Assessing Post-Inflammatory Pigmentation in Atopic Dermatitis: Reliability of the PDCA-Derm™

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SYNOPSIS

- The PDCA-Derm™ is a single-item clinician-reported outcome measure of post-inflammatory hyperpigmentation and hypopigmentation (PIH).
- The PDCA-Derm was developed for use in patients with atopic dermatitis (AD).
- The clinical presentation of AD and PIH varies among patients, including patients with skin of color.[1] A measurement tool is needed to assess PIH in patients with AD.
- The PDCA-Derm is currently the only measure of PIH in AD, and it addresses a key gap in AD skin assessment.

OBJECTIVE

- Using qualitative and quantitative data obtained from dermatologists, this observational study assessed the content validity, inter-rater reliability, and intra-rater reliability of the PDCA-Derm to support its suitability for use in patients with moderate-to-severe AD.

CONCLUSION

- All dermatologists interpreted the PDCA-Derm instructions and response options correctly, and all reported that the response options were distinct from one another. Data support the use of the PDCA-Derm.
- The PDCA-Derm had good to excellent inter-rater and intra-rater reliability, but rater accuracy was poor to fair. More research is needed to understand the sources of rater inaccuracy.
- These findings suggest that the PDCA-Derm is suitable for assessing PIH in patients with moderate-to-severe AD.
- Additional studies investigating dermatologists' assessments of the PDCA-Derm are needed to make solid conclusions about the instrument's validity.

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RESULTS: Participant characteristics

- Ten dermatologists participated **(Table 1)**.

Table 1. Participant characteristics

Characteristic	Total (n=10)
Age in years	
Min–max	37.0–77.0
Mean (SD)	51.4 (13.7)
Gender, n (%)	
Female	6 (60)
Male	4 (40)
Years of experience treating patients with AD, n (%)	
More than 20	4 (40)
11–20	4 (40)
6–10	1 (10)
Not answered	1 (10)
Average number of patients with AD treated per month, n (%)	
More than 25	6 (60)
16–20	2 (20)
11–15	1 (10)
6–10	1 (10)
Proportion of treated patients with AD who have skin of color, n (%)	
More than 75%	1 (10)
51%–75%	2 (20)
26%–50%	6 (60)
25% or less	1 (10)

AD, atopic dermatitis; SD, standard deviation.

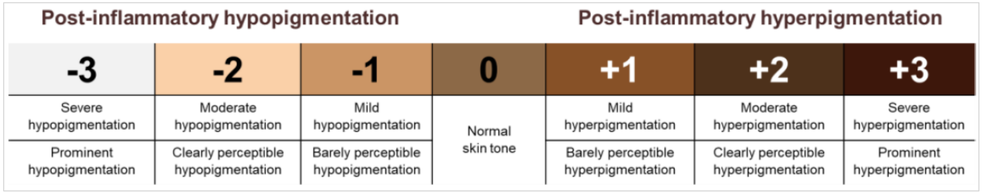


Figure 2. The PDCA-Derm scale with example colors shown in the PDCA-Derm training.
0 is always normal skin. The scale evaluates hyperpigmentation and hypopigmentation compared to normal skin.

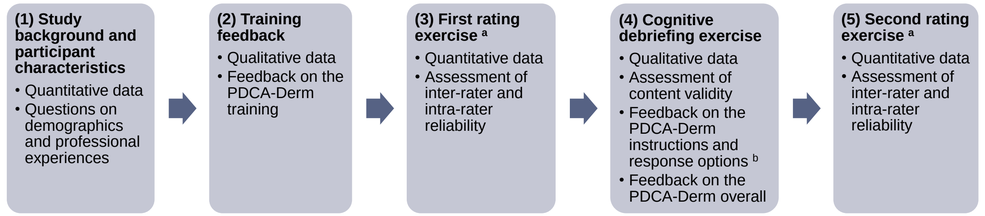


Figure 3. The five stages of the cognitive debriefing meeting.
[a] Dermatologists rated 22 randomized photographs of PIH in patients with moderate-to-severe AD. The same photographs were presented at each timepoint but in a different order. Different skin tones were represented. At least one photograph for each PIH severity level on the PDCA-Derm scale was included. Intraclass correlation coefficients (ICCs) were calculated to evaluate intra- and inter-rater reliability. Rater accuracy was also assessed by comparing the dermatologist rating for each post-inflammatory lesion photograph against the "gold standard" rating provided *a priori* by an expert clinician. [b] Dermatologists verbalized their interpretation of the instructions and response options according to developer definitions.

RESULTS: Quantitative data

Intra-rater reliability:

- Intra-rater reliability was good (ICC=0.76–0.87, n=2) or excellent (ICC=0.93–0.99, n=6) for most dermatologists (n=8; 80%).

Inter-rater reliability:

- Inter-rater reliability was good at timepoint 1 (ICC=0.75, n=10) and excellent at timepoint 2 (ICC=0.90, n=10).

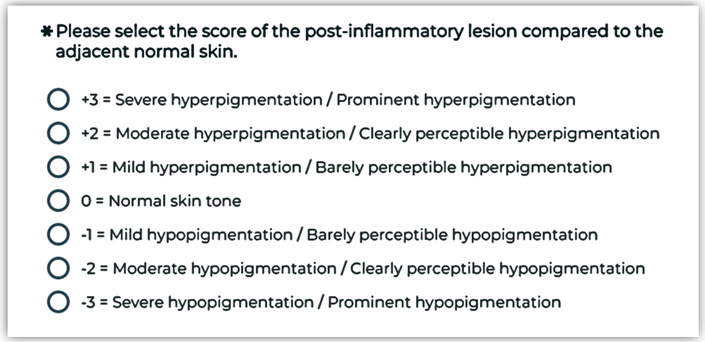
Rater accuracy:

- Five dermatologists (50%) demonstrated fair accuracy (70%–80%), and five (50%) demonstrated poor accuracy (<70%).

METHODS

- **Design:** This observational study collected qualitative and quantitative data about the PDCA-Derm **(Figure 1)**.
- **Participants:** Participants were clinical trial dermatologists and general dermatologists who were residing in the US and actively treating patients with moderate-to-severe AD. Potential participants were identified by Eli Lilly and Company via convenience sampling (ie, professional contacts) and enrolled by Adelphi Values.
- **Procedures:** Dermatologists first completed self-paced PDCA-Derm training via PowerPoint slides. The PDCA-Derm scale with example colors of PIH compared to normal skin was shown **(Figure 2)**. Each dermatologist then completed a 60-minute cognitive debriefing meeting via Microsoft Teams **(Figure 3)**.

Figure 1. The PDCA-Derm instructions and response options used for the cognitive debriefing and rating exercises.



0 is always normal skin. The scale evaluates hyperpigmentation and hypopigmentation compared to normal skin. The figure color has been adapted for the purpose of the poster.

RESULTS: Qualitative data

PDCA-Derm overall:

- Most dermatologists reported that the PDCA-Derm was easy to use (n=7; 70%), had appropriate response options (n=6; 60%), and had response options that were distinct enough to detect changes in PIH (n=7; 70%). Five dermatologists (50%) noted that the PDCA-Derm would be able to assess changes in PIH in patients with moderate-to-severe AD, and nine (90%) reported that the PDCA-Derm would be useful to evaluate treatment efficacy in a clinical trial.
- Three dermatologists (30%) reported that the PDCA-Derm was difficult to use because PIH can look different in different patients and can vary depending on the location of the lesions. Three dermatologists (30%) reported that the response options were not specific or distinct enough to detect changes in PIH and recommended using a larger scale.

PDCA-Derm instructions and response options:

- All dermatologists (n=10; 100%) correctly interpreted the PDCA-Derm instructions, correctly interpreted the response options, and reported that the response options were distinct from one another.
- Eight dermatologists (80%) suggested changes to the PDCA-Derm to make it easier to assess PIH. Four (40%) suggested changes to the instructions, and four (40%) suggested changes to the response options. For example, three dermatologists (30%) suggested changing "adjacent normal skin tone" to "unaffected skin". One dermatologist (10%) noted that a larger scale with four response options on either side of "normal skin tone" (ie, a 9-point scale) would be more helpful.

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References

1. Kaufman BP, Aman T, Alexis AF. Postinflammatory Hyperpigmentation: Epidemiology, Clinical Presentation, Pathogenesis and Treatment. Am J Clin Dermatol. 2018 Aug;19(4):489-503. doi: 10.1007/s40257-017-0333-6. PMID: 29222629.

Disclosures
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