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Breast

Usefulness of Harmonic ACE+7 Scalpel in Breast Reconstruction with Extended Latissimus Dorsi Flap: An Open-label Single Institution Pilot Study

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Background: The extended latissimus dorsi (ELD) flap is a safe and aesthetically acceptable method to reconstruct small to medium-sized breasts. However, the long time required for flap elevation and intraoperative bleeding contributes to various postoperative complications. We investigated the use of alternative devices, such as the Harmonic ACE+7, which has a long arm that can help simultaneously detach and seal tissues to prevent such complications.

Methods: We compared 27 patients who underwent breast reconstruction with the ELD flap using the Harmonic ACE +7 scalpel, and 28 patients who underwent breast reconstruction using an electrocautery scalpel, between May 2019 and March 2022. Data on patient demographics, surgery, and postoperative complications were collected. Surgical outcomes were compared between electrocautery (EC) and Harmonic ACE+7 (HA) groups.

Results: The median age of the patients was 50.2 years. The patient demographics between the groups did not show significant differences. Flap necrosis and hematomas did not occur, and seroma was the major postoperative complication (65.7% in the EC group and 70% in the HA group). The time required for flap elevation was significantly shorter in the HA group than in the EC group (286.0 minutes and 179.0 minutes, respectively). Blood loss reduced significantly in the HA and EC groups (138.5 mL and 78.2 mL, respectively). Moreover, decreased drainage was observed for the breast area. There were no significant differences in other end points.

Conclusion: In breast reconstruction with ELD flaps, using the Harmonic ACE+7 can help reduce the rate of seroma, operative time, and intraoperative bleeding without further disadvantages. *(Plast Reconstr Surg Glob Open 2023; 11:e5163; doi: 10.1097/GOX.0000000000005163; Published online 3 August 2023.)*

INTRODUCTION

The latissimus dorsi (LD) flap is one of the most common and viable techniques for breast reconstruction following mastectomy. This procedure can be performed with minimal complications, does not require special instrumentation or microvascular surgery, and the patient remains hemodynamically stable.[1] The extended LD (ELD) flap was first reported by Hokin in 1983.[2] This method involves harvesting a larger amount of paraspinal and lumbar fat to secure the volume of the flap, and provides an aesthetically pleasing breast shape without requiring implants. This procedure includes skin complications at the donor site, late flap necrosis, limited shoulder range of motion, and, most commonly, seroma at the donor site. Previous reports indicate that seroma at the back after ELD occurs in 25%–70% of patients,[3–5] which can lead to unfavorable outcomes, such as frequent postoperative aspiration, surgical removal, or prolonged chemotherapy and radiation therapy. Although the causes underlying seroma formation remain unknown, they are multifactorial and include disruption of lymphatic and vascular channels, shear effects between the subcutaneous surface and the underlying muscle, surgically created dead space, and mediators of inflammation.[6] Particularly, it has been theorized that the use of electrocautery during skin flap elevation can lead to inadequate sealing

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of the vascular and lymphatic cuts, resulting in trace or severe effusion leakage.[7,8] Furthermore, some problems, such as prolonged operative time and increased blood loss, are associated with the wide extraction of the lumbar fat through incisions in the back because of the surgeon's need to make distant dissecting incisions with a narrow field of view. Because prolonged operative time and blood loss contribute to the development of seroma, surgeons must perform surgery swiftly and with little blood loss.

The Harmonic ACE+7 (Ethicon Endo-Surgery, Cincinnati, Ohio) is an ultrasonic scalpel that cuts and coagulates tissue at temperatures below 100°C (Fig. 1). This device uses ultrasonic energy by converting it into mechanical energy, and the surface of the scalpel vibrates in the 55,500 Hz range to cut the tissue. The high-frequency vibration of tissue molecules generates stress and friction within the tissue, generating heat and causing protein denaturation. This technique is expected to minimize collateral damage because it minimizes energy transfer to the surrounding tissue.[9,10] Ultrasonic scalpels have recently been reported to be useful in preventing seroma in mastectomies.[11] Additionally, a study using the Harmonic Focus+ Shears in LD flap reconstruction found that compared with electrocautery, the Harmonic Focus+ Shears were associated with reduced seroma formation, shorter drainage period operative time, and hospital stay.[12] In Japan, harmonic scalpels were included in the insurance for breast reconstruction in 2020. We hypothesized that the Harmonic ACE+7, a novel surgical device, can be useful in ELD flap surgery because it has a long arm, a nonstick tip, and the ability to coagulate vessels less than 7 mm.[13]

This study aimed to evaluate the advantages of the Harmonic ACE+7 regarding operative time and complications, and to assess its efficacy in patients undergoing breast reconstruction with ELD flaps, compared with the conventional electrocautery device.

Takeaways

Question: Does the Harmonic ACE+7 scalpel in breast reconstruction with an extended latissimus dorsi (ELD) flap provide a surgical advantage?

Findings: The use of the Harmonic ACE+7 scalpel in breast reconstruction with an ELD flap reduced operative time and blood loss compared with electrocautery.

Meaning: Use of the Harmonic ACE+7 scalpel improves the quality of ELD flap surgery.

METHODS

This study was conducted in accordance with the Declaration of Helsinki. The study protocol was approved by the institutional review board (approval no.: 201904003). Written informed consent was obtained from the patients before study participation, including consent to participate and publish the findings.

Patients

Patients with pathologically confirmed unilateral breast cancer who met the selection criteria summarized in Table 1 were enrolled. We excluded patients with peripheral vascular diseases (arterial stenosis, arterial embolism, thromboangiitis obliterans, or deep vein thrombosis). Notably, patients who were overweight and obese [body mass index (BMI) >25 kg/m^2] were excluded from the study because of their suspected high risk of seroma formation, based on the findings from previous cohort studies.[14,15] All patients had a tissue expander inserted and underwent two-stage breast reconstruction with an ELD flap.

The conventional electrocautery (EC) group consisted of 28 patients who underwent breast reconstruction with the ELD flap between May 2019 and February 2020 using a monopolar electrocautery device for dissection and hemostasis. All EC groups used the Bovie monopolar system. The Harmonic (HA) group consisted of 27 patients who underwent breast reconstruction with the ELD flap using the Harmonic ACE+7 between April 2020 and March 2022.

The patients' medical records were reviewed, and information (such as age, BMI, type of reconstruction, drainage volume before drain removal, number of outpatient puncture aspirations, puncture-aspirated drainage

Fig. 1. Harmonic ACE+7 scalpel.

Table 1. Inclusion/Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
Patients were women between the ages of 18 and 70 years	Patients had residual gross malignancy after mastectomy
Patients underwent skin-sparing mastectomy or nipple-sparing mastectomy, with or without sentinel node biopsy	Patients had a current infection at the intended expansion site
Patients had elected two-stage breast reconstruction with tissue expanders	Patients had clinically significant radiation fibrosis at the expansion site
Patients' tissue was amenable to tissue expansion	Patients had any co-morbid condition determined by the investigator to place the subject at an increased risk of complications (eg, severe collagen vascular disease, poorly managed diabetes)
Patients were able to provide informed written consent	Patients are currently participating in a concurrent investigational drug or device study
Patients had the physical, perceptual, and cognitive capacity to understand and manage at home	Patients were overweight with a BMI of >25
	Patients had implants such as a pacemaker, defibrillator, neuro-stimulator device, or drug infusion device
	Patients were pregnant or planning to conceive during the study period
	Patients had a history of psychological condition, drug abuse, or alcohol misuse
	Large flap (>450 g) for reconstructions
	Patients undergoing combined flap and implant reconstruction

volume after drain removal, duration of drain placement, length of hospital stay, operative time, and blood loss) was collected for each patient.

The evaluation parameters included the amount of blood loss during flap extraction, the operative time required for flap elevation, postoperative seroma formation rate, total drainage volume from the donor site (back) and implanted site (chest), duration of drain retention at the donor site and implanted site, and days of hospitalization. Seroma was defined as persistent serous fluid retention requiring drainage for at least 4 weeks postoperation.

Surgical Procedure

One well-trained breast surgeon was involved in the mastectomy, and one well-trained plastic surgeon, in the reconstruction using the skin flap. In addition, two plastic surgeons were involved as assistants, all of whom performed the surgery with the same team. The surgical procedure was performed as follows: a mastectomy, either a skin-sparing mastectomy or nipple-sparing mastectomy, was performed in the supine position. The excised mammary tissue was weighed intraoperatively on a weighing scale. For two-stage reconstruction, an expander was placed in the breast. The elevation of the ELD flap was performed in the lateral recumbent position, with the affected upper extremity abducted. In the HA group, the Harmonic ACE+7 (Ethicon Endo-Surgery, Inc., Cincinnati, Ohio) was used as a substitute for the electrocautery device. Although electrocautery dissection was required from the skin incision to 2 cm around the skin island, the Harmonic ACE+7 was used for dissection of the LD muscle body, sealing off the perforating branch of the intercostal artery behind the flap and collection of lumbar fat. In contrast, the electrocautery device was used for all procedures in the EC group. For the ELD flap, the lumbar area was dissected 8–10 cm beyond the iliac crest to acquire more fat by dissecting the adipose tissue over the superficial fascia. Flap size (weight) was measured intraoperatively by suspending the flap on a spring scale. After flap elevation, the ELD flap was transferred through the axillary subcutaneous tunnel to the breast pocket and sutured in the appropriate location. Skin flap elevation time was defined as the time from when the incision was made in the skin until the flap reached the anterior thoracic region. The rest of the surgical procedure was similar in both groups. All patients had a 15-Fr suction drain placed under the implanted flap (anterior chest) and at the donor site (back). Blood loss calculations were made using the weight difference between dry and wet gauze sponges, and the volume difference between cleaning solution and aspirate. Postoperatively, the skin flap donor area on the back was compressed using gauze and stretchy tape, and all patients were provided with an abdominal binder to prevent seroma formation. Patients were instructed to avoid shoulder abduction of more than 90 degrees for 1 week after surgery. The drain was removed when the drainage volume was less than 30 mL for 24 hours; otherwise, it was removed 2 weeks postoperatively. After drain removal, the patient was discharged from the hospital after 1–3 days of follow-up. To prevent massive serous retention and to monitor the patient's progress, the patient visited the outpatient clinic every 3 days. The presence or absence of serous fluid treatment was confirmed by palpation and ultrasound echocardiography. If retention was observed, the site was punctured. The drainage volume was divided into multiple aspirations with a graduated syringe, and the total volume was calculated.

Statistical Analysis

Statistical analysis was performed using Statistica software, version 9.0 (StatSoft, Tulsa, Okla.). To analyze the effect of the intervention, independent *t* tests (age, BMI, and duration of drainage), Mann–Whitney *U* test (flap size, drainage volume, operative time, and duration of hospitalization), and Pearson chi-square test (frequency of seroma) were used. A *P* value of less than 0.05 was considered statistically significant. All results are presented as mean ± standard deviation or median (interquartile range).

RESULTS

The mean age of all patients was 50.2 ± 7.6 years, and the mean BMI was 20.5 ± 1.7 kg/m^2. The mean flap weight was 257.4 (161–601) g. The data of the EC and HA groups according to age, BMI, the weight of excised mammary glands, the weight of ELD flaps, radiation therapy, and chemotherapy are summarized in Table 2. No statistically significant factor was identified. No hematoma, infection, flap necrosis, fat necrosis, or skin necrosis occurred in all cases.

The incidence of seroma was 53.6% in the EC group and 25.9% in the HA group; however, the difference was statistically significant ($P = 0.0364$). The total drainage volume of the anterior chest (implanted site) was significantly decreased in the HA group at 140.6 mL (110–197 mL) versus 206.9 mL (98–453 mL) in the EC group ($P = 0.038$). In contrast, total drainage of the back increased in the HA group from a median of 1543.9 mL (260–1115 mL) to 1669.8 mL (90–985 mL); however, this difference was not statistically significant. The HA group showed no difference in the duration of drain placement in the back [median, EC 12.0 (10–14) versus HA 12.3 (10–14) days] and in the anterior chest [median, EC 6.3 (4–8) versus HA 5.9 (4–8) days].

The time required for flap elevation was markedly shorter in the HA group, with a median of 179.0 minutes (125–203), than in the EC group, with a median of 286.0 minutes (190–400) ($P = 0.00018$). In addition, blood loss at flap elevation reduced significantly from 138.5 mL (25–325) in the EC group to 78.2 mL (60–91) in the HA group ($P = 0.0096$) (Table 3).

In summary, statistical analysis showed that the incidence of seroma, total anterior thoracic drainage volume, the time required for flap harvesting, and blood loss were significantly reduced in the HA group compared with those in the EC group.

Table 3. Results of the Outcome Measures

	EC	HA	*P*
No. seromas	15	7	—
Rate of seroma formation	53.57	25.93	0.036*
Total volume of drain discharge, mL (back)	1543.9 ± 557.9	1669.8 ± 384.8	0.28†
Indwelling period of drainage, d (back)	12.0 ± 1.5	12.3 ± 1.3	0.67‡
Total volume of drain discharge, mL (breast)	206.9 ± 87.0	140.6 ± 31.2	0.039†§
Indwelling period of drainage, d (breast)	6.3 ± 1.2	5.9 ± 1.1	0.38‡
Time for ELD flap harvest, min	286.0 ± 60.3	179.0 ± 59.3	0.00018†§
Amount of bleeding, mL	138.5 ± 73.9	78.2 ± 10.7	0.0096†¶
Hospital day, d	14.4 (11–16)	14.5 (12–16)	1†

Values are presented as mean ± standard deviation or median (interquartile range).
*Pearson chi-squared test.
†Mann–Whitney *U* test.
‡Independent *t* test.
§*P* less than 0.05.
¶*P* less than 0.01.

DISCUSSION

The ELD flap is widely used for medium to small-sized breast reconstruction because of its advantages (such as reliable vascularization, proximity to the defect site, relatively simple dissection, and provision of greater volume than the LD flap).[16,17] However, its disadvantages include the development of seroma at the donor site, prolonged drainage, and limited shoulder range of motion.[18,19] Additionally, in breast reconstruction, surgeons must aim for shorter operative time and less invasive procedures because prolonged operative time and increased intraoperative bleeding increase the risk of seroma, reoperation, and fat necrosis.[20]

Various ultrasound devices are currently available for dissection and hemostasis in surgical operations, particularly harmonic devices used for breast reconstruction. The blade-type Harmonic Synergy VR reportedly reduced the incidence of postoperative seroma.[21] Alternatively, the Harmonic Focus+ Shears reportedly contribute to reducing the incidence of seroma, postoperative donor site drainage time, operative time, and hospital stay in the reconstruction of LD flaps.[11] The advantages of ultrasonic cutting and coagulation compared with conventional electrocautery are numerous and include less inflammation because of less heat generation in the tissue,[21] enhanced blood flow,[22] and faster fibrosis remodeling.[23] Furthermore, it has been shown that ultrasound energy produces fewer inflammatory mediators during the acute phase of wound healing after tissue incision than electrocautery, resulting in less tissue damage.[24] However, no studies have been reported using the Harmonic ACE+7 on the ELD flap.

We used the Harmonic ACE+7 because we believe it is useful for the dissection of blood vessels, lymphatic vessels, and fascia in ELD flap elevation due to the ability to automatically adjust the power level of the energy system for each tissue, reducing the risk of thermal damage to the tissue and increasing the dissection speed. Additionally, this device is designed such that there is no need to change surgical instruments during dissection and sealing; it can seal large vessels up to 7 mm in diameter, and its long, thin arm enables manipulation in a narrow surgical field.[11] In ELD surgery, which requires dissection of the fat layer above the superficial fascia over a wider area than normal

Table 2. Patient Demographics

	EC Group	HA Group	*P*
Number	28	27	—
Age (y)	49.6 ± 6.1	51.9 ± 10.1	0.43*
BMI (kg/m^2)	20.3 ± 1.9	21.1 ± 6.1	0.22†
Operation side (right)	16	13	0.79‡
Chemotherapy	8	5	0.82‡
Radiotherapy	12	9	0.71‡
Smoking	3	1	0.34‡
Excised mass weight (g)	202.6 ± 90.1	180.7 ± 58.2	0.5†
ELD flap weight (g)	258.8 ± 99.0	254.4 ± 65.3	0.94†

Values are presented as mean ± standard deviation or median.
*Independent *t* test.
†Mann–Whitney *U* test.
‡Pearson chi-squared test.

LD, we considered this to be advantageous because it is easier to maintain a constant layer of dissection in the physical curve around the lumbar area.

The diameter of the intercostal artery perforating branch, one of the most significant elements of postoperative hematoma, is 1–2 mm,[25] and sealing this branch allows for the operation to progress without thread ligation. A marked reduction in operative time and blood loss was observed during flap elevation in the group operated on using the Harmonic ACE+7. Particularly, the long arm and small blade enabled the operation to be performed from a narrow field of view and made vascular ligation more reliable and easier while collecting lumbar fat.

In the HA group, the amount of drainage in the breast area and the incidence of seroma in the back were significantly reduced. These findings are consistent with previous reports of LD flap using the Harmonic device[11,21]; however, it should be noted that these studies used the classic LD flap, and no mention was made of the ELD flap. The mechanism of seroma formation remains unclear. Theories suggest that the effluent emerging from the destruction of lymphatic vessels and capillaries during surgical manipulation accumulates in the dead space,[26] and that it is an inflammation-induced exudate.[27] Anatomically, the subcutaneous fat layer contains numerous collecting lymphatic vessels or superficial lymph-collecting vessels of 150–500 μm diameter.[28] In other words, contrary to the usual LD flap that is dissected over the deep fascia of the LD, the ELD flap is dissected within the adipose tissue overlying the superficial fascia, which may be the cause of the present results, as ELD flap procurement involves more damage to the lymphatic vessels. It should be noted that the incidence of seroma has been reduced, although the greater damage to the lymphatic vessels tends to result in relatively more effusion. It is also possible that the ELD flap does not show a statistically significant decrease in back drainage volume due to the larger dead space at the dorsal donor site, which results in more exudate accumulation because the ELD flap collects a larger volume of tissue than the LD flap. The reduced drainage in the breast area suggests that there was adequate sealing of the tissue on the flap side.

In terms of Japanese insurance coverage, the cost of using this device in breast reconstruction surgery using an arterial skin flap is covered under the "Ultrasonic coagulation and incision device" item. The cost is about $215, and considering the benefits to be gained, there will be many cases in which this device is applicable.

The small sample size remains a key limitation of the study, and more cases must be accumulated. Furthermore, obesity in Asian people is defined as having a BMI of more than 25, and obesity in White people, as having a BMI of more than 30, which introduces a selection bias into the study; however, the impact of varying degrees of obesity among races cannot be investigated in this study, and more cases should be obtained through collaboration with other centers. Additionally, because a reduction of seroma of the back, the most worrisome complication of the ELD flap, could not be achieved, the use of other reported techniques, such as fibrin sealants[29] and quilting sutures,[30] should be considered in combination. Furthermore, the present study is subject to detection and selection bias. To address these challenges, further prospective randomized controlled trials are needed to provide evidence that the Harmonic ACE+7 is significantly more useful in reconstruction with the ELD flap than with conventional electrocautery. In addition, although the use of this device is covered by Japanese insurance, the balance between the costs and benefits of its use will be a matter of discussion.

The ELD flap is a practical, stable, and volume-adjustable technique in reconstructive surgery involving breast reconstruction; however, it is crucial to prove the usefulness of this new device in reducing seroma, the most important complication. We intend to collect more cases and update the surgical technique by integrating technology and devices.

CONCLUSION

In ELD flap surgery (a surgical technique used in this study that can obtain an aesthetic breast), the use of Harmonic ACE+7 to elevate the flap is expected to reduce the rate of seroma, intraoperative bleeding, and surgical time.

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DISCLOSURE

The authors have no financial interest to declare in relation to the content of this article.

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