

**Comparison of the Moorehead-Ardelt quality of life questionnaire and the BODY-Q in Danish patients undergoing weight loss and body contouring surgery**

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## TITLE PAGE

**Full title:** Comparison of the Moorehead-Ardelt Quality of Life Questionnaire and the BODY-Q in Danish patients undergoing weight loss and body contouring surgery.

**Short title (max 30 characters incl. space):** The MAQOL-II versus the BODY-Q

**Keywords:** BODY-Q; MAQOL; massive weight loss; bariatric; body contouring; patient-reported outcome measure.

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**d**

## **INTRODUCTION**

More than 14,500 patients have undergone bariatric surgery (BS) in Denmark between 2009 and 2017 [1]. Most people undergoing BS develop excessive skin following massive weight loss (MWL) [2]. In several studies, excessive skin has been shown to have a negative impact on health-related quality of life (HR-QOL) and self-perceived appearance despite the beneficial effects of weight loss [3-5].

To gain accurate insights into the impact of BS and body contouring (BC) after massive weight loss on patient HR-QOL, it is necessary to use a reliable and valid patient-reported outcome measure (PROM) [6]. Decisions about treatment in clinical practice for the individual patient, in research and health policy are increasingly informed by PROM data. Given the prominent role PROMs currently play in healthcare, it is crucial they provide scientifically sound measurement. The use of PROMs that are not properly developed or validated could lead to collection and use of data that is imprecise or biased, which can lead to wrong conclusions. The Consensus-based Standards for the selection of health Measurement Instruments (COSMIN) provides a consensus based checklist for evaluation of the methodological quality of studies on measurement properties, enabling a systematic and transparent evaluation [7].

For BS and BC, a recently published systematic review by de Vries et al concluded that the most rigorously developed PROM was the BODY-Q. The review was based on the COSMIN checklist and found that the BODY-Q had the strongest evidence for content validity [8]. The BODY-Q was designed in accordance with internationally accepted guidelines and methods [6,7,9-13] to measure change in important PRO over the entire

weight loss journey from obesity to post-BC. The BODY-Q measures 3 domains - appearance, HR-QOL, and experience of healthcare - via 21 independently functioning scales [3]. A detailed description of the BODY-Q and the measurement properties found in the original BODY-Q study is provided elsewhere [3,14].

In Denmark, the Danish Bariatric Surgery Database (DBSD) uses the Moorehead-Ardelt Quality of life Questionnaire-II (MAQOL-II) for the evaluation of HR-QOL in Danish patients undergoing BS and BC. The MAQOL-II is a condition-specific PROM developed for BS patients. It contains 6 items covering self-esteem, physical, social, work, sexuality and eating behaviour that are summed to produce a total score. A detailed description of the original described measurement properties can be found in the MAQOL-II development study [15].

The aim of this study was to determine whether the MAQOL-II or the BODY-Q is best suited for measuring PROs along the patient journey from obesity to after BC.

## **METHOD AND MATERIAL**

Before commencement, the Danish Data Protection Agency approved the study.

Questionnaire surveys in Denmark do not require Ethical approval [16].

### **Qualitative comparison**

To judge the content validity of the MAQOL-II and the BODY-Q we followed key concepts from the updated COSMIN guideline, covering PROM development. The COSMIN guideline states that content validity should be assessed in terms of relevance (i.e., whether

PROM-items were relevant for the construct of interest), comprehensiveness (i.e., are any key aspects of the construct missing?) and comprehensibility (i.e., are the items understood by patients as intended?)[17]. The COSMIN guideline further states that the most important measurement property of a PROM is content validity – and in the absence, the assessment of other measurement properties is meaningless [18]. Content validity was therefore evaluated as the primary factor in our qualitative comparison. The COSMIN rating was performed individually by two reviewers followed by a consensus meeting. The overall score was, as the guideline prescribe, determined by a worst score counts principle.

### **Quantitative comparison**

MAQOL-II data was obtained from the DBSD, and BODY-Q assessments were collected by our research team at 2 hospitals using a REDCap (i.e., Research Electronic Data Capture) survey provided by Odense Patient Explorative Network (OPEN) [19]. Details about the methods for data collection are provided underneath and in previous publications [5,20,21].

#### *MAQOL-II data collection*

The MAQOL-II is routinely collected pre- and postoperatively at all public and private hospitals providing BS and BC in Denmark. It is has not been possible to obtain information on whether MAQOL-II is fulfilled with interference from the clinicians or by the patients on their own, which could mean that different sites collect data differently. The data are afterwards entered in the DBSD. From the inception of the DBSD in September 2010, all BS patients were asked to complete the MAQOL-II preoperatively and 12-months after surgery.

BC patients were added to the DBSD in January 2015 and complete the MAQOL-II preoperatively and at 3- plus 12-months follow-up. Our data extraction from the DBSD was performed in November 2017.

#### *BODY-Q data collection*

Patients were recruited at the Departments of Endocrinology and Plastic Surgery at Hospital of Southwest Jutland and Odense University Hospital in the period June 2015 to March 2018. Patients were asked to complete the BODY-Q at the following time points: (1) first appointment at the weight loss clinic; (2) before BS; (3) 3-6 months after BS; (4) 12 months after BS; (5) 24 months after BS; (6) before BC; (7) 3 months after BC; and (8) 12 months after BC.

#### *Data analysis*

All MAQOL-II and BODY-Q assessments were categorised into 4 groups (phase of weight loss journey): (1) Pre-BS, (2) post-BS, (3) pre-BC (patients referred to BC after MWL who had not undergone any previous BC), and (4) post-BC (patients who had undergone  $\geq 1$  BC procedure following MWL). Data was analysed using SPSS (IBM SPSS Statistics, version 25.0, IBM Corp.) and RUMM 2030 software (RUMM version 2030, RUMM Lab) for Rasch Measurement Theory (RMT) analysis.

RUMM 2030 software was used to select a random sample from the MAQOL-II dataset to match the size and characteristics of the BODY-Q sample. Data were stratified to ensure both samples had a similar composition in terms of patient age, gender, and time of weight loss journey. To match the two PROMs further, we excluded the BODY-Q patient experience

of care scales. Figure 1 illustrates the selection of MAQOL-II and BODY-Q samples used for the quantitative analysis.

The psychometric measurement properties evaluated for the MAQOL-II and the BODY-Q in the RMT analysis were:

- 1) *Category threshold order (Threshold for item Response Options)*: To evaluate if the response options for each item were ordered as intended in accordance with the Rasch Model, we examined thresholds between response options.
- 2) *Item Fit Statistics*: We examined the following three indices of item fit to the Rasch model:  $\chi^2$  values (item-trait interaction); Log residuals (item-person interaction) and item characteristic curves (ICC). These indices provide complementary information and every index was interpreted in the context of the others and within the clinical importance of each item [22]. Items fit the Rasch model if  $\chi^2$  values were nonsignificant after Bonferroni adjustment and fit residuals were between -2.5 and +2.5.
- 3) *Dependency*: Between pairs of items, residual correlations were examined to judge if any of the items directly influenced responses to other items. Residual correlations should be lower than 0.3, and if above criteria was satisfied subtest analysis was performed to examine the impact [5].
- 4) *Differential item functioning (DIF)*: To evaluate if scales worked the same across subgroups within the study population, we explored differential item functioning (DIF) according to gender, age-groups, and time-groups. Identification of items with



potential DIF, was done by looking for significant chi-square values after Bonferroni adjustment.

5) *Targeting*: To determine if items were evenly spread over a range that matched the range of the construct reported by the sample, person and item locations were examined.

6) *Measurement precision*: The Person Separation index (PSI) was calculated for every scale. PSI is a measure of the error associated with the measurement of people in a sample. Higher PSI values mean higher reliability.

In addition to RMT analysis, we performed Classical Test Theory (CTT) analysis to compute Cronbach alpha (internal consistency reliability). Values should be at least 0.70 for group comparison and 0.90-0.95 for individual comparisons to be acceptable [13].

Floor and ceiling effects for the MAQOL scores and BODY-Q scales scores were computed. We used the scoring keys provided by the developers of each instrument, BODY-Q scores range from 0 (worst) to 100 (best). MAQOL-II scores range from -3 (worst) to 3 (best).

## **RESULTS**

### **Qualitative analysis**

Table 1 summarizes the qualitative findings for both the MAQOL-II and the BODY-Q, and Appendix 1 shows the complete rating of the COSMIN standards for evaluating the quality of development and content validity studies of PROMs, and criteria for content validity.

The COSMIN rating is based on the reported development and validation studies, respectively for the MAQOL-II [15,23,24] and the BODY-Q [3,25,26].

#### *MAQOL-II qualitative analysis*

##### *PROM development, relevance and comprehensiveness*

Following the “Bariatric Analysis and Reporting Outcome System” (BAROS) initiative the MAQOL was developed in 1998 and further revised in 2009 to MAQOL-II [23,24]. In terms of development, we did not find any evidence of target patient involvement (i.e., obese, BS or BC) in the content generation phase [23]. The 2003 follow-up study reported further refinements based on feedback from users, however the users and the nature of the feedback were not described [15,24]. Due to lack of patient input, relevance and comprehensiveness were not verified in the initial development of the MAQOL-II. *Comprehensibility*

The construct measured by the MAQOL-II is “quality of life” which is derived from a total score based on 6 items measuring different concepts that are answered via 10 response options. The MAQOL-II does not provide a recall time. Each item in the MAQOL-II uses a picture (placed at each end) to illustrate the concept being measured. A limitation is that the relationship between the words and the pictures are ambiguous. For example, the activity item states: “I Enjoy Physical Activities” but the pictures at either end of the item are of rain and sunshine [15]. Importantly, several drawings in the Danish version are different from the original version but no publications are available that account for these changes. There are also no publications supporting the linguistic and psychometric validation of the MAQOL-II for use in Danish BS- and BC patients [20,27,28]. The lack of linguistic validation can possibly explain obvious differences in meaning. For example, the physical activity item in

the English version says: “I Enjoy Physical Activities” but in Danish the translation says “My Physical Activity Level Is”.

Overall our evaluation of the MAQOL-II, using the COSMIN methodology for assessing content validity, leads to the conclusion that the development and validation of the MAQOL-II was inadequate. However, the reported studies [15,23,24] were of very low quality and hence the quality of the content validity of the MAQOL-II cannot be evaluated sufficiently and is in fact unclear [17]. .

#### *BODY-Q qualitative analysis*

##### *PROM development, relevance and comprehensiveness*

The BODY-Q’s conceptual framework and set of scales were developed based on a literature review, patient interviews and expert input [6,25,26]. The literature review helped to form an interview guide that was used in 63 qualitative patient interviews. Patient stories from the interviews were used to create the scales and items of the BODY-Q. A total of 22 cognitive interviews were performed to refine the scales, and 9 experts were asked for input, which led to the BODY-Q field-test version. Relevance, comprehensiveness, and comprehensibility were achieved by the extensive patient and expert involvement. The field-test [3] included 734 patients, and RMT analysis was used to refine the scales.

##### *Comprehensibility*

For every scale a recall time was provided, and the response options were limited to 4 and labelled in accordance with recommendations [29]. The final version of the BODY-Q included 18 individual functioning scales [3]. Subsequently, a stretch marks scale and a chest

module were added [30,31,32]. The BODY-Q was linguistically- and psychometrically validated for use in Danish BS and BC patients according to ISPOR [33] and WHO [34] guidelines [5,19].

Overall, our evaluation of the BODY-Q using the COSMIN methodology for assessing content validity, leads to the conclusion that there is high quality evidence [3,25,26] for sufficient content validity of the BODY-Q [17].

### **Quantitative analysis**

#### *MAQOL RMT analysis*

We received 33,941 observations from the DBSD, and of these 9,147 patients completed the MAQOL-II providing 16,965 completed assessments. Table 2 shows the distribution of assessments according to number of patients. The response rate for the MAQOL-II in the BS population has been reported elsewhere as 62% from the period 2011 to 2016, ranging from 35% to 83% [35-40]. The response rates beyond this period and for the BC population were not available. Removing cases with missing data led to a sample of 16,473 assessments from which the random sample was selected. Patient characteristics are shown in Table 3a.

Appendix 2 provides detailed information on scale performance and item fit statistics for MAQOL-II. In the RMT analysis, 3 of the 6 MAQOL-II items had disordered thresholds (item 4, 5 and 6). Figure 2a shows the threshold map, illustrating disordered items. Item fit statistics revealed that fit was outside the criteria of -2.5 to +2.5 for 3 items, and 1 item had a significant chi-square P value after Bonferroni adjustment. There were no item residual correlations  $> 0.3$ . Differential item functioning (DIF) was observed for 4 items for age and

time of journey. When items with DIF were split according to the relevant person factors and the new person locations were correlated with the original, there was no evidence that the DIF had an impact on scoring (Pearson correlations  $\geq 1.0$ ). In terms of reliability, with extremes included, the Cronbach  $\alpha$  was 0.82 and the person separation index (PSI) was 0.79. Person-item threshold distribution figures for all person factors (i.e. gender, age, and time of journey) showed evidence that the sample fit on the range of measurement provided by the MAQOL-II. Figure 3 gives an example of the person-item threshold distribution according to where patients were in their weight loss journey. Item locations are illustrated in the lower histogram and person locations in the upper histogram.

#### *BODY-Q RMT analysis*

The BODY-Q sample consisted of 2,259 assessments from 1,425 patients. BODY-Q sample characteristics are available in Table 3b. The overall response rate was 83%. For the BS group, the response rate was 90%, and for the BC group it was 77%.

Appendix 3 provides detailed information on scale performance statistics and item fit statistics for the 17 BODY-Q scales included in the analyses. All 123 items that formed the 17 BODY-Q scales had ordered thresholds. Figure 2b illustrates the threshold map for the physical function scale as an example, which shows that the location order is identical with the serial order. This finding means that the clinical hierarchy for the set of items in the Danish sample matched that of the original sample. Item fit was outside criteria for 64 of 123 items. Out of these, 10 had a significant chi-square P value after Bonferroni adjustment. DIF was found for 48 items according to one or more person factors (gender, age, and time of journey). However, items with DIF were split on the relevant person factor and

the Pearson correlations performed were  $\geq 0.95$ , i.e. only negligible impact of DIF. For scale reliability, all scales evidenced high Cronbach  $\alpha$  values  $\geq 0.90$  (with extremes), and PSI values  $\geq 0.81$  (with extremes). Item residual correlations were outside criteria for 10 pairs of items within 6 scales (range 0.31 – 0.51). However, in subtest analysis, the PSI values (range 0.86 – 0.93 (with extremes)) dropped (range 0.83-0.93 (with extremes)), indicating only minor impact. Person-item threshold distribution figures for the 17 BODY-Q scales and person factors (gender, age, and time of journey) show that the scales mapped out the construct as experienced by the sample. Table 4 summarizes the quantitative findings for both MAQOL-II and BODY-Q.

## **DISCUSSION**

Overall, our study provides evidence that the BODY-Q is superior to MAQOL-II in assessment of PRO over the entire weight loss journey from obese to post-BC due to its rigorous development and psychometric performance.

As summarized in Table 1, there were several important differences between MAQOL-II and the BODY-Q in the evaluation of content validity. First, the MAQOL-II was developed for use in bariatric surgery patients, while the BODY-Q was developed for patients who lose weight by surgical or medical means and post-weight loss body contouring patients (i.e., any point during the weight loss journey). Furthermore, the lack of patient involvement in the MAQOL-II development represents an important limitation. The COSMIN checklist states that the quality of a PROM strongly depends on patient involvement [17]. Second, the construct measured by MAQOL-II is not clear, and the provision of 10 response options was

shown to be too many, with half the items having disordered thresholds [29]. Furthermore, the lack of recall time can affect reliability as there is no frame of reference to guide respondents in their answers. While the brevity of the MAQOL-II is attractive, the total score obtained by adding up 6 different concepts makes it impossible to interpret the meaning of change in scores [22,41]. The BODY-Q, in contrast, has a large number of scales, which possibly can create respondent burden if all are administered. The high response rate in our study of 83% and the fact that patients have described feeling that they appreciate the opportunity to express their feelings [20,42], suggest that respondent burden is not a problem. It is important to note that each BODY-Q scale is independently functioning, and therefore researchers or clinicians can pick and choose the scales to use. More recently, the BODY-Q team has developed a CAT (computer adaptive testing) version of the BODY-Q, which significantly limits patient burden [43]. Third, the MAQOL-II represents a legacy tool that was developed using a classical test theory (CTT) approach. Today, PROM developers are increasingly using modern psychometric approaches. This approach does not provide total scores but instead scales that measure unidimensional constructs. The multiple scales of the BODY-Q make it possible to measure the effect of treatment on different PROs, and the use of RMT provides the opportunity to add qualitative statements to subscale scores and thereby enhance interpretability [44,45]. In contrast, the MAQOL-II's use of a single total score makes it difficult to identify and measure change in PROs given issues of reliability, validity, and responsiveness [46,47]. Finally, the Danish version of MAQOL-II did not undergo a careful linguistic validation. For the BODY-Q we found evidence that criteria for content validity, construct, and the psychometric analysis were all met.

As summarized in Table 4, both PROMs more or less fit the Rasch model, though the BODY-Q outperformed the MAQOL-II in several areas. First, the Cronbach  $\alpha$  was 0.82 for MAQOL-II, while all BODY-Q scales had Cronbach  $\alpha$  values  $\geq 0.90$  (mean 0.95). Second, 3 of 6 MAQOL-II items had disordered thresholds compared with none in the BODY-Q, which confirmed that the items in the MAQOL-II did not work as intended [29]. Finally, item fit was outside criteria for 17% of items in the MAQOL-II versus 8% of items in the BODY-Q. This finding highlights the fact that the BODY-Q was developed to fit the Rasch model, while the MAQOL-II was developed using CTT, where item fit is not evaluated. For the MAQOL-II, even though the Cronbach  $\alpha$  was adequate, suggesting the scale was reliable according to a CTT approach, other concerns were identified under the lens of the modern psychometric approach. As our findings suggest, poor translations and limitations in content validity can affect all other measurements [17]. Our results are comparable with previous research showing that even though psychometric analysis declared a PROM as valid, the qualitative part of the study showed that the MAQOL-II lacks content validity, which is the most important measurement property [17,48]. For the BODY-Q, the psychometric findings are in line with the previous Danish psychometric validation of the BODY-Q [5]. The newly developed scales (stretch marks, male chest and nipple) were also found to be reliable and valid [30,31].

Our study has some limitations. First, the psychometric comparison was based on different samples. While it would have been preferable to have had the same patients complete both questionnaires, such data were not available and we were able to extract a sample from the MAQOL-II dataset that was similar to the BODY-Q sample in terms of



gender, age, and treatment group. Second, the MAQOL-II sample came from more centres than the BODY-Q sample. However, Denmark is a small and relatively monocultural society with free and equal access to health services, and we think it unlikely that the difference in recruitment sites would change the findings reported here. Third, we did not have access to patient files. Complications and comorbidity could potentially affect patients' perception and answers. Finally, our study is based on the Danish versions of the MAQOL-II and the BODY-Q, which could limit generalisation to other countries and translations of these tools. In Denmark, the BODY-Q underwent a thorough linguistic and psychometric validation such that scores for the BODY-Q should be comparable to scores for patients in other countries.

## **CONCLUSION**

PROMs are used for various purposes, including clinical trials, patient education, and quality improvement and to inform health policy decisions, which has increased the demand for reliable and valid PROMs. The MAQOL-II represents a legacy tool developed in 1998 to measure HR-QOL in BS patients. This tool has important limitations based on today's high standards for rigorously developed PROMs. The BODY-Q, in contrast, provides substantial, accurate and interpretable measurement capturing the relevant constructs for patients undergoing BS and BC.

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The Danish BODY-Q study is funded by the Region of Southern Denmark.

## **Conflicts of interest**

Author 1b, 4, 5, 6, 7 and 8 declares no conflict of interest. Author 1a has translated and validated the BODY-Q for use in Danish patients. The BODY-Q is owned by McMaster University and Memorial Sloan Kettering Cancer Centre. Author 2 and 3 are a co-developers of the BODYQ and as such, will receive a share of any license revenues as royalties based on the inventor sharing policy.

## **Ethics statements**

The study was approved by the Danish Data Protection Agency. Questionnaire surveys in Denmark do not require Ethical approval.

## **Consent statements**

Informed consent was obtained from all participants in the BODY-Q study.

The Danish Bariatric Surgery Database provided the MAQOL data.

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## ABSTRACT

**Introduction:** This study compared the measurement properties of the Moorehead-Ardelt Quality of Life Questionnaire-II (MAQOL-II) and the BODY-Q, to determine which was more suitable for measuring patient-reported outcome (PRO) in Danish bariatric surgery (BS) and body contouring surgery (BC) patients.

**Methods:** We examined content validity against the COSMIN guidelines and compared psychometric performance using Rasch Measurement Theory methods and criteria. MAQOL-II data were obtained from the Danish Bariatric Surgery Database from September 2010 to November 2017, and BODY-Q data were collected from June 2015 to March 2018.

**Results:** The MAQOL-II failed to meet recommended standards for content validity, while all criteria were met for the BODY-Q. A total of 16,965 MAQOL-II and 2,259 BODY-Q assessments were obtained. A random sample was selected from the MAQOL-II dataset to match the BODY-Q sample. Psychometrically, the BODY-Q performed better than the MAQOL-II. For example, Cronbach  $\alpha$  was 0.82 for the MAQOL-II versus  $\geq 0.90$  for all BODY-Q scales. Fifty percent (3/6) of MAQOL-II items had disordered thresholds, while all BODY-Q items had ordered thresholds (123/123). Poor item fit was revealed for 17% (1/6) of MAQOL-II and 8% (10/123) of BODY-Q items. For scale reliability, Person separation index was 0.79 for the MAQOL-II and 0.88 (range 0.81-0.93) for the BODY-Q.

**Conclusion:** The MAQOL-II does not meet today's standards for a rigorously developed PRO measure. The BODY-Q, on the other hand, gives substantial, accurate and interpretable measurement and should be recommended for use in PRO in BS and BC patients.

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**Appendix 1a. RMT Scale Performance Statistics for MAQOL-II.**

Scale	Sample Size	Reliability				Item-trait interaction			F/C (%) <sup>c</sup>	Patients measured within the scale range (%) <sup>d</sup>
		PSI (with extremes)	PSI (without extremes)	Crohnbach's alpha (with extremes)	Crohnbach's alpha (without extremes)	Chi-square	DF <sup>a</sup>	P <sup>b</sup>		
MAQOL-II	2157	0.79	0.78	0.82	0.81	92.85	54	0.001	0/1	98

a: Degree of freedom, b: Probability, c: Percentage of patients to score at floor or ceiling, d: ((Total n) – (total extremes))/ (total n) x 100.

**Appendix 1b. RMT Statistical Indicators of Item Fit for MAQOL-II.**

Scale	Item	Item number	Difficulty		Item fit				
			Item location	SE <sup>a</sup>	Fit Residual	DF <sup>b</sup>	Chi-square	DF <sup>b</sup>	P <sup>c</sup>
MAQOL-II	SELF-ESTEEM	1	-0.028	0.012	-5.417	1770.33	27.65	9	0.001**
	PHYSICAL ACTIVITY	2	0.224	0.012	-0.243	1770.33	6.65	9	0.673
	SOCIAL	3	-0.446	0.013	-4.829	1770.33	22.42	9	0.008
	WORK	4	-0.023	0.01	0.349	1770.33	7.37	9	0.599
	SEXUAL	5	0.285	0.01	1.962	1770.33	6.86	9	0.652
	EATING	6	-0.012	0.012	8.747	1770.33	21.91	9	0.009

a: Standard error, b: Degree of freedom, c: Probability, \*\*P-values significant after Bonferroni adjustment.

**Appendix 2a.** RMT Scale Performance Statistics for all included BODY-Q scales.

Scale	Sample Size	Reliability				Item-trait interaction			F/C (%) <sup>c</sup>	Patients measured within the scale range (%) <sup>d</sup>
		PSI (with extremes)	PSI (without extremes)	Cronbach's alpha (with extremes)	Cronbach's alpha (without extremes)	Chi-square	DF <sup>a</sup>	P <sup>b</sup>		
BODY	2246	0.91	0.91	0.95	0.93	122.95	90	0.012	11/1	89
ARMS	2238	0.91	0.90	0.95	0.92	115.95	63	0.000	14/3	84
ABDOMEN	2239	0.92	0.93	0.98	0.95	142.10	63	0.000	35/5	60
BACK	2217	0.88	0.85	0.96	0.89	92.69	20	0.000	17/10	73
BUTTOCKS	2227	0.89	0.84	0.95	0.88	32.07	30	0.364	19/7	74
INNER THIGHS	2223	0.81	0.82	0.96	0.87	87.75	28	0.000	46/3	52
OUTER THIGHS	2228	0.91	0.85	0.97	0.91	23.81	30	0.781	21/8	71
SKIN	1803	0.86	0.87	0.95	0.91	62.99	63	0.477	26/2	77
STRETCHMARKS	2009	0.93	0.93	0.97	0.94	91.38	90	0.440	4/19	72
CHEST (male)	263	0.93	0.94	0.98	0.96	51.35	20	0.000	19/4	78
NIPPLE (male)	259	0.87	0.80	0.94	0.84	5.73	10	0.837	0/2	72
SCAR (post BC)	421	0.83	0.88	0.95	0.93	143.50	40	0.000	0/32	68
BODYIMAGE	2226	0.90	0.90	0.95	0.92	63.16	63	0.471	22/1	77
PSYCHOLOGICAL	2233	0.92	0.92	0.95	0.94	94.75	90	0.345	3/7	90
SOCIAL	2234	0.90	0.90	0.94	0.92	80.23	90	0.760	1/10	89
SEXUAL	2208	0.81	0.76	0.90	0.83	41.32	45	0.629	15/5	80
PHYSICAL FUNCTION	1838	0.83	0.84	0.94	0.90	76.31	42	0.001	2/23	75

a: Degree of freedom, b: Probability, c: Percentage of patients to score at floor or ceiling, d: ((Total n) – (total extremes))/ (total n) x 100



**Appendix 2b.** RMT Statistical Indicators of item Fit for all included BODY-Q scales.

Scale	Item	Item number	Difficulty		Item fit				
			Item location	SE <sup>a</sup>	Fit Residual	DF <sup>b</sup>	Chi-square	DF <sup>b</sup>	P <sup>c</sup>
BODY	...looks when dressed	1	-1.302	0.039	-2.595	1782	10.97	9	0.278
	...how clothes fit	2	-1.046	0.039	-2.383	1779.3	15.19	9	0.086
	...size	3	-1.192	0.035	8.304	1781.1	34.40	9	0.0001**
	...shape	4	-0.163	0.038	-1.237	1782	4.35	9	0.888
	...looks in photos	5	-0.261	0.037	-6.273	1777.5	16.17	9	0.063
	...looks from behind	6	-0.667	0.037	2.030	1773	5.38	9	0.800
	...looks from the side	7	-0.075	0.037	-5.866	1769.4	12.53	9	0.185
	...looks in summer clothes	8	0.939	0.039	0.143	1775.7	7.13	9	0.624
	...looks in a swimsuit	9	2.056	0.043	-1.895	1769.4	6.67	9	0.671
	...looks in mirror unclothed	10	1.711	0.042	4.066	1774.8	10.16	9	0.338
ARMS	...size	11	-0.453	0.040	-2.033	1598.57	6.40	9	0.700
	...how smooth	12	-0.957	0.042	-3.326	1595.15	10.70	9	0.297
	...shape	13	-0.229	0.042	-12.056	1586.61	27.74	9	0.001**
	...how skin looks	14	-0.608	0.041	1.541	1590.03	7.95	9	0.540
	...how toned	15	0.828	0.043	9.604	1589.17	38.21	9	0.000**
	...look when lifted up	16	0.590	0.042	-5.976	1593.45	16.26	9	0.062
	...look when not covered	17	0.829	0.042	-1.428	1590.03	8.70	9	0.466
ABDOMEN	...how clothes fit	18	-1.582	0.052	1.385	1156.21	13.28	9	0.150
	...size	19	-0.952	0.051	-4.495	1152.8	26.16	9	0.002
	...looks from the side	20	-0.621	0.052	-6.672	1154.5	21.72	9	0.010
	...shape	21	-0.185	0.053	-6.839	1155.36	16.43	9	0.058
	...looks in a swimsuit	22	0.541	0.055	-1.447	1143.4	12.25	9	0.200
	...how toned	23	1.702	0.059	5.872	1152.8	32.59	9	0.000**
	...looks when naked	24	1.097	0.057	-0.639	1151.94	19.66	9	0.020
BACK	...how smooth	25	-1.100	0.054	-5.353	1208.31	33.62	5	0.000**
	...looks from different angles	26	-0.425	0.056	-9.063	1207.56	9.84	5	0.080
	...how toned	27	1.210	0.054	0.736	1209.06	39.96	5	0.000**
	...lookes when naked	28	0.315	0.052	-7.375	1206.07	9.28	5	0.098
BUTTOCKS	...size	29	-0.294	0.044	-3.198	1319.2	4.61	6	0.595
	...look from the side	30	0.039	0.045	-7.435	1318.4	6.56	6	0.363
	...shape	31	0.244	0.046	-7.690	1317.6	12.54	6	0.051

	...how smooth	32	0.148	0.045	-3.799	1318.4	1.53	6	0.958
	...how skin looks	33	-0.137	0.044	2.359	1318.4	6.83	6	0.337
INNER THIGHS	...how smooth	34	-0.422	0.059	-7.061	857.25	14.68	7	0.040
	...how skin looks	35	-0.585	0.058	-5.393	856.5	24.21	7	0.001**
	...how toned	36	0.584	0.059	2.987	856.5	29.47	7	0.000**
	...look when naked	37	0.424	0.058	-4.543	855.75	19.39	7	0.007
OUTER THIGHS	...size	38	0.118	0.050	-5.606	1256.74	3.47	6	0.749
	...shape	39	0.122	0.052	-9.171	1252.76	4.60	6	0.596
	...how skin looks	40	-0.463	0.051	-5.256	1251.96	10.36	6	0.110
	...how smooth	41	-0.063	0.053	-4.640	1249.57	0.63	6	0.996
	...look from behind	42	0.287	0.051	-7.672	1247.97	4.75	6	0.576
SKIN	...look bigger then you are	43	-0.479	0.049	1.174	1103.91	7.91	9	0.543
	...dress in a way to hide	44	-0.434	0.048	-2.420	1100.49	7.56	9	0.579
	...not able to wear certain clothes	45	-0.268	0.047	-1.367	1099.64	3.69	9	0.930
	...how much it hangs	46	0.413	0.051	-2.389	1103.05	6.46	9	0.693
	...amount of skin	47	0.217	0.051	-3.019	1101.35	9.16	9	0.422
	...people seeing	48	-0.519	0.046	5.511	1098.78	19.55	9	0.021
	...looks when naked	49	1.069	0.054	-2.056	1098.78	8.65	9	0.470
STRETCH-MARKS	...not able to wear certain clothes	50	-0.307	0.046	-2.249	1391.52	7.04	9	0.633
	...how wide	51	0.301	0.046	-4.820	1386.14	8.91	9	0.446
	...having to dress in a way to hide	52	-0.241	0.046	-3.722	1391.52	7.19	9	0.618
	...the length	53	-0.005	0.046	-6.340	1387.93	11.65	9	0.234
	...the location	54	-0.030	0.043	-0.098	1387.93	2.76	9	0.973
	...how old	55	0.185	0.045	-2.210	1388.83	6.02	9	0.738
	...how noticeable	56	-0.536	0.042	6.069	1386.14	16.96	9	0.049
	...the amount	57	-0.366	0.042	1.312	1390.63	7.17	9	0.620
	...people seeing	58	0.379	0.041	3.584	1389.73	14.73	9	0.099
	...how your stretch marks look close up	59	0.620	0.044	-2.684	1390.63	8.96	9	0.441
CHEST (male)	...looks in a loose T-shirt	60	-1.290	0.133	0.381	180.61	0.95	2	0.623
	...looks in a snug T-shirt	61	0.104	0.130	1.102	180.61	1.20	2	0.368
	...how masculine	62	0.083	0.139	2.260	179.72	4.53	2	0.104
	...how flat	63	-0.195	0.136	-2.295	179.72	1.27	2	0.531
	...looks when you lie on your back	64	-1.263	0.132	2.409	180.61	6.41	2	0.041

	...looks when you are active	65	0.202	0.135	-0.433	179.72	1.45	2	0.486
	...looks when you bend over	66	0.804	0.140	0.604	179.72	0.43	2	0.809
	...the shape without a T-shirt	67	0.321	0.139	-5.318	180.61	10.83	2	0.004
	...looks from the side	68	0.480	0.140	-4.971	179.72	12.97	2	0.002
	...looks in the mirror	69	0.754	0.142	-4.135	177.95	10.52	2	0.005
NIPPLE (male)	...show through a snug T-shirt	70	0.853	0.118	1.247	145.91	1.87	2	0.394
	...the size	71	-0.614	0.122	-3.056	145.91	0.96	2	0.620
	...the shape	72	-0.742	0.128	-2.795	144.34	0.61	2	0.737
	...how flat	73	-0.085	0.119	0.170	145.91	1.82	2	0.402
	...look without a T-shirt	74	0.588	0.113	1.899	145.91	0.48	2	0.788
SCAR (post BC)	...dress in way to hide	75	-0.300	0.106	0.853	253.51	14.23	4	0.007
	...how wide	76	-0.093	0.104	-2.008	253.51	11.73	4	0.020
	...location	77	-0.227	0.104	-0.835	253.51	11.29	4	0.024
	...length	78	-0.620	0.110	-2.463	253.51	17.39	4	0.002
	...noticeable	79	0.397	0.102	-3.993	253.51	9.66	4	0.047
	...color	80	-0.059	0.107	0.450	248.17	3.17	4	0.530
	...how thick	81	0.450	0.099	1.308	253.51	14.67	4	0.005
	...looking crooked	82	-0.197	0.104	4.260	252.62	30.97	4	0.000**
	...people seeing	83	-0.056	0.104	0.775	252.62	15.38	4	0.004
	...look when not covered	84	0.705	0.102	-2.608	253.51	15.02	4	0.005
BODY-IMAGE	...positive towards my body	85	-1.192	0.045	0.767	1454.94	3.21	9	0.955
	...not perfect but I like it	86	-1.389	0.045	-3.332	1455.79	6.81	9	0.657
	...happy with my body	87	-0.873	0.045	-8.127	1455.79	20.49	9	0.015
	...proud of my body	88	-0.770	0.042	0.440	1454.94	7.67	9	0.568
	...think body is attractive	89	1.072	0.046	-1.574	1451.52	9.41	9	0.400
	...feel good when naked	90	1.219	0.046	3.096	1455.79	8.79	9	0.457
	...have body I want	91	1.934	0.048	2.329	1453.23	6.77	9	0.661
PSYCHO-LOGICAL	...believe in myself	92	-0.708	0.037	1.226	1808.61	5.63	9	0.776
	...proud of myself	93	-0.478	0.035	-0.620	1808.61	6.11	9	0.729
	...happy	94	-0.010	0.037	-0.073	1808.61	2.18	9	0.988
	...like myself	95	0.024	0.036	-5.579	1808.61	10.90	9	0.283
	...emotionally strong	96	-0.592	0.036	8.867	1809.51	26.06	9	0.002
	...in control of my life	97	-0.563	0.037	4.553	1809.51	5.50	9	0.789
	...confident	98	-0.003	0.037	-4.984	1805.91	9.08	9	0.430

	...accepting of myself	99	0.085	0.036	-0.285	1808.61	5.29	9	0.809
	...comfortable with myself	100	0.757	0.037	-4.661	1805.91	8.27	9	0.508
	...feel great about myself	101	1.488	0.037	-5.418	1804.12	15.73	9	0.073
SOCIAL	...gathering with people I know	102	-0.596	0.037	6.958	1785.92	15.53	9	0.077
	...people listen to what I say	103	-1.446	0.043	1.375	1782.32	3.44	9	0.944
	...accepted by people	104	-1.301	0.042	-4.448	1785.02	8.81	9	0.455
	...included in social situations	105	-1.011	0.040	-5.517	1781.42	13.92	9	0.125
	...make good first impression	106	-0.443	0.038	1.540	1784.12	3.90	9	0.918
	...take part in life	107	-0.242	0.037	-1.359	1784.12	3.75	9	0.927
	...easy to make new friends	108	0.461	0.036	3.886	1783.22	12.30	9	0.197
	...confident in group situations	109	0.865	0.035	-4.121	1785.92	8.47	9	0.488
	...people I don't know well	110	1.697	0.036	-3.716	1780.53	6.03	9	0.737
	...confident walking into a room	111	2.016	0.035	-1.803	1781.42	4.09	9	0.905
	SEXUAL	...fulfilling	112	-0.860	0.033	2.052	1402.12	3.84	9
...comfortable undressing		113	-0.302	0.032	-2.108	1402.12	9.37	9	0.404
...satisfied with sex life		114	-0.230	0.032	1.392	1397.33	4.66	9	0.863
...comfortable having lights on		115	-0.096	0.032	-1.808	1398.13	10.48	9	0.313
...feel sexually attractive naked		116	1.487	0.037	-2.482	1401.32	12.97	9	0.164
PHYSICAL FUNCTION	...getting up from a bed	117	-0.779	0.043	3.236	1178.84	5.44	6	0.488
	...bending from side to side	118	-0.717	0.043	1.073	1180.55	5.51	6	0.480
	...walking or moving around	119	-0.381	0.042	-6.926	1177.98	26.88	6	0.000**
	...bending over	120	0.277	0.038	-0.567	1180.55	7.53	6	0.274
	...moderate exercise	121	0.393	0.039	-0.423	1180.55	7.89	6	0.246
	...walking stairs	122	0.587	0.039	-3.591	1179.69	13.08	6	0.042
	...standing for a long time	123	0.620	0.039	3.260	1178.84	9.98	6	0.126

a: Standard error, b: Degree of freedom, c: Probability, \*\*: P-values significant after Bonferroni adjustment.

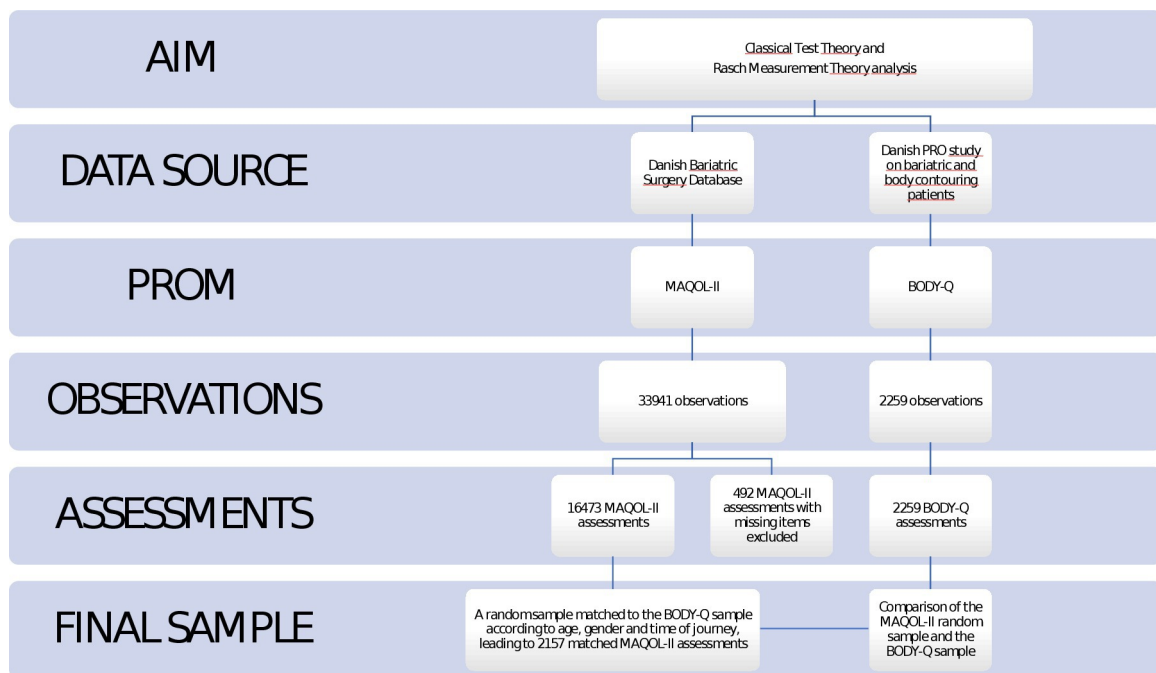
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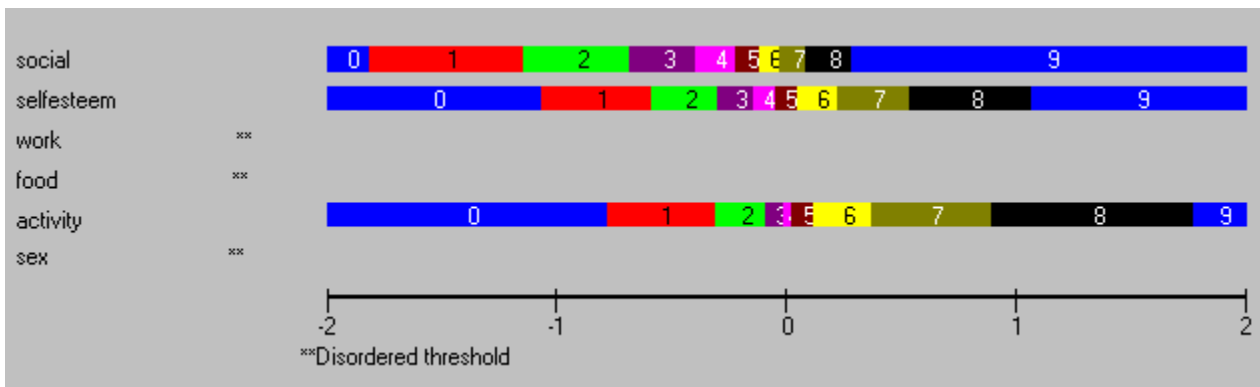
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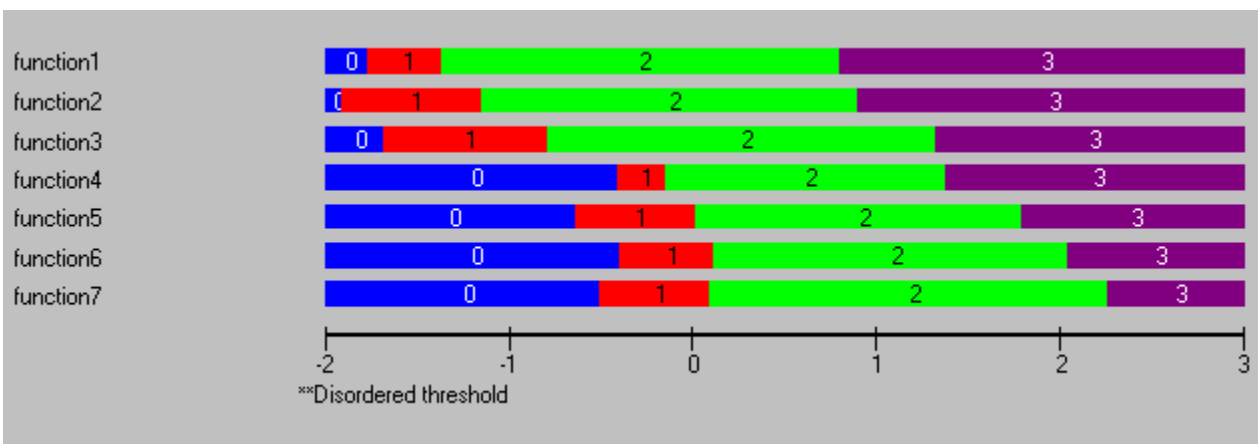
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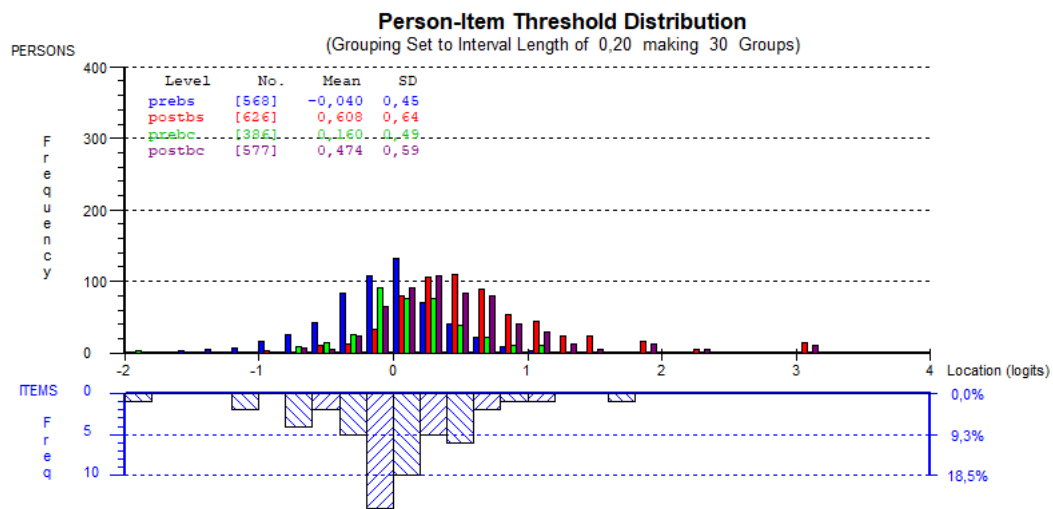


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**Table 1.** Summarized qualitative comparison of MAQOL-II and BODY-Q.

	MAQOL-II	BODY-Q
<b>Construct</b>		
Target population	Bariatric surgery patients	Obese to post-body contouring surgery patients
Number of items	6	163*
Number of subscales	None	21*
Response categories	10 point likert-type scale	4 point likert-type scale
Scoring algorithm	Summed score	Individual scores for each subscale
Recall period	None	1 week
<b>Development</b>		
Patient involvement	No evidence	Clear evidence
<b>Validation</b>	Neither linguistically nor psychometrically validated for use in Danish patients	Linguistically and psychometrically validated for use in Danish patients
* All BODY-Q scales, including patient experience of care scales.		

**Table 2.** Distribution of MAQOL-II and BODY-Q assessments according to number of patients.

No of assessments per patient	MAQOL <sup>a</sup>		BODY-Q <sup>b</sup>	
	Patients (n=9147)	% of total	Patients (n=1425)	% of total
1	3455	38%	918	64%
2	3944	43%	281	20%
3	1466	16%	161	11%
4	209	2 %	42	3%
5	54	1 %	14	1%
6	15	0 %	5	0%
7	4	0 %	4	0%

a: 16,965 MAQOL-II assessments, b: 2,259 BODY-Q assessments



**Table 3a.** MAQOL-II sample characteristics by no of assessments, divided by phase of weight loss journey.

	N	Pre-bariatric surgery (%)	Post-bariatric surgery (%)	Pre-body contouring (%)	Post-body contouring (%)
Assessments (N)	2157	568 (26%)	626 (29%)	386 (18%)	577 (27%)
Age, yr	2149				
Mean (SD)		41.8 (10.0)	43.2 (10.2)	41.1 (10.0)	43.0 (9.4)
Range		17-70	19-72	19-69	20-69
Sex	2152				
Female		422 (75%)	459 (73%)	328 (85%)	518 (90%)
Male		142 (25%)	166 (27%)	58 (15%)	59 (10%)
BMI	2059				
Mean (SD)		45.2 (6.7)	29.7 (5.4)	26.8 (3.7)	26.7 (2.9)
Range		34.0-76.9	17.8-62.6	17.7-54.6	18.1-38.4
BMI (kg/m <sup>2</sup> )	2095				
Normal (18.5-24.9)		0	97 (16%)	117 (31%)	159 (29%)
Overweight (25-29.9)		0	266 (44%)	217 (58%)	323 (59%)
Class I (30-34.9)		2 (0%)	164 (27%)	31 (8%)	66 (12%)
Class II (35-39.9)		120 (22%)	50 (8%)	4 (1%)	3 (1%)
Class III (≥40)		435 (78%)	33 (5%)	4 (1%)	0
Underweight (<18.5)		0	2(0%)	1 (0%)	1 (0%)
Bariatric surgery	2123				
Yes		0	626 (100%)	296 (77%)	453 (81%)
No		557 (100%)	0	87 (23%)	104 (19%)
Type of bariatric surgery	1192				
Gastric Bypass		0	590 (97%)	243 (99%)	335 (99%)
Gastric Sleeve		0	18 (3%)	2 (1%)	4 (1%)

a: Work status is only collected at pre-BS, pre -and post-BC consultation.

**Table 3b.** BODY-Q sample characteristics by no of assessments, divided by phase of weight loss journey.

	N	Pre-bariatric surgery (%)	Post-bariatric surgery (%)	Pre-body contouring (%)	Post-body contouring (%)
Assessments (N)	2231	568 (25%)	626 (28%)	386 (17%)	651 (29%)
Age, yr	2217				
Mean (SD)		41.6 (10.3)	43.2 (9.0)	40.0 (10.0)	43.1 (9.5)
Range		19-73	22-66	16-67	20-75
Sex	2230				
Female	1740	409 (72%)	456 (73%)	306 (79%)	569 (87%)
Male	490	158 (28%)	170 (27%)	80 (21%)	82 (13%)
BMI	2170				
Mean (SD)		46.2 (7.2)	31.8 (5.8)	27.2 (3.6)	26.8 (3.2)
Range		26.1-73.3	18.2-61.7	19.0-48.9	19.1-53.6
BMI kg/m <sup>2</sup>	2170				
Normal (18.5-24.9)		0 (0%)	49 (8%)	108 (29%)	201 (31%)
Overweight (25-29.9)		2 (0%)	208 (35%)	198 (53%)	367 (57%)

Class I (30-34.99)		10 (2%)	175 (29%)	62 (16%)	68 (11%)
Class II (35-39.99)		95 (17%)	121 (20%)	7 (2%)	8 (1%)
Class III ( $\geq 40$ )		443 (81%)	43 (7%)	2 (1%)	2 (0%)
Underweight (<18.5)		0 (0%)	1 (0%)	0 (0%)	0 (0%)
Bariatric surgery	2230				
Yes		0 (0%)	626 (100%)	224 (58%)	434 (67%)
No		568 (100%)	0 (0%)	162 (42%)	216 (33%)
Type of bariatric surgery	1270				
Gastric Banding		0	2 (0%)	5 (2%)	11 (3%)
Gastric Bypass		0	485 (78%)	195 (88)	405 (96%)
Gastric Sleeve		0	137 (22%)	21 (10%)	4 (1%)
Unknown		0	0 (0%)	0 (0%)	0 (0%)
Other		0	1 (0%)	0 (0%)	4 (1%)

**Table 4.** Summarized quantitative comparison of MAQOL-II and BODY-Q.

	<b>MAQOL-II</b>	<b>BODY-Q</b>
Cronbach Alpha (with extremes)	0.82	0.95* (range 0.90-0.98)
PSI (with extremes)	0.79	0.88* (range 0.81-0.93)
Floor (percentage of patients)	0	8* (range 0-46)
Ceiling (percentage of patients)	1	15* (range 1-32)
Disordered items	50 %	0 %
Poor item fit after Bonferroni adjustment	17 % (1 out of 6)	8 % (10 out of 123)
Dependency	None	Minor impact
Targeting	Targeted to sample	Targeted to sample
*Computed mean for the 17 included BODY-Q scales		

## Table and Figure Legends

**Table 1.** Summarized qualitative comparison of MAQOL-II and BODY-Q.

**Table 2.** Distribution of MAQOL-II and BODY-Q assessments according to number of patients.

**Table 3a.** MAQOL-II sample characteristics by no of assessments, divided by phase of weight loss journey.

**Table 3b.** BODY-Q sample characteristics by no of assessments, divided by phase of weight loss journey.

**Table 4.** Summarized quantitative comparison of MAQOL-II and BODY-Q.

**Figure 1.** Flowchart illustrating the origin of the MAQOL-II and BODY-Q samples applied in the quantitative analysis.

**Figure 2a.** MAQOL threshold map showing disordered items and location order.

**Figure 2b.** BODY-Q threshold map for the physical function scale in location order.

**Figure 3.** MAQOL Person-item threshold distribution for time of weight loss journey.

**Appendix 1a.** COSMIN box 1. Standards for evaluating the quality of PROM development.

**Appendix 1b.** COSMIN box 2. Standards for evaluating the quality of content validity studies of PROMs.

**Appendix 1c.** Criteria for content validity – MAQOL-II.

**Appendix 1d.** Criteria for content validity – BODY-Q.

**Appendix 2a.** RMT Scale Performance Statistics for MAQOL-II.

**Appendix 2b.** RMT Statistical Indicators of Item Fit for MAQOL-II.

**Appendix 3a.** RMT Scale Performance Statistics for all included BODY-Q scales.

**Appendix 3b.** RMT Statistical Indicators of item Fit for all included BODY-Q scales.

## TITLE PAGE

**Full title:** Comparison of the Moorehead-Ardelt Quality of Life Questionnaire and the BODY-Q in Danish patients undergoing weight loss and body contouring surgery.

**Short title (max 30 characters incl. space):** The MAQOL-II versus the BODY-Q

**Keywords:** BODY-Q; MAQOL; massive weight loss; bariatric; body contouring; patient-reported outcome measure.

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