

# Alexis double ring wound protector and postoperative wound infections, HTA-report 2014:9

## Included and excluded articles

CDC= Centers for Disease Control and Prevention SSI= surgical site infections LOS= length of stay

Publication	Patient population	Study design	Intervention, with wound retractor	Control without wound retractor	Results	Drop-outs	Quality	Comments
Reid et al. 2010 Australia	Elective colorectal surgery	RCT multicenter End point: deep or superficial SSI < 30 days of surgery.	n=64	n= 66	Total SSI: 3 (I) vs 15 (C) p=0,004. All were superficial incisional SSI except 1 deep incisional SSI in C group. In addition, one organ space infections in each group and 2 intestinal leakage in the I group.	2 deaths (one in each group), 3 protocol violations	High	ITT analysis. The predefined end point is all SSI but results focus on superficial SSI. Leakage was not regarded as SSI. The accumulated number of all SSI seems to be 6 (I) vs 16 (C) P=0,04
Horiuchi et al. 2007 Japan	Gastrointestinal surgery including liver biliary and pancreas surgery. Excluding trauma.	RCT, single center No predefined end points stated	N= 111  N=40 (Colorectal surgery)	N= 110  N=52 (Colorectal surgery)	Total SSI: 8 (I) vs 16 (C) p=0,08 Superficial incisional SSI: 0 (I) vs 9 (C) p=0,002, intestinal leakage 6 (I) vs 5 (C) NS, abscess 2 (I) vs 2 (C) NS. Less superficial wound inf also in subgroup of patients with colorectal surgery (p=0.0158)	Not stated	Medium	No power calculation. Randomization procedure not stated Observation time not stated, No prospective end points stated
Lee et al. 2009 USA	Open surgery appendectomy	RCT, single center End point: wound infection < 21 days of surgery	N= 61	N=48	Superficial wound infections: 1 (I) vs 7 (C) p=0.02 No deep SSI in either group	3 not committed to follow-up, 1 lost to follow-up	Medium	Stopped after 113 patients (planned for 330) after interim analysis showed significance. Unclear if this was according to a predefined stopping rule. Alpha spending for interim analyses was not considered
Cheng et al. 2012 Malaysia	Elective colorectal surgery	RCT, single center End point: SSI <30 days of surgery	N=34	N= 30	SSI: 0 (I) vs 6 (C) p=0,006 All superficial incisional SSI.	8 excl; relap n=4, contraind for PCA-pump, n=2, cancelled operation, n=1, too long incision n=1. The allocation for the dropouts not stated	Medium	Allocation of dropouts not given. P value for primary end point should be 0,008 (Fisher, too few events to use Chi-square). Predefined primary end point was all SSI but definition, results and discussion only deal with superficial infections. Incidence of deep SSI not reported and reason for 4 re-laparotomies (dropouts) not stated.
Theodoridis et al. 2010 Greece	Elective or emergency cesarean section	RCT Single center Unclear end point.	N=115	N=116	SSI: 0 (I) vs 3 (C), one wound dehiscence, depth of infection unclear	Not stated	Low	No power calculation. Poorly defined end points, No/incomplete data on statistics, randomization procedure, concealment, follow-up, dropouts. Relevant baseline data missing

## Excluded articles

SSI= surgical site infection

Authors, year	Comment
Horiuchi, T., et al. (2010). A wound protector shields incision sites from bacterial invasion. <i>Surg Infect (Larchmt)</i> <b>11</b> (6): 501-503.	Not according to PICO. Observational study. No control group. Prim outcome bacterial culture, sec outcome SSI
Mohan, H. M., et al. (2012). Plastic wound retractors as bacteriological barriers in gastrointestinal surgery: a prospective multi-institutional trial. <i>Journal of Hospital Infection</i> <b>81</b> (2): 109-113.	Not according to PICO. No SSI results.
Nishimura, A., et al. (2011). Totally laparoscopic sigmoid colectomy with trans anal specimen extraction. <i>Surg Endosc</i> <b>25</b> (10): 3459-3463.	Not according to PICO. Documentation of surgical technique.