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Minimal important difference in weight loss following bariatric surgery: Enhancing BODY-Q interpretability

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Summary

BODY-Q is a patient-reported outcome measure for comprehensive assessment of outcomes specific to patients undergoing bariatric surgery. The clinical utility of BODY-Q is hampered by the lack of guidance on score interpretation. This study aimed to determine minimal important difference (MID) for assessment of BODY-Q. Prospective BODY-Q data from Denmark and the Netherlands pre- and post-bariatric surgery were collected. Two distribution-based methods were used to estimate MID by 0.2 standard deviations of baseline scores and the mean standardized response change of scores from baseline to 3-years postoperatively. In total, 5476 assessments from 2253 participants were included of which 1628 (72.3%) underwent Roux-en-Y

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gastric bypass, 586 (26.0%) sleeve gastrectomy, 33 (1.5%) gastric banding, and 6 (0.03%) other surgeries. The mean age was 45.1 ± 10.9 with a mean BMI of 46.6 ± 9.6. Baseline MID ranged from 1 to 4 in health-related quality of life (HRQL) and from 2 to 8 in appearance scales. The mean change of scores ranged from 4 to 5 in HRQL and from 4 to 7 in the appearance scales. The estimated MID for the change in BODY-Q HRQL and appearance scales ranged from 3 to 8 and is recommended for use to interpret BODY-Q scores and assess treatment effects in bariatric surgery.

KEYWORDS
bariatric surgery, BODY-Q, metabolic surgery, minimal important clinical difference, minimal important difference, patient-reported outcome measure, weight loss surgery

What is already known about this subject

- For accurate assessment of the impact of bariatric surgery on patients' health-related quality of life, the use of reliable and valid condition-specific patient reported outcome measures (PROMs) is essential.
- Among these measures, BODY-Q is recognized for having the strongest psychometric properties for use in patients undergoing medical and surgical weight management treatments.
- The minimal important difference (MID) for PROMs represents the smallest score change considered meaningful. MIDs are crucial for the interpretation and understanding of patients' scores.

What this study adds

- This study is the first to provide BODY-Q MID scores for patients undergoing bariatric surgery. This represents a significant advancement in PROM assessment.
- Previously, the clinical utility of BODY-Q was limited due to the lack of MID scores. This study addresses this gap, facilitating improved interpretation of scores and more effective evaluation of patient progress and the impact of bariatric surgery.
- By establishing MID scores, this study enhances the consistency in synthesizing patient-reported outcomes. It allows clinicians to interpret patient results, monitor progress over time, and engage in more informed shared decision-making with patients more accurately.

1 | INTRODUCTION

Bariatric surgery is recognized as the most effective weight loss therapy for patients living with morbid obesity, resulting in long-term weight loss, remission of obesity-related conditions, and an improvement in health-related quality of life (HRQL).[1] While the effectiveness of bariatric surgery has traditionally focused on weight loss only, it is currently evolving to encompass HRQL as a key outcome measure as well.[2,3] To measure the impact of bariatric surgery on patients' lives and HRQL, it is essential to use reliable and valid patient reported outcome measures (PROMs).[4] BODY-Q is a comprehensive PROM designed specifically to measure patient-reported outcomes (PRO) in patients undergoing bariatric surgery.[5] In recent systematic reviews, BODY-Q possessed the strongest measurement properties for patients seeking medical and surgical weight management treatment.[6,7]

Despite the benefits of BODY-Q, the clinical utility is hampered by the lack of guidance on score interpretation. There is a lack of the minimal important difference (MID) to evaluate patient progress and to demonstrate the magnitude of an intervention's effect, such as bariatric surgery. The MID is defined as the smallest change in score on the construct to be measured.[8,9] Without the MID, it can be difficult to determine whether an observed significant difference or change in BODY-Q scores are clinically meaningful or not, resulting in an inability to draw valid conclusions about the effectiveness of an intervention.[10]

The methodology to estimate the MID can broadly be classified into distribution-based and anchor-based methods. Distribution-based methods estimate the MID based on the distribution of observed scores in a relevant sample, using the variability of scores either between patients (e.g., the standard deviation (SD) of patients at baseline) or within-patient variability (e.g., the SD of the change that patients experience during a study period).[11–13] When using a distribution-based method a reasonable effect size for discriminating change must be determined. Cohen has provided benchmarks for the interpretation of effect sizes: 0.2 for small effects, 0.5 for moderate effects, and 0.8 for large effects.[14] An effect size of 0.2 serve as an appropriate definition of a the MID based on a literature review of Samsa et al.[15] The anchor-based methods use an external, patient-

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based indicator, to compare the change in PRO score to the external anchor.[16,17] The anchor can be a single anchor (individual focused) or multiple anchors (population focused).[11,18,19] As anchor-based methods are patient-centred approaches, they are considered superior to distribution-based methods that rely solely on the statistical properties of a sample.[20] However, the variety and subjectivity of possible anchors, combined with the uncertainty in defining the MID anchor cut point, make determining a single MID estimate challenging.[10] Concurrently, the distribution-based methods offer an easily accessible insight into measurement variability and serve as a starting point for establishing the MID.[21]

The growing interest in measuring PRO in bariatric surgery emphasizes the need of the BODY-Q to be able to detect meaningful changes in patents' lives.[2,3,22] Estimating the MID is crucial to enhance the interpretability of the change in scores of the BODY-Q. The aim of this study was to establish a MID starting point for the BODY-Q in a multinational cohort of patients undergoing bariatric surgery using the distribution-based methods. The MID is essential for accurate assessment of the impact of bariatric surgery on patients' HRQL to provide applicable and valuable information for healthcare professionals, research investigators, and decision-makers.[23,24]

2 | METHODS

Data for this study was extracted from a multicentre, international prospective cohort study investigating change in HRQL and appearance throughout the weight loss trajectory from pre-bariatric surgery to post-bariatric body contouring surgery. The cohort is registered in ClinicalTrials.gov (https://clinicaltrials.gov) with the following identification number: NCT05272215. Only patients undergoing bariatric surgery were included in this study to provide bariatric-specific MIDs. The study was conducted according to the Declaration of Helsinki principles and was approved by the local ethics committee from the respective site prior to study commencement.

2.1 | Study population

The cohort was recruited from the following countries and hospitals: Denmark (Department of Endocrinology, Odense University Hospital, Odense and Department of Endocrinology, Hospital of Southwest Jutland, Esbjerg) and the Netherlands (OLVG West Hospital, Amsterdam, and St. Antonius Hospital, Nieuwegein). Patients aged 18 years or older who visited one of five hospitals were invited to participate in the study. Patients with insufficient proficiency in the Danish or in Dutch language or with cognitive impairments were excluded.

2.2 | Questionnaire administration

Data were collected at baseline (preoperatively) and postoperatively at the following timepoints: 3–6 months, 1 year, 2 years, and 3 years.

In Denmark, patients were recruited between June 2015 and November 2021. Patients received a direct link to the questionnaire through either the Research Electronic Data Capture (REDCap), Open Patient data Explorative Network (OPEN), or Odense University Hospital, through patient's secure electronic mailbox. Patients were also offered the chance to fill out the questionnaire at their hospital appointments in the clinic using an iPad. In the Netherlands, patient was recruited between October 2018 and October 2019. Participants were recruited via a URL link directly in Castor EDC. Patients were encouraged to complete the entire questionnaire. However, as the individual scales making up the BODY-Q function independently, partially completed assessments were also included. Besides the BODY-Q scales, patients were asked to provide the following characteristics: age, gender, weight, height, marital status, educational level, comorbidities prior to bariatric surgery, and type of bariatric surgery. The inclusion period for the two countries differed as the BODY-Q was translated and validated in Denmark and the Netherlands at different times.[25,26] Specifically, the Danish BODY-Q database was established in 2015. Subsequently, the Dutch Obesity Clinic began its data collection for the BODY-Q. Data from the Netherlands was transferred to Denmark in 2019 in accordance with our data transfer agreement.

2.3 | Outcome measure: The BODY-Q

BODY-Q was developed using Rasch Measurement Theory and details regarding the development and validation have previously been published.[5] In brief, BODY-Q consists of four domains, HRQL, appearance, eating-related concerns, and experience of care.[27] The BODY-Q scales were translated into the given language of each country in accordance with recommended guidelines of the International Society for Pharmacoeconomics and Outcomes Research and the World Health Organization.[24,26,28] In this study, the following scales were included: HRQL (psychological, physical function, body image, sexual, and social) and appearance (body, abdomen, arms, back, buttocks, hips and outer thighs, inner thighs, chest, nipples, stretchmarks, and skin).

Each scale of BODY-Q has between four and 10 items, scored on a Likert scale from 1 (i.e., very dissatisfied) to 4 (i.e., very satisfied). The summed raw scores of all items in a scale are transformed using Rasch Conversion Tables to generate a score between 0 and 100. A score of 0 indicates the worst outcome, while 100 indicates the best outcome. There is no total score of the BODY-Q as each scale is scored independently.[5]

3 | STATISTICAL ANALYSIS AND DETERMINATION OF MID

Descriptive statistics including mean, standard deviation, and 95% confidence interval (95% CI) for patient characteristics were computed for continuous variables, and percentages were computed for

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categorical variables. The summed raw BODY-Q scores for each scale, were transformed to Rasch converted scores (from 0 to 100). For all scales, the median and interquartile range (IQR: 25th percentile, and 75th percentile) of the patients' scores were used to generate a score interpretation tool.

To determine the MID for the BODY-Q scales, two distribution-based analyses were performed. First, the sample baseline standard deviation (SD) was used as a measure of the sample variation. In this approach, we choose a conservative threshold to discriminate change, hence one one-fifth of the SD was used as a distribution-based threshold.[15]

The 0.2 SD of preoperative (baseline) BODY-Q scores were determined. The percentage of patients achieving the estimated MID at each timepoint from baseline to 3 years postoperatively was calculated. This method and effect size have previously been used in the BREAST-Q Reconstruction module and for Breast-Conserving Therapy.[29,30] Second, 0.2 of the standardized response change of mean (SRM) from baseline to each postoperative timepoint was used to calculate the change MID. In addition, the MID was also estimated based on Body Mass Index (BMI) groups (BMI <18.49, 18.5–24.9, 25.0–29.9, 30–34.9, 35–39.9, >40 kg/m^2), gender (male and female), and age groups (18–29, 30–39, 40–49, 50–59, >60 years) to evaluate if a separate MID would increase the interpretability of the scores based on stratification of patient characteristics. We used a mixed-effects linear regression model to investigate the impact of patient covariates including age, gender, and BMI on each scale. All data analyses were performed using StataBE Version 17 (College Station, TX, California, United States).

4 | RESULTS

4.1 | Baseline characteristics

In total, the sample consisted of 5476 assessments from 2253 patients of which 73.8% underwent laparoscopic Roux-en-Y gastric bypass (LRYGB), 24.4% underwent laparoscopic sleeve gastrectomy (LSG), 1.4% underwent gastric banding, and 0.1% underwent other surgeries. Participant demographics and characteristics are presented in Table 1. The follow-up period ranged from pre-bariatric surgery to 3 years postoperatively. The cohort consisted of 76% females and 24% males, with a mean age of 45.1 ± 10.9 years and a mean baseline BMI of 45.2 ± 7.5 kg/m^2. Three-years postoperatively, the patients had a mean BMI of 30.4 ± 7.3 kg/m^2.

4.2 | Minimal important difference

Baseline 0.2 SD derived BODY-Q MID scores are presented in Table 2. On the Rasch transformed (0–100) scale, the MID estimate was between 1 and 4 in the HRQL domain and between 2 and 8 in the appearance domain. The MID estimates based on 0.2 SRM from baseline to 3 years postoperatively for the HRQL- and appearance domains are presented in Table 3. The MID estimates for the change from baseline to 6 months, 1-, 2-, and 3-years were between 4 and 7.

4.3 | Proportion of patients with clinically meaningful improvement

Figure 1 shows the median, 25th percentile and 75th percentile BODY-Q scores for each HRQL and appearance scale from baseline to 3 years after bariatric surgery. Additionally, the percentage of patients who achieved MID at each timepoint are presented. In all the scales, the BODY-Q scores improved and stabilized after surgery except for the skin, chest, and nipple scales, where the median was unchanged after surgery and slightly lower 2 years post-bariatric surgery compared to baseline values. See supplementary for the total number of patients in each scale and percentage of patients who achieved the estimated MID (Supplementary 1).

4.4 | BMI stratified minimal important difference

The 0.2 SD from baseline MIDs were stratified in age, BMI, and gender groups presented in Table 4. In all scales, older age was associated with a higher MID score. Overall, there were no differences between male and female participants.

5 | DISCUSSION

In this study, BODY-Q MID estimates were determined for patients undergoing bariatric surgery based on two distribution-based methods. The MID based on SRM from baseline to 3 years postoperatively was between 4 and 5 for HRQL scales and 4 and 7 for the appearance scales, while the baseline MID estimates were between 1 and 4 for HRQL scales and 2 and 8 for appearance scales. Stratifying the MID by BMI and gender showed no overall differences. However, higher age was associated with higher MID scores. To the best of our knowledge, this is the first effort to establish MID for the BODY-Q in a bariatric cohort. Patients, physicians, and research investigators can compare their results with these MID reference values over time, to identify patients who may benefit from potential interventions.

The use of the SRM instead of baseline SD for determining the MID offers a distinct benefit as it includes the variability in change, and thus, does not rely on the baseline heterogeneity of the sample.[18,29,30] Therefore, we currently recommend the use of the mean MID derived from the SRM from baseline to 3 years postoperatively shown in Table 3 for research and clinical use. This study contributes with a conservative starting estimate for the MID with the use of a Cohens' small effect size of 0.2 as used in the BREAST-Q MID studies.[29,30] Figure 1 shows that most patients achieved the MID estimates determined from 0.2 SRM with HRQL ranging from 59% (sexual) to 93% (body image) and the appearance scales from 29% (skin) to 96% (body). In all scales, BODY-Q scores improved and

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TABLE 1 Participant characteristics.

Characteristics	Total	Netherlands	Denmark
Patients *n* (%)	2253	697 (30.1)	1556 (69.1)
Assessments *n* (%)	10 355	7088 (68.5)	3267 (31.5)
Gender *n* (%)	2253	697	1556
Female	1711 (75.9)	571 (81.9)	1140 (73.3)
Male	542 (24.1)	126 (18.1)	416 (26.7)
Other	0 (0)	0 (0)	0 (0)
Age	2139	583	1556
Mean (SD)	45.1 (10.9)	44.6 (11.4)	45.6 (10.3)
Minimum: Maximum	18.0; 78.2	18.0; 68.1	21.3; 78.2
Age group	2139	583	1556
17–29	227 (10.6)	90 (15.4)	137 (8.8)
30–39	513 (24.0)	114 (19.6)	399 (25.6)
40–49	652 (30.5)	172 (29.5)	480 (30.8)
50–59	587 (27.4)	168 (28.8)	419 (26.9)
>60	160 (7.5)	39 (6.7)	121 (7.8)
Missing	114	114 (19.5)	0
BMI (baseline)	2075	583	1492
Mean (SD)	46.6 (9.61)	43.9 (7.91)	49.3 (11.23)
Minimum: Maximum	30.1; 79.7	30.8; 67.9	30.1; 79.7
BMI groups	2075	583	1492
<18.49	0 (0)	0 (0)	0 (0)
18.5–24.9	1 (0.04)	1 (0.1)	0 (0)
25–29.9	10 (0.5)	3 (0.5)	7 (0.5)
30–34.9	30 (1.4)	9 (1.5)	21 (1.4)
35–39.9	351 (16.9)	135 (23.2)	216 (14.5)
>40	1683 (81.1)	435 (74.6)	1248 (83.6)
Missing	178	114	64
Comorbidities *n* (%)	2253	697	1556
Diabetes	266 (11.8)	86 (12.3)	180 (11.6)
Hypertension	350 (15.5)	174 (25.0)	176 (11.3)
Hyperlipidaemia	117 (5.1)	75 (10.8)	42 (2.7)
Obstructive sleep apnoea	294 (13.0)	204 (29.3)	90 (5.8)
Osteoarthritic disease	253 (11.2)	109 (15.6)	144 (9.3)
Cardiovascular or coagulation disease	101 (4.5)	69 (9.9)	32 (2.1)
Psychiatric	141 (6.3)	141 (20.2)	-
Reflux disease	223 (9.9)	223 (32.0)	-
No medical condition	994 (4.4)	213 (30.6)	781 (50.2)
Missing	0	0	0
Educational level *n* (%)	2109	558	1551
Elementary	54 (2.6)	21 (3.8)	33 (2.1)
Attending high school	350 (16.6)	78 (14.0)	272 (17.5)
High school diploma	510 (24.2)	238 (42.7)	473 (30.5)
Some college-, trade-, or university degree	336 (15.9)	148 (26.5)	324 (20.9)
University bachelor's degree	627 (29.7)	37 (6.6)	389 (25.1)
University master's degree	201 (9.5)	12 (2.2)	53 (3.4)
Doctoral degree	31 (1.5)	24 (4.3)	7 (0.4)
Missing	144	139	5
Marital status *n* (%)	2109	559	1550
Married	976 (46.3)	271 (48.5)	705 (45.5)
Living common law/relationship	501 (23.8)	127 (22.7)	374 (24.1)
Widowed	17 (0.8)	8 (1.4)	9 (0.6)
Separated/divorced	217 (10.3)	60 (10.7)	157 (10.1)
Single	398 (18.9)	93 (16.6)	305 (19.7)
Missing	145	139	6
Type of weight loss surgery	2253	697	1556
LRYGB (gastric bypass)	1628 (72.3)	430 (61.7)	1.198 (77.0)
LSG (gastric sleeve)	586 (26.0)	249 (35.7)	337 (21.7)
Gastric banding	33 (1.5)	14 (2.0)	19 (1.2)
Other	6 (0.03)	4 (0.06)	2 (0.01)

Abbreviations: %, indicates the proportion of patients; *n*, number of patients; SD, standard deviation.

TABLE 2 Baseline minimal important differences.

	Appearance			
Scales	*N*	SD	0.2 SD	MID estimate 0.2
Body	2065	12.85	2.57	3
Abdomen	2090	10.36	2.07	2
Back	2067	23.54	4.71	5
Buttocks	2058	23.00	4.60	5
Arms	2073	22.87	4.57	5
Inner thighs	2052	20.89	4.18	4
Hips and outer thighs	2044	22.76	4.55	5
Chest	415	17.98	3.60	4
Nipples	409	28.80	5.76	6
Stretch marks	1723	28.07	5.61	6
Skin	1031	38.67	7.73	8
	Health-related quality of life			
Scales	*N*	SD	0.2 SD	MID estimate 0.2
Psychological	1684	6.40	1.28	1
Social	1684	5.47	1.09	1
Sexual	1656	5.42	1.08	1
Physical	1679	9.22	1.84	2
Body image	1683	6.23	1.25	1

Abbreviations: MID, minimal important difference; *N*, number of patients; SD, standard deviation.

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TABLE 3 Standardized response mean.

BODY-Q Timepoint after BS	Psychological			Social			Sexual			Physical			Body image		
	N	0.2 SRM	MID estimate	*N*	0.2 SRM	MID estimate	*N*	0.2 SRM	MID estimate	*N*	0.2 SRM	MID estimate	*N*	0.2 SRM	MID estimate
6 months	440	4.25	4	438	3.64	4	411	4.29	5	439	5.00	5	438	4.50	5
1-Year post-BS	457	4.92	5	456	3.90	4	427	4.79	5	455	5.52	6	456	4.91	5
2-Years post-BS	375	4.67	5	376	4.00	4	346	5.01	5	374	5.28	5	375	5.29	5
3-Years post-BS	92	4.78	5	91	4.09	4	72	4.48	5	93	5.13	5	94	5.55	6
Mean			5			4			5			5			5

BODY-Q BS	Body			Abdomen			Back			Buttocks			Arms			Inner thighs			Hips and outer thighs		
Timepoint	*N*	0.2 SRM	MID estimate	*N*	0.2 SRM	MID estimate	*N*	0.2 SRM	MID estimate	*N*	0.2 SRM	MID estimate	*N*	0.2 SRM	MID estimate	*N*	0.2 SRM	MID estimate	*N*	0.2 SRM	MID estimate
6 months post-BS	454	4.30	4	468	4.80	5	459	5.86	6	450	5.19	5	465	4.47	5	446	5.02	5	450	5.72	6
1-Year post-BS	486	4.30	4	493	4.88	5	484	5.95	6	478	5.55	6	486	4.34	4	475	5.03	5	472	5.89	6
2-Years post-BS	400	4.41	4	412	5.56	6	400	6.16	6	395	5.80	6	409	4.27	4	393	5.54	6	394	5.93	6
3-Years post-BS	100	4.98	5	109	6.07	6	104	5.75	6	98	5.94	6	106	4.76	5	97	5.29	5	95	6.35	6
Mean			4			6			6			6			5			5			6

BODY-Q BS Timepoint	Nipples			Chest			Stretch Marks			Skin		
	N	0.2 SRM	MID estimate	*N*	0.2 SRM	MID estimate	*N*	0.2 SRM	MID estimate	*N*	0.2 SRM	MID estimate
6 months post-BS	71	5.34	5	73	4.43	4	365	5.18	5	274	6.75	7
1-Year post-BS	79	5.14	5	80	4.77	5	386	4.95	5	263	5.83	6
2-Years post-BS	65	5.22	5	65	4.66	5	312	5.32	5	240	6.25	6
3-Years post-BS	12	5.14	5	12	4.67	5	59	6.18	6	77	7.78	8
Mean			5			5			5			7

Abbreviations: MID, minimal important difference; *N*, number of patients; post-BS, post bariatric surgery; SRM, standardized response mean.

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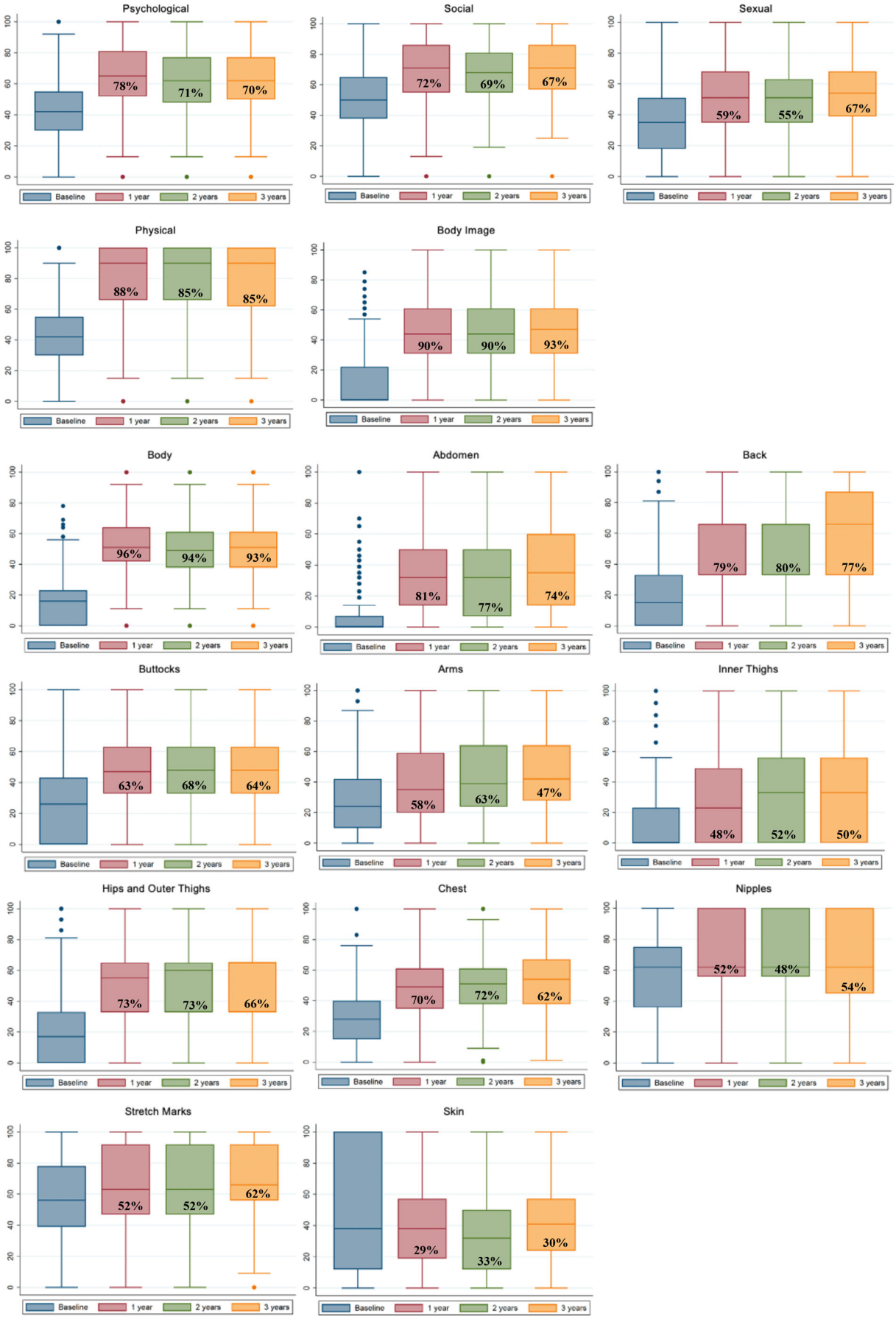

FIGURE 1 BODY-Q scores from baseline to 3 years after bariatric surgery.

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TABLE 4 Gender, age, and BMI stratified minimal important differences.

		Body		Abdomen		Arms		Back		Buttocks		Hips		Thighs		Stretch Marks		Skin	
		N	MID	*N*	MID	*N*	MID	*N*	MID	*N*	MID	*N*	MID	*N*	MID	*N*	MID	*N*	MID
Age	17–29	136	2	136	1	135	3	135	3	135	4	136	4	136	2	135	5	39	6
	30–39	396	2	396	2	394	4	395	4	396	4	396	4	395	3	395	5	131	4
	40–49	478	3	475	2	476	5	474	4	475	5	474	5	474	4	439	5	168	5
	50–59	413	2	412	2	411	5	411	4	411	5	411	5	411	4	342	6	144	4
	>60	121	3	121	2	121	5	120	5	120	5	121	5	119	5	78	5	35	4
BMI	<18.5	0	–	0	–	0	–	0	–	0	–	0	–	0	–	0	–	0	–
	18.5–24.9	0	–	0	–	0	–	0	–	0	–	0	–	0	–	0	–	0	–
	25–29.9	6	1	6	1	6	1	6	2	6	1	6	1	6	1	6	0.2	6	2
	30–34.9	21	1	21	1	21	1	21	2	21	2	21	1	21	0.5	19	1	10	4
	35–39.9	214	2	213	1	213	1	212	2	213	2	213	3	212	2	177	2	82	5
	>40	1241	1	1239	1	1236	1	1233	2	1236	1	1237	2	1234	2	1132	1	402	4
Gender	Female	1571	3	1591	2	1577	4	1574	4	1566	4	1555	4	1562	3	1347	6	863	8
	Male	494	3	499	2	496	5	493	5	492	5	489	5	490	5	376	6	168	8

		Psychological		Physical		Sexual		Social		Body Image	
		N	MID	*N*	MID	*N*	MID	*N*	MID	*N*	MID
Age	17–29	135	4	135	4	133	4	135	3	135	3
	30–39	395	4	395	4	388	4	395	4	393	3
	40–49	470	4	470	4	470	5	472	4	472	3
	50–59	410	4	409	4	403	5	411	4	410	3
	>60	121	4	121	6	120	5	121	4	120	3
BMI	<18.5	0	–	0	–	0	–	0	–	0	–
	18.5–24.9	0	–	0	–	0	–	0	–	0	–
	25–29.9	6	1	6	1	6	1	6	3	6	3
	30–34.9	21	2	21	3	21	2	21	1	21	1
	35–39.9	212	2	208	3	210	1	212	2	213	1
	>40	1232	1	1230	2	1217	1	1234	1	1230	1
Gender	Female	1553	4	1549	4	1515	5	1544	4	1549	3
	Male	485	4	485	4	469	5	486	4	484	3

Abbreviations: BMI, body mass index; MID, minimal important difference; *N*, number of patients.

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stabilized after surgery except for the skin scale, where the score median was unchanged after surgery, and in fact slightly lower 2 years after surgery compared to baseline values. This might be due to the fact that most of these patients did not undergo post-bariatric body contouring surgery at the time of measurement. In a recent up to 10-year longitudinal follow-up, our team showed, that patients who did not undergo body contouring after bariatric surgery reported lower HRQL and satisfaction with appearance.[31]

Previous studies investigating the effect of bariatric surgery on HRQL, and appearance showed improvement after bariatric surgery across various scales of the BODY-Q. The clinical relevance of these effect sizes, however, were limited by the inability to compare the change in scores with reference values.[3,32–34] Consequently, the BODY-Q normative scores were determined to facilitate the comparison of patients undergoing bariatric surgery and reference values derived from the general population.[35,36] However, despite this development, the magnitude of a clinically relevant change in BODY-Q scores for patients undergoing bariatric surgery remained unknown. Together with the BODY-Q normative reference values, the MID reported in this paper can enhance the interpretability of the BODY-Q by providing a context for understanding the meaning and significance of changes in the scores.[37] For clinicians, the MIDs can be used to better understand patient's perception of HRQL and satisfaction with appearance, monitor patient progress over time, and evaluate the impact and efficacy of different treatments.[20] Overall, the use of MIDs to interpret scores can aid in shared decision-making and improve patient care. Additionally, research investigators can use the MIDs in future studies to guide the calculation of sample size and help interpret results.[29]

This study only generates the MID for patients undergoing bariatric surgery. The strengths of this study include the use of a reliable, psychometrically validated, and responsive condition-specific PROM in a large multinational cohort for the MID estimation of the BODY-Q scales. The large sample size of 2253 patients should not influence the magnitude of the MID, as it is expressed as an average variation around a mean value.[18] Furthermore, we accounted for the potential different clinical characteristics (BMI, gender, age) by performing subgroup analyses, and verified that BMI and gender did not impact the MID estimates, only higher age was associated with higher MID estimates.

The study had some limitations that must be acknowledged. First, the use of a distribution-based method to estimate the MID, solely based on statistical measures, may not capture the clinical significance of the change in PRO.[24] The U.S. Food and Drug Administration (FDA) recent guidance recommend the use of either the anchor-based method or a combination of multiple methods, as the change in HRQL is linked to a meaningful external anchor, and hence incorporates the patient's perspective.[24] However, one of the limitations of anchor-based methods are the selection of appropriate anchors, as the subjective choice of individual patients may not be generalizable.[20] The distribution-based method has been criticized by the use of sample variability that may differ from study to study, and therefore not necessarily reflect the patient's perspective.[20,24] Due to this limitation, the 0.2 SRM was estimated and recommended, which is not dependent on the sample's baseline heterogeneity.[18,38] Furthermore, the results of three centres located in two different countries were combined in this study to increase the generalizability of the minimal important estimates.

In future, a combined distribution-based and anchor-based method should be applied due to the limitations of each method, hence we acknowledge that future studies may demonstrate different MID values.[20] However, until the minimally important values obtained through the anchor-based method become available, the estimates presented in this study is recommended for use.

6 | CONCLUSION

The estimated BODY-Q MID scores from baseline to 3 years postoperatively ranged between 3 and 5 for the HRQL and between 4 and 8 for the appearance domain. These clinical reference values provide valuable information for the interpretation of BODY-Q scores in future studies, improving the utility of this PROM as a tool for clinical research and patient care. Further studies should be performed using a combined distribution-based and anchor-based method to compare with the estimates in this study.

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CONFLICT OF INTEREST STATEMENT

The BODY-Q is co-developed by Stefan Cano, Anne F. Klassen, and Andrea L. Pusic, and they all receive a share of any licence revenues based on their institutions inventor sharing policy. Stefan Cano is CSO of Modus Outcomes, a Division of Thread. Anne F. Klassen is the owner of EVENTUM Research which provides consulting services to the pharmaceutical industry. The remaining authors declare no conflicts of interest.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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Minimal important difference in weight loss following bariatric surgery: Enhancing BODY-Q interpretability

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Supplementary

Supplementary 1 - Total number of patients in each scale and percentage of patients who achieved the estimated minimal important differences

HRQL	Timepoint	MID	N	N achieved MID	% achieved MID
Psychological	1 year	5	400	313	78
	2 years	5	300	212	71
	3 years	5	76	53	70
Social	1 year	4	396	285	72
	2 years	4	297	204	69
	3 years	4	73	49	67
Sexual	1 year	5	364	215	59
	2 years	5	262	144	55
	3 years	5	55	37	67
Physical	1 year	6	397	358	88
	2 years	5	299	269	85
	3 years	5	75	70	85
Body Image	1 year	5	397	350	90
	2 years	5	298	253	90
	3 years	6	78	66	93

Appearance	Timepoint	MID	N	N achieved MID	% achieved MID
Body	1 year	4	416	400	96
	2 years	4	304	285	94
	3 years	4	88	82	93
Abdomen	1 year	5	430	350	81
	2 years	6	315	241	77
	3 years	6	97	72	74
Back	1 year	6	421	334	79
	2 years	6	309	246	80
	3 years	6	93	72	77
Buttocks	1 year	6	414	261	63
	2 years	6	303	206	68
	3 years	6	87	56	64
	1 year	4	424	244	58

Arms	2 years	4	312	195	63
	3 years	5	94	44	47
Inner thighs	1 year	5	413	200	48
	2 years	6	304	158	52
	3 years	5	84	42	50
Hips and outer thighs	1 year	6	411	302	73
	2 years	6	301	220	73
	3 years	6	83	55	66
Chest	1 year	5	64	45	70
	2 years	5	46	33	72
	3 years	5	13	8	62
Nipples	1 year	5	63	33	52
	2 years	5	44	21	48
	3 years	5	13	7	54
Stretch marks	1 year	5	319	167	52
	2 years	5	223	117	52
	3 years	6	47	29	62
Skin	1 year	6	195	57	29
	2 years	6	147	49	33
	3 years	8	63	19	30

HRQL = Health-related quality of life, MID = minimal important difference, N = number

The supplementary shows the number of patients (N achieved MID) who achieved the estimated minimal important difference (MID) score and the percentage of patients who achieved MID (% achieved MID) in each scale.