Allergy Alert Test – Update

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Carsten Goebel, Ph.D., Wella Company
Cosmetics Europe
Hair Colorant Product Safety

Background:

Regulations in many countries (e.g. USA, Canada, Australia, Japan, some Lat-Am countries) require consumer self-testing.

No standardised protocol or harmonised instructions; exposure dose, site and duration vary.

Concern about consumers' ability to interpret test reactions.

Concern about risk of induction of sensitisation.

Aim:

To show in those who have a proven contact allergy to hair-dye *(PPD positive patch test/history of hair dye use)*

-the feasibility of a defined test protocol

-whether it can elicit a reaction (‘alert’) noticeable by the subject

-whether it corresponds to a dermatological assessment

-whether the reactivity on the forearm is comparable to reactivity behind the ear

It is not intended to be a surrogate for a patch-test to diagnose contact allergy

Reference: DERMATITIS; 29(5):250-257; 2018

STUDIES

OPEN

The Allergy Alert Test: Introduction of a Protocol Suitable to Provide an Alert Signal in *p*-Phenylenediamine–Allergic Hair Dye Users

Pieter-Jan Coenraads, MD, PhD,* Werner Aberer, MD, PhD,† Antonio Cristaudo, MD, PhD,‡
Thomas Diepgen, MD, PhD,§ Catherine Holden, MD,|| Lukas Koch, MD,† Marie-Louise Schuttelaar, MD, PhD,*
Elke Weisshaar, MD, PhD,§ Anne Fuchs, PhD,¶ Kordula Schlotmann, MD,# Carsten Goebel, PhD,**
Brunhilde Blömeke, PhD,†† and Maya Krasteva, MD, PhD‡‡

Background: Contact dermatitis to hair dyes remains a health concern. Regulations in many countries require consumer self-testing for hair dyes, but no standardized procedure exists.

Objective: The aim of this study was to develop a self-test protocol for an allergy alert test (AAT) that can elicit a self-noticeable alert signal in *p*-phenylenediamine (PPD)–allergic consumers.

Methods: Simulating consumer use conditions (open application after mixing with a developer for 45 minutes), PPD-positive hair dye–allergic subjects and PPD-negative control subjects were tested on the forearm and behind the ear with experimental products containing 0.05%, 0.25%, 0.75%, and 2% PPD. Reactions were self-evaluated by subjects and independently assessed by dermatologists.

Conclusions: The AAT caused a reaction self-noticeable on the forearm in 90.5% (38/42) and behind the ear in 93% (39/42) of the PPD-positive subjects. This was objectified by a dermatological evaluation. The strength of the AAT response and the number of responding subjects increased with increasing PPD concentrations. Allergy alert test responses were also dependent on the reaction strength of the diagnostic patch test to PPD before the study; in subjects with (+++) patch test reactions, 19 of 19 were positive. All 48 control subjects were negative to the AAT. Therefore, the AAT protocol provides a signal indicative of an allergic reaction in PPD-allergic hair dye consumers.

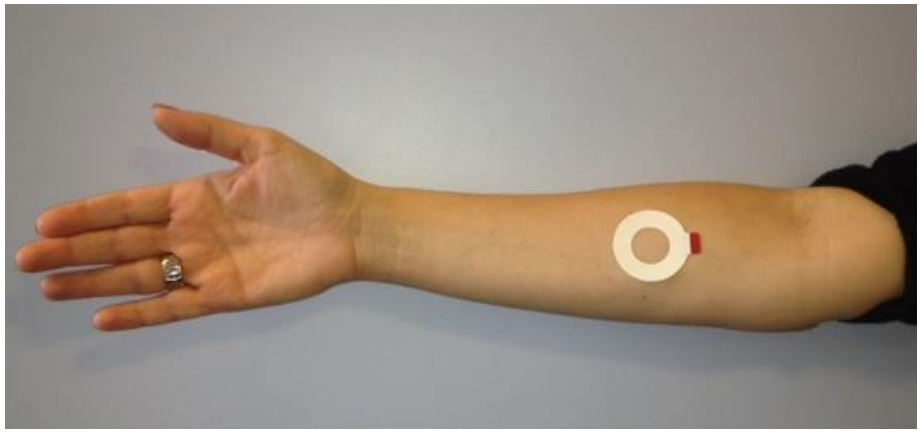
Design (1):

The experimental test product and the corresponding control product are tested

- 0.150 ml applied open for 45 minutes on a surface area of 3.6 cm^2
- behind the ears and on volar aspects of forearms according to a scheme

Wash out time: 3 – 6 weeks between two consecutive applications

Application	Left	Right
Forearm Retro-auricular area	Experimental products *with increasing PPD concentrations [%]* 0.05➔0.25➔0.75➔2	Control product Y



Design (2):

Daily reading and self-evaluation by subject (detailed diary)

Dermatological scoring of skin site immediately after rinse-off, at day 2 (48 hrs) and day 4 (72 hrs)

Instruction to report any late reaction

Photography of test area at every evaluation/scoring

A use test on a small occipital area was envisaged for those who did not react to the highest test concentration

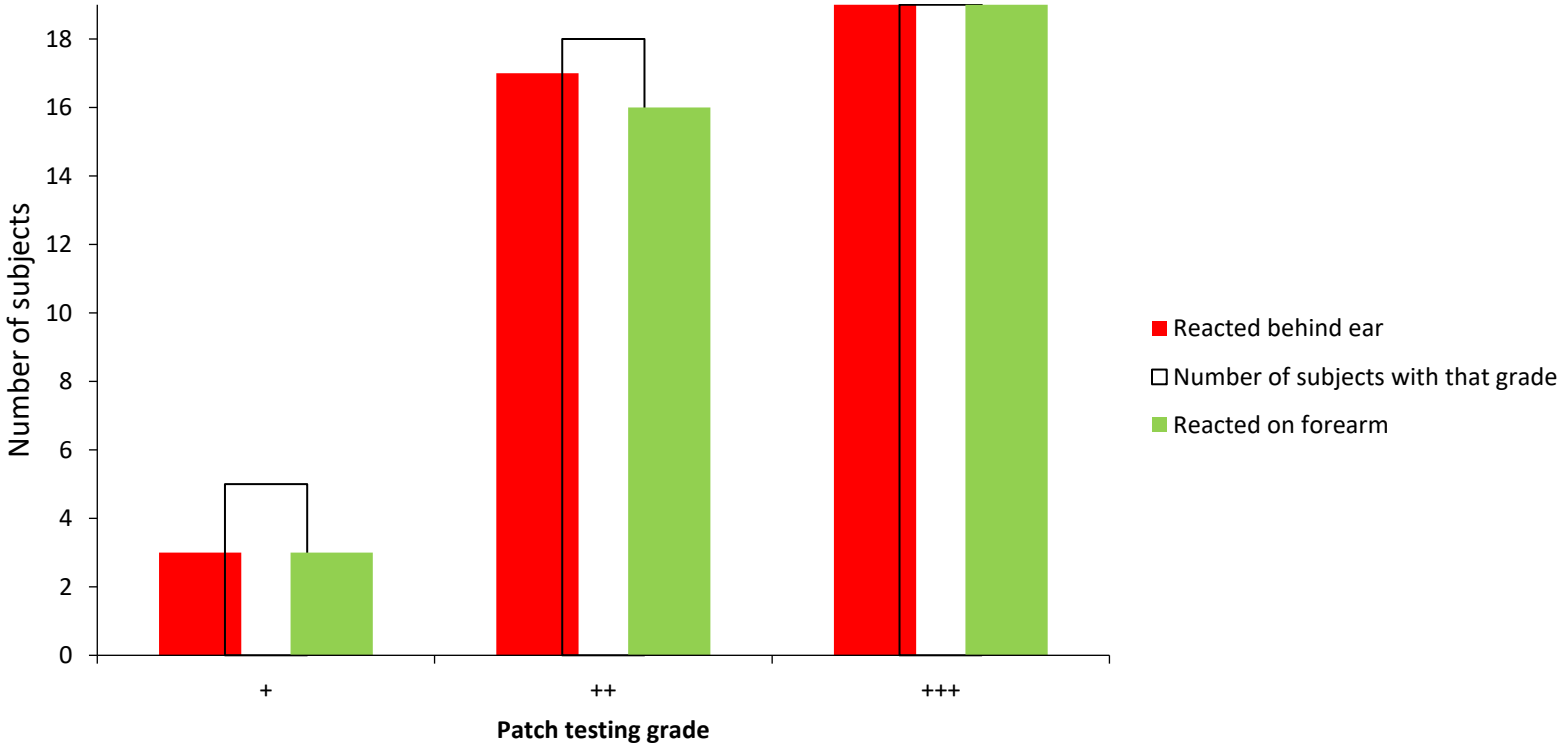
Results: Stratification of AAT reactivity by past patch test grade

Of the 42 analysed subjects, 3 did not react to the test.

Of these, 2 had a weak (one +) patch-test reaction to PPD before entering the study.

Of those with PPD ++ before the study, one did not react.

Of those with PPD +++, all reacted.

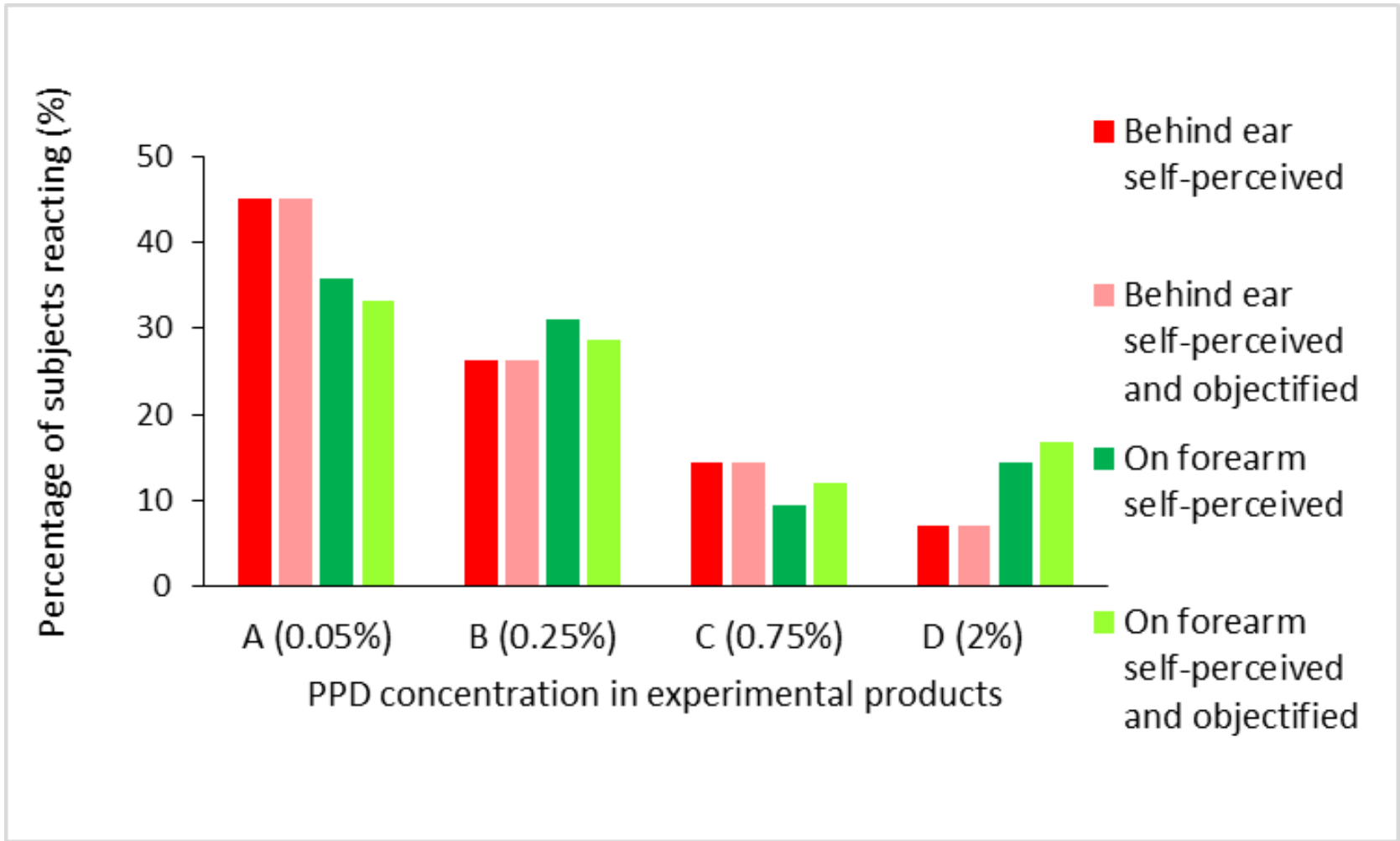


Reaction to any product (*PPD concentration, 0.05%–2%)*;

Reactions self-perceived by subjects and objectified by dermatologists at day 2 *(N = 42 subjects)*.

No higher PPD concentration was tested when a positive response was obtained.

Concentration dependency of positive AAT *(in 42 subjects available for the analysis)*.



Good agreement between self-perceived and dermatologist-objectified reaction

Summary / Conclusions:

Alert test-reaction self-noticeable in most of subjects: 90% reacted

Results objectified by dermatological evaluation

Strength of test response was dependent on strength of patch-test reaction to PPD

Of the subjects with a +++ patch-test reaction, all responded to (‘were alerted by’) the test

Note:

- The risk of induction of sensitisation by the test was not assessed in this study
- The test is not intended as a surrogate for a diagnostic patch-test

Basic points of Cosmetics Europe Proposed Recommandation for Allergy Alert Test (AAT)

Final product	Tint mixed with developer at use conditions
Amount	Pea-size, spread evenly across 2 by 2 cm in a thin layer
Site	Inner side of forearm
Application time	Leave the mixture applied for **45 minutes** without covering or touching it; after 45 minutes wash the test area with water and pat dry with a clean tissue.
Positive AAT	Any perceived changes to normal skin appearance, redness, swelling on and around the test area during the testing time, or **during the following 48hrs**, you/your client should rinse off the test area immediately, should do not use the product and should consult a doctor
Timing	AAT recommendation is under final approval by Cosmetics Europe

Basic points of Cosmetics Europe Recommendation for Allergy Alert Test across industry

Product: mixed with the developer at use conditions

Amount: pea-size, spread evenly across 2 by 2 cm in a thin layer

Site: inner side of forearm

Application: Leave the mixture applied for **45 minutes** without covering or touching it; after 45 minutes wash the test area with water and pat dry with a clean tissue.

Positive AAT: any perceived changes to normal skin appearcance, redness, swelling on and around the test area during the testing time, or **during the following 48hrs**, you/your client should rinse off the test area immediately, should do not use the product and should consult a doctor

Detailed harmonized instructions are currently beeing worked

QUESTIONS?