

Efficacy of the LouseBuster, a New Medical Device for Treating Head Lice (Anoplura: Pediculidae)

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ABSTRACT Human head lice (*Pediculus humanus capitis* De Geer) occur worldwide and infest millions of children and adults every year. Head lice infestations, which are known as pediculosis capitis, are psychologically stressful, physically irritating, and are one of the leading causes of K-6 school absence. The prevalence of head lice in many countries is increasing rapidly because of resistance to chemicals used in many head lice treatments. We tested the efficacy of an alternative method for controlling head lice, the LouseBuster, a custom-built medical device designed to kill head lice and their eggs using controlled, heated air. A total of 56 infested subjects was treated with the LouseBuster, and the efficacy of the treatment was evaluated by comparing the viability of lice and eggs on randomly assigned pre- and posttreatment sides of each subject's scalp. We evaluate treatment efficacy in the hands of novice versus experienced operators. We also evaluate treatment efficacy on different hair types and at different ambient humidities. Overall mortality of lice and eggs was 94.8% after treatment by experienced operators. Novice operators also achieved good results after a short training session; their results did not differ significantly from those of experienced operators. No adverse events were associated with the LouseBuster treatment. The LouseBuster is efficacious for killing head lice and their eggs. The use of heated air is appealing because it is a fast, safe, nonchemical treatment. Head lice are also unlikely to evolve resistance to desiccation, which is the apparent mode of action.

KEY WORDS *Pediculus humanus capitis*, pediculicide, nonchemical treatment, heated air

Head lice (*Pediculus humanus capitis* De Geer) are a major problem for children and their parents throughout the world (Roberts 2002, Burgess 2004, Frankowski and Bocchini 2010). Symptoms of head lice infestations (pediculosis capitis) include itching, psychological stress, and the possibility of secondary bacterial infections (Meinking 1999). Millions of cases occur annually (Frankowski and Bocchini 2010), and it has been estimated that children in the United States miss 12–24 million days of school per year because of head lice (Roberts 2002). Unfortunately, the problem is increasingly difficult to treat because head lice have evolved resistance to some of the most common pediculicides in several regions of the world (Pollack et

al. 1999, Burkhart and Burkhart 2000, Lee et al. 2003, Kwon et al. 2008). Moreover, some pediculicidal products have side effects, ranging from mild allergic reactions to severe seizures (Frankowski and Bocchini 2010), and many parents prefer not to treat their children with chemicals, even if they are safe (Burkhart 2004).

One strategy for dealing with resistant populations of head lice is to use chemicals to which head lice have not yet acquired resistance, such as oral ivermectin (Chosidow et al. 2010). Another strategy is to use a nonchemical approach; one possibility is heated air. Heated air has been shown to kill other medically important arthropods, such as ticks (Carroll 2003). In the case of lice, Kobayashi et al. (1995) reported that body lice (*P. h. coporis*) can be killed in vitro with air from a blow dryer at 50°C for 5 min, and that body louse eggs fail to hatch in vitro after exposure to hot air at 55°C for 90 s. More recently, Goates et al. (2006) evaluated several approaches for killing head lice and their eggs with large volumes of heated air. The most promising method was a custom-built, heated-air blower with a comb-like hand piece. The prototype device, dubbed the LouseBuster, was tested by experienced operators on a limited number of subjects in an arid climate (Utah, where it was developed). The prototype showed promise, but the comb-like hand

Disclosure of potential conflicts of interest: Larada Sciences is a University of Utah spin-off company involved in the creation and marketing of the LouseBuster device tested in this study. D.H.C., a Professor of Biology at the University of Utah, coined the LouseBuster and is a cofounder of and consultant to Larada Sciences. A.N.R. is an employee of Larada Sciences, and S.L.J. and J.R.M. were employees in the past.

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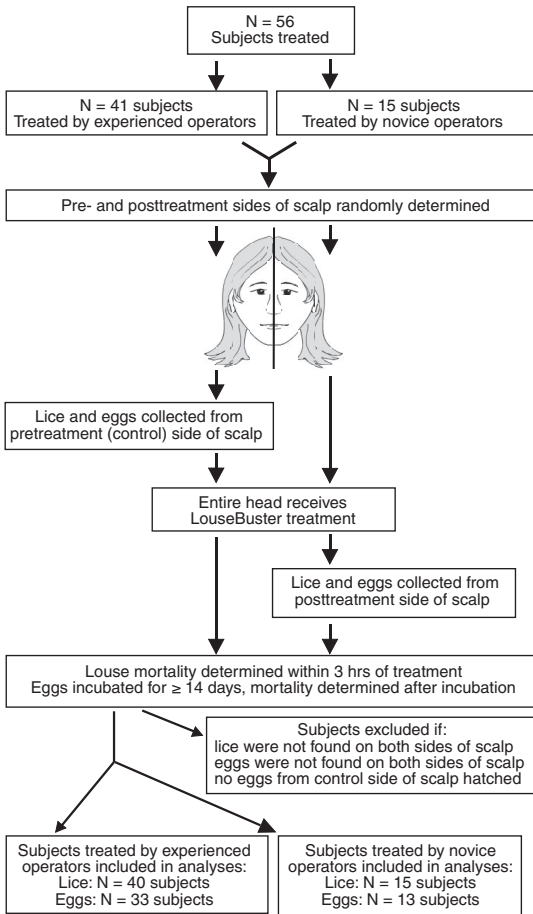


Fig. 1. Design of efficacy trials.

piece was difficult to use on subjects with curly hair. Furthermore, it was not clear whether the machine would work in more humid geographic regions, nor whether novice operators could use the machine successfully. In this study, we report the efficacy of a modified LouseBuster with a diffuser-like applicator that can be used on subjects with any hair type. The device was tested on a sample of 56 subjects treated by experienced or novice operators in humid and arid regions of the country.

Materials and Methods

Recruitment. The study was conducted at three clinical sites: Larada Sciences, Salt Lake City, UT; Lice Solutions Resource Network, West Palm Beach, FL; and Lice Solutions Resource Network, Nashville, TN. Personnel at the three clinical sites recruited subjects from the community by means of outreach activities; 56 subjects were included in the study (Fig. 1). Subjects met inclusion criteria if at least one live, moving louse was detected on the scalp, as described below. We excluded children younger than 4 yr of age because the treatment takes 30 min, which is longer than

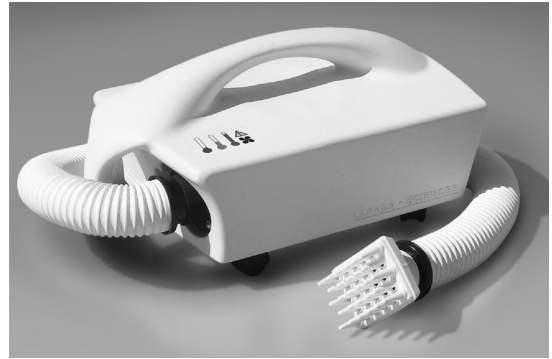


Fig. 2. The LouseBuster is a custom-built medical device designed to kill all life stages of head lice by delivering precisely controlled, heated air ($59 \pm 1.5^\circ\text{C}$) at an airflow two to three times greater than that of a hand-held blow dryer. A removable hose directs the air through a disposable, diffuser-like applicator that distributes air to the scalp and bases of hair shafts, where lice and their eggs congregate. During treatment the applicator is held in overlapping positions on the scalp (30 s per position). A specific pattern is followed to ensure that all areas of the scalp receive adequate coverage. The entire scalp can be treated in ≈ 30 min, independent of hair length.

young children can realistically remain seated (the device is not indicated for use on children under the age of 4). Subjects signed written consent forms approved by our Institutional Review Board after being fully briefed. Minors were given age-appropriate consent forms, and their consent was recorded in addition to the written informed consent provided by their parents or guardians.

LouseBuster Device. The LouseBuster device (U.S. patent no. 7,789,902) has received clearance from the Food and Drug Administration under 510(k) pre-market notifications. A production quality LouseBuster (LB-3120; Fig. 2) is currently available on the market (Larada Sciences, Salt Lake City, UT; www.lousebuster.com). The LouseBuster prototype (Goates et al. 2006) required a 20 amp circuit; the modified device tested in this study operates on a standard 15 amp circuit (120V/15A; 240V/10A).

Study Design

Experienced Operators. Subjects were asked to arrive at treatment facilities with clean, dry, untangled hair. They were fitted with a disposable barber-style smock and seated in a chair over a white drop cloth (7 m^2). One of five experienced operators recorded each subject's hair type according to the following parameters: length, short (hair above chin line) versus long (hair extending below chin line); thickness, thick (hair ≥ 3 cm diameter in ponytail, or similar thickness if short) versus thin (< 3 cm diameter in ponytail, or similar thickness if short); curliness, curly (=wavy or curly hair) versus straight.

To measure efficacy of the LouseBuster device, we used a paired sampling design in which each subject's

scalp was randomly divided into two halves, as follows: a pretreatment side and a posttreatment side (Fig. 1). This study design is more powerful than a standard randomized controlled trial because each subject serves as his or her own control. The design minimized any influence of genetic or environmental variation in the subjects or their lice, including any effects introduced by previous head lice treatments. For each subject, the operator randomly selected a pretreatment side of the subject's scalp and combed it using 20 careful swipes of a LiceMeister comb (National Pediculosis Association, Needham, MA) (Goates et al. 2006). If one or more live, moving lice were detected while combing the pretreatment side, the subject was considered to have an active infestation and was included in the study (Roberts 2002, Frankowski and Bocchini 2010). All lice and eggs removed during combing of the pretreatment side were placed in a petri dish that was kept in an incubator set at 29–32°C and >50% RH.

After combing the pretreatment side of the scalp, the operator treated the subject's entire scalp with the LouseBuster, which required 30 min. Immediately after the treatment, the operator combed the posttreatment side of the scalp, again using 20 careful swipes of the LiceMeister comb. Lice and eggs from the posttreatment side of the scalp were placed in a separate petri dish in the same incubator. The subject's smock and the drop cloth were carefully examined to recover any lice blown off the scalp during treatment. These lice were placed in a third petri dish in the same incubator. A new smock was used for each subject, and the drop cloth was cleaned thoroughly between subjects.

Within 3 h of treatment, the numbers of live versus dead lice in the pre- and posttreatment samples were tallied under a dissecting microscope, as described in Goates et al. (2006). Lice that showed any movement were considered live. Lice that showed no movement, even after being nudged with a forceps or dissecting needle, were considered dead. Goates et al. (2006) scored lice using these same criteria, then monitored dead individuals for up to 18 h to test for a "resurrection effect," in which "dead" lice are not really dead (Burkhart 2004). Goates et al. (2006) found no cases of resurrection. The lice were scored as blindly as possible, although it was often obvious which ones had been treated; lice from the posttreatment side of the scalp often differed in appearance from lice on the control side. Lice from the posttreatment side were often shriveled and darker than lice from the pretreatment side, which tended to be plump and lighter in color.

Eggs were kept in the incubator for a minimum of 14 d to allow time for hatching (head lice hatch in 8.5–12 d; Lebowhl et al. 2007). After incubation, the hatching success of eggs was scored under a dissecting scope by one of two researchers, both of whom were blind to treatment. The percentage of eggs that hatched (%Hatch) was calculated as follows: $N/(V + N)$, where N was the number of fully or partially emerged nymphs and V was the number of potentially

viable eggs (those with intact opercula). Egg mortality was calculated as $100\% - \%Hatch$. Efficacy was determined by comparing the percentage of mortality of lice and eggs from the pre- and posttreatment samples of lice.

Before treatment, subjects were instructed to give a "thumbs-down" signal to indicate any discomfort from the heated air (Goates et al. 2006). If this occurred, we immediately removed the applicator from the hair for a few seconds to allow the scalp to cool, then resumed treatment. Although subjects were informed to let us know whether they wanted to discontinue treatment because of any discomfort, none of the subjects found this to be necessary.

Novice Operators. We also tested the efficacy of the LouseBuster in the hands of novice operators. Potential novice operators were screened to verify that they were at least 18 yr of age and physically capable of delivering a treatment. They were excluded if they had previous experience with a LouseBuster device, any muscular or joint pain, carpal tunnel syndrome, upper extremity neurological deficits, or if they were unable to stand comfortably for at least 1 h. Novice operators represented a variety of professional backgrounds. All operators signed Institutional Review Board-approved informed consent forms.

The training of novice operators was multifaceted. Novice operators received the LouseBuster Operator's Manual, viewed a multimedia presentation, and received interactive hands-on training in which they were given an opportunity to ask questions and perform practice treatments on mannequins. Training was typically completed in less than 2 h. After training, each novice operator took a short written and practical exam. An experienced operator reviewed and discussed incorrect answers and techniques with each novice operator. Each novice operator then administered a LouseBuster treatment to one subject with head lice. Treatments by novice operators took place 1–36 d (mean = 8.4 d) after they were trained.

Inclusion criteria for subjects treated by novice operators were the same as those treated by experienced operators. The treatment procedure was also the same. One of two researchers at each site, who were experienced operators, observed each novice operator and subject during the treatment, while completing a check sheet with questions regarding the quality of the novice operator's technique. Researchers did not provide advice or answer questions during the treatment.

Statistical Analyses. We determined the efficacy of the LouseBuster by comparing data from pre- and posttreatment sides of the scalp using Wilcoxon signed-rank tests for matched pairs. To compare the efficacy of novice operators with experienced operators, we used Wilcoxon rank sum tests. We also used Wilcoxon rank sum tests to compare the efficacy of the LouseBuster between different hair types and ambient humidities. Values of $P < 0.05$ were considered to indicate statistical significance. Statistical analyses were performed using the JMP v.7.0 statistical package

Table 1. Baseline characteristics of study subjects

	Experienced operator study	Novice operator study
Subjects	41	15
Age: mean yr (range)	12.9 (6–60)	14.9 (4–43)
Sex: N (%)		
Male	5 (12%)	0 (0%)
Female	36 (88%)	15 (100%)
Hair density: N (%)		
Thin	24 (62%)	8 (53%)
Thick	15 (38%)	7 (47%)
Hair curliness: N (%)		
Curly	15 (37%)	5 (33%)
Straight	26 (63%)	10 (67%)
Hair length: N (%)		
Short	16 (40%)	2 (13%)
Long	24 (60%)	13 (87%)
Lice per subject: mean \pm SE (no. of subjects)	53.4 \pm 14.1 (40)	167.4 \pm 65.4 (15)
Viable eggs per subject: mean \pm SE (no. of subjects)	93.0 \pm 24.1 (33)	93.1 \pm 19.3 (13)

(SAS Institute, Cary, NC). If $P \geq 0.05$, we determined statistical power using G*Power v.3 (Faul et al. 2007).

Results

Experienced Operators. Experienced operators treated 41 subjects who met the inclusion criteria of having at least one live, moving louse on the pretreatment side of the scalp (Fig. 1). Baseline characteristics of these study subjects were recorded (Table 1). A single subject was excluded from the analysis of lice because no lice were recovered from the posttreatment side of the scalp, making it impossible to compare pre- and posttreatment mortality. Eight subjects were excluded from the analysis of eggs because, in seven cases, subjects did not have viable egg infestations (no pretreatment eggs from these subjects hatched in the incubator); no eggs were recovered from the posttreatment side of the eighth subject's scalp. The analysis of hatched lice thus included data from 40 subjects, whereas the analysis of eggs included data from 33 of these subjects (Fig. 1).

The LouseBuster killed the majority of hatched lice (Fig. 3A, Experienced Operator). Posttreatment mortality was 88.2% ($\pm 2.2\%$), compared with 2.5% ($\pm 0.9\%$) on the pretreatment side of the scalp (Wilcoxon matched pairs $Z = 410.0$, $P < 0.0001$, $n = 40$). After treatment, about one-half of the lice ($54.2 \pm 4.6\%$) were still on the scalp; the rest had been removed, that is, blown onto the smock or drop cloth. Most of these lice ($85.1 \pm 4.4\%$) were dead. The rest were considered dead because head lice cannot survive off the host (Takano-Lee et al. 2003, Burgess 2004), particularly after exposure to heated air (Buxton 1946, Kobayashi et al. 1995).

The LouseBuster killed virtually all eggs (Fig. 3B, Experienced Operator). Egg mortality on the posttreatment side of the scalp was 99.2% ($\pm 0.3\%$), compared with 55.3% ($\pm 5.1\%$) on the pretreatment side (Wilcoxon matched pairs $Z = 279.5$, $P < 0.0001$, $n = 33$). Pretreatment (control) egg-hatching rates were consistent with those in other studies (Buxton 1946, Burgess et al. 1994, Goates et al. 2006). No eggs were

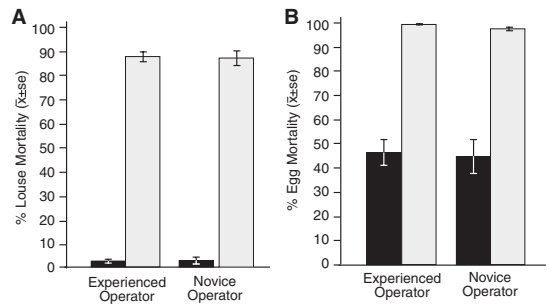


Fig. 3. Efficacy of the LouseBuster device for treating head lice and their eggs. (A) Mortality of lice on the posttreatment side of the scalp (▨) was much greater than that on the pretreatment side (■), both for experienced and novice operators. (B) Mortality of eggs on the posttreatment side of the scalp (▨) was also greater than on the pretreatment side (■), both for experienced and novice operators.

blown off during treatment; they remained glued to the hair shafts.

Posttreatment mortality of lice and eggs combined was 94.8% (± 1.0), compared with 42.6% (± 4.7) pretreatment mortality ($n = 33$).

Novice Operators. Novice operators treated 15 subjects (Table 1; Fig. 1). Two subjects were excluded from the analysis of eggs because they did not have viable egg infestations (no pretreatment eggs hatched in the incubator). Consequently, the analysis of lice included data from 15 subjects, and the analysis of eggs included data from 13 subjects (Fig. 1). All of the novice operators used correct technique when treating subjects, according to evaluations by the experienced operators who observed them closely during the treatment procedure.

As before, the LouseBuster killed the majority of hatched lice (Fig. 3A, Novice Operator). Posttreatment mortality was 87.7% ($\pm 3.4\%$), compared with 2.6% ($\pm 1.6\%$) on the pretreatment side of the scalp (Wilcoxon matched pairs $Z = 60.0$, $P < 0.0001$, $n = 15$). The LouseBuster also killed the majority of eggs (Fig. 3B, Novice Operator). Egg mortality on the posttreatment side of the scalp was 97.4% ($\pm 0.9\%$) compared with 55.3% ($\pm 7.1\%$) on the pretreatment side (Wilcoxon matched pairs $Z = 45.5$, $P = 0.0002$, $n = 13$).

Posttreatment mortality of lice and eggs combined was 93.6% (± 1.2), compared with 36.5% (± 6.1) pretreatment mortality ($n = 13$). The efficacy of novice operators did not differ significantly from that of experienced operators (Wilcoxon rank sum $Z = -1.31$, $P = 0.19$; one-tailed power = 0.83 with effect size $d = 0.86$, capable of detecting $\geq 5\%$ poorer efficacy by novices compared with experienced operators).

Hair Type. Efficacy was independent of hair type. Posttreatment mortality of lice and eggs did not differ significantly between subjects with long versus short hair, curly versus straight hair, or thick versus thin hair (all comparisons: Wilcoxon rank sum $P \geq 0.37$; two-tailed power ≥ 0.80 with effect size $d = 0.86$, capable of detecting a difference $\geq 5\%$ between categories).

Ambient Humidity. Efficacy was high in both humid and arid regions of the country. Posttreatment mortality of lice and eggs was 93.7% ($\pm 1.0\%$) for the 19 subjects treated in Florida and Tennessee (66–75% mean annual relative humidity) (NOAA 2002). It was 95.0% ($\pm 1.2\%$) for the 27 subjects treated in Utah (46–55% mean annual relative humidity) (NOAA 2002). There was a significant difference in efficacy between humid and arid regions; however, the difference was only 1.3% (Wilcoxon rank sum $Z = -1.98$, $P = 0.048$).

Adverse Events. No adverse events attributed to the LouseBuster were noted by experienced or novice operators or their subjects. Similarly, no adverse events were reported by any of several hundred subjects treated with earlier LouseBuster prototypes (Goates et al. 2006) (our unpublished data).

Discussion

The results of this study show that the LouseBuster device kills the majority of head lice and their eggs. After a single 30-min treatment by experienced operators, the combined mortality of lice and eggs was 94.8% ($\pm 1.0\%$). The high posttreatment mortality of eggs in our study is particularly noteworthy because eggs are impervious to most other methods of treatment, which typically require a second application or second dose once the eggs hatch (Burgess et al. 2007, Lebwohl et al. 2007, Chosidow et al. 2010). The timing of the second application is crucial; if the narrow window between hatching and reproductive maturity is missed, the cycle repeats itself and more than two treatments are needed over the course of several weeks (Lebwohl et al. 2007, Frankowski and Bocchini 2010). The LouseBuster kills most lice and virtually all eggs in a single 30-min treatment.

We did not do a follow-up study of cure rate because it is difficult, if not impossible, to account for cases of reinfestation (Heukelbach et al. 2008). Goates et al. (2006) performed a small-scale follow-up study ($n = 11$ subjects) in which they reported elimination of 100% of viable head louse infestations 1 wk after treatment with the LouseBuster prototype. Given that the device does not kill 100% of hatched lice, the results of their study suggest there may be a delayed effect on the small number of lice or eggs not killed outright by the device.

The LouseBuster appears to work by desiccating lice and their eggs. Lice are particularly susceptible to desiccation because their small size and flattened shape give them a high surface area to volume ratio (Moyer et al. 2002, Goates et al. 2006). Buxton (1946) reported that dry, heated air also reduces the amount of amniotic fluid in louse eggs, making it more difficult for them to hatch, which may explain why heated air has such a devastating effect on eggs when applied correctly. It is unlikely that head lice can evolve resistance to desiccation because water is such a fundamental component of their physiology, and one that is already a limiting factor in the survival of small insects (Rudolph 1983, Moyer et al. 2002, Renault and

Coray 2004). The evolution of resistance to many pediculicides, by comparison, is relatively simple (Kwon et al. 2008).

No adverse events attributed to the LouseBuster took place in this study. The efficacy of the LouseBuster is also independent of hair length, thickness, and curliness. The device is easy to use with any hair type because the applicator is not moved through the hair like a comb, but is held in place on each section of the scalp being treated. The results of this study also demonstrate high efficacy of the LouseBuster in both humid and arid regions of the country. Moreover, the device performed well in the hands of novice operators, whose results did not differ significantly from those of experienced operators.

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Study protocols were reviewed and approved by the University of Utah Institutional Review Board (Salt Lake City, UT) or by Sterling Institutional Review Board (Atlanta, GA). Trials were registered at ClinicalTrials.gov (NCT00731718, NCT00732134, NCT00732264).

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