Measuring Outcomes Relevant to the Décolletage From the Patient Perspective: Development and Validation of the BODY-Q Décolletage Scale

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Abstract

Background: A range of cosmetic treatments to improve skin quality of the décolletage are available. To measure outcomes from the patient perspective, a rigorously developed patient-reported outcome measure (PROM) is needed.

Objectives: The aim of this study was to develop and validate the BODY-Q Décolletage scale.

Methods: Appearance-related codes from BODY-Q concept elicitation interviews were re-examined and 13 items drafted and refined through qualitative interviews with patients and clinicians. The scale was tested in an online international sample of women aged ≥25 years who had previously received a treatment for the décolletage, or in the past 12 months had received a cosmetic treatment at a plastic surgery or dermatology clinic. Data were analysed with both Rasch measurement theory and classical test theory. Construct validity involved testing 20 hypotheses. Convergent validity tests included correlations between the décolletage scale and other BODY-Q scales and the SKIN-Q.

Results: Interviews conducted with 15 patients and 5 clinicians led to a 16-item scale with items that covered scenarios (mirror, photographs, low neckline, lay on side, breasts together, arms crossed, get up, up close), comparisons (with other people), age concerns (youthful, age), qualitative concerns (attractive, healthy), skin tone (even-colored), and texture (smooth, texture). The field test included 334 participants. An item with poor fit to the Rasch model was dropped. Data for the remaining 15 items fit the Rasch model ($\chi^2 = 76.72$, df = 60, P = .07). All items had ordered thresholds and good item fit. All reliability statistics were >0.93. A total of 19 of 20 predefined hypotheses (95%) were met, providing evidence of construct validity.

Conclusions: The BODY-Q Décolletage scale is available to incorporate the perspective of patients into clinical care and clinical trials of minimally invasive treatments to improve skin quality.

The décolletage has delicate skin that can prematurely age and be damaged through sun exposure. Signs of aging in this area include fine lines and wrinkles, loose skin, and hyperpigmentation. Treatments to improve décolletage skin quality are available, such as injectables, chemical peels, lasers, and light therapies. To measure the outcomes of aethestic treatments that aim to improve how the décolletage looks from the patient perspective, a patient-reported outcome measure (PROM) is needed.

The BODY-Q is a widely used PROM designed to measure outcomes of people who undergo weight loss through diet, exercise, bariatric surgery or medicine, and body contouring following weight loss or for cosmetic improvements. This PROM (Figure 1) is composed of 30 published independently functioning scales and checklists that can be used in research or clinical care to measure appearance, eating concerns, health-related quality of life, and experience of care from the patient perspective. The BODY-Q was singled out in 2018 as the PROM with the strongest evidence for quality of measurement properties of 24 PROMs for bariatric surgery and body contouring. With numerous translations available, BODY-Q is increasingly used around the world to inform patient care and in clinical research studies. To aid in the interpretation of BODY-Q scores for

weight loss and body contouring, minimally important differences^{14,15} and population norms have been published.¹⁶

The modular approach taken to develop the BODY-Q makes it possible to add new scales to measure concepts of interest not covered by existing scales. An area of the body for which there is no BODY-Q scale is the décolletage. To fill this gap, our team re-examined qualitative codes from the original 63 patient interviews and drafted 13 potential scale items for further testing. The aim of the present study was to refine the draft scale based on patient and expert input, and to field test the scale in an international online sample of women aged 25 or older who had been to a plastic surgeon or dermatology for any

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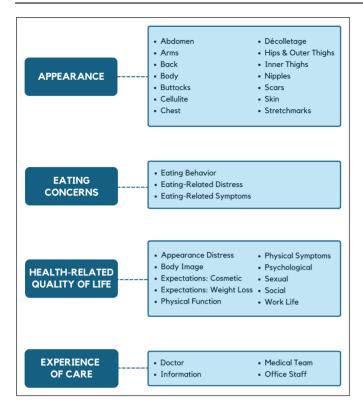


Figure 1. BODY-Q conceptual framework.

form of cosmetic treatment in the past 12 months, or who had previously had a cosmetic treatment to improve the appearance of their décolletage.

METHODS

Elsewhere we describe the development and validation of the BODY-Q, 7-12,16 which adhered to PROM development guidelines. 17-21 To develop the décolletage scale, a mixed-methods study was conducted. In a qualitative study, we re-examined the general and specific appearance codes from the original set of 63 coded BODY-Q qualitative interviews. Thirteen items were drafted and content validity was established through multiple rounds of interviews with patients and clinicians. In a quantitative study, we used Rasch measurement theory (RMT) and classical test theory (CTT) to analyze data collected for the décolletage scale. Both of these studies are described below in detail.

Qualitative Study

The qualitative study used an interpretive description approach, which presumes theoretical knowledge, clinical knowledge, and a scientific basis underlying a study.²² Ethics board approval was granted by the Copernicus Group IRB in the United States.

Recruitment of patients took place at 1 plastic surgery and 3 dermatology clinics in the United States. At each site, a research coordinator was instructed to recruit a diverse sample of women that varied by age, ethnicity, and severity of wrinkling in the upper chest area. Inclusion criteria were adult females able to read and speak English, seeking or had had a minimally invasive treatment to improve appearance of the décolletage, and willing and able to participate in a telephone interview lasting about 60 minutes. Recruitment took place between September 2020 and November 2020.

Research coordinators approached eligible participants and introduced the study. If the patient was interested in taking part, permission was sought to pass on their contact details to the research team. The interviewer contacted participants, explained the study in detail, ensured that the signed informed consent was returned, and scheduled a telephone interview. Clinicians were also recruited to provide feedback on the scale to ensure that clinically relevant concepts were included. Clinicians signed a consent letter prior to the interview. All interviews were conducted over the telephone by a highly skilled qualitative researcher. Recruitment continued until the point of saturation, which was when no new concepts were elicited in subsequent interviews.²³ Interviews took place between September and November 2020.

At the start of an interview, consent was reconfirmed, as was permission to record the interview. Each interview consisted of 2 parts. For patients, Part 1 was open-ended and included 5 questions with probes to elicit concepts related to the appearance of their décolletage. For clinicians, Part 1 included 2 questions to elicit concepts related to the décolletage before and after treatment. Appendix A shows the interview questions. In Part 2, a cognitive debriefing interview was conducted²⁴ using the "think aloud" approach²⁵ to understand thought processes as participants read through the draft scale.

Audio-recordings were transcribed verbatim in Microsoft Word (Redmond, WA) with all identifiable information removed. Patients were provided with a gift card worth US\$100 to thank them for their time, and clinicians were compensated for an hour of their time. Data collection and analysis took place in rounds to allow for changes to be made to the décolletage scale between rounds. Part 1 data were coded by one team member and checked by a second team member. Coding discrepancies were resolved through consensus. Codes from the transcripts were moved to Microsoft Excel for constant comparison to ensure consistency across codes. ²⁶ For Part 2 data, codes that pertained to any aspect of the décolletage scale were examined and used to make revisions to the scales as needed.

Quantitative Study

Ethics board approval was granted by the Hamilton Integrated Ethics Board (Canada) (No. 13603) at McMaster University ahead of the field test. Survey data were collected from a Prolific Academic (London, UK; www.prolific.co) sample using REDCap.²⁷ Data collection took place in June and July 2024.

To identify a sample, women aged 25 years or older, fluent in English and residing in the United States, Canada, the United Kingdom, Ireland, Australia, or New Zealand, were invited to complete a short screening survey. The denominator for participants active on the platform in the past 90 days who met these criteria was 56,652. The screening survey defined the décolletage area as the area of skin that shows in a low neckline (ie, below the collarbone and above the breasts) and provided an image. Two screening questions were asked as follows:

- 1. In the past 12 months, have you been to a Dermatology or Plastic surgery clinic for any type of cosmetic treatment (eg, Botox, filler, skin laser, skin tightening)?
- 2. Have you ever been to a Dermatology or Plastic Surgery clinic for a cosmetic treatment for your upper chest area (ie, décolletage)?

Anyone who answered yes to either of the screening questions was invited to complete the full REDCap survey.

At the start of the survey, participants were asked to read the consent form and to provide their consent. The survey included

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Table 1. Psychometric Tests Performed

Test	Description
Thresholds for item responses	Item response options need to be ordered on a continuum (eg, a score of 1 lower than a score of 2) to create a hierarchy of items.
Item fit	Item fit to the Rasch model was assessed by examining fit residuals and χ^2 statistics. Fit residuals summarize the sample's observed and expected responses to items. Values ideally lie within the range -2.5 and $+2.5$. Items with χ^2 values significant after adjusting with the Bonferroni adjustment were dropped.
Local dependency	Any correlations of residuals >0.20 above the average correlations were included in a subtest analysis to determine the impact of local dependency on scale reliability. ³⁰
Scale-to-sample targeting	We examined the spread of person locations (ie, satisfaction with décolletage) and item locations (ie, range of the items measuring satisfaction). A better targeted scale has more coverage with the mean person location close to the scale centre. 31 We also computed the proportion of the sample that scored on scale.
DIF	We examined DIF by age (ie, 25-39, 40-49, 50-49, ≥60 years) and country (US and UK). This test uses ANOVA to examine estimated person ability differences between class intervals within subgroups. Even-sized random samples were selected and DIF was repeated 3 times to see if the result was stable. When DIF was identified, variables were split for the relevant items, and the original and split person locations correlated to examine the impact on scale scoring. 32
Reliability	 Person Separation Index—this statistic determined how well people in the sample were separated by the scale items.³³ Cronbach α—this statistic was used to examine internal reliability. Test-retest reliability—a subset of participants completed the survey twice 7 days after the initial assessment. Anyone who reported an important change in satisfaction with their décolletage or had treatment for the décolletage were excluded. Intraclass correlation coefficients with a 2-way random effects model were used to evaluate consistency. Reliability values should be >0.70.^{34,35}
Construct validity	Rasch logit scores were transformed from 0 (least satisfied) to 100 (most satisfied). Statistical significance was set at a 2-tailed <i>P</i> -value of <.05. Predefined hypotheses were tested with acceptance of >75% of the hypotheses providing sufficient evidence of validity. ANOVA or independent <i>t</i> -test were used to test for differences between groups. Hypotheses are provided in Appendix J. Participants were asked the following questions: 1. How HAPPY are you with how your upper chest area (ie, décolletage) LOOKS OVERALL? 2. How does your upper chest area (décolletage) look compared with other people your age? 3. Thinking ONLY of your UPPER CHEST area (décolletage): Please choose one answer that best describes your CURRENT situation in regards to cosmetic treatment (eg, filler, skin tightening, skin resurfacing) for your UPPER CHEST (décolletage). 4. Does the SKIN in your upper chest area (décolletage) look WRINKLED? 5. How BOTHERED are you by WRINKLY SKIN on your upper chest area (décolletage)? 6. Does the SKIN in your upper chest area (décolletage) look SMOOTH? 7. How SATISFIED are you by how SMOOTH the SKIN in your upper chest area (décolletage) looks? 8. Does the SKIN in your upper chest area (décolletage) have an EVEN SKIN TONE? By EVEN SKIN TONE we mean skin has an even color and has no discoloration (eg, sunspots, age spots). 9. How BOTHERED are you by any DISCOLORATION (eg, sunspots, age spots) on your upper chest area (décolletage)? 10. Which picture BEST matches how your upper chest area (décolletage) looks when you are AT REST? 11. Which picture BEST matches how your upper chest area (décolletage) looks when you ACTIVE? 12. Which picture BEST matches how your upper chest area (décolletage) looks when you ACTIVE? 13. Which picture BEST matches how your upper chest area (décolletage) looks when you ACTIVE? 14. Which picture BEST matches how your upper chest area (décolletage) looks when you ACTIVE? 15. Which picture BEST matches how your upper chest area (décolletage) looks when you ACT
Convergent validity	SKIN-Q item libraries and short-form scales measure similar constructs and would correlate with an <i>r</i> > .5 with the décolletage scale. BODY-Q Body Image and Psychological Function scales measure dissimilar but related constructs to the décolletage scale and would correlate with an <i>r</i> between .3 and .5. ³⁴

ANOVA, analysis of variance; DIF, differential item functioning.

demographic and clinical questions followed by validated Merz photonumeric scales that measure severity (ie, none, mild, moderate, severe, very severe) of décolletage wrinkles at rest, wrinkles when active, and pigmentation in the décolletage skin. ²⁸ To examine construct validity, participants completed the BODY-Q Body Image and Psychological Function scales, ⁸ and the SKIN-Q, a PROM that measures satisfaction with how the skin feels and looks in terms of 2 item libraries and 5 short-form scales. ²⁹ For the SKIN-Q, participants were instructed to answer based on their décolletage skin.

At the end of the survey, participants were asked (yes/no) if they would complete the décolletage scale again in 7 days for a test-retest study. The test-retest asked participants if in the past week they had had any cosmetic treatments for their décolletage (yes/no), and if

there had been any important change in their satisfaction with their décolletage area (yes/no).

Table 1 shows the RMT^{30-33,36,37} and CTT^{34,35} psychometric tests conducted to examine item and scale performance. RMT analysis was performed with RUMM2030 software (Perth, Australia)³⁸ and the unrestricted Rasch model for polytomous ordered responses. Any items with extreme misfit to the Rasch model were removed. Person locations from the Rasch analysis were used to transform the décolletage scale scores into 0 (most dissatisfied) to 100 (most satisfied) scores. The BODY-Q and SKIN-Q item libraries and short-form scales were transformed according to the User Guide instructions (higher scores = better outcome) and used in test-retest analysis and construct validation tests shown in Table 1.

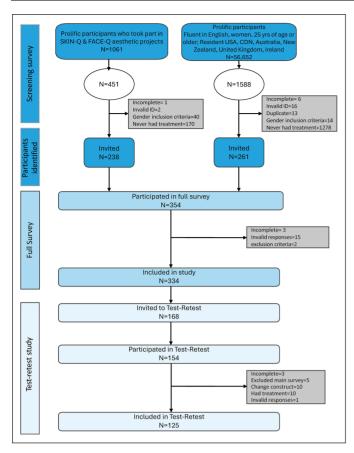


Figure 2. Study recruitment.

RESULTS Qualitative Study

Fifteen patients and 5 clinical experts were interviewed. Interviews took place in 4 rounds, with 5 participants in each round. The first 3 rounds included patients, and the final round included experts.

The patient sample included women aged 27 to 69 years. Thirteen participants were White and 2 were Hispanic. Most patients were married, had completed a university degree, and were employed. Fourteen women had undergone a treatment of their décolletage in the past, with the most common treatment being Sculptra (n = 7). At the time of the interview, 1 woman was not bothered by her décolletage appearance, 7 were mildly bothered, 5 were moderately bothered, and 2 were extremely bothered. Four experts were from the United States and 1 was from Germany. Experts had a minimum of 13 and maximum of 35 years of experience and ranged in age from 39 to 68 years.

Part 1 interview data provided 576 (403 unique) appearance codes and 83 (38 unique) skin texture codes. These codes provided evidence of content validity for drafted items as well as new concepts that were developed into items for testing. Example codes are provided in Appendix C.

Appendix D shows the participant-level findings for instructions, timeframe, responses, scale length, and perceived importance of the concept of interest. After Rounds 1 and 4, the instructions were modified to provide a more precise description of the décolletage area. The revised instructions were deemed easy to understand by the subsequent patients and the 5 experts. No changes were made to the timeframe response options, which were deemed

Table 2. Demographic Characteristics for the Field Test Sample

Characteristic	Categories	n	%
Age groups (years)	25-39	85	25.4
	40-49	89	26.6
	50-59	99	29.6
	≥60	61	18.3
Country	United States	154	46.1
	Canada	27	8.1
	United Kingdom	110	32.9
	Australia	39	11.7
	New Zealand	4	1.2
Fitzpatrick skin type	Always burn and never tan	31	9.3
	Usually burn and minimally tan	108	32.3
	Sometimes get a mild burn and tan uniformly	141	42.2
	Rarely burn and always tan	36	10.8
	Rarely burn and tan very easily	16	4.8
	Never burn and never tan	2	0.6
Education	Some/completed high school	31	9.3
	Some college or trade school or university	48	14.4
	Completed college or trade school or university degree	155	46.4
	Some masters or doctoral degree	30	9.0
	Completed masters or doctoral degree	67	20.1
	Prefer not to answer	3	0.9
Difficulty covering household expenses and bills in past 3	Not at all difficult	123	36.8
months	A little difficult	111	33.2
	Somewhat difficult	66	19.8
	Very difficult	20	6.0
	Extremely difficult	8	2.4
	Prefer not to answer	6	1.8
Race	White		82.3
	Black	24	7.2
	East Asian	7	2.1
	Other	15	4.5
	Multiple races	13	3.9
Marital status	Never married	67	20.1
	Separated	5	1.5

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Table 2. Continued

Characteristic	Categories	n	%
	Divorced	50	15
	Widowed	7	2.1
	Living common-law	28	8.4
	Married	172	51.5
	Other	5	1.5

Table 4. Statistical Indicators of Item Fit to the Rasch Model

Item	Location	SE	Fit Residual	df	χ²	df	Р
Compared	-1.20	0.11	0.12	303	11.40	4	.02
Smooth	-0.65	0.12	-1.75	303	1.33	4	.86
Healthy	-0.37	0.11	-0.07	303	1.90	4	.75
Age	-0.29	0.11	-2.05	303	3.64	4	.46
Photograph	-0.16	0.11	-1.60	303	1.65	4	.80
Low neckline	-0.15	0.11	-2.42	303	6.66	4	.16
Texture	0.11	0.11	0.55	303	2.85	4	.58
Morning	0.15	0.11	-0.56	303	0.70	4	.95
Youthful	0.18	0.11	-1.04	303	3.10	4	.54
Attractive	0.18	0.11	-2.69	303	5.94	4	.20
Breasts together	0.20	0.11	-0.10	303	2.67	4	.61
Mirror	0.24	0.12	-2.64	303	8.28	4	.08
Cross arms	0.41	0.11	-1.12	303	3.41	4	.49
Up close	0.60	0.11	-2.60	303	11.46	4	.02
Lay on side	0.76	0.11	2.87	303	11.74	4	.02

appropriate by most participants. Most participants found the length acceptable and all participants who answered the question thought the scale measured an important concept of interest.

Changes made to the décolletage scale after each round are shown in Appendix E. Appendix F shows the item-level decisions; items retained in the final scale were deemed easy to understand and relevant to most of the patients and experts in the study. Rounds 1 to 3 included the 15 patients, with 5 in each round, and Round 4 included the 5 clinicians. Over the 4 rounds, 14 new items were added, 8 items were revised, and 11 items were dropped. Appendix G shows the summary findings for changes made in each round. Items for the 16-item scale covered 6 qualitative themes as follows: scenarios (mirror, photographs, low neckline, lay on side, breasts together, arms crossed, get up, up close), comparisons (with other people), age concerns (youthful, age), qualitative concerns (attractive, healthy), skin tone (even-colored), and texture (smooth, texture). Items that resonated the most with patients included up close, youthful, smooth, and lay on side. For experts, the top items were low neckline, mirror, and even-colored.

Table 3. Treatment Characteristics of Field Test Sample

Characteristic	Categories	n	%
Treatment status for décolletage	I do not plan to have treatment	93	29.0
	I want treatment	171	53.3
	I had treatment	38	11.8
	I had treatment and need more	19	5.9
Type of décolletage treatment participant had (Note: could	Botulinum toxin A	7	11.9
choose more than one answer)	Filler	6	10.2
	Platelet-rich plasma	3	5.1
	Skin tightening with ultrasound	11	18.6
	Skin tightening with radiofrequency	14	23.7
	Chemical peel	11	18.6
	Microdermabrasion	13	22.0
	Laser	14	23.7
	Intense pulsed light	8	13.6
	Microneedling	7	11.9
	Other	3	5.1
Length of time since cosmetic treatment for décolletage (years)	<1	29	50.9
treatment for deconerage (years)	1	10	17.5
	2	8	14.0
	≥3	10	17.5
Treatment location for most recent	Plastic surgery clinic	3	5.3
décolletage treatment	Dermatology clinic	37	64.9
	Day/beauty spa	14	24.6
	Other	2	3.5
	None of the above	1	1.8
Had cosmetic treatment in past 12 months	Face	259	77.5
montus	Body	57	17.1

Quantitative Study

Figure 2 shows the detailed recruitment process. A total of 2039 Prolific participants responded to the screening survey. After exclusions, 499 endorsed one or both of our screening questions and were invited to complete the survey. Of these, 354 accessed the survey. We excluded 3 who did not complete the décolletage scale, 2 who were incorrectly invited, and 15 who provided unreliable answers (eg, gave different answers for age or country on the screen and full survey).

The 334 participants ranged in age from 25 to 80 years (mean [standard deviation], 48 [12] years). Most participants were residents

			ICC		Means for scales by time point							SDC		
ICC	N	ICC	959	% CI						SEM	SDC individual	SDC group		
			LB	UB	T1 mean score	T1 SD	T2 mean score	T2 SD	Mean score difference	Mean difference SD	${ m SD_{pooled}}^* \ \sqrt{(1-)} \ { m ICC_{avg}}$	1.96*√2 *SEM	SDC _{individual} /√n	
Single	125	.86	.81	.90	43	16	43	16	0.6	8.4	4.4	12.1	1.1	
Average	125	.93	.89	.95										

Table 5. Test-Retest Reliability and Measurement Error Results

The * is the sign used for multiplication in the formula provided.

ICC, intraclass correlation coefficient; LB, lower bound; SD, standard deviation; SDC, smallest detectable change; SEM, standard error of the mean; UB, upper bound.

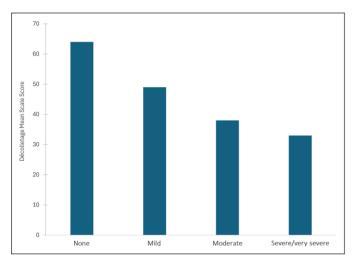


Figure 3. Mean décolletage scale score by severity of wrinkles on upper chest area assessed with the Merz (Merz Aesthetics, Raleigh, NC) photonumeric scale for wrinkles at rest.

of the United States or the United Kingdom. Table 2 shows the sample characteristics and Table 3 shows the treatment characteristics. Most participants (N = 171, 53.3%) reported that they wanted treatment of their décolletage.

The RMT analysis provided support for the reliability and validity of the décolletage scale. Only 1 item ("How even-coloured the skin on your upper chest looks?") had a poor fit to the Rasch model and was dropped ($\chi^2 = 59.7$, df = 4, P < .000001). The remaining items had ordered thresholds (Appendix H). Items fit the Rasch model with nonsignificant χ^2 and P-values after Bonferroni adjustment (Table 4). Eleven items had fit residuals within ± 2.5 . Three pairs of items had residual correlations between 0.25 and 0.34. Subtests performed on the 3 pairs of items had marginal impact on scale reliability (drop of 0.02). Differential item functioning (DIF) was not detected for country (US vs UK), but was evident on 2 of the 3 random samples for the age-group variable for the item "How your upper chest looks compared with other people your age?" This item was retained in the scale as DIF had no impact on scoring; Pearson correlations between person locations before and after splitting for DIF was 1.00

In terms of the scale level findings, the observed data for the set of items fit the Rasch model (χ^2 = 76.72, df = 60, P = .07). The scale was well targeted to the sample: 328 (95.6%) participants scored within the scale's range of measurement (see Person-item threshold distribution in Appendix I). There was little evidence of a floor or ceiling

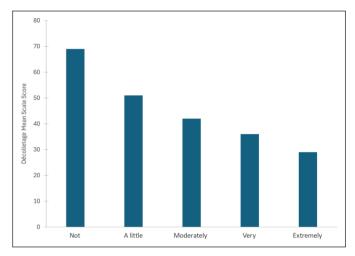


Figure 4. Mean décolletage scale score by response to the question: How bothered are you by wrinkly skin on your upper chest area (décolletage)?

effect on the 0 to 100 transformed scores; 5 (1.5%) participants scored at the floor (ie, 0), and 1 (0.3%) participant scored at the ceiling (ie, 100). Scores for the sample were normally distributed with a mean of 43.6 [SD = 16.4].

The reliability statistics with and without extremes for the person separation index were .95 and .94, and for Cronbach's α were .96 and .95 respectively. Demographic characteristics for the test-retest sample are provided in Appendix J. The average intraclass correlation coefficient based on 125 participants who completed the scale a second time was .93. The smallest detectable change at the group-level was 1.1 (Table 5).

The detailed results for the construct validation hypotheses of group difference are displayed in Appendix J. Figures 3-6 provide examples of results for 4 construct validation hypotheses. Eleven of the 12 proposed hypotheses were accepted (P < .001), with only the hypothesis for self-reported discoloration of the upper chest rejected (P = .07). For the 3 photonumeric scales, as expected mean décolletage scale scores decreased incrementally with increased reported severity on the photonumeric scales (P < .001). There were 8 hypotheses tested that compared the décolletage scale to other measurement instruments. For the BODY-Q scales and SKIN-Q item libraries and short-form scales, all correlations were as expected (P < .001; Appendix K). In total 19 out of 20 hypotheses were accepted, meeting the >75% acceptance criteria for evidence of construct validity. ³⁹

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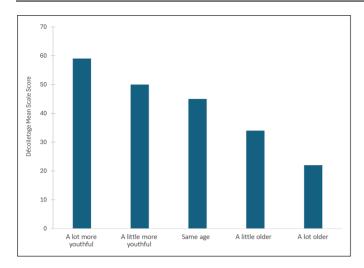


Figure 5. Mean décolletage scale score by response to the question: How does your upper chest area (décolletage) look compared with other people your age?

DISCUSSION

Measuring effectiveness of cosmetic treatments for the décolletage from the patient perspective has been hampered to date by the lack of a specific PROM. Our team carefully designed and tested a new BODY-Q scale for use in research to incorporate the patient perspective into treatment studies, and for use in clinical care to inform patient encounters. In the qualitative phase, the 15 participants interviewed differed in terms of age, ethnicity, and severity of wrinkling in the upper chest area, providing different perspectives within the context of a cosmetic procedure-seeking patient population. The new décolletage scale evidenced high content validity, which is the most important psychometric property of a PROM. 40 Participants found the scale easy to understand and that it asked about concepts relevant to décolletage treatment. Interviews with the clinical experts, who had many years of experience treating the décolletage area, helped to ensure that the final content of the scale was important clinically. The survey data provided evidence of the scale's reliability and validity in a large international sample. The 15 items worked well together to map out a range of measurement for the concept of satisfaction with appearance with strong evidence of reliability and validity.

Likely due to the lack of validated tools, patient satisfaction with their décolletage area has rarely been measured from the patient perspective in treatment studies. Instead, most studies in the literature used ad hoc instruments^{39,41} or clinician-reported outcome measures (ClinROs) such as the Merz Aesthetics Décolleté Wrinkles Scales²⁴ (Merz Aesthetics, Raleigh, NC) or the Fabi-Bolton Chest Wrinkle Scale. 42 For example, Casabona and Nogueira Teixeira used both ClinROs to measure décolletage outcomes following microfocused ultrasound in combination with diluted calcium hydroxylapatite for improving skin laxity. 43 The Fabi-Bolton scale alongside the Global Aesthetic Improvement Scale was used in a study that combined high-intensity ultrasound and a laser treatment in a study ofr 19 women followed up for 16 weeks. 44 Although ClinROs play an important role in outcome assessment, how women feel about the appearance of their décolletage skin is subjective and evaluation of treatment needs to incorporate their perspective.

Our study has certain limitations. First, the qualitative phase of our study only included US participants. To address this limitation, we opened the field test survey to women in 6 English-speaking countries and we examined DIF by country, but recognize that our

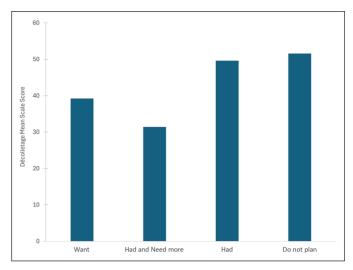


Figure 6. Mean décolletage scale score by the current status of cosmetic treatment for the décolletage.

subgroup sample size only made it possible to examine DIF for the United States and the United Kingdom, Second, the use of online samples to collect research data makes it quick to accrue a sample and relatively inexpensive. While there are limitations to using online platforms that can affect data quality (eg, speed, lack of attention or comprehension), the use of Prolific by our team was intentional as research suggest that data collected using this platform are of high quality. 45 We performed data checks to identify participants whose answers were unreliable (eg, answers differed between the screen and survey) and excluded 15 participants from the survey and 1 participant from the test-retest study. Third, psychometric validation is an ongoing process. While our team examined a range of psychometric properties for the BODY-Q décolletage scale and found strong evidence of its reliability and validity, further research could examine its ability to measure clinical change (ie, responsiveness) and estimate a minimally important difference.

CONCLUSIONS

The BODY-Q Décolletage scale was rigorously designed and validated. This new scale can be used to inform clinical practice, quality improvement, and research to evaluate treatments to improve the appearance of the décolletage skin.

Supplemental Material

This article contains supplemental material located online at https://doi.org/10.1093/asj/sjae229.

Disclosures

BODY-Q Upper Chest scale is owned by McMaster University (Hamilton, ON, Canada). Dr Klassen is a developer of the BODY-Q and receives a share of any license revenues as royalties based on McMaster University's inventor sharing policy. Dr Klassen is an owner of EVENTUM Research (Seattle, WA) which provides consulting services to the pharmaceutical industry.

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