ORIGINAL ARTICLE

# Linguistic Validation and Psychometric Testing of the Filipino Version of the Breast-Q Reconstruction Module

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## ABSTRACT

**Background.** The introduction of new therapeutic options and advances in the field of breast surgery has put the importance of patient satisfaction and quality of life at par with long-term survival. These essential parameters help physicians and patients decide on the appropriate approach when managing both malignant and benign breast conditions. They have also been used to measure the outcome and success of breast surgery, whether cosmetic or reconstructive, using patients' perspectives. To date, there is no available questionnaire that is translated, culturally adapted, and validated among Filipino patients to specifically assess their quality of life (QOL) and satisfaction after breast reconstructive surgery.

**Objective.** This study aims to translate a previously validated, internationally accepted, patient-reported outcome (PRO) instrument, the Breast-Q Reconstruction Module, and validate its use among Filipino patients.

**Methods.** This is a tool validation study of a Filipino translation of the Breast-Q Reconstruction Module for the preoperative and postoperative settings. Forward and backward translations were done for the two questionnaires and were finalized after assessment of accuracy and feasibility by language professionals and bilingual patients. We recruited patients referred to the Division of Plastic Surgery of a tertiary government hospital for breast reconstruction to answer the final questionnaires, with 15 re-taking each questionnaire after two weeks. Psychometric properties of the questionnaires, including internal consistency, construct validity, test-retest reliability, and acceptability, were then evaluated.

**Results.** We included 30 patients in this validation study. The internal consistencies of the translated Preoperative and Postoperative Breast-Q Reconstruction Module had high Cronbach's $\alpha$ coefficients (range: 0.92–0.98 and 0.97–1.00, respectively). Internal consistency was also supported by high mean item-total correlations in all dimensions. The two questionnaires had good test-retest reliability as supported by high intraclass correlation (range for Preoperative: 0.995–1.000 and for Postoperative: 0.95–1.00). Construct validity was supported by inter-scale correlations with low to moderate Spearman's coefficients (range for Preoperative: 0.22–0.34 and for Postoperative: 0.11–0.27). The sexual well-being dimension had the lowest inter-scale Spearman's coefficient in both questionnaires and is the only dimension with low acceptability.

**Conclusion.** The translated Preoperative and Postoperative Breast-Q Reconstruction Module has high internal consistency, test-retest reliability, acceptability, and low to moderate construct validity among Filipino patients after breast reconstruction surgery. However, the "Satisfaction with the Nipple Reconstruction" subscale is pending since there were no qualified respondents in the sample population. In considering how their relatively conservative culture influences the way Filipino patients tend to view the importance of sexual satisfaction as it relates to their medical management, the sexual well-being domain is suggested to be interpreted separately when assessing the patient's overall satisfaction with breast reconstruction procedure.

*Keywords: Mammaplasty, patient-reported outcome measures, health-related quality of life*

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## INTRODUCTION

With the introduction of new therapeutic options and advances in breast surgery, there is now a growing emphasis on patients' involvement in their surgical decision-making. Patient satisfaction and health-related quality of life (QOL) have become important tools in assessing the results and success of breast surgery, whether cosmetic or reconstructive.[1-4] In plastic surgery, these patient-centered outcomes are significant as it is the aim of the majority of the operative interventions to improve appearance, function, and quality of life.[5] But to accurately measure these outcome variables from the patient's perspective, the use of high-quality patient-reported outcome instruments or questionnaires is recommended.[2-4]

The Breast-Q™ is a well-validated patient-reported outcome (PRO) instrument developed by its authors at the Memorial Sloan Kettering Cancer Center, now translated and validated into at least thirty languages, which specifically evaluates the impact of cosmetic and reconstructive breast surgeries.[5] Currently, there are three main modules depending on the type of surgery: cancer, reduction or mastopexy, and augmentation, with the cancer module being further subdivided into reconstruction, mastectomy, and breast conservation surgery. Its framework is different from other known PRO instruments as it broadly covers health-related QOL outcomes under three domains of physical, psycho-social, and sexual well-being, as well as patient satisfaction under three domains of satisfaction with the breast, outcome, and care (which includes satisfaction with the information and care provided by the surgeon, medical team, and office staff).[6-8]

Since its inception in 2006, the Breast-Q™ has become widely used in clinical practice and research. The Breast-Q Reconstruction module, for instance, has been cited in at least 39 publications worldwide.[5] Unfortunately, to date there is no questionnaire that is translated, culturally adapted and validated for Filipino patients to specifically measure these new outcome parameters after breast surgery. To ensure a consistent standard of service, a PRO instrument developed in an internationally recognized manner is fundamental as this can further be utilized to better understand and provide an evidence-based, patient-centered surgical practice.

## METHODS

Approval from the Memorial Sloan Kettering Cancer Center and the Mapi Research Institute, who hold the copyright for the Breast-Q™ Reconstruction Module, was sought before the initiation of the study. Translation and linguistic validation procedures and recommendations by the said institution were followed. The protocol developed was reviewed and subsequently approved by the University of the Philippines Manila Research Ethics Board.

### Translation Methodology

The Breast Q Reconstruction module has been validated for use by any patient undergoing breast reconstruction, regardless of the timing (whether immediate or delayed) and manner (using implants or autologous tissue) of the procedure. Except for some scales in the Postoperative Module [specifically: item 2 for those who had implant reconstruction; items 7, 8, and 9 for those who underwent transverse rectus myocutaneous (TRAM) or deep inferior epigastric artery perforator (DIEP) flap reconstruction; and item 10 for those who had also completed nipple reconstruction], short qualifying phrases added to the main stem of the questions allows their use by any patient for breast reconstruction.

To ensure that the psychometric properties established in the original work were not altered or invalidated, the syntax and format of the original questionnaire were maintained, while also strictly following the procedures and recommendations for translation and linguistic validation provided in the original work.[8]

### Questionnaire Forward and Backward Translation

Two forward translations of the original English version of the Breast-Q Reconstruction module (both Pre- and Post-operative) into Filipino (Versions 1 and 2) were made by one of the investigators and by a professional translator from the *Sentro ng Wikang Filipino-Manila,* who were both fluent in Filipino and English languages. The two translated questionnaires were then consolidated into one questionnaire by a team composed of the investigators and another professional translator from the *Surian ng Wikang Pambansa* (Version 3).

The newly formed Filipino questionnaire (Version 3) was again translated into English (the backward translation) by another professional translator who was not involved in the initial translation process and who had no access to the original English version of the Breast-Q Reconstruction module.

The investigators compared the backward translation to the original version and after scrutiny made the necessary modifications for misinterpretations and inaccuracies. The translation (Version 3) and the back-translation were then sent to the Mapi Research Institute for review and approval.

### Translated Questionnaire Pre-Testing

After receiving the approval, the translated Filipino version of the questionnaire (Version 3) was administered to five (5) bilingual patients who had no prior knowledge of the questionnaires, and who had signed the informed consent before the initiation of the study.

A short, structured interview was done after each patient completed answering the questionnaires. Questions included (1) difficulty in understanding the questions, (2) difficulty in understanding the choices, and (3) suggested ways to improve the questionnaire. Information elicited from the

structured interviews was used to revise and formulate the final translated questionnaire (Version 4).

### Translated Questionnaire Validation

#### *Patient Selection and Sample Size*

The final translated Filipino version of the Preoperative and Postoperative questionnaires were administered to patients referred to the Division of Plastic Surgery from the Breast Care Center of a tertiary government hospital, aged at least 19 years old and older, and who underwent breast reconstruction between January 2015 to June 2018. Informed consent was sought before their inclusion, and those who were illiterate or mentally incapacitated were excluded from the study. A sample size of 30 respondents was set for the preliminary test of the translated questionnaire, as recommended in "Sample Size for Pre-test of Questionnaires" by Perneger et al.[9] Convenience sampling was employed, with all patients who satisfied the inclusion criteria and consented to participate during the identified study period being subsequently asked to answer the questionnaire.

#### *Mode of Administration*

The Breast-Q Module is designed to be a self-administered questionnaire, with brief written instructions provided to the respondents at the beginning of each scale. For respondents who requested clarifications as they answered the questions, the researcher present adhered to the guidelines set in the Breast Q module and did so only by rereading each question verbatim and encouraging the respondents to use their interpretation or understanding of it.[8] This was with the exception of medical terminologies, however, which do not have a direct translation in the Filipino language and for which the researcher only gave a technical definition or explanation of when requested.

#### *Timing of Administration and Re-Testing*

As intended by the original authors, the Preoperative and Postoperative questionnaires may be completed at any time before and after the surgery, depending on the set objectives of the researchers.[8] For this study, patients who met the inclusion criteria after the initial screening procedure and who agreed to take part in the study were then asked to answer the Preoperative Module during their next scheduled follow-up. For the Postoperative Module, the questionnaires were administered during the patients' scheduled follow-up after the removal of all the operative sutures and drains. This was to allow the patients to better visualize and evaluate the outcome of their surgery without the presence of any residual materials used in the conduct of the surgery. The first 15 respondents for each group (and who had not yet undergone surgery in the preoperative patients) were then asked to re-take the same questionnaire after two weeks.

### Data Interpretation and Analysis

Each domain of the Breast-Q Module is subdivided into multiple scales which have been formulated to function independently and do not have a computed overall Breast Q score. As such, researchers may include only pertinent scales and may not require respondents to complete the entire module, depending on the study's objectives. While there is no total for the entire module, a higher score in each of the Breast-Q scales is reflective of greater patient satisfaction or better quality of life.[8] Data collated were encoded in Microsoft Office Excel 2013. Acceptability, reliability, and validity were calculated statistically from the data obtained using IBM SPSS Version 25.

To evaluate the acceptability, score distribution and missing rates were examined. Test-retest reliability, which verifies the stability and reproducibility of the measurement, was assessed by the intraclass correlation coefficient (ICC). Internal consistency, the extent to which items comprising these subscale measures the same concept, was assessed by Cronbach's alpha coefficients (>0.70) and item-total correlation (>0.3). To demonstrate construct validity (i.e., the evidence that the instrument measures what it purports to measure), the Inter-scale Spearman's coefficient was utilized.

## RESULTS

### Questionnaire Translation

For the translated Breast-Q Reconstruction module, two sections as drawn in the original English version were maintained: (1) a Preoperative Section containing 6 questions and 42 items, and (2) a Postoperative Section having 14 questions and 116 items. The format of the instructions, questions, and response options were made consistent with the original in both modules, and the tenses and verbs were used uniformly. All the logos, underlines, question marks, and bold types were also retained. The number of resulting pages increased, however, due to the differences in the formatting and construction of the Filipino language: some of the English terms when translated to the Filipino language either needed more or lengthier words to be explained clearly. Some English terms were maintained as their direct translations to the Filipino language were considered unacceptable.

### Questionnaire Pilot Testing

The translated Filipino questionnaires (Version 3) were administered to five patients referred from the Breast Care Center of a tertiary government hospital who were diagnosed with either benign or malignant breast pathologies. All the patients included were bilingual, being able to understand both the spoken and written English and Filipino languages. The mean time of completion of the Preoperative and Postoperative Modules were 7.1 minutes and 12.3 minutes, respectively (Table 1).

Following the administration of the questionnaire, a short, structured interview was conducted to elicit the

**Table 1.** Pilot patient testing

| Module | N | Mean Age (Range) | Number of Items | Time to Completion (min), Mean (Range) |
|---|---|---|---|---|
| ***Pre-operative*** | 5 | 37.6 (21-62) | 42 | 7.1 (6.2-8.4) |
| ***Post-operative*** | 5 | 37.6 (21-62) | 116 | 12.3 (11.8-13.3) |

issues encountered by the patients in understanding some of the words and phrases that were used, and from which adjustments were made to formulate the final version of the questionnaire. The issues identified in the Preoperative and the Postoperative Sections have been detailed in Tables 2 and 3, respectively. The title "Reconstruction Module" was chosen instead of *"Modyul sa Reconstruction"* as it appeared to be more acceptable. The respondents found the response options to be clear and straightforward. The need to spell out and define some of the terminologies was also identified.

## Questionnaire Validation and Psychometric Testing

A total of 30 patients were included in this study. The demographic characteristics of the respondents and the types of breast reconstruction used for the respondents are presented in Tables 4 and 5, respectively. The mean time for administration of the Preoperative Module was 8.9 days (range, 2 to 29) before the scheduled surgery. For the Post-operative Module, the mean time for administration was 12.03 days (range, 10 to 18) after the reconstructive procedure.

### *Acceptability*

Missing data (or no response from the subjects) was low for the Preoperative Breast-Q_Reconstruction Module, with subjects providing an answer for all questions except for the sexual well-being domain. There were 8 (26.7%) subjects who did not provide an answer to two of the questions (*"Komportable habang nakikipagtalik?"* and *"Nasisiyahan sa*

**Table 2.** Comments and Recommendations of the Respondents on the Initial Version of the Breast-Q™ Reconstruction Module (Preoperative) Filipino Questionnaire

| | |
|---|---|
| ***Difficulty in understanding the words and phrases used in the questions*** | • Question 3i: "*Paghihigpit sa bahagi ng suso*" (tightness in your bra area) was changed to "*Pakiramdam na may masikip sa bahagi ng suso.*"<br>• Question 3k: "*Patuloy na pangit na pakiramdam sa bahagi ng suso*" (Nagging feeling in your breast area?) was found to be vague but this was considered to be the nearest translation in the Filipino language, hence, was maintained.<br>• Question 6e: "*May tiwala sa kakayahang pangseksuwal sa hitsura ng iyong suso kung nakahubad?*" (Confident sexually about how your breast(s) look when unclothed? was considered to be verbose and was changed to *"Komportable sa hitsura ng suso kung nakahubad?"* while still maintaining its conceptual equivalence.<br>• Question 6f: In the question *"Kaakit-akit na seksuwal kung nakahubad?"* (Sexually attractive when unclothed?), the term "seksuwal" was considered contextually unnecessary and thus deleted, revising the question to "Kaakit-akit kung nakahubad?" |
| ***Difficulty in understanding the choices*** | None |
| ***How to improve the questionnaire*** | • Plastic surgery terminologies should be well defined.<br>• The questions regarding sexuality should be phrased in a less offensive manner.<br>• The font size of the response choices and the spaces in-between should be increased. |

**Table 3.** Comments and Recommendations of the Respondents on the Initial Version of the Breast-Q™ Reconstruction Module (Postoperative) Filipino Questionnaire

| | |
|---|---|
| ***Difficulty in understanding the words and phrases used in the questions*** | • Question 1b: The word *"niretoke"* was viewed with some negative connotations, hence, the question was changed to *"Hugis ng iyong inayos na suso kapag ikaw ay may suot na bra?"*<br>• Question 1n: The word *"magkapantay"* was changed to *"kalapit,"* which was considered to capture the original concept of the question, thus, it was changed to *"Kung gaano kalapit ang iyong mga suso sa isa't isa?"*<br>• Question 3e: *"Ang pagsasailalim sa ganitong operasyon ay nagpabago sa aking buhay nang higit na maganda"* (Having this surgery changed my life for the better) was considered verbose, hence, changed to *"Nakabuti sa aking buhay ang pagpapaopera."*<br>• Question 8c: The word *"pilat"* was not a common translation of the word "scar", thus, the question was changed to *"Itsura ng peklat sa tiyan."*<br>• Question 10b: The word "areola" did not have a direct Filipino translation thus a brief definition was placed (enclosed in parenthesis).<br>• Question 10e: To better elaborate the question, the word "projection" was still maintained enclosed in parenthesis beside the word *"pagkausli."* |
| ***Difficulty in understanding the choices*** | None |
| ***How to improve the questionnaire*** | • Plastic surgery terminologies should be well defined.<br>• The questions regarding sexuality should be phrased in a less direct or offensive manner.<br>• The usage of words with minimal sexual connotation.<br>• The font size of the response choices and the spaces in-between should be increased.<br>• The module should be shortened. |

**Table 4.** Patient demographic characteristics

| Characteristics | N (30) | % |
|---|---|---|
| ***Age at participation*** | | |
| Mean (range) | 42.8 (25-57) | |
| ***Age group*** | | |
| 19-30 | 2 | 6.7 |
| 30-40 | 8 | 26.6 |
| 40-50 | 13 | 43.4 |
| >50 | 7 | 23.3 |
| ***Marital status*** | | |
| Single | 4 | 13.3 |
| Married | 24 | 80.0 |
| Widowed | 2 | 6.4 |
| ***Education*** | | |
| High school or less | 5 | 16.7 |
| College education | 25 | 83.3 |
| ***Employment status*** | | |
| Not working | 16 | 53.3 |
| Working | 14 | 46.7 |
| ***Pathology*** | | |
| Benign | 11 | 36.7 |
| Malignant | 19 | 63.3 |
| ***Laterality of mastectomy*** | | |
| Unilateral | 28 | 93.3 |
| Bilateral | 2 | 6.7 |

**Table 5.** Types of breast reconstruction involved

| Type of Breast Reconstruction | Number of Patients |
|---|---|
| ***Timing of Reconstruction*** | |
| Immediate | 30 |
| Delayed | 0 |
| ***Technique of Reconstruction*** | |
| Autologous | 15 |
| TRAM Flap | (14) |
| Latissimus Dorsi | (1) |
| Implant | 14 |
| Combined | 1 |
| Latissimus Dorsi + Implant | (1) |
| ***Total*** | 30 |

*pakikipagtalik?"*), reflective of low acceptability of the questions to them. (Table 6A.)

As seen in Table 6B, missing data was also low for the translated Postoperative Breast-Q Reconstruction Module and was noted only in the 'sexual well-being' domain. The response rate for the questions *"Komportable habang nakikipagtalik?"* (7 no response, 23.3%), and *"Nasisiyahan sa pakikipagtalik?"* (7 no response, 23.3%) were again reflective of low acceptability of these questions. In addition, there was 1 respondent who gave no answer to the question *"Kaakit-akit sa pananamit?"* (3.3%).

None of the respondents provided answers in the 'satisfaction with nipple' domain as all of the patients included had not yet undergone nipple reconstruction at the time of questionnaire administration. In addition, there were only 15 expected respondents for Item 2 (to be answered by those who underwent implant reconstruction), and 14 respondents for Items 7 to 9 (to be answered by those who underwent TRAM or DIEP reconstruction), but all of whom provided answers to the respective questions. One patient did not answer Items 2, 7, 8 and 9 because she had only undergone a latissimus dorsi flap reconstruction.

### *Test-Retest Reliability*

The data extracted from 15 patients who were asked to re-take the questionnaires after two weeks were used to evaluate test-retest reliability. The translated Preoperative Breast-Q Reconstruction Module had moderate to high test-retest reliability as supported by high intraclass correlation coefficient (range: 0.995-1.000) (Table 7A). The dimension 'psychosocial wellbeing' had the lowest intraclass correlation coefficient (0.995).

The translated Postoperative Breast-Q Reconstruction module had moderate to high test-retest reliability as supported by high intraclass correlation coefficient (range: 0.954-1.000) (Table 7B). The dimension "Satisfaction with medical team" had the lowest intraclass correlation coefficient (0.954).

**Table 6A.** Item frequency distribution and missing data (%), Preoperative Module

| Domain | Item and Sub-questions | Number of Sub-questions | Expected Number of Responses (n) | Actual Number of Responses (n) | Missing Data (%) |
|---|---|---|---|---|---|
| Satisfaction with breast | 1 (a–d) | 4 | 30 | 30 | 0 |
| Psychosocial well-being | 2 (a–j) | 10 | 30 | 30 | 0 |
| Physical well-being | 3 (a–p) | 16 | 30 | 30 | 0 |
| Physical well-being (abdomen) | 4 (a–e) | 5 | 30 | 30 | 0 |
| Satisfaction with abdomen | 5 (a) | 1 | 30 | 30 | 0 |
| Sexual well-being | 6 | 6 | | | |
| | (a) | | 30 | 30 | 0 |
| | (b) | | 30 | 22 | 26.7 |
| | (c) | | 30 | 30 | 0 |
| | (d) | | 30 | 22 | 26.7 |
| | (e) | | 30 | 30 | 0 |
| | (f) | | 30 | 30 | 0 |

**Table 6B.** Item frequency distribution and missing data (%), Postoperative Module

| Domain | Item and Sub-questions | Number of Sub-questions | Expected Number of Responses (n) | Actual Number of Responses (n) | Missing Data (%) |
|---|---|---|---|---|---|
| Satisfaction with breast | 1 (a–p) | 16 | 30 | 30 | 0 |
| | 2 (a–b) [a] | 2 | 15 | 15 | 0 |
| Satisfaction with outcome | 3 (a–g) | 7 | 30 | 30 | 0 |
| Psychosocial well-being | 4 (a–j) | 10 | 30 | 30 | 0 |
| Sexual well-being | 5 | 5 | | | |
| | (a) | | 30 | 29 | 3.3 |
| | (b) | | 30 | 23 | 23.3 |
| | (c) | | 30 | 30 | 0 |
| | (d) | | 30 | 23 | 23.3 |
| | (e) | | 30 | 30 | 0 |
| | (f) | | 30 | 30 | 0 |
| Physical well-being | 6 (a–p) | 16 | 30 | 30 | 0 |
| Physical well-being (abdomen) | 7 (a–h) [b] | 8 | 14 | 14 | 0 |
| Satisfaction with abdomen | 8 (a–c) [b] | 3 | 14 | 14 | 0 |
| | 9 (a–b) [b] | 2 | 14 | | |
| Satisfaction with nipple | 10 (a–e) [c] | 5 | 0 | - | - |
| Satisfaction with information | 11 (a–o) | 15 | 30 | 30 | 0 |
| Satisfaction with surgeon | 12 (a–k) | 11 | 30 | 30 | 0 |
| Satisfaction with medical team | 13 (a–g) | 7 | 30 | 30 | 0 |
| Satisfaction with office staff | 14 (a–g) | 7 | 30 | 30 | 0 |

[a] *To be answered only by those who underwent implant reconstruction*
[b] *To be answered only by those who underwent TRAM or DIEP reconstruction*
[c] *To be answered only by those who underwent nipple reconstruction*

**Table 7A.** Test–retest reliability (Preoperative)

| Subscale | 1st administration (N=30) | | 2nd administration (N=15) | | ICC | p-value |
|---|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | | |
| 1. Satisfaction with breast | 15.33 | 0.84 | 15.07 | 0.80 | 1.000 | n.s. (1.00000000) |
| 2. Psychosocial well-being | 47.40 | 2.16 | 47.87 | 1.81 | 0.995 | n.s. (0.99998945) |
| 3. Physical well-being | 75.97 | 5.29 | 75.73 | 5.34 | 1.000 | n.s. (1.00000000) |
| 4-5. Physical well-being (abdomen) and Satisfaction with abdomen | 28.13 | 0.82 | 27.93 | 0.80 | 1.000 | n.s. (1.00000000) |
| 6. Sexual well-being | 23.83 | 5.00 | 23.27 | 4.65 | 0.996 | n.s. (0.99999325) |

*n.s. = p-value>0.05, high reliability*

### *Internal consistency*

The internal consistency of the translated Preoperative Breast-Q Reconstruction Module was supported by high Cronbach's α coefficients (range: 0.92–0.98) (Table 8A). The 'satisfaction with breast' dimension had the lowest Cronbach's α coefficient (0.92), while the 'physical well-being' dimension had the highest Cronbach's α coefficient (0.98). The internal consistency was also supported by high mean item-total correlations in all dimensions of the translated questionnaire. The 'physical well-being' dimension had the lowest mean item-total correlation (0.88, with range of 0.80–0.96) while the dimension 'sexual well-being dimension had the highest value (0.92, range 0.89–0.95).

The internal consistency of the translated Postoperative Breast-Q Reconstruction Module was supported by high Cronbach's α coefficients (range: 0.965-1.000) (Table 8B). The domain "Sexual well-being" had the lowest Cronbach's α coefficient (0.965) while the "Satisfaction with outcome" had the highest Cronbach's α coefficient (1.000). The internal consistency was also supported by high mean item-total correlations in all dimensions of the translated questionnaire. The "Physical well-being" scale had the lowest mean item-total correlation (0.903, with range of 0.777-0.979) while the "Satisfaction with outcome" and "Satisfaction with abdomen" had the highest values (1.000, with range of 1.000-1.000).

### *Construct validity*

The construct validity of the translated Preoperative Breast-Q Reconstruction Module was supported by inter-scale correlations with moderate Spearman's coefficients (range: 0.217-0.339) (Table 8A). The domain "sexual well-being" had the lowest inter-scale Spearman's coefficient

**Table 7B.** Test–Retest reliability (Postoperative)

| Subscale | 1st administration (N=30) | | 2nd administration (N=15) | | ICC | p-value |
|---|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | | |
| 1-2. Satisfaction with breast | 65.73 | 5.65 | 65.47 | 3.94 | 0.997 | 0.999 |
| 3. Satisfaction with outcome | 21.00 | 0.00 | 21.00 | 0.00 | 1.000 | 1.000 |
| 4. Psychosocial well-being | 48.97 | 1.61 | 49.07 | 0.96 | 1.000 | 1.000 |
| 5. Sexual well-being | 25.47 | 4.01 | 25.13 | 4.03 | 1.000 | 1.000 |
| 6. Physical well-being | 77.53 | 2.33 | 77.27 | 2.87 | 1.000 | 1.000 |
| 7. Physical well-being (abdomen) | 6.43 | 14.65 | 12.87 | 18.87 | 1.000 | 1.000 |
| 8-9. Satisfaction with abdomen | 2.67 | 6.06 | 4.67 | 6.83 | 0.972 | 0.999 |
| 10. Satisfaction with nipple | N/A | N/A | N/A | N/A | N/A | N/A |
| 11. Satisfaction with information | 59.23 | 2.01 | 59.80 | 0.56 | 1.000 | 1.000 |
| 12. Satisfaction with surgeon | 47.80 | 0.55 | 47.93 | 0.26 | 1.000 | 1.000 |
| 13. Satisfaction with medical team | 24.60 | 2.36 | 24.93 | 1.67 | 0.954 | 0.999 |
| 14. Satisfaction with office staff | 24.63 | 1.99 | 25.40 | 1.68 | 0.967 | 0.999 |

*n.s. = p-value>0.05*

**Table 8A.** Internal Consistency and Construct Validity (Preoperative Module)

| Subscale | Number of Items | Internal consistency: Cronbach's α coefficient | Internal consistency: Item-total correlations | | Construct validity: Inter-scale Spearman's coefficient | |
|---|---|---|---|---|---|---|
| | | | Mean | Range | Mean | Range |
| 1. Satisfaction with breast | 4 | 0.916 | 0.898 | (0.841-0.940) | 0.339 | (0.034-0.245) |
| 2. Psychosocial well-being | 10 | 0.974 | 0.900 | (0.830-0.959) | 0.259 | (0.027-0.386 |
| 3. Physical well-being | 16 | 0.980 | 0.883 | (0.797-0.959) | 0.225 | (0.027-0.418) |
| 4-5. Physical well-being (abdomen) and Satisfaction with abdomen | 6 | 0.962 | 0.916 | (0.756-0.980) | 0.301 | (0.179-0.418) |
| 6. Sexual well-being | 6 | 0.965 | 0.924 | (0.885-0.947) | 0.217 | (0.034-0.386) |

**Table 8B.** Internal Consistency and Construct Validity (Postoperative Module)

| Subscale | Number of Items | Internal consistency: Cronbach's α coefficient | Internal consistency: Item-total correlations | | Construct validity: Inter-scale Spearman's coefficient | |
|---|---|---|---|---|---|---|
| | | | Mean | Range | Mean | Range |
| 1-2. Satisfaction with breast | 18 | 0.996 | 0.974 | (0.944-0.989) | 0.244 | (0.023-0.757) |
| 3. Satisfaction with outcome | 7 | 1.000 | 1.000 | (1.000-1.000) | N/A* | N/A* |
| 4. Psychosocial well-being | 10 | 0.989 | 0.956 | (0.863-0.990) | 0.214 | (0.057-0.757) |
| 5. Sexual well-being | 6 | 0.965 | 0.922 | (0.893-0.958) | 0.108 | (0.082-0.195) |
| 6. Physical well-being | 16 | 0.983 | 0.903 | (0.777-0.979) | 0.160 | (0.048-0.441) |
| 7. Physical well-being (abdomen) | 8 | 0.993 | 0.978 | (0.963-0.992) | N/A† | N/A† |
| 8-9. Satisfaction with abdomen | 5 | 0.992 | 1.000 | (1.000-1.000) | N/A† | N/A† |
| 10. Satisfaction with nipple | 5 | N/A | N/A | N/A | N/A† | N/A† |
| 11. Satisfaction with information | 15 | 0.993 | 0.957 | (0.915-0.979) | 0.140 | (0.024-0.294) |
| 12. Satisfaction with surgeon | 12 | 0.996 | 0.979 | (0.901-0.996) | 0.124 | (0.023-0.349) |
| 13. Satisfaction with medical team | 7 | 0.946 | 0.869 | (0.812-0.913) | 0.265 | (0.107-0.551) |
| 14. Satisfaction with office staff | 7 | 0.929 | 0.837 | (0.748-0.859) | 0.249 | (0.066-0.551) |

** Spearman's coefficient cannot be computed since all have the same response.*
*† Spearman's coefficient cannot be computed since there are lot of "not applicable" responses.*

(0.217, with range: 0.034-0.386) while the "satisfaction with breast" had the highest value (0.339, with range: 0.034-0.245).

The construct validity of the translated Postoperative Breast-Q Reconstruction Module was supported by inter-scale correlations with low to moderate Spearman's coefficients (range: 0.108-0.265) (Table 8B). The domain "sexual well-being" had the lowest inter-scale Spearman's coefficient (0.108) while the "satisfaction with the medical team" had the highest value (0.265).

## DISCUSSION

In acknowledging the increasing role that patients play in their own management, the development of validated patient-reported outcome (PRO) measurement tools that allow them to better assess the quality of care that they receive has become more important. This is particularly true for reconstructive procedures in which the main objective of treatment remains the restoration of form and function in varying degrees, factors which play a direct role in a patient's daily functioning and thereby affecting how they perceive the success of a procedure.

This study involved the development of a Filipino version of the Breast-Q Reconstruction Module, which is an internationally validated and accepted PRO instrument designed to be administered before and after the reconstructive procedure. The translation process used is based on the internationally recognized methodology which has been designed to maintain the linguistic and conceptual equivalence even after the language change. The questionnaire is divided into the Preoperative and Postoperative sections, with the Postoperative section containing all the items specified in the Preoperative section in addition to questions that address unique postoperative issues such as scarring.

The Preoperative and Postoperative scales are linked psychometrically to measure changes.[8] For this preliminary study, the psychometric properties that were tested included the following: acceptability (reflected through the regularity in which the patient population responded to the translated questions, as questionnaires are only effective if study subjects consistently provide answers), internal consistency (pertaining to its reliability in measuring the dimensions of patients' perception regarding breast reconstruction), test-retest reliability (describing whether the questionnaire is considered stable and can consistently produce the same measurement outcome in patients' perceptions regarding their breast reconstruction), and construct validity (which means that the dimensions are correlated with each other and fit modestly in the tool).[10-11] Based on the study population, high internal consistency and test-retest reliability, and acceptable construct validity were demonstrated. These results are comparable with the findings in previous studies which reported good psychometric properties for the Breast-Q subscales (Test–retest reliability 0.73–0.96, Cronbach's alpha 0.81–0.96).[12]

Subject responses in both the Preoperative and Postoperative translated questionnaires were found to reflect a high satisfaction with the reconstructive procedures, except for the domain involving "Sexual Well-being" where the patients were found to have only moderate satisfaction. This domain was additionally found to have the lowest Inter-scale Spearman's coefficient, while also being the only parameter to demonstrate low to moderate acceptability in the translated questions. Ideally, all domains should have high inter-scale Spearman's coefficient values to show a good correlation between them.[10-11]

Varying perceptions of sexuality as influenced by cultural norms must be taken into account when considering this aspect, however. As reported in the literature, Asian women are more likely to have suppressive sexual attitudes and tend to endorse beliefs of sexual behavior being more oriented towards reproduction.[13-14] Filipino women may attribute a lower premium on "sexual well-being," and thereby credit their satisfaction with the reconstructive outcome less than their Western counterparts would. The impact of culture on a patient's willingness to discuss sexual issues has also been recognized, with a number of studies ascribing this hesitation among Asian respondents to their relatively conservative values which consider these as private concerns such that any discussion about the topic is deemed uncomfortable or even embarrassing.[15-18]

This was similarly observed in the study by Saiga et al. in the validation of the Japanese translation of the Breast Q Module, where a floor effect on the response rates was noted (with most of the participants choosing a score of 1 or "Not applicable" as their responses), and high missing rates were also generated from Items 4b and 4d of the sexual satisfaction domain. While studies using the Breast Q among Asian populations remain limited, the lower scores were deemed consistent with previous findings, and the consideration that Western conceptualized measures are not adequate to assess the sexual well-being in Asian women was made. Nonetheless, with one of the main goals of the Japanese translation being the establishment of a universal standard instrument in the form of the Breast Q Module, the study asserted that the sexual subscale should not be excluded and would perhaps be more relevant in studies involving younger subjects who are within the reproductive age and thereby more aligned with the purported Asian concept of sexual well-being.[4,13-14]

While cultural nuances may limit the perceived effects of breast reconstruction on a patient's sexual relations, studies have consistently shown that breast cancer survivors may experience varying degrees of sexual dysfunction due to the cancer treatment and the psychosocial effects of the disease, and the inherent contribution of breast reconstruction to sexual well-being is recognized.[19-24] As such, this subscale must still be considered as an important domain to better understand how Filipino patients will ultimately be affected by surgeries. For purposes of evaluating the overall satisfaction and quality of life of patients following breast

reconstruction, however, and in consideration of how culture may influence this domain, the suggestion to interpret it in the proper context and perhaps even separately from the other parameters is likewise made.

With the acknowledged value of patient-reported outcomes, the success of any thrust to develop PRO instruments must necessarily take its ease of use into consideration, and any factor that can lead to respondent burden and the resultant poor compliance is an important aspect to take into account.[25] This Filipino translation of the questionnaire is composed of 13 pages (compared with 12 pages in the original English version) containing many items, which led to average time for completion at about 15 minutes. This makes it potentially cumbersome and may influence respondents' answers to the module as a whole. One option that may be considered (and which has also been previously suggested in other studies) is for investigators to include only subscales deemed relevant to their main objectives, as each subscale is designed to function independently. In addition to reducing the respondents' burden, this may also serve to minimize their discomfort at being made to answer questions which they may deem too probing as what appeared to be the case with the "sexual well-being" domain, and thereby preserve their privacy for the duration of the study.[4,26]

Another notable limitation encountered during the development of the translated questionnaire was the unavoidable use of medical terminologies that have no direct translation in the Filipino language (including the terms mastectomy, implant, and TRAM or DIEP flap). To circumvent this issue, a member of the investigating team made themselves available to the respondents to define the terms and to answer queries, as necessary. This need to guide the respondents through unfamiliar terminology may also reflect inadequacies during the preoperative counselling, as the terms should have been brought up and sufficiently discussed at this time. To remedy this, and to improve the questionnaire's use as a self-administered PRO tool, a more thorough explanation of the technical aspects of the procedure in the initial consultation is emphasized and must be ensured by the surgical team involved.

Despite the issues identified and the current limitations in this preliminary study, the Filipino translation of the Breast-Q Reconstruction Module as a patient-reported outcome instrument will be an invaluable tool as strides continue to be made in the field of breast surgery in the country. Breast reconstruction is a vital component of breast cancer treatment and is supported by numerous studies that show an overall improvement in the outcome that is associated with a high degree of patient satisfaction, while being conferred with long-term psychosocial benefits. And as with any procedure in which the ultimate goal is to help improve a patient's quality of life, it is essential that they be involved as early as possible in the preoperative planning period, as their perceptions may offer potentially valuable insights into the effectiveness of the surgical intervention.[27-29]

This as much is true for Filipino patients with breast cancer, who are increasingly being given access to all the available options that could potentially improve the overall results following treatment, financial capabilities notwithstanding. Through a translated and properly validated questionnaire, surgeons may be better able to assess the outcome of their reconstruction in the proper cultural context. In addition, this will also provide greater inclusivity for Filipino patients to actively take part in evaluating the operative results based on their health-related quality of life and other patient-relevant feedback.

## CONCLUSION

A validated Breast-Q Reconstruction Module in the Filipino language can be used to better evaluate the satisfaction and health-related QOL following breast reconstructive surgery in the local setting. Preliminary psychometric testing of this translation showed high internal consistency, high test-retest reliability, high acceptability, and low to moderate construct validity, supporting its use as a PRO measurement tool. Further studies will need to fully validate these results, however, and these will need to encompass a larger sample size of respondents while also including those who have undergone nipple reconstruction. The initial results also suggest that for purposes of evaluating the patient's overall satisfaction with the reconstructive procedure, it may be better to interpret the "sexual well-being" subscale separately because of the influence that culture may play in this regard, and this is an aspect that must be explored more thoroughly before more definitive conclusions can be made.

### Statement of Authorship

All authors contributed in the conceptualization of work, acquisition and analysis of data, drafting and revising, and approved the final version submitted.

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