ORIGINAL ARTICLE

https://doi.org/10.14730/aaps.2023.00906
Arch Aesthetic Plast Surg 2023;29(4):183-189
pISSN: 2234-0831 eISSN: 2288-9337

aaps
Archives of Aesthetic Plastic Surgery

Subpectoral dissection using an ultrasonic energy device in prosthetic breast reconstruction

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Background Ultrasonic devices have potential advantages over electrocautery surgical scalpels for muscle dissection, as they eliminate the risk of muscle contraction caused by electric currents. In this study, we investigated the outcomes of using both device types in subpectoral dissection for breast reconstruction.

Methods In this retrospective single-center study, we examined the electronic medical records of female patients with non-recurrent breast cancer who underwent breast reconstruction. The patients were treated with either Harmonic Focus+ Shears (HFS) or a Bovie electrocautery scalpel (BES) between January 2015 and April 2020. The primary clinical outcomes evaluated were total drainage volume, time to drainage tube removal, and operation time. To control for confounding, outcomes were stratified based on the type of tissue expander used—either Mentor or Natrelle.

Results The study included 303 patients; 155 (51.2%) were treated with HFS (mean age, 45.28±7.38 years) and 148 (48.8%) with BES (mean age, 44.41±9.37 years). Within each expander type, the frequency of drainage exceeding 30 cc per day after 21 postoperative days showed no statistical difference between the HFS and BES devices. The operation time was shorter for HFS in both the Mentor (85.13±19.81 minutes vs. 109.56±21.66 minutes, P<0.001) and Natrelle (88.09±20.64 minutes vs. 99.88±22.66, P<0.001) groups.

Conclusions When controlling for the type of tissue expander as a confounding factor, HFS was associated with reduced operation time. Furthermore, it demonstrated superior clinical effectiveness compared to BES regarding operator convenience.

Keywords Breast reconstruction / Mastectomy / Drainage / Electrocoagulation / Electronic health records

INTRODUCTION

Implant-based breast reconstruction has emerged as the preferred method due to its versatility in facilitating either two-stage or direct-to-implant reconstruction, compared to other techniques [1,2]. Implants can be positioned in either the prepectoral or subpectoral plane. To accomplish this, flap dissection is usually performed using electrocautery surgical scalpels, such as the Bovie electrocautery scalpel (BES; Bovie Manufacturing).

During the dissection, the abdominal and partial sternocostal origin of the muscle is severed to create sufficient space in the breast pocket for the tissue expander. As the procedure moves towards the cephalic portion, the medial and lateral pectoral nerves may be stimulated by an electric current. This can lead to unwanted muscle contractions or spasms and intraoperative bleeding from the pectoral branch of the thoracoacromial trunk [3]. Furthermore, due to the rich blood supply of the muscle, patients may experience considerable bleeding or hematoma formation after surgery [4,5].

Ultrasonic dissection devices, such as the Harmonic Focus+ Shears

Received: Apr 12, 2023 **Revised:** May 31, 2023 **Accepted:** Jun 27, 2023
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(HFS; Ethicon), facilitate tissue cutting and vessel sealing without the need for an electric current. Compared to electrocautery surgical scalpels, which can cause incidental damage to surrounding tissues via thermal energy, HFS devices produce less heat. They are also capable of sealing both blood and lymphatic vessels [6].

HFS devices have been utilized in a range of procedures, such as thyroidectomy, resection of the pancreas and duodenum, and inguinal exposure for abdominal aortic aneurysm repair [7-12]. The present authors aimed to investigate the potential of HFS to reduce postoperative drainage, operative bleeding, and operation time in subpectoral dissection by eliminating the risk of unwanted pectoralis major contraction/spasm. Consequently, this study involved the use of electronic medical records from patients who underwent breast reconstruction to evaluate the clinical outcomes of pectoralis major dissection using both HFS and BES.

METHODS

Data source

This retrospective single-center study involved electronic medical record data from the Severance Hospital, which is affiliated with the Yonsei University College of Medicine in Seoul, Republic of Korea. The Department of Plastic and Reconstructive Surgery recorded all data pertinent to this study between January 1, 2015 and April 30, 2020.

Data collection

The study included patients with breast cancer who had undergone breast reconstruction by a single surgeon (SYS), using a tissue expander after a total mastectomy. All patients were treated with either HFS or BES. The exclusion criteria for patients were as follows: being under the age of 18 years; lack of documentation regarding the device used or drainage volume; not being female; having recurrent breast cancer; being a primary breast cancer patient who had previously undergone breast surgery; undergoing direct-to-implant reconstruction; having received a prepectoral expander; history of preoperative radiation therapy; or having undergone robotic surgery. Patients were categorized into two treatment groups based on the device used in the procedure: HFS or BES. To illustrate the differences between the two devices, brief videos of procedures performed with HFS and BES are included.

We collected demographic information about the patients, including age and body mass index. We also gathered data on their clinical characteristics, such as history of diabetes, history of neoadjuvant chemotherapy, and hemoglobin levels within the 2 months prior to surgery. Procedural characteristics were also collected, including the weight of the specimen after mastectomy (indicating breast size), the type of tissue expander used, the initial inflation volume, and the number of lymph nodes biopsied. The choice of device (HFS or BES) and other procedural components was left to the treating physician's discretion and was therefore not randomized. All patients were treated with an acellular dermal matrix.

Outcomes

The clinical outcomes of interest included the total volume of drainage until all tubes had been removed, the time to removal of the drainage tube, the duration of the operation, the volume of drainage on the first postoperative day, the volume of blood lost during the operation, whether a blood transfusion was needed during surgery, and any complications related to the procedure that occurred during the hospital stay. Potential complications included blood transfusions, hemorrhage or hematoma, or infection. Only the time of plastic surgery team involvement was counted for the operation time. We also included patients who underwent bilateral breast reconstruction. In those cases, the operation time was calculated by halving the total time. The drainage tube was removed when the Hemovac drain began collecting less than 30 cc per day.

Statistical analysis

The available data were examined using descriptive statistics and bivariate analysis. Counts and proportions were provided for dichotomous and polychotomous variables, while means and standard deviations were calculated for continuous variables. Bivariate comparisons of baseline characteristics were conducted by treatment group. Independent two-sample t-tests were utilized for continuous variables. The chi-square test or Fisher exact test was used for categorical variables. If more than 20% of cells had expected frequencies below 5, the Fisher exact test was used [13].

Research has indicated that maintaining a Hemovac drain for an extended period may heighten the risk of infection, thus suggesting the removal of the drain after 21 postoperative days [14]. After this time, the measurement of drain volume is typically discontinued. Consequently, patients who exhibited a drainage volume exceeding 30 cc per day after the 21 postoperative days were omitted from the clinical outcome analysis. All patients were administered antibiotics for the duration of the drain's presence. The analysis of outcomes was divided based on the type of tissue expander used, to account for potential confounding variables. The tissue expanders utilized in this study were Mentor (Mentor Worldwide LLC) and Natrelle (AbbVie), both of the textured surface types. The threshold for significance in the analyses was established at $P = 0.05$. All analyses were performed using SAS (SAS Institute) for Windows.

RESULTS

Overall population characteristics

A total of 303 patients met the inclusion criteria for this study. Of these, 155 (51.2%) were treated with HFS (mean age, 45.28 ± 7.38 years), and 148 (48.8%) were treated with BES (mean age, 44.41 ± 9.37 years). The baseline characteristics of the patients and the de-

Table 1. Patient and operation characteristics

Characteristic	HFS (n=155)	BES (n=148)	P-value[a]
Age (yr)	45.28±7.38	44.41±9.37	0.367
BMI (kg/m^2)	21.93±2.74	22.29±3.62	0.330
Diabetes mellitus			0.525
No	149 (96.13)	140 (94.59)	
Yes	6 (3.87)	8 (5.41)	
Neoadjuvant chemotherapy			0.739
No	131 (84.52)	123 (83.11)	
Yes	24 (15.48)	25 (16.89)	
Hemoglobin level (g/dL)	12.54±1.46	12.59±1.65	0.759
Specimen weight after mastectomy (g)	381.93±193.27	402.15±220.53	0.404
Tissue expander type			<0.001
Mentor	66 (42.58)	25 (16.89)	
Natrelle	89 (57.42)	123 (83.11)	
Initial inflation volume (cc)	104.52±32.42	103.14±32.36	0.712
No. of lymph nodes biopsied	4.39±3.66	5.32±5.34	0.079

Values are presented as mean±SD or number (%).
HFS, Harmonic Focus+Shears; BES, Bovie electrocautery scalpel; BMI, body mass index.
[a]Independent two-sample t-test or chi-square test. Statistically significant, P<0.05.

tails of the operations are presented in Table 1. The patients in both study groups were similar in terms of age (P=0.367), body mass index (P=0.330), rate of diabetes (P=0.525), rate of neoadjuvant chemotherapy (P=0.739), hemoglobin level (P=0.759), specimen weight after mastectomy (P=0.404), initial inflation volume (P=0.712), and number of lymph nodes biopsied (P=0.079). During the procedure, the operator chose either an expander or surgical

Table 2. Drainage volume after POD 21, stratified by device and tissue expander type

	Total (n=303)	After POD 21		P-value[a]
		Drainage ≤30 cc (n=270)	Drainage >30 cc (n=33)	
Mentor				0.904
HFS	66 (100)	44 (66.67)	22 (33.33)	
BES	25 (100)	17 (68.00)	8 (32.00)	
Natrelle				>0.999
HFS	89 (100)	88 (98.88)	1 (1.12)	
BES	123 (100)	121 (98.37)	2 (1.63)	

Values are presented as number (%).
POD, postoperative day; HFS, Harmonic Focus+Shears; BES, Bovie electrocautery scalpel.
[a]Independent two-sample t-test or chi-square test. Statistically significant, P<0.05.

Table 3. Surgical outcomes for patients treated with Mentor tissue expander

Variable	HFS (n=66)	BES (n=25)	P-value[c]
Operation time for breast reconstruction (min)	85.13±19.81	109.56±21.66	<0.001
Total drainage volume until drainage tube removal (cc)[a,b]	1,547±505	1,402±418	0.296
Time until drainage tube removal (day)[b]	18.27±4.99	16.71±2.82	0.130
Drainage volume on the first postoperative day (cc)[b]	197.28±43.12	202.62±94.28	0.825
Intraoperative blood loss volume (cc)	39.92±45.17	50.40±34.09	0.296
Blood transfusion			>0.999
No	66 (100)	25 (100)	
Yes	0	0	
Hemorrhage during hospitalization			>0.999
No	66 (100)	25 (100)	
Yes	0	0	
Hematoma during hospitalization			>0.999
No	66 (100)	25 (100)	
Yes	0	0	
Infection during hospitalization			>0.999
No	66 (100)	25 (100)	
Yes	0	0	

Values are presented as mean±SD or as number (%).
HFS, Harmonic Focus+ Shears; BES, Bovie electrocautery scalpel.
[a]The drainage tube was removed when the Hemovac drain collected <30 cc/day; [b]Outcomes analyzed based on the patients who displayed drainage ≤30 cc after postoperative day 21 (HFS+Mentor, n=44; BES+Mentor, n=17); [c]Independent two-sample t-test or chi-square test, statistically significant, P<0.05.

tools for each patient group. This allowed for a retrospective analysis of the cases to obtain P-values, which indicated no significant differences other than the type of expander used. The assignment of expander types was not evenly distributed across the groups. In the HFS group, 57.4% (89/155) of patients received Natrelle and 42.6% (66/155) received Mentor. In contrast, in the BES group, 83.1% (123/148) of patients received Natrelle and 16.9% (25/148) received Mentor (P < 0.001). The rate of exhibiting a drainage volume of > 30 cc/day after 21 postoperative days did not significantly differ by device among patients treated with the same type of tissue expander (Table 2).

Stratified surgical outcomes

The type of tissue expander significantly impacts the total drainage volume and the day of drainage tube removal [15,16]. To account for this, we examined the surgical outcomes stratified by expander type. Table 3 presents the surgical outcomes for patients treated with Mentor tissue expanders, with a comparison of HFS and BES. Among those who received Mentor expanders, HFS patients had significantly shorter operation times (HFS: 85.13 ± 19.81 minutes vs. BES: 109.56 ± 21.66 minutes, P < 0.001). However, no other outcomes showed significant differences. Both the HFS and BES groups showed no complications during hospitalization, such as hemorrhage, hematoma, or infection. Table 4 provides the surgical outcomes for patients treated with Natrelle tissue expanders, also with a comparison of HFS and BES. Among those who received Natrelle expanders, HFS patients had significantly shorter operation times (HFS: 88.09 ± 20.64 minutes vs. BES: 99.88 ± 22.66 minutes, P = 0.001), greater total drainage volume (HFS: 1,366 ± 564 cc vs. BES: 1,064 ± 553 cc, P < 0.001), and longer time to drainage tube removal (HFS: 14.77 ± 4.52 days vs. BES: 12.00 ± 5.30 days, P < 0.001) than patients treated with BES. All other outcomes were statistically insignificant. Three acellular dermal matrix products were used: Megaderm (L&C BIO Inc.), CGCryoDerm (CGBio Co.), and DermACELL (Stryker Corp.). However, no significant difference in drainage volume was observed among these products (data not provided).

DISCUSSION

Electrocautery scalpels, such as the BES, have been a primary tool for dissecting the subpectoral expander pocket during breast reconstruction [17]. However, in our experience, the use of BES often leads to incomplete coagulation and challenges with bleeding, particularly in cases of strong muscle activation in the pectoralis muscle (Fig. 1) [18]. In contrast, ultrasonic devices such as the HFS dissect tissue through physiological vibration, not electric current [6], thereby preventing muscle contraction. This offers potential benefits for both patients and operators; patients may experience less intraoperative and perioperative bleeding, while operators can

Table 4. Surgical outcomes for patients treated with Natrelle tissue expander

Variable	HFS (n = 89)	BES (n = 123)	P-value[c]
Operation time for breast reconstruction (min)	88.09 ± 20.64	99.88 ± 22.66	< 0.001
Total drainage volume until drainage tube removal (cc)[a,b]	1,366 ± 564	1,064 ± 553	< 0.001
Time until drainage tube removal (day)[b]	14.77 ± 4.52	12.00 ± 5.30	< 0.001
Drainage volume on the first postoperative day (cc)[b]	193.47 ± 83.19	203.90 ± 93.83	0.407
Intraoperative blood loss volume (cc)	49.55 ± 109.13	43.33 ± 40.95	0.610
Blood transfusion			> 0.999
No	89 (100)	123 (100)	
Yes	0	0	
Hemorrhage during hospitalization			0.420
No	88 (98.88)	123 (100)	
Yes	1 (1.12)	0	
Hematoma during hospitalization			> 0.999
No	88 (98.88)	121 (98.37)	
Yes	1 (1.12)	2 (1.63)	
Infection during hospitalization			> 0.999
No	89 (100)	122 (99.19)	
Yes	0	1 (0.81)	

Values are presented as mean ± SD or as number (%).
HFS, Harmonic Focus+ Shears; BES, Bovie electrocautery scalpel.
[a]The drainage tube was removed when the Hemovac drain collected < 30 cc/day; [b]Outcomes analyzed based on the patients who displayed drainage ≤ 30 cc after postoperative day 21 (HFS+Natrelle, n = 88; BES+Mentor, n = 121); [c]Independent two-sample t-test or chi-square test, statistically significant, P < 0.05.

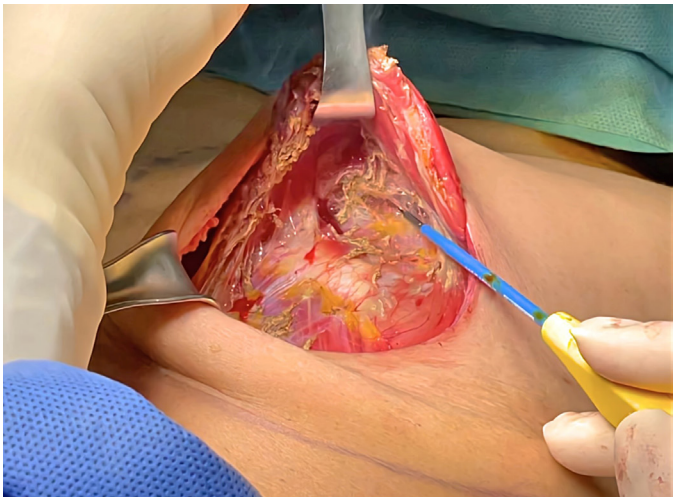

Fig. 1. Intraoperative photo demonstrating the use of a Bovie electrocautery scalpel.

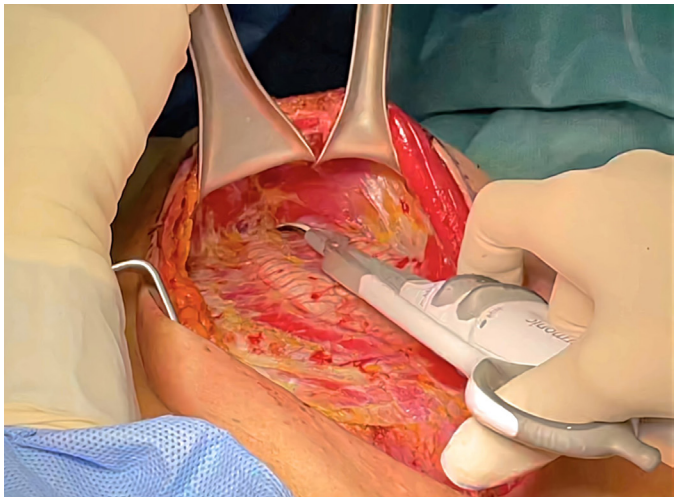

Fig. 2. Intraoperative photo demonstrating the use of Harmonic Focus+ Shears.

enjoy a clearer surgical field (Fig. 2). For these reasons, we investigated the differences between HFS and BES in terms of operation time, early postoperative bleeding, and total drainage volume.

This study revealed that patients undergoing breast reconstruction with HFS experienced shorter operation times compared to those treated with BES. This finding held true even when the analysis was stratified based on the type of tissue expander used. While the difference in operation time between the two surgical methods—ranging from 10 to 24 minutes—may not seem meaningful, it constitutes a significant difference relative to the total operation time of 85 to 110 minutes. The need for a subgroup analysis based on expander type was also identified, as significant differences were observed between the two groups (Table 1). The patients treated with BES and Natrelle expanders exhibited a decrease in total drainage volume and day of drainage tube removal. However, this comparison has become less relevant, since the macrotextured expander is no longer available due to its association with anaplastic large cell lymphoma [19-24]. These differences were not observed in the Mentor expander group, raising the question of whether the tissue expander type acted as a confounding variable. Statistical analysis has indicated that microtextured expanders resulted in a higher drainage volume [14]. The primary differences between the two expanders are related to their surfaces. The Allergan implant has a macrotextured surface (200–300 mm^2), while the Mentor implant has a microtextured surface (100–200 mm^2) [17]. This leads us to hypothesize that the difference in surface texturing may contribute to the variation in drainage volume. We propose that the difference in surface texturing triggers different tissue reactions, influencing the time required to form a capsule, the characteristics of the capsule, and ultimately the amount of drainage volume. Both groups demonstrated low complication rates, suggesting that both treatments were largely successful. The findings of this study suggest that, given the relatively similar safety and efficacy profiles, HFS may offer an advantage over BES in terms of operation time.

However, this retrospective analysis did not reveal a significant difference in the total volume of drainage. The total drainage volume can be influenced by numerous factors beyond the devices used. These factors include the patient's baseline characteristics, the technique of the mastectomy surgeon, and other materials utilized, such as tissue expanders or acellular dermal matrix [15,16,25]. Of note, the tissue expander manufacturer was significantly associated with the rate of exhibiting more than 30 cc of drainage after 21 postoperative days in the present study. Patients in the HFS group received Mentor expanders at a significantly higher rate than those in the BES group. Furthermore, patients who had more than 30 cc of drainage after 21 postoperative days were significantly more likely to have received Mentor expanders.

While the literature presents varied evidence regarding the use of HFS in breast reconstruction, certain trends are evident in mastectomy procedures, such as reduced drainage volume and shorter operation time. In a meta-analysis of 11 studies involving a total of 702 patients, Huang et al. [26] found that HFS was linked to significantly lower postoperative drainage volume, decreased rate of seroma development, reduced intraoperative blood loss, and fewer wound complications. However, no difference in operation time was found. Notably, all of the included studies were either randomized controlled trials or prospective comparative studies, contrasting with the current retrospective study. In a retrospective study by Sowa et al. [27], involving 82 patients who underwent breast reconstruction in Kyoto, those treated with HFS experienced less than half of the incidence of seroma relative to the electrocautery group (20.8% vs. 45.8%). Additionally, the HFS patients had a shorter average hospital stay by 1.8 days, less total drainage volume by 61 cc, and a marginally shorter operation time by 12 minutes, although

this was not statistically significant. Interestingly, the present study found that HFS operation time was significantly shorter than the operation time associated with BES. The differing surgical methods and study populations could account for the varied outcomes observed in the literature and in this study. However, when viewed collectively, these results suggest potential benefits of HFS that warrant further investigation and consideration.

Breast reconstruction surgery is increasingly acknowledged as a key part of treatment for patients who have undergone a mastectomy. With a rising number of patients choosing this form of care [28], it is essential to identify the most suitable devices for every aspect of the procedure. Studies indicate that breast reconstruction can enhance body image, self-esteem, and sexual function and even alleviate depressive symptoms [29-31]. Given this context, it is imperative to deliver surgical care that ensures the safest and most effective results. Further research is required to compare the impacts of HFS and other scalpels on patients undergoing breast reconstruction using different techniques.

This study had several limitations, including the non-random allocation of devices and its retrospective single-center design. These factors restrict the ability to draw causal inferences and generalize the findings. Additionally, significant differences existed in patient and procedural characteristics between the device groups, which could have acted as confounding variables. These included the tissue expander type, making it challenging to ascertain whether the differences in outcomes can be solely attributed to the device used.

In conclusion, this study revealed that patients who underwent breast reconstruction using HFS had a shorter operation time compared to those treated with BES. The attached brief video demonstrates the surgical process, showing that HFS allows for complete coagulation without causing muscle contracture. The findings of this study indicate that the safety and efficacy profiles of HFS and BES for breast reconstruction after mastectomy are not significantly different. Further studies are needed to investigate the impact of these devices on breast reconstruction surgery.

NOTES

Conflict of interest

This study was supported by Johnson & Johnson Medical Korea. Seung Yong Song is an editorial board member of the journal but was not involved in the peer reviewer selection, evaluation, or decision process of this article. Except for that, no other potential conflicts of interest relevant to this article were reported.

Ethical approval

The study was approved by the Institutional Review Board of Yonsei Severance Hospital (IRB No. 1-2020-0040) and performed in accordance with the principles of the Declaration of Helsinki. The board also approved a request to waive the requirement for informed consent from the patients included in the study.

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