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## **Evaluation of the Measurement Properties and Validation of the Skindex-16 Among Patients with Acne**

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***To the editor:***

Patient-reported outcome measures (PROMs) assessing quality of life can complement clinician assessments in routine practice and clinical trials.<sup>1</sup> However, PROMs are infrequently used in acne trials.<sup>2</sup> The Skindex-16 is a dermatology-specific quality of life measure that is frequently used in clinical studies. Although there is evidence to support the content validity and measurement properties of the Skindex-16 for general dermatology patients, there is insufficient evidence regarding the measurement properties of the Skindex-16 among patients with acne, which might limit its use in this population.<sup>3</sup>

To assess the structural validity, internal consistency, and construct validity of Skindex-16 among patients with acne, patients  $\geq 18$  years of age with a diagnosis of acne who were fluent in English were recruited from an outpatient clinic at Brigham and Women's Hospital in the United States. Patients completed self-administered questionnaires including CompAQ, Skindex-16, and a patient global assessment (PGA) (Supplement). Skindex-16 consists of 3 domains containing a total of 16 items (emotions [7 items], functioning [5 items], symptoms [4 items]).<sup>4</sup> A dermatologist assessed acne severity using the Comprehensive Acne Severity Scale (CASS).<sup>5</sup> Structural validity was evaluated using factor analysis. Internal consistency was evaluated using Cronbach alpha. Construct validity was evaluated using convergent and known groups validity. Statistical analyses were performed in Stata, version 17 (StataCorp LLC).

Between July 2022 and May 2023, 170 Skindex-16 records were collected for 113 unique patients (Table 1). Confirmatory factor analysis supported the structural validity of the symptoms, emotions, and functioning domains (Table 2). In addition, Cronbach's alpha ( $>0.70$ ) supported good internal consistency for each of the domains (Table 2). Construct validity was supported by moderate correlations between the corresponding CompAQ domain scores (Table 2) and by known groups validity with increasing Skindex-16 domain scores with increasing levels of disease severity (Supplemental Figure 1).

The results of this study support that the Skindex-16 is a reliable and valid instrument for measuring quality of life among patients with acne. Although some floor effects were noted for the symptoms and

functioning domain, these were less common among those with active acne. However, it is also possible that items in these domains may have less relevance for patients with acne or may be less sensitive among those with milder severity.

In routine clinical practice, the 1-page Skindex-16 could serve as an efficient and useful PROM for assessing quality of life for patients with acne as well as those with other skin diseases. In clinical trials, collecting data on the Skindex-16 could enable comparisons with other studies among patients with acne and other skin diseases.

This study has several strengths, including the large sample size and conduct within the rigorous COSMIN framework. Limitations include that patients were recruited from one outpatient clinic at Brigham and Women's Hospital in the United States and treated by a single clinician. Additional studies are needed to evaluate whether these findings generalize to other populations and to examine content validity and other measurement properties such as test-retest reliability, responsiveness, and interpretability.

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**Table 1: Demographics (N=170)**

<b>Age, mean (SD)</b>	25.1 (5.7)
<b>Age, n (%)</b>	
18-25	108 (63.5)
26-35	50 (29.4)
36-45	8 (4.7)
>45	1 (0.6)
Did not disclose	3 (1.8)
<b>Female, n (%)</b>	118 (69.4)
<b>Race, n (%)</b>	
White	107 (62.9)
Asian	35 (20.6)
Black or African American	9 (5.3)
American Indian or Alaska Native	1 (0.6)
Native Hawaiian or Other Pacific Islander	0 (0)
More Than One Race	9 (5.3)
Other	7 (4.1)
Prefer Not to Disclose	2 (1.2)
<b>Hispanic, n (%)</b>	15 (8.8)
<b>Current Treatment, n (%)</b>	
Benzoyl Peroxide	59 (34.7)
Topical Retinoid	59 (34.7)
Topical Antibiotics	61 (35.9)
Clascoterone	8 (4.7)
Oral Antibiotics	21 (12.4)
Spirolactone	28 (16.5)
Isotretinoin	56 (32.9)
No Treatment	25 (14.7)
<b>PGA, n (%)</b>	
Clear (0)	8 (4.7)
Almost Clear (1)	55 (32.4)
Mild (2)	50 (29.4)
Moderate (3)	46 (27.1)
Severe (4)	11 (6.5)
<b>CASS Max Score, n (%)</b>	
Clear (0)	26 (15.3)
Almost Clear (1)	46 (27.1)
Mild (2)	63 (37.1)
Moderate (3)	33 (19.4)
Severe (4)	2 (1.2)
Very Severe (5)	0 (0)

**Abbreviations:** PGA - patient global assessment, CASS - Comprehensive Acne Severity Scale.

**Table 2: Measurement Properties of Skindex-16 Domains**

	Symptoms Domain	Emotions Domain	Functioning Domain
<b>Item #s</b>	1 – 4	5 – 11	12 – 16
<b>Mean ± Standard Deviation</b>	21.1 ± 23.0	42.7 ± 28.7	22.9 ± 28.2
<b>Median (IQR)</b>	12.5 (29.2)	42.9 (50.0)	13.3 (36.7)
<b>Floor</b>	22.9%†	9.4%	33.5%‡
<b>Ceiling</b>	0.6%	1.8%	1.18%
<b>Confirmatory Factor Analysis</b>			
RMSEA	0.28	0.16	0.29
CFI	0.94	0.96	0.93
TLI	0.83	0.93	0.86
SRMR	0.04	0.03	0.03
<b>Internal Consistency</b>			
Cronbach’s alpha	0.89	0.96	0.96
<b>Known Groups Validity (Linear Regression Coef [95% CI])</b>			
PGA	10.67 [7.67, 13.68]	14.13 [10.44, 17.81]	7.64 [3.61, 11.67]
CASS Max	9.23 [6.03, 12.43]	11.69 [7.70, 15.67]	5.86 [1.66, 10.06]
<b>Correlations (r)</b>			
PGA	0.48	0.50	0.28
CASS Max	0.40	0.41	0.21
CompAQ Symptoms	0.64	0.73	0.55
CompAQ Emotions	0.50	0.78	0.67
CompAQ Social Judgement	0.45	0.69	0.74
CompAQ Social Interaction	0.40	0.63	0.84

**Abbreviations:** IQR – Interquartile Range, RMSEA – Root Mean Squared Error of Approximation, CFI – Comparative Fit Index, TLI – Tucker-Lewis Index, SRMR - Standard Root Mean Squared Residual, PGA - patient global assessment, CASS - Comprehensive Acne Severity Scale

\*CompAQ data available for 116/170 encounters

† The frequency of floor effects for the symptoms domain decreased to 12.2% if those whose acne was rated as clear or almost clear were excluded

‡ The frequency of floor effects for the functioning domain decreased to 24.5% if those whose acne was rated as clear or almost clear were excluded



## **Supplement Methods: Outcome Measures**

### **Skindex-16**

Skindex-16 was used to capture the dermatology-specific health-related quality of life. It consists of 3 domains containing a total of 16 items (emotions [7 items], functioning [5 items], symptoms [4 items]).<sup>7</sup> Each item was rated on a 7-point (0 = never bothered to 6 = always bothered) Likert-type scale. The recall period is 7 days. All responses are transformed to a linear 0-100 scale and the total score for each domain is calculated as the mean of the respondent's responses to each item in that domain. Higher scores indicate greater effects for each domain.

### **CompAQ**

CompAQ was used to measure acne-specific health-related quality of life. It consists of 5 domains containing a total of 20 items (psychological/emotional [4 items], social-judgment [4 items], social-interactions [4 items], treatment concerns [4 items], and symptoms [4 items]).<sup>6</sup> Each item was rated on a 9-point (0 = never, 2 = rarely, 4 = sometimes, 6 = often, 8 = all the time) Likert-type scale. The recall period is 30 days. A total score is calculated for each domain which could range from 0 to 32, with greater scores indicating greater effects for each domain.

### **DermSat-7**

DermSat-7 was used to measure treatment satisfaction in patients currently on prescription treatment regimens for acne. It consists of 3 domains containing a total of 7 items (effectiveness [3 items], convenience [3 items], and overall satisfaction [1 item]).<sup>5</sup> Each item is rated on a 5-point (1 = not satisfied, 2 = slightly satisfied, 3 = somewhat satisfied, 4 = mostly satisfied, 5 = completely satisfied) scale. The recall period is 7 days. The total score for each domain is transformed to a linear 0-100 scale, with higher scores representing greater satisfaction.

### **Patient Global Assessment**

Patient global assessment (PGA) captured the patient's assessment of their acne severity. It was defined as: Clear (0) = no blackheads or whiteheads, no raised acne bumps, Almost Clear (1) = rare blackheads or whiteheads, no more than one or two raised acne bumps, Mild (2) = worse than almost clear some

blackheads or whiteheads, no more than a few raised acne bumps, Moderate (3) = worse than mild there may be many blackheads or whiteheads and some raised acne bumps but no more than one or two deeper acne spots under the skin, Severe (4) = worse than moderate there may be many blackheads or whiteheads and raised acne bumps, many deeper acne spots under the skin.

### **Anchor**

The anchor was used to assess how patients felt that their acne severity had changed since their last visit.<sup>8</sup>

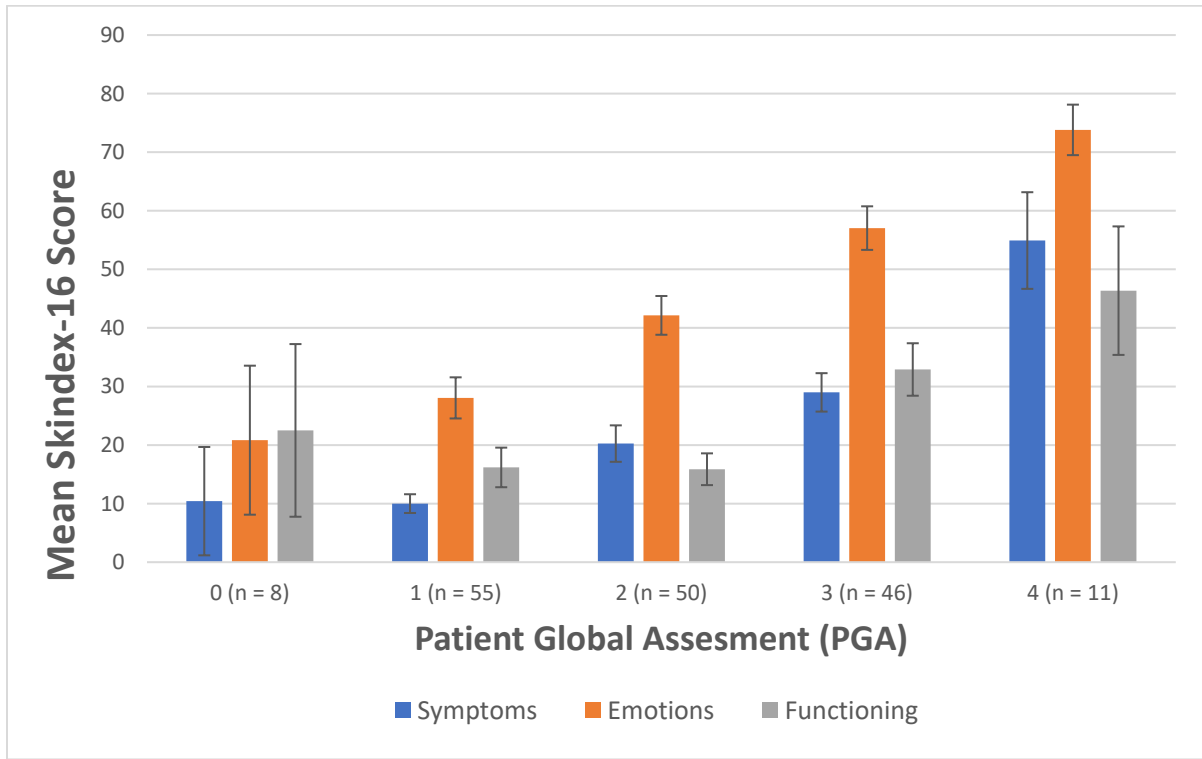
It was rated as 3 = much better, 2 = somewhat better, 1 = a little better, 0 = no difference, -1 = a little worse, -2 = somewhat worse, and -3 = much worse.

### **Comprehensive Acne Severity Scale**

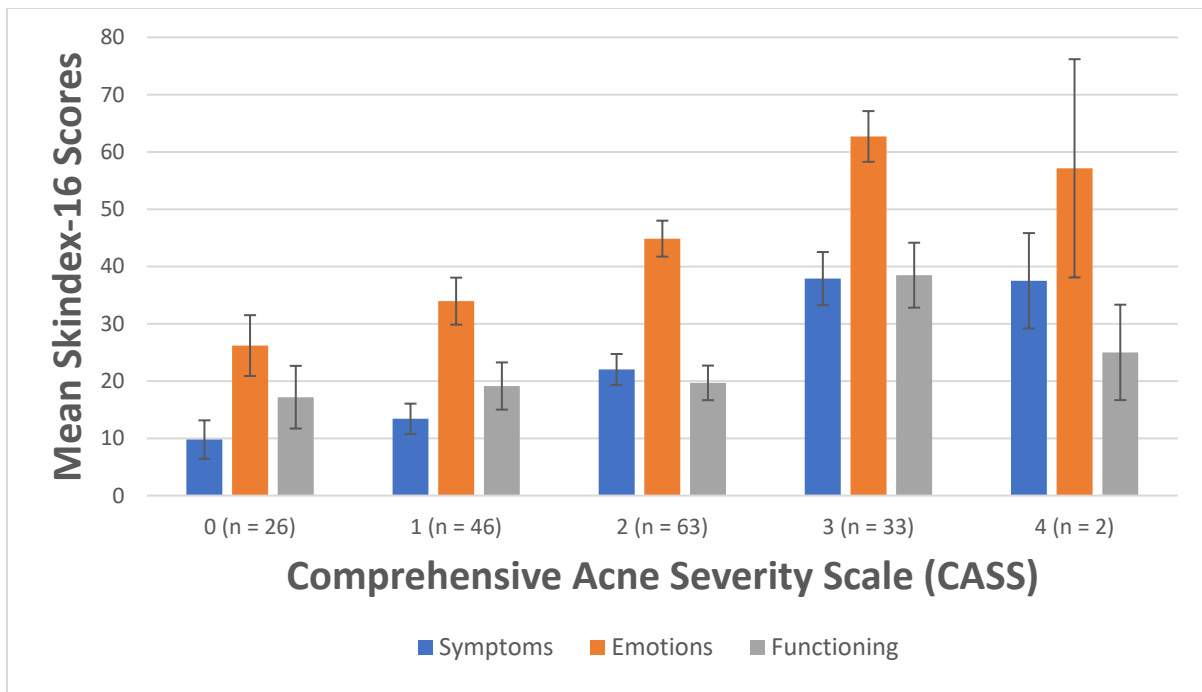
The Comprehensive Acne Severity Scale (CASS) score served as an investigator global assessment.<sup>9</sup>

Patients received a CASS score which ranged from: Clear (0), Almost Clear (1), Mild (2), Moderate (3), Severe (4), and Very Severe (5) for the face, chest, and back.

**Supplement Figure 1:**



**Figure 1a:** Known-Groups Validity Assessment of Skindex-16 Domain Scores and Patient Global Assessment in Patients with Acne



**Figure 1b:** Known-Groups Validity Assessment of Skindex-16 Domain Scores and Comprehensive Acne Severity Scale in Patients with Acne