

Introduction

Dandruff is a skin condition that is visible to other people and is embarrassing for many dandruff sufferers. Fortunately, there are a number of anti-dandruff products available in the market to help to reduce the visible dandruff. In order to prove the efficiency of an anti-dandruff product we describe here an evaluation based on three pillars. 1. a visual subjective score system, 2. an image analytical test and 3. a home-in-use test with self assessment.

Study design

To standardize hair conditions all test subjects need to undergo a two or three week washout period with a basic cleansing shampoo during which they shampoo their hair daily or at least twice a week. The next step includes a four to six week treatment phase, followed by a further rinsing phase of two to four weeks with a basic cleansing shampoo. Test subjects enrolled in the study need to use the assigned treatment at least three times per week. It is advisable to examine the dandruff status prior to the conditioning phase (week -2 or -3), at the beginning of the treatment (baseline, week 0) and then weekly or at least fortnightly during treatment as well as in the rinsing phase (Fig. 1).

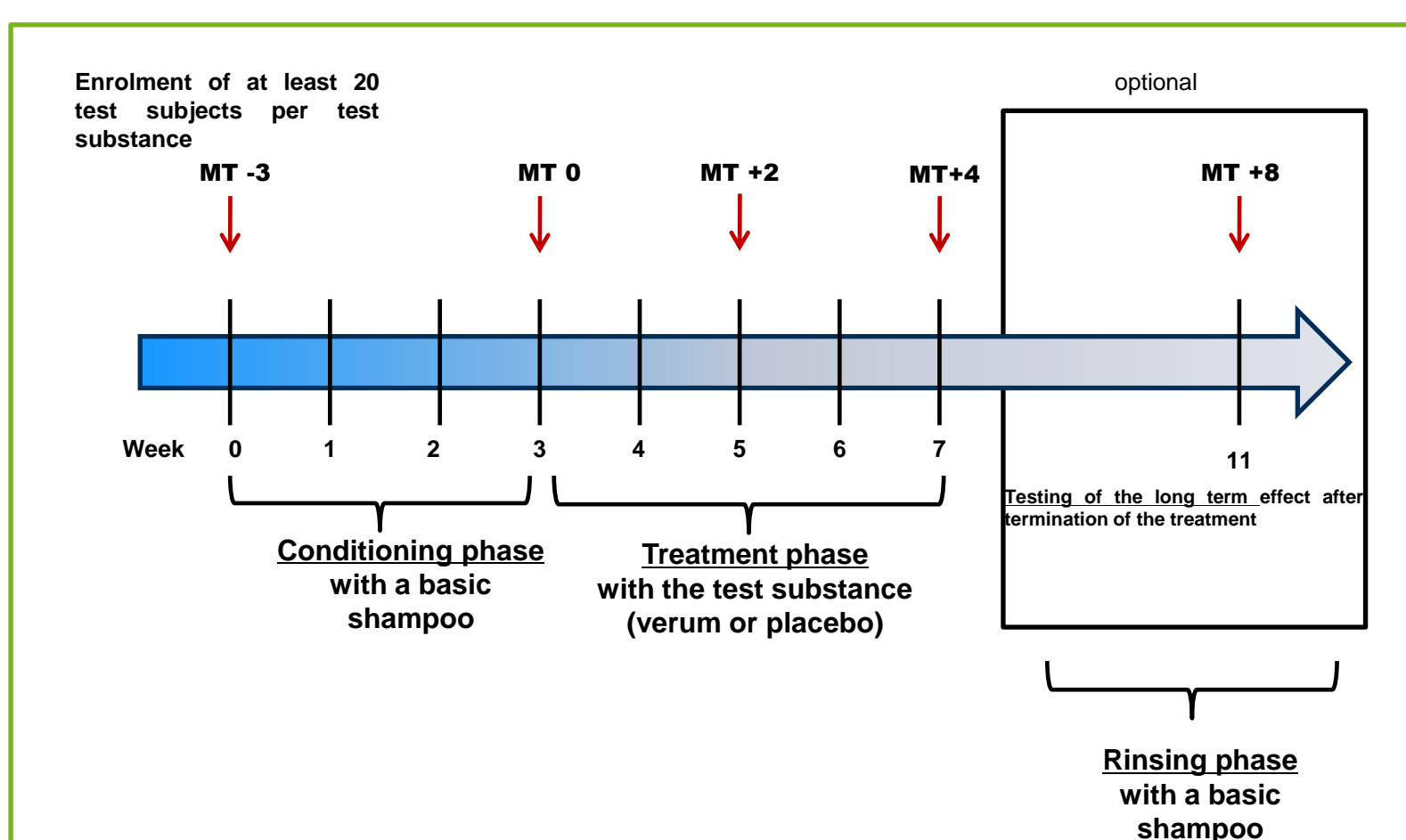


Figure 1: Study design (MT = measurement time point)

Evaluation of the product efficacy

Scalp flake scoring

The first step in order to determine the efficacy of an anti-dandruff product is a visual subjective evaluation of the dandruff status of each individual test subject done by a qualified examiner. For this purpose the head is divided into 4 sections: front – back – right – left. Initially the 4 quadrants are evaluated separately according to a scale ranging from 0 (no scaling) to 4 (very dense dandruff) (Tab. 1). The final score (sum of the grades for all 4 quadrants) and the mean value for each test subject are calculated. Furthermore, the mean values and standard deviations per test group are determined.

Table 1

Score	0	=	not visible
	1	=	individual scales
	2	=	several scales
	3	=	dense dandruff
	4	=	very dense dandruff

Image analytical test

Parallel to the visual scalp flaking scoring, an image-analytical test procedure, which was co-developed in our institute, is applied. In this procedure the dandruff scales are combed or shaken off the hair under defined conditions, transferred into a petri dish and evenly distributed in the measuring field with a fine brush and then, the scales are illuminated by white LED light, arranged circularly. The dandruff program calculates the total number of scales and analyses the frequency distribution of the scale sizes in per cent. In addition, the percentage part of scales of the total area in comparison to the background is analyzed.

Table 2

Categorie	I	>	0.23 mm	
	II	up to	0.23 mm	
	III	up to	0.20 mm	
	IV	up to	0.18 mm	
	V	up to	0.15 mm	
	VI	up to	0.13 mm	Visible to the naked eye
	VII	up to	0.10 mm	Hardly visible to the naked eye
	VIII	up to	0.08 mm	Invisible to the naked eye
	IX	<	0.05 mm	Invisible to the naked eye

Overall cosmetic evaluation

A high quality anti-dandruff product not only has to provide a good efficacy but at the same time excellent cosmetic and hair care benefits are essential. Not at least for these reasons galenic parameters, cosmetic acceptance, skin compatibility and efficacy of all tested substances are evaluated in a home-in-use test using a special questionnaire for self assessment.

Test of an antimycotic azole shampoo and the corresponding placebo

Scalp flaking score

The scalp flaking scores were assessed fortnightly for 8 weeks and compared to the scores at baseline. Initially, the dandruff became worse after the conditioning phase. This can often be observed and indicates that the test subjects had used different hair care products before. The overall dandruff score declined statistically throughout the treatment period for the antimycotic azole shampoo. The reduction in mean total dandruff scores was 36.0% at 4 weeks of treatment and showed a slight increase during the rinsing phase. As expected, the overall dandruff score did not change significantly during the course of the study in the placebo control group (Fig. 2).

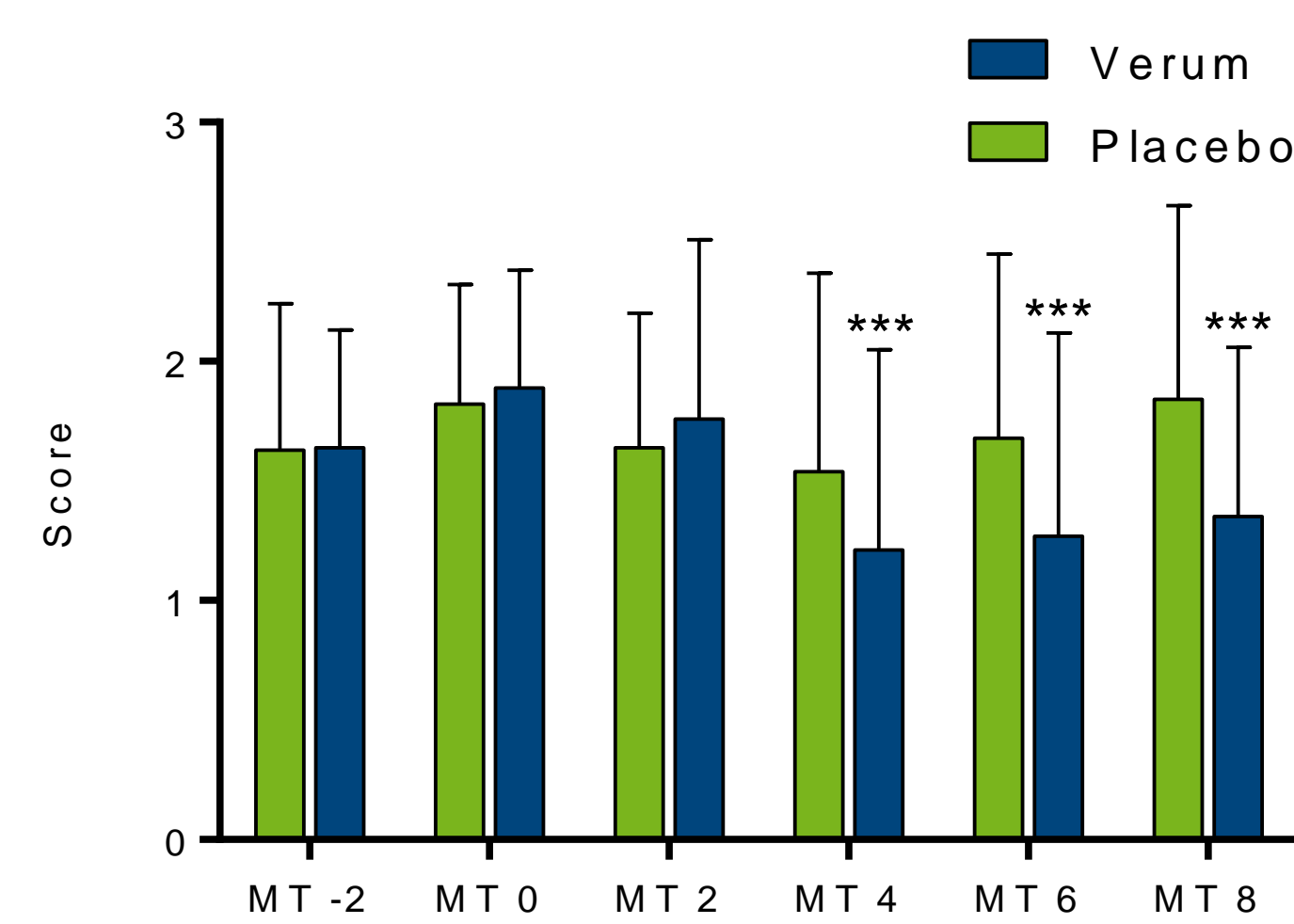


Figure 2: Kinetics of the mean score per group treated either with a verum (n=24) or a placebo shampoo (n=26) are shown (t-test, *** for p<0.001).

Image analytical test

Test subjects treated for 4 weeks with the antimycotic azole shampoo showed an increase of 21 % of flakes classified in category I, that are invisible to the naked eye. In contrast all other flake sizes (category II-XI) decreased ranging from 45 % to 21 % compared to baseline. In the rinsing phase, flakes classified in category I decreased continually and vice versa the larger scales increased (Fig. 3).

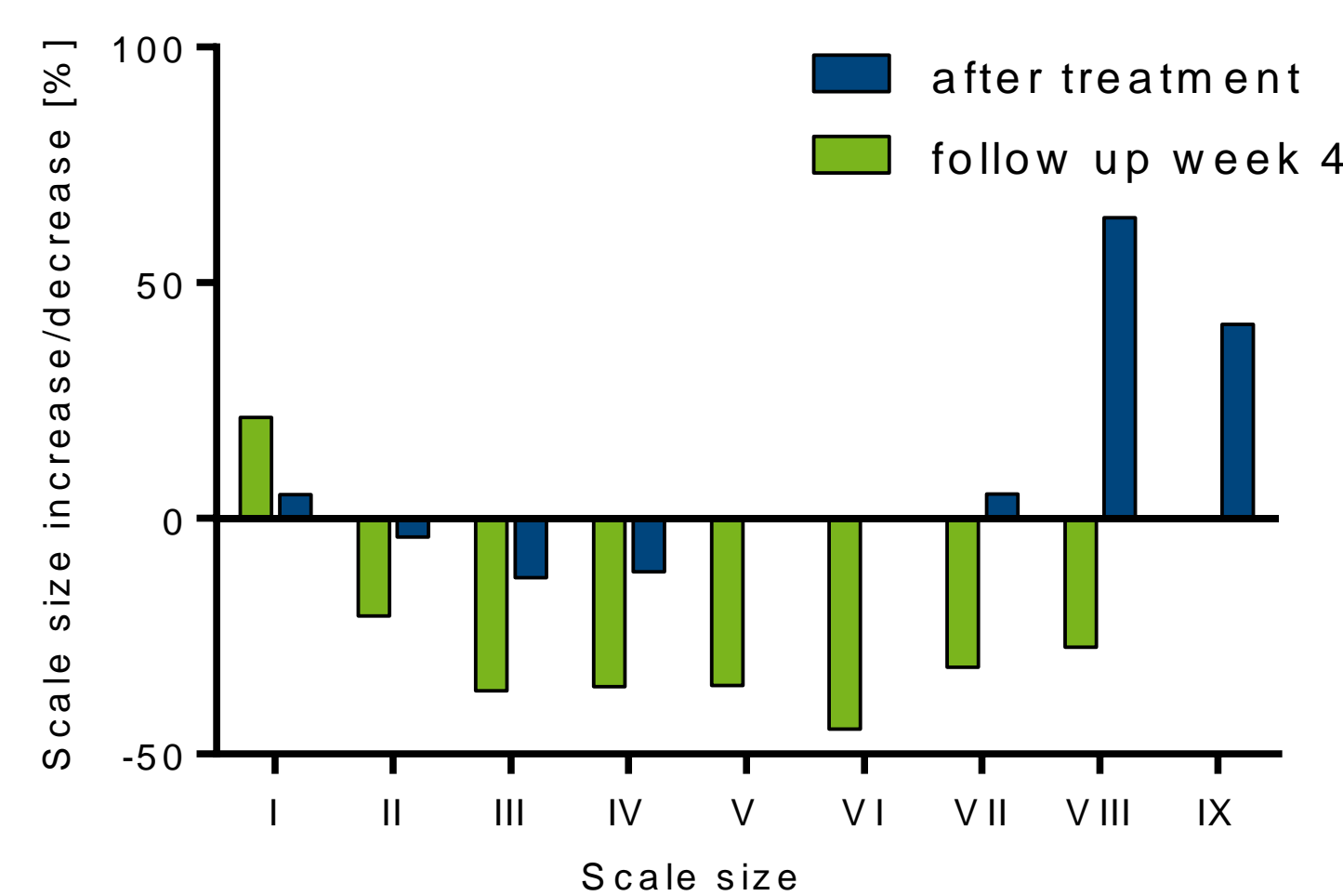


Figure 3: Scale size distribution. The percentage increase/decrease is shown for every nine scale sizes, comparing how much the scale size changed after 4 weeks of treatment and in the follow up week 4 to baseline.



Figure 4



Figure 5

Test of two different basic formulations with the same active ingredient

Scalp flaking score

Treatment with the test substances formulation A or formulation B showed a significant decrease (p<0.01) of the dandruff by 49% and 53 %, respectively (measuring time week 0 and week +4). During the rinsing phase with a neutral shampoo, there was a slight increase in the number of scales (Tab. 3).

Image analytical test

The evaluation of the image-analytical data showed a significant decrease (p<0.01) in the number of scales by 50% for formulation A and 56 % for formulation B (Tab. 3).

Table 3 Image-analytical comparison of two formulas. MT = measurement time, NS = number of scales, AS = measured area covered with scales, SS = relative scale size

MTP	Product	Formulation A				Formulation B			
		NS	SA	SS	Score	NS	SA	SS	Score
-3	P	274	10.8	4.0	1.04	356	13.1	3.7	1.03
0	V	475	18.4	3.9	1.39	458	16.9	3.7	1.04
1	V	428	16.5	3.8	1.41	353	12.8	3.6	1.21
2	V	362	14.4	4.0	1.17	326	10	3.1	1.15
3	V	265	9.3	3.5	0.80	243	8.1	3.4	0.86
4	V	240	7.8	3.3	0.71	200	6.3	3.2	0.59
5	P	209	6.7	3.2	0.71	231	6.8	2.9	0.68
6	P	231	7.9	3.4	0.67	224	7.7	3.5	0.70
7	P	264	9.3	3.5	0.77	320	12.0	3.7	0.93
8	P	278	13.3	4.8	1.12	311	14.3	4.6	1.05

Home use test with self assessment

However, the efficacy of a product doesn't make any statement regarding the cosmetic acceptance among the dandruff sufferers and should not be underestimated especially when it comes to compliance. With an overall assessment of 2.27, the acceptance of the test product anti-dandruff formulation A by the test subjects was good. However, with an overall assessment of 2.53, the acceptance of the test product anti-dandruff formulation B was rated only good to fair by the test subjects. In summary, both test substances are effective anti-dandruff shampoos, but in a home-in-use test the subjective evaluation of the compatibility formulation A was on first place compared to formulation B (Fig. 6).

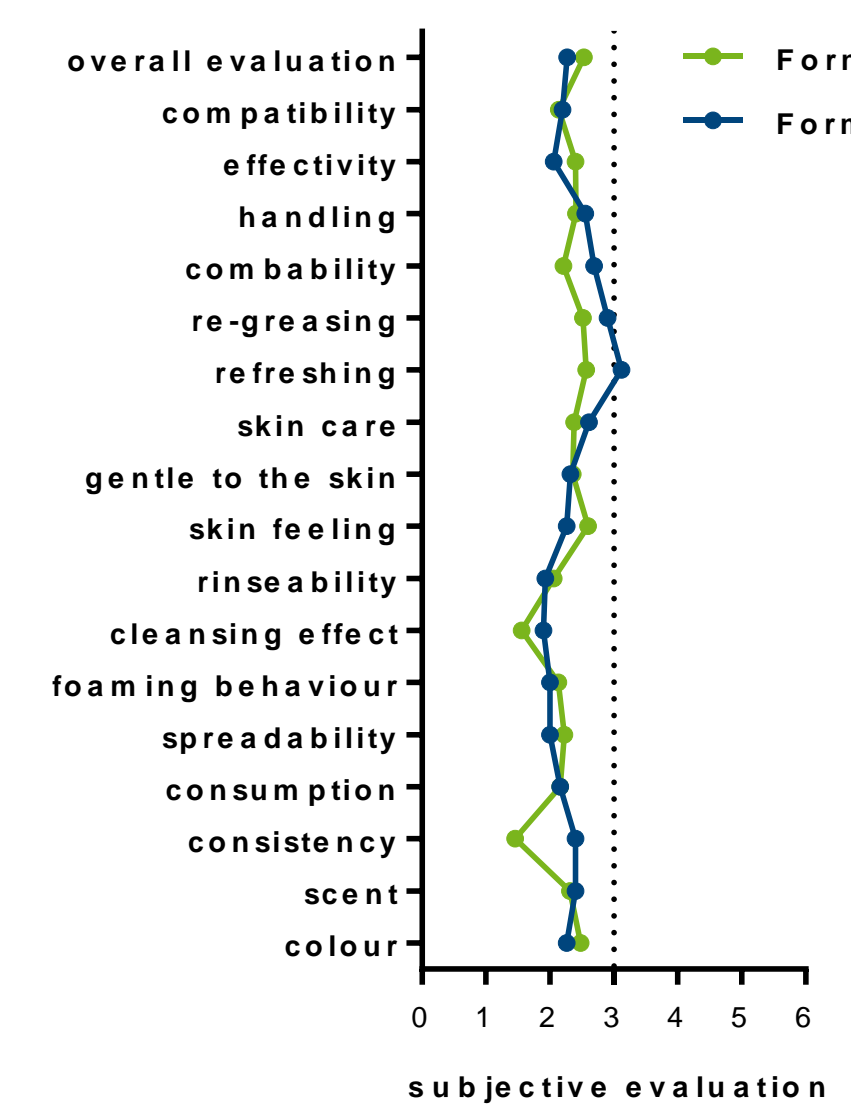


Figure 6: By using a questionnaire the test subjects evaluated the products on a 6-point scale, whereby 1 denotes the highest grade and 6 the lowest.

Conclusion

The image analytical test contributes to a more objective assessment of the effect of an anti-dandruff treatment and supplements the visual scoring. Especially the classification of scale sizes in 9 categories gives a more detailed picture of the scalp conditions and pathogenesis of the dandruff. In addition, we suggest to perform home-in-use tests with self assessment, which are most useful to cosmetics like anti-dandruff shampoos and complete the picture of a product.

References

- Gerlach N, Herling M, Tronnier H, Heinrich U (2011) Combination of three tests for a meaningful efficacy evaluation of anti-dandruff products. *SOFW-Journal*. 9: 2-9.
- Tronnier H, Heinrich U. (1999) Diagnostic process and treatment monitoring of seborrheic dandruff by means of an image analytical procedure. *J. Appl. Cosmetol.* 17: 36-45.