



## Electronic Device against Mite Allergy

### Scientific Documentation

#### CLINICAL TRIALS

The attached documentation is concerning the Clinical Trials, as follows:

**A. Three studies conducted by the Allergy Centre of Mandic Merate Hospital, Italy.**

*B. Double blind placebo controlled trial performed by Pediatrician Dept. and Pediatric Allergy Centre of Macedonio Melloni Hospital in Milan, Italy.*

*(See separate document)*

**A**

## **A. THREE WORKS ARE HERE REPORTED AS PERFORMED ON MITE'S ALLERGIC PATIENTS AT THE ALLERGY CENTRE OF MERATE HOSPITAL, ITALY.**

**These studies have been published at the European Congress of Allergology and Clinical Immunology.**

### **Briefly the aim and the conclusions of the works:**

**Trial n° 1: "Ultrasonic waves as an environmental protection measure against house dust mites".**

**Aim:** evaluation of electronic device's effectiveness in reducing both symptoms and drugs' use.

**Patients:** 20 patients using the electronic device for a 3 months period + 20 patients as control group.

**Results:** a 28% decrease in days with symptoms and a 22% decrease in drugs' intake, in the group of patients who used the electronic device.

**Conclusions:** the Authors explain the results, thanks to a possible action on mite's fecal pellet that is rich in allergens.

**Trial n° 2: "A comparison between 2 means of environmental protection against mites: mattress cover vs. ultrasonic wave emitter".**

**Aim:** comparison of electronic device's vs. cover mattress' effectiveness in reducing both symptoms and drugs' use.

**Patients:** 15 patients using the electronic device for a 6 months period + 15 patients using a cover mattress + 15 patients as control group.

**Results:** same decrease in days with symptoms (16%) in the group with the electronic device and in the group with the cover mattress, compared to the control group.

The decrease in drugs' consumption was also similar (about 10% compared to the control).

**Conclusions:** Both the cover mattress and the electronic device show their validity in reducing symptoms and drugs.

**Trial n° 3: "A comparison between an ultrasonic wave emitter and a chemical acaricide in implementing environmental protection against mites".**

**Aim:** comparison of electronic device's vs. acaricide's effectiveness in reducing both symptoms-drugs and mites' presence in houses.

**Patients:** 16 patients using the electronic device for a 5 months period + 16 patients using an acaricide + 16 patients as control group.

**Results:** similar decrease in days with symptoms (about 19%) in the group with the electronic device and in the group with the acaricide, compared to the control group.

The decrease in drugs' use was also similar (about 10% compared to the control).

About a 20% reduction in presence of mites inside patients' homes was observed, in the group using the electronic device or the acaricide, compared to the control group.

**Conclusions:** Both the acaricide and the electronic device show their validity in reducing symptoms and drugs. Both the methods are able to control mites' presence in houses.

## ULTRASONIC WAVES AS AN ENVIRONMENTAL PROTECTION MEASURE AGAINST DUST MITES.

G. BRIVIO; M.A. BOSCOLO, DEPT. OF ALLERGOLOGY, "S.L MANDIC" HOSPITAL, MERATE (LECCO), ITALY

### Introduction

House dust mites are one of the major causes of allergy disorders. Numerous studies confirm that a reduction in the concentration of mites in the domestic environment produces an appreciable improvement in the symptoms of allergy sufferers. It follows that action, using the right methods, must be taken to secure such a reduction, especially in places where allergy sufferers spend prolonged periods of time.

### Aim Of The Study

The aim of this study was to assess whether a device producing ultrasonic waves could bring about a reduction in the quantity of mites in the environment and, therefore, an abatement in the rhinitis and asthma symptoms suffered by patients allergic to dust mites.

### Materials And Methods

The investigation concerned 40 patients who were allergic to Der.pter. and Der.far. and reacted with symptoms of rhinitis and/or asthma. No patient was currently undergoing SIT (Specific Immunotherapy) or had ever been so treated. Of the patients, 20 received a 40.000- Hz ultrasonic wave emitter. This device was sited in the patients bedrooms for a 3 month period (October – December) and during this period it emitted ultrasonic waves uninterruptedly.

No kind of environmental protection was prescribed for the other 20 patients (the control group).

All the patients made notes daily of any allergy symptoms they experienced (dyspnoea, coughing, rhinorrhoea) and their use of anti-allergy and/or anti-asthma medication.

### Discussion

The effect of the ultrasonic waves on the dust mites is not entirely clear. It is scarcely plausible that the ultrasonic waves acted directly and immediately on the mites exerting, as it were, an action in the nature of a "disturbance".

It could be hypothesised that the waves acted on the dust mites reproductive cycle or, alternatively or concurrently, on their faecal matter, deactivating it and transforming it into allergenically inert matter.

#### **SYMPTOMATIC DAYS**

	ULTRASONIC WAVES Group (20 patients)	CONTROL Group (20 patients)
- Dyspnoea	56	79
-Rhinorrhoea	63	91
-Nasal Cong	78	102

#### **DRUGS TAKEN DURING 3 MONTHS**

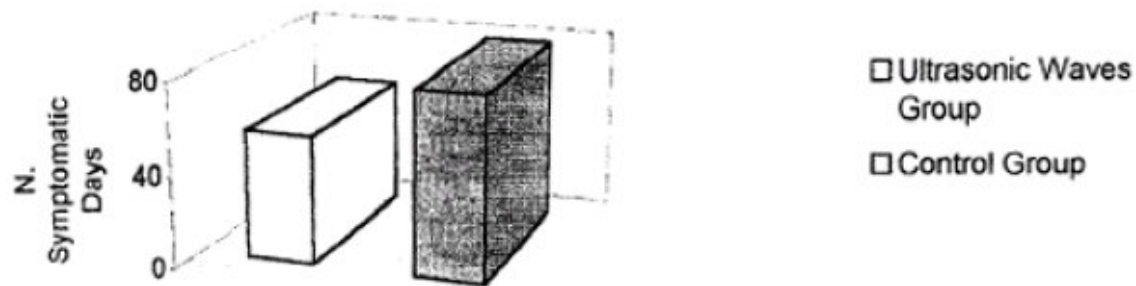
ULTRASONIC WAVES Group (20 patients)	CONTROL Group (20 patients)
108	139

### Conclusions

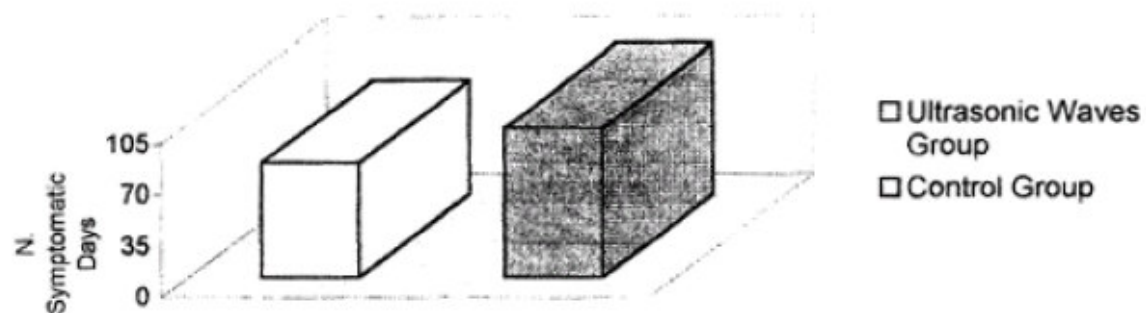
After 3 months the group of patients that had protected their environment with Ultrasonic Waves showed less allergy symptoms than the Control Group.

At the same time the group that had used the ultrasonic waves had had less recourse to medication.

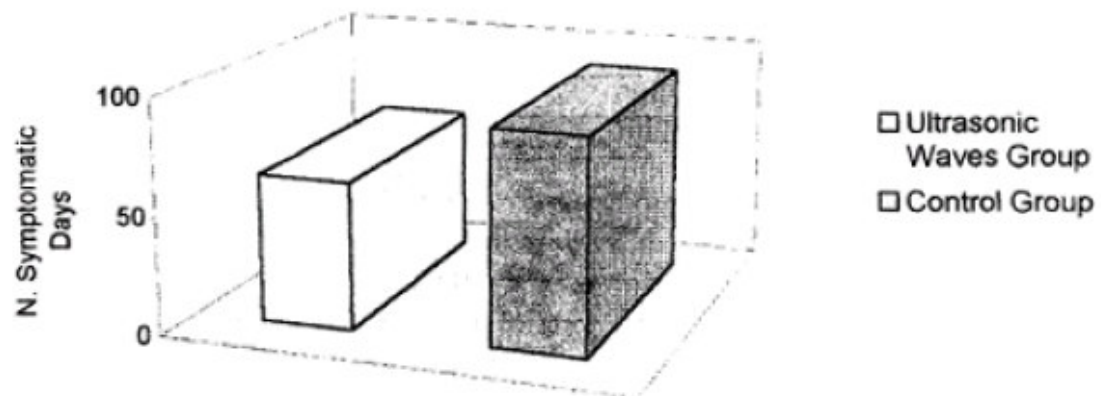
### DYSPNOEA



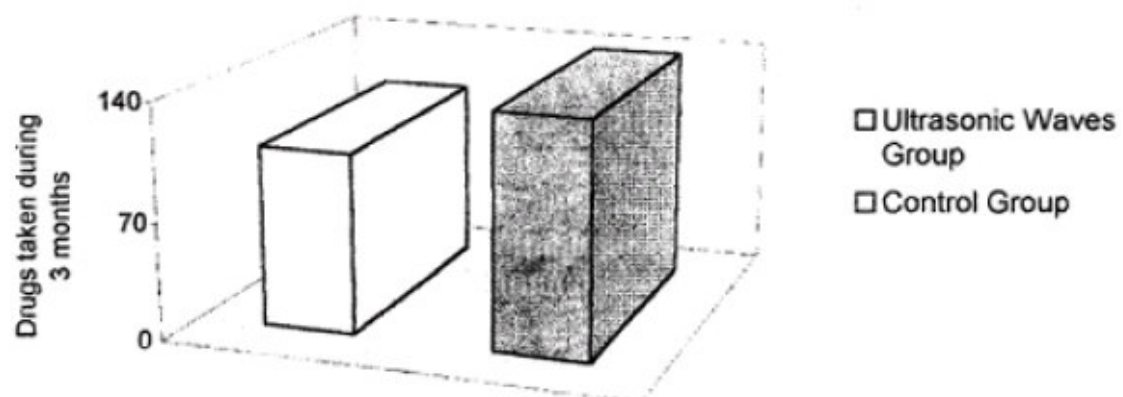
### RHINORRHOEA



### COUGHING



### DRUGS





# A COMPARISON BETWEEN 2 MEANS OF ENVIRONMENTAL PROTECTION AGAINST MITES: MATTRESS COVER VS ULTRASONIC WAVES EMITTER.

G.BRIVIO: M.A. BOSCOLO, DEPT. OF ALLERGOLOGY- "S.L. MANDIC" HOPSITAL, MERATE (LECCO), ITALY.

## Introduction:

The elimination of dust mites in the home (or at least a reduction in their concentration) is the method of choice for preventing symptoms in patients with al allergy to Dermatophagoides. (dust mites).

Over time numerous methods have been proposed as possible aids to extensively reducing mites and rendering the allergy-producing substances they release inactive.

## Aim Of Trial:

The aim of the trial was to compare a method that has been in use for years, viz. cotton-made polyurethane-lined mattress covers, with ultrasonic wave emitters.

Clinical trials have demonstrated that ultrasonic wave at a frequency of 40,000 Hz disrupt the reproductive cycle and the development of mites.

## Materials and Methods:

The trial was conducted on 45 patients allergic to mites and suffering from asthma and/or rhinitis. No patient had previously undergone Specific Immunotherapy, nor at the time was any patient undergoing it.

All patients were instructed in the rules for properly protecting the environment.

- 15 patients used mattress cover
- 15 patients used ultrasonic wave emitter
- 15 patients (the control group) relied exclusively on the general rules for protecting the quality of their environment.

All of the patients were subject to clinical observation over 6- month period (October-April).

During this period, using a diary on a daily basis, each patient recorded the presence of following symptoms: Dyspnoea, Rhinorrhoea and Nasal Congestion.

In addition, a record was kept by all patients of any anti-histamine and/or anti-allergy medication.

## Results:

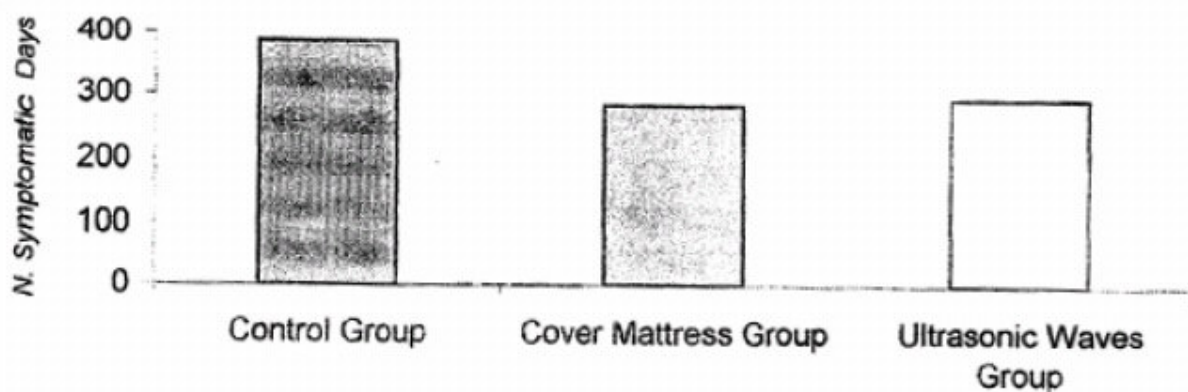
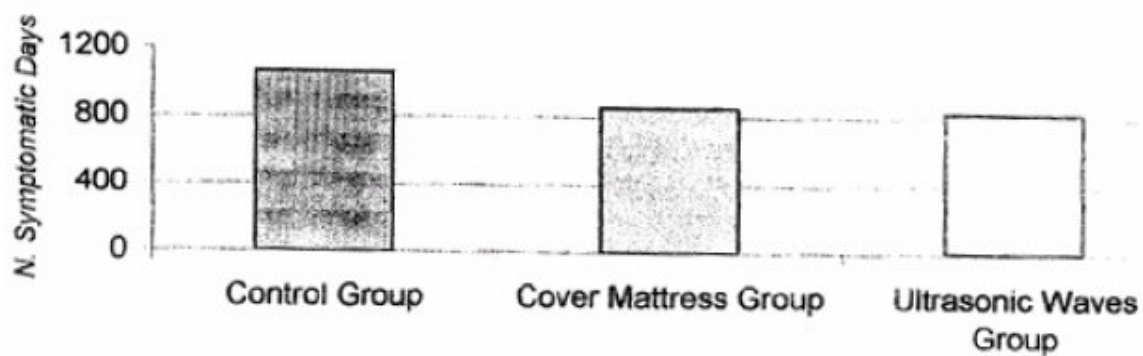
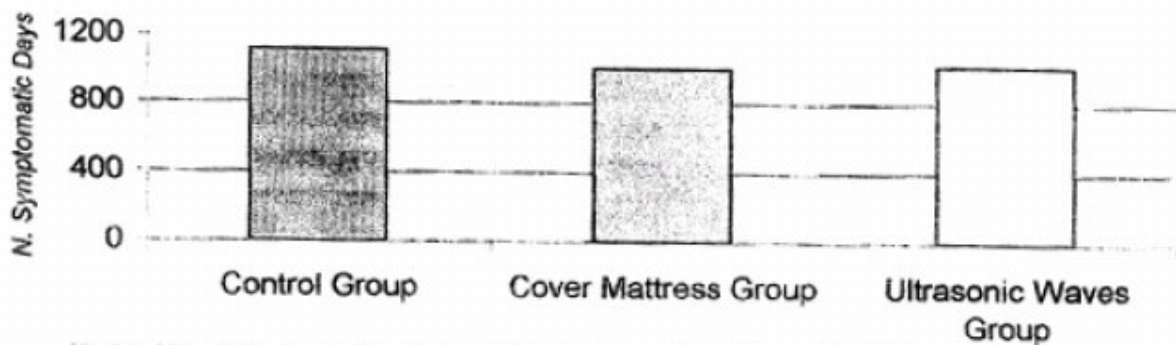
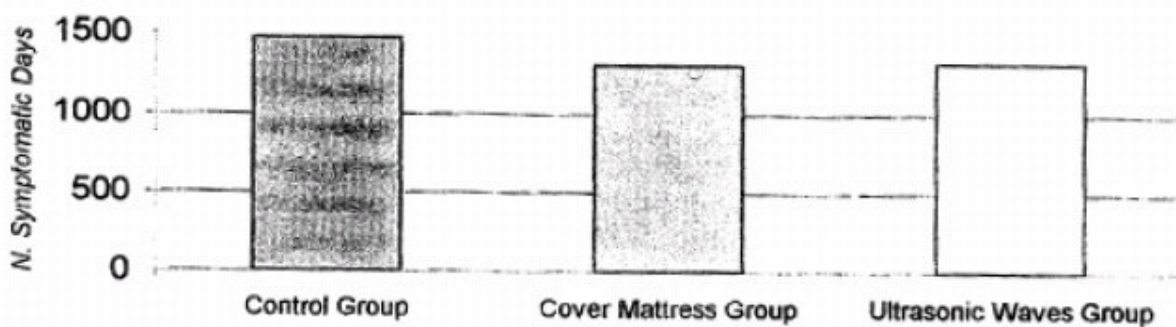
SYMPTOMATIC DAYS			
	CONTROL Group	COVER MATTRESS Group	ULTRASONIC WAVES Group
Dyspnoea	384	282	294
Rhinorrhoea	1056	852	828
Nasal Obstruction	1116	1008	1032
DRUGS TAKEN DURING 6 MONTHS			
	CONTROL Group	COVER MATTRESS Group	ULTRASONIC WAVES Group
	1470	1305	1325

## Conclusions:

The trial demonstrates that those patients who used either the mattress covers or the ultrasonic wave emitters displayed less symptoms and made less use of their medication than those in the control group.

No significant differences (as to symptoms and/or use of medication) were noted between the patients using the mattress covers and those using the ultrasound wave emitters.

Accordingly, the trial demonstrates that both the mattress covers and the ultrasound wave emitter improve the quality of life for patients with an allergy to dust mites.

**DYSPNOEA****RHINORRHEA****NASAL OBSTRUCTION****DRUGS TAKEN DURING 6 MONTHS**

## A COMPARISON BETWEEN AN ULTRASONIC WAVE EMITTER AND A CHEMICAL ACARICIDE IN IMPLEMENTING ENVIRONMENTAL PROTECTION AGAINST DUST MITES.

G.BRIVIO; M.A BOSCOLO, DEPT. OF ALLERGOLGY, "S.L MANDIC HOSPITAL, MERATE (LECCO), ITALY

### Introduction

In cases of respiratory allergy disorders caused by Dermatophagoides it is important to raise the level of hygiene in the home. The quantity of mites present may be reduced by adopting environmental control arrangements and employing aids to this end.

Of the latter the most commonly used to date are mattress covers and chemical acaricides.

Recently an ultrasonic wave emitter device was made available for sale. A number of trials have demonstrated that the continuous emission of ultrasonic waves can relieve the symptoms of patients who are suffering from mite-related allergy.

### Aim of the Study

The aim of this study was to effect a comparison between a 40,000 Hz ultrasonic wave emitter and a traditional chemical mean of protection, such as benzyl benzoate in powder form in implementing environmental protection against mites.

### Materials and methods

The patients in the study numbered 48, were suffering from allergy to mites, and had symptoms of rhinitis and/or asthma. None of the patients had previously undergone Specific Immunotherapy and nor was any undergoing such treatment at the time. All the patients in the study adopted general, non-specific, measures for environmental protection.

16 patients (control group) relied solely on the normal measures involved in environmental protection.

16 patients used the chemical Acaricide.

16 patients used the ultrasonic wave emitter.

The study lasted 5 months (October-February).

Throughout the entire period of observation the following symptoms were assessed for each patient by means of clinical diary that was written up daily: Dyspnoea, Rhinorrhoea, and Nasal Congestion.

In addition each patient made a daily note of any anti-allergy and/or ant-asthma medication that they used.

In addition, applying the "Acarex test" method, an assessment was made of the environmental concentration of mites at times T0 (October), T1 (December), T2 (February).

The "Acarex test" provides a semi-quantitative determination of guanine in the dust in a given environment. It works through comparison with a colour chart and records the quantity of nitrogenous products excreted by mites.

### Results

Symptomatic Days ( 5 months)			
	Control group	Acaricide	Ultra. Waves
Dyspnoea	370	281	308
Rhinorrhoea	631013	814	825
Nasl Cong	1044	879	904
Drugs ( 5 months)			
	1416	1278	1301

Environmental Concentration of Mites (Acarex Test – Reference colour chart. H:high; L: low)			
	Control group	Acaricide	Ultra. Waves
- T 0	H:86%; L:14%	H:88%; L:12%	H:86%; L:14%
- T 1	H:85%; L:15%	H:62%; L:38%	H:66%; L:34%
- T 2	H:86%; L:14%	H:67%; L:33%	H:64%; L:36%

### Conclusions

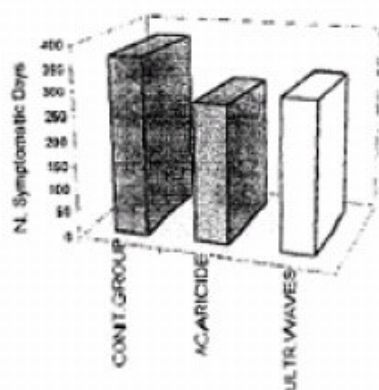
The patients who used either the ultrasonic wave emitter or the chemical acaricide displayed fewer symptoms and resorted less to medication as compared with the control group.

Moreover, the period T0-T2, the concentration of mites in the environment was significantly reduced.

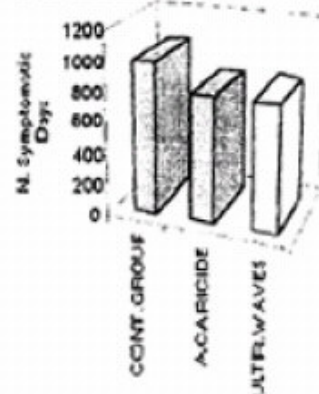
As to comparatively evaluating the use of the ultrasonic wave device and that of the chemical acaricide, no significant differences were noted.



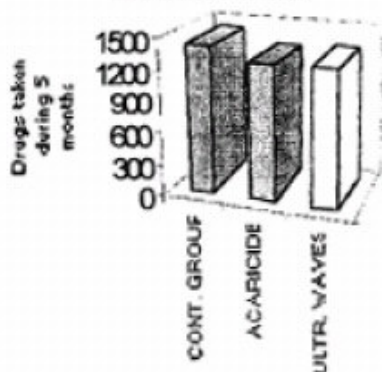
## D Y S P N O E A



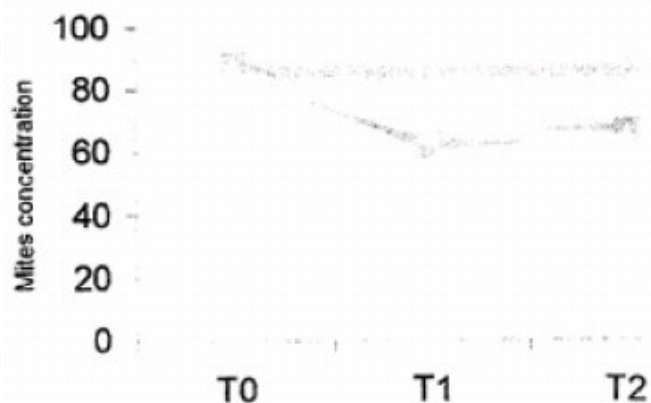
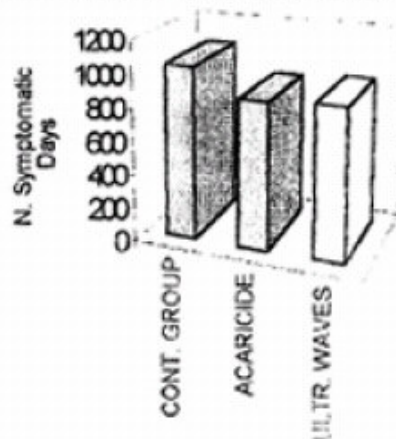
## R H I N O R R H O E A



## D R U G S T A K E N D U R I N G 5 M O N T H S



## N A S A L C O N G E S T I O N



CONTR.  
GROUP  
ACARICIDE  
ULTR. WAVES



## **B. DOUBLE BLIND PLACEBO CONTROLLED TRIAL PERFORMED AT THE PEDIATRICIAN AND ALLERGY DEPARTMENT OF MACEDONIO MELLONI HOSPITAL IN MILAN - ITALY.**

**The study has been presented at the 5<sup>o</sup> Congress of the Italian Society of Pediatric Allergology and Immunology at Riva del Garda – Italy. April 1 – 4 2003.**

Briefly, 40 patients have been enrolled and later split into 2 groups.

40 devices have been distributed to the patients. 20 devices were properly working while the remaining 20, even if identical to the other ones, were not working.

The distribution of patients and devices into the two groups has occurred according to a random scheme, so to design and perform a double blind placebo controlled trial.

The patients (range: 4 to 15.5 years old) were allergic to mites and suffering from asthma. Each patient has received a diary for reporting symptoms and the related data have been analysed from a statistical point of view at the end of the study. The attached original paper lets to see the details concerning the inclusion criteria, the clinical monitoring, the therapies, the results of the study.

Regarding trial's results, it has been observed that at the end of the study (at 4<sup>th</sup> month) the difference in score symptoms between the two groups was in favour of the use of the electronic device. The difference was significant from a statistical point of view concerning rhinorrhea, nocturnal cough, nasal obstruction, sneezes.

Both Italian original paper and the translation into English are here attached.

**5° CONGRESSO NAZIONALE SIAIP**  
Società Italiana di Allergologia  
e Immunologia Pediatrica



RIVA DEL GARDA (TN)  
1-4 APRILE 2003

**Riassunti dei posters**

PERCORSI INTERATTIVI



PER IL PEDIATRA



IN ALLERGOLOGIA

E IMMUNOLOGIA



# CLINIC EFFICACY OF A DEVICE OF ULTRASONIC REVULSION IN THE THERAPY CONNECTED TO CHILDREN WITH PERSISTENT ASTHMA DUE TO ALLERGY TO ACARI

## EFFICACIA CLINICA DI UN DISPOSITIVO DI REVULSIONE ULTRASONICO NELLA TERAPIA DI BAMBINI AFFETTI DA ASMA PERSISTENTE DA ALLERGIA AD ACARI

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### ABSTRACT

**INTRODUCTION.** The house dust mite allergy represents the most frequent cause of first breathing sensitivity in children under 6 years and one of the main reasons till 18 years. In the field of the allergy to dust mites, after the specific immunotherapy (SIT), at the moment the most effective way to prevent and/or lessen the severity of this disease is reducing the house dust mite allergen levels by environmental reclamation. For this reason the application of devices of revulsion based on the use of ultrasounds has been recently proposed, but there are no scientific proves of its efficacy in paediatrics. We intend evaluate its efficacy, in terms of subjective symptomatology, in children with intermittent asthma or mild persistent, allergic to dust mites.

**MATERIALS AND METHODS.** Fourty children (27 M, 13 F, average age 6.5 years, range 4-15.5 years), of our allergologic surgery who corresponded to the criteria of inclusion/exclusion, have become part of a prospective, randomized, double blind study of an expected 6 months lenght, having received undistinguishable devices, working or disactivated. The devices have been supplied by: Kem-o-Tek Italia s.r.l., Caronno Pertusella (MI). Daily clinic diaries, returned at the monthly checks, revealed the number of episodes of dyspnoea, wheezing, nasal obstruction, itchiness, rhinorrea, sneezes, night and exercise-induced cough. Every check included also an examination of the clinical status, compliance to the protocol, the taken therapy, the right filling in of the returned diary, handing over the new diary, efficacy and integrity of the device. The collected data have been submitted to statistic analysis by Student test.

**RESULTS.** The survey has been suspended at the fourth month having reached a significant statistics. All the patients have completed the survey. The first month of the treatment didn't show any significant statistics differences. In the second month significant differences related to 4/8 symptoms (nasal obstruction, sneezes, itchiness and rhinorrea) have been revealed. Only 2 symptoms (nasal obstruction and wheezing) were different between the 2 groups in the third month, while in the fourth all the symptoms except dyspnoea displayed relevant statistics values. The whole evaluation of the 4 months revealed a significant reduction of the subjective symptomatology concerning wheezing, nasal obstruction, sneezes, rhinorrea and night cough. The mirror-like check by counting the days without symptomatology confirmed what had been found.

**CONCLUSIONS.** The results demonstrate the clinical efficacy of this ultrasound device, but we can't tie up the results, even if it can be perceived by intuition, to the reduction of the house dust mite allergen level, as a direct measurement hasn't been conducted. Besides the reduction of the number of mites has been introduced in a previous work by a nother Author'. The most relevant benefits are connected to rhinorrea, nasal obstruction, sneezes, night cough and wheezing, with a lighter effect on the reduction of other symptoms such as itchiness, exercise-induced cough and dyspnoea. The efficacy grows day by day. The results look promising and it would be interesting to extend the evaluation to a wider paediatric population, including the measurement of the dust mite allergen levels. The acceptance of the device by the patients has been good and no collateral effect has been reported.

**Key words:** dust mite, allergy, prevention, childhood, ear, ultrasound, exposure



A comparison between an ultrasonic waver emitter and a chemical acaricide in implementing environmental protection against mites.

The Annual Meeting of the European Academy of Allergology and Clinical Immunology, Berlin 2001; abstract section

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Exposure to house-dust mite allergen (Der p I) and the development of asthma in childhood. A prospective study.

N Engl J Med. 1990 Aug 23;323(8):502-7

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J Allergy Clin Immunol. 1999 Jan;103(1 Pt 1):1-10

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House dust mite allergen in US beds: results from the First National Survey of Lead and Allergens in Housing.

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Relationship of house-dust mite allergen exposure in children's bedrooms in infancy to bronchial hyperresponsiveness and asthma diagnosis by age 6 to 7.

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Asthma in the United States: burden and current theories.

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Influence of allergen avoidance at high altitude on serum markers of eosinophil activation in children with allergic asthma.

Clin Exp Allergy. 1993 Dec;23(12):1021-6

<sup>8</sup> Nelson HS.

The importance of allergens in the development of asthma and the persistence of symptoms.

J Allergy Clin Immunol. 2000 Jun;105(6 Pt 2):S628-32

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The role of house dust mite elimination in the management of childhood asthma: an unresolved issue.

Allergy. 2002;57 Suppl 74:23-31. Review

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Prevention of new sensitizations in asthmatic children monosensitized to house dust mite by specific immunotherapy. A six-year follow-up study.

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Effect of mattress encasings on atopic dermatitis outcome measures in a double-blind, placebo-controlled study: the Dutch mite avoidance study.

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The effect of anti-allergic mattress encasings on house dust mite-induced early- and late-airway reactions in asthmatic patients. A double-blind, placebo-controlled study.

Clin Exp Allergy. 2002 Jan;32(1):117-25

# **Electronic Device against Mite Allergy**

## **Scientific Documentation**

### **EVALUATION OF THE CLINICAL TRIALS Conducted at Merate Hospital**

The obtained results have been first split into the various periods (months) and then considered as a daily basis (data attached).

This approach has permitted a better understanding of the improvement trend for the groups that used the electronic device.

In this way it was also feasible to look at the results from a statistical point of view. The statistical analysis shows that the difference between the group with the electronic device and the control group is statistically significant.

Clinical Study No 1:

## **ULTRASONIC WAVES AS AN ENVIRONMENTAL PROTECTION AGAINST DUST MITES.**

**(European Congress, Bruxelles 1999)**

Source: Brivio Giulio, MD

### **ELECTRONIC DEVICE**

	Days with symptoms (20 patients)	
	1st Month	2nd and 3rd Month
Dyspnoea	21	25
Rhinorrhoea	29	34
Nasl Cong	33	45
<i>Drugs intake</i>	<i>47</i>	<i>61</i>

### **CONTROL**

	Days with symptoms (20 patients)	
	1st Month	2nd and 3rd Month
Dyspnoea	31	48
Rhinorrhoea	35	56
Nasl Cong	39	63
<i>Drugs intake</i>	<i>50</i>	<i>89</i>



**A COMPARISON BETWEEN 2 MEANS OF ENVIRONMENTAL  
PROTECTION AGAINST MITES:  
MATTRESSES COVER VS. ULTRASONIC WAVES EMITTER.  
(European Congress, Lisbon 2000)**

**ELECTRONIC DEVICE**

	Days with symptoms (15 patients)		
	1st Month	2nd and 3rd Month	4th, 5th and 6th Month
Dyspnoea	72	101	121
Rhinorrhoea	268	289	271
Nasl Cong	376	407	249
<i>Drugs intake</i>	402	496	427

**COVER MATTRESS**

	Days with symptoms (15 patients)		
	1st Month	2nd and 3rd Month	4th, 5th and 6th Month
Dyspnoea	56	98	128
Rhinorrhoea	137	322	393
Nasl Cong	178	382	448
<i>Drugs intake</i>	283	426	596

**CONTROL**

	Days with symptoms (15 patients)		
	1st Month	2nd and 3rd Month	4th, 5th and 6th Month
Dyspnoea	73	120	191
Rhinorrhoea	181	341	534
Nasl Cong	198	368	550
<i>Drugs intake</i>	289	447	734

**A COMPARISON BETWEEN ULTRASONIC WAVES EMITTER  
AND A CHEMICAL ACARICIDE IN IMPLEMENTING  
ENVIRONMENTAL PROTECTION AGAINST MITES  
(European Congress, Berlin 2001)**

**ELECTRONIC DEVICE**

Days with symptoms (16 patients)			
	1st Month	2nd and 3rd Month	4th, 5th and 6th Month
Dyspnoea	78	116	114
Rhinorrhoea	209	299	317
Nasl Cong	321	351	232
<i>Drugs intake</i>	<i>386</i>	<i>461</i>	<i>454</i>

**ACARICIDE**

Days with symptoms (16 patients)			
	1st Month	2nd and 3rd Month	4th, 5th and 6th Month
Dyspnoea	56	107	118
Rhinorrhoea	154	301	359
Nasl Cong	160	333	386
<i>Drugs intake</i>	<i>273</i>	<i>497</i>	<i>508</i>

**CONTROL**

Days with symptoms (16 patients)			
	1st Month	2nd and 3rd Month	4th, 5th and 6th Month
Dyspnoea	76	143	151
Rhinorrhoea	199	408	406
Nasl Cong	203	429	412
<i>Drugs intake</i>	<i>270</i>	<i>591</i>	<i>555</i>

## **ANALYSIS OF THE DATA**

In order to better understand the trend and the relevance of the results, the various types of symptoms have been considered as a single kind of symptom.

The data concerning the day with symptoms and the drugs intake have been split into different periods (1st month, 2nd- 3rd month, 4th - 6th month).

Finally, the data have been considered on a daily basis. In other words, the following calculation was done:

daily average 1st month = total days with symptoms 1st month / 30 days;

daily average 2nd and 3rd month = total days with symptoms 2nd -3rd month / 60 days;

and so on (and the same for drugs).

### **CLINICAL STUDY Nth 1**

#### **Symptoms**

Group	Total days with symptoms 1st Month	Daily Average 1st Month	Total days with symptoms, 2nd and 3rd Month	Daily Average 2nd and 3rd Month	Trend
Electronic Device	83	<b>2.7</b>	104	<b>1.7</b>	<b>-37 %</b>
Control	105	<b>3.5</b>	167	<b>2.7</b>	<b>-23 %</b>

#### **Drugs**

Group	Total days with symptoms 1st Month	Daily Average 1st Month	Total days with symptoms, 2nd and 3rd Month	Daily Average 2nd and 3rd Month	Trend
Electronic Device	47	<b>1.5</b>	61	<b>1.0</b>	<b>-34 %</b>
Control	50	<b>1.6</b>	89	<b>1.4</b>	<b>-13 %</b>

### **CLINICAL STUDY Nth2**

#### **Symptoms**

Group	Total days with symptoms 1st Month	Daily Average 1st Month	Total days with symptoms 2nd, 3rd Month	Daily Average 2nd, 3rd Month	Total days with symptoms 4th, 5th, 6th Month	Daily Average 4th, 5th, 6th Month	Trend
Electronic Device	716	<b>23.8</b>	797	<b>13.2</b>	641	<b>7.1</b>	Strong decrease
Cover mattress	371	<b>12.3</b>	802	<b>13.3</b>	969	<b>10.7</b>	Poor decrease
Control	452	<b>15.0</b>	829	<b>13.8</b>	1275	<b>14.1</b>	No change

#### **Drugs**

Group	Total days with symptoms 1st Month	Daily Average 1st Month	Total days with symptoms 2nd, 3rd Month	Daily Average 2nd, 3rd Month	Total days with symptoms 4th, 5th, 6th Month	Daily Average 4th, 5th, 6th Month	Trend
Electronic Device	402	<b>13.4</b>	496	<b>8.2</b>	427	<b>4.7</b>	Strong decrease
Cover mattress	283	<b>9.4</b>	426	<b>7.1</b>	596	<b>6.6</b>	Poor decrease
Control	289	<b>9.6</b>	447	<b>7.4</b>	734	<b>8.1</b>	No change



### CLINICAL STUDY Nth3

#### Symptoms

Group	Total days with symptoms 1st Month	Daily Average 1st Month	Total days with symptoms 2nd, 3 <sup>rd</sup> Month	Daily Average 2nd, 3rd Month	Total days with symptoms 4th & 5th Month	Daily Average 4th and 5th Month	Trend
Electronic Device	608	<b>20.8</b>	766	<b>12.7</b>	663	<b>11</b>	<b>Strong decrease</b>
Acaricide	370	<b>12.3</b>	741	<b>12.3</b>	863	<b>14.3</b>	No change
Control	478	<b>15.9</b>	980	<b>16.3</b>	969	<b>16.1</b>	No change

#### Drugs

Group	Total days with symptoms 1st Month	Daily Average 1st Month	Total days with symptoms 2nd, 3 <sup>rd</sup> Month	Daily Average 2nd, 3rd Month	Total days with symptoms 4th & 5th Month	Daily Average 4th & 5th Month	Trend
Electronic Device	386	<b>12.8</b>	461	<b>7.6</b>	454	<b>7.5</b>	<b>Strong decrease</b>
Acaricide	273	<b>9.1</b>	497	<b>8.2</b>	508	<b>8.4</b>	No change
Control	270	<b>9.0</b>	591	<b>9.8</b>	555	<b>9.2</b>	No change

### BRIEF REMARKS

The first study ends at 3rd month.

#### Result:

The improvement of symptoms and the reduction of drugs intake in the group with the electronic device are better than in the control group.

The second study ends at 6<sup>th</sup> month.

A longer time can probably permit more detailed evaluations.

#### Result:

The group with the electronic Device has shown a consistent improvement, both in symptoms and drugs use, up to reach, in the period 4th-6th month, a very high rate.

No changes in the control group, while the improvement in the group with cover mattress seems less than in the group with the electronic device.

**The data has been analysed from a statistical point of view: the improvement in the group with the electronic device is statistically significant.**

The third study ends at 5th month.

#### Result:

Substantial confirmation of the results of second study.

**The data has been analysed from a statistical point of view: The improvement in the group with the electronic device is statistically significant.**

# **DUST MITE**

## **CONTROLLER**

### **Electronic Device against Mite Allergy**

#### **Scientific Documentation**

### **LABORATORY TEST**

The attached documentation is concerning the tests performed by Prof. L. Suss and Prof. G. Lozzia at the University of Milan – Italy.

The authors have tested the device in laboratory, in order to evaluate the product's ability to denaturate Der p1, the major allergen of *Dermatophagoides pteronyssinus* mite. It is known that *Dermatophagoides* are responsible for allergic disorders such as rhinitis and asthma.

The Investigators have dispensed the media into vials. These have been kept at selected temperature and humidity rates for a 4 month period, under the consistent action of the electronic device.

The test results show an interesting decrease of active allergen presence (20% reduction at 4th month), due to the device's action.

## **Test of the denaturant activity of the allergens of equipments creators of ultrasounds SA05/B, version fed by network, and ZPC02/B, version with battery**

A test, in order to judge the denaturant activity of the allergenic proteins produced by the dust mite *Dermatophagoides pteronyssinus* due to ultrasound creator equipments SA05/B and ZPC02/B, has been carried out.

The action has been carried out by means of a laboratory test on an exhausted ground coming from a farm of *D. pteronyssinus*.

### **Methodology**

The test has been carried out by using the product named SA05/B, a ultrasound creator with emission at 40.000 Hertz with a power of 300mA functioning at 14V tension provided with a transformer and fed by the domestic electric network, to be used in houses. The radiated substratum is made of exhausted substratum coming from a laboratory farm of the house dust mite *Dermatophagoides pteronyssinus* diluted in a ratio 1:19 with inert substances (sterile sand) to stimulate the dust of the houses. Exhausted ground has been used to avoid the presence of food residuals, which could have favoured the colonization of mites or other arthropods. The obtained substratum has been put in test tubes, each containing 250mg, of which 12.5 mg of exhausted ground and 237.5 mg. of sand. 16 test tubes have been positioned in a thermo stated cell at 25 C and 85% of UR, over them at the distance of 30 cm, the equipment has been placed. All this was placed in a cage, which was placed in a tray containing Vaseline to avoid any infestation by arthropods.

SA05/B was connected to the electric network and kept on functioning non-stop for 4 months. The samples for the control of the content of the allergen Der p I have been drawn after 2 weeks, 1, 2 and 4 months from the beginning of the test. Other 4 test tubes have been used as non-treated witness.

The company Alk Abello has carried out the determination of the allergen content.

### **Achieved Results**

The achieved results are stated in the present list:

Denaturant activity of the equipment sa05/b on the allergen Der p I.

Thesis	Repetitions Der p I in $\mu$ /g	Average data	Reduction %
Witness	26.69-62.00-41.60-38.60	42.2225	-
14 days	63.07-78.71-25.53-27.28	48.6475	0.00
1 month	58.93-82.65-11.48-28.12	45.2950	0.00
2 months	6.91-27.21-14.16-18.92	16.8000	60.21
4 months	30.00-37.30-30.39-33.00	32.6950	22.58

### **Conclusions**

The product SA05/B, even if there is a certain data heterogeneity, reveals a certain denaturant activity at the charge of the allergen D er 0 1 of *Dermatophagoides pteronyssinus*, which starts to be evident after about 2 months from the beginning of the test and it allows a reduction of about 20% after 4 months.

- Cod. SA05/ equal to our portable electronic device against mites.
- Cod. ZPC02/B equal to our fixed electronic device against mites.