

Technical Report
EFFICACY OF *LICE FREEE*®
FOR HEAD LOUSE INFESTATIONS

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SUMMARY – Following an established protocol for testing the efficacy for head lice infestations, a new homeopathic compound, *Lice Freee*, was shown an effective treatment.

INTRODUCTION

The head louse, *Pediculus humanus capitis*, is the etiological agent of pediculosis capitis; it is not a vector of infectious disease. It is a common condition in school children in North America. Another morphologically identical variety, the body louse, *P. h. corporis*, is found on clothing but does not invade the head; it is a vector of typhus and related microorganisms. In North America, the body louse is found almost solely in the indigent population and the chronic condition is sometimes called ‘vagabond’s disease’. The head louse is an insect with incomplete development, meaning that the immature stages are similar in morphology and ecology to the adult. The head louse is an obligate ectoparasite found only on human hosts. Transmission is through close contact between hosts. Passage of lice through other means, such as furniture contamination, is likely not epidemiologically important since survival off the host is limited. The egg, called a nit, is strongly cemented to a hair shaft. Following incubation of 5-10 days, the immature stage or nymph will molt three times, the last into a sexually mature adult which will lay 5 to 10 eggs a day for a month or so. All stages (3 nymphal stages and adult) suck blood from the host. The egg to egg cycle is approximately 3 weeks. General references are Rossignol and Feinsod (1990), Spielman and Rossignol (1984) and Ebeling (1975).

The commercial over-the-counter product, *Lice Freee*, is a homeopathic compound containing 10% *natrum muriaticum* in a proprietary gel designed not to liquefy below 60°C. The compound is manufactured by Tec Labs, Inc., Albany, OR.

PROTOCOL

The protocol followed was based on published procedures used to assess ovicidal activity and ‘killing’ time of the head louse (Meinking et al., 1986). For this particular test, only killing times of nymphs and adults were carried out.

Lice were collected from 10 volunteers from the Albany, OR, area. Hair was combed with a louse comb and collected lice placed in petri dishes. The test area was kept at a warm ambient temperature (27-30°C). Routine spraying of storage and test areas were prohibited. Within 2 hours, the lice were placed on the forearm of volunteer and allowed to feed to repletion. Tests were then initiated.

Three treatments were carried out, each consisting of a sample and a control. For each, 34 lice, containing both nymphs and adults, were placed in a petri dish lined with gauze and covered with purified water or *Lice Freee* gel (lot no. 9421). For the latter, the lice were covered with a thin layer of gel such that each louse was immersed in the

material but still visible, for a period of one hour. Lice were monitored for peristalsis at five-minute intervals for the first hour and then every 30 minutes.

Experiments were carried on April 30, 1999 at the Tec Labs building in Albany, OR.

RESULTS

All lice treated with *Lice Freee* stopped moving within a half hour, while the average survival time of lice treated with water was approximately a half day. All three treatments were consistent with each other (Table 1).

Sample	No. of lice	Period to last movement
Experiment 1		
<i>Lice Freee</i>	34	25m
Water	34	18h 12m
Experiment 2		
<i>Lice Freee</i>	34	23m
Water	34	16h 45m
Experiment 3		
<i>Lice Freee</i>	34	16m
Water	34	14h 45m

Table 1. Time to last movement of lice treated with *Lice Freee* and water.

COMMENTS

The conditions of the tests were representative of actual treatment with *Lice Freee*, which requires a one-hour application followed by a rinse.

The product is clearly not a chemical insecticidal treatment, as are other commonly available pediculicides, since it contains no active ingredient that comes under the definition of an insecticide. The mode of killing is likely physical, possibly asphyxiation, and osmotic, although that remains to be determined with certainty. Nevertheless, assuming ovicidal properties (not tested here), the proper application of *Lice Freee* provides a significant measure of protection against pediculosis with the added benefit of no adverse reaction, exposure or resistance to synthetic insecticides.

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TEC LABORATORIES, INC.
GMP PROTOCOL

SUBJECT:

Edition No.: 01 Protocol No. P76
Effective Date: 4-28-99 Page 1 of 4
Prepared By: Wendy S. Dennis

PROTOCOL FOR IN-VITRO EFFICACY
TESTING OF LICE FREEE!

Signature: Wendy S. Dennis

I. PURPOSE/INTRODUCTION

- A. This protocol outlines the method to be used to determine the killing time of current-formula LiceFreee against the human head louse, *Pediculus humanus capitis* in vitro. The conditions of this test procedure represent a maximum exposure test, since the lice will be in close contact with undiluted product until death. The results will indicate the maximum effect that could be achieved in actual clinical use.
- B. Ideally, this test will be performed by an outside individual, laboratory, or university contracted by Tec Laboratories, Inc. (referred to in this protocol as "contractor").
1. If an appropriate outside individual, laboratory, or university cannot be contracted, this protocol may be carried out in-house.
- C. The study, "Comparative Efficacy of Treatments for Pediculosis Capitis Infestations," (*Arch Dermotol* 1986; 122:267-271) a copy of which is attached, is used as a model for this study; disregarding all reference to ovicidal activity and modifying the size and number of sample sets evaluated.

II. SCOPE

- A. This protocol directs the in-vitro efficacy (killing time) testing of current-formula Lice Freee against the human head louse.
1. The ovicidal activity of LiceFreee will not be evaluated under this protocol.

III. RESPONSIBILITY

- A. It is the responsibility of Tec Labs' Research & Development team to ensure this protocol is followed and deviations are documented.
- B. The contractor will conduct the trial in compliance with this protocol and an official copy of this protocol will be signed by the contractor and Tec Laboratories to confirm this agreement.

Bill Ch... 4-28-99
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Robert L. Smith 4-28-99
Research & Development

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GMP PROTOCOL

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PROTOCOL FOR IN-VITRO EFFICACY
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1. Emergency deviations from the approved protocol will be immediately documented, explained, and submitted to Tec Labs' Quality Assurance for approval through the Emergency Deviation Report (EDR) System.
2. Planned deviations require prior approval and will be reported through Tec Labs' Planned Deviation Report (PDR) system.

IV. PROTOCOL

A. Environmental conditions

1. Artificial lighting at ambient temperature and humidity.
2. Protect materials and supplies at all times from pesticide or other chemical contamination. Routine spraying of storage and laboratory areas is prohibited.

B. Materials and Supplies

1. Three four-ounce bottles of a recently released batch of Lice Freee.
 - a. Protect product from heat and sunlight.
2. Room-temperature purified water.
3. At least seven (7) sterile Petri dishes.
4. At least seven (7) disks cut from cotton-polyester kitchen towels that have been boiled with a small quantity of nonmedicated anionic shampoo, thoroughly rinsed in several changes of boiling water, air dried, then sterilized by autoclaving. Disks should be one (1) cm smaller in diameter than the Petri dishes.
5. At least 68 head lice for each experiment, consisting of a combination of adult male and female head lice and nymphs collected from the heads of infested people (at least 204 lice total).

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PROTOCOL FOR IN-VITRO EFFICACY
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- a. Obtain informed consent before collecting the lice.
 - b. Pool the lice in a Petri dish containing a cloth disk dampened with distilled water.
 - c. The specimens must be used within three hours of collection--protect from sunlight and excess heat.
 - d. Before use, allow the lice to feed on an alcohol-cleansed forearm.
6. At least one (1) 10X magnification device.
 7. Temperature recording device.

C. Method

1. Activate the temperature recording device.
2. Place one cloth disk into each of two Petri dishes.
3. Evenly distribute an amount of Lice Freee over one of the cloths and allow to thoroughly impregnate. Gently transfer 34 lice, including adults of both sexes and nymphs, to the petri dish using a human hair. Measure additional Lice Freee onto the cloth until a thin film of product is distributed and remains on top of the lice. Put the cover on the Petri dish. Record the amount of Lice Freee used and the time.
4. Evenly distribute an amount of purified water over the second cloth and allow to thoroughly impregnate. Gently transfer 34 lice, including adults of both sexes and nymphs, to the petri dish using a human hair. Measure the same amount of water as the Lice Freee above and evenly distribute over the lice. Put the cover on the petri dish. This will be used as the control. Record the time.
5. Observe the lice with 10X magnification until the death of the last louse. Record time of death

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when all movement and peristalsis of the gut ceases.

6. Evaluate sets of test material and control at least three (3) times.

D. Analysis of Data

1. Estimate the mean killing time for the three (3) experiments and calculate the standard deviation.

V. DOCUMENTATION

- A. Record all results from experiments in an R & D notebook and/or data collection form. Include the product batch number, amount of product used, number of lice observed, test start date and time, date and time of death of last louse (end time), and dated signature for each experiment.
- B. Compile a report of the findings and submit to Tec Laboratories, Inc.

Attachment (1)

STATEMENT OF INTENT TO COMPLY

This protocol has been read and understood and will be followed as outlined in section III.B..

Wendy S. Dennis

Contractor

April 30, 1999

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Comparative Efficacy of Treatments for Pediculosis Capitis Infestations

Terri Lynn Meinking; David Taplin; Debra Chester Kalter, MD; Mark W. Eberle, PhD

Ovicidal activity and killing times were evaluated for six pediculicides, using viable eggs and recently fed head lice from infested children. Lice were continuously exposed to the products until death, and elapsed time was recorded. Eggs were immersed for ten minutes, rinsed, and dried. Four synergized pyrethrin products (RID, R&C Shampoo, A-200 Pyrinax Shampoo, A-200 Pyrinax Liquid) killed all lice in ten to 23 minutes, and 23% to 32% of treated eggs hatched; 0.5% malathion lotion (Prioderm Lotion) killed lice within five minutes and was highly ovicidal, with only 5% of eggs hatching. One percent lindane shampoo (Kwell Shampoo) was the slowest-acting pediculicide, requiring approximately three hours to kill all lice; 30% of the eggs hatched after treatment. The in vitro results for RID, Prioderm Lotion, and Kwell Shampoo were validated by clinical trials.

(Arch Dermatol 1986; 122:267-271)

Pediculosis capitis has become a widespread problem in the United States, reaching epidemic proportions in some areas.¹ In 1973² and 1976,³ it was estimated that there were 6 million cases in this country annually. Rasmussen⁴ has observed an increase in new cases of head lice since then, with a substantial rise in the last five years. Most cases of pediculosis capitis are unreported. Market sales of over-the-counter pediculicides do not indicate

See also p 259.

whether the product was purchased for pediculosis capitis, corporis, or pubis. The incidence of head lice in the United States, therefore, is not truly known.⁵

Parents, school health officials, and physicians face a dilemma in the choice of therapy, and advertising claims by manufacturers of pediculicides make the evaluation of relative efficacy difficult. Although the preferred method of testing therapeutic products involves adequately controlled clinical trials con-

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Reprint requests to the Department of Dermatology and Cutaneous Surgery R-117, University of Miami School of Medicine, PO Box 016960, Miami, FL 33101 (Ms Meinking).

ducted by experienced, unbiased investigators, these studies are costly, time consuming, and would require several hundred patients.

In 1981, we initiated studies to develop an in vitro method that would be standardized and reproducible and that would reflect the results to be expected in a full-scale clinical trial with respect to pediculicidal and ovicidal activity. Our previous experience with the most currently used in vitro method^{6,7} did not reflect the results we obtained in clinical trials. Our in vitro method takes into account not only the active ingredients but also the activity of the vehicle that is often an important component of the finished product's activity.

To our knowledge, all attempts to establish laboratory colonies of *Pediculus humanus var capitis*,^{8,9} the human-head louse (Fig 1), have failed. Those colonies that do exist are those of the body louse^{10,12} or possibly hybrids of body lice and head lice.¹¹ They have been maintained through hundreds or thousands of generations, are fed on rabbits, and have become attenuated to an artificial laboratory existence.^{14,16} For these reasons, they differ in feeding habits, life-style, and appearance (Fig 2) from body lice obtained from infested humans and bear even less resemblance to head lice.¹⁷

We therefore based our model on recently captured head lice from infested children. Ovicidal activity was also evaluated for freshly collected viable eggs on hairs clipped from the same subjects.

The test results reported herein are from a study requested by the National Pediculosis Association, Newton, Mass. The study was conducted in Central America between April and August of 1984 in a population with endemic pediculosis capitis. The study site was an isolated mainland village with no prior history of pediculicide or pesticide usage, so that previous exposure or tolerance to any of the products tested was not a factor. Informed consent was obtained from the parents of children from whom lice were collected. These subjects and other family contacts were offered treatment with approved pediculicides.

Early work showed that careful attention to techniques and environmental variables is vital to standardization and reproducibility. The methodology is therefore reported in detail.

Table 1.—Killing Time of Head Lice as Determined by In Vitro Method*

Pediculicide	No. of Lice Exposed	Killing Time, min (Mean ± SD)
Prioderm Lotion	110	4.4 ± 0.6
RID	100	10.5 ± 3.4
RAC Shampoo	180	18.6 ± 6.0
A-200 Pyrinate Shampoo	120	22.5 ± 7.9
A-200 Pyrinate Liquid	130	22.5 ± 9.0
Kwell Shampoo	100	190.2 ± 46.5
Control (water)	140	12 hr 6 ± 2 hr 11

*Times were recorded on the deaths of all lice.

MATERIALS AND METHODS

Killing Time

Materials and supplies were protected at all times from pesticide or other chemical contamination. Routine spraying of storage and laboratory areas was prohibited. Three bottles of each product tested were obtained from different pharmacies in the United States and protected from heat and sunlight. Expiration date (which were all within one year), lot number, and place of purchase were recorded for each bottle.

All water used in these experiments was unchlorinated and filtered through 0.45- μ m-dense charcoal to remove any bacteria or chemical contaminants (Pressure Pure, Seagull IV filter system).

Cotton-polyester kitchen towels were boiled with a small quantity of nonmedicated anionic shampoo, thoroughly rinsed in several changes of boiling water, and air dried. Five-centimeter diameter disks were cut from these prepared towels and sterilized by autoclaving.

At the time of testing, one prepared cloth disk was placed in the bottom of a sterile plastic 60 × 15-mm Petri dish.

For each experiment, at least 70 adult male and female head lice and nymphs were collected from the heads of six or more infested children. These lice were pooled in a Petri dish containing a cloth disk dampened with filtered water.

Specimens were tested within three hours of collection and were protected from sunlight and excess heat. Prior to testing, all lice were allowed to feed on the alcohol-cleansed forearms of one of us (T.L.M.). This circumvented the differences in susceptibility we had noted in pilot studies between starved and freshly fed lice.

One milliliter of the test material was evenly distributed over the cloth disk and allowed to thoroughly impregnate. This amount of product produced a wet surface with which the lice remained in intimate contact. One milliliter of water was used in control dishes. The lice grasped the threads of this cloth as if they were human hairs. This open system simulated an in vivo treatment but allowed the lice to remain in contact with the product until death.

Ten lice, including adults of both sexes and nymphs, were gently transferred to the test dishes

using single strands of human hair to avoid physical damage to the lice.

They were observed with a ×10 hand-held lens until the death of the last louse. Time of death was recorded when all movement and peristalsis of the gut had ceased.

Tests were conducted under artificial lighting at ambient temperatures (27 to 30 °C) and humidity levels of 70% to 90% relative humidity. Sets of test materials and controls were evaluated at least ten times on different days. The mean killing time for ten or more experiments was estimated, and the SD was calculated. On each test day, ten or more lice were used as controls.

Ovicidal Activity

Three- to 4-centimeter lengths of single hairs, each with a viable egg attached, were snipped from infested children and placed in a clean polyethylene container. Viable eggs were plump, shiny, and tan to coffee colored, with an intact operculum and, frequently, a pigmented eye spot. Nits that were empty, shriveled, misshapen, or indented and those that contained air pockets were discarded (Fig 3).

Ten hairs with viable eggs were attached to small adhesive labels, allowing a 2-cm-long strand of hair to protrude, with the eggs aligned at the distal end. When clamped with hemostat forceps, the label formed a convenient holder for transferring ten eggs simultaneously to the test solutions and rinses.

Immediately prior to testing, medications were dispensed into clean 8-mL glass vials, which were discarded after the test. Each set of ten eggs was immersed in the product for exactly ten minutes. The eggs were then agitated in several changes of filtered water and air dried at an ambient temperature.

Each set of ten hairs with eggs were transferred to clean sterile glass vials (15 × 45 mm), which were capped and incubated at 30 to 34 °C for two weeks in the dark. Each experiment was replicated ten or more times. On each day experiments were conducted, ten eggs were dipped in filtered water for ten minutes and air dried as controls.

Ovicidal activity was expressed as the percentage of eggs hatched after 14 days, using the following formula:

$$\frac{\text{Number Hatched}}{\text{Number Tested}} \times 100 = \text{Percent Hatched}$$

Eggs from which the newborn nymph was able to lift the operculum but did not fully emerge were termed *stillbirths* (Fig 4). These were not counted as hatched.

RESULTS

Killing Time

There was considerable variation in the killing time between products (Table 1); 0.5% malathion lotion (Prioderm Lotion) demonstrated the quickest knock down and kill. No louse survived five minutes after initial contact (Fig 5). The synergized natural pyrethrin products were the next quickest killers,

Pediculicide	No. of Eggs Hatched / Tested	% of Eggs	
		Hatched	Stillborn (Nonviable)
Prioderm Lotion	5 / 123	5	0
A-200 Pyrinate Shampoo	23 / 98	23	23
R&C Shampoo	29 / 117	25	18
RID	26 / 99	26	34
Kwell Shampoo	42 / 141	30	18
A-200 Pyrinate Liquid	32 / 100	32	23
Control (water)	91 / 98	93	0

Pediculicide	No. (%) of Eggs Hatched	
	Clinical Trials	In Vitro Method
Prioderm Lotion (0.5% malathion lotion)	28 / 960 (3)	5 / 103 (5)
Kwell (1% lindane shampoo)	288 / 560 (51)	42 / 141 (30)
Controls	1,338 / 1,480 (90)	91 / 98 (93)

* All clinical trials were conducted in accordance with manufacturers' instructions (Prioderm Lotion, eight- to 12-hour application; Kwell Shampoo four-minute application). Ovicidal activity in clinical trials was determined by taking ten viable nits from patients before treatment and ten viable nits from patients after treatment. Our in vitro method consisted of a ten-minute exposure.

with killing times from 10.5 (± 3.4) minutes for RID to 22.5 (± 9.0) minutes for A-200 Pyrinate Liquid. Finally, 1% lindane shampoo (Kwell Shampoo) was consistently the slowest-killing product (190.2 [± 46.5] minutes). In none of the ten experiments did this product kill all lice in less than two hours.

All products tested killed lice within four hours. All control lice were alive and active at four hours, with none surviving longer than 15 hours. Six to 15 hours is the normal longevity of head lice removed from the host and given no opportunity to feed.

Ovicidal Activity

Our results are shown in Table 2. Prioderm Lotion was the most effective ovicide, killing 95% of the eggs. It was the only alcoholic lotion tested and the only one that penetrated the eggs to kill the nymphs in situ. All other products yielded significant numbers of stillbirths after treatment. The synergized pyrethrin products were not completely ovicidal. The percentage of eggs that produced viable nymphs after treatment with these products ranged from 23% (A-200 Pyrinate Shampoo) to 32% (A-200 Pyrinate Liquid); 1% lindane shampoo (Kwell Shampoo) showed ovicidal activity in the same range as the synergized pyrethrin products (30% hatch rate).

We were concerned with the value of this in vitro model in reflecting the results of actual clinical use. In all clinical trials, the products were used in accordance with the manufacturer's directions. During 1984, in a nearby community not previously exposed to pesticides, our team personally treated more than 300 patients with 1% lindane shampoo (Kwell Shampoo). Seventy-nine of these subjects were closely followed up on a daily basis for two weeks. We found live lice on all subjects 15 minutes after treatment; in several patients, live lice were found six hours later. Many patients complained that they could feel lice "dancing" on their scalps for several hours after treatment. We have consistently observed hyperactivity and twitching of lice after exposure to lindane. Thus, the slow-killing effect of lindane shampoo was confirmed by clinical experience.

In clinical trials conducted in two similar villages in this area, none of 280 subjects treated with Prioderm Lotion and none of 98 subjects treated with RID complained of "dancing" lice, and no live lice were found 15 minutes after application of the products. The relatively quick-killing effect of RID and Prioderm Lotion was therefore confirmed in clinical use. Pediculicidal activity of the other products tested has not been validated in clinical trials by us.

Ovicidal activity in clinical trials was also precisely measured by collecting eggs from each patient before and after treatment and determining hatching rates. Table 3 shows the comparison of hatch rates obtained by our in vitro method compared with results obtained in clinical trials with Kwell Shampoo and Prioderm Lotion.

The low hatch rates for malathion lotion and the considerably higher rates following treatment with lindane shampoo are therefore evident in both the in vitro method and clinical use.

Other products have not been evaluated for ovicidal activity in clinical trials by our team.

COMMENT

We consider the conditions of this test procedure to represent a maximum exposure test, since the lice were in close contact with the undiluted product until death. Similarly, the eggs were totally immersed in the formulations for ten minutes and protected in vials until hatching. We believe that the results indicate the maximum effect that could be achieved in actual clinical use. The times chosen for the test were standardized to allow direct comparison of activity and, for all products except Prioderm Lotion, the time of exposure of lice and eggs equalled or exceeded the manufacturers' instructions.

The results suggest several guidelines for those faced with the management of pediculosis. First, 1% lindane shampoo, which is available only by prescription, offers no advantage in pediculicidal activity compared with several over-the-counter products. It is cosmetically elegant and requires less than ten minutes for treatment.

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tical purposes, the four synergized pyrethrin preparations ranked approximately equal in effectiveness as pediculicides and ovicides. All were considered cosmetically elegant and easy to use, requiring only ten minutes' application.

Second, 0.5% malathion lotion is a highly effective, rapid-acting pediculicide and was the only product tested that showed excellent ovicidal activity. Many patients found the odor unpleasant and objected to the eight- to 12-hour application time; the high alcohol content necessitates precautions to avoid open flames and hair dryers. The particular product (Prioderm Lotion) used in our study is no longer available in the United States. The results of the pediculicidal and ovicidal activity of 0.5% malathion lotion have been included as a positive control. All pediculicides require careful application to avoid potential irritation of eyes and mucous membranes.

We stress that head lice exposed to all of the tested products died within four hours. Thus, they may all be considered effective pediculicides. In our experience, however, patients prefer a product that kills lice quickly. The appearance of crawling or twitching lice or the sensation of crawling lice on the scalp is often a source of emotional stress.

The relatively poor ovicidal activity of the synergized pyrethrin preparations after a single treatment leaves something to be desired. However, current recommendations instruct the user to repeat the treatment seven to ten days later. Our in vitro studies suggest that this should prove effective in killing nymphs that have hatched from eggs still viable after the first treatment, but we have not had the opportunity to test this hypothesis in clinical trials.

The high rate of stillbirths (18% to 34%) in eggs treated with all formulations except Prioderm Lotion raises questions concerning the mechanism of ovicidal activity. It suggests that the product did not penetrate the egg to kill the nymph in situ. No

stillbirths occurred in control eggs, and we have not observed this phenomenon in the examination of several thousand untreated eggs.

Since all eggs were treated alike, differences in exposure to the pediculicides or residues on the hairs are unlikely explanations. One variable over which we have no control is the age of the eggs when collected. We believe that the mechanism of action of ovicides is by exchange through the spiraclelike structures of the operculum (Fig 6). The results presented herein suggest that head lice eggs differ in permeability depending on their stage of development or that the unborn nymphs differ in susceptibility at different stages of growth.

Previous attempts to evaluate pesticides and pediculicides by in vitro methods have been marred by high mortality rates of control lice, use of non-commercial formulations, extrapolations from colonies of body lice, and other difficulties summarized by Kucirka et al.¹³

We believe that the system reported herein represents an advance in technology. We used marketed products and freshly collected, recently fed head lice. The end point of time required to kill all lice more accurately reflects the desired clinical results as an alternative to the laboratory variable of LD₅₀. Similarly, we believe that the percent of eggs hatching into viable nymphs following treatment is more pertinent to the clinical situation.

In attempting to control the current epidemic of head lice, we should be concerned with the lice and eggs that survive treatment. Our results suggest that a single-treatment, fast-acting, completely ovicidal, and cosmetically elegant pediculicide has yet to be developed.

The authors gratefully acknowledge the support of the National Pediculosis Association (NPA) and the encouragement of the NPA Scientific Advisory Board; the medical assistance of R. Sanchez, MD, J. A. Chen Lee, MD, and P. Castellero, MD; the field assistance of Isedelia Perez; the photography of Fig 2 by Jack Clark; and the secretarial assistance of Gloria Hernandez.

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