Project No.
COOP-CT-2005-017916

Project acronym
CLEARBRUSH

Project title
A Novel Integrated Ultrasonic Brush and Sonically Activated Lotion to Provide a Full System Approach to the Eradication of the European Head Louse Menace

Instrument: **Co-operative research projects**

Thematic priority: **Horizontal Research Activities Involving SMEs**

PUBLISHABLE FINAL ACTIVITY REPORT

Period covered: **01.09.2006 to 29.02.2009**

Date of preparation: **13.06.2008**

Start date of project: **01.09.2005**

Duration: **30 months**

Project coordinator name: **Peter Palmer**

Revision: **1**

Project coordinator organisation: **A. Nelsons & Co. td.**

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1 - Publishable final activity report

1.1– Overview of general project objectives

Except for the common cold, head lice infestation is more common than all the other childhood communicable conditions combined (20 million people in the EU become infested each year with a treatment cost of approximately 375 million € and untold contamination problems). The current treatment – fine-tooth combing, which is unpleasant and difficult to administer, and pesticides, to which resistance is building rapidly – have failed to solve the problem.

The CLEARBRUSH system is based on a full system approach to eradication of head lice. It aims to develop these innovative features and benefits:

1. Active Brush to remove eggs and lice

    - The brush will be usable in the same way as an ordinary brush / comb. The ultrasonic bristles will vibrate in a carefully designed lateral mode, allowing all hair to pass through but exerting a vibrating force on the attached eggs.
    - The brush will be designed to capture and remove any lice that can still move.

2. Active Lotion to immobilise lice and kill, penetrate and kill eggs, and lubricate nit removal.

    - A novel lotion for a superior lubrication and killing of head lice and eggs, guided to the target area and given highly increased penetration by the ultrasonic brush bristles.
    - Naturally active Neem compounds, to give a new mode of *pediculicidal* (louse killing) effect,

The specific scientific and technical objectives were established in order to ensure the basic principles behind Clearbrush were designed in an optimum way and subsequently tested to ensure the project could progress in a logical and constructive manner – to deliver a working prototype system.
The key scientific objectives in the latter part of the project period aimed at proving and comparing the efficacy of the system:

Scientific objectives

At the first project stage the scientific objectives were:

- To research the design parameters for the layout and amplitude of the laterally activated bristles, to provide the required forces at the hair surface to disrupt egg case material with no damage to the hair shaft.
- Research on the physical dimensions of the pores and shell-hair gaps of egg cases, to provide input into the acoustic amplitude and the surface tension and thixotropy requirements of the active lotion.
- Validate the action of the chosen Neem extract and research the lubricative and penetrative properties of the active lotion.
- Additionally, to research the possibilities of extending the use of piezoelectric devices into potential future power applications, such as surface sanding.

The main scientific objectives of the work during the second project period concerned mainly the clinical validation of the Clearbrush system and thus the knowledge and understanding gained from the trials, and how the outcome would support the further development of the project

- Establish that the active lotion(s) could be an effective treatment on its own, compared with a benchmark product.
- Establish that the Clearbrush system (the active lotion together with the Clearbrush) could be effective in head lice infections in principle and achieving superior efficacy compared with benchmarks.
- Understand as far as possible the principle of how the Clearbrush system works.
- Establish further through testing that the Clearbrush system components are safe in treating human beings.

Technological objectives built on the scientific principles established in the early stages of the project, using the knowledge to develop and test the prototype system.

- A piezoelectric polymer actuator to work from a battery supply generating an ultrasonic signal to power the bristles' at an estimated maximum of 5W and the optimum ultrasound frequency.
- A specially designed bristle, to transmit the signal onto its targets through lateral means such as surface Lamb or Rayleigh waves, and to be engineered to the required hygiene and scalp safety tolerances.
- A novel means of coupling the multiple bristle assembly to the actuator, maintaining the ultrasound signal strength.
- To develop a carrier medium (active lotion) with sufficiently low viscosity and surface tension to penetrate the operculum and hair / egg case gaps under the influence of the applied sonic field from the brush.

In the latter project stage, the main objectives involved finalisation of design work on the Clearbrush unit, development and manufacture of the components making up Clearbrush, demonstration that the Clearbrush was capable of delivering ultrasound to the tips of the stainless steel comb unit – resulting in a clinically effective product.

Further work to improve the active lotion was also carried out during this phase of the project.

- Collation of the detail and construction of the Clearbrush working mechanism.
- Design and manufacture of working prototypes, these were then tested for output by a specialist ultrasound development company (Cedrat).
- Development of a new formula for the active lotion based on silicone as main active ingredient as well as functional bulk ingredient.
- Development of clinical trial protocol designed to test the efficacy of the Clearbrush system.
- Running of clinical validation trials on some 140 subjects, evaluation and reporting of the results – consider the impact of the results on further project developments.
- Further related objectives involved the investigations on competing patents and plans for protecting the intellectual property and preparation of material to publicise the project and its results, including presentations at conferences or other similar venues.

The components making the Clearbrush system; Ultrasonic comb & Active Lotion

1.2- Contractors involved

The contractors involved in the work during the project term:

1. A. Nelson & Co. Ltd, United Kingdom – the project coordinator – established in 1860 in Mayfair, London, probably the oldest manufacturer of homeopathic medicines in the world. The company facilities are staffed and equipped to help in development, to test and transfer products to manufacturing scale and are on hand for manufacturing trouble shooting as required. The team is used to delivering practical innovation solutions, and is backed by a strong regulatory affairs team who ensure that all development work is in line with the stringent medicines regulations and industry standards. Contact details: A. Nelson & Co. Ltd., Broadheath House, 83 Parkside, Wimbledon, London, SW19 5LP, e-mail: Info@nelsons.co.uk.

2. Denman International Ltd., United Kingdom – one of Europe's leading suppliers of brushes and all hair-care items, particularly to the professional market. Their main filed of activity is plastic moulding of brushes and plastic covers of the hair-care electric equipment such as hairdryers, trimmers etc. Denman possess highly developed workshop facilities equipped with modern moulding machinery. They are cooperating with companies specializing in the fast prototyping and with many designers to develop the highest quality products in the world market. Combining all above-mentioned facts Denman created world known reliable and recognized trademark.

3. Laboratorios Lac S.L., Spain – work in different analytical areas (as food, water and environment facilities, etc), with the purpose of guaranteeing the quality and safety of the final product and the elaboration of new processes. Laboratorios LAC are credited according to the International Norm ISO 17025 and Norm EC 45004, which guarantee the technical competition of the research laboratories. They have the professional experience to satisfy the necessities that the market demands, adapting their equipment and human guaranteeing the best service.

4. Diafarm Laboratorios S.A., Spain – own and manage a well established wholesale operation, Famadem, based in Monaco and supply France through this operation. Diafarm have an experience in distributing healthcare products to pharmacies (and health stores) and have the infrastructure to provide product information and training

5. Innowacja Polska Sp. z o.o., Poland –company has always been very much involved in supporting SMEs, as most of their customer base is made up of SMEs and for this reason they understand their very individual needs and difficulties. They possess a proven industry facing technology base with strong links in the internationally renowned local academic sector. Innowacja Polska closely co-operates with well known technical universities in Poland and abroad. As a multidisciplinary research centre they provide researchers and scientists

able to work at the highest level of scientific excellence in the development of high performance electronic technology, and the techniques involved in encapsulating these into industrial and consumer products.

6. Insect Research & Development Ltd., United Kingdom – founded in 1984 since when it has been at the forefront of entomological research. Experts have a broad range of knowledge covering all insects, arachnids and other arthropods. The company is a research based organisation with extensive experience in laboratory studies for a wide range of clients from small individual companies to large international pharmaceutical and agrochemical companies.

7. Sub-Contractors – Cedrat, France
   A company from France, CEDRAT TECHNOLOGIES (also having previous experience of the EU Craft projects) was identified in summer 2006 and was invited to join the project. In the mean time, CEDRAT have been involved in providing advice and services to the Consortium. After a long time of negotiations CEDRAT has declined joining the project as a partner citing high procedural bureaucracy of the EC projects in relation to low level of direct funding from the EC. CEDRAT agreed to participate as a sub-contractor and this was approved by the EC in a letter dated 30th of July 2007., .

All the partners were working to develop robust core components that will be incorporated into the CLEARBRUSH system with the intention that the first sales via Nelsons & Co. Ltd., the project coordinator, can take place within 12 – 18 months after the project time frame ended. The consortium will maintain contact with community healthcare practitioners through Nelsons and Diafarm, to ensure that the final design and performance of the CLEARBRUSH system meets customer needs for ease of use and effectiveness across the various EU countries.

1.3 - Work performed

First Reporting Period

The work carried out in the first twelve month period of the project focused on the scientific studies, development of the active lotion in aqueous base with active ingredients, development of the ultrasonic system and integration of the Clearbrush components including piezoelectric actuator, brush bristles and cover. Further more, *in vitro* examinations took place, during which alternative solutions were tested for their ability to lubricate nit removal with and without ultrasound, and the first part of the clinical validation trials was also conducted on the active lotion in the aqueous base.

The main design parameters of the Clearbrush device and active lotion were researched; establishing layout and amplitude of the ultrasonically activated bristles, establishing the required forces at the hair surface for disrupting the egg case material

with no damage to the hair shaft and scalp, and to improve human louse eradication method. Research on the physical parameters of the egg cases and egg clamp mechanism were carried out to provide input into the acoustic amplitude, the surface tension, and thixotropy / lubrication requirements of the active lotion. A validation method was developed to provide a reliable measure for verification of the activity the active lotion has against lice and their eggs. A specific in vitro testing was conducted on the active lotion and comparative products in order to evaluate lubricative and penetrative properties.

Project's current relation to the State-of-the-Art

One of the project reports (deliverable report no. 7) describes test results on four different formulations tested with dry and wet hair controls. All the tests were performed with and without ultrasound to demonstrate the effect of ultrasound and to compare, its influence on the formulations under test:

- Active lotion ***(AL)***
- Hedrin 4% ***(Hedrin) – Market leading product in UK***
- Full Marks solution **(FMS) – Market leading brand in the UK**
- Nitty Gritty lotion (essential oils in a vegetable oil carrier) ***(NG) – on of "natural" brands in UK based on essential oils***

Table 1: Results of slip peel testing* without ultrasound (US); PK – peak, AV – average.

No US	*AL*		*NG*		*Hedrin*		*FMS*		*Dry*	
	PK	AV	PK	AV	PK	AV	PK	AV	PK	AV
Mean	**5.14**	**0.56**	**19.86**	**3.46**	**25.45**	**1.69**	**4.0**	**1.24**	**12.83**	**1.76**
St. dev.	**3.9**	**0.3**	**13.7**	**2.5**	**11.5**	**1.2**	**15.2**	**7.8**	**5.7**	**0.7**

Table 0: Results of slip peel testing with ultrasound (US) for 10 seconds; PK – peak, AV – average.

US 10 seconds	*AL*		*NG*		*Hedrin*		*FMS*		*Dry*	
	PK	AV	PK	AV	PK	AV	PK	AV	PK	AV
Mean	**2.48**	**0.26**	**35.9**	**4.6**	**12.64**	**1.85**	**2.2**	**0.3**	**12.39**	**1.31**
St. dev.	**2.8**	**0.1**	**20.9**	**3.7**	**12.8**	**4.0**	**13.4**	**5.9**	**7.7**	**1.3**

* Slip peel test: Measures the force required (with a specific device) to pull a nit of a single strand of hair

The results show that those formulations with a higher standard deviation have a greater fluctuation from the mean average measurement which indicates that the results are very variable and therefore not consistent. This would mean that the ability of these formulations to remove eggs from the hair is variable and therefore not reliable. Those

formulations when tested without ultrasound that had a high standard deviation were Nitty Gritty, Hedrin and Full Marks Solution.

The active lotion produced results with a lower standard deviation both with and without ultrasound. The average was below 1 which shows that the use of active lotion as an aid to removing eggs is more effective than dry hair and facilitates the removal of eggs. Further tests were performed using the ultrasound and active lotion with 10, 20 and 30 seconds ultrasound however they show that longer ultrasound does not increase efficacy.

The development of the active lotion has established that certain lotions, such as aqueous emulsions, appear to have the greatest ability, especially in the presence of ultrasound, to lubricate hair and facilitate nit removal. Silicone compounds appear to effective as well in such lubrication, however not quite as good as the aqueous solutions.

Further insight into the test results from the clinical trials shows that the effects of the silicone based formula are enhanced by ultrasound (the silicone achieves killing of head lice by coating and closing breathing openings in the head louse armour). This is in contrast to the older version of the active lotion which had lower intrinsic activity against head lice – ultrasound did not seem to increase the efficacy of this version of the active lotion. This further indicated that the neem extract which has been shown to act as an insecticide (in a number of papers) had less of a role to play in the efficacy of the Clearbrush system. It was rather the coating / suffocating effect of the silicone which appears to be delivered better with the help of ultrasound and hence higher killing efficacy shown by the Clearbrush system.

Notably there are other treatment systems which use ultrasound, and one patent claims use of ultrasound device with various (unspecified) head lice products, leading to less of head louse product having to be used to achieve efficacy.

The research conducted also established that metals, in particular stainless steel, aluminium and titanium, had the best properties in transferring ultrasound. This discovery lead to a change in the planned work program, where the comb teeth / bristle building material, was made from stainless steel instead of the polymer material which original designs were based on.

At the same time a further change, to simplify the design of the Cleabrush unit and making its use more reliable, was made where the plans for dispensing active lotion through the Clearbrush bristles were scrapped as it was believed this would both make the production of the unit cost prohibitive and its operation unreliable due to active lotion having the potential to harden and block the dispensing mechanism. In stead the active lotion is now dispensed by hand into hair (as with other head lice treatments) and the Clearbrush applied afterwards.

The technology development also concentrated on designing the specially shaped brush bristles to allow optimum transmission of ultrasound to site of action, eg. hair. This work resulted in an aluminium lever being coupled with the comb teeth to form a unit with a lateral dimension equivalent to the wave length of the ultrasound. In this way optimum energy use could be achieved from the least power source.

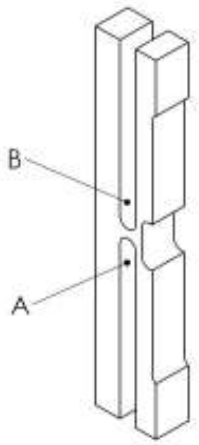


Fig. 1 Aluminum lever

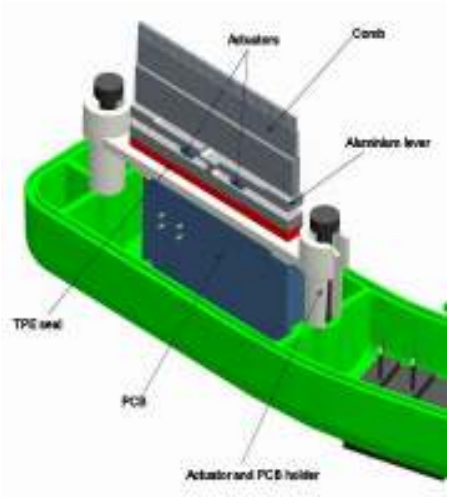


Fig. 2 The comb supported by the lever*

* The comb is supported by vibrating lever and ultrasound is transmitted to the comb

The active lotion based on the natural neem extract was improved to satisfy very restricted ultrasonic system. A thixotropic carrier medium was tailored to reduce its viscosity and surface tension to low enough levels to penetrate the operculum and hair / egg case gaps under the influence of the applied sonic field from the brush. The mechanical action of the brush-system is, as in effect, enhanced by the combination with a lotion type product which acts as a lubricant and is pushed by the force of ultrasound into narrow cavities between the egg-glue-shaft and hair shaft, as well as narrow openings in head louse coat and louse eggs.
As such the system can be classed as a Type I Medical device in accordance with the EU Medical Device Directive (93/42/EEC) and UK SI 2002 No. 618.

First version of the Active Lotion (in an aqueous, thixotropic base)

The key element of knowledge to disseminate is the capability of supplying for the first time a properly effective *pediculosis* treatment system that is easy and safe enough to use to actually reduce the infestation rate. The step-change in capability to achieve this is the unique combination of the piezoelectric ultrasonic brush and the specially designed active lotion. The project partners predict to enhance European technological progress beyond the state of the art and become leaders in the technology and market exploitation. The consortium considers the wider applications of the thixotropic and ultrasonic technology embodiments, once the initial market has been successfully penetrated. They consider the formation of alternative supply chain networks for such alternative uses of the Clearbrush system, as well as cooperation with larger distributors of healthcare products in Europe and beyond.

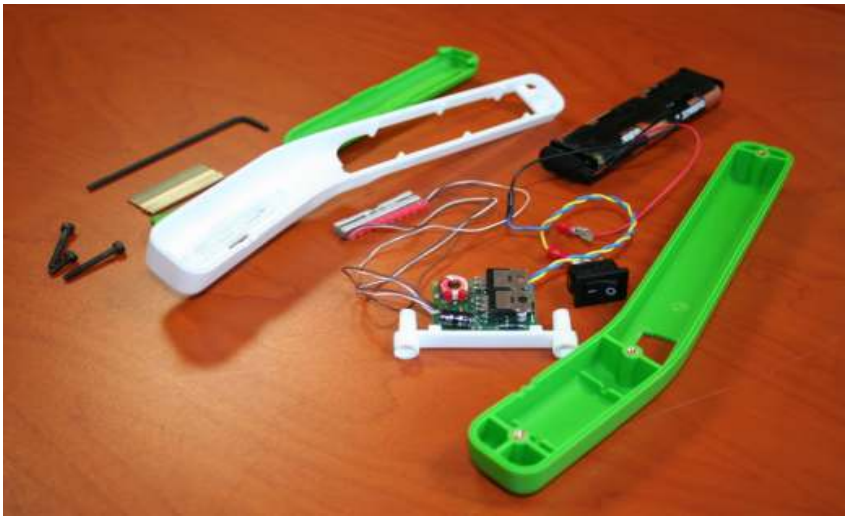
Second Reporting Peroid

Work performed in the second project period focused on qualifying the design of the Clearbrush unit, the making of prototype Clearbrush units, further improvement of the active lotion with active ingredients, manufacture of fully functioning Clearbrush prototypes as well as scale-up and manufacture of the improved active lotion, and running of full clinical validation trial involving about 140 subjects in total.

In general the technological objectives during this period were first to establish that the components, either identified or specially made, for the construction of the Clearbrush prototypes, functioned as intended once combined and that the Clearbrush unit was capable of delivering the required level of ultrasound. The assistance of Cedrat (subcontractor to the Consortium) a specialist company in ultrasound devices was obtained in order to measure the output from the fully functioning prototypes.

The photo below shows the components of the Clearbrush working prototype in a disassembled unit.

-Bottom casing.
-Top casing.
-Battery door.
-Teeth guard.
-Actuators / Aluminium lever and PCB holder.



The disassembled prototype

Secondly, the objective was to develop an effective, ergonomic and robust comb unit (the Clearbrush outer casing) which could be used in clinical trials on human subjects. The work also involved identifying and adapting specific moulding of the outer casing for Clearbrush and to manufacture 5 fully functioning prototypes which were then used in the clinical validation trials.

During the second project period, additional work to improve the so-called active lotion (it is necessary to coat hair with a particular type of lotion in order to allow the energy from ultrasound waves to be delivered to the site of application helping to lubricate and make combing action easier as well as functioning as a killing agent on head lice and eggs) was carried out. This resulted in a lotion with a superior efficacy in killing head lice compared with the previous version of the active lotion, although lubrication properties were not quite as good as with the previous version.

The ultimate objective was to develop a treatment system with a high efficacy and ease of use in order to improve on existing methods for eradication of head lice infections.
The combination of mechanical action of the brush-system using ultrasound and the action of the active lotion, acting both as a lubricant and killing agent - with both component parts developed successfully during the second project period - , was shown to be successful, both in the laboratory and ultimately in a clinical validation trial involving 136 subjects. As such both components (Clearbrush and the Active Lotion) of

the treatment system can be classed as a Type I Medical device in accordance with the EU Medical Device Directive (93/42/EEC) and UK SI 2002 No. 618.

The main and the significant objective which was implemented in the second period (which required the project time-span to be extended due time taken to recruit, collate results and then analyse) involved designing and then running a full scale clinical trail on the Clearbrush treatment system together with a benchmark head lice product in order to validate its function under the conditions the system is designed to treat. This was completed successfully in February 2008 and results show, 1) that the active lotion on its own has an equivalent treatment efficacy compared to a market leading comparative product (from the UK) and, 2) that the Clearbrush system using the improved version of the active lotion, achieves greater efficacy than both the active lotion on its own and the comparative product. The efficacy of the Clearbrush system successfully treaed human subjects in about 82% of cases, against 70% for either of the 'single' treatments.

The results from the validation trial have been documented in a separate report which are detailed in one of the project deliverables (D23). The results show that the Clearbrush treatment system works in principle as intended and that the system appears to have superior efficacy compared to treatments currently available on the market – although more trials with greater number of trial subjects would ideally be carried out to further establish the success of the Clearbrush system.

1.4 - End results

The Clearbrush project, which consists of the development of a ultrasonic combing device (Clearbrush) and an Active Lotion (necessary to transfer ultrasonic energy to the site of action) has now been completed where all key objectives have been achieved and fully functioning Clearbrush ultrasonic, combs have been produced as well as fully developed Active Lotion.

The Clearbrush system has been successfully trialled in clinical validation trials on human subjects with head lice infestation, demonstrating high level of efficacy in comparison with benchmark head lice products, 82% vs. 70% kill rate.

There are further modifications planned to the ultrasonic Clearbrush as a part of the production stage, however the Active Lotion is ready for market and can be sold as a separate entity due to its high level of efficacy against head lice and eggs.

The partners have worked to develop robust core components which have been incorporated into the CLEARBRUSH system. The further plan is to improve on the ergonomic and aesthetic design of the Clearbrush unit itself and fully establish the production process before marketing the full Clearbrush system as an effective treatment for head lice infections. The plan is however to market the Active Lotion

component as a single product first, during the course of 2008, through the distribution network established by Nelsons and Diafarm.

There are further opportunities to market the treatment system for other applications such as animal healthcare and the Consortium is open to possible licensing agreements or other forms of cooperation in order to gain wide distribution of the Clearbrush system, in Europe at first.

The project website can be found at;
http://www.innowacjapolska.pl/?page=Structure&id=16

2 – Dissemination and Use

2.1– Publishable results of the final plan for using and disseminating the knowledge

Section 1 – Exploitable knowledge and its use

The final exploitation plan is set out in deliverable report 32 in detail.

Overview Table

Exploitable Knowledge	**Exploitable product(s) or measures(s)**	**Sector(s) of application**	**Timetable for commercial use**	**Patents or other IPR protection**	**Owner & Other Partner(s) involved**
1. Ultrasounds influence on lotion	Lotion production	1. production process 2. medical	2006 2007	In-house knowledge	**Nelsons (owner)**, InnoPol, LAC, IRD
2. Active components determination method	Lotion production and quality validation	1. production process 2. postproduction process	2006 2007		**Nelsons (owner)**, LAC, IRD
3. Ultrasonic materials performance	Brush	Brush production	2007	Patent application being considered	**Nelsons (owner)**, Denman, InnoPol
4. Comb teeth (bristles) design and performance	Brush	Brush production	2007	Patent application being considered	**Nelsons (owner)**, Denman, InnoPol, IRD
5. Active Lotion influence on lubrication of hair	Active Lotion	1. medical 2. cosmetic	2007	Patent application being considered	**Nelsons (owner)** IRD
6. Comparative Efficacy of Active Lotion formulas	Active Lotion	1. Medical	2008	In-house formula Clinical report on file	**Nelsons (owner)** Diafarm
7. Clearbrush system efficacy	Clearbrush unit + Active Lotion	1. Medical	2009	Patent application being considered Clinical report on file	**Nelsons (owner)** Denman Diafarm

Items 1 – 4 were established during the 1st reporting period of the project. The tests on the influence of ultrasound on the active lotion increases knowledge on interaction of sonic fields and fluids / oils. The results were used to adjust the production process of the active lotion and modify the lotion formulation in order to decrease foaming (applicable to the previous aqueous formula).
Research on the active neem component of the lotion provided information on the main compounds acting as natural insecticides present in neem extracts.
Piezoelectric and carrier materials were tested. The tests provided information on piezoelectric materials best suited for the brush concept and which materials were most effective in carrying ultrasound energy. These tests showed that certain metals are the best choice.; aluminium, titanium and stainless steel.

In order to develop a system for eradication of head lice, bristles with the optimal shape and length were designed based on the wavelength of the ultrasound used. This will further inform selection of final comb / bristles used for marketable versions of Clearbrush, whether a specific comb-unit is designed or commercially available metal combs are utilised.

The 2nd project period, established items 5 – 7 where the outcome of the human clinical validation trial and in vitro trials (on lubrication properties in particular) managed to establish the level of efficacy achieved with the Clearbrush system and active lotions respectively in comparison with a benchmark head lice product.

The next steps in exploiting the Clearbrush system will be to improve both working mechanism and aesthetic appearance of the Clearbrush in order to make it robust and reliable once in commercial distribution.
Manufacturing will need to be fully established and cost of production components confirmed.
The evaluation of whether to apply for a patent, and notably whether the idea potentially infringes on other established patents, will need to be completed.

Following this it will be possible to start commercialising the Clearbrush system, first by using existing distribution network established by the partners and then seek cooperation with a larger pharmaceutical / healthcare distribution network in Europe in order to get the system into as wide a distribution as feasible.
Once the Clearbrush system is cleared as concerns patent issues, it will be possible to discuss the product with the larger healthcare companies and possibly achieve licensing agreements in parallel with initial marketing of the system by the Consortium.

As well as discussing the Clearbrush system with the trade it will be of importance to present the system to healthcare professionals and policy makers. The results from the clinical trial will be very important in this dissemination activity and will help to encourage further clinical results, potentially by other researchers, in order to establish the value of the Clearbrush system which in turn would help the re-imbursement of treatment by European health authorities.


The Clearbrush, ultrasonic comb, first version of the active lotion and second version of the active lotion

Potential barriers.

Potential barriers to the introduction of the Clearbrush head lice treatment system are:

- Acceptance of clinical results by health care practitioners and recommenders in head lice treatment.
- Low cost chemical treatments and health authorities resisting payment for treatment on prescription.
- Fragmented local European markets with niche players. In order to succeed Clearbrush must get into wide distribution quickly and to benefit from favourable review from opinion leaders in the field of human infestation control / head louse treatment.

Section 2 – Dissemination of knowledge

Overview Table

Planned /actual Dates	Type	Tape of audience	Countries addressed	Size of audience	Partner responsible /involved
2007	Project web-site	Public	International		InnoPol
2008	Flyers	pharmacy	European		Nelsons / Diafarm
2009	Meetings with key retailers / distributors	Trade	1. UK, Ireland 2. Europe mainland		Nelsons / Diafarm
2009	Publication	pharmacy, entomology	European		Nelsons, IRD,

As discussed in other project reports (Activity Report, 2nd project period / Deliverable 32 – Final Dissemination & Use Plan) the successful introduction of the Clearbrush head lice treatment system will in particular depend on the wider distribution achieved and the success people perceive from treating head lice infections with the system.

The current plan is to approach companies within the current distribution network covered by the Consortium members and present commercial material which of course builds on the success from the clinical validation trials.
Secondly, it will be important to recruit the help of opinion leaders in the field of head lice treatment. Dr. Ian Burgess, of IRD, is one of these opinion leaders where he enjoys world wide recognition as an expert in his field. The plan is to work with Dr. Burgess to help promote the system further and help educate both the public and healthcare workers – in particular pharmacists based in retail pharmacies and nurses working in community care, such as head lice infections as well as school nurses.

The user experience has been evaluated as a part of the clinical trial, where a questionnaire was completed by each patient after completing treatment and evaluation by a nurse practitioner (responsible for administering treatment). This helped establish that the treatment with either the active lotion(s) or the full Clearbrush system was generally liked. However, this cannot fully replace a user trial where the patient is treated by another member of their household, opposed to being treated as in the trial by an experienced nurse / study practitioner.
The user experience gained so far will however be important in informing communication in both product literature and education for both the public and professionals.

Section 3 – Publishable results

No results have been published as of yet.

The outcome of the clinical validation trial and interpretation is now set up in a report which can be used for extracting information which will typically be used for publication in trade journals, in particular clinical journals which focus on infection control as well as general healthcare.