hysterotomy type, estimated blood loss, surgical time, and rate of peritoneal closure. Subjects in the Seprafilm group were significantly more likely to have dense pelvic adhesions present at the index delivery (22% vs. 11% in the control group, *P*=.02), and were less likely to have labored before their Cesarean section (27% vs. 41%, *P*=.04). Both groups

Table 2. Predictors of dense adhesions at the follow-up surgical procedure

Predictor	Dense adhesions n=96 (42%)[a]	No dense adhesions n=135 (58%)[a]	*P* Value (X^2)
Prior C-sections			.18
1	54 (38%)	89 (62%)	.14[b]
2	34 (45%)	41 (55%)	
3+	8 (62%)	5 (38%)	.15[b]
Race			<.01
White	57 (34%)	108 (65%)	<.01[b]
Black	22 (73%)	8 (27%)	<.01[b]
Asian	11 (61%)	7 (39%)	.09[b]
Hispanic	6 (38%)	10 (62%)	.80[b]
Medical/Surgical history			
Endometriosis	8 (67%)	4 (33%)	.08
Fibroids	13 (42%)	18 (58%)	.96
Index surgery factors			
Presence of labor	36 (43%)	48 (57%)	.76
Any adhesions	31 (65%)	17 (35%)	<.01
Dense adhesions	25 (74%)	9 (26%)	<.01
Peritoneal closure	13 (36%)	23 (64%)	.47
Vertical hysterotomy	30 (58%)	22 (42%)	<.01
Hysterotomy extensions	21 (60%)	14 (40%)	.02
Arterial devascularization	4 (80%)	1 (20%)	.16
Postoperative infection	8 (67%)	4 (33%)	.08

[a]Column percentages reflect the dense adhesion rate by predictor; [b]When compared to all other groups in that category.

showed similar rates of hysterotomy extensions, infection, and major hemorrhage. Only one subject in the Seprafilm group experienced an organ injury, while one subject in the control group developed a postoperative pelvic hematoma. Five subjects in the Seprafilm group underwent a uterine artery devascularization procedure, including four uterine artery ligations and one intraoperative uterine artery embolization, while no control subjects had similar procedures (**Table 1**).

For the second surgical procedure, at which time the primary outcome was measured, 71 Seprafilm patients (92%) and 147 control patients (95%) underwent a repeat Cesarean delivery. Of the thirteen who had an alternate pelvic surgery, eleven underwent gynecologic pelviscopies, one had an abdominal hysterectomy, and one had an abdominal myomectomy. The median time between the first and second procedures was 27.9 months and did not significantly vary between the groups.

Overall, 42% of subjects had dense pelvic adhesions present at the follow-up pelvic surgery, and we evaluated predictors of this outcome (**Table 2**). We observed the highest rates of dense adhesion formation among those with three or more prior Cesarean sections (62%), vertical hysterotomy at the index delivery (58%), Black or Asian race (73% and 61%, respectively), presence of dense adhesions at the index delivery (74%), a history of endometriosis (67%), prior postoperative pelvic infection (67%), hysterotomy extensions at index delivery (60%), and prior performance of an arterial devascularization procedure (80%). Neither a history of fibroids nor laboring prior to the index delivery was associated with dense adhesion formation, with 42% and 43% adhesion rates, respectively. Of the above factors, race, hysterotomy type, hysterotomy extensions, and dense adhesions at the index delivery were statistically significant predictors of dense adhesions at follow-up surgery.

Our primary analysis is detailed in **Table 3**. Forty-three percent of patients who received Seprafilm had dense adhesions at follow-up, while this rate was 42% in the control group (*P*=.78). Because Seprafilm was placed over the anterior uterus, and thus was expected to prevent adhesions at this location, we separately evaluated dense anterior uterine adhesions as an endpoint. Again, we found no significant association, with a 34% dense uterine adhesion rate in the Seprafilm group and a 31% rate in the control group (*P*=.62).

After evaluating multiple variables, black race, the presence of adhesions at the index surgery, and use of a prior devascularization procedure were significant confounders in the association, altering the odds ratio by 10% or more. After controlling for all of these factors, there remained no significant reduction in the formation of any (aOR=0.79, 95% CI=.43-1.45) or anterior uterine dense adhesions (aOR=0.88, 95% CI=.46-1.65).

Table 3. Surgical outcomes as a function of seprafilm placement

Outcome at Follow-Up surgery	Seprafilm (n=77)	No barrier (n=154)	Unadjusted odds ratio (95% CI)	Adjusted odds ratio (95% CI)
Dense adhesions				
Any	33 (43%)	64 (42%)	1.08 (.62-1.88)	0.79 (.43-1.45)[a]
Anterior uterine	26 (34%)	47 (31%)	1.16 (.65-2.08)	0.88 (.46-1.65)[a]
Other outcomes C-sections only	*(n=71)*	*(n=147)*		
Delivery time (min)[b]	11 (9-17)	11 (8-15)	1.08 (.61-1.90)	0.86 (.47-1.59)[a]
Delta-delivery time (min)[b]	3.5 (0-6)	2 (0-6)	1.05 (.59-1.86)	1.16 (.64-2.08)[a]
Hemorrhage	6 (8%)	4 (3%)	2.13 (.52-8.79)	1.33 (.28-6.44)
Organ injury[c]	0	2 (1%)	N/A	N/A
Hysterotomy dehiscence	5 (6%)	6 (4%)	1.71 (.51-5.8)	2.37 (.68-8.26)[d]

[a]Adjusted for Black race, prior dense adhesions, and arterial devascularization at index surgery; [b]Expressed as median (Interquartile range). Differences were non-significant by Wilcoxon tests (*P*=.54 for delivery times and *P*=.53 for delta-delivery times). Results were dichotomized to perform logistic regressions; [c]Unadjusted *P*-value=.55 by Fisher's Exact test; [d]Adjusted for Black race, prior dense adhesions, arterial devascularization at index surgery, and history of fibroids.

With regards to our secondary endpoints, we saw no reduction in the delivery time at follow-up Cesarean section between the two groups. The median time from incision to delivery was 11 minutes in both the Seprafilm (interquartile range 9-17) and control group (interquartile range 8-15), *P*=.54. We adjusted for patient-specific factors by calculating a delta-delivery time (defined as the difference in delivery time between the follow-up Cesarean and index Cesarean deliveries). Again we saw no significant reduction in the delta-time for the Seprafilm group, in which the follow-up Cesarean delivery took an additional 3.5 minutes (IQR 0-6) vs. 2 extra minutes (IQR 0-6) in the control group, *P*=.53. The time variables were dichotomized in order to control for race, preexisting dense adhesions, and uterine devascularization, and the resulting odds ratios remained non-significant for delivery times (aOR=0.86, 95% CI=0.47-1.59) and delta-delivery time (aOR=1.16, 95% CI=0.64-2.08, **Table 3**).

In terms of surgical complications, we observed identical rates of pelvic infection following the index surgery (5% for both the Seprafilm and control groups, *P*=1.0, **Table 1**). There was no significant difference in the rate of major hemorrhage at follow-up surgery (8% of those who had received Seprafilm and 3% who had not, aOR=1.33, 95% CI=0.28-6.44 (**Table 3**). Two subjects in the control group experienced bowel injuries at follow-up surgery, while there were no organ injuries in the Seprafilm group (*P*=0.55). No uterine ruptures, bowel obstruction, or cases of postoperative ileus occurred.

We observed an increased incidence of hysterotomy dehiscence in the Seprafilm group, though this outcome was too rare to show statistical significance (6% in the Seprafilm group vs. 4% in the control group, OR=1.71, 95% CI=0.51-5.80). This observation remained after controlling for race, dense adhesions at index delivery, prior devascularization, and history of fibroids (aOR=2.37, 95% CI=0.68-8.26). Notably, none of the patients who experienced hysterotomy dehiscence had undergone a prior uterine artery devascularization procedure.

Discussion

We hypothesized that women receiving Seprafilm at Cesarean section would have significantly fewer dense adhesions at follow-up surgery. After controlling for multiple potential confounders, we found no significant association between Seprafilm use and dense uterine adhesion formation. Notably, the adjusted odds ratio of 0.88 did not come close to the 85% adhesion reduction seen when Seprafilm was studied at myomectomy [4], nor to the 50% reduction that we predicted. Similarly, we saw no significant differences in delivery times or operative complications at either the index Cesarean section or follow-up surgery.

We recognize the potential for confounding with a nonrandomized study design, and we therefore matched subjects on factors that we considered potentially important in adhesion formation: hysterotomy type, surgeon, and whether the index delivery involved a primary or repeat Cesarean section. We considered hys-

terotomy type to be important because the low transverse incisions may lead to different adhesion patterns compared to uterine incisions for abdominal myomectomy. One study investigating the effectiveness of Seprafilm at the time of abdominal myomectomy suggested that the location of the uterine incision (vertical versus low transverse) might play a role in its future adhesive potential [4].

We matched for the surgeon performing the operation, believing that variations in surgical technique may affect adhesion formation. Adherence to Halstedian principles of surgery-avoidance of infection, tissue damage, and tissue desiccation-has been shown to reduce adhesions [11]. Given these findings, individual surgeons' techniques can potentially lead to variation in postoperative adhesion formation, and can be difficult to identify and specifically control. For 22% of our cases we had to match for a surgeon in the same group practice rather than to the exact surgeon. We believe that surgical practice was well controlled in our study, as the total operating time, estimated blood loss, and rates of peritoneal closure and hysterotomy extension were balanced between the comparison groups.

The number of previous Cesarean sections plays a role in the rate of future adhesion formation, as multiple studies have shown that the number and severity of adhesions will increase with each subsequent Cesarean delivery [7, 8, 10]. We matched subjects based on whether they underwent a primary or repeat Cesarean for the index delivery, and found that in doing so, the groups were well-matched in terms of specific Cesarean order.

The retrospective nature of our study forced us to rely on the surgeons' dictations and patients' medical records. Surgeons may have failed to report or specifically detail the nature of adhesions found at the index or follow-up operations. However, we feel that clinically insignificant (filmy) adhesions are more likely to be underreported in the operative notes, while those adhesions altering the surgical procedure--the primary outcome of our study-are more likely to be mentioned. Additionally, only a subset of our hospital's obstetricians is represented in this study. It is unclear whether the cohort represented in these obstetric practices accurately reflects the obstetric population as a whole.

We are aware of three other studies that evaluated the use of carboxymethylcellulose adhesion barrier at the time of Cesarean delivery. The first study by Fushiki et al found significant benefits in time to delivery, duration of surgical procedure, and incidence of adhesions in patients receiving Seprafilm during prior Cesarean sections [12]. This study was conducted in Japan, and subjects were of primarily Asian descent. Our study, with a multi-racial population, found that Asian women have a higher overall rate of adhesion formation than their white or Hispanic counterparts (61% vs. 34% and 38%, respectively), suggesting that the effect of Seprafilm may vary based on maternal race and underlying genetic factors. Notably, the Fushiki study did not adjust for potential confounders associated with dense adhesions. In a retrospective study by Edwards et al, carboxymethylcellulose adhesion barrier placement at primary Cesarean section was not associated with decreased time to delivery, operative complications, or decreased adhesion formation [13]. In addition, the authors noted a statistically significant rate of hospital readmission in the group receiving the adhesion barrier. This was reinforced by a recent publication by Gaspar-Oishi and Aeby, which found no operative time benefit with barrier placement in a population that is 80% Asian [14].

Unlike the Fushiki and Edwards studies, our study design focused on the severity and location of the adhesions, using a previously published and validated scoring system for adhesion classification at Cesarean section [9]. We felt that clinically relevant adhesions are those that may alter the course of the follow-up surgery, either by requiring additional procedures or changing the type and/or location of the hysterotomy. The Fushiki et al study did not focus on the clinical relevance of adhesions in their cohort. The Edwards et al study used a surrogate clinical variable-time to delivery at the subsequent Cesarean delivery-as their primary outcome, but did not otherwise characterize the adhesions at follow-up. Our study adds to the findings by Edwards et al, in that we found no association between adhesion barrier placement and either the prevention of dense uterine adhesions or a reduced time to delivery at the subsequent Cesarean section. These findings are similar to those of Gaspar-Oishi et al, who also showed no benefit when adhesions

were graded by severity, and expands these findings to a racially diverse population.

We found one randomized trial investigating Seprafilm use during open uterine myomectomies [4]. This study showed a significant benefit to using Seprafilm after myomectomy, with an 85% reduction in the rate of anterior uterine adhesions after placement (from 39% with no barrier to 6% with Seprafilm). This contrasts with the lack of effect found with our study. Cesarean sections are generally of short duration (median operative time in our study group was 47 minutes at the index delivery), which may produce less tissue desiccation. Other factors, such as the alkaline environment created by amniotic fluid and the fundal hysterotomy location at myomectomy, could also explain the discrepancy in findings.

In an earlier study of gynecologic cancer surgery, a trend towards increased pelvic abscesses was noted in patients receiving Seprafilm [6]. Our analysis revealed no difference in major morbid outcomes among patients who received Seprafilm and those who did not. We observed the same 5% rate of postoperative infection in the Seprafilm and control groups, which promotes the safety of the barrier in the immediate postpartum period.

In a prospective trial examining post-operative bowel obstructions after abdomino-pelvic surgery, an increased rate of bowel anastamosis leak was noted in patients who had Seprafilm placed directly over their bowel anastamoses (13.5 % vs. 5.1%, $P<0.001$) [5]. This finding led to a revision in the Seprafilm package insert, warning users that Seprafilm "should not be wrapped directly around a fresh anastamotic suture or staple line" (http://www.seprafilm.com/SeprafilmPackageInsert.pdf). We observed a non-significant increase in the rate of hysterotomy dehiscence in patients who received Seprafilm compared to those who did not. However, the small size of this study and rarity of the outcome does not allow us to draw conclusions regarding the effects of Seprafilm on hysterotomy healing.

We were unable to show that the adhesion reduction demonstrated with Seprafilm at gynecologic surgery can be extrapolated to Cesarean section. Given the potential for residual confounding, results of randomized trials are needed to understand whether or not seprafilm is an effective adhesion barrier at Cesarean delivery. We also believe that larger studies are needed to assess whether Seprafilm placement compromises hysterotomy scar formation, analogous to what has been shown when the product is placed over a fresh bowel anastamosis [5].

Given the lack of data demonstrating a clear benefit to Seprafilm at time of Cesarean, and the lack of adequate data regarding the effects on hysterotomy scar formation, any decision for the routine use of Seprafilm during Cesarean delivery should await the results of randomized trials.

Disclosure of conflict of interest

None.

Address correspondence to: Dr. Daniela Carusi, Department of Obstetrics & Gynecology, Brigham & Women's Hospital, 75 Francis Street, Boston, MA 02115, USA. Tel: 617-732-5452; Fax: 617-232-6346; E-mail: dcarusi@partners.org

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