Wound drainage after plastic and reconstructive surgery of the breast (Review)

Khan SM, Smeulders MJC, Van der Horst CM

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Wound drainage after plastic and reconstructive surgery of the breast

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A B S T R A C T

Background

Wound drains are often used after plastic and reconstructive surgery of the breast, in order to reduce potential complications. It is unclear whether there is any evidence to support this practice and we therefore undertook a systematic review of the best evidence available.

Objectives

To compare the safety and efficacy of the use of wound drains following elective plastic and reconstructive surgery procedures of the breast.

Search methods

For the first update of this review we searched the Cochrane Wounds Group Specialised Register (searched 4 March 2015); The Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library 2015, Issue 2); Ovid MEDLINE (2012 to March 3 2015); Ovid MEDLINE (In-Process & Other Non-Indexed Citations March 3 2015); Ovid EMBASE (2012 to March 3 2015); and EBSCO CINAHL (2012 to March 4 2015). There were no restrictions on the basis of date or language of publication.

Selection criteria

Three review authors undertook independent screening of the search results. All randomised trials (RCTs) that compared the use of a wound drain with no wound drain following plastic and reconstructive surgery of the breast (breast augmentation, breast reduction and breast reconstruction) in women were eligible.

Data collection and analysis

Two review authors undertook independent data extraction of study characteristics, methodological quality and outcomes (e.g. infection, other wound complications, pain, and length of hospital stay). Risk of bias was assessed independently by two review authors. We calculated the risk ratio (RR) for dichotomous outcomes and mean differences (MD) for continuous outcomes, with 95% confidence intervals. Analysis was on an intention-to-treat basis.
Main results

Three randomised trials were identified and included in the review out of 190 studies that were initially screened; all evaluated wound drainage after breast reduction surgery. No new trials were identified for this first update. In total there were 306 women in the three trials, and 505 breasts were studied (254 drained, and 251 who were not drained). Apart from a significantly shorter duration of hospital stay for those participants who did not have drains (MD 0.77; 95% CI 0.40 to 1.14), there was no statistically significant impact of the use of drains on outcomes.

Authors’ conclusions

The limited evidence available shows no significant benefit of using post-operative wound drains in reduction mammoplasty, though hospital stay may be shorter when drains are not used. No data are available for breast augmentation or breast reconstruction, and this requires investigation.

PLAIN LANGUAGE SUMMARY

No evidence that insertion of drains after plastic and reconstructive surgery of the breast reduces complications

Plastic and reconstructive surgery of the breast can include breast enlargement, breast reduction, and breast reconstruction (e.g. after breast removal in breast cancer patients). Such operations are routinely performed in most hospitals. The typical duration of hospital stay is about 3 days. These operations carry a risk of complications such as wound infection, fluid accumulation, death of parts of the breast tissue, and wound healing problems. These are often minor and do not affect the end result, but can result in a longer stay in hospital and extra medical treatment. For several decades surgeons have been inserting wound drains after these procedures expecting to minimize possible complications, although it is unclear whether there is any evidence to support this. We reviewed the limited evidence available from clinical trials, and found no evidence that the use of drains improves patient outcomes in breast reduction surgery. On the contrary, the use of drains seemed to be associated with a slightly longer stay in hospital of about one day. There were no trials in people undergoing breast augmentation or reconstruction.

BACKGROUND

Plastic and reconstructive surgery of the breast

Common plastic and reconstructive surgical procedures of the breast include breast reduction (reduction mammoplasty), breast enlargement (augmentation mammoplasty), and breast reconstruction.

Breast reduction is a surgical procedure in which breast volume is reduced to achieve a smaller breast mound. Disproportionally large and heavy breasts (mammary hypertrophy) may cause both health and emotional problems. The aim of this procedure is to relieve potential symptoms caused by large breasts (e.g. head, neck and back pain, or discomfort), and to make the breasts more pleasing aesthetically (Mathes 2006). Excess fat, glandular tissue and skin can be removed through a variety of techniques, with different approaches and incisions.

The goal of breast augmentation is to enhance the form and volume of the female breast. Small breasts can result from natural development or can occur after childbirth, and can be the reason to undergo breast augmentation. An implant of appropriate dimensions, filling (saline or silicone gel/solution), texture and form can be placed beneath the breast gland or behind the pectoral (chest) muscle. Different types of incisions are possible (Mathes 2006). Plastic surgeons have an important role in the multidisciplinary care of people with breast cancer. Many breast cancer patients pursue breast reconstruction after breast amputation (mastectomy). Breast reconstruction can be achieved through many different techniques. Individual factors and specific indications determine which technique is the most appropriate for each person. Reconstruction can be immediate (at the time of the mastectomy) or delayed (with a second operation). Delayed reconstruction may be advised if radiation to the chest area is needed after the mastectomy in order to minimize postoperative complications. Insertion of a permanent implant under the pectoral muscle can be done only after skin-sparing mastectomy, in which enough skin is left to cover the new breast. Usually it is necessary to expand or stretch the skin prior to reconstructive surgery with a temporary subcu-

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taneous tissue expander. The expander will then be replaced by a permanent implant in a second operation (Mathes 2006).

There is an alternative reconstruction technique that involves the use of tissue flaps, sometimes in combination with implants (Mathes 2006; Mimoun 2006). This technique uses autogenous (i.e. the person’s own) tissue (skin, fat and/or muscle) which is removed from the abdomen, back, thighs, or buttocks and is transplanted to the chest to reconstruct the breast. This can either be done in a pedicled fashion (leaving the flap attached to the main vascular structures as a stalk/pedicle) or a free fashion (disconnecting the blood vessels and later reattaching them to vessels in the chest). Two frequently used types of tissue-flap surgery include the transverse rectus abdominis musculocutaneous flap (TRAM) flap, which uses tissue (including the rectus abdominis muscle from the lower abdominal wall, and the latissimus dorsi (LD) flap, which uses tissue (including the latissimus dorsi muscle) from the upper back. A newer type of flap procedure is reconstruction through so-called perforator flaps. An example of this is the deep inferior epigastric perforator (DIEP) flap, which, like the TRAM flap, uses fat and skin from the abdomen, but leaves the rectus muscle intact (Mathes 2006; Nahabedian 2002).

Complications

Complications can occur with any type of surgery, including plastic and reconstructive surgical procedures of the breast. Severity of complications range from the minor to the life threatening, and, occasionally, secondary surgery may be required. The most common complications in breast reduction mammoplasty include haematoma (collection of blood due to internal bleeding), affecting fewer than 1% of procedures; seroma (pocket of serous fluid in the body), affecting 1% to 5% of procedures; infection, affecting 1% of procedures; wound-healing complications, affecting 3% to 19% of procedures; and nipple-areola necrosis due to insufficient vascularisation after surgery, affecting 1% to 6% of procedures (Cruz-Korchin 2003; Lejour 1999; Mandrekas 1996; Mathes 2006; Tapia 1996).

In augmentation mammoplasty, there are both implant and surgical complications. Complications caused by implants include displacement, rippling and deflation of saline implants, affecting 5.5% to 8.3% of procedures and rupture of gel implants, affecting up to 4% of procedures, depending on the type of implant used. Surgical complications include infection, affecting 1% to 2.5% of procedures; haematoma, affecting 1% to 6% of procedures; Mondor’s disease (inflammation of the blood vessels that run under the surface of the breast), affecting 1% to 2% of procedures; and alterations in nipple sensation, affecting 3% to 5% of procedures (Cunningham 2000; Mathes 2006; McCarthy 2007). Infection and capsular contraction (when the capsule that forms naturally around the implant as part of the healing process tightens and squeezes the implant) remain the most common complications of breast augmentation, with infection rates of 1% to 2.5% and capsular contraction rates between 0.5% and 30% (Cunningham 2000; Gui 2003; Mathes 2006; McCarthy 2007).

Breast reconstruction procedures share the potential complications of breast augmentation, but the mastectomy provides an additional risk of complication. The wound surrounding the implant in the case of immediate reconstruction after mastectomy is more dramatic than with breast augmentation. In the case of delayed reconstruction after mastectomy, dissection of the skin envelope/pocket for the implant is more difficult due to the development of scar tissue after the mastectomy. Both procedures have an increased risk of implant loss through the skin, infection, and capsule contracture, which often leads to secondary removal of the implant. Possible complications of flap reconstructions are (partial) flap loss through necrosis (cell death), infection, seroma, haematoma and wound dehiscence (splitting open of a previously closed wound) (Alderman 2002; Mathes 2006). The incidence of complications related to the breast after free TRAM reconstruction ranges from 8% to 13% (Nahabedian 2002). Reports of complications after the DIEP flap vary; some demonstrate a similar low flap loss rate to the TRAM flap (Hamdi 1999; Nahabedian 2002), while others report an increased incidence of breast-related morbidity, including fat necrosis, ranging from 6% to 62.5% (Blondeel 2000; Kroll 2000). Some of the variation may be due to the fact that DIEP flap surgery is the most demanding reconstruction option that involves microscopic revascularization of the tissue flap. Such technique requires experience. Post-operative pain is often a symptom of all of these complications.

Drains

The primary reason for inserting a drain is to prevent fluid collection and minimize dead space, in order to prevent subsequent infection and other complications. For reduction mammoplasty, the current recommendation is that attention to securing haemostasis (arresting bleeding) is more important in reducing haematoma rates than the use of drains (Mathes 2006). Despite this, a survey of 140 consultant plastic surgeons in the UK and Ireland found that 79% always used drains, 11% often did, and 10% either never or occasionally used drains in breast reduction surgery (Iwuagwu 2006). No clear recommendations exist for use of drains following breast augmentation or reconstruction; nevertheless, drains are often inserted after these procedures.

Surgical drains can be categorized as open or closed. With an open drain, an artificial conduit is left in the wound to allow drainage of fluids to the outside of the body (e.g. corrugated drain, Penrose drain and Yeates drain). With a closed drain, an artificial conduit is left in the wound and with a closed system connected to a container that is placed outside of the body. A closed drain may be passive, and rely upon gravity (e.g. the Robinson drain), or active, and rely upon negative pressure (e.g. the Redon drain), where the pressure in the container is negative compared to the body cavity allowing fluids to be actively drained by suction.
The use of drains should reduce the accumulation of blood and fluid (Perkins 1997; Scevola 2002), however, some suggest that the rate of fluid collection is not changed by the use of drains (White 1998), and haematomas and seromas can occur despite their presence (Debry 1999; Hurtado-Lopez 2001; Pai 1999). Moreover, the use of a drainage system might even be associated with complications such as potential drain migration (with injury to internal organs), blockage of the drain by clotted blood (Ernst 1997), and drain removal problems (such as drain retention or painful removal). Drains are often associated with discomfort and pain (Debry 1999; Schoretsanitis 1998). Length of hospital stay can be increased by the use of drains (Benedetti 1997; Hurtado-Lopez 2001; Schoretsanitis 1998), consequently increasing costs. Furthermore, drain sites can leave scars. A drain may also constitute a potential source of infection, acting as a foreign body (Pessaux 2003; Tang 2001; White 1998). Therefore, the use of prophylactic drains in plastic and reconstructive surgery remains controversial.

Rationale for this review
In plastic and reconstructive surgery drains are often used as a matter of routine. Studies in several of the surgical specialties, such as colorectal surgery (Urbach 1999), orthopaedic surgery (Parker 2007), and thyroid surgery (Samraj 2007), have questioned drain usage. In this review we seek to review the evidence regarding the advantages of using drains in plastic and reconstructive surgery of the breast.

OBJECTIVES
To compare the efficacy and safety of the use of wound drains following elective plastic and reconstructive surgery procedures of the breast.

METHODS

Criteria for considering studies for this review

Types of studies
Only randomised controlled trials (RCTs) that compared use of a wound drain with no wound drain after plastic and reconstructive surgery of the breast (breast augmentation, breast reduction and breast reconstruction) were eligible for inclusion in this review.

Types of participants
Female patients, irrespective of age, who have undergone elective plastic or reconstructive surgery of the breast. Eligible procedures included breast reduction surgery, breast augmentation surgery (with implants) and breast reconstructive surgery (with implants or flap procedures such as TRAM, DIEP or LD reconstruction).

Types of interventions
Studies comparing the use of any type of wound drain with no drain after plastic and reconstructive surgery of the breast.

Types of outcome measures
Outcome measures were categorised into primary outcomes and secondary outcomes. Primary outcomes were further categorised into major (i.e. those in which re-operation was necessary) and minor (i.e. those in which no intervention was necessary, or interventions other than re-operation were necessary (e.g. antibiotic treatments)) complications.

Primary outcomes
- Wound infection.
- Haematoma.
- Oedema (localised oedema or breast oedema).
- Seroma.
- Fat necrosis.
- (Partial) nipple loss.
- (Partial) flap loss (in case of autogenous tissue reconstruction).
- Capsular contracture rate (in case of implants).
- Other implant complications.
- Wound problems (e.g. post-operative wound dehiscence, healing complications, hypertrophic scarring).
- Complications associated with the use of the drain (e.g. drain migration and injury to internal organs; problems with drain removal).

Secondary outcomes
- Discomfort.
- Pain.
- Length of hospital stay (days).
- Costs.

Search methods for identification of studies

Electronic searches
For the first update of this review we searched the following electronic databases to find reports of relevant RCTs:

- Cochrane Wounds Group Specialised Register (searched 4 March 2015);
- The Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library 2015, Issue 2);
- Ovid MEDLINE (2012 to March 3 2015);
- Ovid MEDLINE (In-Process & Other Non-Indexed Citations March 3 2015);
- Ovid EMBASE (2012 to March 3 2015);

We used the following strategy in CENTRAL:

#1 MeSH descriptor Surgery, Plastic explode all trees
#2 MeSH descriptor Breast explode all trees
#3 (#1 AND #2)
#4 ((plastic or esthetic or aesthetic or reconstructive or cosmetic) NEXT surgery) NEAR/5 breast*:ti,ab,kw
#5 MeSH descriptor Mammoplasty explode all trees
#6 (mammaplast* or mammoplast*):ti,ab,kw
#7 (reduction NEXT surgery) or (breast NEXT surgery) or (breast NEXT reduction*):ti,ab,kw
#8 MeSH descriptor Breast Implantation explode all trees
#9 MeSH descriptor Breast Implants explode all trees
#10 breast NEXT (augmentation* or enlargement* or enhancement*):ti,ab,kw
#11 breast NEXT (implant* or prosthes*):ti,ab,kw
#12 breast NEXT reconstruction*:ti,ab,kw
#13 breast NEAR/5 flap*:ti,ab,kw
#14 TRAM or “transverse rectus abdominis musculocutaneous”:ti,ab,kw
#15 “transverse rectus abdominis musculocutaneous”:ti,ab,kw
#16 “rectus abdominis myocutaneous”:ti,ab,kw
#17 DIEP or “deep inferior epigastric perforator”:ti,ab,kw
#18 latissimus NEXT dorsi NEXT flap*:ti,ab,kw
#19 (#3 OR #4 OR #5 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18)
#20 MeSH descriptor Drainage explode all trees
#21 MeSH descriptor Suction explode all trees
#22 MeSH descriptor Catheterization explode all trees
#23 (drain* or suction* or catheter*):ti,ab,kw
#24 (#20 OR #21 OR #22 OR #23)
#25 (#19 AND #24)

The search strategies for Ovid MEDLINE, Ovid EMBASE and EBSCO CINAHL can be found in Appendix 1, Appendix 2 and Appendix 3, respectively. We combined the Ovid MEDLINE search with the Cochrane Highly Sensitive Search Strategy for identifying randomized trials in MEDLINE: sensitivity- and precision-maximizing version (2008 revision) (Lefebvre 2011). The Ovid EMBASE and EBSCO CINAHL searches were combined with the trial filters developed by the Scottish Intercollegiate Guidelines Network (SIGN) (SIGN 2009). There were no restrictions on the basis of date or language of publication.

**Searching other resources**

The reference lists of identified studies were also searched for potentially relevant studies. Authors of relevant studies were contacted to see if they were aware of other potentially relevant unpublished studies for the original review, this was not undertaken for the update.

**Data collection and analysis**

We used the standard method for conducting a systematic review, as described in The Cochrane Collaboration Handbook for Systematic Reviews of Interventions, (Higgins 2011), for this review.

**Selection of studies**

Study selection was undertaken by three review authors (CS, MS and SK). Titles and abstracts of all studies identified through the search strategy were scanned independently by authors according to specific selection criteria. The full text of potentially relevant articles was obtained. In instances where the title and abstract were inconclusive, full text versions were obtained for further assessment. The articles were then assessed independently by the three review authors (CS, MS and SK), and included or excluded on the basis of our inclusion and exclusion criteria for the review. Any differences of opinion were resolved by discussion.

**Data extraction and management**

Data extraction and assessment of the risk of bias of all eligible articles was undertaken independently by two review authors (CS and MS), without masking for study author names. Details of the selected studies were extracted and summarised using a data extraction form. If data were missing from articles, or clarification was needed, the trial authors were contacted with a request for missing information. Any discrepancies between review authors were resolved by discussion.

We extracted the following data:

- Details of the trial/study (first author, year of publication, journal, publication status, period and country of study).
- Inclusion and exclusion criteria.
- Baseline characteristics of participants (age, sex, type of surgery and prior treatment status).
- Number of participants in each arm of the trial.
- Design/methodological quality data as described below.
- Type of operation.
- Type of intervention (drain).
- Details of the comparison.
- Mean duration of drain use.
- Duration of follow up.
Assessment of risk of bias in included studies

Two authors independently assessed the risk of bias in accordance with guidelines in *The Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011), using a pre-defined quality assessment form based on the criteria outlined below. The main criteria were the assessment of generation of allocation sequence, allocation concealment, blinding, and extent of follow up.

Generation of the allocation sequence

Generation of the allocation sequence was scored as:
- Low Risk: if the allocation sequence was generated by a computer or random number table. Drawing of lots, tossing of a coin, shuffling of cards, or throwing dice were considered to be at low risk of bias if a person not otherwise involved in the recruitment of participants performed the procedure.
- Unclear Risk: if the trial was described as randomised, but the method used for the allocation sequence generation was not described.
- High Risk: if a system involving dates, names, or admittance numbers were used for the allocation of patients. These studies are known as quasi-randomised, and, once identified, would be excluded from the review.

Allocation concealment

Allocation concealment was scored as:
- Low Risk: if the allocation of patients involved a central independent unit, on-site locked computer, or sealed envelopes.
- Unclear Risk: if the trial was described as randomised, but the method used to conceal the allocation was not described.
- High Risk: if the allocation sequence was known to the investigators who assigned participants, or if the study was quasi-randomised.

Blinding of participants

Blinding of participants was scored as:
- Low Risk: if the participant was described as blinded and the method of blinding was described.
- Unclear Risk: if the participant was described as blinded, but the method of blinding was not described.
- High Risk: if there was no blinding at all.

Blinding of outcome assessor

Blinding of the outcome assessor was scored as:
- Low Risk: if the outcome assessor was described as blinded and the method of blinding was described.
- Unclear Risk: if the outcome assessor was described as blinded, but the method of blinding was not described.
- High Risk: if there was no blinding at all.

Completeness of follow up

Completeness of follow up refers to the percentage of trial participants for whom data were complete at the defined end-point of the study. Follow up was deemed to be:
- Low Risk: when 80% of people initially randomised to the trial were included at the final outcome measurement.
- Unclear Risk: when it was not clear how many people initially randomised to the trial were included at the final outcome measurement.
- High Risk: when less than 80% of people initially randomised to the trial were included at the final outcome measurement.

Intention-to-treat analysis

Intention-to-treat analysis (Hollis 1999) was considered to be:
- Low Risk: if clearly mentioned in methods, and analysis performed on an intention-to-treat basis, i.e. whether participants were analysed in the groups to which they were originally randomised.
- Unclear Risk: if not mentioned, but implied in the analysis.
- High Risk: if analysis was not performed on an intention-to-treat basis.

Studies with adequate allocation concealment; low levels of post-randomisation losses or exclusions and adequate blinding were considered as high quality studies and at low risk of bias. If the information we required was not available in the published study, we contacted the study authors in order to assess the trials correctly. Disagreements between review authors were resolved by discussion.

Assessment of heterogeneity

Heterogeneity between trials was considered and tested where appropriate. We assessed this using the $I^2$ statistic (Higgins 2002). Heterogeneity values over 50% were taken as indicative of substantial heterogeneity. Where there were sufficient studies to pool, we used a fixed-effect model (DeMets 1987). We intended to use the random-effects model when there was evidence of considerable heterogeneity in order to see if the results differed between fixed and random effects models (DerSimonian 1986).

Assessment of reporting biases

We intended to explore publication bias through a funnel plot (Egger 1997), if we found enough included studies for this to be possible.
Data synthesis
We intended to analyse data from the various plastic and reconstructive surgical operations on the breast in three separate categories; breast reduction, breast augmentation and breast reconstruction procedures; only breast reduction was conducted in the included trials.

Where appropriate and possible, the results of eligible studies were combined and statistically analysed by meta-analysis. We performed the meta-analyses according to the recommendations of The Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2011). We used the software package Review Manager (RevMan 5) provided by The Cochrane Collaboration. Where possible, all analyses were by intention-to-treat (ITT).

For dichotomous variables, we calculated the relative risks (RR) with 95% confidence interval (CI). For continuous data, we calculated mean differences (MD) with 95% CI. When possible, groups of similar studies were pooled depending on their quality and heterogeneity.

Subgroup analysis and investigation of heterogeneity
We intended to undertake subgroup analyses in order to investigate heterogeneity. Subgroup analyses would have included immediate reconstruction compared with delayed reconstruction (after mastectomy); open drains compared with closed drainage; suction compared with closed passive drainage, and trials that used routine antibiotic prophylaxis compared with those that did not. None of these analyses were possible.

Sensitivity analysis
A sensitivity analysis of trials with intermediate to high methodological quality was pre-planned and performed to explore the effect of methodological quality.

RESULTS

Description of studies
For a description of the included studies and the reason for exclusion of the excluded studies, see Characteristics of included studies and Characteristics of excluded studies, respectively.

A total of 190 references were identified by the search. Independent screening of titles and abstracts by both review authors identified 108 papers reporting prospective randomised trials, eight of which were duplicates. Of the 108 randomised trials, 11 were potentially relevant and the full text of these studies was obtained. Both review authors independently assessed these articles against the inclusion and exclusion criteria. Three studies met the inclusion criteria and were included in the review (Collis 2005; Corion 2009; Wrye 2003). The eight excluded randomised trials either compared different types of drain to each other (Hassan 2012; Rayatt 2005), did not place the drain in the breast (Rossetto 2014) or did not include people undergoing plastic or reconstructive surgery (Burak 1997; Cameron 1988; Gupta 2001; Johnson 2005; Purushotham 2002).

References of all potentially relevant articles were searched; no additional RCTs were identified. We contacted the authors of the included studies, but no other potentially relevant or unpublished studies were found through this process.

The studies were published between 2003 and 2009 (Collis 2005; Corion 2009; Wrye 2003), and were performed in the United States (Wrye 2003), the United Kingdom (Collis 2005), and the Netherlands (Corion 2009).

All the trials studied the use of drains in breast reduction surgery. No studies were found that compared the use of drains in breast augmentation or breast reconstruction surgery. Two of the included studies compared the insertion of a drain in one breast with no drain in the other breast on the same person (Collis 2005; Wrye 2003), whilst the third study compared a group of patients with drains in both breasts with a group of patients without drains (Corion 2009). Sample sizes were 49 women (Wrye 2003), 107 women (Corion 2009), and 150 women (Collis 2005).

Participants’ ages ranged from 17 to 73 years of age, with a mean age of 33 years (Wrye 2003), 37 years (Collis 2005) and 35 years (Corion 2009). The mean body mass index (BMI) was reported in two trials: 29 (range 18 to 40) for Collis 2005, and 26 (range 20 to 40) for Corion 2009. Two trials clearly reported the reduction mammoplasties as being bilateral (Collis 2005; Corion 2009); the third trial suggested this, but it was not specifically mentioned (Wrye 2003). One trial performed small reductions only, with a mean reduction of 675 g per breast (range 360 to 1090 g) (Wrye 2003). The other two trials included both small and large reductions, with mean reductions of 1110 g (SD 0.545 g) in the drain group and 1085 g (SD 0.487 g) in the no drain group in one trial (Corion 2009), and a mean reduction of 799 g (25% > 1000 g) in the other (Collis 2005). All participants in the Wrye 2003 trial received intravenous antibiotics peri-operatively, and five days of oral antibiotics after discharge; no antibiotics were given in the Corion 2009 trial, and antibiotic usage in the Collis 2005 trial was not mentioned. One trial excluded patients on anticoagulant medication or with a history of coagulation disorders (Corion 2009).

Two trials specified the use of closed suction drains (Collis 2005; Wrye 2003); the type of drain used was not reported in the third trial (Corion 2009). Drain removal criteria differed between trials; in Wrye 2003 all drains were removed on day one post-operatively; in Collis 2005 the drain was removed when fluid production was less than 30 ml in 24 hours; and in Corion 2009 drains were removed when fluid production was 20 ml or less for at least 24 hours. A variety of outcome measures were used across the three trials.
Risk of bias in included studies

For full results of the risk of bias assessment, see Characteristics of included studies

Allocation

Random sequence generation
All three included studies reported they were randomised but did not report how the random sequence was generated. In one study the unit of randomisation was the participant (Corion 2009) and in the remaining two studies the unit of randomisation was the breast (Collis 2005; Wrye 2003).

Allocation concealment

Corion 2009 reported they achieved allocation concealment via an independent investigator. The remaining two trials (Collis 2005; Wrye 2003) did not report how allocation concealment was achieved.

Blinding

Blinding is difficult to achieve in trials where wound care is involved, particularly as drains are clearly visible.

Participant Blinding

Participant blinding could not be achieved in any of the three trials (Collis 2005; Corion 2009; Wrye 2003) as the participant would have been aware whether or not a drain was inserted and into which breast.

Treatment Provider Blinding (Surgeon)

One trial (Corion 2009) specifically reported the surgeon was unaware if the participant was to receive a drain or not until near the end of the procedure; this was deemed to be low risk of bias. The remaining two trials (Collis 2005; Wrye 2003) did not report if the treatment provider was blinded or not.

Blinding of Outcome Assessor

The outcome assessor in these trials could not have been blinded as a scar would be visible from the placement of the drain, even after removal. This domain was judged to be high risk in all three trials (Collis 2005; Corion 2009; Wrye 2003)

Incomplete outcome data

No patients were lost to follow-up in Corion 2009. Collis 2005 reported one participant was excluded after the drain was accidentally avulsed post operatively. It was not clear if intention to treat analysis was carried out or not. In Wrye 2003, although all primary outcome data was available, follow up data only included 40% of the initial participants.

Selective reporting

Study protocols were not sought for the three trials (Collis 2005; Corion 2009; Wrye 2003), however, the trials did report results of all outcomes which were specified in the methods.

Effects of interventions

Primary outcomes

Wrye 2003
Six of 49 drained breasts had complications and all were minor: one partial loss of the nipple due to necrosis; two breasts with wound dehiscence; two breasts with fat necrosis; and one haematoma. Five of 49 undrained breasts had complications: one haematoma that required reoperation; three breasts with wound dehiscence; and one breast with fat necrosis. No wound infections were reported.

Collis 2005
Fifty-two of 150 drained breasts had complications, some of which were major and some minor: three haematomas and three abscesses requiring reoperation; one seroma needing aspiration; one haematoma which drained spontaneously; three breasts with fat necrosis; five other wound infections; two breasts with hypertrophic scarring; and 34 breasts with wound dehiscence. Forty-seven complications occurred in the 150 undrained breasts: four haematoma requiring reoperation; seven wound infections, including one abscess requiring reoperation; one seroma requiring aspiration; one breast with fat necrosis; two breasts with hypertrophic scarring; and 32 breasts with wound dehiscence.

Corion 2009
Twenty two of the 55 patients in the drained group had a complication: six patients experienced haematomas, of which three required reoperation; eight had wound infections, including two abscesses which required reoperation; one had an oedema; five experienced wound dehiscence; and two patients had some stitches removed to prevent partial nipple loss. Twelve of the 52 patients in the undrained group had a complication: four experienced
haematomas of which two needed reoperation; two experienced breast oedema; three contracted wound infections; and three experienced wound dehiscence.

Pooling of the data
In order to combine the data from all three trials in a meta-analysis, we compared drained breasts with non-drained breasts, and each patient in the between-patient comparison was considered as a single breast. As such, complications were scored for 306 patients, i.e. 254 drained breasts and 251 non-drained breasts. Since there was no indication for heterogeneity the trials were pooled using a fixed effects model.

Haematoma
Both Corion 2009 and Wrye 2003 defined haematoma as “a breast more swollen and firm than the contralateral breast”. Collis 2005 gave no clear definition of haematoma. Haematoma occurred in 11/254 of the drain group and 9/251 of the non-drained group, and did not significantly differ between the two groups (505 breasts from three studies, RR 1.19; 95% CI 0.50 to 2.80; I² = 0%) (Analysis 1.1). Analysis of the high quality study only showed no significant difference (107 breasts, RR 1.42; 95% CI 0.42 to 4.74) (Corion 2009) (Analysis 1.1).

Wound infection
All three trials reported on infection, and one trial (Corion 2009) gave a definition: “increasing redness of the skin with or without swelling, warmth or pain” (Corion 2009). The overall rates of wound infection were 16/254 in the drain group and 10/251 in the non-drained group. The incidence of infection was not significantly different between the groups across the three trials (505 breasts, RR 1.56; 95% CI 0.73 to 3.37; I² = 0%) (Analysis 1.2) or in the one high quality trial (Corion 2009) (107 breasts, RR 2.52; 95% CI 0.71 to 8.99) (Analysis 1.2).

Oedema
Oedema was studied only in the high-quality trial (Corion 2009). The trial authors defined oedema as: “a more swollen, firmer breast than the contralateral breast occurring in a course of days or weeks after the reduction, without signs of infection”. It occurred in only 1/55 in the drained group and 2/52 in the non-drained group, with no statistically significant difference between the groups (107 breasts, RR 0.47; 95% CI 0.04 to 5.06) (Analysis 1.3).

Seroma
Two trials reported on seroma (Collis 2005; Wrye 2003), with only one case observed in each group in the same study (Collis 2005). Both required aspiration, considered a minor intervention (398 breasts, RR 1.00; 95% CI 0.06 to 15.84) (Analysis 1.4).

Fat necrosis
Two trials reported fat necrosis as an outcome (Collis 2005; Wrye 2003), but only one gave a definition: “a firm nodule of varying size with or without tenderness identified in the post-operative period” (Wrye 2003). Rates of fat necrosis were 5/199 in the drained group and 2/199 in the non-drained group; there was no significant difference between the groups (398 breasts from two studies, RR 2.50; 95% CI 0.49 to 12.70; I² = 0%) (Analysis 1.5).

Nipple loss
All three trials reported on nipple loss and this was a rare complication. Overall, partial or total, nipple loss occurred in 3/254 in the drained group and in 0/251 in the non-drained group. Statistical analysis showed no significant difference between the drained and non-drained group across the three trials (RR 3.88; 95% CI 0.44 to 34.24; I² = 0%) (Analysis 1.6), or in the high quality trial (RR 4.73; 95% CI 0.23 to 96.30) (Analysis 1.6) (Corion 2009). There was no nipple loss in Collis 2005.

Wound problems
Two trials studied hypertrophic scarring separately from other wound problems (skin loss, wound dehiscence), and overall this occurred in 2/199 in the drained group and 2/199 in the non-drained group (Collis 2005; Wrye 2003). Pooling data of total wound problems from all three trials, gave rates of 43/254 in the drained group and 40/251 in the non-drained group. There was no significant difference between the two groups across the three studies (505 breasts, RR 1.07; 95% CI 0.73 to 1.57; I² = 0%) (Analysis 1.7) or in the high quality study (RR 1.58; 95% CI 0.40 to 6.26) (Corion 2009) (Analysis 1.7).

Major complications
Major complications that required reoperation consisted only of surgical evacuation of abscess and haematoma fluids. They occurred in 11/254 in the drained group, and 8/251 in the non-drained group. There was no significant difference between the groups (505 breasts, RR 1.33; 95% CI 0.56 to 3.17; I² = 0%) (Analysis 1.10). Major haematomas that required reoperation occurred in 6/254 in the drained group, and 7/251 in the non-drained group, and did not significantly differ (505 breasts, RR 0.84; 95% CI 0.29 to 2.46; I² = 0%) (Analysis 1.11).

Rates of major abscess drainage were low, with 5/254 in the drained group and 1/251 in the non-drained group. There was no significant difference between the groups across the three trials (505 breasts, RR 3.59; 95% CI 0.59 to 21.64; I² = 0%) (Analysis 1.12).
or the high quality study (107 breasts, RR 4.73; 95% CI 0.23 to 96.30) (Analysis 1.12) (Corion 2009).

Other
There were no reports of complications directly related to drain placement or removal, or tissue damage directly related to drain placement. As no trials were met the inclusion criteria that studied drain usage in breast augmentation or reconstruction, capsular contracture, implant problems, and flap loss were not assessed.

Secondary outcomes

Pain/discomfort
Two studies assessed post-operative pain. One reported mean visual analogue scale (VAS) scores of 3.35 (SD 1.91) (55 breasts) in the drained group, and 2.95 (SD 1.75) (52 breasts) in the non-drained group; there was no significant difference between the groups (MD 0.40; 95% CI 0.29 to 1.09) (Analysis 1.8) (Corion 2009).

In the other study (Wrye 2003), the 49 participants were given a two-part questionnaire on the day of discharge. The first part asked about the comfort level (including pain) of each breast (i.e., comparison of the drained breast with the non-drained one) immediately after discharge. The second part asked about long-term satisfaction; participants returned this three months after surgery. Thirty questionnaires were distributed, and nineteen were returned. The results showed that 17/19 respondents (89%) found the non-drained breast more comfortable in the postoperative period; either the drained breast was more painful, or there were other problems with the use of drains in the drained breast. A further 2/19 (11%) experienced little or no difference in comfort in the early post-operative period.

The data from these two trials could not be combined due to differences in methods of assessment and reporting.

Length of hospital stay
Only one study assessed length of hospital stay (Corion 2009): the mean stay for the drained group (55 breasts) was 2.62 days (SD 0.89), and 1.85 days (SD 1.04) for the non-drained group (52 breasts). Statistical analysis of the mean difference between the groups showed that the length of hospital stay was significantly shorter for the non-drained group (mean difference 0.77; 95% CI 0.40 to 1.14) (Analysis 1.9).

Costs
None of the trials reported on costs.

DISCUSSION
Drains are commonly used in plastic and reconstructive surgery of the breast, despite a lack of clarity about their benefits. Our literature search resulted in the identification of three randomised trials that investigated the use of drains after breast reduction surgery: no randomised trials were identified that evaluated the use of drains in breast augmentation or breast reconstruction surgery. Two of the included trials randomised on a per breast basis with one breast drained and the other not, and one trial randomised on a per patient basis with both breasts, or neither breast, having post-surgical drainage. In total there were 505 breasts across the three studies (254 drained; 251 non-drained); not all the outcomes of interest were reported in all three studies. Only one study was assessed as being of good methodological quality (intermediate to high quality) (Corion 2009), with blinding as its only factor to score ‘unclear or inadequate’, though effective blinding is difficult to achieve in the case of drain insertion. Although the surgeon was not aware of the randomisation until the end of the operation, he was aware that the patient may not receive a drain, and this fact alone could have influenced the surgical technique. The other two studies were considered to be of low to intermediate quality, and the possible bias that this may have caused should be taken into account. Nonetheless, analysis of the high quality study alone did not demonstrate any different results. With only three included trials, valid evaluation of publication bias was not possible.

Overall complication rate was low and this does affect the statistical power of the included studies; only one trial calculated a sample size (Corion 2009). The definition of complications varied between the studies, but we found the descriptions similar enough for a meta-analysis in which data for all breasts or patients with a drain were compared with all breasts or patients without a drain; however, the subjectivity in defining a complication may have biased the results. Our review found no evidence that the risk of wound infection, haematoma, oedema, seroma, fat necrosis, nipple loss or wound problems differed significantly between the drained and non-drained breasts. Data regarding major complications (i.e. reoperation) also showed no significant difference between the drained and non-drained groups. Collis 2005 studied both the rate of haematoma that required surgical drainage and seroma aspiration, and both Collis 2005 and Corion 2009 showed no significant difference in abscess drainage between the two groups. Also, there were no statistically significant differences in pain, although the drains were painful and caused discomfort in many patients. Limited evidence was available on hospital stay; one study found that patients without a drain had a significantly shorter hospital stay (Corion 2009). Drain migration, or tissue damage as a consequence of drain placement were not observed in any of the identified trials. Cost analysis was not performed.

In addition to the diversity in the definitions of the complications, the surgical technique and types of drains used also varied across trials. In the trials of Wrye 2003 and Collis 2005 the inferior pedi-
 ARTICLE

The technique was mainly used, while Corion 2009 studied the outcomes of the cranio-medial pedicle technique. Some suggest that the superior pedicle breast reduction techniques are associated with a higher risk of postoperative complications, because a larger space is created within the breast (Anzarut 2008). The present review does not support this suggestion, although sample size was too small to perform subgroup analysis. Collis 2005 did not find evidence that the size of the breast reduction affected the complication rate, as there was no relationship between the amount of tissue removed and the number of complications, but again, sample size was too small to draw strong conclusions. Pre-and post-operative antibiotic and corticosteroid usage differed between our selected trials; Wrye 2003 studied patients who had received antibiotics both peri- and post-operatively, though no details were given about corticosteroid usage; Corion 2009 gave no prophylactic antibiotics or corticosteroids; and Collis 2005 did not report antibiotic or corticosteroid administration. Corion 2009 concluded that omission of drains is safe without routine administration of antibiotics or corticosteroids. All studies used closed suction drains, although removal guidelines differed. Since no trials were identified that used other types of drains, only conclusions regarding closed suction drains can be made. Other types of drains, however, are not expected to decrease complications, as closed suction drains are considered the superior choice because of the active suction of the wound. Finally, there are other risk factors for post-operative complications (such as age, body mass index (BMI), diabetes mellitus and smoking). It is imaginable that certain groups of high-risk patients may benefit from the use of drains, but no subgroups were made in the included studies.

A U T H O R S ’ C O N C L U S I O N S

Implications for practice

The limited evidence available shows no benefit in using post-operative closed suction drains in breast reduction surgery; however, this is based on only three trials, two of which had methodological limitations that put them at a high risk of bias. There is no evidence available evaluating the impact of using drains in breast augmentation and breast reconstruction surgery.

Implications for research

Larger, methodologically sound, prospective randomised trials may have increased power to show a function of the use of drains in decreasing complications. Trials that study the use of drains in breast augmentation and reconstruction surgery are especially indicated. The definitions of complications should be standardized and clearly stated. If possible, a distinction should be made between minor and major complications. Studies with different subgroups (e.g. age, breast size, co-morbidity, amount of tissue removed) are necessary to determine whether omission of drains is safe in all patients. A within patient design comparison has advantages as less patients are needed, but a between patient design allows for comparison of patient related factors, rather than breast related factors, such as hospital stay and the use of antibiotics. Both designs may be needed.

A C K N O W L E D G E M E N T S

The review authors would like to acknowledge the contribution of the peer referees, Wounds Group Editors (Julie Bruce, Nicky Cullum, Andrea Nelson, Gill Worthy), Wounds Group referees (Rachel Richardson, Kumarakrishnan Samraj), Breast Cancer referees (Melissa Bochner, Katrina Moore), Consumer referee Anne Lyddiatt and Cochrane Copy Editor Elizabeth Royle.

We would like to acknowledge the substantial contribution of Christa Stojkovic who wrote the protocol and the first published version of this review, however she no longer has the time to remain involved in the updating process.

R E F E R E N C E S

References to studies included in this review

Collis 2005 (published data only)

Corion 2009 (published data only)

Wrye 2003 (published data only)

References to studies excluded from this review

Burak 1997 (published data only)
Wound drainage after plastic and reconstructive surgery of the breast (Review)

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Additional references

Alderman 2002

Anzarut 2008

Benedetti 1997

Blondeel 2000

Cruz-Korchin 2003

Cunningham 2000

Debry 1999

DeMets 1987

DerSimonian 1986

Egger 1997

Ernst 1997

Gui 2003

Hamdi 1999

Hassan 2012

Higgins 2002

Higgins 2011
Higgins JPT, Altman DG, on behalf of the Cochrane Statistical Methods Group and the Cochrane Bias Methods Group (Editors). Chapter 8: Assessing risk

Hollis 1999

Hurtado-Lopez 2001

Iwuagwu 2006

Kroll 2000

Lefebvre 2011

Lejour 1999

Mandrekas 1996

Mathes 2006

McCarthy 2007

Mimoun 2006

Nahabedian 2002

Pai 1999

Parker 2007

Perkins 1997

Pessaux 2003

Rossetto 2014

Schoretsanitis 1998

Samraj 2007

Scevola 2002

Schoretsanitis 1999

SIGN 2009

Tang 2001

**Tapia 1996**


**Urbach 1999**


**White 1998**


* Indicates the major publication for the study
Characteristics of included studies  [ordered by study ID]

Collis 2005

<table>
<thead>
<tr>
<th>Methods</th>
<th>Randomised controlled trial, with two breasts in each patient being randomised</th>
</tr>
</thead>
</table>
| Participants                  | Number: 150 patients enrolled (300 breasts) (mean age 37 years; mean BMI 29 (range 18-40)):  
  - inferior pedicle technique 141;  
  - superomedial pedicle 9;  
  - 25% of total > 1000g reduction per breast (mean 799g).  
  Inclusion criteria: routine bilateral breast reduction surgery, female patients.  
  Exclusion criteria: one patient excluded after the drain was accidentally avulsed in the early post-operative period |
| Interventions                 | Intervention 1: unilateral Bellovac closed suction drain in one breast.  
  Intervention 2: no drain in the other breast (on the same patient).  
  Drain removed when production < 30 ml in 24 hours:  
  - 43% removed on 1st post-operative day;  
  - 49% removed on 2nd post-operative day;  
  - 7% removed on 3rd + 4th post-operative day.  
  Mean volume drained 72 ml (range 0-392 ml).  
  No mention of antibiotic use. |
| Outcomes                      | Haematoma (surgically drained); spontaneous haematoma drainage; minor wound healing (skin loss <1 cm²); major wound healing (skin loss > 1 cm²); fat necrosis; abscess drainage; minor infection; major infection; seroma aspiration; hypertrophic scarring; nipple loss |
| Notes                         | Trial location: UK. Setting: university hospital.  
  Follow up: 3 months. |

Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors’ judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
</table>
| Random sequence generation (selection bias) | Unclear risk | Quote: Participants were ‘prospectively randomised intra-operatively’  
  Did not report randomisation procedure.  
  Each participant acted as their own control.  
  Unit of randomisation was the breast |
| Allocation concealment (selection bias) | Unclear risk | Did not report allocation concealment. |
| Blinding (performance bias and detection bias) | High risk | Each participant had a bilateral breast reduction; one breast received a drain and the other did not.  
  Binding could not be carried out in this setting |
### Collis 2005  
(Continued)

<table>
<thead>
<tr>
<th>Bias Type</th>
<th>Risk Assessment</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>Unclear risk</td>
<td>It is not clear whether the treatment provider (surgeon) was aware of which breast would receive a drain or when this was allocated.</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>High risk</td>
<td>Each participant had a bilateral breast reduction; one breast received a drain and the other did not. Binding of the outcome assessor could not be achieved irrespective of whether the drain was in situ at the time of assessment as there would have been a physical scar indicating the presence of a drain.</td>
</tr>
</tbody>
</table>
| Incomplete outcome data (attrition bias)            | Low risk       | Quote: 'One patient was excluded after the drain was accidentally avulsed in the early post-operative period'  
Reason for exclusion reported. It is not clear if this participant was included in the final analysis or not. |
| Selective reporting (reporting bias)                | Low risk       | Comment: Study protocol not available. However, the outcomes stated in the methods of the report were all described in the results and discussion. |
| Adequate follow up?                                 | Low risk       | All participant data reported.                                                                                                                                 |
| Intention-to-treat analysis?                         | Unclear risk   | One participant excluded due to drain avulsion- unclear if this participant was included in analysis.                                           |

### Corion 2009

#### Methods
Randomised controlled trial, with patients individually randomised.  

#### Participants
Number: 107 patients enrolled (mean age 35 years; mean BMI 26 (range 20-40)):
- drain: 55 patients;  
- no drain: 52 patients.  
Mean volume of reduction: drained group 1110 g; no drain group 1085 g.  
Inclusion criteria: bilateral breast reduction surgery, craniomedical pedicle technique, female patients.  
Exclusion criteria: patients on anticoagulant medication or with a history of coagulation disorders.

#### Interventions
Group 1: patients with drains in both breasts.  
Group 2: patients with no drains in either of their breasts.
Corion 2009  (Continued)

Drains were removed when production was \( \leq 20 \text{ ml} \) for at least 24 hours. Patients with drains were discharged on the day of drain removal unless they felt comfortable leaving hospital earlier with the drains still in place.

No antibiotics given.

**Outcomes**

- **Primary outcome:** Occurrence of a complication: haematoma; infection; oedema; necrosis; wound dehiscence
- **Secondary outcome measures (visual analogue scale):** Pain; discomfort due to drains; satisfaction rate (satisfaction rate was not assessed in the review)

**Notes**

- Calculated sample size 100.
- No pre- or peri-operative antibiotics or corticosteroids were given.
- Patients were discharged as soon as they felt comfortable about leaving the hospital

**Risk of bias**

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors’ judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Unclear risk</td>
<td>Quote: Participants were 'prospectively randomised during surgery'. Participants were 'assigned…to one of two groups using a randomisation scheme' Did not report randomisation procedure. Unit of randomisation was the participant</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Low risk</td>
<td>Quote: ‘An independent investigator (MS) who assigned the patient to one of the two groups’ Allocation concealment was achieved.</td>
</tr>
<tr>
<td>Blinding (performance bias and detection bias) All outcomes</td>
<td>High risk</td>
<td>Binding could not be carried out in this setting as the participant would have been aware of the presence of a drain or not</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>Low risk</td>
<td>Quote: ‘Patients were not assigned to the experimental groups until the subcutaneous sutures were placed’ The treatment provider (surgeon) was not aware if the patient would receive a drain or not till near completion of the surgical procedure</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) All outcomes</td>
<td>High risk</td>
<td>Binding of the outcome assessor could not be achieved irrespective of whether the drain was in situ at the time of assessment as there would have been a physical scar in-</td>
</tr>
</tbody>
</table>
### Corion 2009  
(Continued)

<table>
<thead>
<tr>
<th>Bias Type</th>
<th>Risk</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Low</td>
<td>Quote: ’Intention to treat analysis was not performed, because all the patients received the treatment they were selected for’ No patient data lost.</td>
</tr>
<tr>
<td>All outcomes</td>
<td>Low</td>
<td>Study protocol not available. However, the outcomes stated in the methods of the report were all described in the results and discussion.</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Low</td>
<td>All participant data reported.</td>
</tr>
<tr>
<td>Adequate follow up?</td>
<td>Low</td>
<td>Intention to treat analysis carried out.</td>
</tr>
<tr>
<td>Intention-to-treat analysis?</td>
<td>Low</td>
<td></td>
</tr>
</tbody>
</table>

### Wrye 2003

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methods</td>
<td>Randomised controlled trial, with two breasts in each patient being randomised. Study duration: inclusion of patients from May 1999-March 2000, follow-up time ranging 5-17 months. Total duration: 27 months.</td>
</tr>
</tbody>
</table>
| Participants | Number: 49 patients enrolled (mean age 33 years; mean BMI not reported):  
|              | • inferior pedicle technique 48;  
|              | • amputation and free nipple grafting 1;  
|              | Small volume reductions (mean reduction 675 g; range 360-1090 g)  
|              | Inclusion criteria: (implied bilateral) breast reduction surgery, female patients. Exclusion criteria: not stated. |
| Interventions | Intervention 1: drain (no. 10 flat Blake or Jackson-Pratt) in one breast.  
|               | Intervention 2: no drain in the other breast (on the same patient). All drains were removed one day after surgery. |
| Outcomes    | Complication rates for: partial nipple loss; wound breakdown; fat necrosis; haematoma; seroma; infection; hypertrophic scarring; difference in nipple sensation*; significant asymmetry*  
|             | Patient satisfaction (via a post-operative questionnaires completed directly after surgery and 3 months later)  
|             | 1st section: comfort level of each breast:  
|             | • pain;  
|             | • pinching*;  
|             | • drain getting caught*;  
|             | • drain removed due to discomfort*.  
|             | 2nd section: long-term patient satisfaction*.  
|             | * Difference in nipple sensation, significant asymmetry, comfort level (except for pain) and patient satisfaction are not assessed in the review. |
Notes

All patients received IV antibiotics peri-operatively, and oral antibiotics for 5 days post-operatively.
Follow up mean/average 9 months (range 5-17 months).
All patients were discharged the morning after surgery wearing sports brassieres, which they were to wear for the next 6 weeks.

Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Unclear risk</td>
<td>Quote: ‘Each patient was randomised to having a drain.. in either the right or left’ Did not report method of generating randomisation sequence. Each participant acted as their own control. Unit of randomisation was the breast</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Did not report allocation concealment.</td>
</tr>
<tr>
<td>Blinding (performance bias and detection bias) All outcomes</td>
<td>High risk</td>
<td>Each participant had a bilateral breast reduction; one breast received a drain and the other did not. Binding could not be carried out in this setting.</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>Unclear risk</td>
<td>Quote: ‘Surgical technique did not differ between the three senior authors, with the exception of suture material used at the time of closing’ It is not clear whether the treatment provider (surgeon) was aware of which breast would receive a drain or when this was allocated.</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) All outcomes</td>
<td>High risk</td>
<td>Binding of the outcome assessor could not be achieved irrespective of whether the drain was in situ at the time of assessment as there would have been a physical scar indicating the presence of a drain</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias) All outcomes</td>
<td>Low risk</td>
<td>Quote: ‘Of the 30 questionnaires distributed, 19 were returned (63 percent)’ All participants’ data was available at the final outcome assessment for wound complications (primary outcome). However participants were followed up for a review of complications and patient satisfaction and this data were incomplete (40% of total</td>
</tr>
</tbody>
</table>
Characteristics of excluded studies  [ordered by study ID]

<table>
<thead>
<tr>
<th>Study</th>
<th>Reason for exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Burak 1997</td>
<td>Did not study plastic or reconstructive surgery.</td>
</tr>
<tr>
<td>Cameron 1988</td>
<td>Did not study plastic or reconstructive surgery.</td>
</tr>
<tr>
<td>Gupta 2001</td>
<td>Did not study plastic or reconstructive surgery.</td>
</tr>
<tr>
<td>Hassan 2012</td>
<td>Did not place drains in the breast - placed in the abdomen (donor site for reconstruction)</td>
</tr>
<tr>
<td>Johnson 2005</td>
<td>Did not study plastic or reconstructive surgery. Furthermore, compared drain usage and fibrin sealant instead of drain usage versus no drain usage</td>
</tr>
<tr>
<td>Purushotham 2002</td>
<td>Did not study plastic or reconstructive surgery.</td>
</tr>
<tr>
<td>Rayatt 2005</td>
<td>Did not compare drain usage to no drain usage, but compared one type of drain with another type</td>
</tr>
<tr>
<td>Rossetto 2014</td>
<td>Did not randomise participants.</td>
</tr>
</tbody>
</table>
## DATA AND ANALYSES

Comparison 1. Drain compared with no drain

<table>
<thead>
<tr>
<th>Outcome or subgroup title</th>
<th>No. of studies</th>
<th>No. of participants</th>
<th>Statistical method</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Haematoma</td>
<td>3</td>
<td>505</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>1.19 [0.50, 2.80]</td>
</tr>
<tr>
<td>1.1 Studies of poorer quality</td>
<td>2</td>
<td>398</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>1.0 [0.29, 3.40]</td>
</tr>
<tr>
<td>1.2 Study of high quality</td>
<td>1</td>
<td>107</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>1.42 [0.42, 4.74]</td>
</tr>
<tr>
<td>2 Infection</td>
<td>3</td>
<td>505</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>1.56 [0.73, 3.37]</td>
</tr>
<tr>
<td>2.1 Studies of poorer quality</td>
<td>2</td>
<td>398</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>1.14 [0.43, 3.07]</td>
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<td>2.2 Study of high quality</td>
<td>1</td>
<td>107</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>2.52 [0.71, 8.99]</td>
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<td>3 Oedema</td>
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<td>107</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>0.47 [0.04, 5.06]</td>
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<td>4 Seroma</td>
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<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>1.0 [0.06, 15.84]</td>
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<td>5 Fat necrosis</td>
<td>2</td>
<td>398</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>2.5 [0.49, 12.70]</td>
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<tr>
<td>6 (Partial) nipple loss</td>
<td>3</td>
<td>505</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>3.88 [0.44, 34.24]</td>
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<td>6.1 Studies of poorer quality</td>
<td>2</td>
<td>398</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>3.0 [0.13, 71.89]</td>
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<td>6.2 Study of high quality</td>
<td>1</td>
<td>107</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>4.73 [0.23, 96.30]</td>
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<tr>
<td>7 Wound problems</td>
<td>3</td>
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<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>1.07 [0.73, 1.57]</td>
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<td>7.1 Studies of poorer quality</td>
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<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>1.03 [0.69, 1.53]</td>
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<td>7.2 Study of high quality</td>
<td>1</td>
<td>107</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>1.58 [0.40, 6.26]</td>
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<td>8 Pain</td>
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<td>Mean Difference (IV, Fixed, 95% CI)</td>
<td>0.40 [-0.29, 1.09]</td>
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<tr>
<td>9 Length of hospital stay (days)</td>
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<td>Mean Difference (IV, Fixed, 95% CI)</td>
<td>0.77 [0.40, 1.14]</td>
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<td>10 Major complication</td>
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<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>1.33 [0.56, 3.17]</td>
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<tr>
<td>11 Major haematoma</td>
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<td>0.85 [0.30, 2.40]</td>
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<td>12 Abscess drainage</td>
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<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>3.59 [0.59, 21.64]</td>
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<td>12.1 Study of poorer quality</td>
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<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>3.0 [0.32, 28.52]</td>
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<td>12.2 Study of high quality</td>
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<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>4.73 [0.23, 96.30]</td>
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## WHAT’S NEW

Last assessed as up-to-date: 4 March 2015.

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
<th>Description</th>
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<tbody>
<tr>
<td>28 September 2015</td>
<td>New citation required but conclusions have not changed</td>
<td>New search, no new included studies identified.</td>
</tr>
<tr>
<td>28 September 2015</td>
<td>New search has been performed</td>
<td>First update, new contact author.</td>
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</table>
CONTRIBUTIONS OF AUTHORS

Sam Khan checked search results for the review, undertook the risk of bias assessments, commented on the text of the draft review and updated the review.

Mark Smeulders is co-author and has given support for writing of the review. He independently selected studies, extracted data, assessed study quality and cross checked with Christa Stojkovic.

Chantal Van der Horst is also co-author and has given feedback on the final version of the review. She has also participated in the interpretation of the analysis.

Contributions of editorial base:
Nicky Cullum: edited the review, advised on methodology, interpretation and review content.
Julie Bruce, Editor: approved the final review prior to submission.
Sally Bell-Syer: coordinated the editorial process. Advised on methodology, interpretation and content. Edited the review and updated review.
Ruth Foxlee: designed the search strategy, ran the searches and edited the search methods section.

DECLARATIONS OF INTEREST

None

SOURCES OF SUPPORT

Internal sources
- No sources of support supplied

External sources
- NIHR/Department of Health (England), (Cochrane Wounds Group), UK.

INDEX TERMS

Medical Subject Headings (MeSH)
*Drainage; *Length of Stay; Mammaplasty [*adverse effects]; Postoperative Complications [*prevention & control]; Randomized Controlled Trials as Topic

MeSH check words
Female; Humans