

# A systematic review of flap fixation techniques in reducing seroma formation and its sequelae after mastectomy

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# A systematic review of flap fixation techniques in reducing seroma formation and its sequelae after mastectomy

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## Abstract

**Background** Seroma formation is a common complication after mastectomy. This review aims to elucidate which surgical techniques are most effective in reducing the dead space and therefore seroma formation in patients undergoing mastectomy.

**Methods** A literature search was performed to identify clinical studies comparing any form of flap fixation to conventional closure technique in patients undergoing mastectomy with or without axillary clearance. Studies were eligible for inclusion if outcome was described in terms of seroma formation and/or complications of seroma formation. Studies on animal research or breast reconstruction with tissue expanders or flap harvesting (latissimus dorsi) were excluded.

**Results** A total of nine articles were eligible for inclusion. Five were retrospective studies and four were prospective. Retrospective and prospective studies have demonstrated the higher incidence of seroma formation in patients not undergoing mechanical flap fixation. The incidence of seroma-related complications in these studies vary. Four out of the nine studies demonstrate that patients undergoing flap fixation, need significantly fewer seroma aspirations. There are very few studies on the use of tissue glues preventing seroma formation.

**Conclusion** The scientific body of evidence favoring flap fixation after mastectomy is convincing. Mechanical flap fixation seems to reduce seroma formation and seroma aspiration after mastectomy. There are, however, no well-powered randomized controlled trials evaluating all aspects of seroma formation and its sequelae. Further research should elucidate whether flap fixation using sutures or tissue glue is superior.

**Keywords** Mastectomy · Seroma formation · Seroma aspiration · Flap fixation

## Introduction

Seroma formation after mastectomy is defined as a collection of serous fluid containing blood plasma and/or lymph fluid under the skin flaps or in the axilla. The reported incidence of seroma varies greatly, ranging from 3% to more than 90% [1–3]. Seroma formation should be regarded as a complication following mastectomy, although some consider it to be an unavoidable surgical nuisance. Seroma formation can lead to patient discomfort, repeated seroma aspirations with the risk of infection, prolonged hospital stay, delayed wound healing, skin flap necrosis, delay in commencing adjuvant therapies, and higher surgical expenditures [4–6].

The pathophysiology of seroma formation has been extensively analyzed. The extent of axillary lymph node involvement, type and extent of breast surgery, and the use of electrocautery have all been related to seroma formation [7–10]. In recent years, there have been many publications on effective techniques to prevent seroma formation. These techniques all appear to have one common denominator: reduction of the dead space [11]. Various methods have been described to reduce the dead space after mastectomy: closed suction drainage, quilting of

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the skin flaps, and application of adhesive tissue glues [12–16]. This review aims to elucidate which surgical flap fixation techniques are most effective in reducing the dead space and therefore seroma formation and its sequelae in patients undergoing mastectomy.

## Materials and methods

This systematic review was performed using the recommendations of the systematic reviews and meta-analyses (PRISMA) guideline [17]. A review of the literature was performed to identify consecutive studies on flap fixation in breast cancer patients undergoing mastectomy. Medline, Cochrane Library, and Embase were searched for the following MESH terms: ‘mastectomy’ and ‘seroma.’ In order to retrieve all potentially eligible articles, the following search terms were added: ‘quilting,’ ‘flap anchoring,’ and ‘flap fixation.’ Cross-referencing of the bibliography of selected articles was performed.

We limited this review to studies with a retrospective or prospective nature, reporting on patients undergoing mastectomy with or without axillary clearance. Articles were selected that included patients undergoing any form of flap fixation (reducing the dead space between the skin flaps and pectoral muscle) that was compared to a conventional closure technique. If outcome was described in terms of seroma formation and/or complications of seroma formation, studies were eligible for inclusion. Articles older than 20 years and articles not written in English were excluded. Furthermore, all studies involving animal research or cases involving patients undergoing direct breast reconstruction with tissue expanders or flap harvesting (lattisimus dorsi) were excluded from this review.

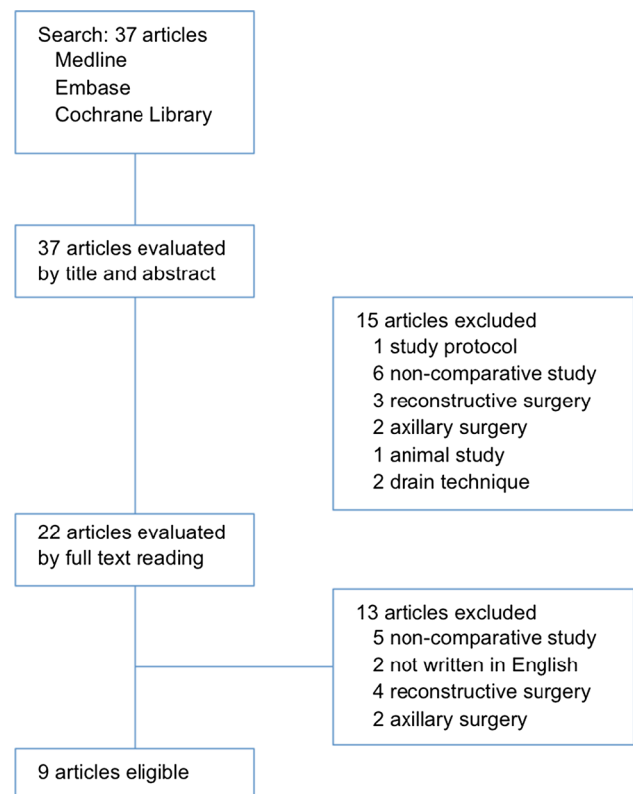
Search and selection of articles was independently performed by two authors (RG, LvR). First selection was based on title and abstract screening and final selection of eligible articles was made after article reading. In case of inconsistency in selection, a third author (JvB) was involved to make the final decision.

Assessment of the clinical and methodological quality of the eligible studies was undertaken. In case of a randomized controlled trial, we assessed the generation of random sequence, concealment of allocation, and blinding of allocation (Cochrane Handbook for Systematic Reviews of Interventions Version 5.0.2. <http://www.cochrane-handbook.org>). A descriptive analysis was performed in the analysis of seroma-related complications, as it was not possible to perform a meta-analysis due to the high level of heterogeneity of the interventions.

## Results

The search resulted in 37 articles. Fifteen articles were excluded based on title and abstract. Final selection after article reading resulted in nine articles that met the predefined inclusion criteria (Fig. 1). Of these studies, five were retrospective in nature and four studies were prospective (Tables 1, 2). Cross-referencing did not provide additional eligible articles. Table 3 represents a listing of the various studies in chronological order with specific seroma complications per study.

Almond et al. [6] performed a prospective study in which 135 patients undergoing mastectomy and/or axillary clearance were allocated to either a control group with suction drain placement or flap fixation. Flap fixation was achieved by using multiple rows of interrupted Vicryl sutures; all sutures were buried and placed 2.5 cm apart. Drains were removed when draining less than 50 ml of serous fluid per day. There was no difference in seroma formation between the drain group (59%) and the flap fixation group (49%). Median length of stay was significantly longer in the group undergoing suction drain placement (2.67 vs. 1.88 days) in the flap fixation group ( $p < 0.0001$ ). The authors state that when looking at costs, flap fixation seems to lead to considerable overall financial savings [6].



**Fig. 1** Flowchart of the selection of eligible articles

**Table 1** Retrospective studies comparing the clinical presence of seroma in patients undergoing flap fixation

Authors	Year	Procedure performed	N	Reference	p value
Ten Wolde	2014	Flap fixation using sutures	176	[19]	<b>0.000*</b>
Ouldamer	2015	Quilting using running sutures	119	[20]	<b>&lt; 0.001*</b>
Van Bastelaar	2016	Flap fixation using sutures	180	[23]	<b>0.002*</b>
Eichler	2016	Flap fixation using TissuGlu®	205	[24]	0.06
Van Bastelaar	2017	Flap fixation using ARTISS®	138	[25]	0.30

Bold values indicate significance at  $p < 0.05$

**Table 2** Prospective studies comparing the clinical presence of seroma in patients undergoing flap fixation

Authors	Year	Procedure performed	N	Reference	p value
Almond	2010	Flap fixation using sutures	135	[6]	0.22
Sakkary	2012	Flap fixation using sutures	40	[18]	<b>0.028*</b>
Khater	2015	Quilting using running sutures	120	[21]	<b>&lt; 0.001*</b>
Mazouni	2015	Flap fixation using sutures	87	[22]	<b>0.03 *</b>

Bold values indicate significance at  $p < 0.05$

Sakkary et al. [18] performed a comparative study in which 40 patients scheduled for modified radical mastectomy were prospectively included. Patients were randomly divided into two groups: a group undergoing flap fixation using interrupted Vicryl 3.0 sutures 3 cm apart with obliteration of the dead space in the axilla. A closed suction drain was used. In the control group, only a closed suction drain was applied before skin closure. Seroma formation was significantly less in the flap fixation group (10% vs. 40%,  $p = 0.028$ ) when compared to the drain-only group. Drains remained in situ significantly longer in the drain-only group (13.4 vs. 5 days mean,  $p < 0.001$ ). Total amount of drained fluid was also less in the flap fixation group (524.8 ml vs. 2017.8 ml,  $p < 0.001$ ). There were no other significant differences in complications between these two groups [18].

Ten Wolde et al. [19] retrospectively analyzed 176 patients who underwent mastectomy and/or axillary clearance. The historical control group ( $n = 87$ ) consisted of patients undergoing surgery followed by low vacuum drainage in the axilla. Hereafter, a total of 89 consecutive patients underwent surgery and quilting of the skin flaps with rows of running polyglycolic acid stitches, 3 cm apart. Rows varied from 4 to 8 in total depending on the extent of the cranial and caudal skin flaps. All patients received a low vacuum drain. There were significantly fewer patients in the quilting group with clinically significant seroma (22.5% vs. 80.5%,  $p = 0.000$ ). In cases where patients developed seroma, the mean number of aspirations decreased with quilting (2.4 vs. 4.86,  $p = 0.015$ ), as did the surgical site infections (10% vs. 31%,  $p = 0.001$ ) [19].

Ouldamer et al. [20] performed a retrospective observational study ( $n = 119$ ) including patients undergoing mastectomy with or without axillary clearance. Eligible patients either underwent conventional wound closure with a closed

suction drain or wound closure with quilting sutures. Quilting consisted of several evenly spaced ( $< 2$  cm) parallel rows of running Vicryl 0/0 sutures to close the dead space. Only patients undergoing modified radical mastectomy in the quilting group received a suction drain. There was a significant reduction of clinically evident seromas in the quilting group (17% vs. 51.7%,  $p < 0.001$ ). The length of hospital stay was significantly shorter in the quilting group (4.24 days vs. 5.43 days,  $p < 0.0001$ ). Self-assessment (cosmesis) was significantly better in the quilting suture group: good and excellent versus poor and acceptable in the group undergoing conventional wound closure ( $p = 0.003$ ). There were no significant differences in postoperative hematomas or surgical site infections [20].

A prospective randomized controlled trial by Khater et al. was published in 2015. Patients undergoing modified radical mastectomy ( $n = 120$ ) were randomized into one of two groups. In the first group, quilting was applied to the skin flaps using a Vicryl 2/0 suture. In the second group, mastectomy was performed in the same fashion without quilting of the skin flaps. All patients received a 18-French tube drain. Seroma was present in 20% of the patients that underwent quilting and in 78.3% of the patients in the drain-only group ( $p < 0.001$ ). There was a significantly higher number of aspirations in the drain-only group (4.7 vs. 2.1,  $p < 0.001$ ). Postoperative hematoma formation and skin flap necrosis were indifferent. Patients in the intervention group had a significantly longer operative time in comparison to the drain-only group (127 min vs. 105 min,  $p < 0.001$ ). Patients and doctors were not blinded regarding the application of flap fixation [21].

Mazouni et al. [22] conducted a prospective monocentric observational non-randomized study. They included 82 patients undergoing mastectomy with or without axillary

**Table 3** An overview of the clinical seroma studies with seroma outcome and complications

Reference	Study design	No. of pts	Types of surgery	Drains	Incidence of clinical seroma FF vs. conventional	<i>p</i> value in favor of FF	Complications FF vs. conventional	<i>p</i> value in favor of FF
Almond et al. [6]	Prospective	135	Mastectomy and or ALND	1 or 2 Redivac drains in the routine drainage group, no drain in FF group	49% vs. 59%	NS	Hospital Stay 1.88 vs. 2.67 days Infection 8% vs. 2%	< 0.0001
Sakkary et al. [18]	Prospective comparative study	40	MRM	Closed suction drains	10% vs. 40%	<b><i>p</i> = 0.028</b>	Cellulitis 10% vs. 10% Flap necrosis 0 vs. 10%	-
Ten Wolde et al. [19]	Retrospective	176	Mastectomy and or ALND	1 low vacuum drain in the axilla	22.5% vs. 80.5%	<b><i>p</i> = 0.000</b>	Aspirations (psp) 2.4 vs. 4.86	<b>0.015</b>
Ouldamer et al. [20]	Retrospective observational study	119	Mastectomy or MRM	Closed suction	17% vs. 51.7%	<b><i>p</i> &lt; 0.001</b>	SSI 11.2% vs. 31% Hematoma 6.8% vs. 10%	<b>0.001</b> NS
Khater et al. [21]	Prospective RCT	120	MRM	Not all patients in FF group received a drain 18-Fr tube drain in the axilla	20% vs. 78.3%	<b><i>p</i> &lt; 0.001</b>	SSI 3.4% vs. 8.3% VAS week 3 39% vs. 70% Self-assessment (cosmesis) No. of aspirations 2.1 vs 4.7	NS < 0.001 <b>0.003</b> < 0.001
Mazouni et al. [22]	Prospective observational non-randomized	82	Mastectomy or MRM	1 or 2 suction drains	34.1% vs 58.5%	<b><i>p</i> = 0.03</b>	Total volume of aspirations 45 ml vs. 189 ml Hematoma 30% vs. 26.7%	< 0.001 NS
Van Bastelaar et al. [23]	Retrospective observational study	180	Mastectomy or MRM	1 low vacuum drain	35.9% vs. 59.1%	<b><i>p</i> = 0.002</b>	Operative time 127 vs. 105 m All complications Hematoma 10% vs. 0% Mean no. of aspirations	< 0.001 NS NS NS
							Aspirations 15.2% vs. 43.2% No. of aspirations Hematoma 5.4% vs. 1.1% SSI 12% vs. 17%	< 0.001 < 0.001 NS NS

**Table 3** (continued)

Reference	Study design	No. of pts	Types of surgery	Drains	Incidence of clinical seroma FF vs. conventional	<i>p</i> value in favor of FF	Complications FF vs. conventional	<i>p</i> value in favor of FF
Eichler et al. [24]	Retrospective	205	Mastectomy or MRM	1 or 2 non-suction drains	27.6% vs. 15.6%	NS	Hematoma 3.1% vs. 16.8%	<b>0.045</b>
Van Bastelaar et al. [25]	Retrospective observational study	138	Mastectomy or MRM	1 low vacuum drain	50% vs. 59%	NS	Aspiration/infection 0% vs. 6.9% Aspirations 14% vs. 43%	<b>0.22</b> <b>&lt; 0.001</b>
							No. of aspirations Hematoma 6% vs. 1% SSI 16% vs. 17%	<b>&lt; 0.001</b> NS

FF flap fixation, NS not significant, *psp* per seroma patient, SSI surgical site infection, MRM modified radical mastectomy  
- not specified

staging. Either flap fixation using 5–6 interrupted Vicryl 2/0 sutures was applied or no closure of the dead space. All patients received 1 or 2 suction drains. The incidence of clinical significant seroma was lower in the flap fixation group (34.1% vs. 58.8%,  $p = 0.03$ ). There were, however, no significant differences in seroma-related complications between both the groups [22].

The study done by Van Bastelaar et al. in 2016 was a retrospective multicenter study conducted in patients undergoing mastectomy with or without axillary clearance. Patients either underwent flap fixation with interrupted Vicryl 3/0 sutures at 3-cm intervals or wound closure without flap fixation. All patients received a low vacuum drain. A total of 180 patients were included. There were significantly fewer patients with clinically evident seroma formation in the flap fixation group (35.9% vs. 59.1%,  $p = 0.002$ ). Significantly more patients underwent seroma aspiration in the historical control group (15.2% vs. 43.2%,  $p < 0.001$ ). The number of aspirations per patient were higher in the historical control group ( $p < 0.001$ ). The occurrence of hematoma or surgical site infections was not significantly different [23].

Only two studies have reported on flap fixation using tissue glue.

Eichler et al. [24] conducted a retrospective study in which 205 patients undergoing mastectomy with or without axillary clearance were analyzed. There were 173 patients in the control group and 32 in the TissuGlu® group. In the intervention group, TissuGlu® was applied to achieve equally spaced droplet placement on the pectoral muscle. Following wound closure, wound compression was performed with an elastic bandage for the first 24 h. All patients received 1 or 2 non-suction drains. Seroma occurred in 27.6% of the patients in the intervention group, while only 15.6% of the patients in the control group developed seroma ( $p = 0.06$ ). There was significantly more post-surgical hematoma formation in the control group (16.8% vs. 3.2%,  $p = 0.045$ ). There were no further differences in adverse events (revision, infection) [24].

Van Bastelaar et al. [23] published a retrospective observational cohort study in 2017. In this study, 138 patients undergoing mastectomy with or without axillary clearance were included. There were three groups: flap fixation with sutures (as published in 2016), flap fixation using ARTISS® tissue glue, and a drain-only group. The method of wound closure depended on the period in which patients underwent mastectomy. As these authors had previously published the results of the group with flap fixation using sutures, these patients were excluded from this review. All patients received low vacuum drainage. There was no significant differences in clinical seroma formation (flap fixation using ARTISS® 50% vs the drain-only group 59%,  $p = 0.30$ ). There were, however, significantly more patients undergoing seroma aspiration in the drain-only group (43%) compared to



the ARTISS® group (14%) ( $p < 0.001$ ). Other complications showed no significant differences [25].

Figure 2 is a forest plot representing the effect of flap fixation on clinically evident seroma formation. All 9 reported studies have been included. There is a significant improvement in clinically evident seroma formation when flap fixation is applied.

## Discussion

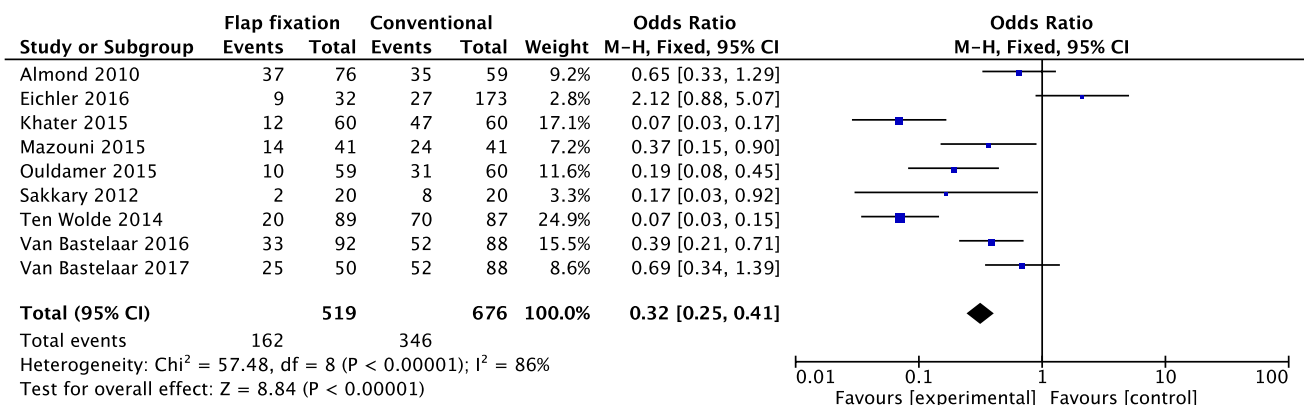
Effectively, few articles have been published on the occurrence of seroma and its sequelae in patients undergoing flap fixation after mastectomy with or without axillary clearance. We identified five retrospective studies and four prospective studies. Techniques used for flap fixation in these studies are quilting or tissue glue.

The most frequently employed technique for prevention of seroma is closed suction drainage. In the last decades, there have been many publications on the use of suction drainage to prevent seroma formation [26–31]. Until now, closed suction drainage is regarded as standard treatment and should be seen as the gold standard in reducing the dead space. For this reason, all studies investigating the effect of mechanical flap fixation should compare their results to patients being treated with a drain policy.

In the study conducted by Almond et al. [6], performing flap fixation was determined by their assigned consultant, possibly leading to some form of selection bias. One consultant always used drains while the other consultant applied flap fixation without drain placement. When evaluating the effectiveness of a new treatment strategy, it is difficult to assess the result of instituted treatment if more than one variable has been changed [(1) applying flap fixation and (2) omitting drains in the same group]. There were also patients that only underwent axillary clearance in this study (52/135).

Ideally, we would have excluded these patients from the review. Moreover, patients in the flap fixation group did not receive drains. Median length of stay was longer for patients with a drain. Flap fixation seemed to lead to overall financial savings. Institution of home nursing for most patients nowadays makes this outcome less relevant. In Sakkary's study, there was a significantly higher occurrence of seroma in the drain-only group and no significant differences in seroma-related complications. Drains were left in situ for a long period (median 13.4 days) in the drain-only group. These days, drains are often removed irrespective of drain output and are left in situ for a maximum of 5–7 days. Ten Wolde conducted a study in patients undergoing mastectomy and/or axillary clearance. Twenty-seven patients (15.3%) with only axillary clearance were included. There were significantly more patients in the non-quilting group undergoing axillary dissection (60.9% vs. 38.2%,  $p = 0.002$ ). This could definitely be related to the higher incidence of seroma and higher incidence of seroma aspirations and surgical site infections in this study.

In the publications by Ouldamer et al., it was not clear if all participants received a drain. The authors were contacted and patients in the quilting group without axillary clearance did not receive a drain. Patients' self-assessment of cosmesis seemed significantly better in the quilting group. One should remember that patients were not blinded and this should be seen as a significant bias in this study. The study performed by Khater et al. is the only study that could be considered a randomized controlled trial. Only patients undergoing modified radical mastectomy were included in this study. This study showed very clear differences in seroma formation and seroma aspirations in favor of flap fixation. In the study performed by Mazouni et al., the main limitation was the relatively low number of patients. No conclusions could be drawn on the incidence of seroma and the mean number of seroma aspirations in both groups. Both studies published by van Bastelaar et al. are retrospective in nature, and as



**Fig. 2** Forest plot for seroma formation. *M-H* Mantel–Haenszel, *CI* confidence interval

patients were sequentially assigned to a group determining whether flap fixation was performed, there might be a raised awareness for seroma as the study progressed. This could be considered a bias. In the retrospective study published by Eichler, 205 patients were included, but only 32 patients were in the intervention group. Seroma formation was nearly significantly higher in the intervention (TissuGlu®) group. The intervention group was, however, also more frequently monitored than the control group, therefore possibly leading to an underestimation of seroma in the control group. Higher numbers of patients in the intervention group might have revealed significant differences.

The scientific body of evidence for flap fixation after mastectomy seems convincing. Retrospective and prospective studies have demonstrated the higher incidence of seroma formation in patients not undergoing mechanical flap fixation. There are, however, no well-powered randomized controlled trials evaluating all aspects of seroma formation and its sequelae. The incidence of seroma-related complications in the studies reviewed varies. Four out of the nine studies demonstrate that patients undergoing flap fixation, need significantly fewer seroma aspirations. There are very few studies on the use of tissue glues preventing seroma formation. Flap fixation using Fibrin Glue (Tisseel) was evaluated in a Cochrane review in 2013 [32]. The authors found no influence on the incidence of postoperative seroma formation, the mean volume of seroma, wound infections, complications, and the length of hospital stay after mastectomy for breast cancer [32]. However, due to a broad heterogeneity of included articles in the Cochrane review (e.g., population, type of surgery), it is difficult to extrapolate these results to our group of patients. More studies need to be conducted to evaluate the effect of tissue glues in relation to flap fixation using sutures.

One should take care when interpreting the results of the forest plot in Fig. 2 due to the large heterogeneity ( $I^2 = 86\%$ ). Due to the diversity in reporting of seroma-related complications (aspiration, hematoma formation, and SSI's), forest plots could not be performed.

Van Bastelaar et al. have started a prospective randomized controlled trial (seroma reduction after mastectomy-trial, SAM TRIAL) to evaluate the effects of flap fixation (no flap fixation vs. flap fixation using sutures vs. flap fixation using tissue glue), including seroma formation and its sequelae, as well as long-term outcome measures, such as cosmesis, shoulder function, patient satisfaction, quality of life, and cost effectiveness.

## Conclusion

The scientific body of evidence favoring flap fixation after mastectomy is convincing. Mechanical flap fixation seems

to reduce seroma formation and seroma aspiration after mastectomy with or without axillary clearance. There are, however, no well-powered randomized controlled trials evaluating all aspects of seroma formation and its sequelae. Further research should elucidate whether flap fixation using sutures or tissue glue is superior.

## Compliance with ethical standards

**Conflict of interest** All authors declare that they have no conflict of interest and that no funding was involved.

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