



Surgical site infection in cesarean sections with the use of a plastic sheath wound retractor compared to the traditional self-retaining metal retractor



Larry Hinkson*, Jan-Peter Siedentopf, Alexander Weichert, Wolfgang Henrich

Department of Obstetrics, Charité – Universitätsmedizin Berlin, Berlin 13353, Germany

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ABSTRACT

Objective: A cesarean section rate of up to 19.4% is reported worldwide. Surgical site infection occurs with rates of up to 13.5%. Plastic-sheath wound retractors show reduced rates of surgical site infections in abdominal surgery. There is limited evidence in women having cesarean sections.

This study evaluates the use of the Alexis[®] O C-Section Retractor in the prevention of surgical site infection in patients undergoing their first planned cesarean section compared to the traditional Collins self-retaining metal retractor.

Study design: A single center, prospective, randomized, controlled, observational trial. The primary outcome is surgical site infection as defined by the Centers for Disease Control and Prevention. The secondary outcomes included intraoperative surgical parameters, postoperative pain scores and the short and long-term satisfaction with wound healing. From October 2013 to December 2015 at the Charité University Hospital, Berlin. 98 patients to the Alexis[®] O C-Section Retractor group and 100 to the traditional Collins self-retaining metal retractor group.

Results: A statistically significant reduction in the rate of surgical site infections, when the Alexis[®] O C-Section Retractor was used for wound retraction compared to the traditional Collins metal self-retaining wound retractor, 1% vs. 8% (RR 7.84, 95% CI (2.45–70.71) $p = 0.035$).

Conclusions: The use of plastic-sheath wound retractors compared to the traditional self-retaining metal retractor in low risk women, having the first cesarean section is associated with a significantly reduced risk of surgical site infection.

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Introduction

Cesarean section is the commonest operation performed on women of reproductive age worldwide, with estimates of 1 in 5 births being by cesarean. In a 2016 study, Betrán et al. showed in an analysis from 150 countries, an unprecedented global rise in the rate of cesareans from 6.7% in 1990 to 19.4% in 2014 [1].

Surgical site infection (SSI) can occur at the site of surgery [2–4]. Readmissions and wound revisions pose prolonged risks in addition to intra-abdominal adhesion formation and chronic pelvic pain [5–7]. Psychological trauma and negative feelings also persist after SSI [8].

Sepsis is a leading cause of maternal mortality [9–11]. The single most important risk factor for maternal death from sepsis is the cesarean section. Furthermore, the mortality rate with surgical site infection is 3% and 75% of SSI deaths are directly caused by SSI [12].

The cost of dealing with infection after planned surgery has a significant impact on health care provision. The financial burden of 6.5 Billion US dollars per annum is estimated [13].

The method of wound retraction at cesarean sections plays a role in the risk of SSI. Mihaljevic et al. published in 2015, a systematic review of 16 trials including 3695 patients, showing that wound protectors significantly reduces SSI (relative risk 0.45; 95%CI, 0.24–0.82) [14].

The Alexis[®] O C-Section Retractor (Applied Medical, Rancho Santa Margarita, California, USA) consists of 2 plastic rings separated by a cylindrical reinforced polyurethane sheath. The soft inner ring is flexible and placed into the peritoneal cavity and

* Corresponding author at: Department of Obstetrics, Charité – Universitätsmedizin Berlin, Augustenburger Platz 1, Berlin 13353, Germany.

E-mail address: Larry.Hinkson@charite.de (L. Hinkson).



Fig. 1. The Alexis[®] O C-Section retractor.

the outer ring lies externally on the outside of the abdomen, providing 360° circular retraction with a simultaneous tamponade effect (Fig. 1).

Studies performed in abdominal surgery, show a reduction in SSI with the Alexis[®] O Retractor. Cheng et al. looked at 72 patients and showed a reduction from 20% in the control group to 0% in the study group. Hariouchi and colleagues showed in 272 patients a significant reduction in bacterial wound infection with the Alexis[®] O Retractor [15,16].

The Collins self-retaining retractor is made of polished stainless steel and utilizes a ratchet system to spread, lock and hold the lateral blades of the retractor apart. The abdominal wound edges are held apart within lateral tissue holding blades that swivel and come to rest against the lateral corners of the transverse abdominal incision (Fig. 2).

There is no work comparing the use of the new Alexis[®] O C-Section Retractor with other self-retaining retractors. We therefore designed a prospective, randomized, controlled, observational study to test the hypothesis that the use of the Alexis[®] O C-Section Retractor, in comparison to the traditional Collins self-retaining metal wound retractor, reduces SSI in primary elective cesarean in women without major comorbidities for wound infections and without previous cesarean.



Fig. 2. The traditional Collins metal self-retaining retractor.

Materials and methods

Ethical approval

Ethical approval was granted from the Charité Ethics Committee; Ethics Approval Number: EA1/091/13.

Sample size calculation

We estimated a sample size based on a rate of surgical site infection of 8%. Recently, in a study published in the New England Journal of Medicine by Tuuli et al., the SSI reference rate is 8% [17,18].

We estimated 186 participants with 93 in each arm in order to have 80% power to detect a difference in the rates of surgical site infection. To accommodate possible loss to follow up we anticipated enrolling 200 patients. 100 Alexis[®] O C-Section Retractors were provided by the Applied Medical Company, Rancho Santa Margarita, California, USA.

Inclusion criteria

Only patients having their first planned cesarean are included.

Exclusion criteria

Patients with diabetes, chronic autoimmune diseases such as systemic lupus erythematosus, immune deficiency diseases such as HIV, known bleeding disorders, patients receiving full anti-coagulation therapy, patients with a history of wound healing problems, patients who had a previous cesarean, patients who had previous major abdominal surgery, patients in the active phase of labor and patients with suspected or confirmed chorioamnionitis, are excluded.

Recruitment

All women attending the Charité University Obstetric Department for the first planned cesarean were invited to participate. Participants received an information form and documented their consent.

Primary outcome

The primary aim is to investigate the incidence of surgical site infection (SSI) (as defined by the Center for Disease Control and Prevention) in low risk women having a first time, planned cesarean using the Alexis[®] O C-Section Retractor compared with the traditional Collins Self Retaining Metal Retractor.

Secondary outcomes

The secondary outcomes are to investigate other aspects of retractor use, which play an important role in the performance of the operation and the patient satisfaction with wound healing. These included an assessment of intraoperative surgical parameters and the outcomes, as well as subjective experience, ease of application and removal of the retractor, postoperative pain scores and short and long term satisfaction with wound healing.

Randomization

Patients were prospectively randomized using the method of computer generated block randomization into two groups. Group 1 received the Alexis[®] O C-Section Retractor and Group 2 received

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