

Development of a Comprehensive Quality-of-Life Measure for Facial and Torso Acne

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Abstract

Background: Acne is a chronic skin disorder which generally presents in adolescence but continues into adulthood, and negatively affects both physical and psychosocial well-being. Presently, there are no validated acne-specific quality-of-life (QoL) measures that include dimensions for both facial and torso acne.

Objective: The objective of this study was to develop a QoL instrument for both facial and torso acne (CompAQ) in accordance with recommended standards.

Methods: A literature review and Delphi survey of patients and clinicians were used to develop the conceptual framework for outcomes perceived important to acne patients. An initial version of the measure was developed, CompAQ-v1, and pilot tested with patients via cognitive interviews.

Results: The Delphi survey generated 4 domains (physical, psychological, sociological, and treatment) and 54 items. These, along with a literature review and input from clinical experts, informed the development of the CompAQ-v1. Eleven cognitive interviews were conducted, resulting in the second version of the measure, CompAQ-v2. Psychometric validation resulted in the final 20-item CompAQ measure comprising 5 domains. An abbreviated 5-item measure was also developed (CompAQ-SF).

Conclusion: CompAQ and CompAQ-SF are instruments intended to evaluate QoL in patients with acne on their face or torso. The former is a 21-item QoL intended for research, while the latter is intended for clinical practice.

Keywords

acne, quality of life (QoL), patient-reported outcomes (PRO), CompAQ, impacts, measure development

Acne is one of the most common skin conditions, estimated to affect 60% to 100% of adolescents and ranked among the top 10 most prevalent diseases globally.^{1,2} While the condition typically develops during adolescence, it can continue into adulthood.³ Given the long-term nature of acne, quality of life (QoL) has been an important consideration for physicians and patients. For individuals with acne, the impact on QoL can help establish overall severity of the condition and serve as an outcome measure of treatment effectiveness.⁴

Interest in health-related QoL has been increasing since the World Health Organization (WHO) altered its definition of health to include not just the absence of disease but also the presence of physical and psychological well-being.^{5,6} Health-related QoL is defined as physical, psychological, and social well-being, as reported by the patient.⁷

Previous research has demonstrated that acne can have a negative impact on all aspects of QoL. Acne has been related to decreased self-esteem, poor body image, general emotional or psychological distress (eg, anxiety, frustration, helplessness), and decreased willingness to engage in social interaction.⁸⁻¹⁰ In high-risk patients, acne has been related to suicidal ideation.⁹

Various instruments have been used to assess QoL in acne patients. There are 3 types of QoL instruments, increasing in specificity from generic to dermatology-specific and acne-specific instruments.¹¹ Generic QoL instruments, like the 36-item Short Form Health Survey (SF-36),¹² are infrequently used in dermatology and, more specifically, acne research. Dermatology-specific QoL instruments, such as the Dermatology Life Quality Index (DLQI)¹³ and Skindex,¹⁴

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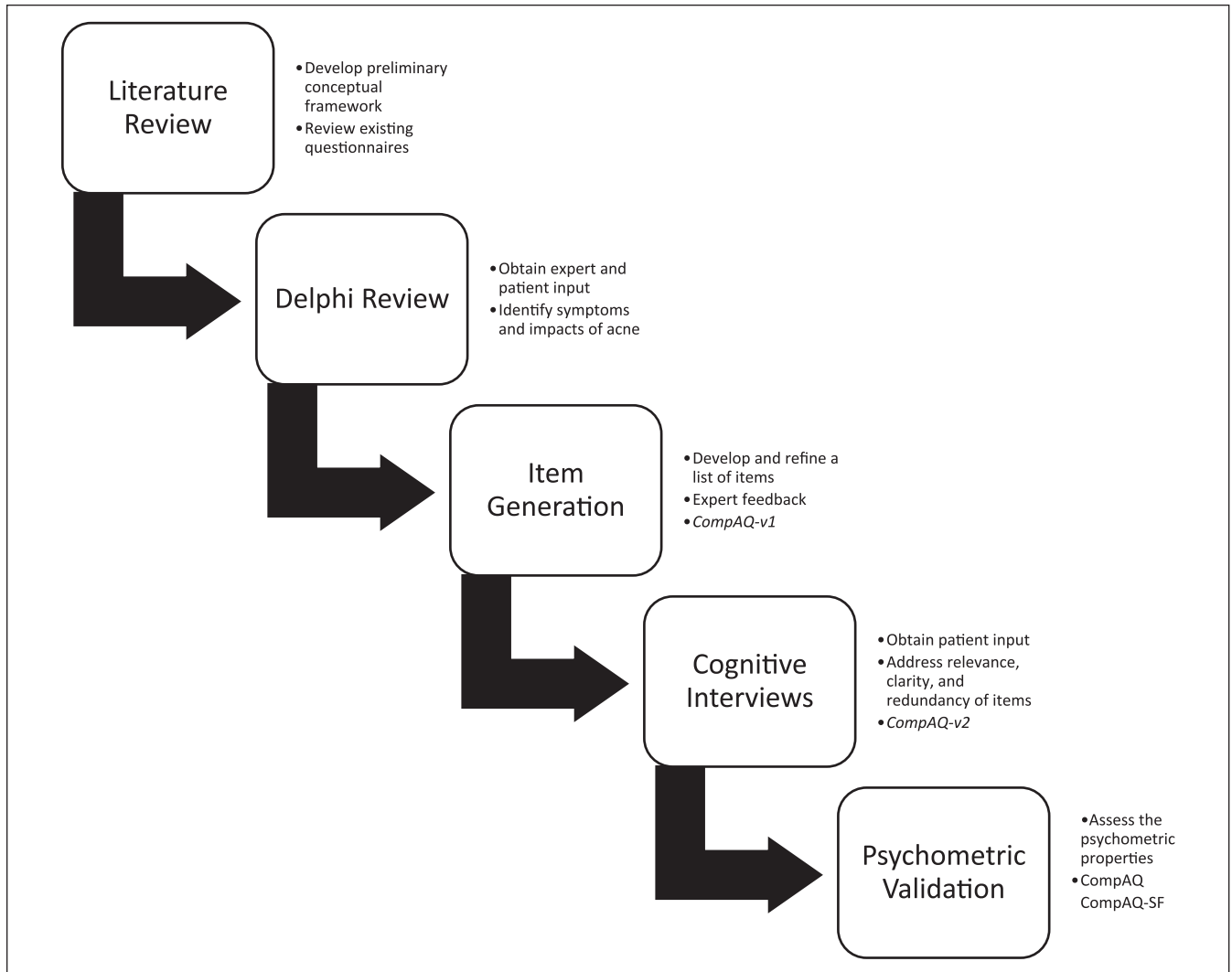


Figure 1. CompAQ development process.

and acne-specific QoL instruments, such as Acne-QoL,¹⁵ the Cardiff Acne Disability Index (CADI),¹⁶ and Acne Symptoms and Impacts Scale (ASIS),^{4,17} are more commonly used in acne research. Disease-specific instruments are typically more responsive to clinical change than generic instruments,¹⁸ an important feature for their use in clinical trials.

Existing acne-specific QoL measures are primarily focussed on facial acne and have only been validated for use with patients who have facial acne.^{15,17} As acne also affects the chest and back, these measures inadequately capture the impact of the lived experience of acne patients. One study demonstrated that approximately 50% of patients presenting with facial acne also reported acne on the chest or back.¹⁹

The purpose of this project was to develop a comprehensive QoL measure inclusive of facial and torso acne (CompAQ). CompAQ was developed in 3 phases: (1) Delphi survey, (2) cognitive interviews, and (3) psychometric validation (see Figure 1 for steps in the development process).

Methods

The methods used herein were in accordance with guidance from the US Food and Drug Administration (FDA) and the National Institutes of Health for development of patient-reported outcomes (PROs) based on modern measurement theory.^{20,21} Development began with a literature review of acne outcomes, input from clinical experts, and interviews with acne patients to explore the patient experience with acne and provide evidence of content validity. All research components received ethics approval at all participating sites.

Phase I: Delphi Survey (*CompAQ-v1*)

Patients recruited for this study were identified from an electronic database of medical records from 3 dermatology practices in Canada, the United States, and the United Kingdom.

Patients who had, or have had, acne were asked to participate if they were older than 13 years (United States) or 16 years (Canada and United Kingdom). Experts were recruited via digital correspondence through relevant dermatological agencies, as well as requests for participants at primary and specialized care facilities. Experts included nurses, primary care physicians, and dermatologists.

A 3-round online Delphi survey was conducted. This multiround consensus-building process consisted of 1 initial qualitative round, followed by 2 quantitative rounds. In round 1, participants responded to 8 open-ended questions in which they provided detail on their lived experience with acne or their professional perception of the lived experience of acne (for the expert group). In rounds 2 and 3, participants were provided with summary information from the previous round. Each summary contained a list of items, generated in the previous round, that represented acne QoL. Participants were asked to rank the importance of each item using a Likert scale ranging from 1 to 6, where 1 indicated *extremely unimportant* and 6 indicated *extremely important*. Criteria to establish consensus were in line with previous research; any item deemed important was required to have a median response of 5 or 6, an interquartile range less than 2, and at least 60% of respondents responding between 5 and 6.²²⁻²⁴ The resulting domains represent important components of the lived experience of acne from the perspective of both patients and experts.

These themes were used to generate the items for the CompAQ-v1. Items from other QoL measures used in previous instruments were extracted, and those items deemed relevant were also included in the preliminary measure. A team of 5 dermatologists examined the measure to ensure that clinically relevant aspects of each concept were captured.

Phase 2: Pilot Test With Cognitive Interviews (CompAQ-v2)

Cognitive interviews were used to assess the preliminary 65-item CompAQ-v1 for comprehension of items, thoroughness of the questionnaire, and adequacy of response options.²⁵ Participants were provided the measure to review and asked open-ended questions regarding the overall measure, individual items, and response options.

Participants were identified from an electronic database of medical records (January-April 2016) from a local dermatology practice (office of J.T.). Patients older than 16 years who had at least moderate acne on their chest or back and had indicated that they would be interested in participating in research were contacted by phone or in person (during a scheduled appointment) and invited to participate in a 30-minute interview.

Prior to the interview, all participants received, via email, a letter of information, a copy of the initial QoL questionnaire, and a copy of the questions to be asked during the interview. Participants were asked to review the questionnaire and to be prepared to discuss the questions during the interview.

The interviewer followed a structured guide to ensure that all participants received the same questions. All of the interviews were audio-recorded and later transcribed; thematic analysis was then used to analyze the transcripts.

Phase 3: Psychometric Validation (CompAQ-v3, Short and Long Form)

Participants were recruited for this study from 2 sources. The first was a local dermatology practice (office of J.T.) where patients were identified from an electronic database of medical records (August 2016). Patients older than 16 years who had acne on their face or torso and had indicated that they would be interested in participating in research were mailed a letter inviting them to participate in the 30-minute online survey. Second, participants with acne on their face or torso were recruited from a local university. Upon enrolling, participants completed an online survey and a brief demographic inventory. This study was approved by the Research Ethics Board at the University of Windsor.

Confirmatory factor analysis (CFA) was conducted to confirm the structure of the CompAQ-v2 (ie, to confirm the proposed domains), to inform refinement of CompAQ-v2, and to test for measurement invariance (differences in how the questionnaire is answered) based on acne location (face or torso). Correlation analysis was used to assess convergent validity; we expected that CompAQ-v3 (the final version of CompAQ) scale scores would be related to other measures of QoL, psychological well-being, and life satisfaction (measured by DLQI, Depression Anxiety and Stress Scale-21 [DASS-21], and Quality of Life Enjoyment and Satisfaction Questionnaire-Short Form [QLES], respectively). Last, CFA informed the development of a short-form version of CompAQ (CompAQ-SF). The short form is intended for clinical use, where health care providers may not have time to administer the long form of CompAQ.

Results

A systematic literature review was conducted to identify any existing measures used to assess QoL of patients with acne and other dermatological diseases. From this review, we identified that no validated measure existed, specifically for patients who have acne on their torso. Based on the findings of this literature review, as well as the domains and items identified from the Delphi survey (see below), we thematically pulled relevant items from existing measures and adapted or modified their content to create a bank of items that would accurately reflect the unique and specific impacts on QoL that patients with acne on their torso and face may encounter.

Phase 1: Delphi

In total, 50 participants completed the first round of the Delphi survey (n = 28 patients, n = 22 experts). Of those, 38

completed round 2 ($n = 21$ patients, $n = 17$ experts [77% of initial sample]) and 36 completed round 3 ($n = 20$ patients, $n = 17$ experts [72% of initial sample]).

Upon completion of the 3-round Delphi, 4 domains and 54 items emerged. Four themes emerged in the first round: psychological concerns (23 items), sociological concerns (24 items), physical concerns (15 items), and treatment concerns (17 items). These 79 items were then circulated in the round 2 summary where 36 items met consensus criteria for experts and 29 items for patients. For round 3, items that reached consensus as equivocal or important in round 2 were recirculated along with those that did not reach consensus; 49 items met consensus for experts and 42 items for patients (see Table 1). From these domains and items, the initial 65-item CompAQ-v1 measure was developed.

Phase 2: Pilot Test With Cognitive Interview

Eleven participants (age range, 16-32 years [mean (SD), 21.3 (5.41)]; 46% female [$n = 5$], 73% white [$n = 8$]) completed cognitive interviews to assess CompAQ-v1 domains and items.

Participants indicated that the initial CompAQ-v1 items were easy to understand, detailed, and comprehensive. Five main issues emerged (see Table 2): (1) 2 items were unclear to participants, (2) a total of 17 items were considered redundant, (3) most participants considered the response options to be good or adequate, (4) nearly half of the participants defined their acne as active lesions and not scarring, and (5) nearly all participants indicated that they would respond to the items differently based on the location of their acne.

Based on these findings, the preliminary CompAQ-v1 measure was further modified: enhanced clarity of a number of items, elimination of items, and improved appearance of the questionnaire to make it more user-friendly. The refined CompAQ-v2 measure consisted of 41 items and was used in phase 3, the validation study.

Phase 3: Psychometric Validation (CompAQ-v3 and CompAQ-SF)

In total, 234 participants (age range, 16-42 years [mean (SD), 20.3 (3.04)]; 85% female [$n = 198$], 69% white [$n = 161$]) completed an online survey. Most ($n = 199$, 85%) reported having acne on their face. Nearly half of participants ($n = 106$) reported having acne on their torso (defined as chest, back, or shoulders). These categories are not mutually exclusive; 93 participants (85%) who reported having acne on their torso also reported having acne on their face. Only 8% of the sample ($n = 18$) reported having acne exclusively on their torso. As a result, group analyses proceeded with 2 groups: facial acne exclusively and torso acne (included those who also had acne on their face).

Model fit. Initially, CFA was used to assess the proposed 4-domain structure of CompAQ-v2. A number of measures

were used to assess the fit of the model: Chi-square (χ^2), comparative fit index (CFI), Tucker-Lewis Index (TLI), root mean square error of approximation (RMSEA), and standardized root mean residual (SRMR). The 4-domain structure did not fit the data well, and as a result, a more exploratory approach was taken. Specifically, a 5-domain model was compared to the 4-domain model, as the fourth domain appeared to separate into 2 domains in the initial analysis. Based on these results, the 5-domain structure was deemed more appropriate than the original 4-domain structure. The 5 domains assessed a variety of domains of QoL, including, psychological/emotional, social (judgement from others), social interactions, treatment concerns, and physical symptoms.

To refine the measure, only the highest loading items were retained on each factor, resulting in the reduced 20-item version of CompAQ(-v3). Two confirmatory factor analyses suggested moderate fit²⁶ for the 5-domain structure: facial acne ($\chi^2_{df=158} = 367.687$, $P < .001$; CFI = 0.929; TLI = 0.915; RMSEA = 0.08; SRMR = 0.056) and torso acne ($\chi^2_{df=158} = 294.015$, $P < .001$; CFI = 0.931; TLI = 0.917; RMSEA = 0.098; SRMR = 0.054).

The measure was further refined to produce a short-form version, intended for use in clinical settings. The 5-item CompAQ-SF consists of 5 items, one from each domain. The item selected from each domain was the most representative of the construct (deemed so based on CFA results and expert review). CFA conducted on the short form suggests good fit for both face ($\chi^2_{df=3} = 3.60$, $P < .001$; CFI = 0.999; TLI = 0.997; RMSEA = 0.025; SRMR = 0.013) and torso acne ($\chi^2_{df=3} = 5.65$, $P < .001$; CFI = 0.987; TLI = 0.958; RMSEA = 0.098; SRMR = 0.027). See online Appendix A for both the short and long forms of the measure.

Invariance testing (face vs torso/both). Next, we tested for measurement invariance (see Table 3 for the fit indices). Model 4 (strict invariance) has the lowest Bayesian Information Criterion (BIC) value and therefore the best trade-off between model fit and model complexity. This indicates that CompAQ is measuring the same constructs/domains for both facial and torso acne, and thus it is appropriate for use with patients who have either facial or torso acne.

Correlations (evidence of convergent validity). Correlation analysis with other measures of QoL, psychological well-being, and life satisfaction was used to establish convergent validity. All correlations were significant at the $P < .01$ level and in the expected direction (see Table 4). All 5 CompAQ domains were positively related to depression, anxiety, and stress scales scores. These 5 domains were negatively related to DLQI and QLES scores; for these scales, higher scores indicated better QoL, while higher scores on CompAQ indicated worse QoL. In addition, the short form of CompAQ was also related to DLQI, QLES, and DASS-21 scores.

Table I. Delphi Results.

Theme	Item	Patient IQR	Patient Median	Expert IQR	Expert Median	Considered Important to Patients	Considered Important to Experts
Psychological	Depressed	2	5	2	6	Yes	Yes
	Sad	2	5	2	6	Yes	Yes
	Upset	2	5	2	6	Yes	Yes
	Stressed	2	6	1	5	Yes	Yes
	Self-conscious	1	6	0	6	Yes	Yes
	Ashamed	1	5	2	6	Yes	Yes
	Unattractive	1	6	1	6	Yes	Yes
	Frustrated	2	5	2	6	Yes	Yes
	Insecure	1	5	2	5	Yes	Yes
	Anxious	—	—	2	5	No	Yes
	Annoyed	2	5	—	—	Yes	No
	Uncomfortable in my own skin	1	6	2	5	Yes	Yes
	Unclean	—	—	2	5	No	Yes
	I am lacking confidence	2	5	1	5	Yes	Yes
	I have less value	—	—	1	5	No	Yes
I could not stop thinking about my acne	2	6	2	5	Yes	Yes	
Physical	Discomfort	—	—	1	5	No	Yes
	Dissatisfied with the appearance of my skin	1	6	1	5	Yes	Yes
	Dissatisfied with the redness of my skin	1	5	1	5	Yes	Yes
	Dirty feeling skin	1	5	—	—	Yes	No
	Scars	1	6	1	6	Yes	Yes
	Skin that felt uneven	2	5	—	—	Yes	No
	Skin color changes	—	—	0	5	No	Yes
	Frequent breakouts	1	6	2	5	Yes	Yes
	Greasy-looking skin	2	5	—	—	Yes	No
	Embarrassed	2	5	2	5	Yes	Yes
Sociological	Shy	2	6	2	5	Yes	Yes
	Unattractive to others	1	6	2	5	Yes	Yes
	Others only see my acne	2	5	2	5	Yes	Yes
	Others do not understand my acne	2	5	2	5	Yes	Yes
	Others are thinking negatively of me	2	5	1	5	Yes	Yes
	Avoid social interactions	2	5	1	5	Yes	Yes
	I have decreased job opportunities	—	—	1	5	No	Yes
	I have decreased social opportunities	—	—	1	5	No	Yes
	Stressed about social events	2	5	2	5	Yes	Yes
	I would not want pictures taken of me	1	6	2	5	Yes	Yes
	Avoid physical contact	2	5	—	—	Yes	No
	Affects my personal relationships	—	—	1	5	No	Yes
	Sexual relationships are more difficult	—	—	1	5	No	Yes
	Uncomfortable looking others in the face	2	5	1	5	Yes	Yes
	Envious of people with clear skin	1	6	2	5	Yes	Yes
Treatment	Treatment is not convenient	—	—	2	5	No	Yes
	Time spent managing acne	1	5	2	5	Yes	Yes
	Money spent treating acne	—	—	2	5	No	Yes
	Difficulty finding effective treatment	2	6	2	5	Yes	Yes
	Frustration with the lack of treatment results	2	6	2	6	Yes	Yes
	Time/effort spent concealing acne	2	6	2	5	Yes	Yes
	Time/effort spent concealing scarring	1	6	2	5	No	Yes
	Managing treatment side effects	—	—	1	5	No	Yes
	Worrying that my acne will never go away	2	6	2	5	Yes	Yes
	Frequently thinking about managing acne	2	5	2	5	Yes	Yes
	Managing long-term acne	2	5	2	5	Yes	Yes
	My treatment isn't going to work as I'd hoped	2	5	1	5	Yes	Yes
Trying to stop myself from picking my acne spots	2	5	2	5	Yes	Yes	

IQR, interquartile range; —, item was not reported on by that group (patients or experts).

Table 2. Cognitive Interview Results.

Theme	Example	% (n)
Unclear items	“I spend time covering up my skin”	19 (2)
Redundant items	“I am concerned that my acne treatments aren’t working fast enough”	64 (7)
	“I feel less confident”/“I feel like I lack self confidence”	
Response options	“People make fun of me”/“I feel bullied by others”	64 (7)
	“I feel like I lack self-confidence”/“I feel unsure of myself”	
Definition of acne	Good/adequate	45 (5)
	Active lesions only	55 (6)
Location of acne	Active lesions and scarring	82 (9)
	Would respond to items differently based on location of acne	

Table 3. Measurement Invariance (CompAQ-v3 Long Form).

	χ^2	df	P Value	CFI	RMSEA	BIC
Model 1: configural invariance	775.16	316	<.001	0.921	0.098	22 650.59
Model 2: weak invariance (equal loadings)	789.11	331	<.001	0.922	0.096	22578.88
Model 3: strong invariance (equal loadings + intercepts)	819.09	346	<.001	0.919	0.095	22 523.21
Model 4: Strict invariance (equal loadings + intercepts + means)	820.733	351	<.001	0.920	0.094	22 496.30
Model Comparison	Delta χ^2	Delta df	Delta P Value	Delta CFI		
Model 1 vs model 2	13.95	15	.529	0.00		
Model 1 vs model 3	43.93	30	.048	0.002		
Model 2 vs model 3	29.98	15	.0122	0.003		
Model 1 vs model 4	45.574	35	.109	0.002		
Model 3 vs model 4	1.65	5	.896	−0.001		

BIC, Bayesian Information Criterion; CFI, comparative fit index; RMSEA, root mean square error of approximation.

Table 4. Correlation Results and Cronbach’s α for all Scales.^a

	1	2	3	4	5	6	7	8	9	10	11
1. CompAQ, Psychological/Emotional	.951										
2. CompAQ, Social (Judgement From Others)	0.75	.908									
3. CompAQ, Social Interactions	0.75	0.81	.944								
4. CompAQ, Treatment Concerns	0.77	0.61	0.58	.864							
5. CompAQ, Physical Symptoms	0.68	0.59	0.60	0.71	.839						
6. CompAQ, Short Form	0.87	0.87	0.85	0.79	0.78	0.840					
7. DLQI	−0.44	−0.43	−0.49	−0.40	−0.46	−0.55	.724				
8. DASS-21, Depression	0.428	0.50	0.56	0.38	0.39	0.51	−0.33	.905			
9. DASS-21, Anxiety	0.50	0.54	0.54	0.67	0.45	0.48	−0.37	0.78	.851		
10. DASS-21, Stress	0.43	0.50	0.54	0.34	0.38	0.55	−0.31	0.71	0.79	.881	
11. QLES (Life Satisfaction)	−0.36	−0.42	−0.40	−0.24	−0.35	−0.40	0.26	−0.54	−0.54	−0.45	.909

DASS-21, Depression Anxiety and Stress Scale–21; DLQI, Dermatology Life Quality Index; QLES, Quality of Life Enjoyment and Satisfaction Questionnaire–Short Form.

^aAll correlations significant at $P < .01$. Cronbach’s α on diagonal.

Discussion

The purpose of the current project was to develop an acne-specific measure of QoL (CompAQ), inclusive of facial and torso acne. A literature search and results from a patient and expert Delphi survey provided the foundation for development. The final 20-item CompAQ is suitable

for use with patients who have acne on their face or torso and may be most appropriate for use in research settings, while the 5-item CompAQ-SF is practical for use in clinical practice.

The final version of CompAQ consists of 5 domains that assess a variety of psychosocial and physical impacts of acne:

1. Psychological/Emotional: This domain assesses the extent to which patients experience psychological or emotional distress because of their acne. For example, "I feel depressed, sad, or upset."
2. Social (Judgement From Others): This domain assesses the extent to which patients are concerned about social judgements from others. For example, "I feel like people judge me."
3. Social Interactions: This domain assesses the extent to which patients are concerned about social interactions. For example, "I spend less time with my friends."
4. Treatment Concerns: This domain measures patient concerns about treatments. For example, "I am concerned about side effects from treatment."
5. Physical Symptoms: This domain assesses patient concern with physical symptoms, such as their skin feeling dirty, appearing red, or causing them pain. For example, "My skin causes me pain or discomfort."

These domains are similar to those reported in existing QoL measures and were supported by the Delphi survey results, cognitive interview feedback, and psychometric validation. The final versions of CompAQ (both short and long) will undergo a final round of psychometric validation in the future. The main strength of CompAQ is that it is not limited to those with only facial acne; it is also valid for assessing QoL in patients with acne on their torso.

Previous acne QoL studies have been predominantly focused on facial acne and relied on both global dermatology QoL measures and acne-specific QoL measures. The DLQI¹³ and Skindex¹⁴ are important and commonly used measures for general health-related and skin-specific QoL. However, they are not acne specific, and each of the measures has its own shortcomings.

The DLQI was the first dermatology-specific QoL measure. The DLQI is a 10-item QoL measure intended for use with patients with any skin condition. While the DLQI has demonstrated good reliability and clinical application in the past, it predates FDA PRO guidelines. Recent research has suggested that the DLQI no longer meets rigorous psychometric standards.²⁷ For example, the DLQI suffers from item bias (due to sex, age, or nationality). Furthermore, the DLQI focuses primarily on physical impacts rather than psychological or social impacts of the condition. In addition, the DLQI is intended to be a single-factor scale, but no analysis of dimensionality was performed during initial development of the measure (ie, factor analysis), and subsequent studies have not been able to confirm the unidimensionality of the measure.²⁸

Skindex, another global dermatology QoL measure, is intended to measure 3 domains: functioning, emotions, and symptoms. Although not acne specific, Skindex was validated with acne patients, but only those with facial acne.^{11,29} Similarly, AcneQoL¹⁵ and AcneQ4³⁰ are well-developed and psychometrically valid measures but only for facial acne.

Alexis et al⁴ reviewed existing QoL measures and evaluated their development. They determined that there were no suitable acne-specific QoL measures and developed a measure (ASIS) to satisfy FDA PRO guidelines. However, their measure is only indicated for use with individuals who have facial acne and does not correlate with acne severity.¹¹

The Cardiff Acne Disability Index (CADI)¹⁶ is one existing acne QoL measure that is not exclusively intended for facial acne. However, its development predates FDA PRO guidelines, and the instrument consists of only 5 items that are answered using a 4-point scale. The CADI is limited in scope; given its brevity, the instrument is not intended to thoroughly assess the various domains of QoL (eg, social, psychological, etc).

QoL measures can be used to assess treatment efficacy, inform the future course of treatment, and help detect the need for psychological follow-up or intervention.^{13,16,29,31} Acne on the chest and back has been shown to have an equal or greater negative impact on QoL compared to facial acne,^{32,33} yet there are no tools available to adequately assess the impact of torso acne on QoL. CompAQ is the first comprehensive acne-specific QoL measure intended for use with patients who have facial or torso acne. CompAQ was developed with multiple rounds of input from clinicians and patients, adheres to FDA PRO guidelines, and demonstrates sound psychometric properties. A well-developed QoL measure of acne inclusive of truncal acne is required in view of the prevalence of truncal acne, acne treatment effects, and the development of interventions for acne beyond facial involvement.

Declaration of Conflicting Interests

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Ethics Approval

Research Ethics Board (REB 16-214), University of Windsor. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. This article does not contain any studies with animals performed by any of the authors.

Informed Consent

Informed consent was obtained from all participants in the study.

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