Nipple-areolar complex reconstruction and patient satisfaction: a systematic review and meta-analysis

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Background: Nipple-areola complex (NAC) reconstruction transforms a mound of soft tissue into a breast and often marks the final stage of breast reconstruction after mastectomy.

Methods: A systematic review and meta-analysis were conducted in accordance with the preferred reporting items for systematic reviews and meta-analysis (PRISMA) guidelines. Articles were classified based on the nipple reconstructive technique—either composite nipple sharing or local flap with nipple-sparing mastectomy (NSM) used as a control. A standardized "Satisfaction Score" (SS) for "nipple appearance" and "nipple sensation" was calculated for each technique. A Fisher's exact test was used to compare the SS with local flap reconstruction with NSM.

Results: Twenty-three studies met the systematic review inclusion criteria. Nine NSM articles were identified with patient satisfaction data from 473 patients. The weighted average SS for NSM was 80.5%. Fourteen local flap technique articles were identified with satisfaction data from 984 patients and a weighted average SS of 73.9%. This was a statistically significant difference (P=0.0079). C-V and badge local flap techniques were associated with the highest SS, 92.6% and 90.5%, respectively. C-V and modified C-V flap technique was associated with a higher SS when compared to those using one or more other flap techniques (P=0.0001).

Conclusions: While patient satisfaction with nipple reconstruction is high regardless of technique, it is higher with NSM. When NSM is not an option, local flap reconstruction with a C-V or modified C-V flap may be associated with higher satisfaction than alternative local flap techniques.

Keywords: Mastectomy; breast reconstruction; nipple reconstruction; nipple-areola reconstruction; nipple-areola complex (NAC) reconstruction; preferred reporting items for systematic reviews and meta-analysis (PRISMA); meta-analysis

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Introduction

Nipple-areola complex (NAC) reconstruction traditionally marks the final stage of breast reconstruction following mastectomy, making it an important component of the multidisciplinary approach to breast cancer. Many women endorse that the presence of a nipple following mastectomy improves body image and decreases the sense of mutilation that can accompany a mastectomy. Although preservation of

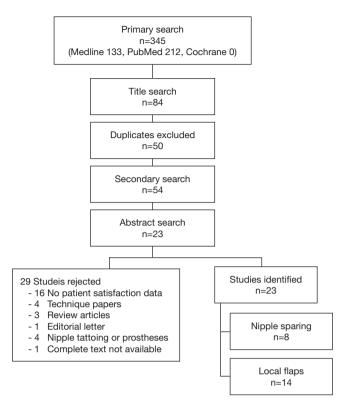


Figure 1 Relevant article identification process. One article contained patient satisfaction data for both nipple-sparing mastectomy (NSM) and local flap nipple reconstruction.

a patient's native nipple using a nipple-sparing mastectomy (NSM) technique may obviate this reconstructive step (1-8), it is sometimes not an option for patients from an oncologic perspective.

In the case of a unilateral mastectomy, composite nipple sharing can often provide a symmetric, satisfactory result (9,10). More often, however, local tissue rearrangement is used to create a nipple, followed by tattooing of the reconstructed nipple and the surrounding skin that is to become the areola. A variety of local flaps has been described in the literature (1,9-23).

Given that the benefit of breast and nipple reconstruction is aimed at psychosocial well-being rather than disease treatment, patient satisfaction is the most important outcome assessment measure. While separate studies exist that evaluate patient satisfaction with NSM and individual NAC reconstructive techniques, there is a lack of literature offering comparison between the level of satisfaction with the different methods of NAC reconstruction described and between NAC reconstruction and NSM among women

undergoing mastectomy. This systematic review and metaanalysis sought to provide such comparisons.

Methods

This systematic review and meta-analysis was conducted in accordance with the preferred reporting items for systematic reviews and meta-analysis (PRISMA) guidelines (24).

Systematic review

A literature search was conducted using the U.S. National Library of Medicine (MEDLINE), PubMed and the Cochrane Database to identify relevant English (language) articles published between 1992 and March 2012. Keywords "nipple reconstruction" and "patient satisfaction" were used. Medical subject heading (MeSH) terms "nipples", "reconstructive surgical procedures", "satisfaction" and "sensation" were also exploded. Resulting article titles were examined for relevance, and duplicate title were excluded. A secondary search was conducted by evaluating references of all primary articles for any additional relevant studies. Article abstracts, and when necessary full text, were then reviewed for relevance. Exclusion criteria included technique papers, case reports and reviews. To facilitate comparison, only articles including quantitative measures of patient satisfaction were utilized. Articles were then classified based on nipple reconstructive technique—either composite nipple sharing or local flap reconstruction, with NSM used as a control. This article selection process is detailed in Figure 1.

Quality of evidence

Each selected study was reviewed using the GRADE approach to assess the confidence in its estimate of effect. This included an assessment of the risk of bias and validity of the patient-report outcome measure used.

Data extraction and analysis

Given that a variety of aspects of patient satisfaction were evaluated with different measures used as a mark of satisfaction, a method of determining a standardized "Satisfaction Score" (SS) for the most commonly reported data points for each reconstructive method was used for the purpose of this review. A SS for both "nipple appearance" and "nipple sensation" was calculated for local flap

reconstruction, as well as NSM as a control. No SS was calculated for composite nipple sharing as too few data points were identified.

The majority of studies used patient surveys with Likert scale response choices. The SS for such data was determined as the percentage of patients providing a satisfactory response as designated in the article text or decided by the reviewers. For example, many studies designated "satisfied" or "very satisfied" as survey responses indicating that the patient was satisfied. For studies utilizing a numerical scale where patients selected an integer on a scale of 1 to 5 or 1 to 10 to indicate their satisfaction, the percentage of patients providing numerical responses deemed to indicate satisfaction as described by the authors was used as the SS. In studies providing only an average numerical satisfaction value, that value was converted to a percentage by dividing by the total possible score. For example, an average satisfaction value of 3.5 on a scale of 1 to 5 translated to an SS of 70%. Similarly, for surveys asking patients to report their overall satisfaction as a percentage, the average percentage reported was used as the SS. The type of data used to determine the SS for each study is detailed in Tables 1,2. The overall SS for local flap reconstruction and NSM was determined by calculating an average SS weighted by the number of subjects in each study as shown in Tables 3,4.

Data analysis also included a Fisher's exact test to determine if there was a statistically significant difference between the SS with local flap reconstruction compared to that with NSM, as well as between the individual local flap reconstruction techniques compared to all other flap techniques combined.

Results

Data extraction and analysis

Initial primary search identified 345 articles with four additional articles found in the secondary search of the references from relevant articles. Of these, a total of 23 studies met the systematic review inclusion criteria, all containing patient satisfaction data. For use as a control, eight articles examining satisfaction with nipple-sparing mastectomies on 473 patients were included. Two articles evaluating the use of composite nipple sharing in 91 patients were identified. Fourteen studies contained satisfaction data from 984 patients undergoing nipple reconstruction with various local skin flaps.

For each included article, the number of subjects, length

of follow-up, surgical technique and patient satisfaction data was determined and recorded in *Tables 1,2,5*. *Table 1* reflects data from patients undergoing NSM with various methods of reconstruction including both immediate and staged implants, as well as pedicled and free autologous flaps. Of the nine NSM articles identified, six contained patient satisfaction data for nipple appearance from 386 patients. The weighted average SS was 80.5% (95% CI, 0.765–0.844) as calculated in *Table 3* and shown in *Figure 2*. Only two studies included satisfaction data for nipple sensation from 237 patients, which yielded a weighted average SS of 27.4%.

The data from articles evaluating the use of local skin flap reconstruction is shown in *Table 2*. The most commonly used local flap techniques included C-V, S, star, skate and badge flaps, with or without modification. All 14 included studies contained data for calculation of an SS for nipple appearance; the weighted average SS was 73.9% (95% CI, 0.725–0.753) as calculated in *Table 4* and shown in *Figure 3*. Seven of the articles provided nipple sensation satisfaction data with a weighted average SS of 35.9%. The studies with the highest reported SS for appearance were those which used the C-V and badge local flap techniques with a SS of 92.6% and 90.5%, respectively.

A Fisher's exact test comparing patient satisfaction with local flap reconstruction compared to NSM had a P value of 0.0079. A significant difference in SS (P=0.0001) was also seen in studies which utilized only a C-V or modified C-V flap technique compared to those using one or more other flap techniques.

Only one of the two nipple sharing studies provided results for each nipple appearance and nipple sensitivity (*Table 5*). For this reason, no SS was calculated for either category.

Quality of evidence

Using the GRADE approach, the studies were evaluated for the confidence in their estimate of effect. As no widely-accepted, validated questionnaire for nipple reconstruction satisfaction exists, the validity of patient-reported outcome measures utilized cannot be established. All 23 included studies were performed retrospectively and relied on patient questionnaire responses, making them inherently prone to response bias. The eight studies with response rates less than 80% were considered to be at higher risk of bias due to low response rates. There were also four studies which did not disclose a response rate. A lower confidence was also attributed to studies of smaller size. In reviewing the

Table 1 Summary of studies on patient satisfaction with nipple sparing mastectomy

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	Subjects			Responses	Satisfaction (%)	ion (%)	
Study	(response rate)	Follow-up	Surgical technique	considered "satisfied"	Nipple appearance	Nipple sensation	Other results
Didier et al. (1)	159 (51.2)	Survey at 1 year	Subcutaneous NSM with intraoperative areolar ELIOT, implant reconstruction	Quite a bit, much, very much	79	36	54% felt sexually attractive compared to 91% pre-operatively; 93% reported nipple preservation helped them cope with disease/consequences
Djohan et al. (2)	78 (55.3)	9-100 months, mean 50.4	NSM, reconstruction with implant, DIEP, TRAM or other	Good, excellent	72	10	66% satisfied with symmetry; 80% satisfied with color; 61% satisfied with position; 26% satisfied with arousal; 68% satisfied with texture
Mosahebi et al. (3)	61 (93.0)	8–109 months, mean 48	NSM through mid-axillary incision, reconstruction with implant, implant + LD or DIEP	Satisfied, extremely satisfied	∀ Z	₹	Satisfaction scores ranged 0.6 to 0.8 for all reconstruction types, with and without radiation (no significant difference); scores determined by comparing scores for reconstructed breast to contralateral or group average for unaffected breast in categories of satisfaction, comfort with brassiere and effect on sexual/social life
Munhoz et al. (4)	18 (100.0)	6-62 months, mean 29	NSM with DCPI, BEIS reconstruction	Satisfied, very satisfied	94.4	N A	ı
Nahabedian and Tsangaris (5)	12 (100.0)	Survey at 6 months	Subcutaneous NSM, implant or flap reconstruction	Yes	57.1	42.9 (present)	ı
Sacchini et al. (6)	110 (89.4)	2–570.4 months, median 24.6	NSM, implant or TRAM flap reconstruction	Score 7–10/10	06	& Z	Satisfaction 89%, 96% and 86% for implant, tissue expander and TRAM flap respectively; 94% satisfaction in prophylactic versus 87% in therapeutic
Ueda et al. (7)	26 (79.0)	Median 16 months after chemotherapy and radiation	NSM, implant, LD, TRAM or DIEP reconstruction	Score out of 100%	₹ Z	₹ Z	Satisfaction scores using quality of life questionnaire for cancer patients treated with anticancer drugs: social activity 95%, physical aspects 88%, general condition 79%, bodily pain 76%, body image 73.5%, sexual aspects 60%
Yueh <i>et al.</i> (8)	(0.06) 6	2–89 months, mean 23	NSM, implant or flap reconstruction	Satisfied, very satisfied	2.99	80 (present)	8.8/10 symmetry satisfaction score; 8.6/10 pigmentation satisfaction score
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NSM, nipple-sparing mastectomy; ELIOT, electron-beam radiotherapy; DIEP, deep inferior epigastric perforator flap; TRAM, transverse rectus abdominus muscle; LD, latissimus dorsi muscle; NA, not applicable; DCPI, double concentric periareolar incision; BEIS, biodimensional anatomical expander-implant system.

Table 2 Summary of studies on patient satisfaction with local flap nipple reconstruction

	or or or or			Baenoneae	Satis	Satisfaction (%)	
Study	(response rate)	e Follow-up	Surgical technique	considered "satisfied"	Nipple	Nipple	Other results
Chen et al. (11)	11 (100.0)	12–27 months, mean 17	Badge flap + tattooing on free or pedicled TRAM flap reconstruction	Score out of 100%	90.5	AN	Mean pigmentation score 8.5/10
Cheng e <i>t al.</i> (12)	22 (88.0)	6–36 months, mean 18	Modified S dermal-fat flap + tattooing on free or pedicled TRAM, implant-only or LD + implant	Moderately pleased, very pleased	86.4	13.6	50% satisfied with nipple projection; 90.9% satisfied with nipple symmetry; 54.5% satisfied with nipple size; 100% satisfied with nipple color; 100% would recommend the procedure
Costa and Ferreira (13)	122	Survey at 3 years	C-V flap + tattooing on double-pedicled TRAM or implant	Good, excellent	92.6	NA	35% satisfaction in patients who underwent NAC reconstruction with skin graft from medial thigh
Didier et al. (1)	92 (67.8)	Survey at 1 year	Unspecified	Quite a bit, much, very much	43.0	20.0	72% felt sexually attractive compared to 98% pre-operatively; 34% found it difficult to look at themselves naked
El-Ali <i>et al.</i> (14)	50 (100.0)	6-36 months, mean 15.4	Modified C-V flap + tattooing on LD, pedicled TRAM or implant	Good, very good	80.0	28.0 (sensation present)	82% satisfied with reconstructed NAC compared to opposite side; 82% reported body image improvement
Goh et al. (15)	91 (100.0)	1–86 months, mean 38.5*	Various flaps + tattooing on TRAM, DIEP, LD +/- implant or implant	Satisfactory, good, excellent	*88.0*	NA	95% rated NAC position "about right"*; 87% rated NAC dimension "about right"*; 58% rated NAC projection "about right"*
Gullo et al. (16)	161	Survey at 1 year	Star flap enhanced by scar tissue* + tattooing on DIEP, TRAM or implant	Good (5- 6.9/10), very good (≥7/10)	6.61/10 (SS =66.1%)	4.11/10 (SS =41.1%)	Color satisfaction score of 6.36; position satisfaction score of 7.24; symmetry satisfaction score of 7.97
Harcourt et al. (17)	127 (51.4)	3-84 months	Unspecified	Satisfied, very satisfied	71.6	56.5	81.9% satisfied with nipple color; decision regret most strongly correlated with dissatisfaction and high depression score
Jabor et al. (18)	43 (41.0)	≥6 months	Various flaps + immediate tattooing on TRAM, LD + implant or implant	Good, excellent	64.0	∀ Z	No significant difference in NAC satisfaction with different breast mound or NAC types; factors most disliked in descending order: projection, color, size, texture, position; mean interval between mound and NAC reconstruction of 9.71 & 7.25 months in satisfied & unsatisfied patients, respectively (P=0.003)
Losken <i>et al.</i> (19)	11 ("poor")	3-7 years, mean 5.3	C-V flap + tattooing on TRAM flap	Score out of 100%	81.0	26.0	42% satisfied with projection; 62% satisfied with pigmentation
Lossing et al. (20)	21 (100.0)	29–46 months, mean 36	Modified S-flap + tattooing on lateral thoracodorsal flap	Score out of 10	8.2/10 (SS =82%)	29.0 (sensation present)	Overall breast reconstruction satisfaction score of 8.9
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Table 2 (continued)

Table 2 (continued)

	Subjects			Responses	Satisfa	Satisfaction (%)	
Study	(response rate)	(response Follow-up rate)	Surgical technique	considered "satisfied"	Nipple appearance	Nipple sensation	Other results
Otterburn et al. (22)		199 >1 year	C-V flap + tattooing on TRAM, implant or LD + implant	Score out of 5	3.8/5 (SS =76%)	1.3/5 (SS =26%)	Color satisfaction score of 3.2/5; position satisfaction score of 4.2/5; projection satisfaction score of 3.3/5
Valdatta et al. (23)	29 (100.0)	Survey at 1 year	C-V flap + tattooing on	Score out of 10	6.65/10 (SS =66.5%)	5.57/10 (SS =55.7%)	Color satisfaction score of 6.14; position satisfaction score of 7.85; projection satisfaction score of 6.28; symmetry satisfaction score of 7.42

*, data includes results for ten additional patients who underwent composite nipple sharing; ", primary procedure in 98 patients, secondary procedure for projection failure in 63 patients. TRAM, transverse rectus abdominus muscle; NA, not applicable; LD, latissimus dorsi muscle; NAC, nipple-areolar complex; DIEP, deep inferior epigastric

perforator flap

Table 3 Meta-analysis data for patient satisfaction with nipple sparing mastectomy	ient satis.	faction wit	th nipple spari	ng mastectomy	Table 4 Meta-analysis data for patient satisfaction with local flap reconstruction	for patie	nt satisfacı	tion with loca	ıl flap reconstruction
Variable	SS (%)	SE	Weight (%)	SS, 95% CI	Variable	(%) SS	SE	Weight (%)	SS, 95% CI
Study					Study				
Didier et al. (1)	79.0	0.0323	41.2	0.79 (0.727, 0.853)	Chen <i>et al.</i> (11)	90.5	0.0884	1.12	0.905 (0.817, 0.994)
Djohan e <i>t al.</i> (2)	72.0	0.0508	20.2	0.72 (0.620, 0.820)	Cheng <i>et al.</i> (12)	86.4	0.0730	2.24	0.864 (0.791, 0.937)
Munhoz et al. (4)	94.4	0.0542	4.7	0.944 (0.838, 1.050)	Costa and Ferreira (13)	95.6	0.0237	12.40	0.926 (0.902, 0.950)
Nahabedian and Tsangaris (5)	57.1	0.1429	3.1	0.571 (0.359, 0.975)	Didier et al. (1)	43.0	0.0516	9.35	0.430 (0.378, 0.482)
Sacchini et al. (6)	90.0	0.0286	28.5	0.90 (0.844, 0.956)	El-Ali <i>et al</i> . (14)	80.0	0.0565	5.08	0.800 (0.743, 0.857)
Ueda <i>et al.</i> (7)	Ϋ́	ΑN	ΑĀ	NA	Goh <i>et al.</i> (15)	88.0	0.0340	9.25	0.880 (0.856, 0.914)
Yueh <i>et al.</i> (8)	2.99	0.1571	2.3	0.667 (0.359, 0.975)	Gullo et al. (16)	66.1	0.0373	16.36	0.661 (0.624, 0.698)
Pooled estimate	80.5	I	100.0	0.805 (0.765, 0.844)	Harcourt et al. (17)	71.6	0.0400	12.91	0.716 (0.676, 0.756)
SS, satisfaction score; SE, standard error; CI, confidence interval; NA, not applicable.	ard error;	; CI, confic	dence interval	l; NA, not applicable.	Jabor et al. (18)	64.0	0.0731	4.37	0.640 (0.567, 0.713)
					Losken <i>et al.</i> (19)	81.0	0.1182	1.12	0.810 (0.692, 0.928)
					Lossing <i>et al.</i> (20)	82.0	0.0838	2.13	0.820 (0.736, 0.904)

0.926 (0.902, 0.950) 0.430 (0.378, 0.482) 0.800 (0.743, 0.857) 0.880 (0.856, 0.914) 0.661 (0.624, 0.698) 0.716 (0.676, 0.756) 0.640 (0.567, 0.713) 0.810 (0.692, 0.928) 0.820 (0.736, 0.904) 0.800 (0.621, 0.979) 0.760 (0.730, 0.790) 0.665 (0.577, 0.753) 0.739 (0.725, 0.753)

SE, standard error; Cl, confidence interval; NA, not SS, satisfaction score; applicable.

100.00

Pooled estimate

0.0876

20.22 2.95

Otterburn et al. (22) Valdatta et al. (23)

Oliveira et al. (21)

0.51

0.1788 0.0302

80.0 76.0 66.5 73.9

Table 5 Summary of studies on patient satisfaction with composite nipple sharing

	Subjects		Responses	Satisfact	ion (%)	
Study	(response rate)	Follow-up	considered "satisfied"	Nipple appearance	Nipple	Other results
Spear et al. (9)	34 (57.6)	0–16 years	Satisfied, very satisfied	92	NA	88% satisfied with naturalness of nipple; 92% satisfied with color; 85% satisfied with projection; 63% reported minimal or no decrease in donor nipple sensation; 63% reported role of donor nipple in femininity/sexuality was slightly decreased or unchanged; 80% probably or definitely would undergo procedure again
Zenn and Garofalo (10)	,	2–69 months, mean 33	Reasonable to same as before (3–5/5)	NA	35	91%, 93% & 87% satisfied with color, shape & size, respectively; 96% reported donor nipple appeared "not bad" or better; 87% with donor nipple sensation present; 87% with residual donor nipple erectile function; 87% would undergo procedure again

NA, not applicable.

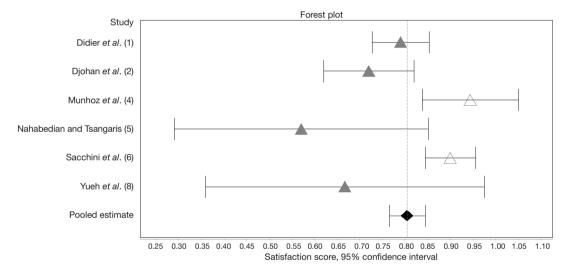


Figure 2 Forest plot showing satisfaction scores with nipple-sparing mastectomy (NSM) (1,2,4-6,8).

collection of studies as a whole, a great deal of publication bias is likely also present due to the reluctance to report low patient satisfaction results.

Discussion

Breast reconstruction has become a fundamental component of the multidisciplinary approach toward the treatment of women with breast cancer, making the plastic surgeon an integral part of this treatment team. The breast is an important component of the female identity. Following mastectomy, women report that undergoing reconstruction helps them to feel as though they have overcome the disease, to cope with their feelings regarding the loss of their breast and to improve their body image (25).

Previous studies assessing patient satisfaction with various methods of breast reconstruction have established that the presence of a nipple, whether native or reconstructed, positively impacts overall patient satisfaction with the breast. Posited explanations include the creation of a finished looking breast, an increased sense of attractiveness, a feeling of a more normal appearance and improvement in symmetry in cases of unilateral reconstruction (18,26-29).

Given that both breast mound and nipple reconstruction

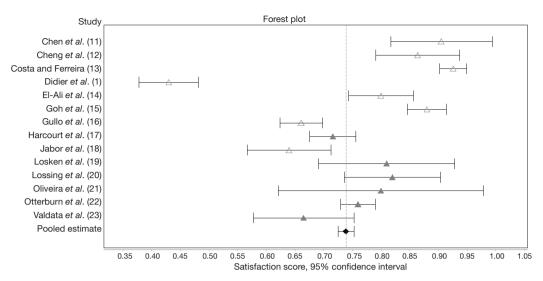


Figure 3 Forest plot showing satisfaction scores with local flap nipple reconstruction (1,11-23).

play a psychosocial, rather than a disease-modification role, patient satisfaction and health-related quality of life (HR-QoL) improvement are the most important outcomes of interest. Assessment of these outcome measures, however, is subjective and difficult to evaluate. It relies on the use of patient surveys and questionnaires which introduce response and self-selection bias. In a systematic review such as this, further difficulty exists due to the lack of consistency in the manner in which "satisfaction" is measured, both in the aspects of the reconstruction evaluated and the quantification of the responses. The ability to draw conclusions based on the statistical results of this review is extremely limited by the created SS. While we feel this was the best available method to allow comparison between the included studies, it was clearly less than ideal.

The utilization of standardized patient-reported outcome measures like the BREAST-Q provides a way to quantify patient satisfaction and HR-QoL outcomes (29). Currently, this type of validated outcome measure does not exist specifically for nipple reconstruction, but it would be beneficial in providing surgeons a tool to assess their own outcomes and facilitate comparison between the many different local flap techniques. It would also allow for more consistency when assessing multiple different studies or conducting multi-center studies.

Despite the imperfect comparative analysis technique utilized due to the limitations of the available publications, a significantly higher patient SS was seen with use of the C-V or modified C-V flap. Reasons authors cited for

favoring this flap included its ease, consistency, reliability and lack of donor site morbidity (14,19,22,23). With the high satisfaction seen regardless of technique, however, factors such as surgeon preference and experience should be considered when choosing a nipple reconstruction technique.

As the oncologic safety of nipple-sparring mastectomy continues to be better understood and accepted, more and more patients will likely be able to keep their native nipples. There will, however, always be cases in which resection of the NAC is necessary, making ever-relevant the quest for an ideal nipple reconstruction technique that provides a realistic, well-projected nipple with a high patient satisfaction rate.

Conclusions

Patient satisfaction with nipple reconstruction is high, regardless of the technique used. Although patient satisfaction with breast reconstruction has previously been demonstrated to be higher with nipple reconstruction compared to foregoing nipple reconstruction, patient satisfaction is significantly higher among those who undergo NSM than those who require nipple reconstruction with one of a variety of popular local flap techniques. When safe from an oncologic perspective, NSM should be performed when possible. When NSM is not an option, local flap reconstruction with C-V or modified C-V flap may be associated with higher satisfaction than alternative local flap

techniques.

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Footnote

Conflicts of Interest: Dr. Nahabedian is a speaker/consultant for LifeCell, Sientra, and Allergan. Dr. Satteson and Dr. Brown have no conflicts of interest to declare.

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