

Preliminary Report

Reduced Pain and Accelerated Recovery Following Primary Breast Augmentation With Lightweight Breast Implants

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Abstract

Background: The posttreatment pain associated with breast augmentation is a top concern of most patients and can affect the decision concerning surgery.

Objectives: This study aimed to compare the posttreatment pain and recovery times of patients undergoing primary breast augmentation with lightweight vs full-mass implants of similar volumes. The authors hypothesized that the reduced mechanical strain applied by lightweight implants elicits less pain.

Methods: In this retrospective, observational study, 100 women who had undergone primary breast augmentation with either a lightweight breast implant or a traditional full-mass silicone implant ($n = 50$), were contacted by phone and asked about their posttreatment experiences and overall satisfaction with the outcome. All women were treated by the same surgical team, and the two groups were matched by date of surgery.

Results: Most patients in the two cohorts had a self-reported preoperative B cup size and relatively high tolerance to pain. On average, LWBI patients were 6 years older than those undergoing full-mass implantation (32.4 ± 8.7 vs 26.2 ± 8.0 ; $P = .0004$) and more had experienced at least one pregnancy (61.2% vs 24%, $P = .0002$). LWBI patients opted for implants 39 ± 28.4 cc larger than patients in the control group. Subglandular placement was selected in most cases (LWBI: 83.7% and full-mass: 90.0%). Mean posttreatment pain was lower in the LWBI cohort (5.5 ± 2.4 vs 6.5 ± 2.4) and required a shorter duration of analgesics (3.87 ± 1.77 days vs 5.26 ± 2.94 days; $P = .009$). Age- and parity-adjusted measures demonstrated a respective 2-day and 5-day shorter recovery period and return to normal activities interval in the LWBI versus full-mass implant cohorts ($P = .04$ and $P = .002$, respectively).

Conclusions: As compared to traditional silicone filled full-mass implants, breast augmentations with B-Lite lightweight breast implants (G&G Biotechnology Ltd., Haifa, Israel) elicit less posttreatment pain and require less down-time, ultimately, meeting patients' quest for desired breast shape at minimal discomfort.

Level of Evidence: 3

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Breast augmentation procedures are one of the most prevalent aesthetic surgeries performed worldwide.^{1,2} Nonetheless, during consultation visits, patients often express apprehension regarding posttreatment pain. Indeed, 59% of the 250 adults who had undergone any type of surgical procedure and had been contacted in a national survey, expressed posttreatment pain as their top concern.³ With regards to breast surgery in particular, such

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fears seem substantiated, as evidenced in a survey of 648 patients undergoing ambulatory surgeries, in which plastic surgery of the breasts ranked among the most painful procedures (VAS > 4) in the first 48 hours after surgery.⁴ While patients and physicians alike seek to minimize pain, some degree of posttreatment pain is inevitable.⁵ Excessive narcotic use is associated with substantial nausea and vomiting,⁴ which, in turn, can trigger wound dehiscence and bleeding, directly impacting the length of the hospital stay. To date, no formal studies have been conducted to assess the role of implant weight on short-term pain and recovery associated with breast augmentation procedures.

The viscoelastic properties of breast tissues are largely dictated by the glandular-to-fat ratios,⁶ which undergo natural fluctuations in response to hormonal and weight changes, as well as advancing age.⁷⁻¹² These ratios directly impact tissue elasticity and ultimately determine tissue resilience to loading and compressive forces. For this reason, the weight, rather than the volume, of breast implants has been suggested to be the second-most critical variable affecting breast augmentation outcomes, where dismissal of the tissue characteristics, runs greater risk of revisional surgery.¹³ The B-Lite® lightweight breast implant (LWBI; G&G Biotechnology Ltd., Haifa, Israel) has been developed to reduce the mechanical strain applied by the weight in combination with gravitational and accelerative forces on the natural soft tissue. Its unique design affords a 25–30% reduction in implant weight, in comparison to full-mass breast implants of equivalent sizes.¹⁴ Anecdotal data reported by the nursing staff during initial surgeries with the B-Lite® implants indicated less pain and faster recovery in these patients. This unexpected feedback spurred us to conduct an organized survey to check the validity of these observations in a controlled manner. The survey compared posttreatment pain levels, recovery times and satisfaction with the healing process reported by patients undergoing implantation of the LWBI vs full-mass silicone breast implants.

METHODS

The study protocol was approved by the institutional Helsinki Committee at the Bnai Zion Medical Center.

Study Design

The study was a retrospective, observational study involving 100 female patients undergoing primary breast augmentation and presented with two implant options at the initial consultation visit. Patients could reach an informed decision on their own. Implant size was selected by coupling patient requests with the surgeon's evaluation of breast and tissue characteristics, based on his experience in such procedures. The analysis included 50 consecutive patients with the lightweight breast implants

and 50 patients with full-mass silicone breast implants (41 Eurosilicone, Style 811, 9 Allergan CUI), with procedures that were date- and surgical team-matched to the LWBI cohort. All surgeries were performed in the same clinic, by the same surgeon (J.G.Y.) and anesthesiologist (Y.M.). Patients were contacted by a member of the clinic's administrative staff between 2.5 and 3.5 months (3.0 ± 0.26) after surgery and asked to participate in a telephone survey focusing on the recovery process. The surveys were conducted between February and June 2014. To limit noise, only eventless recoveries were compared; patients with significant posttreatment complications were excluded from the analysis.

Study Measures

Aside from questions concerning demographics, baseline parameters and lifestyle habits, patients were asked to complete an 11-question survey relating to the post-implantation recovery period and satisfaction with surgical outcomes (Appendix A).

Statistical Analysis

The required significance level of findings was $p \leq 5\%$. All statistical tests were two-sided. Where appropriate, confidence levels were 95%. For comparison of means, the two-sample t-test was done. For comparison of proportions, the Fisher's exact test was used. Recovery parameters were analyzed with analysis of variance (ANOVA) models, which were repeated twice – once as a univariate model and once adjusted for previous pregnancy, age and average implant volume. In addition, a Cox's regression model (adjusted for previous pregnancy, age and average implant volume) was done to assess the hazard ratio of the LWBI implant in reducing time to recovery and time to return to normal activities. All statistical analyses were performed using SAS v9.3 (SAS®, SAS Institute Cary, NC, USA) software.

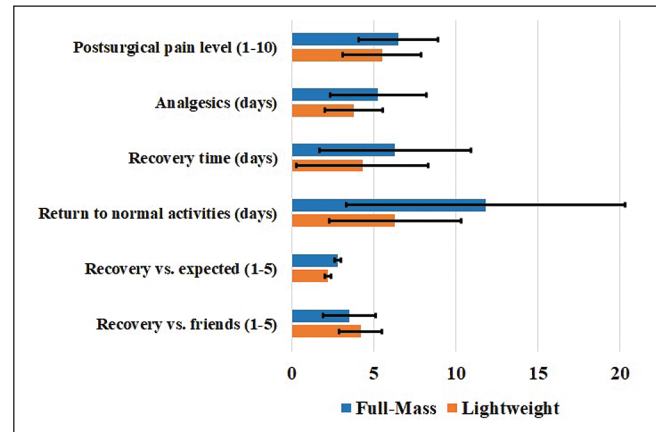
RESULTS

All contacted patients agreed to participate in the survey. One LWBI patient was excluded from the study because of a posttreatment hematoma that led to reoperation one day after her initial surgery. The cohort of patients undergoing LWBI implantation was 6 years older (32.4 ± 8.7 vs. 26.2 ± 8.0 ; $P = .0004$) and more had experienced a pregnancy (61.2% vs. 24%, $P = .0002$) as compared to those undergoing full-mass implantation (Table 1). The clear majority of patients had a self-reported B cup size before surgery (LWBI: 83.7% vs standard: 80.0%) and described their tolerance to pain as 4–5 (moderate-high; LWBI: 75.6% and full-mass: 82.0%) (Table 1).

Table 1. Patient Baseline Characteristics and Implant Volumes

	LWBI (N = 49)	Full-mass (N = 50)
Age (years)		
Mean (SD)	32.4 (8.7)	26.2 (8.0)
Range	20–53	18–52
Previous pregnancy		
Yes	30 (61.2)	12 (24.0)
No	19 (38.8)	38 (76.0)
Bra cup size before surgery, n (%)		
A	2 (4.1)	6 (12.0)
B	41 (83.7)	40 (80.0)
C	4 (8.2)	4 (8.0)
D	1 (2.0)	
Unknown	1 (2.0)	
Pain tolerance, n (%)		
1	5 (10.2)	2 (4.0)
2	2 (4.1)	1 (2.0)
3	5 (10.2)	6 (12.0)
4	10 (20.4)	18 (36.0)
5	27 (55.1)	23 (46.0)
Daily physical exertion, n (%)		
1	9 (18.4)	12 (24.0)
2	5 (10.2)	3 (6.0)
3	17 (34.7)	17 (34.0)
4	14 (28.6)	16 (32.0)
5	4 (8.2)	2 (4.0)
Right implant volume, cc		
Mean (SD)	417.9 (77.5)	380.5 (50.8)
Range	300–440	280–500
Left implant volume, cc		
Mean (SD)	426.8 (75.7)	366.0 (47.9)
Range	300, 615	280, 500
Implant placement, n (%)		
Subglandular	41 (83.7)	45 (90.0)
Submuscular	8 (16.3)	5 (10.0)

Patients undergoing LWBI implantation opted for implants that were, on average, 39 ± 28.4 cc larger than the implants for the full-mass implant group (Table 1;

**Figure 1.** Post-surgical recovery indicators.

$P = .0029$). In both cohorts, the clear majority of implants were placed in the subglandular plane (LWBI: 83.7% and full-mass: 90.0%), with the remainder of implants placed in the submuscular plane; submuscular placement was only performed in cases of thin tissue cover. Inframammary incisions were made in all cases.

Posttreatment pain level, mostly localized at the incision/stitches area, was scored a mean 5.5 ± 2.4 by LWBI patients, while full-mass implant patients reported higher levels averaging 6.5 ± 2.4 (Figure 1; $P = .07$). Most patients reported analgesic use following surgery; 4 LWBI and 5 full-mass patients did not take analgesics at all (Table 2). Among those who took analgesics, treatment duration extended for an average of 3.87 ± 1.77 days vs 5.26 ± 2.94 days following surgery with the LWBI vs full-mass implants, respectively (Figure 1; $P = .009$). Patient age and parity were shown to have no significant predictive impact of any of the study measures. When adjusting for age, implant volume and previous pregnancy, three baseline parameters that differed between the two cohorts, the LWBI group recovered a mean 2 days earlier (4.3 ± 4.0 vs 6.3 ± 4.6 days, respectively; $P = .04$) and returned to normal activities 5 days earlier (6.5 vs 11.3 days, respectively; $P = .002$) than the full-mass implant cohort. In both adjusted and non-adjusted assessments, the LWBI demonstrated superiority over full-mass implants. Hazard ratios of 1.16 (95% CI: [0.95; 2.77]) for length of recovery period and of 2.21 (95% CI: [1.3; 3.7]) for return to normal activities were calculated, in favor of LWBI. The recovery process was better than anticipated in the LWBI cohort (2.2 ± 0.2) but only slightly easier than expected for the full-mass cohort (2.8 ± 0.2 ; $P = .009$). When compared to friends and family that underwent full-mass implant surgery, recovery in the LWBI cohort was easier (1.8 ± 1.3) while recovery in the full-mass implant cohort was similar (2.5 ± 1.6 , $P = .038$).

Table 2. Recovery Measures

	LWBI (N = 49)	Full-mass (N = 50)
Recovery time (days)		
Mean (SD)	4.3 (4.0)	6.3 (4.6)
Range	0–14	0–17
Return to work (days)		
Mean (SD)	6.3 (4.0)	11.8 (8.5)
Range	1–17	2–45
Pain (10-point VAS)		
Mean (SD)	5.5 (2.4)	6.5 (2.4)
Range	1–10	1–10
No use of analgesics (patients)		
Patients (%)	4 (8.2)	5 (10)
Use of analgesics (days)		
Mean (SD)	3.87 (1.77)	5.26 (2.94)
Range	1–7	1–14

DISCUSSION

This study was designed to characterize the short-term recovery period following primary breast augmentation and to identify possible differences between LWBI implantation as compared to full-mass silicone breast implants, while controlling for the same surgical staff, same surgical procedures, and postoperative care. In both adjusted and non-adjusted assessments, LWBI patients consistently reported lower pain levels and shorter recovery periods as compared to those undergoing augmentation with a full-mass implant, despite the larger LWBI implant volumes selected and subsequently larger incision lengths required. Of note, a relatively large discrepancy was observed between recovery times and time to return to work/activities in both cohorts, likely due to a preoperative decision to take a sick leave for a predetermined period. Accordingly, time of return to work cannot be taken as a reliable estimate of the recovery process.

While subpectoral placement is typically associated with slightly elevated posttreatment pain,¹⁵ the observed differences in pain levels and recovery times could not be ascribed to disparity in placement locations, as the most of the implants, in both cohorts, were placed in the subglandular plane. In addition, sub-analysis of the mean duration for analgesics as a function of implantation plane, consistently yielded a shorter need for relief in the LWBI as compared to the full-mass cohort (4 vs 7 days, respectively [subpectoral], and 3 vs 4 days, respectively [subglandular]). This sub-analysis, however, remains to be

verified with larger cohorts. The most patients reported pain sensations at the incision area, likely arising from tissue trauma, presumably exacerbated by the pressure of the implant on the incision. As the inherently lower weight of the LWBI exerts less pressure on the incision site (LWBI: 422.3 ± 75.8 cc = 316.7 ± 56.9 g vs full-mass: 383.3 ± 47.4 cc/g), it was not surprising that these patients reported lower pain levels, despite the greater tissue trauma caused by larger pocket size and slightly longer incision lengths (typically 5–7 mm) for LWBI vs full-mass implants. In parallel, the LWBIs are inherently form-stable and mimic breast tissue in that they have a characteristic slightly slower response time to deformation. It is hypothesized that the biomimetic responsiveness of LWBIs as compared to traditional breast implants, can be viewed as a low-pass mechanical filter, which dampens pressure changes, vibrations and overall displacement stimuli or responses. This shock-isolation effect in response to breast movement, makes the LWBI more likely to exert gradual and continuous pressure as opposed to the intermittent or jerky pressure applied by traditional, full-mass implants on the breast tissues and incision site. Experience with negative pressure wound healing techniques has consistently demonstrated that continuous pressure is followed by a plateau in pain levels, while intermittent pressure modes, each dressing replacement, and sudden jarring of the affected area, lead to restimulation of pain sensations.¹⁶

The retrospective nature of this survey, which questioned patients three months after the procedure, may have been biased by short-term memory relating to pain perception and patient responses may, in fact, reflect their overall satisfaction from the breast augmentation procedure. In addition, LWBI patients were an average 6 years older than full-mass implant patients and a higher percentage had experienced at least one pregnancy, two factors which could have impacted recovery and pain thresholds. Yet, despite these limitations, biases were kept to a minimum, with all patients treated by the same surgeon, anesthesiologist, and medical staff. In the combined group of all 99 patients, age and parity were not found to be independent predictors of pain and recovery outcomes. In addition, the ANOVA analysis adjusted for prior pregnancy, age and average implant size and still demonstrated a significant inter-cohort difference. A prospective, multi-center study, in which patients will record postoperative impressions and score pain levels and quantify recovery parameters over a one-week period is currently ongoing.

CONCLUSIONS

This initial comparison of the recovery period following LWBI- vs. full-mass silicone implant-based breast augmentation surgery, associated the LWBI with less postoperative pain and a faster recovery period. Patients with lightweight

implants reported less pain, took less pain medication and resumed their normal routine faster as compared to patients with full-mass implants. Such postoperative experiences have been consistently linked to significantly higher patient satisfaction and quality of life.^{13,16} These most desirable findings are expected to quench the constant pursuit of minimized pain, with considerable clinical advantages, in addition to the long-term benefits of the lightweight implant.

Supplementary Material

This article contains supplementary material located online at www.aestheticsurgeryjournal.com.

Disclosures

Dr J. Govrin-Yehudain is the President of G&G Biotechnology Ltd. (Haifa, Israel), manufacturer of the device studied. Dr O. Govrin-Yehudain has no direct conflict of interest, but is the son of Dr J. Govrin-Yehudain. Dr Matanis declared no potential conflicts of interest with respect to the research, authorship, and publication of this article.

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