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# Does the Alexis wound retractor increase the risk of blood splashes to the eyes? Early closure of a double blinded randomised controlled trial

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Blood splashes to the eye during surgery create a risk to the surgeon and other theatre staff for the transmission of blood-borne infections, especially HIV and hepatitis B or C [1].

The Alexis wound retractor is commonly used during abdominal surgery. It is a double ring polyurethane retractor, consisting of two plastic rings joined by a flexible plastic sleeve. It provides effective retraction of the wound and protects the wound from infection [2–9]. However, when the retractor is removed (by unrolling the outer ring of the retractor), there is a risk that blood droplets are sprayed into the air which may increase the risk of blood splashes to the surgeon or assistant's eyes.

The purpose of this study was to determine whether the use of the Alexis retractor for abdominal surgery leads to an increased risk of blood splashes to the surgeon's or assistant's eyes.

This was a double blinded randomised controlled trial on adult patients undergoing surgery requiring an intraperitoneal abdominal incision at the University Hospital, Geelong (a regional referral hospital in Victoria, Australia).

The operations were randomly assigned to one group where the Alexis retractor was used, and the control group in which it was not. Operative technique in the two arms was similar.

In both groups, the surgeon and assistant wore transparent visors. An investigator who was blinded to whether the Alexis retractor had been used counted the number of macroscopic blood spots on the visor (in keeping with previous methodology [10]).

The study was designed to detect an increase in mean blood splashes from 2.5 to 5 per visor, with a standard deviation of 3.6 (from Ogendo et al. [11]). The required sample size was 44 operations in each arm.

During the study period, the WHO published guidelines recommending routine use of the Alexis retractor for bowel surgery [12], so we decided that we could no longer ethically randomize patients into the control arm, and closed the trial prematurely. At this time, 25 operations had been included in the study (twelve in the Alexis group and 13 controls), so 50 visors were studied. A median of zero (range 0–5) blood splashes were detected in the Alexis group, and zero (range 0–9) in the controls (P = .91).

This is the only study which has attempted to determine whether using the Alexis retractor poses any risk to the surgical team through blood splashes. Unfortunately the trial was underpowered to definitely answer that question. However, the number of blood splashes in the Alexis groups were low (median of zero blood splashes to the masks of surgeons or assistants), so it seems reasonable to conclude that the use of the Alexis retractor does not add any clinically significant risk.

In summary, we could not detect any increased risk of blood splashes to the eyes of surgeons or their assistants from the use of the Alexis retractor, but the study was underpowered due to early trial closure.

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### Appendix A. Supplementary data

Supplementary data related to this article can be found at http://dx.doi.org/10.1016/j.conctc.2018.01.001.

#### References

- [1] C.G. Davies, et al., Blood and body fluid splashes during surgery the need for eye protection and masks, Ann. R. Coll. Surg. Engl. 89 (8) (2007) 770-772.
- [2] J.P. Edwards, et al., Wound protectors reduce surgical site infection: a meta-analysis of randomized controlled trials, Ann. Surg. 256 (1) (2012) 53-59.
- [3] A. Gheorghe, et al., Systematic review of the clinical effectiveness of wound-edge protection devices in reducing surgical site infection in patients undergoing open abdominal surgery, Ann. Surg. 255 (6) (2012) 1017–1029.
- [4] T. Horiuchi, et al., Randomized, controlled investigation of the anti-infective properties of the Alexis retractor/protector of incision site, J. Trauma 62 (1) (2007) 212-215.

[5] H.M. Mohan, et al., Plastic wound retractors as bacteriological barriers in gastrointestinal surgery: a prospective multi-institutional trial, J. Hosp. Infect. 81 (2) (2012) 109–113.
[6] T.M. Connolly, et al., Impact of a surgical site infection reduction strategy after colorectal resection, Colorectal Dis. 18 (9) (2016) 910–918.

- [7] K.P. Cheng, et al., ALEXIS O-Ring wound retractor vs conventional wound protection for the prevention of surgical site infections in colorectal resections(1), Colorectal Dis. 14 (6) (2012) e346–e351.
- [8] K. Reid, et al., Barrier wound protection decreases surgical site infection in open elective colorectal surgery: a randomized clinical trial, Dis. Colon Rectum 53 (10) (2010) 1374–1380.
- [9] M.X. Zhang, et al., Wound edge protector for prevention of surgical site infection in laparotomy: an updated systematic review and meta-analysis, ANZ J. Surg. 85 (5) (2015) 308–314.
- [10] R. De Silva, et al., Risk of blood splashes to the eye during surgery, S. Afr. J. Surg. 47 (1) (2009) 7-9.

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[11] S.W. Ogendo, et al., Risk of conjunctival contamination from blood splashes during surgery at the Kenyatta National Hospital, Nairobi, East Afr. Med. J. 85 (9) (2008) 432–437.
[12] World-Health-Organization, Global Guidelines for the Prevention of Surgical Site Infection, (2016), pp. 136–139.

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