

a cross-over design with a larger number of subjects and a single aspirin-antacid preparation, will be needed to permit more definitive conclusions. It is significant however that the more rapidly absorbed aspirin preparations *F-I* and *F-II* definitely do not cause more bleeding than the more slowly absorbed Preparation *E*. It therefore appears feasible to design aspirin tablet preparations with rapid drug release characteristics and relatively low gastrointestinal bleeding liability.

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Comparative Study of Two Antidandruff Preparations

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Abstract □ The relative antidandruff efficacy of a commercially available 2% zinc pyrithione shampoo, a 2.5% selenium sulfide suspension, and an unmedicated control shampoo was measured using a well-tested visual technique. The zinc pyrithione shampoo and the selenium sulfide suspension were found to be equally effective, both being significantly more effective than the control shampoo. A supplemental evaluation of the effects of the test products on scalp oiliness is also reported.

Keyphrases □ Antidandruff shampoos—effectiveness testing □ Zinc pyrithione, selenium sulfide—activity comparison

The question of whether dandruff is a mild form of seborrheic dermatitis, and thus a potential medical problem, or is just a deviation from a normal process of desquamation and thus a strictly cosmetic problem, remains open. In any event, the interest in dandruff seems clear from the many papers on the subject that have been published over the years (1-8).

A variety of agents have been used for the treatment of dandruff. Among these are sulfur, salicylic acid, hexachlorophene, tar, and quaternary ammonium compounds. One of the most popular remedies, in medical circles, has been a suspension of selenium sulfide (9). A relative newcomer, and a compound that has shown considerable promise, is zinc pyrithione.¹

A clinical test of zinc pyrithione in a hairdressing vehicle has demonstrated that it is effective in the treatment of dandruff (10), and its safety in a shampoo has been documented (11). There has not been heretofore, however, any published clinical evidence that zinc pyrithione is effective in a shampoo.

This paper presents the results obtained in a controlled clinical study with the zinc pyrithione shampoo, using a visual grading method that has been developed

during considerable experience in such testing. The purpose of the study was to determine whether the zinc pyrithione shampoo, offering some advantages in availability and convenience of use, provided dandruff control comparable to that offered by a selenium sulfide suspension.

MATERIALS AND METHODS

Three products were evaluated in the study: a commercially available zinc pyrithione shampoo² with an approximate composition shown in Formula I; a placebo shampoo, identical to the zinc pyrithione shampoo except for the omission of zinc pyrithione; a commercially available selenium sulfide suspension³ with an approximate composition, as previously reported (12), shown in Formula II.

<i>Formula I</i>	
	%
Zinc pyrithione	2.0
Surfactant	20.0
Foam builder	4.0
Thickeners	1.2
Perfume, color, stabilizer	2.0
Water	<i>q.s.</i> 100.0
<i>Formula II</i>	
	%
Selenium sulfide	2.5
Surfactant	17.0
Inert and stabilizing ingredients	5.2
Water	<i>q.s.</i> 100.0

All three were packaged in identical containers.

Label instructions for the first two products called for use as any regular shampoo. Label instructions for the selenium sulfide suspension called for washing the hair with bland soap, rinsing, massaging the suspension into the scalp, letting it remain there for 5 min., and rinsing.

The testing procedure incorporated the following features:

1. The products were tested on comparable groups to which

¹ Zinc 2-pyridinethiol-1-oxide.

² Head & Shoulders Shampoo.

³ Selsun.

Table I—Effect of Test Products on Dandruff

	Zinc Pyrrithione Shampoo	Selenium Sulfide Suspension	Control Shampoo
Number of Subjects	48	46	46
Average starting grade	13.9	13.2	13.3
Average final grade	5.9	6.0	13.0
Average grade change ^a	— 8.0 ^b	— 7.2 ^b	— 0.3
Standard deviation	6.4	4.7	5.3

^a Negative numbers represent reduction in dandruff. ^b Significant product effect, $\alpha = 0.05$

subjects were assigned, in a balanced fashion, on the basis of dandruff severity. In this way each of the three groups included the same percentage of subjects with mild, moderate, and severe degrees of dandruff.

2. No one was allowed to be a subject if he had used an anti-dandruff preparation within the 4-week period preceding the initial examination.

3. Subjects were not allowed to use any other antidandruff preparation during the course of the study. Otherwise, they followed their normal habits of hair and scalp care.

4. The severity of dandruff was evaluated before and after the period of use. The minimum period of use was 6 weeks.

5. All grading was done approximately 1 week (7 ± 2 days) following the most recent shampoo. In that way the ability of a product to slow the return of dandruff rather than its ability to clean the scalp was measured.

6. The study was run as a double-blind test in all cases (except to the extent that the test products might have been unavoidably recognized by some subjects).

The severity of the dandruff condition was determined visually, by imaginarily dividing the scalp into nine sections and assigning a grade to each section using a 0 (no significant dandruff) to 4 (severe dandruff) scale. In borderline cases, intermediate grades, such as 2.5, were assigned. The sum of the grades for the nine sections was recorded as the dandruff grade.

As an attendant part of the study, the effect of the test products on scalp oiliness was also examined. A single grade from 0 (dry) to 4 (very oily) was assigned according to the examiner's assessment of the oiliness of the subject's scalp. No attempt was made to balance the groups on the basis of initial oiliness grades.

All grading was done by three physicians; however, one physician did the grading on any one subject. In addition, each grader saw approximately the same number of subjects in each product group.

RESULTS

One hundred and forty complete clinical evaluations were made. Forty-eight subjects used the zinc pyrithione shampoo; forty-six, the selenium sulfide suspension; and forty-six, the placebo shampoo.

Table II—Relationship Between Initial Dandruff Grade and Change in Dandruff Grade

Starting Grade	Average Grade Change ^a		
	Zinc Pyrrithione Shampoo	Selenium Sulfide Suspension	Control Shampoo
0-10.9	— 4.9	— 3.7	+1.3
11-20.9	— 7.8	— 8.4	— 1.1
Above 21	— 14.2	— 11.4	— 2.0

^a Negative numbers represent reductions in dandruff.

Table III—Effect of Test Products on Scalp Oiliness

	Zinc Pyrrithione Shampoo	Selenium Sulfide Suspension	Control Shampoo
Number of subjects	48	43	43
Average starting grade	1.3	1.8	1.3
Average final grade	1.3	1.7	1.1
Average grade change ^a	0.0	— 0.1	— 0.2

^a Negative numbers represent decreases in scalp oiliness.

As the data in Table I show, the zinc pyrithione shampoo and the selenium sulfide shampoo are significantly more effective than the control shampoo and are not significantly different from each other. Both the zinc pyrithione shampoo and the selenium sulfide suspension produced greater effects on subjects with higher starting grades (Table II), whereas the control product had no significant effect on any of the sub-groups.

A few of the subjects in this study exhibited frank seborrheic dermatitis. The investigators believe, however, that these findings should not be extended to that medical condition without further investigation.

The oiliness data (Table III) indicate that none of the products had an appreciable effect on the greasiness of the scalp. In addition, the data show no apparent correlation between level of dandruff and oiliness of the scalp.

CONCLUSIONS

Both zinc pyrithione, at a level of 2.0% in a shampoo vehicle, and selenium sulfide, as a 2.5% suspension, are effective in the treatment of dandruff. The two products do not differ significantly in effectiveness.

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