Danish translation and linguistic validation of the BREAST-Q

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ABSTRACT

INTRODUCTION: The primary purpose of reconstructive and cosmetic breast surgery is to improve patients' quality of life, and patient-reported outcome measurements are important in outcome assessment of breast surgery. The BREAST-Q questionnaire measures changes in quality of life and patient satisfaction in patients undergoing breast surgery. The aim of this work was to translate and linguistically validate all BREAST-Q modules for use in Denmark.

METHODS: The Danish version of the BREAST-Q was developed through forward translation, back translation and cognitive debriefing following the guidelines from the MAPI Research Trust Foundation and approved by the developers. The aim was to achieve a conceptually equivalent Danish version using colloquial language rather than undertaking a simple literal translation.

RESULTS: A conceptually equivalent Danish version of all five BREAST-Q modules was achieved. The cognitive debriefing revealed good content validity. A cultural difference regarding the Satisfaction with Office Staff Scale was discovered.

CONCLUSIONS: The BREAST-Q can now be used for patients undergoing breast surgery in Denmark to measure change in quality of life and patient satisfaction as part of the outcome assessment. The BREAST-Q may be used for both individual and group measurements in clinical and research settings alike. Data collection with BREAST-Q can provide valuable information for use in clinical counseling of women undergoing breast surgery. A psychometric validation of the Danish version of the BREAST-Q is currently underway.

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Breast surgery comprises aesthetic, oncological and reconstructive breast procedures including augmentation mammoplasty, reduction mammoplasty, mastopexy, breast-conserving surgery, mastectomy as well as post-mastectomy reconstructions. The aim of cosmetic and reconstructive breast surgery is to improve the patients' quality of life (QoL). As morbidity and mortality does not suffice as a measurement of success in cosmetic and reconstructive breast surgery, it is important to be able to assess the patients' QoL [1-3]. Patients' perception of both their preoperative state and their result after surgery might differ from that of the surgeon's, and it is therefore important to address the effects of the surgeries by measuring aspects of QoL such as psychosocial and physical functioning and sexual wellbeing [1].

To evaluate the outcome of breast surgery, the use of patient-reported outcome measurements (PROM) is valuable for both surgeon and patient. To properly capture the patient-reported outcome after breast surgery, a measurement instrument should be able to measure specific changes due to surgery, i.e., it should have a high level of responsiveness [3]. Since responsiveness is greater in specific than in generic measurement instruments, generic questionnaires such as the Short Form (SF)-36 are not ideal for this purpose [1, 4]. Various specific PROM for breast surgery exist, e.g. the Breast-related Symptom Questionnaire and the Michigan Breast Reconstruction Outcomes. A systematic review evaluating PROM for breast surgery patients revealed that only one in seven of these instruments had undergone adequate development and validation, and the authors decided to develop BREAST-Q [1, 2]. BREAST-Q has become an internationally used PROM measuring QoL and patient satisfaction in patients undergoing breast surgery. Separate modules for five different procedures (mastectomy, breast-conserving therapy, breast reconstruction, breast reduction and breast augmentation) have been created. All modules contain three subdomains on health-related QoL: physical, psychosocial and sexual wellbeing, and three subdomains on patient satisfaction: satisfaction with breasts, outcome and care [5].

BREAST-Q is designed to measure changes in health-related QoL and thus has pre- and post-operative versions for all modules. Response categories correspond to an integer, and each scale is accompanied by a conversion table to calculate a total scale score of 0-100. BREAST-Q has been developed according to recommended guidelines and validated with measures of high reliability (e.g. Cronbach's ⍺ > 0.80) both using the paper and the electronic version [6-8]. It can be used for both individual and group measurements and is translated into more than 30 languages and has been used in numerous studies on QoL after breast surgery [5, 9].

A systematic review of 49 studies using BREAST-Q concluded that levels of satisfaction and health-related QoL were higher in patients receiving autologous-based

versus implant-based breast reconstructions, and outcomes of satisfaction, psychological and sexual well-being were better with silicone versus saline implants in breast augmentation patients [10]. Differences in outcomes among patient categories were evident; e.g., women who had undergone breast augmentation had a mean global Satisfaction with Breasts Q-score of 84 compared with breast reconstructed women who on average scored 65 [11, 12].

In Denmark, PROM to evaluate the outcome of breast surgery has not been common due to a lack of a specific Danish measurement instrument. The patient's point of view is touched upon during consultation with the surgeon where time may be limited, and thus less apparent topics important to the patient might not be addressed. In addition, some patients may not feel comfortable expressing their honest opinion about their post-operative result for various reasons and may not feel comfortable elaborating on intimate issues such as sexual well-being with their doctor. Prior to this study, there was no specific PROM with which to evaluate the outcome of breast surgery in Denmark. The aim of this study was therefore to translate BREAST-Q into Danish and linguistically validate the translated BREAST-Q modules.

METHODS

Permission to translate the BREAST-Q into Danish was granted by the BREAST-Q developers through the MAPI Research Trust Foundation (MAPI), to whom the developers had delegated the role as project manager of the BREAST-Q linguistic validations. The translation and linguistic validation of instructions and items (questions and their response categories) in all BREAST-Q modules were carried out according to guidelines set forth by MAPI [13]. MAPI was responsible for all communication with the developers of the BREAST-Q during the process. In the following description of the process, we will use the terminology suggested by the International Society of Pharmacoeconomics and Outcomes Research in their report on Principles of Good Practice for the Translation and Cultural Adaptation Process for Patient-Reported Outcomes [14].

Firstly, two translators, one of whom was the key in-country person, performed independent forward translations from English into Danish. Identical scales for the pre- and post-operative versions as well as scales repeated in more than one module were only translated once. The first Danish draft was created at a reconciliation meeting with the two translators. A third translator who had not been given access to the original English versions performed the back translation from Danish into English of the first Danish draft. A back-translation review was conducted at a meeting with all three translators present, where the back trans-

lations of all five modules were compared to the original versions to resolve discrepancies. This resulted in second drafts of all Danish modules. All back translations were subsequently approved by MAPI. For cognitive debriefing, the BREAST-Q questionnaires were completed by 46 native Danish female patients (pre- and post-operative patients completing each of the five modules). This included cognitive face-to-face interviews and measuring the time spent to complete the questionnaires. The patients were instructed to answer the questionnaire systematically and state whether any items were difficult to understand and, if so, they were asked to suggest a different phrasing of the item/question. They were also asked to judge the relevance of each item and suggest additional items if they felt something was missing. For items that had proved difficult to translate, the patients were asked which of two possible phrasings they preferred, or if they had alternative suggestions. Encountered difficulties and suggested solutions were registered. All interviews were carried out in the same manner and performed by the same person. Review of the cognitive debriefing results produced the third Danish draft. This draft was then proofread by the key in-country person, and the final versions of all fives modules were ready. Written reports composed by the key in-country consultant were sent to MAPI after forward translation, back translation, patient testing and proofreading. MAPI contacted the instrument developers for review and approval before the subsequent step of the process was undertaken. The focus of all translations was to produce a conceptually equivalent instrument in a colloquial language rather than a mere literal translation.

Trial registration: not relevant.

RESULTS

Discrepancies between the two independent forward translations were discussed and either resolved or noted to be investigated at a later stage. Most medical terms (e.g., lumpectomy, areola) were translated into more colloquial versions as medical terms are not commonly used in Danish. An example of a difficult translation is *aching feeling,* which was back translated into *a dull sensation/pain*. Another difficult translation was that of the word *confident* because it can be hard to discriminate between the meanings of *self-confident, confident* or *comfortable* in Danish. In addition, the Danish word for *confident* has the same meaning as *safe/secure*. To overcome this difficulty, the context of *confident* was critically evaluated and discussed for each item to translate into a semantically and conceptually equivalent word. Another example of a difficult translation is that of *how comfortably your bras fit,* which was back translated to *how well your bras fit*. This was ruled to be

conceptually different, since *well* refers more to the fit, whereas *comfortably* refers more to the sensation of wearing the bra. However, the Danish word used was judged to cover both concepts, and the item was therefore left unchanged.

All modules were well received by the patients, and several commented that they felt it highly relevant and were pleased with the opportunity to express their opinions. Comments also included a praise towards the Sexual Wellbeing Scale, since it is an area that can be difficult to address, yet is very important for the patients. Several patients commented that it was difficult to answer questions about the office staff because they had very little contact with them. Some patients found a redundancy of questions regarding pain in the Physical Wellbeing Scale but did manage to discriminate among them upon elaboration. Other comments that did not lead to any change of items included a patient having trouble answering *how you look in the mirror unclothed*?, because her answer depended on the side from which she looked; a patient who encountered difficulty answering questions regarding use of bras since she never wore a bra; and a patient who had trouble

with items regarding radiation therapy as she had received it during surgery.

All patients found the recall time (i.e., the period that patients were asked to consider when answering) of two weeks appropriate. **Table 1** shows the translation and linguistic validation process with the example of the Satisfaction with Breasts Scale in the preoperative mastectomy/breast-conserving therapy module. **Table 2** provides an overview of all results and **Table 3** of cognitive debriefing results.

DISCUSSION

All five original English BREAST-Q instruments were translated into Danish and linguistically validated following the MAPI guidelines. In the translations, we focused on preserving the meaning and ensure cultural adaptation. All scales, including both the pre- and post-operative questionnaire, were completed by ten patients rather than the recommended minimum of five in the cognitive debriefing, which strengthens this step of the process [14]. The cognitive debriefing suggested good content validity with no patients finding the items irrelevant except for the Satisfaction with

TABLE 1 / Detailed example of the translation into Danish and linguistic validation process using the Satisfaction with Breasts Scale from the BREAST-Q mastectomy and breast conserving therapy module preoperative version.

Satisfaction with Breasts Scale	Forward translation	Back translation	Changes made in the Danish version after comparing the back translation with the original version	Changes made in the Danish version after cognitive interviews with patients
Title: BREAST-Q mastectomy module (preoperative/post-operative)	*BREAST-Q questionnaire before/after mastectomy* because pre- and post-operative are not colloquial words in Danish	BREAST-Q Questionnaire before/after mastectomy	No changes	Patients were not familiar with the term *mastectomy*. *Mastectomy* was changed into *removal of the breast*
With your breast area in mind, in the past 2 wks, how *satisfied or dissatisfied* have you been with?:	Straightforward	With regard to your breast area how *satisfied or dissatisfied* have you been within the last 2 wks with?:	No changes *With you breast area in mind* and *with regard to…* were found to have the same meaning	No changes
Response categories: Very dissatisfied/somewhat dissatisfied/somewhat satisfied/very satisfied	Straightforward	Very dissatisfied/moderately dissatisfied/moderately satisfied/very satisfied	No changes *Somewhat* and *moderately* were found to have the same meaning	No changes
a. How you look in the mirror clothed	*How you look in the mirror with clothes on* because the direct translation of *clothed* is rarely used in Danish	The way you look when you see yourself in the mirror when *dressed*	No changes The discrepancies were found not to influence the meaning	No changes Patients confirmed the correct translation
b. How comfortably your bras fit	*How well your bras fit* because comfortable used in this context sounds odd in Danish	How well your bras fits	No changes	No changes Patients confirmed the correct translation
c. Being able to wear clothing that is more fitted	*More* was left out because it sounded odd in the Danish sentence *Fitted* was difficult to translate, and 2 words separated by a slash were chosen	Wearing tight fitting clothing	No changes	No changes Patients confirmed the correct translation
d. How you look in the mirror unclothed	*How you look in the mirror without clothes on* because the direct translation of *clothed* is rarely used in Danish	The way you look when you see yourself in the mirror undressed	No changes The discrepancies were found not to influence the meaning	No changes Patients confirmed the correct translation

TABLE 2 / Overview of results from translation into Danish of all five BREAST-Q modules.

BREAST-Q module	Scales (items), n	Forward translation	Back translation	Cognitive debriefing	Proofreading
Mastectomy	7 (62)	22 items were identical 29 items had literal discrepancies but same meaning which the translators reconciled upon 11 items had both literal and conceptual discrepancies which after thorough discussions were agreed upon	24 items were identical with the original English version 33 items had literal discrepancies but same meaning 5 items without same meaning were discussed and retranslated Changes were made in the introduction in 1 scale to clarify which persons the questions concerned	0 items were marked as difficult to understand by ≥ 3 patients Most patients commented that they were unsure what the word *mastectomy* meant At the discussion meeting it was decided to change *mastectomy* to *removal of the breast* throughout the questionnaire 0 items changed Change of layout so that the response categories flow onto the next page if the scale is 〉1 page	Minor spelling errors corrected
Breast-conserving therapy	13 (134)	40 items were identical 71 items had literal discrepancies but same meaning which the translators reconciled upon 23 items had both literal and conceptual discrepancies which after thorough discussions were agreed upon	35 items were identical with the original English version 91 items had literal discrepancies but same meaning 8 items without same meaning were discussed and retranslated Changes were made in the introduction in 1 scale to clarify which persons the questions concerned	0 items were marked as difficult to understand by ≥ 3 patients 4 items changed due to change of *mastectomy* to *removal of the breast* Change of layout so that the response categories flow onto the next page if the scale is 〉1 page	Minor spelling errors corrected
Breast reconstruction	17 (126)	27 items were identical 85 items had literal discrepancies but same meaning which the translators reconciled upon 12 items had both literal and conceptual discrepancies which after thorough discussions were agreed upon 2 problematic items to be discussed after back translation	34 items were identical with the original English version 83 items had literal discrepancies but same meaning 9 items without same meaning were discussed and retranslated It was decided to leave the 2 problematic items unchanged since the back translation was of equal meaning but to ask the patients to identify the wording they preferred Changes were made in the introduction in 1 scale to clarify which persons the questions concerned	0 items were marked as difficult to understand by ≥ 3 patients The 2 problematic items were changed Change of layout so that the response categories flow onto the next page if the scale is 〉1 page	Minor spelling errors corrected
Breast reduction	11 (104)	41 items were identical 50 items had literal discrepancies but same meaning which the translators reconciled upon 13 items had both literal and conceptual discrepancies which after thorough discussions were agreed upon	31 items identical with the original English version 66 items with literal discrepancies but same meaning 7 items without same meaning were discussed and retranslated Changes were made in the introduction in 1 scale to better clarify which persons the questions concerned	0 items marked as difficult to understand by ≥ 3 patients 0 items changed Change of layout so that the response categories flow onto the next page if the scale is 〉1 page	Minor spelling errors corrected
Breast augmentation	11 (99)	35 items were identical 55 items had literal discrepancies but same meaning which the translators reconciled upon 9 items had both literal and conceptual discrepancies which after thorough discussions were agreed upon	23 items identical with the original English version 71 items had literal discrepancies but same meaning 4 items without same meaning were discussed and retranslated Changes were made in the introduction in 1 scale to clarify which persons the questions concerned	1 item was marked as difficult to understand by ≥ 3 patients 1 item changed Change of the phrasing of the instructions in the scale introductions Change of layout so that the response categories flow onto the next page if the scale is 〉1 page	Minor spelling errors corrected

TABLE 3 / Cognitive debriefing records from all BREAST-Q modules.

	Breast augmentation	Breast reduction	Mastectomy	Breast-conserving therapy	Breast reconstruction
Patients (preoperatively/post-operatively), n	10 (5/5)	10 (5/5)	11 (6ª/5)	5 (0ª/5)	10 (5/5)
Age, median (range), yrs	30 (19-37)	47 (30-70)	52 (43-73)	63 (42-79)	48 (38-67)
Completion time, median (range), min.					
Preoperative	5 (4-8)	6 (5-8)	4 (3-4)ª	4 (3-4)ª	6 (5-6)
Post-operative	10 (6-13)	10 (10-15)	7 (4-10)	15 (10-20)	16 (11-20)
Recall period of 2 wks appropriate? Yes/no, n	10/0	10/0	10/1	10/0	10/0
Comments leading to change	3 patients suggested to change the item *self-confident* to a more fluent sentence in Danish	-	10/11 patients did not understand the word *mastectomy*	Comments from the mastectomy module lead to change of 4 items	-
Recruitment site	Printzlau Private Hospital	Department of Plastic Surgery, Herlev Hospital	Department of Breast Surgery, Herlev Hospital	Department of Breast Surgery, Herlev Hospital	Department of Plastic Surgery, Herlev Hospital

a) The preoperative versions for the mastectomy and breast-conserving therapy modules are identical.

Office Staff Scale, and no patients suggested deleting any items or topics.

The back-translation discrepancies should be considered in the light of the number of words in Danish and English. In the Danish Dictionary, 102,619 words can be found, whereas the English language contains at least 250,000 words [15, 16], and Danish words often cover more than one meaning.

The BREAST-Q contains a rather large number of items; and like in the Japanese version produced by *Saiga et al*, the average completion time in all post-operative modules was ≥ 10 minutes (Table 3) except for the mastectomy module [17]. This may reduce compliance and increase the risk of missing data or introduce less valid responses as the patient might be tired when completing the last scales. A solution may be to leave out some of the scales, focusing exclusively on certain topics, which is unproblematic since each scale functions independently, and scores are calculated for each scale separately.

The use of PROM within plastic surgery in Denmark has been limited, but focus on this important subject has intensified, which is underpinned by our work and the linguistic and psychometric validation of the BODY-Q instrument to massive weight loss patients [18, 19].

CONCLUSIONS

The use of PROM instruments within cosmetic and reconstructive breast surgery has been very limited in Denmark. However, with the translation and linguistic validation of BREAST-Q, it is now possible to include the patient's perspective in outcome assessment following mastectomy, breast-conserving therapy, breast reconstruction, breast reduction and breast augmenta-

tion. This is important as the primary aim of cosmetic and reconstructive breast surgery is to improve the patient's QoL.

After completion of our study, BREAST-Q has been updated to version 2.0, which has brought minor changes to the existing scales. Furthermore, the following new scales have been added: a scale on expectations, two scales on breast reconstruction with latissimus dorsi flap and a scale on adverse effects of radiation therapy. The Danish version has been updated with assistance from our team, and the Latissimus Dorsi and Adverse Effects of Radiation Scales have recently been translated and linguistically validated into Danish using the method described herein. Before the adapted instrument is suitable for use in research and clinical practice, psychometric validation is needed to test if the measurement properties (e.g., reliability) of the original instruments are retained after translation [20]. Our team is currently performing such a validation of the Danish BREAST-Q oncological scales, and we welcome future translations of PROM instruments intended for plastic surgery and encourage use of recommended guidelines in the process to ensure high quality Danish instruments.

In conclusion, all five BREAST-Q modules are now available in Danish and have been linguistically validated. This will enable a standardised assessment of PRO in different types of breast surgery and thus help facilitate an evidence-based approach to the management of breast surgery patients in Denmark.

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