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Normative Data for Interpreting the BREAST-Q: Augmentation

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Abstract

Background—The BREAST-Q is a rigorously developed, well-validated, patient-reported outcome (PRO) instrument with a module designed for evaluating breast augmentation outcomes. However, there are no published normative BREAST-Q scores, limiting interpretation.

Methods—Normative data were generated for the BREAST-Q Augmentation Module via the Army of Women (AOW), an online community of women (with and without breast cancer) engaged in breast-cancer related research. Members were recruited via email, with women 18 years or older without a history of breast cancer or breast surgery invited to participate. Descriptive statistics and a linear multivariate regression were performed. A separate analysis compared normative scores to findings from previously published BREAST-Q augmentation studies.

Results—The preoperative BREAST-Q Augmentation Module was completed by 1,211 women. Mean age was 54 ± 24 years, mean body mass index (BMI) was 27 ± 6 , and 39% ($n=467$) had a bra cup size D. Mean scores were Satisfaction with Breasts (54 ± 19), Psychosocial Well-being (66 ± 20), Sexual Well-being (49 ± 20), and Physical Well-being (86 ± 15). Women with a BMI of 30 or greater and bra cup size D or greater had lower scores. In comparison to AOW scores, published

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BREAST-Q augmentation scores were lower before and higher after surgery for all scales except Physical Well-being.

Conclusions—The AOW normative data represent breast-related satisfaction and well-being in woman not actively seeking breast augmentation. This data may be used as normative comparison values for those seeking and undergoing surgery as we did, demonstrating the value of breast augmentation in this patient population.

Introduction

Breast augmentation is the second most common aesthetic surgery procedure performed by plastic surgeons in the United States (US), second only to liposuction. There are over 305,000 breast augmentations performed yearly, for a total US market expenditure of over 1 billion dollars (1). Worldwide, it is estimated that between 5 and 10 million women have breast implants (2), thus necessitating the use of rigorous scientific research methods to evaluate patient presentations, technical choices within surgery and long-term outcomes.

To measure surgical outcomes, traditional surgical measures of morbidity and mortality are important, but possibly not as relevant in this patient population undergoing elective aesthetic surgery. Breast augmentation is a relatively safe procedure. In a recent study of 725 patients who underwent augmentation, the overall complication rate was less than 1.5 percent and life-threatening complications were exceedingly rare (3). Of more utility in this patient population, is the evaluation of changes in quality of life, body image, patient satisfaction and self-esteem. Such constructs are best measured from the patient perspective using breast surgery specific patient-reported outcome (PRO) instruments.

Since generic PRO instruments do not ask about breast-specific concerns, validated breast-specific PRO questionnaires are needed to ensure that meaningful before and after data relevant to a given intervention are collected (4). One of the most widely used breast surgery PRO questionnaires, the BREAST-Q, is a rigorously designed, well-validated disease-specific PRO instrument that has now been used in research with over 22,000 women having different types of breast surgery (5–10). The BREAST-Q has modules for different types of breast surgery, each with questions specific to that subset of breast surgery, including a module with questions designed specifically for patients undergoing breast augmentation (11). The BREAST-Q Augmentation Module has been used to compare pre- and post-operative outcomes in women undergoing breast augmentation, with consistent post-augmentation improvements in satisfaction and well-being (2, 10, 12, 13).

A current limitation of the BREAST-Q Augmentation Module is a lack of normative scores for breast satisfaction and well-being of women in the general population. Therefore, while the BREAST-Q has been used to demonstrate the efficacy of breast augmentation, it is not yet known how these pre- and post-operative patients, in regards to breast satisfaction and well-being, compare to population norms. The primary aim of this study was to generate normative scores for the BREAST-Q Augmentation Module. The secondary aim was to compare these normative scores to published BREAST-Q scores for breast augmentation, in efforts to bring greater clinical context to previously determined findings.

Methods

Study Population

The Army of Women (AOW) is an online community of women (breast cancer patients as well as healthy women), with a primary goal of promoting breast cancer related research. The AOW was started in 2008 by the Dr. Susan Love Research Foundation. Prior to utilizing the AOW community for study recruitment, the Scientific Advisory Committee at the AOW accepted the study, and IRB waiver was obtained from Dartmouth College's Committee for the Protection of Human Subjects. An electronic recruitment email (e-blast) was circulated to AOW members with a short study description and the following inclusion criteria: age 18 years or greater, no prior history of breast cancer or breast surgery, and the ability to complete a questionnaire online, in English.

Recruitment

The e-blast was sent to 121,688 AOW members describing the study. AOW of women members who were interested and self-selected to meet inclusion criteria followed the e-blast to complete a module of the BREAST-Q. The BREAST-Q was administered using Qualtrics, an online web-based software for questionnaire administration (Provo, UT; www.qualtrics.com). Participants were recruited as part of a study to generate normative scores for 3 different modules of the BREAST-Q: augmentation, reduction and reconstruction. All participants were also asked to provide demographic information, as well as bra cup size, height, and weight. An algorithm was written into the Qualtrics link to automatically reroute participants to the next BREAST-Q module once 1,200 participants had completed one of the modules. The algorithm started with the Reduction Module, followed by the Augmentation and then the Reconstruction Modules. Normative data for the two other BREAST-Q modules will be published separately.

BREAST-Q

The BREAST-Q, developed for all types of breast surgery, is a rigorously developed and well-validated PRO instrument with an Augmentation Module designed specifically for the evaluation of outcomes in patients seeking and undergoing breast augmentation (6, 9, 11). The development of the conceptual framework and set of scales involved a literature review, 48 patient interviews, 46 cognitive patient interviews, and expert opinion from a panel of plastic surgeons and other healthcare professionals (phase 1). The BREAST-Q was tested in a sample of 401 patients, which included 174 pre- and 227 post-augmentation patients (14, 15). The BREAST-Q Augmentation Module has 4 pre-operative scales: Satisfaction with Breasts (n=6 items), Psychosocial Well-being (n=9 items), Sexual Well-being (n=5 items), and Physical Well-being (n=5 items). Scale items are summed and transformed on a scale from 0 (worst) to 100 (best) using the Q-Score program (New York, NY; <https://webcore.mskcc.org/breastq/scoring.html>). In the BREAST-Q development sample (n=401), scales had Cronbach's alpha scores between 0.81 and 0.94, item total correlations from 0.55 to 0.82, and test-retest reliability (n=68) with intraclass correlation coefficients between 0.85 and 0.94.

Data Analysis

Descriptive statistics were computed, including the mean, standard deviation, and a 95% confidence interval (CI) for continuous variables, with percentages listed for categorical variables. A primary analysis was performed with a backward-selection linear multivariate regression to identify variables associated with BREAST-Q scores. All variables were converted into dichotomous variables as follows: BMI = 30 vs. BMI <30, age = 40 vs. age <40, bra size = D vs. <D, ethnicity = white non-Hispanic vs. other, education = college degree or higher vs. less than college degree, employment = full-time vs. other than full-time, income = \$40,000 vs. <\$40,000/year, and marital status = married vs. other. Binomial variables with a probability of less than 0.2 were rejected and removed from the model, and the model was rerun with only the significant variables ($p < 0.05$). Data analysis was performed using Stata/SE 11.0 (College Station, Texas).

Once normative data had been generated, a separate analysis compared the normative scores to previously published BREAST-Q data using 95% CIs. Previously published studies were identified by electronic literature search in PubMed (January 2016) using “BREAST-Q” and “BREASTQ” as search terms, and then manually evaluating publications for studies utilizing the augmentation module of the BREAST-Q. Data from each identified study were extracted, including, study design, sample size and BREAST-Q scores. Authors were contacted for additional information as needed. The selected studies were the largest sample size with complete data. From each publication, the sample size and BREAST-Q mean score and standard deviation were used to calculate a 95% CI.

Results

At the time of the e-blast, there were 121,688 members of the AOW. A second e-blast was circulated three months following the first, in order to generate the remaining 409 participants needed to reach the study minimum of 3,600 for all 3 BREAST-Q modules. There were 4,326 women who self-selected to meet study inclusion criteria, with 3,618 women completing the study. In addition, there were 142 not included in the study who attempted to participate after capacity was reached, yet prior to the AOW closing the study. Overall response rate across the study was 87%. Of the respondents, a total of 1,211 women completed the BREAST-Q Augmentation module pre-operative questionnaire.

For the Augmentation sample, the mean age was 54 ± 24 years, mean BMI was 27 ± 6 , and 39% had a bra cup size D or greater ($n=467$). Women were primarily non-Hispanic white (89%) and married (70%). Gross household income was \$100,000 or greater in 45% of participants. A chronic health condition was reported in 43% ($n=521$), with commonly cited conditions as follows: hypothyroidism, diabetes, hypertension, hyperlipidemia, asthma, gastroesophageal reflux disease, inflammatory bowel disease, irritable bowel syndrome, arthritis, psoriasis, and headaches. The remaining demographic data is shown in Table 1.

The normative scores are shown in Table 2. Specific instructions for Sexual Well-being scale states not to complete items if the participant was uncomfortable with the content or felt the items were not applicable. These instructions are consistent with the instructions for the BREAST-Q. A total of 1092 participants completed the sexual well-being scale.

The linear multivariate regression models for the 4 BREAST-Q scales generated between 2 and 4 variables (BMI, bra cup size, age, education, employment status, and the presence of a chronic disease) were associated with the augmentation scale scores. Women with a BMI of 30 or greater, as well as women with a bra cup size of D or greater, had lower BREAST-Q scores when compared to reference groups of those with BMI less than 30 and bra cup size less than D across all 4 augmentation scales. The remaining significant variables using a 95% CI are detailed in Figure 1.

The literature search revealed 8 studies for data comparison. A study published in 2014 by Alderman et al. was selected, as well as data from the Breast Implant Follow-up Study (BIFS) published in 2016, as these were the largest studies utilizing both pre- and post-operative augmentation questionnaires (2, 16). Alderman et al. collected data at three time points, pre-operative, 6 weeks post-operative, and 6 months post-operative. Data from 218 patients from the pre-operative and 6 weeks post-operative time points are used here for comparison. The BIFS authors collected Satisfaction with Breasts and Psychosocial Well-being data at pre-op, 1 year post-op and 4 years post-op for 12,726 patients with silicone implants and 1,788 patients with saline implants.

Figure 2 outlines the comparison between the Alderman et al. data, the BIFS data, and the normative scores. With 95% confidence intervals, for Satisfaction with Breasts, Psychosocial Well-being, and Sexual Well-being, pre-operative scores are lower than normative scores, and post-operative scores are higher than normative scores. Physical Well-being pre-operative scores are higher than the norm, and 6 week post-operative scores are lower than both pre-operative scores and the norm, also with 95% confidence intervals.

Discussion

The utility of PRO questionnaires, and a focus on patient-centered data, evaluating quality of life, well-being, self-esteem and body image, is well established for the breast augmentation population. However, while some studies using ad hoc or generic quality of life questionnaires have demonstrated global differences in these variables for women presenting for breast augmentation in comparison to population controls (17, 18), not all studies have found this to be the case (19). It was instead lower *breast-specific* quality of life and well-being, in the setting of an overall unchanged body image and self-esteem, that has been shown in these women (20). These findings highlight the importance of using a disease-specific PRO questionnaire in order to measure outcomes that matter to this patient population. The BREAST-Q does just this, generating objective, reliable, and valid patient-centered data that is clinically relevant to the breast augmentation patients.

The BREAST-Q Augmentation Module has been used successfully in a number of studies (10). Coriddi et al. evaluated 49 patients prior to surgery and 6 weeks post-surgery, and demonstrated improvements in satisfaction with breasts, and psychosocial, sexual and physical well-being (13). Alderman et al., as discussed earlier, demonstrated improvements in all scales except physical well-being at 6 weeks post-op, with even greater improvements at 6 months post-op in 611 patients (2). McCarthy et al. studied 41 patients at pre- and post-operative time points, demonstrating an improvement in satisfaction, and psychosocial and

sexual well-being, and quantifying the effect size of breast augmentation. The authors reported an effect size of 2.4 for satisfaction with breasts, similar to other common surgical procedures, such as hip arthroplasty, with a reported effect size of 3.1 (12). While these studies have demonstrated the efficacy and added value of breast augmentation surgery to patients, placing the findings into the context of normative data has been missing. The normative scores presented here provide increased clinical context for the interpretation of the data previously published.

Within our study population, there were certain patient and demographic factors associated with differences in generated augmentation scores. Women who were obese and women with larger breast sizes reported lower BREAST-Q scores compared to women who were not obese and women with smaller breasts. As women presenting for augmentation tend to be smaller than the general population in both body and bra cup size (18), it is possible that a “true” normative score for comparison in this population is likely higher than that presented here. Additionally, in the normative sample, younger women reported lower psychosocial well-being scores compared with older women. It is possible that over time without surgical intervention, women may develop increased psychosocial well-being in regards to their breasts.

In applying our findings to previously published studies in the literature, it is apparent that women presenting for augmentation, with the exception of physical well-being, have lower pre-operative scores than the norm. This supports that there may be actual clinical differences in how women seeking augmentation perceive their breasts, justifying the motivations for pursuing surgery. These are not simply women looking to make “normal” better, as some might infer, but are women who perceive themselves to have a significant psychological or emotionally-oriented burden associated with their breasts, that can be addressed by breast augmentation. Furthermore, post-operative scores were significantly higher than the mean, suggesting that breast augmentation not only corrects the perceived deficit experienced by these women, but also results in substantial breast-related quality-of-life gains in comparison to a population control. The exception to these findings was the physical well-being data presented in the Alderman et al. study. Pre-op scores were higher than the mean, and 6 weeks post-op scores were lower than the mean. However, at 6 months post-op, physical well-being scores increased to close to the normative scores, suggesting that additional follow-up time may be needed to fully establish the relationship between breast augmentation and physical well-being.

This is the first study to generate normative data for the BREAST-Q Augmentation Module. Of particular strength is the large sample size, with over 1,200 women. Furthermore, there was diversity in the ages of women completing the questionnaire. Additionally, there was a focus on women with smaller breasts, as over 60% of participants had bra cup sizes of C or less, a similarity to many of the patients presenting for augmentation. Lastly, the normative scores reported here can be easily compared to current and future data generated with the BREAST-Q both by researchers and clinicians.

The primary limitation of this study is reflective of the study population that completed the questionnaire. Women who are part of the AOW are motivated individuals, looking to donate

their time and energy to the promotion of health outcomes research, typically as it relates to breast cancer prevention and treatment. There is a significant lack of racial diversity in the AOW, as less than 15% of participants completing this study were an ethnicity other than non-Hispanic White. Additionally, a high proportion of participants were highly educated and of a higher income status. While these factors are not representative of a random US population, and are thus limitations to our research, they are similar to previously published data on the BREAST-Q (10), large studies utilizing the AOW (21), and are common limitations faced in large clinical trials (22). Additionally, the women in the AOW had a greater age and BMI in comparison to women in the augmentation literature. This is a limitation of our data as both age and BMI impact BREAST-Q Augmentation scores. Furthermore, the normative data presented here is not stratified by geographic location within the US. As rates of augmentation vary across geographic region, it is possible that normative values also vary, thus this is a limitation in our results. We were able to identify a cohort of 125 women of younger age and lower BMI however we hesitate to call this normative data. Nonetheless, their scores do not appear to differ widely from the lateral cohort: Satisfaction with Breasts (mean 55, SD 20), Psychosocial Well-being (mean 65, SD 18), Sexual Well-being (mean 54, SD 16), and Physical Well-being Chest (mean 88, SD 13). Additional limitations relate to the online administration of the questionnaire, as participants self-selected and a practitioner did not verify eligibility criteria. In addition, while the strength of using the AOW sample to conduct research is its speed and low cost of accrual, the population norms were generated primarily on US women and may not be generalizable outside the USA.

In the data collection phase, an algorithm automatically routed interested participants to complete a given pre-operative BREAST-Q module until the module had reached 1200 responses, before automatically routing to the next module. This method of completing the modules in series, as opposed to randomly assigning participants to module completion may explain the slight variances in demographic values and BREAST-Q scores observed between the three separate pre-operative normative datasets.

Limitations can also be attributed to the published study selected for comparison. The Alderman et al. study is the largest study to date using the complete BREAST-Q augmentation module for both pre- and post-operative data collection. However, this is only one study and is likely not representative of all women presenting for and undergoing breast augmentation. Furthermore, this study is limited by the length of follow-up time. However, the BIFS confirmed the findings demonstrated in the Alderman et al. study for Satisfaction with Breasts and Psychosocial Well-being for a larger patient population with a greater follow-up time. The BIFS is limited by the use of a single implant type, and a portion of patients that were lost to follow-up.

The findings presented here have important implications for future clinical care, research, and health policy. A better understanding of what a “normal” score is will help frame BREAST-Q results both on the level of the individual patient and at the population level. In the clinical setting, use of normative data may help a given patient and surgeon together make decisions regarding surgical indications or timing. Lastly in regards to health policy, such as how it relates to implant regulation, there is utility in having normative PRO scores

for comparison and benchmarking purposes. The ability to demonstrate that some women present with satisfaction and well-being significantly below the norm, undergo breast augmentation, a relatively safe procedure with low complication rates, and report satisfaction and well-being significantly above the norm, helps to generate increased understanding of the potential positive QOL impact of this procedure.

Conclusion

Breast augmentation is a common aesthetic plastic surgery procedure, and the BREAST-Q is an important tool that is widely used for the evaluation of these patients. The normative scores presented here are an important contribution to clinical care and research utilizing the BREAST-Q, as there now exists a normative comparison for data interpretation.

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Figure 1. Augmentation BREAST-Q Normative Data with 95% Confidence Intervals
 - Purple line = mean score with 95% confidence intervals in brackets

Figure 2. Breast-Q Augmentation Domains with 95% Confidence Intervals

Table 1**BREAST-Q Augmentation Module Demographics**

	Number	Percentage
Sample Size	1211	
BMI: mean $\pm$ SD	27 $\pm$ 6	
Bra Size		
<A	14	1%
A	112	9%
B	302	25%
C	305	25%
D	223	19%
DD	144	12%
>DD	100	8%
Age in years: mean $\pm$ SD	54 $\pm$ 24	
Ethnic/cultural group		
South Asian or East Indian	0	0.0%
Asian or Pacific Islander	18	2%
Black Non-Hispanic	27	2%
Black Hispanic	3	0.2%
White Non-Hispanic	1067	89%
White Hispanic	47	4%
Native Canadian/American	22	2%
Other	18	2%
Long-term health condition		
Yes	521	43%
Education		
Some High School	0	0.0%
High School Diploma	28	2%
Some College, Trade or University	171	7%
College, Trade or University Diploma	463	39%
Some Master or Doctoral	85	7%
Master or Doctoral Degree	455	38%
Employment		
Full Time	548	46%
Part Time	156	13%
Voluntary Work	24	2%
Homemaker	87	7%
Student	14	1%
Retired	297	25%
Unable to Work or Disabled	22	2%
Unemployed or Seeking Employment	27	2%
Other	27	2%

	Number	Percentage
Annual Gross Household Income		
<\$20,000	35	3%
\$20,000 – \$39,999	84	7%
\$40,000 – \$59,999	153	13%
\$60,000 – \$79,999	189	17%
\$80,000 – \$99,999	170	15%
\$100,000	508	45%
Marital Status		
Married	846	70%
Living with Significant Other	60	5%
Widowed	49	4%
Separated	9	1%
Divorced	115	10%
Single, Never Married	123	10%

SD = standard deviation

Table 2

BREAST-Q Augmentation Module Normative Scores

	N	Mean	SD
Satisfaction with Breasts	1210	54	19
Psychosocial Wellbeing	1208	66	20
Sexual Wellbeing	1092	49	20
Physical Wellbeing Chest	1209	86	15

N = number; SD = standard deviation