Normative data for interpreting the BODY-Q

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Background and Aim: Many patients who go through bariatric surgery subsequently develop large amounts of loose skin as a result of great weight loss following the procedure. To restore the patient's body image and health related quality of life (HRQOL), surgical removal of the excess skin is often necessary (1).

BODY-Q is a patient-reported outcome measure (PROM) developed to measure satisfaction with the patient's appearance after bariatric and subsequent body-contouring surgeries. Furthermore, the BODY-Q evaluates patients' satisfaction with HRQOL and the improvement of this through their treatment (2). To measure the improvement of the patients HRQOL after surgical interventions it is important to have a comparative basis in the background population. The specific aim of this study is to facilitate this by collecting comparative normative data from the background population in the European countries where the BODY-Q has been translated into the spoken languages (3).

Material and Method: The participants of this study will be recruited through the survey-platform Prolific. Prolific is a website that collects panelists from all over the world to fill out questionnaires against payment. The BODY-Q will be sent out to panelists in the European countries where the PROM is available in the spoken languages.

After the data has been collected a mean-score for the sub elements of the questionnaire will be made. These results will be compared to earlier BODY-Q studies on bariatric patients. Data will be analyzed in the program SPSS.

Results:

Discussion/Conclusion:

1. de Zwaan M, Georgiadou E, Stroh CE, et al. Body image and quality of life in patients with and without body contouring surgery following bariatric surgery: a comparison of pre- and post-surgery groups. Front Psychol. 2014;5:1310.
2. Klassen AF, Cano SJ, Scott A, Tsangaris E, Pusic AL. Assessing outcomes in body contouring. Clin Plast Surg. 2014 Oct;41(4):645-54.
3. Mundy LR, Homa K, Klassen AF, Pusic AL, Kerrigan CL. Breast Cancer and Reconstruction: Normative Data for Interpreting the BREAST-Q. Plast Reconstr Surg. 2017 May;139(5):1046

Development and Psychometric Evaluation of New BREAST-Q Scales to Measure Lymphedema Outcomes

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Background and Aim: Lymphedema occurs in 30 to 50% of women undergoing axillary lymph node dissection and refers to the fibro-adipose deposition and swelling of tissue as a result of having a chronic accumulation of interstitial fluid [1]. Individuals with lymphedema experience persistent pain, decreased function, body image disturbance, and anxiety, resulting in a considerable decline in their well-being [2-3]. Recent studies have shown that some patients may develop symptoms of lymphedema without having any objective changes to their arm, indicating that clinical measurements may underestimate the incidence and impact of lymphedema [4].

To better understand the impact of lymphedema on health-related quality of life (HRQOL), rigorously developed, valid, and reliable patient-reported outcome measures (PROMs) are needed to quantify outcomes of lymphedema and its treatment from the patient's perspective [5-6]. The specific aim of the proposed study is to collect responses for the new lymphedema scales developed in addition to the BREAST-Q PROM and do a psychometric validation of the new scales.

Material and Method: Women, aged 18 years or older, with a history of breast cancer who has undergone breast surgery (i.e., breast-conserving therapy or a mastectomy), currently suffering from arm-lymphedema, and who have the ability to complete a questionnaire online will was included. Participants have been found by applying to the Danish Health Data Authority for a list of all Danish patients who in their health record have been coded with the diagnosis of breast-cancer and subsequently coded to have received treatment for lymphedema. Women who met the inclusion criteria were asked to complete the new BREAST-Q lymphedema scales through *e-boks*. All participants were asked to provide demographic (e.g., height, weight, age, bra cup size,) and clinical (date of diagnosis, type, and timing of breast reconstruction) information.

A Rasch analysis will be made on the data.

Results:

The questionnaire was sent out to 8136 women. Currently 3520 responses have been collected.

Discussion/Conclusion:

1. Pusic AL, Cemal Y, Albornoz C, et al. Quality of life among breast cancer patients with lymphedema: a systematic review of patient-reported outcome instruments and outcomes. J Cancer Surviv. 2013;7(1):83–92
2. US Food and Drug Administration Guidance for Industry. Patient-Reported Outcome Measures: use in medical product development to support labeling claims. Rockville, MD: Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 2009
3. Drug Development Tools Qualification Program - Clinical Outcome Assessment Qualification Program [Internet]. Available from: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugDevelopmentToolsQualificationProgram/ucm284077.htm. Accessed April 16, 2018
4. Hormes JM, Bryan C, Lytle LA, et al. Impact of lymphedema and arm symptoms on quality of life in breast cancer survivors. Lymphology. 2010; 43(1):1–13
5. Winters ZE, Benson JR, Pusic AL. A systematic review of the clinical evidence to guide treatment recommendations in breast reconstruction based on patient-reported outcome measures and health-related quality of life. Ann Surg. 2010; 252(6):929–42
6. Pusic A, Liu JC, Chen CM, et al. A systematic review of patient-reported outcome measures in head and neck cancer surgery. Otolaryngol Head Neck Surg. 2007; 136(4):525–35