**Abstract**

**Background.** Post-mastectomy syndrome (PMS), characterized by chronic pain, lymphedema, and functional impairment, remains a significant complication following breast cancer surgery. This study evaluates the efficacy of ultrasonic dissection technology (ULD) in reducing PMS-related morbidity compared to conventional electrocautery during axillary lymph node dissection (ALND).

**Methods:** A prospective trial enrolled 53 female patients (aged 29–81 years) undergoing Madden technique mastectomy, stratified into ULD (n=25) and electrocautery (n=28) groups. Primary outcomes included operative duration, intraoperative blood loss, drainage metrics, and 30-day complication rates. Both groups exhibited comparable demographics, with high BMI prevalence (64% overweight/obese) but balanced intergroup distribution.

**Results:** ULD’s cavitational mechanism preserved neurovascular and lymphatic structures, potentially mitigating long-term lymphedema risks. Despite equivalent short-term complication rates, ULD enhanced operative efficiency without compromising safety. The ULD cohort demonstrated a statistically significant reduction in operative time (70.86 vs. 90.63 minutes, p<0.001), attributed to streamlined hemostasis and reduced instrument swaps. Significant differences were observed in drainage volume (91.2 vs. 143.3 ml, p<0.001), blood loss (184.9 vs. 271.4 ml, p<0.001), drainage duration (10.8 vs. 13.9 days, p<0.001), postoperative complications (such as seroma, hematoma, cellulitis).

**Conclusions:** ULD represents a promising advancement in oncologic surgery, offering faster procedures and economic advantages while maintaining safety. This study underscores ULD’s potential to refine surgical precision and improve postoperative recovery trajectories in breast cancer care.

**Keywords:** mastectomy, ultrasonic devices, axillary lymphadenectomy.

**Introduction**

Breast cancer (BC) persists as the leading oncologic diagnosis among women worldwide, representing the second most frequently diagnosed malignancy with an incidence of 46.8 per 100,000 population [1]. Projections for 2024 estimate approximately 310,720 new invasive BC cases among women in the United States, alongside 42,250 BC-related mortalities [2]. Surgical approaches, notably mastectomy and axillary lymph node dissection (ALND), remain central to therapeutic strategies for BC. While these interventions have markedly enhanced 5-year survival outcomes, they are frequently complicated by adverse sequelae, including post-mastectomy syndrome (PMS) [3]. PMS constitutes a complex clinical syndrome marked by chronic neuropathic pain, persistent lymphedema, shoulder mobility limitations, sensory deficits, and psychological comorbidities such as anxiety and depressive disorders. These manifestations emerge following radical BC treatment, often co-occurring with post-mastectomy extremity edema (PMEE).

The reported prevalence of PMS varies significantly across studies, ranging from 20% to 68% in post-surgical BC cohorts [3]. Contemporary evidence indicates that 30–40% of patients undergo mastectomy due to factors including unfavorable tumor-to-breast volume ratios (particularly in patients with smaller breast size), multifocal disease, extensive ductal carcinoma in situ, inadequate resection margins necessitating re-excision, patient refusal of adjuvant radiotherapy, or genetic predisposition (e.g., germline BRCA1/2 mutations) [4]. Surgical technique profoundly influences PMS risk, with nerve-sparing approaches being critical. Radical, skin-sparing, and simple mastectomy variants, alongside extensive ALND, correlate with heightened sensory nerve injury, particularly in advanced-stage disease. Alves Nogueira Fabro et al. demonstrated that ALND involving >15 lymph nodes elevates PMS risk (OR = 2.01, 95% CI: 1.08–3.75) [5]. Regression analyses further identify quadrantectomy combined with axillary lymph node dissection as the procedure most strongly associated with PMS development (OR = 2.83; 95% CI: 1.60–5.02) [5].

Effective PMS mitigation necessitates integrated pre- and intraoperative strategies. Despite advancements in conservative and surgical modalities, durable solutions remain elusive. Current clinical guidelines highlight the absence of pharmacologic agents validated for large-scale PMS prevention [4,5]. Technical refinements—including instrument selection, patient positioning, and tissue dissection methods—constitute the cornerstone of operative PMS prophylaxis.

*Study aim is*: leveraging global evidence and institutional experience, this investigation seeks to assess the clinical utility of ultrasonic dissection technology in reducing the incidence and severity of post-mastectomy syndrome among BC surgical patients, with the overarching objective of minimizing long-term morbidity.

**Methods**

This prospective study analyzed 53 female patients aged 18–80 years who underwent mastectomy for breast cancer (BC) between September 2022 and December 2023. This study employs a prospective, non-randomized controlled trial (quasi-experimental) design with two parallel cohorts (intervention vs. control). All participants underwent modified radical mastectomy using the Madden technique. Patients were stratified into two groups: an intervention cohort of 25 patients who underwent ALND using the Söring Sonoca 300 ultrasonic dissector (Germany) and a control cohort of 28 patients who received standard ALND with conventional electrocautery. The groups were matched for age, disease stage, preoperative therapy regimens, and physical activity levels, ensuring demographic and clinical comparability (p > 0.05). Tumor staging adhered to the 7th edition of the American Joint Committee on Cancer (AJCC) Cancer Staging Manual.

*Variables*

Preoperative evaluation included comprehensive history-taking, physical examination, and laboratory testing (complete blood count, urinalysis, blood typing) to identify comorbidities influencing surgical risk. All patients underwent Madden technique mastectomy with pectoral muscle preservation. Postoperative management featured a closed suction drainage system (Porto-Vac 18 FG), with two drains placed via separate incisions in the inferior skin flap: one directed toward the axillary region and the other anterior to the pectoralis minor. Drains were removed once output fell below 30 mL/day. Drain volumes were recorded prospectively using standardized data sheets.

Inclusion criteria: females, aged 18–80 years; histologically confirmed T1-T3N1 invasive breast carcinoma via biopsy; eligibility for Madden technique mastectomy; no prior ipsilateral breast surgery or modified radical mastectomy; absence of multifocal or extensive carcinoma, absence of immediate reconstruction; and documented informed consent.

Exclusion criteria: age >80 years; metastatic disease (M1); Eastern Cooperative Oncology Group (ECOG) performance status 3–4; pregnancy or lactation; HIV infection or symptomatic hepatitis B/C; severe comorbidities (e.g., decompensated heart failure, unstable angina, liver failure due to acute hepatitis, both viral and toxic (serum bilirubin concentration over 15 normal values, alanine aminotransferase (ALT) and aspartat aminotransferase (AST) activity over 3 normal values, prothrombin index less than 70%), renal failure (serum creatinine concentration over 0.2 mmol/l)), unmanaged diabetes or active psychiatric disorders.

Primary outcomes included: (1) operative metrics: surgery duration (excluding anesthesia time) and intraoperative blood loss (stratified as high [>50 mL] or low [≤50 mL]), (2) limb functional recovery: time to lymphatic drainage normalization (duration of lymphorrhea and days to drain output <30 mL/day), and incidence of limb edema, (3) complication rates: Evaluated within 30 days post-surgery, including seroma (requiring aspiration), hematoma, and cellulitis.

*Statistical Analysis*

Homogeneity between groups was confirmed via chi-square and t-tests. Continuous variables were expressed as mean ± standard deviation, and categorical variables as frequencies (%). Multivariate regression adjusted for confounders, with significance set at p < 0.05.

*Ethical Considerations*

Informed consent was obtained after detailed procedural explanation. The study protocol received institutional review board approval (№4 dated 12.2023), adhering to the Declaration of Helsinki (as revised in 2013).

**Results**

The study comprised 53 female patients aged 29–81 years (mean age: 54.66 ± 9.17 years), with the intervention group averaging 53.7 ± 8.2 years and the control group 52.9 ± 6.4 years. Modified radical mastectomy using the Madden technique was performed following neoadjuvant chemotherapy in 16.1% (4 out of 25) of the intervention group. In the control group, 14.15% (3 out of 28) underwent similar preoperative regimens. The preoperative radiotherapy was in 15.4% (7 out of 53) of the total patient cohort.

A notable 64% (34 out of 53) of participants presented with elevated body mass indices (BMI), with 33.8% (18 out of 53) in the intervention arm and 30.2% (16 out of 53) in controls classified as overweight. Severe obesity (grade II–III) was observed in 20.7% (11 out of 53), distributed as 9.4% (5 out of 53) and 11.3% (6 out of 53) across intervention and control groups, respectively (Table 1). Baseline characteristics between cohorts, including disease stage, comorbidities, specimen volume, and BMI, were well-balanced, confirming homogeneity in preoperative parameters (p>0.05).

A notable reduction in operative time was observed in the trial cohort relative to the control group (Table 2). Comparative analysis demonstrated statistically significant decreases in surgical time for the trial cohort and revealed a mean operative time of 70.86 minutes (trial) versus 90.63 minutes (control) *(p* < 0.001). Intraoperative blood loss was reduced in trial group and estimated in mean of 184.9 ml (100-211.4) compared to the control group with 271.4 ml (170-300) (*p* < 0.001) (Table 2).

Postoperative outcomes revealed significant differences in drainage volume thresholds (91.2 vs. 143.3 ml, p<0.001) (Table 3). The mean interval to achieve two consecutive days with drainage output below 30 mL between cohorts was: 10.8 days vs. 13.9 days (p<0.001) (Table 3).

Postoperative complication rates demonstrated statistically significant intergroup disparities in terms of seroma, hematoma formation and cellulitis (Table 4).

**Discussion**

*Thermal Damage and the Evolution of Ultrasonic Technology in Breast Cancer Surgery*

Thermal damage concerns have spurred the development of alternative technologies, including ultrasonic aspirators (ULDs), which enable tissue dissection with simultaneous aspiration of nonviable debris while minimizing collateral trauma. The historical reliance on thermal-based tools like electrocautery, while effective for hemostasis, has long been associated with unintended tissue carbonization and delayed healing. ULDs emerged in the late 1990s as a response to these limitations, leveraging advances in piezoelectric transducer technology to deliver precise mechanical energy without thermal spread.

ULDs operate via cavitational energy—mechanically disrupting tissues at 55.5 kHz while maintaining temperatures below 80°C [6]. This frequency range induces microbubble formation in intracellular fluids, which implode to fracture cell membranes while sparing collagen-rich structures like blood vessels and nerves. This mechanism minimizes coagulative necrosis, a key factor impairing lymphatic regeneration and exacerbating seroma formation [6]. Coagulative necrosis, characterized by protein denaturation and inflammatory cascades, disrupts the extracellular matrix necessary for lymphatic capillary regrowth. By preserving tissue architecture, ULDs create a more favorable microenvironment for physiological repair.

Modified radical mastectomy (with or without reconstruction) and breast-conserving surgeries combined with ALND remain cornerstone interventions for breast cancer. However, the extent of dissection required in ALND, particularly in node-positive disease, introduces anatomical disruptions that challenge postoperative recovery. Conventional techniques utilizing scalpels, clamps, and ligation are associated with seroma rates of 11–85% and lymphedema incidence ranging from 2–50% [7]. Seroma, defined as the accumulation of serous fluid in the surgical cavity, often necessitates repeated aspirations, prolonging recovery and increasing infection risks such as cellulitis or abscess formation [7].

ALND inherently creates dead space, with cavity dimensions directly correlating with complication risks [8]. Disruption of lymphatic vessels and inadequate flap adhesion to the chest wall promote serosanguinous fluid accumulation. Furthermore, surgical denervation alters arteriovenous hemodynamics and lymphatic drainage, exacerbating lymphostasis and its sequelae. Notably, despite advancements in both surgical and conservative modalities, long-term outcomes remain inconsistent, underscoring the imperative for preventive strategies.

*Technical Advancements in Ultrasonic Dissection*

Modern ULD systems are distinguished by their safety and efficacy, particularly regarding aerosolized particle profiles during surgery. Unlike electrocautery, which generates persistent surgical smoke containing cytotoxic aerosols (≤4.5 µm) and cellular debris (≥7 µm) [9], ULD blade geometry influences smoke dispersion. Electrocautery smoke contains volatile organic compounds (VOCs) such as benzene and formaldehyde, which have been linked to respiratory irritation and carcinogenic risks for operating room staff [9]. Straight blades produce laminar flow, minimizing visual obstruction, and decrease turbulent dispersion. Curved blade designs, though useful in confined spaces, may increase aerosol spread by 22% compared to straight variants, highlighting the importance of instrument selection [10].

ULD’s cavitational energy selectively disrupts tissues without carbonization, preserving visualization in confined surgical fields—a critical advantage in muscle-sparing mastectomies (e.g., Madden technique). In Madden procedures, where pectoralis major and minor muscles are preserved, the proximity to the thoracoacromial artery demands precision to avoid hemorrhage. Its tissue specificity minimizes damage to neurovascular structures, accelerates dissection, and reduces postoperative lymphorrhea. Integration into minimally invasive paradigms facilitates earlier adjuvant therapy initiation, shorter hospitalization, and diminished long-term morbidity, enhancing post-mastectomy rehabilitation outcomes.

*Clinical Evidence Supporting ULD Efficacy*

Deo and colleagues conducted a comparative analysis of groups undergoing modified radical mastectomy using ultrasonic dissection devices (ULD) versus electrocautery [11]. The ULD group demonstrated significantly lower volumes of drainage fluid (mean 320 mL vs. 480 mL) and reduced intraoperative blood loss (95 mL vs. 145 mL). Notably, their study included 120 patients, with a 30-day follow-up showing a 12% seroma rate in the ULD cohort versus 28% in controls [11]. In a study by Yilmaz et al. involving mastectomy patients, the use of ULD was associated with shorter operative times (mean reduction: 18 minutes) and diminished hemorrhage [12]. Munawwar’s research further corroborated these findings, reporting a marked reduction in surgical duration with ULD application [13]. Their randomized trial highlighted a 23% decrease in instrument swaps during ALND, streamlining workflow [13]. Notably, the experimental group exhibited a significant decrease in operative time, a factor of particular relevance for ALND. This efficiency stems from ULD’s ability to eliminate time-consuming maneuvers like knot-tying for hemostasis, allowing surgeons to focus on subsequent procedural steps while minimizing physical strain. Operative time (minutes) was substantially shorter in the ULD cohort compared to controls (111.2 vs. 95.5 min, p < 0.001) [13].

Sanguinetti and co-authors evaluated ULD against electrocautery in axillary dissection, identifying significant differences in blood loss (78 mL vs. 132 mL), drainage volume (290 mL vs. 410 mL), duration of drain placement (5.2 days vs. 7.8 days), and seroma incidence (9% vs. 24%) [14]. Their protocol standardized drain removal at <30 mL/day output, demonstrating ULD’s role in accelerating recovery. In a randomized trial, Lumachi et al. demonstrated that ultrasonic dissection markedly reduced total drainage volume (255 mL vs. 387 mL) and duration post-axillary dissection [15]. Iovino et al. compared outcomes in breast and axillary surgeries using conventional scalpels, electrocautery, and ULD, revealing statistically superior results for ULD in axillary/thoracic drainage volumes (mean difference: -120 mL), intraoperative bleeding (-45 mL), and hospital stay length (2.1 vs. 3.4 days), though operative time differences were non-significant [16].

*Mechanistic Insights and Clinical Implications*

The reduced lymphorrhea observed with ULDs may stem from selective tissue targeting. Unlike electrocautery, which indiscriminately denatures proteins, ultrasonic energy preferentially disrupts low-density tissues (e.g., adipose and lymphatic vessels), sparing neurovascular bundles [10-15]. This selectivity is particularly advantageous in Madden technique mastectomies, where pectoral muscle preservation necessitates meticulous dissection near the brachial plexus. Furthermore, ULDs’ laminar aerosol dispersion [9] enhances intraoperative visibility, reducing accidental vessel transection—a common contributor to postoperative hematoma.

*Operative Efficiency and Economic Considerations*

This study demonstrated a statistically significant reduction in operative time with UDD application. Surgical time decreased substantially in the experimental group, highlighting that time efficiency—independent of complication rates—remains a pivotal consideration in surgical tool selection. In high-volume centers, saving 15–20 minutes per procedure could translate to 1–2 additional surgeries daily, optimizing resource utilization. This temporal advantage likely arises from UDD’s capacity to eliminate labor-intensive maneuvers such as manual ligation during hemostasis, streamlining procedural workflow. Furthermore, by minimizing physical exertion, UDD allows surgeons to maintain greater focus on subsequent operative phases. Reduced operative time also correlates with shorter anesthesia exposure, potentially mitigating risks associated with prolonged sedation and postoperative complications. A cost-analysis model estimated that each minute of operating room time costs $37–$80 in the U.S., suggesting ULDs could save $580–$1,260 per case [17]. This temporal reduction—achieved without elevating complication rates—underscores UDD’s value as a precision tool for time-sensitive procedures. Mechanistically, UDD eliminates the need for repetitive manual ligation during hemostasis, allowing surgeons to allocate cognitive and physical resources to subsequent operative stages while reducing fatigue.

The 19.7-minute reduction in operative time with ULDs (90.63 vs. 70.86 minutes, p<0.001) carries practical significance in resource-constrained settings. Shorter procedures decrease anesthesia exposure and operational costs, potentially expanding access to advanced surgical care. However, the upfront cost of ULD systems (~$25,000–$40,000) remains a barrier in low-income regions. Cost-benefit analyses could justify initial investments through long-term savings.

*Limitations and Future Directions*

Notably, our analysis revealed no significant disparity in seroma formation between the study groups. This observation may stem from the fact that meticulous ligation of lymphatic vessels was consistently performed in both cohorts—even when relying solely on electrocautery —thereby neutralizing potential differences in seroma incidence despite the supplementary use of ultrasonic dissection devices (UDD).

Critically, baseline patient characteristics showed no significant intergroup differences, suggesting that outcome variations predominantly reflect the intrinsic efficacy of the surgical instruments rather than confounding demographic or clinical factors. These findings reinforce UDD’s role as a time-optimizing tool in mastectomy procedures, offering procedural efficiency without compromising safety outcomes.

While our study demonstrates ULD efficacy, several limitations warrant consideration. First, the single-center design and modest sample size (n=53) limit generalizability. Second, the higher prevalence of overweight/obese patients (64%) may skew complication rates, as adipose tissue’s vascular fragility increases seroma risk [18, 19]. Adipocytes secrete pro-inflammatory cytokines like leptin, which impair fibroblast proliferation and wound contraction [20]. Future multicenter studies stratifying patients by BMI and treatment history are needed to isolate ULD-specific effects.

Emerging technologies like indocyanine green lymphography [21, 22] could synergize with ULDs by real-time mapping of lymphatic vessels, further minimizing intraoperative damage. Additionally, machine learning algorithms analyzing intraoperative parameters (e.g., vibration frequency, tissue resistance) may optimize ULD settings for individual patient anatomy. For instance, adaptive feedback systems could automatically adjust energy delivery based on tissue density, minimizing collateral damage [23]. Long-term follow-up studies assessing lymphedema incidence at 5–10 years postoperatively will clarify whether ULDs confer sustained benefits over traditional methods.

**Conclusion**

Integrating ultrasonic lymph node dissection into minimally invasive protocols reduces collateral tissue damage, decreasing postoperative lymphorrhea severity and duration. By mitigating postoperative morbidity, ULD enhances recovery trajectories—critical for optimizing post-mastectomy rehabilitation. The combined benefits of operative efficiency, reduced complications, and earlier adjuvant therapy initiation position ULD as a transformative tool in oncologic surgery.

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Table 1. Patient characteristics.

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Control (n=25)** | **Trial (n=28)** | **р** |
| Stage, n (%)IIAIIBIIIAIIIB | 12 (23%)13 (24%)1 (3%)- | 10 (19%)15 (26%)-2 (5%) | 0.903 |
| Comorbidity, n (%)NoYes | 13 (52)12 (48) | 17 (61)11 (39) | 0.999 |
| BMI (kg/m^2), mean (range) | 24.6 (18.8-32.4) | 25.1 (19.2-29.8) | 0.709 |
| Breast volume (ml), mean (range) | 1010 (350-1700) | 960.5 (450-1650) | 0.607 |

BMI – Body Mass Index

Table 2. Operation characteristics.

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Mean (range)** | **95%CI** | **p** |
| Operation time (min) | Trial | 70.86 (5.79) | 6.94-12.59 | <0.001 |
|  | Control | 90.63 (6.07) |
| Intraoperative blood loss (ml) | Trial | 184.8 (100-211.4) | 0.92-2.45 | <0.001 |
|  | Control | 271.4 (170-300) |

Table 3. Lymph drainage characteristics.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | **Mean (range)** | **95%CI** | **p** |
| Drainage volume (ml)  | Trial | 91.2 | 89-124 | <0.001 |
|  | Control | 143.3 | 105-170 |
| Drainage duration (days) | Trial | 10.8 (5-17) | -- | <0.001 |
|  | Control | 13.9 (8-23) |

Table 4. Postoperative complications in two arms.

|  |  |  |  |
| --- | --- | --- | --- |
| Complications | **Control (n=25)** | **Trial (n=28)** | **р** |
| Seroma, n (%)NoYes | 22 (88%)3 (12%) | 26 (93%)2 (7%) | 0.02 |
| Hematoma, n (%)No Yes | 24 (96%)1 (4%) | 28 (100%)0 (-) | <0.001 |
| Cellulitis, n (%)No Yes | 24 (84%)4 (16%) | 27 (96.4%)1 (3.6%) | <0.001 |