

Analysis of Correlations between Patient-Oriented SCORAD (PO-SCORAD) and Other Assessment Scores of Atopic Dermatitis Severity and Quality of Life

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Key Words

Atopic dermatitis · Eczema score, patient-oriented · Scoring of Atopic Dermatitis index · Self-assessment score · Quality of life · Patient-Oriented Eczema Measure · Self-Administered Eczema Area and Severity Index

Abstract

Objective: Self-assessment scores such as the Patient-Oriented Scoring of Atopic Dermatitis (PO-SCORAD) index being recommended by public health authorities for chronic disease management, we aimed at analysing correlations between PO-SCORAD and physician and patient assessment scores of atopic dermatitis (AD) severity and quality of life.

Methods: We performed an observational study conducted in 12 European countries in 4,222 atopic patients aged ≥ 1 month and prescribed Exomega[®] emollient cream. AD severity was measured by the SCORAD index, PO-SCORAD, Patient-Oriented Eczema Measure (POEM) and Self-Administered Eczema Area and Severity Index (SA-EASI) scales, and patient and family quality of life by the Dermatology Life Quality Index (DLQI) and Dermatitis Family Questionnaire Impact (DFQI) scales, respectively. Their correlations were analysed. **Results:** PO-SCORAD was the only self-assessment score to be highly correlated with the SCORAD index and POEM ($r \geq 0.70$). It was also the best correlated with the DLQI

($r = 0.67$) and DFQI ($r = 0.56$). After a 5-week treatment, SCORAD index and PO-SCORAD severity scores had decreased significantly by 60 and 56% ($p < 0.0001$), and quality of life had improved. **Conclusion:** PO-SCORAD is better correlated with quality of life scales than other self-assessment scores.

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Introduction

Current recommendations for chronic diseases like atopic dermatitis (AD) tend to encourage greater involvement of patients in their own therapeutic management [1, 2]. Patients need therefore to be able to reliably assess the severity and extent of their disease themselves. Several self-assessment scales have been proposed, including the Patient-Oriented Eczema Measure (POEM) [3] and Self-Administered Eczema Area and Severity Index (SA-EASI) [4]. In order to have a self-assessment scale that incorporated both subjective and objective criteria, the European Task Force on Atopic Dermatitis developed (in collaboration with the Fondation pour la dermatite atopique) the PO-SCORAD (Patient-Oriented Scoring of Atopic Dermatitis) [5] on the basis of the assessment criteria of the SCORAD index used by physicians, the most widely referenced score in the literature [6–8]. The PO-SCORAD has been vali-

dated in a large-scale European study demonstrating its correlation with the SCORAD index in patients with AD of varying severity [9], but its value compared with other self-assessment scores has not yet been evaluated.

Although AD is not a life-threatening disease, the irritating, painful and disfiguring nature of the disease can profoundly affect the quality of life of patients and their families [10]. AD involves both psychological factors, such as mood and self-esteem, and social and functional factors, such as relationships and daily activities. Specific quality of life scales such as the Dermatology Life Quality Index (DLQI) [11] and Dermatitis Family Questionnaire Impact (DFQI) [12] measure the impact of eczema and its treatment on the quality of life of patients and their family, respectively. Although some studies showed a positive association between SCORAD index and DFQI score [13], other data failed to confirm a correlation between quality of life and clinical AD severity [14, 15].

Considered essential therapy in AD management, the use of emollients is recommended by the different European [16] and American [17] consensus conferences and guidelines. Their efficacy has been demonstrated with respect to both repair of the barrier function of the skin and of patients' signs and symptoms (xerosis, pruritus and flares of AD) [18, 19].

The main objective of this study was therefore to determine if PO-SCORAD was a valuable tool to self-evaluate disease severity and quality of life in patients with AD compared with other self-assessment scores. With this aim, the correlations between AD severity assessment scores (PO-SCORAD, SCORAD index, POEM, SA-EASI) and quality of life scores were analysed in a large international observational study of patients with AD who were prescribed an emollient as adjunctive treatment (Exomega[®] cream, A-Derma, France). The correlations between the changes in AD severity scores and quality of life scores between baseline and follow-up were also assessed.

Patients and Methods

This prospective, observational, open-label, multicentre study was conducted from February 2009 to April 2012 by paediatricians and dermatologists in 12 countries: France, Poland, Italy, Spain, Belgium, Canada, Denmark, Czech Republic, Slovakia, Mexico, Romania and Greece. It was carried out in accordance with applicable regulatory requirements in each country involved in the study. As this study did not require any change in patient management, informed consent and ethics committee approvals were not necessary. Preliminary results including 3 countries (France, Poland, Italy) have previously been published [20].

Study Product

The qualitative composition (INCI list) of Exomega[®] emollient cream is as follows: water (aqua), mineral oil (paraffinum liquidum), cyclomethicone, glycerin, Peg-12, glyceryl stearate, Peg-100 stearate, *Oenothera biennis* (evening primrose) oil, myreth-3 myristate, polyacrylamide, niacinamide, 10-hydroxydecenoic acid, *Avena sativa* (oat) leaf/stem extract, benzoic acid, butylhydroxytoluol, C₁₃₋₁₄ isoparaffin, chlorphenesin, disodium EDTA, laureth-7, maltodextrin, phenoxyethanol, sodium acetate, tocopherol, triethanolamine.

Population

The inclusion criteria were: patients with AD, aged 1 month and over, for whom the physician had decided to prescribe the Exomega[®] emollient cream as adjunctive treatment of AD and for whom a follow-up visit was scheduled 4–8 weeks after the initial visit. Pregnant or breast-feeding women were excluded, as well as patients with an identified sensitivity to one of the ingredients in the Exomega[®] cream or suffering from another pathology that might have interfered in the evaluation of clinical signs.

Study Design

This study included 2 visits (inclusion and follow-up). At the inclusion visit (day 0), the physicians proceeded to dermatological examination of their patient, prescribed Exomega[®] cream, drug therapy and/or other dermocosmetic treatments according to their usual clinical practice. At both visits, the investigator assessed the patient's AD severity using the SCORAD index [6], and the parents assessed the impact of AD on family quality of life using the DFQI validated scale [12]. Independently, the patient, or a parent on behalf of children unable to complete the form themselves, completed 3 questionnaires of AD severity self-assessment and 1 quality of life questionnaire before or after each visit. The patients were instructed to fill in the questionnaires within 48 h after their visit with the physician. At the follow-up visit, the patients (or their parents) and investigators also rated the efficacy and tolerance of Exomega[®] cream.

AD Severity and Quality of Life Self-Assessment Scales

Patients self-assessed AD severity using 3 validated scales: PO-SCORAD [5, 9], SA-EASI [4] and POEM [3]. The SA-EASI validated scale takes into account the body surface area involved and the severity of the pathology [4]. In this study the SA-EASI was an adapted scale, as only the 'severity component' was used to calculate the score (body surface component set to 1).

Patients self-assessed their quality of life using a validated scale specific of their age: the Infant's Dermatitis Quality of Life Index for subjects under 5 years [21], Children's Dermatology Life Quality Index 'cartoon' for children aged 5–10 [22], the Children's Dermatology Life Quality Index for subjects aged 11–16 [23] and the DLQI for subjects above the age of 16 [11].

Evaluation Criteria

The correlations between AD severity scores were measured with the SCORAD index, PO-SCORAD, POEM and SA-EASI scales and the quality of life scores of the patients and their family with the DFQI and DLQI specific quality of life scales at baseline and follow-up, and the correlations between their changes from baseline.

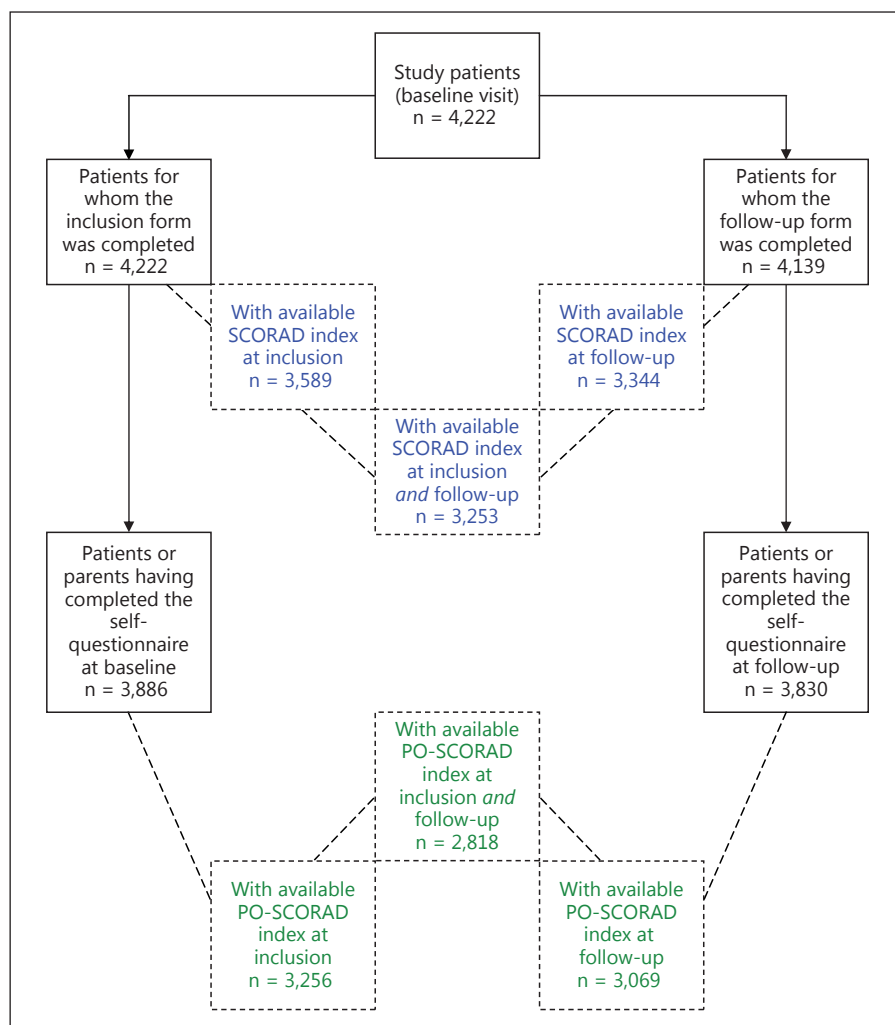


Fig. 1. Flow chart of the study population.

The aim was to estimate the efficacy of Exomega[®] cream as adjunctive treatment of AD by analysing the change in AD severity scores (SCORAD index, PO-SCORAD, adapted SA-EASI, POEM) between the beginning and end of the study.

Statistical Analysis

Statistical analysis was performed on the whole study population (population of the 12 countries combined) using SAS software (version 9.2, SAS Institute Inc., Cary, N.C., USA). Quantitative data were described using the number of patients, missing data, mean and standard deviation (SD), minimum and maximum, and qualitative data such as available data, missing data, total numbers and percentage by category. Between-group comparisons were made using Student's *t* test or the Wilcoxon rank sum test for non-parametric data. Correlations between the different AD severity scores and the quality of life scores at inclusion and follow-up and between absolute changes from baseline were analysed using the Spearman correlation coefficient (*r*), and the 95% confidence interval (CI), which was computed using the Fisher transformation. The cut-off values to interpret the correlations were as follows:

<0.5 = no correlation, >0.5 = correlation, >0.7 = high correlation. No adjustments were made in the statistical analysis. In particular, analyses were not country adjusted. All tests were 2-sided, and the α -risk was set at 5% for the whole study.

Results

Study Population

A total of 727 paediatricians and dermatologists participated in the survey and included 4,222 patients with AD requiring the use of an emollient such as Exomega[®] cream, amongst whom 1,066 were enrolled in France, 930 in Italy and 384 in Poland (table 1). Among them, 83 patients did not attend the follow-up visit (2%; lost to follow-up, premature withdrawal). Self-questionnaires were completed by 92% of subjects at baseline

Table 1. Demographic data and baseline clinical characteristics

	Pooled population (n = 4,222)
<i>Patient characteristics (n = 4,222)</i>	
Country	
France	1,066
Italy	930
Poland	384
Mexico	318
Romania	311
Greece	301
Czechoslovakia	288
Belgium	259
Canada	178
Spain	102
Denmark	85
Gender (n = 3,927)	
Male	1,905 (48.5)
Female	2,022 (51.5)
Age, years (n = 3,914)	
Mean $\pm$ SD	11.9 $\pm$ 13.1
Median	6.7
Min.–max.	0.1–97
SCORAD at baseline (n = 3,589)	
Mean $\pm$ SD	42.2 $\pm$ 17.4
Median	43.00
Min.–max.	0.0–113.2
Severity of AD (n = 3,589)	
Mild to moderate AD (SCORAD $\leq$ 50)	2,467 (68.7)
Severe AD (SCORAD >50)	1,122 (31.3)
<i>Medical history</i>	
Mean age at AD onset $\pm$ SD (n = 3,815), years	3.4 $\pm$ 6.4
Mean seniority of AD $\pm$ SD (n = 3,762), years	8.3 $\pm$ 10.4
Mean number of flare-ups within the last 4 months $\pm$ SD (n = 3,030)	2.0 $\pm$ 1.99
<i>Nature of treatment(s) prescribed at baseline (n = 3,657)</i>	
No medical or dermatocosmetic treatment other than Exomega [®] cream	274 (7.5)
Medical treatment	3,222 (88.1)
Topical corticosteroids	2,621 (81.4)
Calcineurin inhibitor	582 (18.1)
Topical antibiotics	565 (17.5)
Systemic antibiotics	159 (4.9)
Antiseptics	289 (9.0)
Antihistamines	1,720 (53.4)
Results in parentheses are percentages.	

(n = 3,886/4,222) and 90.7% at follow-up (3,830/4,222) (fig. 1). The mean duration of the study per patient (time between baseline and follow-up visits) was 43.5 $\pm$ 42.8 days (range 1–447).

Demographic Data and Baseline Clinical Characteristics

The patients' sociodemographic and clinical characteristics at inclusion are shown in table 1. Patients were aged on average 12 $\pm$ 13 years (1 month to 97 years). They were children (<18 years old) in 73.8% of cases and adults in 26.2%. The study population was well balanced with 51.5% females and 48.5% males. The main motive for the initial consultation was an inflammatory flare-up (70.3% of cases, n = 2,523). The mean SCORAD index at inclusion was 42.2 $\pm$ 17.4, and the majority of patients (68.7%) had mild to moderate AD (SCORAD index $\leq$ 50).

A family history of AD was found in 58.2% of patients (n = 2,267/3,898), and AD was associated with allergic asthma or allergic rhinitis in 18.4% (n = 714/3,871) and 28.6% (n = 1,107/3,865) of cases, respectively.

At inclusion, the prescribed drugs were mainly topical corticosteroids (81.4%, n = 2,621/3,657), in association with a dermatocosmetic product in 49.7% of cases (1,819/3,657).

Analysis of the Correlations between AD Severity Scores Measured with SCORAD Index, PO-SCORAD, Adapted SA-EASI and POEM Scales

Analysis of the correlations showed that PO-SCORAD was the only self-assessment score to be highly correlated with the SCORAD index and POEM (row correlation coefficient $\geq$ 0.70) (table 2). The PO-SCORAD score was better correlated with the SCORAD index than POEM and adapted SA-EASI scores, whether at baseline (r = 0.78, 95% CI = 0.77–0.80 vs. r = 0.64, 95% CI = 0.61–0.67, and r = 0.67, 95% CI = 0.65–0.69), follow-up (r = 0.78, 95% CI = 0.76–0.79 vs. r = 0.66, 95% CI = 0.63–0.69, and r = 0.72, 95% CI = 0.69–0.74) or in terms of changes from baseline (table 2). PO-SCORAD was also well correlated with adapted SA-EASI and POEM at inclusion (r = 0.85, 95% CI = 0.83–0.86, and r = 0.79, 95% CI = 0.77–0.80) and at follow-up (r = 0.86, 95% CI = 0.85–0.88, and r = 0.79, 95% CI = 0.77–0.81) or in terms of changes from baseline (table 2).

Correlation between AD Severity Scores and Quality of Life Scores

Correlations between AD severity scores and quality of life scores are summarised in table 3. PO-SCORAD and POEM scores were better correlated with the DFQI than the SCORAD index and adapted SA-EASI scores. The PO-SCORAD was better correlated with the DFQI than POEM with a higher Spearman's correlation coefficient at baseline (r = 0.59, 95% CI = 0.56–0.61 vs. r = 0.55, 95%

Table 2. Correlations between AD severity scores evaluated by the physician (SCORAD) and the patient (PO-SCORAD, adapted SA-EASI, POEM)

Severity indexes	n	Spearman's correlation coefficient r		
		SCORAD	PO-SCORAD	Adapted SA-EASI
PO-SCORAD				
Baseline	3,256	0.78 [0.77–0.80]		
Follow-up	3,069	0.78 [0.76–0.79]		
Change from baseline	2,818	0.70 [0.68–0.71]		
Adapted SA-EASI				
Baseline	1,964	0.67 [0.65–0.69]	0.85 [0.83–0.86]	
Follow-up	1,840	0.72 [0.69–0.74]	0.86 [0.85–0.88]	
Change from baseline	1,704	0.58 [0.55–0.61]	0.79 [0.77–0.81]	
POEM				
Baseline	1,686	0.64 [0.61–0.67]	0.79 [0.77–0.80]	0.75 [0.73–0.77]
Follow-up	1,646	0.66 [0.63–0.69]	0.79 [0.77–0.81]	0.77 [0.75–0.79]
Change from baseline	1,440	0.58 [0.54–0.61]	0.75 [0.72–0.77]	0.72 [0.70–0.75]

Figures in brackets indicate 95% CI.

Table 3. Correlations between AD severity scores (PO-SCORAD, SA-EASI and POEM) and quality of life (DFQI and DLQI): PO-SCORAD was the score best correlated with DFQI and DLQI

AD severity indexes	n	Spearman's correlation coefficient r	
		DFQI	DLQI
SCORAD			
Baseline	3,589	0.50 [0.48–0.53]	0.56 [0.54–0.58]
Follow-up	3,344	0.49 [0.46–0.51]	0.60 [0.58–0.62]
Change from baseline	3,253	0.41 [0.38–0.44]	0.52 [0.49–0.54]
PO-SCORAD			
Baseline	3,256	0.59 [0.56–0.61]	0.67 [0.65–0.69]
Follow-up	3,069	0.51 [0.48–0.54]	0.67 [0.65–0.69]
Change from baseline	2,818	0.56 [0.53–0.58]	0.67 [0.65–0.69]
Adapted SA-EASI			
Baseline	1,964	0.45 [0.42–0.49]	0.57 [0.54–0.60]
Follow-up	1,840	0.47 [0.44–0.51]	0.63 [0.60–0.66]
Change from baseline	1,704	0.47 [0.43–0.50]	0.60 [0.56–0.63]
POEM			
Baseline	1,686	0.55 [0.51–0.58]	0.64 [0.61–0.67]
Follow-up	1,646	0.53 [0.50–0.57]	0.66 [0.63–0.69]
Change from baseline	1,440	0.53 [0.49–0.57]	0.65 [0.62–0.68]

Figures in brackets indicate 95% CI.

CI = 0.51–0.58) and in terms of change from baseline ($r = 0.56$, 95% CI = 0.53–0.58 vs. $r = 0.53$, 95% CI = 0.49–0.57), and it was slightly less correlated at the follow-up ($r = 0.51$, 95% CI = 0.48–0.54 vs. $r = 0.53$, 95% CI = 0.50–0.57).

PO-SCORAD and POEM were both well correlated with the DLQI score at baseline ($r = 0.67$, 95% CI = 0.65–0.69, and $r = 0.64$, 95% CI = 0.61–0.67), follow-up ($r = 0.67$, 95% CI = 0.65–0.69, and $r = 0.66$, 95% CI = 0.63–0.69) and in terms of change from baseline (table 3).

Table 4. AD severity scores assessed by the physician (SCORAD) and the patient (PO-SCORAD, POEM and adapted SA-EASI) at inclusion and follow-up and change in scores from baseline

Score	Baseline		Follow-up		Change from baseline			
					absolute variation		relative variation, %	
	n	mean $\pm$ SD	n	mean $\pm$ SD	n	mean $\pm$ SD	mean $\pm$ SD	95% CI
SCORAD	3,589	42.2 $\pm$ 17.3	3,344	16.6 $\pm$ 13.2	3,253	25.9 $\pm$ 15.4*	60.2 $\pm$ 34.7	59.0–61.4
PO-SCORAD	3,256	41.5 $\pm$ 18.3	3,069	17.3 $\pm$ 13.7	2,818	24.5 $\pm$ 17.1*	55.6 $\pm$ 40.6	54.1–57.1
SA-EASI ^a	1,964	11.0 $\pm$ 3.3	1,840	6.1 $\pm$ 5.1	1,704	4.9 $\pm$ 5.4*	43.1 $\pm$ 42.2	41.1–45.1
POEM	1,686	12.1 $\pm$ 6.4	1,646	4.2 $\pm$ 4.3	1,440	7.9 $\pm$ 6.0*	60.4 $\pm$ 48.6	57.9–62.9

SCORAD and PO-SCORAD maximum scores = 103; POEM maximum score = 28 and the higher the score, the severer the AD. SA-EASI and POEM scores were measured in only 5 countries: France, Poland, Italy, Spain and Belgium. * $p < 0.0001$: significance of the change.

^a Adapted SA-EASI: second component only, i.e. severity of the lesions, maximum score = 20.

Table 5. DFQI and DLQI scores at baseline and follow-up and absolute and relative changes from baseline

Score	Baseline		Follow-up		Change from baseline			
					absolute variation		relative variation, %	
	n	mean $\pm$ SD	n	mean $\pm$ SD	n	mean $\pm$ SD	n	mean $\pm$ SD 95% CI
DFQI	1,547	8.7 $\pm$ 7.0	1,405	4.1 $\pm$ 4.8	1,285	4.9 $\pm$ 5.5*	1,258	46.1 $\pm$ 71.8 42.2–50.1
DLQI ^a	1,952	10.2 $\pm$ 6.5	1,734	4.0 $\pm$ 4.2	1,579	6.4 $\pm$ 5.8*	1,572	54.2 $\pm$ 62.1 51.1–57.3

For all scales, the maximum score is 30 and the higher the score, the more quality of life is impaired. Quality of life scores were measured in only 5 countries: France, Poland, Italy, Belgium and Spain. * $p < 0.001$: significance of the change.

^a DLQI and all likened scores.

Analysis of Changes in AD Severity and Quality of Life Score

Between the beginning and end of the study, a highly significant decrease ($p < 0.0001$) was observed in all physician- and patient-assessed AD severity scores, with in particular a mean decrease by 60 and 56% from baseline in the SCORAD index and PO-SCORAD scores, respectively (table 4). The PO-SCORAD and SCORAD index improved in 93.1 and 96.4% of patients, respectively. The rate of severe AD dropped from 31.3% at inclusion to 2.5% at follow-up ($p < 0.0001$). Quality of life of the patients and their family was also highly significantly improved at follow-up ($p < 0.0001$) in 86.9% of patients and 78.3% of their family (table 5).

Discussion

In this multicentre observational study we demonstrated that PO-SCORAD was the AD severity self-assessment score that best correlated with the SCORAD index. PO-SCORAD was also highly correlated with the other self-assessment score POEM ($r > 0.76$). Moreover, the PO-SCORAD index exhibited a better correlation with the two quality of life scores dedicated to patients and their families than the other self-assessment scores. We observed a highly significant decrease in all severity scores measured by the patient, i.e. PO-SCORAD, SA-EASI and POEM ($p < 0.0001$), resulting in a reduction in the rate of severe AD in the study population. This improvement in AD severity was accompanied by a very significant improvement in the quality of life of patients, but also of their family ($p < 0.0001$).

The results of this study enabled us to confirm in a large European population (4,222 paediatric and adult patients) the high correlation between PO-SCORAD and SCORAD index ($r > 0.70$) already observed in the validation study [9]. Furthermore, whereas in the validation study no specific intervention was investigated, in this study, some changes were expected and evidenced. This study thus confirmed the good correlation between PO-SCORAD and SCORAD index in patients exhibiting changes in AD severity. This study also showed that PO-SCORAD is easy to use by the patients and reliable in an everyday practice context. Compared with the other AD severity self-assessment tools, PO-SCORAD is the only one that allows a standardised measurement including both the objective and subjective symptoms of the disease, experienced by the patient, who can easily compare his or her symptoms with standardised photographs presented in the booklet accompanying the questionnaire. The learning-by-doing effect, observed in our previous study [9] between the beginning and end of the study 28 days later and characterised by an improvement in the correlation between SCORAD index and PO-SCORAD ($r = 0.79$, 95% CI = 0.75–0.83 vs. $r = 0.67$, 95% CI = 0.62–0.72), was not found in the present study, in which a high correlation coefficient ($r = 0.78$) was obtained from the onset. This indicates good understanding of the tool and the quality of the guidelines associated with the PO-SCORAD rating scale at the beginning of the study to assist them with completion.

The fact that in our study PO-SCORAD correlated well with the DLQI, a reference quality of life scale specific for AD, as well as with the SCORAD index and POEM confirms the validity of this score to determine AD severity and its reliability in relation to other self-assessment scores. This study clearly demonstrated the relationship between disease severity and patient quality of life, with the SCORAD index, PO-SCORAD and DLQI scores all having decreased significantly by 55–60% ($p < 0.0001$) from inclusion. The fact that the SCORAD index was fairly well correlated with the DLQI ($r = 0.52$, change from baseline) contrasts with the results of two recent studies [14, 15], which both showed a poor correlation between the SCORAD index and DLQI.

This poor correlation can be logically explained by the fact that Van Valburg et al. [14] and Haeck et al. [15] used the objective SCORAD index, which does not take into account pruritus and sleep loss. Indeed, these 2 subjective symptoms, which are included in the SCORAD index and PO-SCORAD, play a major role in a patient's quality of life. They make a valuable addition to objective criteria used to grade the severity of AD [24].

In conclusion, by demonstrating the correlation of PO-SCORAD with specific health-related quality of life evaluation scales and also other AD severity scales, this study validated the use of PO-SCORAD for the self-assessment of AD in a large European population of patients with mild to severe AD.

PO-SCORAD is a valuable tool, both for everyday clinical practice and for large-scale epidemiological studies, for evaluating AD severity and its impact on the quality of life of the patient and his/her family, especially in paediatric populations. A computing software and an application for smartphones and tablets (available on Apple Store and Google Play, <http://www.poscorad.com>) have been developed for helping patients to fill out the PO-SCORAD questionnaire, and for transmitting their score and AD severity evolution curve to their physician in between consultations. This process provides the physicians with useful information to evaluate the impact of the treatment prescribed for reducing AD severity in their patient. In the future, physicians might also propose this tool to their patients to assess their long-term dynamic compliance with treatment.

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Disclosure Statement

Investigators received a fee from their subsidiary; in France, the investigator's fees were EUR 25 by included patient. However, as this was an observational study, there was no conflict of interest for the investigators. Christine Coutanceau is an employee of Pierre Fabre Dermocosmétique, Jean-François Stalder received fees from Pierre Fabre Dermocosmétique.

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