

A Simple Treatment for Head Lice: Dry-On, Suffocation-Based Pediculicide

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ABSTRACT. *Objectives.* The emergence of drug-resistant lice has created the need for new therapies. This study assesses a new method without neurotoxins, extensive household cleaning, or nit removal.

Methods. One hundred thirty-three subjects participated in 2 open clinical trials. In the first trial, 93 subjects completed treatment using a nontoxic, dry-on, suffocation-based, pediculicide lotion, minimal household cleaning measures, and physical removal of the nits. In the second trial, 40 subjects completed treatment using an identical protocol except that the nits were not removed. Head lice infestation was defined as a wet combing test showing lice. Cure was defined as a wet combing test showing no lice, with an absence of symptoms. Subjects were contacted 6 months later, for assessment of their disease status.

Results. Cure was achieved for 97% of the patients in the first trial and 95% in the second trial. Remission at the follow-up assessment was reported for 77 of 82 subjects (94%) in the first trial and 36 of 38 subjects (95%) in the second trial. There was no statistical difference in cure rates or remission rates between the protocols with and without nit removal. The overall cure rate was 96%, with a remission rate of 94%. There were no adverse effects.

Conclusions. Dry-on, suffocation-based, pediculicide lotion effectively treats head lice without neurotoxins, nit removal, or extensive house cleaning. These results are comparable or superior to the results previously reported for treatments with permethrin, pyrethrin, and malathion. *Pediatrics* 2004;114:e275–e279. URL: <http://www.pediatrics.org/cgi/content/full/114/3/e275>; lice, *Pediculus humanus var capitis*, resistance, permethrin, pyrethrin, malathion.

ABBREVIATION. DSP, dry-on, suffocation-based pediculicide.

Conventional head lice management usually includes use of a neurotoxic insecticide lotion, extensive home cleaning measures, and complete removal of all nits during treatment.¹ Many parents think that, despite their following these guidelines, head lice are getting much harder to cure.^{2,3} There are several explanations for these treatment failures. Investigators have found lice resistant

to many of the commonly used pediculicides.^{4–11} The recommended household cleaning and nit removal procedures are viewed as a heavy burden, and compliance may be incomplete.^{12–15} Some parents, school nurses, and health care advocates are concerned about the safety and efficacy of neurotoxin-based pediculicides and await the development of safer alternative agents.¹⁶ Finally, experts suggest that “there is strong need for the Food and Drug Administration to approve alternative agents.”^{17(p1381)} Therefore, it was considered worthwhile to evaluate a new approach to treating head lice. The goal of this project was to perform a preliminary evaluation of a nontoxic, dry-on, suffocation-based pediculicide (DSP) and simpler associated cleaning steps.

METHODS

Materials

Nuvo lotion (Family Dermatology Medical Office) is the first of a new class of nontoxic lotions to treat head lice that are called DSPs. The DSP lotion is applied wet and then blown dry with a hair drier, to form an adherent film. This “shrink-wrapped” film layer completely covers the louse, plugging its breathing holes (spiracles) and causing death by suffocation. Figures 1 and 2 present scanning electron microscopic images of an untreated louse and a different louse treated with Nuvo lotion.

Water-soluble Nuvo lotion is composed of stearyl alcohol, propylene glycol, sodium lauryl sulfate, cetyl alcohol, water, methyl 4-hydroxybenzoate, propyl *p*-hydroxybenzoate, and butyl *p*-hydroxybenzoate. All of these ingredients are “generally recognized as safe” by the United States Food and Drug Administration.¹⁸

Subjects

We recruited subjects by advising pediatricians that we were looking for difficult-to-treat head lice cases. The problem could be either that the parents reported failure of a prior treatment or that the parents were resistant to allowing any neurotoxin-based treatment. To enter the study, the participant needed to have an active head lice infestation, as determined with the wet-combing test described below. Siblings and adults in the same family could elect to enter the study on the same basis. Informed consent procedures were followed, and all subjects (or their parents, if the subjects were minors) reviewed and signed an informed consent form before entering the study.

Patients paid a \$200 refundable deposit to participate in the research. The deposit was waived in cases of financial difficulty. The deposit provision was part of the informed consent form. The deposit was refundable at the end of the research for all participants, regardless of outcome or whether they completed the full protocol. The goal was to identify parents who intended to participate and carry out the protocol.

Protocols

An uncontrolled open format was used for both trials. Both trials used the same DSP in the same manner, with the same simplified household cleaning rules. The only difference between the trials was that the nits were mechanically removed in trial 1, whereas they were not removed in trial 2. The first 97 subjects

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Dr Pearlman owns issued US patents and pending foreign patents covering this technology.

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Fig 1. An untreated head louse standing on a hair (from Speare et al,³³ with permission). (Magnification: $\times 37.5$.)

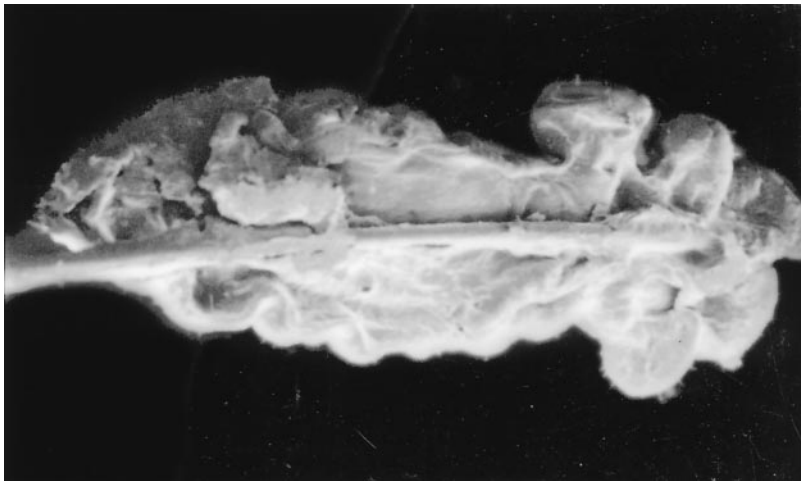


Fig 2. A Nuvo-treated head louse coated with dried-on DSP lotion. (Magnification: $\times 37.5$.)

entered trial 1. The subsequent 40 subjects entered trial 2. All treatment was performed at home by the parents. All materials and combs used in the trials were supplied by the author.

The household cleaning steps performed at the time of DSP application were as follows. 1) Clean all of the subject's combs and brushes at home, by either putting them through a dishwasher cycle or soaking them for 10 minutes in isopropyl alcohol. 2) Change the subject's clothes to fresh clothes. 3) Heat the subject's pillowcase, sheets, blankets, comforter, and bedspreads in the dryer for 10 minutes and then put them back on the bed.

A course of treatment with the DSP lotion was defined as once-weekly application until cure was achieved, up to a maximum of 3 applications. Each application had the following steps. 1) Apply the lotion thoroughly and wait 2 minutes. 2) Comb out all lotion possible. 3) Dry the hair with a handheld hair drier. 4) Shampoo ≥ 8 hours later with the child's usual shampoo. For trial 1, parents were instructed to remove nits during step 2. The parents used first a widely spaced, plastic, detangler comb, then a standard spaced, plastic, pocket comb, and finally a closely spaced, metal-toothed, nit-removal comb (LiceMeister comb, National Pediculosis Association, Needham, MA).¹⁹ For trial 2, parents used only the detangler and pocket combs, which do not remove nits, during step 2. The LiceMeister comb was not used.

Infestations were determined with the wet combing test. An active infestation was defined as present when the author found lice in the lotion combed out by parents in step 2. The parents performed the treatment at home and brought the combed-out lotion, on absorbent pads in sealed plastic bags, to the clinic office for the author to assess. This wet combing method of identifying lice is the most accurate way to diagnose active infestations, because it requires finding lice.²⁰⁻²² It is considered superior to both conventional scalp inspection and dry detection combing.²³ A positive test result means that lice are present. A negative test result means that no lice are present.

Entry Into the Study

Patients were enrolled in the study after they (or their guardian or parent) gave permission and they demonstrated positive wet combing test results. If the wet combing test did not reveal any lice, then the patient did not enter the study.

Determination of Cure

Patients were defined as cured when they met 2 criteria. First, their wet combing test results became negative. Second, the parents said that their children no longer complained of increased scalp itching or exhibited increased head scratching, and no new nits or crawling lice were noted by the parents.

Determination of Long-Term Follow-up Status

We contacted by telephone all participants in the study, or their parents/guardians, ≥ 6 months after completion of treatment. They were asked for any evidence of recurrence, including complaints of itching or observation of increased head scratching, new nits, or crawling lice.

Evaluation of Side Effects

At each office interaction, parents were asked their opinions regarding the work required to perform this treatment and were questioned about any irritation, discomfort, embarrassment, or other symptoms associated with the use of this treatment.

RESULTS

Of the 133 subjects in the trials, more than one-half were reported by their parents to have used treatments that failed before they entered the study (Table 1). Failure was most commonly reported for per-

TABLE 1. Prestudy Treatment History: Untreated or Treatments Reported to Have Failed

Trials	No. of Patients				
	Untreated	Permethrin	Pyrethrin	Malathion	Mayonnaise, Oils, Petroleum Jelly, Short Hair Cut
Trial 1 (total: 93 patients)	25	46	9	2	11
Trial 2 (total: 40 patients)	14	23	2	0	1

methrin and pyrethrins, which are available without prescriptions in the United States.

Table 2 summarizes the results of these trials. In trial 1, with the nit removal protocol, 97 subjects (median age: 8 years; range: 1.5-46 years) were enrolled. Ninety-three subjects (27 male subjects and 66 female subjects) completed the treatment, and 82 of those subjects were available for reevaluation at 6 months. In trial 2, without nit removal, 41 subjects (median age: 9 years; range: 2-66 years) were enrolled. Forty participants (12 male subjects and 28 female subjects) completed the treatment, and 38 of those subjects were available for reevaluation at 6 months. There was no statistical difference between the 2 protocols with respect to either cure rate (97% vs 95%) or long-term remission rate (94% vs 95%) ($\chi^2 = 0.187, P = .001$).

To clarify whether there was a difference in nit removal between the 2 trials, we counted the number of nits removed per patient in the lotion of the wet combing tests (Table 3). More than 100 times more nits were removed in trial 1 with the LiceMeister comb, compared with those removed in trial 2 with the plain comb.

Parents reported >50% reduction in the amount of work and time required to perform this treatment, compared with their prior experience with treatments requiring extensive household cleaning and nit removal. There were no reports of local irritation, discomfort, embarrassment, or other adverse symptoms associated with treatment.

DISCUSSION

This is the first published clinical trial documenting high efficacy for a nonneurotoxic lotion in the treatment of head lice. Although there have been anecdotal reports of petroleum jelly, mayonnaise, essential oils, olive oil, and other "alternative" products being effective in treating head lice, there have been no well-documented published trials evaluating their efficacy.²³ A prior study of the nonneurotoxic "Bug Busting" treatment concluded that its 38% cure rate made it inappropriate as a first-line treatment for head lice.²⁴

The design of this preliminary study was limited

by its lack of blinding, randomization, and inclusion of a control or therapeutic comparative group. However, the results of these open clinical trials should still be of great interest to clinicians treating head lice. The overall 96% cure rate is remarkable, in that it equals or exceeds the best efficacy reported for the currently used pediculicides (Table 4). The cure rate observed was determined by using the most rigorous current method. The patient population in the study is especially relevant to today's clinicians, because the majority of these patients had reported failure of previous treatments. Furthermore, all treatment was performed at home by parents, rather than by nurses or technicians. This type of pragmatic study offers clinicians practical information regarding what other parents may reasonably achieve in their homes.

The results gain additional significance because of the remarkable 6-month follow-up remission data. There is concern that, with conventional pediculicides, children may be cured only temporarily and then quickly become reinfested with head lice from their untreated schoolmates and friends.²⁵ Only 6% of the patients in this study reported reinfestation during the 6-month follow-up period. One hypothesis to explain the lack of reinfestation is that Nuvo has a longer-lasting effect because of properties apart from its suffocation action. Although immunologic concepts of louse protection were described previously,²⁶ it is unclear whether these explain the 94% remission rate with Nuvo treatment.

Physicians familiar with the conventional recommendations for treatment of head lice may find 2 results of this study particularly surprising. First, nit removal was not required or helpful in curing head lice with the DSP. Although trial 1 removed the nits and trial 2 left the nits, there was no difference between the trials in outcome measures. The nits can be left in place because the 3 weekly applications of the DSP lotion kill all potentially hatching lice before they can become contagious, fertile, adult lice. Meinking et al⁹ also reported finding no benefit of nit removal during treatment with a pediculicide.

Physicians may also be surprised that, in this study, a high cure rate was obtained with minimal household cleaning. Parents were not advised to vac-

TABLE 2. Head Lice Treatment Results With a DSP, With and Without Nit Removal

	No. of Patients	No. of Patients Cured at End of Treatment	Percent of Patients Cured at End of Treatment	No. of Patients Available for Follow-up Visit	No. of Patients Reported Lice-Free at 6-mo Follow-up Visit	Percent of Patients Reported Lice-Free at 6-mo Follow-up Visit
Trial 1 (nit removal)	93	90	97	82	77	94
Trial 2 (no nit removal)	40	38	95	38	36	95
Total overall	133	128	96	120	113	94

TABLE 3. Total Nits Removed per Patient During Trials With and Without a Nit Removal Comb

Trial	LiceMeister Comb Used*	Average No. of Total Nits Removed per Patient During Full Course of Treatment
1	Yes	118
2	No	1

* All patients used a detangler and a plain comb.

TABLE 4. Cure Rates for Neurotoxic Pediculicides Used to Treat Head Lice

Agent	Reported Initial Cure Rates, %	Reported Recent Cure Rates, %
Pyrethrin	95 ³⁴	34, ¹⁵ 53 ³⁵
Permethrin	97 ³⁶	78, ⁹ 80 ³⁷
Lindane	85 ³⁸	17 ¹⁵
Malathion	95 ³⁹	78 ²⁴

uum any floors, put away any plush toys during treatment, or wash laundry daily. Lice are mainly transmitted from child to child via close contact of the children's heads during play.²⁷ The environment and fomites play minor roles in lice transmission.^{23,28} There is now growing evidence that viable, contagious, head lice are rarely found in the environment; therefore, cleaning efforts aimed at removing them are of minimal usefulness.^{15,29–31} There is no well-documented study showing that extensive cleaning measures are required for or even contribute to curing head lice.

The simplicity of this method was welcomed by both parents and children. Parents reported that head lice treatment without nit removal and without extensive household cleaning was not an overwhelming burden. Caregivers reported that children were much more cooperative during treatment with a plain comb than they had been during their pre-study treatment with a fine nit comb. Although the lotion must be left in place for at least 8 hours to be effective, in practice it typically was left in place for ≥ 24 hours, until the next day's bath. Patients typically underwent application 1 day, attended school the next morning with it dry in their hair, and waited until bath time the next day to remove it by washing their hair with their usual shampoo. After the DSP lotion was dried in the scalp, the lotion was not visible, and the hair could be styled as usual. Treated children went to school with their hair looking the same as usual.

These results suggest that a DSP lotion can offer a solution to the widespread reports of head lice that are resistant to conventional pediculicides. The majority of patients in this trial reported their lice to be resistant to a wide variety of conventional and alternative pediculicides (Table 1), but these patients were cured with the DSP lotion. The 5 patients who were not cured with the 3 applications allowed in the protocol were all cured by completing a total of 4 applications. There were no cases of DSP treatment failure in this study.

DSP lotions may not be hampered by the evolution of drug-resistant lice, as would be expected for neurotoxic pediculicides.³² The latter agents act by tar-

getting a specific molecule. If that molecule is mutated, then the louse becomes resistant to the neurotoxic pediculicide. Table 4 shows the decrease in neurotoxic pediculicide cure rates as reports of drug-resistant lice have appeared. DSP lotions target the entire exterior of the louse, by coating the louse and mechanically blocking the spiracles (breathing holes). Development of resistance would require complex changes in the breathing mechanism itself and would be unlikely to occur.

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