Appendix 1 to Adie S, Harris I, Naylor J, Mittal R. Are outcomes reported in surgical randomized trials patient-important? A systematic review and meta-analysis. *Can J Surg* 2017.

DOI: 10.1503/cjs.010616

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Appendix 1. Syntax of electronic search strategies employed

MEDLINE via Ovid (2005 - Week 3, May 2009)

1 randomized controlled trial.pt.

2 controlled clinical trial.pt.

3 randomi*ed.ab.

4 placebo.ab.

5 randomly.ab.

6 trial.ab.

7 groups.ab.

8 or/1-7

9 animals/ not (humans/ and animals/)

10 8 not 9

11 exp Specialties, Surgical/

12 exp Surgical Procedures, Operative/

13 surger$.tw.

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14 surgical$.tw.

15 operative$.tw.

16 or/11-15

17 16 and 10

18 limit 17 to yr="2005 -Current"

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EMBASE via Ovid (2005 – Week 21, 2009)

1 randomized controlled trial/

2 crossover procedure/

3 double-blind procedure/

4 single-blind procedure/

5 random$.tw.

6 factorial$.tw.

7 (crossover$ or cross-over$).tw.

8 placebo$.tw.

9 (double$ adj blind$).tw.

10 (singl$ adj blind$).tw.

11 assign$.tw.

12 allocat$.tw.

13 volunteer$.tw.

14 or/1-13

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15 exp surgery/

16 surger$.tw.

17 surgical$.tw.

18 operative$.tw.

19 or/15-18

20 14 and 19

21 limit 20 to yr="2005 -Current"

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CENTRAL via Wiley Interscience (2005 – Week 3, May 2009)

#1 MeSH descriptor “Specialties, Surgical” explode all trees

#2 MeSH descriptor “Surgical Procedures, Operative” explode all trees

#3 surger*:ti,ab

#4 surgical*:ti,ab

#5 operative*:ti,ab

#6 (#1 OR #2 OR #3 OR #4 OR #5), from 2005 to 2009

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Operational definitions of characteristics of surgical RCTs

QUALITY CHARACTERISTICS
"Randomised" in title of study • Adequate: study contained the word "randomised" or any of its variants in the title of the study • Inadequate: "randomised" not in title
Specification of primary outcome(s) • Adequate: the primary outcome was defined explicitly in the text (using the word "primary" or any of its synonyms), was stated explicitly in an aims/hypothesis statement, or was the outcome used in a sample size calculation. Other outcomes were regarded as secondary outcomes. • Unclear: primary outcome(s) not specified
Power calculation • Adequate: authors stated a sample size calculation was performed to determine included study numbers • Unclear: sample size calculation not reported
Generation of random sequence • Adequate: reported method that is completely unpredictable, such as computer random number generation, random number tables, coin flip, or lottery. If adequate, the method will be specified • Unclear: method of random sequence generation not reported
Concealment of treatment allocation • Adequate: reported method where researchers and trial participants are prevented from knowing which study arm they have been allocated in advance, such as a separate central allocation service, coded containers, or envelopes. If adequate, the method will be specified. Envelopes were regarded as adequate without specification as "sealed", "opaque" and "numbered", although this information was also collected • Unclear: method of allocation concealment not reported
Blinding • Adequate: patients, caregivers, and or outcome assessors were unaware of intervention arms, or the study was described as "blinded", or the term "placebo" is used to describe a control, or sham surgery is used. The blinded party will be specified as patients, caregivers and/or outcome assessors • Inadequate: none of the above reported or the trial was described as non-blinded or open label

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Handling of attrition • Adequate: follow up rates are reported for intervention and control arms, and the "intention to treat principle" was used as the primary method of analysis. A description of analysis according randomised group, or a flow diagram representing analysed groups were considered adequate for "intention to treat" • Follow up: follow up is reported in intervention and control groups, but analysis according to intention to treat not reported • Inadequate: none of the above reported
Source of funding • Full industry: the only source(s) of funding is/are stated as an industry (for-profit) source • Part industry: one source of funding or one section of the trial supported by an industry (for-profit) source • Non-industry: the only source(s) of funding is/are stated as a not-for-profit source (such as government grants, charitable trusts, or scholarships) • No external: where no external source of funding is declared (i.e. it is declared the trial was internally funded by the authors' institutions / department) • Unclear: the funding source is not declared
AUTHOR CHARACTERISTICS
Number of authors (continuous variable recorded as an integer)
Stated affiliation of the first author Categorical variable recorded as i) Department of surgery (any specialty recognized by the Royal Australasian College of Surgeons) ii) Department of epidemiology / statistics / public health OR Clinical trials unit OR Cochrane collaboration affiliate iii) Department of medicine iv) Other department
Author background Citation of epidemiology, biostatistics, public health or trials unit background by any one of the authors. Binary variable recorded as yes / no
Country of origin of first author Categorical variable dichotomised into i) research country, defined as USA, Canada, Australia, New Zealand, Japan, Israel, and Western Europe{Balk:2002wh} and ii) other country

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STUDY CHARACTERISTICS
Trial registration Categorical variable recorded as i) trial registered and registration details provided in text ii) trial registered but was not mentioned in text, and was found by performing a search of the World Health Organisation Clinical Trial Portal iii) not stated in text and not found online. The trial registry name was also recorded.
Study design{Hopewell:2010gi} Categorical variable recorded as i) parallel groups ii) split body iii) crossover iv) factorial
Study type{Chan:2005uv} Categorical variable recorded as i) efficacy / superiority ii) equivalence / non-inferiority. This was determined by either explicit definition by authors, from the stated aim / hypothesis, or the sample size calculation
Type of comparison Categorical variable recorded as i) surgical intervention vs. surgical intervention ii) surgical intervention vs. non-surgical intervention. The primary study aim statement or sample size calculation was used to determine the main comparison
Study arms Number of intervention / control arms in the trial. Continuous variable recorded as integer
Sample size Total number of patients examined in the study. Continuous variable
Subspecialty of the intervention Categorical variable recorded as one of the nine specialties in Table 2.1 If the intervention is associated with two subspecialties, then the affiliations of the authors was used to determine the subspecialty
Number of centres Multicentre trial status (dichotomous variable defined as a trial conducted in two or more separate centres) was recorded. For multicenter trials, the number of centres the trial was conducted in, recorded as continuous integer variable.

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JOURNAL AND REPORT CHARACTERISTICS
Journal name and type This was categorised into i) general surgical journal ii) subspecialty surgical journal iii) general medical journal iv) subspecialty medical journal. A “general” journal was regarded as one publishing from multiple non-overlapping specialties
Journal impact factor Recorded as a continuous variable. The Thomson ISI Journal Citation Reports (JCR) was used to reflect the impact of that journal with the JCR edition prior to year of publication used to reflect the time lag in submission to publication of the trial
Article length in words Number of words in the published journal report, excluding abstracts, tables and figures

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Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	4
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	5-6
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	6
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	6
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	6-7
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	7

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Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Appendix 1
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	8
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	8
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	8-9
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	Not applicable for this study
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	8-9
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	8-9

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Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	Not applicable for this study
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	11
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	Fig 1
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	10
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	Not applicable for this study
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	11

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Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	11
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	Not applicable for this study
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	Not applicable for this study
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	12
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	14
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	14-15
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	15

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

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