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EM-91228 March 2022

## ORIGINAL ARTICLE

# Impact of acne on the daily life of adult patients: building a self-administered patient questionnaire

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## Abstract

**Background** Acne is a long-lasting disease in adolescents and adults impacting the patient's daily life. Currently, there is no specific questionnaire that assesses its impact in adult patients.

**Aim** To build a self-administered questionnaire assessing the impact of acne on the daily life in adult patients.

**Method** A multidisciplinary working group was created, including 3 experts in healthcare questionnaires and dermatologists specialized in acne. A questionnaire using a standardized methodology for designing self-administered patient questionnaires according to conceptual, development and validation phases was developed. A cultural and linguistic validation into US English was conducted, based on the original French version.

**Results** A 14-item questionnaire demonstrating consistency, reproducibility and high reliability was build. The questionnaire significantly correlated with the SF-12 mental and SF-12 physical scores and CADL, indicating good external validity.

**Conclusion** The present acne burden questionnaire AI-ADL allows the practitioner to assess quickly and easily the burden of acne in patients during his daily clinical practice. Moreover, its short format allows patients to express easily and quickly their feelings and to initiate a conversation between the practitioner and his patient. Thus, AI-ADL may help to better understand the multidimensional nature of acne, as well as the individual impact on the acne patient's daily life and moreover, it may play a key role in the decision-making process of treatment initiation and involvement of the patient in the management of his acne.

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## Conflicts of interest

Sophie Seité is an employee of La Roche Posay, France. The other authors have no conflict of interest to disclose.

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## Introduction

*Acne vulgaris*, a chronic disease of the pilosebaceous follicle. It causes non-inflammatory lesions, superficial inflammatory lesions and deep inflammatory lesions and if not or insufficiently treated it may result in scars. In the 'Objectifs Peau' study, published by the French Society of Dermatology (SFD), the prevalence of acne was 6.22% [95% CI: 5.89–6.56%] among individuals older than 15 years.<sup>1</sup>

With relapse being more and more frequent, acne is the main reason for dermatological consultation in France.<sup>2,3</sup> For decades, acne has been considered being an adolescent disease. However, it may also persevere into adulthood, with a 60% prevalence reported in women aged 20–29 years and 26% in women between 40 and 49 years.<sup>4</sup> In females, two types of adult acne may be observed: 'persistent acne' which is a disease continuation from adolescence, representing about 80% of adult acne

cases and 'late-onset acne' starting in adulthood, representing about 20%.<sup>2</sup> According to Yentzer *et al.*, one-third of all dermatology visits for acne in the United States are accounted for by women older than 25 years.<sup>5</sup>

Even though acne is neither a devastating nor life-threatening condition, it may cause psychosocial burden, with major implications on the patient's daily life, quality of life and self-esteem.<sup>6–8</sup> Its impact on the patient's psyche has been reported being comparable with that of chronic medical conditions like asthma, diabetes or epilepsy.<sup>9</sup> Gollnick *et al.*, reported that there is a widespread misunderstanding among both physicians and lay people, who generally perceive acne as a simple, self-limited affliction of adolescents.<sup>10</sup> According to the authors, acne is not an acute condition but rather a chronic one in continuous change as to its severity and body distribution.

There are several questionnaires such as the Cardiff Acne Disability Index (CADI), the acne-specific QoL questionnaire, the acne QoL scale and the 4-item index of acne QoL (acne-Q4) that all assess the impact of acne on quality of life or self-esteem of mainly adolescents and during clinical trials.<sup>11–14</sup> However, according to our literature search, there is no specific tool that allows to assess in the daily practice the impact of acne on the daily life of adult patients.

Therefore, we believe that creating such a tool may be useful for both adult patients and clinicians in charge of patient management.

The objective of the present study was to develop a self-administered questionnaire allowing assessing the impact of acne on the daily life of patients with acne.

## Methodology

This method was developed according to the 2010 COSMIN checklist and all items were verified in posteriori versus the updated 2018 COSMIN risk of bias checklist.<sup>15</sup>

The work was approved by the national Ethics committee in June 2018 (Angers, France). According to French regulations for this type of work, no written informed consent was to be obtained from participating patients.

A standard methodology for creating QoL questionnaires was used and multidisciplinary working group of experts (healthcare professionals such as physicians and public health specialists as well as medical experts in acne) was created.<sup>16</sup> The questionnaire followed the format presented Seidenberg *et al.* and Leidy *et al.* for the building of a multiple ability self-report questionnaire and of health-related quality of life claims.<sup>16,17</sup> Response modalities were determined via an expert consensus using the 7-point Likert scale: 'never' (0), 'rarely' (1), 'sometimes' (2), 'often' (3), 'very often' (4), 'constantly' (5) 'not concerned' (0). To prevent any confusion with changes in perception due to symptoms related to comorbidities, the majority of questions included the wording 'due to my acne'.

The interviews ensured broad recruitment and a coherent diversity of patients in terms of geographical location, as well as of age and sociological status. Participating subjects of at least 15 years of age had to have a clinically confirmed acne of any severity assessed on the GEA acne scale.<sup>18</sup>

Building this questionnaire followed the following process steps: conception, development, internal and external validation, test–retest validation and translation, cross-cultural adaptation and cognitive debriefing.

## Conception

A literature research on PubMed was made to identify work about questionnaires and scoring systems related to acne. A series of interviews with dermatologists was conducted and patient reported outcomes (PRO) were comprehensively collected to assess the patients' perceptions and complaints and assess the initial wording. Based on the initial wording reports, a list of items that were reformulated as simple questions were drew up. The final choice of questions was made by the working group, which semantically analysed the initial phrasing. The wording of each question was examined and questions were regrouped if similarities were considered to be too strong.

As a result, a semi-structured 'Acne Impact on Adult Daily Life' (AI-ADL) questionnaire was created covering 4 domains: relationships with others, economic consequences, impact on work, impact on daily life, on sexuality and libido were compiled.

## Development

The questionnaire was administered to a random sample of acne patients. Completed questionnaires were analysed by an exploratory factor analysis. A semantic analysis of the initial conceptual questionnaire was performed and non-discriminating questions and questions, for which wording was considered non-pertinent, were eliminated. An inter-item correlation matrix was created in order to compile a condensed questionnaire and a scree plot was made to determine the number of pertinent dimensions followed by an exploratory factor analysis (EFA). Questions presenting a high cross factor loading of >0.250 were eliminated.

Detailed information about the statistical analysis methods are provided in supplemental material.

## Validation

**Internal validation** The homogeneity of the items in the total score and in each dimension was tested using the Cronbach's  $\alpha$  coefficient.<sup>19</sup> A confirmatory factor analysis with a higher order factor was to demonstrate the questionnaires' factorial validity and greater uni-dimensionality. The model's suitability was measured using the Tucker-Lewis index (TLI), the comparative fit index (CFI) and root mean-square error of approximation

(RMSEA). A Spearman correlation was calculated assessing the reliability between the AI-ADL and the SF-12 and CADI questionnaires and a confirmatory factorial analysis was performed to confirm the structure obtained from the exploratory factorial analysis.<sup>14,20</sup> Burden scores according to their severity were compared to explore in more depth this validation.

Detailed information about the statistical analysis methods are provided in Supplemental Material.

**External validation** To determine the questionnaire's validity, 261 participants completed the shortened version of the questionnaire and 2 validated self-administered questionnaires.

### Test–retest validation

Test–retest analyses were carried out to assess reproducibility. Participating patients answered the AI-ADL questionnaire once and then again after 10 days. Answers were compared and the reliability of measurements confirmed using ICC and Bland and Altman plot.

### Translation, cross-cultural adaptation and cognitive debriefing

The validated methodology was applied to generate a US English-language version according to the recommendations of the ISPOR task force.<sup>21</sup>

Detailed information about the statistical analysis methods for the development and validation steps is provided in Supplementary Material. Statistical analyses were conducted using R software version 3.6.1 for Windows. The level of significance was set at 5%.

## Results

### Conception

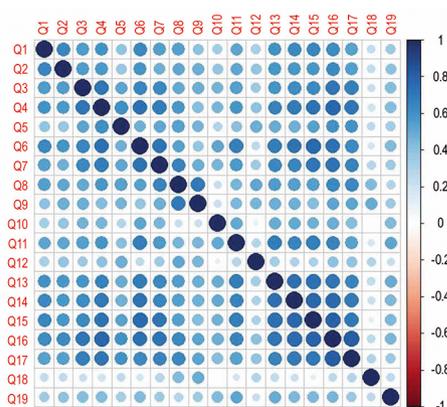
In 2016, Zaenglein *et al.* identified 29 acne scoring systems and quality of life questionnaires.<sup>22</sup> In addition, our literature research identified 4 more acne-related quality of life and other disease-impact questionnaires assessing the effect of acne on the psyche of the patients.<sup>14,23–25</sup>

Verbal exchanges and several face-to-face meetings took place between dermatologists, psychologists, social workers and patient reported outcome (PRO) experts. A total of 160 acne patients expressed and shared their perceptions and complaints regarding their acne. These discussions and interviews resulted in an initial verbatim, leading to a 51-item conceptual questionnaire (Table S1, Supporting Information). Questions were categorised into the following 4 categories: relationships with others, economic consequences, impact on work and impact on everyday life. Moreover, the questionnaire was formatted using a Likert scale with 7 possible answers.

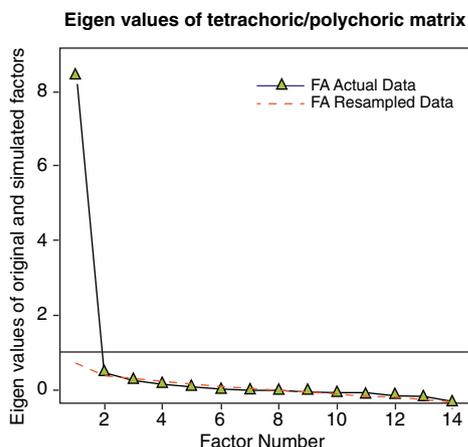
**Table 1** Demographic and disease data of subjects participating in the development of the 19-item questionnaire

	Total		Mild		Moderate		Severe	
	N	%	N	%	N	%	N	%
<b>Gender</b>								
Male	82	32.16%	35	35.71%	31	28.97%	16	32.00%
Female	173	67.84%	63	64.29%	76	71.03%	34	68.00%
<b>Age (years)</b>								
	Mean	SD	Years	SD	Years	SD	Years	SD
	22.1	7.6	23.2	8.6	22.2	7.5	19.5	4.8
<b>Acne Severity</b>								
	N	%	N	%	N	%	N	%
Mild	98	38.43%	98	100.00%	0	0.00%	0	0.00%
Moderate	107	41.96%	0	0.00%	107	100.00%	0	0.00%
Severe	50	19.61%	0	0.00%	0	0.00%	50	100.00%
<b>BMI</b>								
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
	21.9	3.7	21.1	3.0	22.3	4.2	22.7	3.6
<b>Acne duration (years)</b>								
	Years	SD	Years	SD	Years	SD	Years	SD
	7.3	6.3	7.5	6.7	7.9	6.6	5.9	4.5
<b>Lesions type</b>								
	N	%	N	%	N	%	N	%
Lesions	98	38.43%	37	37.76%	41	38.32%	20	40.00%
Scars	55	21.57%	19	19.39%	19	17.76%	17	34.00%
<b>Localization</b>								
Face	250	98.04%	95	96.94%	107	100.00%	48	96.00%
Chest	66	25.88%	17	17.35%	27	25.23%	22	44.00%
Back	119	46.67%	38	38.78%	55	51.40%	26	52.00%

N: number, SD: standard deviation, BMI: Body Mass Index.



**Figure 1** Representation of inter-items polychoric correlation.



**Figure 2** Scree plot representing eigen values for each factor in the dataset and the simulated dataset.

**Development**

In total, 255 adult patients who attended the clinics of 124 French dermatologists tested the conceptual questionnaire.

Detailed demographic and disease data for participants are provided in Table 1.

The semantic analysis of this questionnaire resulted in a 19-item questionnaire.

*Exploratory factor analysis* Results from the inter-item matrix correlation (Fig. 1) eliminated 5 questions, resulting in a 14-item questionnaire.

All KMO scores confirmed a suitable dataset for conducting an EFA; all scores were above 0.87 with 12 items scoring above 0.95. The scree plot (Fig. 2) determined one pertinent dimension, and therefore, the EFA was not performed.

**Validation**

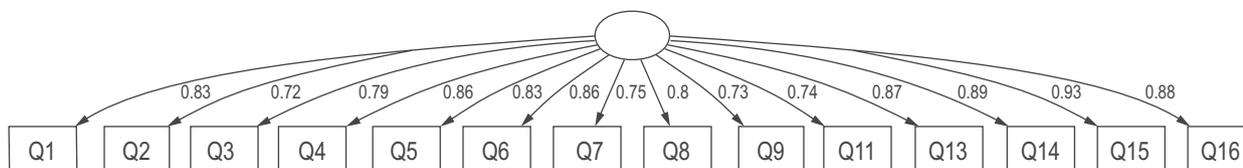
The 14-item questionnaire was distributed together with SF-12 and CADI questionnaires to 207 patients with a clinically confirmed acne according to the GEA scale.<sup>18</sup>

*Internal validation* The Cronbach's  $\alpha$  coefficient was 0.949, confirming a high coherence.

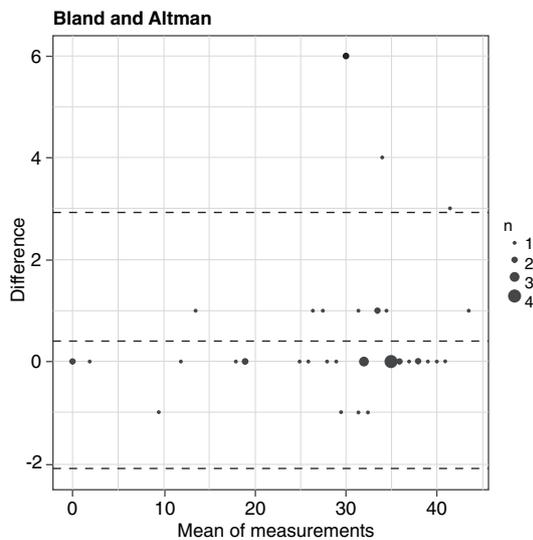
The confirmatory factorial analysis confirmed the robustness of the one factorial solution with values for TLI, CFI and RMSEA of 0.998, 0.998 and 0.054, respectively. Figure 3 represents how each item relates to its subscale and how the subscales relate to the underlying factor.

*External validation* Correlation with the SF-12 and CADI scores were high with a correlation of 0.084 (CI95%: [-0.053; 0.218]) with the SF-12 physical score;  $P = 0.228$ , of -0.558 (CI95%: [-0.645; -0.457];  $P < 0.001$ ) with the SF-12 mental score and of 0.757 (CI95% [0.692; 0.81];  $P < 0.001$ ) with the CADI score correlating the best, confirming the validity of the AI-ADL questionnaire.

The Kruskal-Wallis test confirmed the statistically significant ( $P < 0.001$ ) difference of AI-ADL scores among the different acne severity according to the GEA.<sup>18</sup> The more severe acne, the higher was the AI-ADL score (mean AI-ADL scores for: mild acne  $19.06 \pm 13.36$ , moderate acne:  $27.25 \pm 16.09$  and severe acne:  $35.36 \pm 16.67$ ).



**Figure 3** Confirmatory factor analysis representing how each item relates to its subscale and how the subscales relate to the underlying factor (Burden of treatment).



**Figure 4** Bland and Altman graph for the test–retest of the score representing the difference between test and retest total score by their mean.

#### Test–retest analysis

The test–retest step was realized for 47 participants. Results demonstrated a very good reproducibility, with a total intra-class correlation (ICC) score of 0.992 and a CI 95% of [0.981, 0.997]. The Bland and Altman plot showed that high difference between scores was mainly present for subject with a high overall mean suggesting that this difference was

due to fluctuation in acne manifestation rather than low reproducibility of the test (Fig. 4).

#### Cognitive debriefing, translation and cross-cultural adaptation

Cognitive debriefing did not result in any changes of the wording of the questions. The original French version of the questionnaire was translated and underwent linguistic and cultural validation into US English. The final, validated version of the questionnaire is given in Table 2.

#### Discussion and conclusion

Acne significantly affects patients' quality of life. It occurs not only in adolescents or young adults, it occurs more and more frequently in adults over 25 years and there is a need for specific tools allowing to assess the impact of acne on the adults quality of life.<sup>2,26–30</sup> Several questionnaires and other tools have been developed to assess the quality of life.<sup>14,22–25</sup> However, most of the time, these questionnaires are not specific to acne and are used in clinical studies and are due to their length or their very general aspect not suitable for the daily clinical practice.<sup>31–34</sup>

We herewith present a short and an easy-to-use self-administered questionnaire allowing adult acne patients to assess the individual impact of the disease on their daily life. It is currently available in French and US English using easily understandable questions and with a total score of 70 points acne burden can be easily graded from no to severe burden. Its short format allows patients having difficulties to communicate to express themselves using a standardized mean and thus to initiate an exchange between the practitioner and his patient. Furthermore,

**Table 2** Final 14-item AI-ADL questionnaire

	Always	Very often	Often	Sometimes	Rarely	Never	Not applicable
<b>Score</b>	<b>5</b>	<b>4</b>	<b>3</b>	<b>2</b>	<b>1</b>	<b>0</b>	<b>0</b>
1. Have you felt put down because of your acne?	<input type="checkbox"/>						
2. Have you felt worried about your future because of your acne?	<input type="checkbox"/>						
3. Have you avoided having your photograph taken because of your acne?	<input type="checkbox"/>						
4. Have you felt worried about meeting someone for the first time because of your acne?	<input type="checkbox"/>						
5. Have you felt anxious about kissing someone because of your acne?	<input type="checkbox"/>						
6. Have you felt ashamed because of your acne?	<input type="checkbox"/>						
7. Have you felt that other people stare at you because of your acne?	<input type="checkbox"/>						
8. Do you feel lonely because of your acne?	<input type="checkbox"/>						
9. Have you found it difficult to concentrate because of your acne?	<input type="checkbox"/>						
10. Have you felt angry because of your acne?	<input type="checkbox"/>						
11. Have you felt discouraged because of your acne?	<input type="checkbox"/>						
12. Have you lost confidence in yourself because of your acne?	<input type="checkbox"/>						
13. Have you felt uneasy because of your acne?	<input type="checkbox"/>						
14. Have you felt worried about being out in public because of your acne?	<input type="checkbox"/>						
<b>Sub score (sum of scores for question 1–14)</b>							
<b>Total score (sum for sub scores 0–5)</b>							

Total score: 0 = no burden, from 1 to 20 = mild burden, between 21 and 30 = moderate burden, above 31 = severe burden.

using the questionnaire at subsequent visits allows assessing the evolution over time of acne burden on the patient. However, to confirm its utility, data about its use in the daily clinical practice needs to be gathered through real-life data collections.

In the daily clinical practice, the total burden score will be obtained by summing up scores for each of the 14 questions as defined in the aforementioned method description, with 'never' or 'not applicable' scoring 0, 'rarely' 1, 'sometimes' 2, 'often' 3, 'very often' 4 and 'constantly' 5.

With a total AI-ADL score of 70 points, we suggest the following burden grading: 0 = no burden, from 1 to 20 = mild burden, between 21 and 30 = moderate burden and above 31 = severe burden.

The 9-step methodology required to generate linguistically-validated and cross-culturally-adapted versions in other languages is well-established. It is with an internal consistency exceeding the minimum reliability criterion of 0.90 for individual analysis.

Long-lasting skin diseases affect the patient's physical and mental well-being. Disease impact or burden accounts for the broadest aspects of disease-related disability, covering psychological, physical, social and economic factors, simultaneously taking into account QoL, community integration, organisation of everyday life, as well as medical resource consumption. Thus, using questionnaires allow to evaluate this overarching impact.<sup>16,35–38</sup>

Based on advances made in QoL research over the last decades, healthcare professional and regulatory agencies, such as the US Food and Drug Administration (FDA) and the European Medicine Agency (EMA), currently face complex issues related to the development of health-related quality of life claims for both product labelling and promotion.<sup>36</sup> Leidy *et al.* issued recommendations to the healthcare industry for ensuring that all health-related QoL claims are based on rigorously-designed studies, with appropriate methodology and instrumentation.<sup>39</sup> Development in the clinical research area has led to an ever more widespread use of questionnaires, and this trend is most likely to continue in the near future. The reason for this is the increasing relevance of data that are both closer to clinical practice and increasingly needed to achieve market access. Moreover, QoL, patient wellbeing and patient-centred outcome data are required more and more by reimbursement agencies, such as NICE in the UK and IQWiG in Germany.<sup>38</sup>

In conclusion, the present acne burden questionnaire AI-ADL allows the practitioner to quickly and easily assess the burden of acne in patients during the daily clinical practice. Moreover, its short format allows patients to express easily and quickly their feelings and to initiate a conversation between the practitioner and his patient. Thus, AI-ADL may help to better understand the multidimensional nature of acne, as well as the individual impact on the acne patient's daily life and thus play a key role in the decision-making process of treatment initiation and involvement of the patient in the management of his acne.

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### Supporting information

Additional Supporting Information may be found in the online version of this article:

**Table S1** 51-item conceptual questionnaire (French original version)

**Data S1** Detailed statistical methodology for the development and validation of the questionnaire