



Statistical Assessment of an Application Observation

with

BIOSUN Earcandles

in typical areas of application
Colds - Secondary Effects of Colds, Headaches,
Earaches, Ear noises and Stress

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1. Introduction

In 11 test centres 78 patients were hospitalised with colds, ear noises, headaches, secondary effects of colds, earaches and stress symptoms in an application observation with BIOSUN ear candles between February and June 2000.

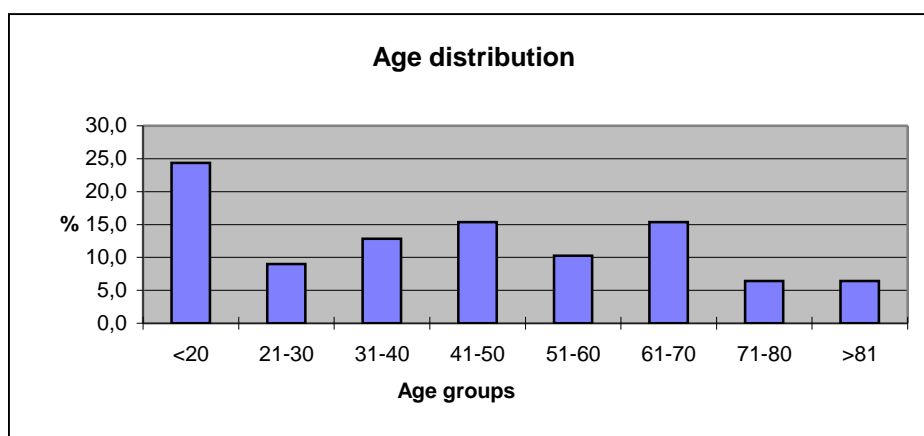
The aim of this investigation was to update and complete through further empirical reports the level of knowledge in the application of the medical product BIOSUN ear candles in the typical application areas of colds and its secondary effects, headaches, earache, ear noises, and stress symptoms. In addition knowledge was to be gained of the acceptance of the product under everyday practice conditions.

The accumulated knowledge gained in the context of this therapeutic application was recorded by the investigators and entered in a report sheet.

In accordance with the terms of the investigation, only descriptive statistical procedures were used by way of comparison. The application of inductive methods was not indicated. An "Intention to Treat" evaluation was carried out, which means that all patients were considered on whom at least one ear candle was applied.

2. Patients who took part

Those who took part in the study numbered 78 patients, of whom 30 were men (38.5%) and 48 were women (61.5%), who suffered from colds, ear noises, headaches, secondary effects of colds, earaches and stress symptoms.



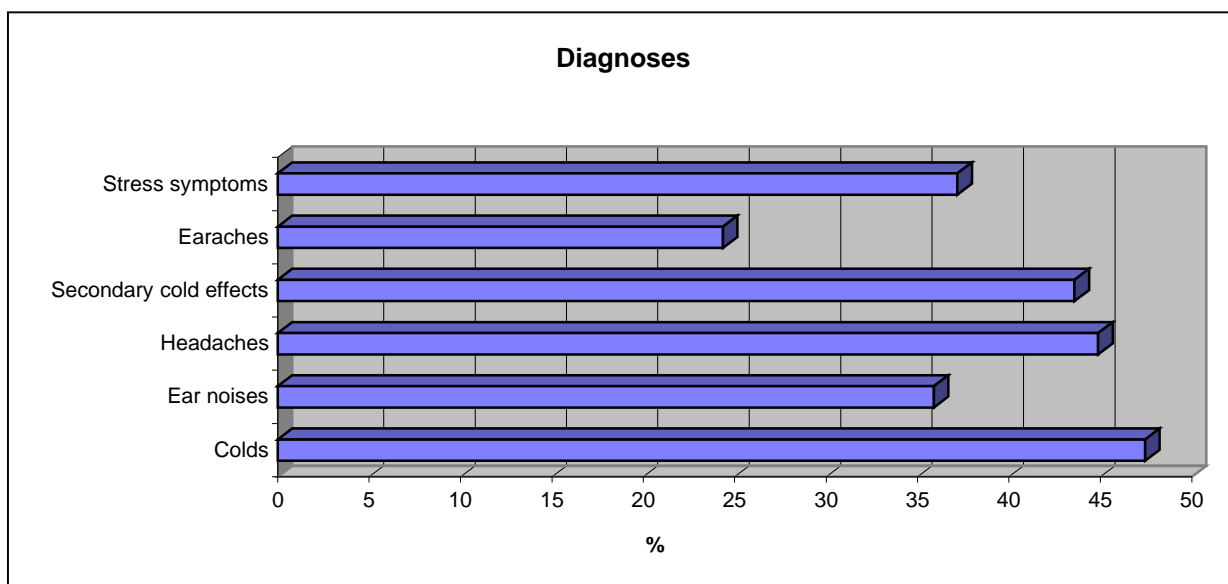
The age of the patients varied between 3 and 91 with an average of 43 years and a standard deviation of 23.6 years. 19 patients (24.4%) were under 20 years

of age, 7 patients (9%) were between 21 and 30 years, and 10 patients (12.8%) were between 31 and 40 years of age. The second largest groups were those between 41 and 50

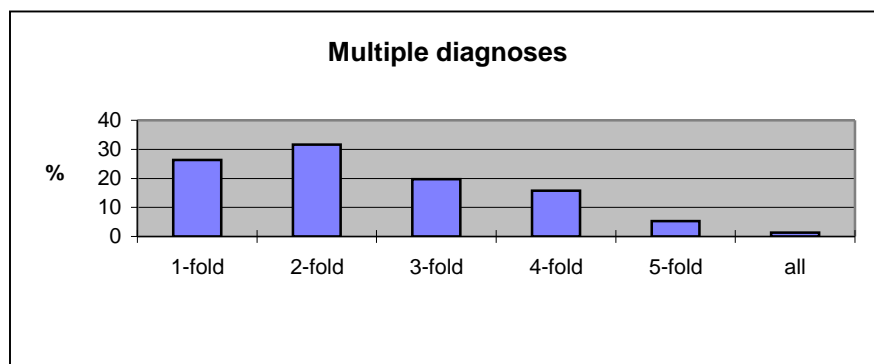
years and 50 to 70 years, with 12 patients in each group (15.4%). There were 8 patients between 51 and 60 years. There were also 5 patients apiece (6.4%) between 71 and 80 years and over 81 years. The men with an average age of 35 years (22.5) were 13 years younger than the women with 48 years (22.6).

2.1 Diagnoses and Accompanying Illnesses

According to the study memorandum the main prescriptive diagnoses were 37 patients who were recorded as having colds, 28 as having ear noises, 35 as having headaches, 34 as having secondary effects of colds, 19 as having earache and 29 patients suffering stress symptoms. Multiple ailments were possible.



A single diagnosis was made in the case of 20 patients, two diagnoses in the case of 24 patients. Triple diagnoses were made in the case of 15 patients and four diagnoses in the case of 12 patients. 4 patients were diagnosed with five ailments and 1 patient suffered from all of them.



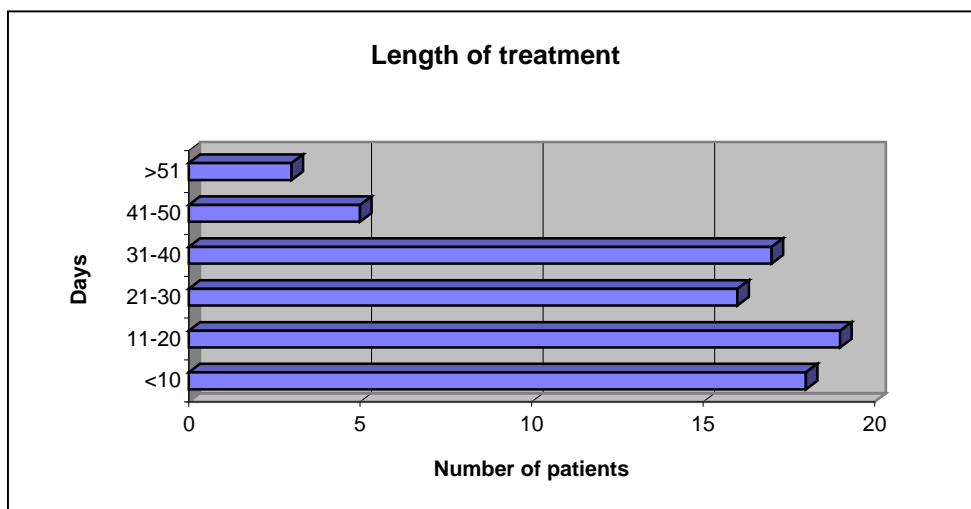
Patients were excluded from treatment who had a perforated ear drum and implanted tympanic cavity wash tubes, ear infections (such as otitis media acuta and otitis externa), high temperature $> 38^{\circ}\text{C}$, mastoiditis, ear skin diseases as well as in the auditory canal (such as eczema and fungus infections).

The previous long-term medication for existing illnesses was to be continued. The use was documented with the names of drugs and a more precise dosage. As far as the area of the ear candle application was concerned, no further medicinal treatment took place.

3. Dosage and Length of Treatment

3.1 Time of Consultation, Length of Treatment

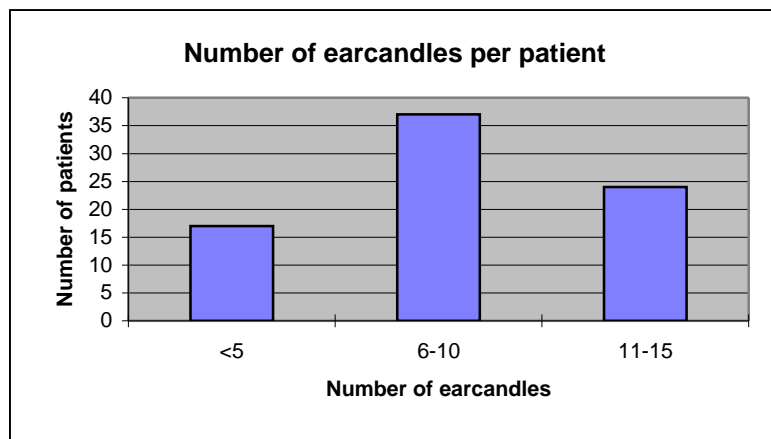
In accordance with the essence of an application observation no fixed time schedule was given to the investigator for the start or finish of the investigation. The length of time for treatment and for observation was determined by the individual symptoms of the patient. It was of an average of 23.3 days, 14.6 days at a minimum length of 1 day, and a maximum length of 75 days' treatment. The patient groups were almost equally divided into treatment lengths of 40 days. 5 patients needed between 41 and 50 days, and 3 patients over 51 days to 75 days.



3.2 Dosage

1 application daily was recommended as normal dosage for acute illnesses. In such cases of acute illnesses the first control examination was already undertaken after 3 application days, and the final examination after 7 days, and up to a maximum of 10 application days. In the case of chronic illnesses a longer investigative time was naturally indicated. The usual dosage was recommended in such a case with 1 application three times a week over a period of 4 weeks. The first control examination was to take place after 6 days of treatment,

and the final examination after 12 days of treatment. In fact the average application frequency was 9.1 3.3 ear candles per patient. In the case of one patient only 1 ear candle was used, and yet in the case of 3 patients 15 ear candles were used.



4. Efficacy

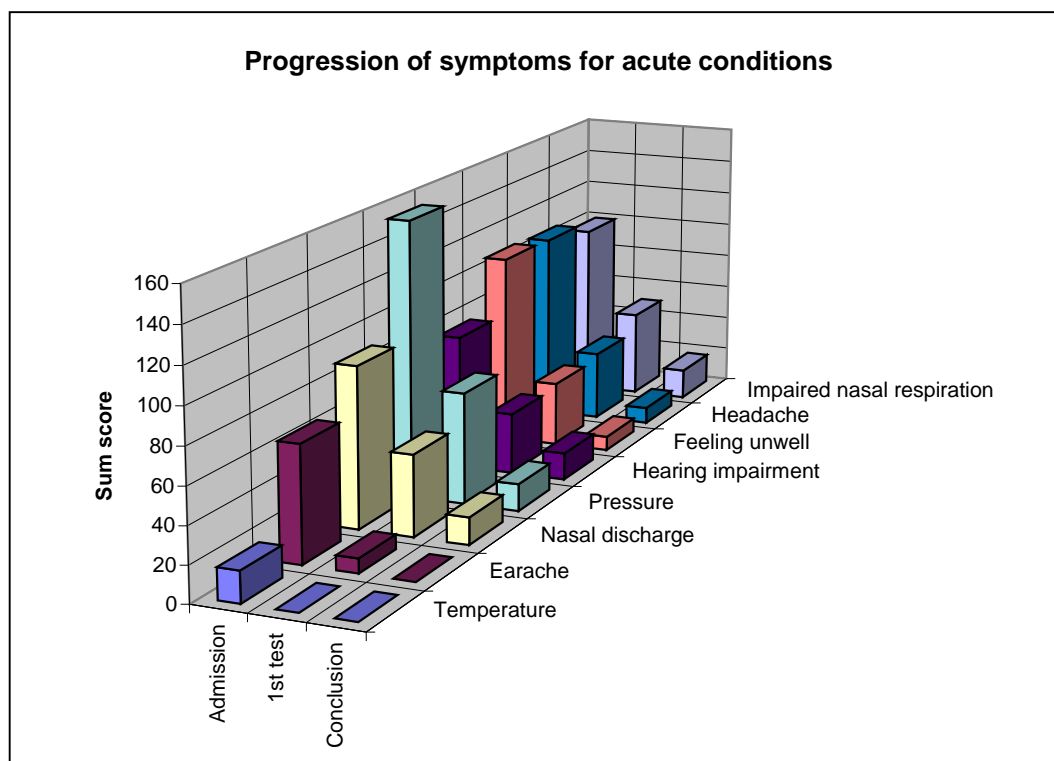
Before the treatment started, and at both the subsequent consultations, the patient was asked about acute symptoms of “transferred nasal respiration” (respiratory obstruction), “nasal discharge”, “pressure in the head or ears”, “hearing disability”, “temperature”, “feeling of illness”, “headaches” and “earache”. Within the chronic symptoms questions were put relating to “noises in the ear” and stress symptoms, such as “tension”, “insomnia”, “intellectual impairment” and “feelings of anxiety”. The designated degrees of intensity were “none”, “slight”, “moderate”, “severe”. In addition a spontaneous reaction could be described in freely after each ear candle application.

In the case of 75 of the 78 patients involved in the study, spontaneous reactions were described immediately after the application of the ear candle. One patient mentioned an ear allergy, and the ear candle application was suspended after the first application in the case of a female patient because the treatment was “unpleasant” for her. Another patient mentioned only “a slight improvement”. The remaining 75 patients described the application in terms of a positive, therapeutically spontaneous reaction, such as “relaxing”, “a feeling of warmth”, “disappearance of pressure”, “freedom from pain” and a short-term increase in nasal discharge.

The intensity of the complaint was expressed as a sum score at the start of the treatment, as well as at both the subsequent consultations.

	Admission	1 st test	Conclusion
Temperature	17	0	0
Impaired respiration	99	49	17
Nasal discharge	89	45	15
Pressure	154	62	15
Hearing impairment	75	34	15
Feeling unwell	107	36	8
Headache	106	39	9
Earache	64	8	0

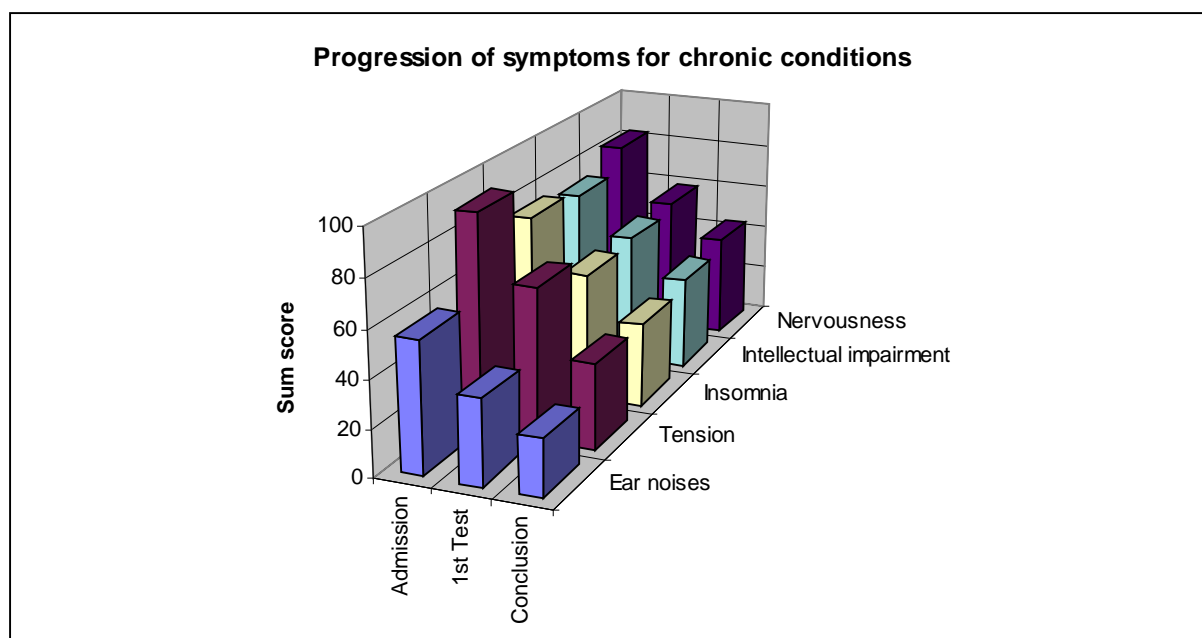
Table : Sum scores of the acute complaints



The sum score course shows a very differentiated picture of the acute conditions in the progress of the symptoms. Over the course of the treatment the sum score declines continually at all questions relating to particular complaints, from the first control test right up to the final test, which indicates a lessening of the symptoms.

	Admission	1st test	Conclusion
Ear noises	56	36	24
Tension	92	64	36
Insomnia	76	54	36
Intellectual impairment	73	56	40
Nervousness	83	59	44

Table 2: Sum score of the chronic symptoms



The course of the sum scores of chronic symptoms is not as intense as the acute conditions. Although the score sums on admission remain throughout at a lower level than at acute conditions, the lessening of the score sums under treatment is considerably shallower than with these chronic conditions. At the end of the treatment the sum score remains at a relatively high level.

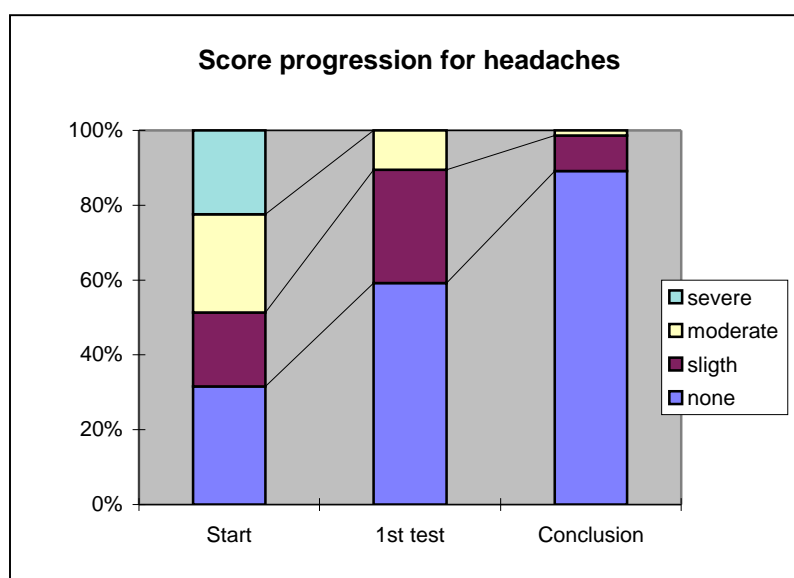
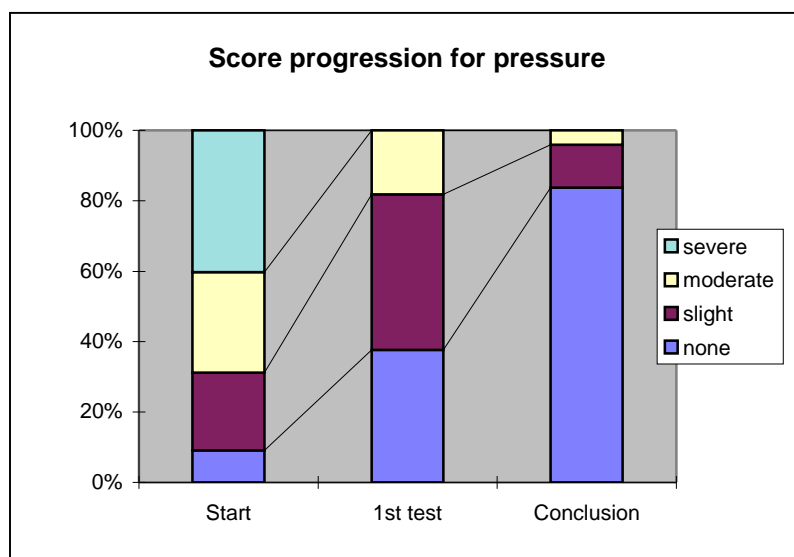
The sum score medium can only give a general picture of the course of a symptom. To bring about a differentiated point of view the intensity of the individual symptoms was compared with three observation times in Table 3. In this way the percentage of patients was recorded whose intensity was described as “none or not present”, “slight”, “medium” and “severe”. The degree of intensity for each symptom can thereby be described at each particular time of observation.

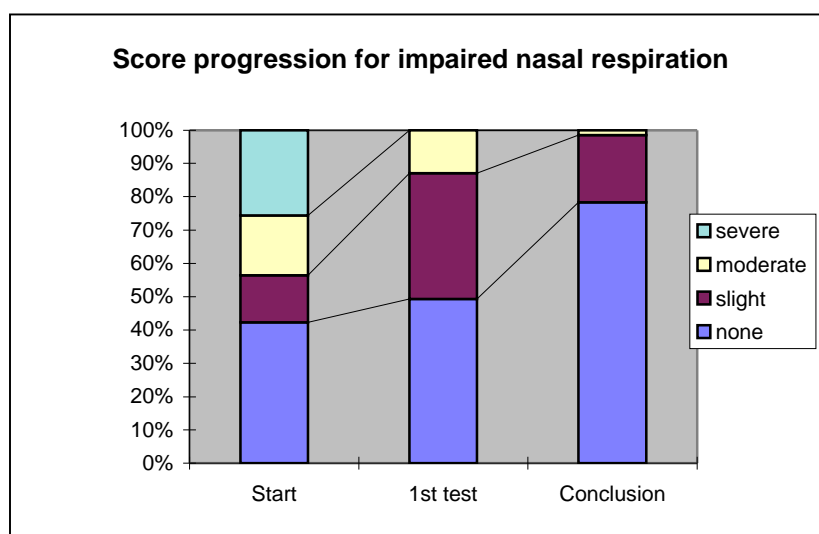
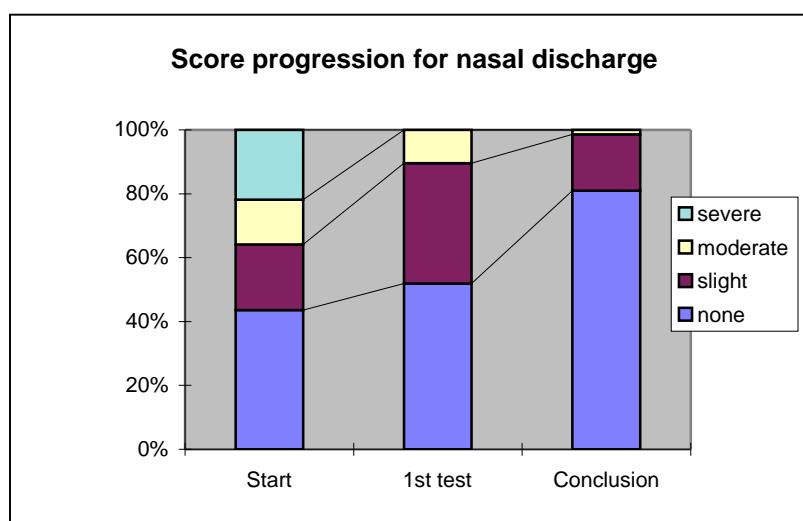
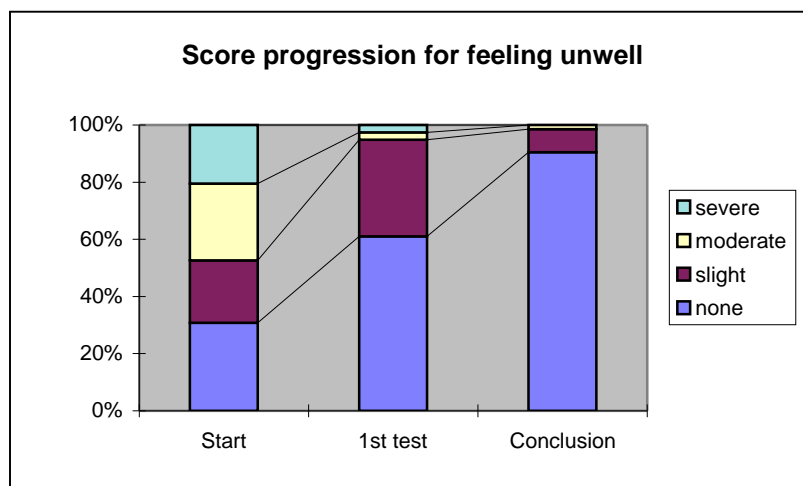
4.1 Acute Conditions

	Percentage Symptom Intensity			
Impaired Nasal Respir.	none	slight	moderate	severe
Start	42,3	14,1	17,9	25,6
1 st test	49,4	37,7	13,0	0
Conclusion	78,4	20,3	1,4	0
Nasal discharge				
Start	43,6	20,5	14,1	21,8
1 st test	51,9	37,7	10,4	0
Conclusion	81,1	17,6	1,4	0
Pressure				
Start	9,1	22,1	28,6	40,3
1 st test	37,7	44,2	18,2	0
Conclusion	83,8	12,2	4,1	0
Hearing Impairment				
Start	50,0	20,5	12,8	16,7
1 st test	70,1	19,5	6,5	3,9
Conclusion	89,0	4,1	4,1	2,7
Temperature				
Start	82,1	14,1	3,8	0
1 st test	100,0	0	0	0
Conclusion	100,0	0	0	0
Feeling unwell				
Start	30,8	21,8	26,9	20,5
1 st test	61,0	33,8	2,6	2,6
Conclusion	90,5	8,1	1,4	0
Headache				
Start	31,6	19,7	26,3	22,4
1 st test	59,2	30,3	10,5	0
Conclusion	89,2	9,5	1,4	0
Earache				
Start	63,6	6,5	13,0	16,9
1 st test	89,6	10,4	0	0
Conclusion	100,0	0	0	0

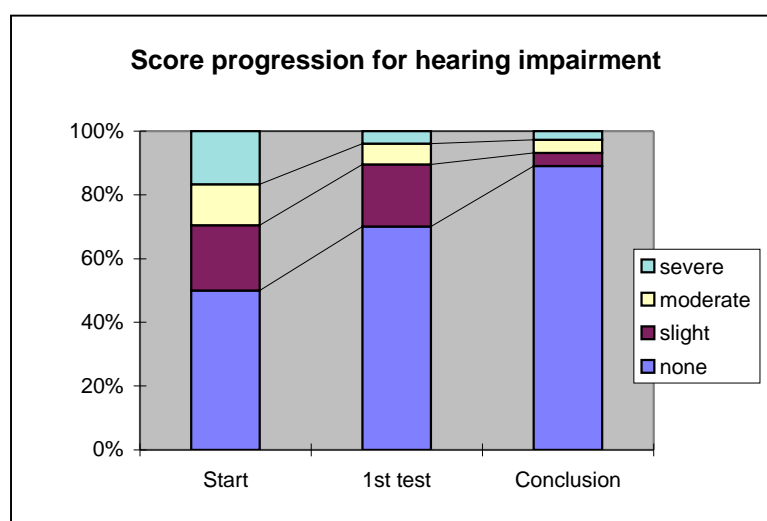
Table 3: Degree of intensity of the acute symptoms in percentages at the time of each observation.

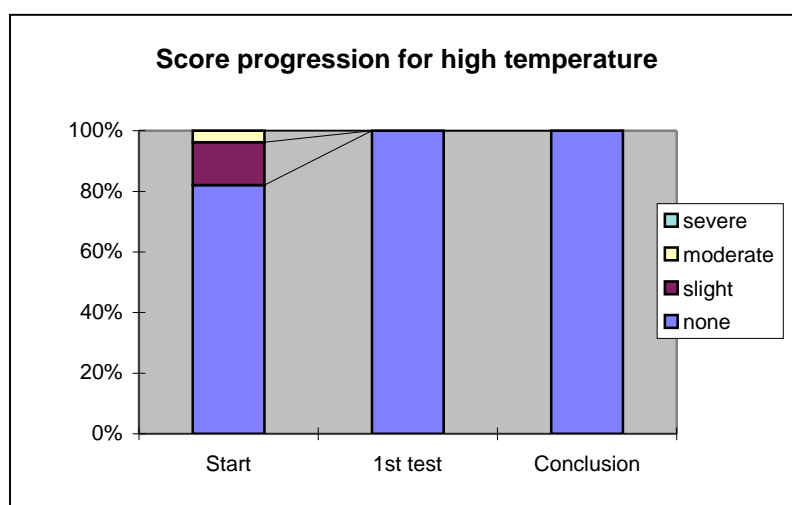
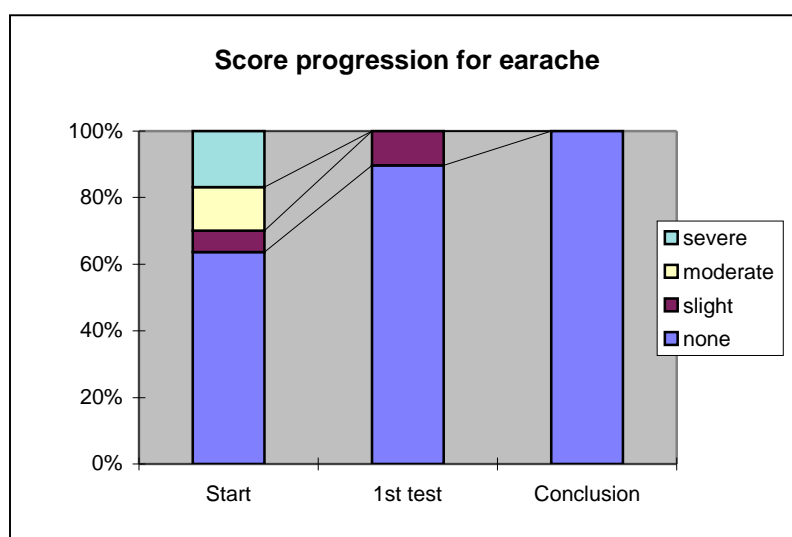
The individual symptom intensities can be divided into two groups. In one group, consisting of symptoms of “pressure, “headache”, “feeling unwell”, “nasal discharge” and “impaired breathing”, there was at the beginning of the treatment more than a 20% “severe” impairment noticeable as the highest score value. Up to the first control test the intensity of the symptom shifts from “severe” to “moderate”, and especially to “slight”, while the increase in the area of “no complaints” turns out very moderately at this time of observation. Only at the final test, where in no case were there more severe complaints mentioned, the percentage share of expressions of “moderate” and “slight” shifted in particular towards “no complaints”.





In a second group consisting of symptoms of “hearing impairment”, “earache” and “high temperature” this development is not so clearly pronounced. Already at the start of treatment nearly 50% of cases expressed “no complaints”. As the intensity of the symptoms was not especially characteristic, over 70% of the cases could be indicated as experiencing “no complaints” already after the first test. A genuine shift of percentage expressions from “severe” through the intermediate stages to “no complaints” did not take place in this symptom group, with the exception of “hearing impairment”. In contrast to all other symptoms there was still a severe hearing impairment in 2.7% cases at the final test as well. The symptom intensities of “severe”, “moderate” and “slight” in fact declined continuously during the course of the three consultations, but still persisted in the final test.





The acute conditions can be summarised by the effect of the symptoms of “pressure”, “headache”, “feeling unwell”, “nasal discharge” and impaired breathing” as being clearly indicated. However, a spontaneous progression cannot be established. There is continuous improvement via the symptom intensities of “moderate” and “slight” right up to freedom from complaint.

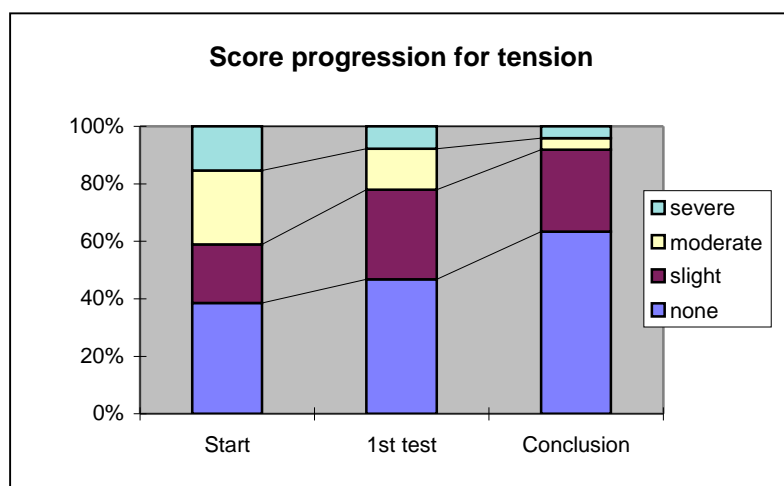
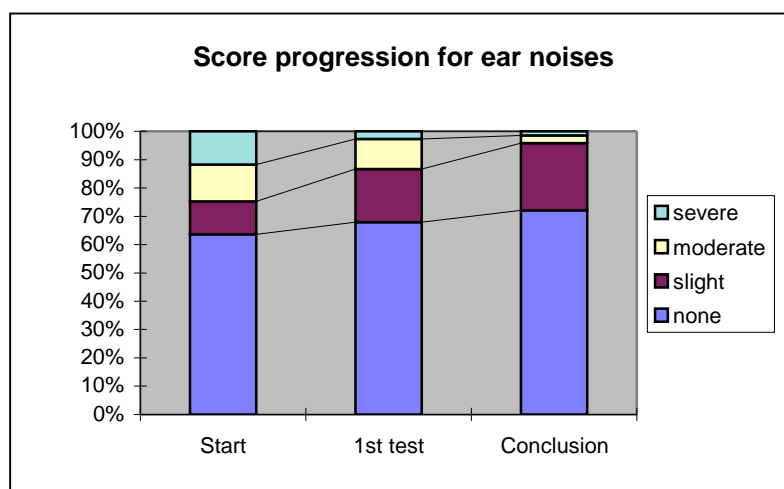
4.2 Chronic Conditions

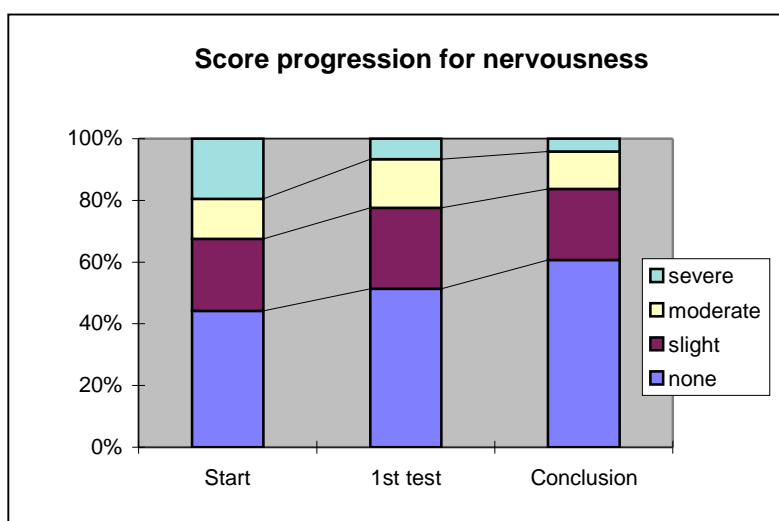
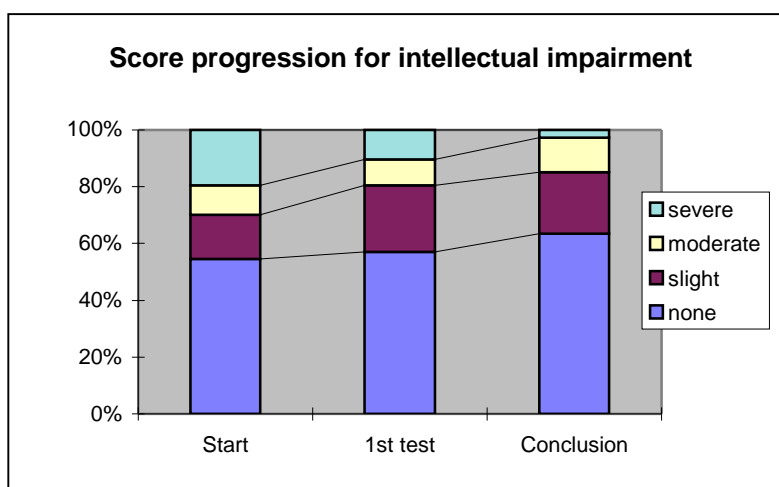
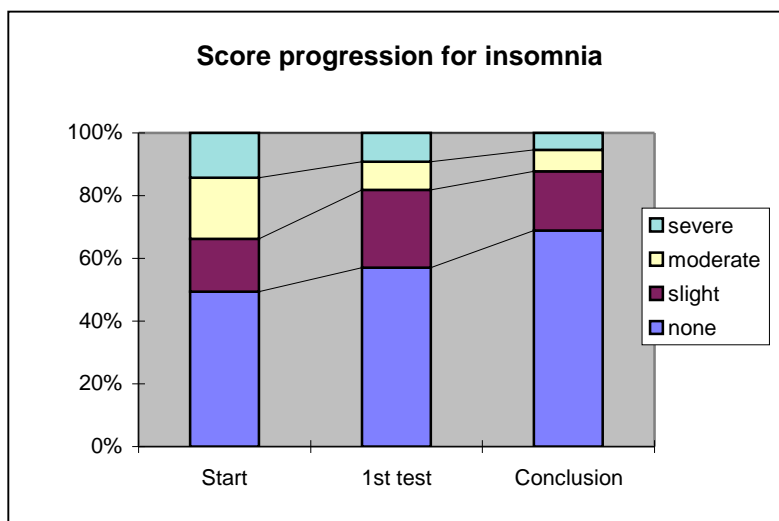
In assessing the sum scores, the symptom improvement curve already showed a considerably shallower course than in the acute conditions. Even on completion of the final test there still remained 1% to 5% of cases of a “severe” nomination.

	Symptom intensity in percent			
Ear noises	none	slight	moderate	severe
Start	63,6	11,7	13,0	11,7
1 st test	68,0	18,7	10,7	2,7
Conclusion	72,2	23,6	2,8	1,4
Tension				
Start	38,5	20,5	25,6	15,4
1 st test	46,8	31,2	14,3	7,8
Conclusion	63,5	28,4	4,1	4,1
Insomnia				
Start	49,4	16,9	19,5	14,3
1 st test	57,1	24,7	9,1	9,1
Conclusion	68,9	18,9	6,8	5,4
Intellectual impairment				
Start	54,5	15,6	10,4	19,5
1 st test	57,1	23,4	9,1	10,4
Conclusion	63,5	21,6	12,2	2,7
Nervousness				
Start	44,2	23,4	13,0	19,5
1 st test	51,3	26,3	15,8	6,6
Conclusion	60,8	23,0	12,2	4,1

Table 4: Degree of intensity of chronic symptoms in percentage at particular observation times.

Only in the “tension” symptom, which, when the patient was asked, included “a feeling of tension, trembling, restlessness, exhaustion and nervousness” could a marked increase in freedom of complaint be achieved from 38.5% at the start to 63.5% at the end. The score progression shows a similar picture to the one in acute conditions through the different stages of “severe” to “no complaints”. In the remaining symptoms there are shifts in degree of intensity from “severe” to “moderate” and “slight”. The percentage increase of the characteristic “no complaints” is, however, not so pronounced as in the treatment of acute conditions. As, on the other hand, symptom progression in the form of relative improvement of complaints could be established, the question that is asked is whether a longer treatment and/or observation time could be striven for in future tests in the area of chronic complaints.

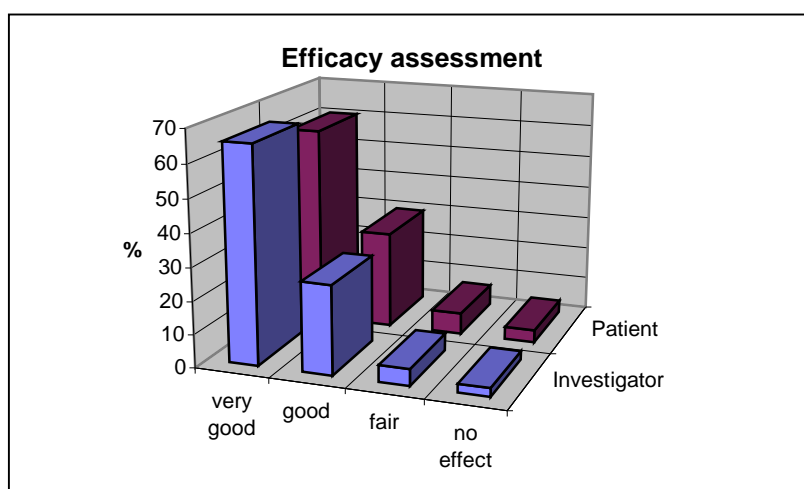




4.3 Efficacy Assessment

In a concluding assessment both patients and investigators were asked to evaluate the efficacy with “very good”, “good”, “fair” or “no effect”. In the overall efficacy assessment 93.3% of investigators and 89.7% of patients expressed the outcome as “very good” and “good”. 2.6% of investigators and 3.8% of patients attributed no effect to the treatment.

	Efficacy assessment			
	Very good	good	fair	no effect
Investigator	65,4%	26,9%	5,1%	2,6%
Patient	60,2%	29,5%	6,5%	3,8%



5. Tolerance

The survey questionnaire asked about possible side effects and incompatibilities, as well as discontinued treatment. In all there were four non-desirable effects. In the case of a 14 year-old female patient an allergic reaction in the ear manifested itself after the 9th day of treatment, which improved after local ointment treatment. After an interval of 11 days the therapy was continued with two days of treatment. A 41 year old patient complained on the 2nd day of treatment of an irritation in the ear. He was treated locally with homeopathic ear drops. The therapy was continued without pause for a further ten days of treatment. The same picture appeared in the case of a 91 year-old female patient who also complained of an ear irritation on the 2nd day of treatment and was treated locally with homeopathic ear drops. The therapy was also continued in this case over a further 7 days of non-stop treatment. A 31 year-old female patient complained of irritation of the ears on the 1st, 4th and 10th days of treatment. Local homeopathic ear drops were given. The three latter cases of

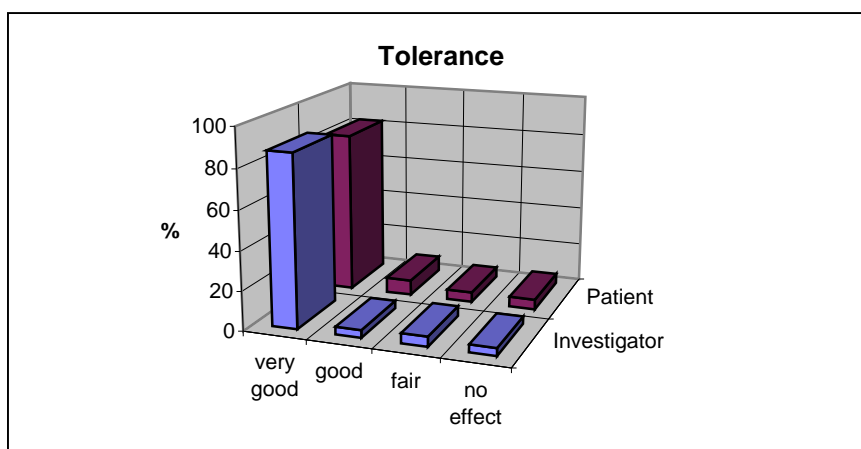
ear irritation were all assigned to an investigator. No serious life-threatening incidents were observed.

In all there were 5 cases of discontinued treatments recorded. In two cases the patient was free of complaints after 5 or 6 days of treatment, so that they did not reappear for final treatment. In one case the therapy was discontinued after 4 treatment days because of antibiotic tonsillitis treatment. 1 patient discontinued treatment after 4 treatment days because of deteriorating headaches and severely restricted nasal respiration. 1 female patient discontinued the treatment after the first application because she found the treatment unpleasant.

5.1 Assessment of Tolerance

At the end of the investigation a tolerance assessment was made by investigators and patients whereby a selective evaluation could be made between “very good”, “good”, “fair” and “bad”. In the overall tolerance assessment 91.1% of investigators and 89.8% of patients expressed themselves with “very good” and “good”. 3.9% of investigators and 5.1% of patients adjudged the tolerance as “bad”.

	Tolerance assessment			
	very good	good	fair	no effect
Investigator	87,2%	3,9%	5,1%	3,9%
Patient	82,1%	7,7%	5,1%	5,1%



6. Summary

In 11 test centres between February 2000 and June 2000 a total of 78 patients (30 men and 48 women), suffering from colds, noises in the ear, headaches, secondary effects of colds, earache and stress symptoms, were hospitalised for an observation application with BIOSUN ear candles. The age of the patients varied between 3 and 91 years with an average of 43 ± 23.6 years.

According to the study memorandum the main prescriptive diagnoses were for 37 patients who were recorded as having colds, 28 as having ear noises, 35 as having headaches, 34 as having secondary effects of colds, 19 as having earache and 29 patients as having stress symptoms. Multiple ailments were possible.

The length of treatment averaged 23.3 days ± 14.6 days with a minimum length of 1 day and a maximum therapy period of 75 days. The average application frequency was 9.1 ± 3.3 ear candles per patient. With a single patient only 1 ear candle was applied and with 3 patients 15 ear candles were used.

Before the treatment started, and at both the subsequent consultations, the patient was asked about acute symptoms of “transferred nasal respiration” (respiratory obstruction), “nasal discharge”, “pressure in the head or ears”, “hearing disability”, “high temperature”, “a feeling of illness”, “headaches” and “earache”. Within the chronic symptoms questions were put relating to “noises in the ear” and stress symptoms, such as “tension”, “insomnia”, “intellectual impairment” and “feelings of anxiety”. The designated degrees of intensity were “none”, “slight”, “moderate”, “severe”.

With all the symptoms about which questions were asked, the sum score continuously declined during the course of the treatment from the time of the 1st test to the final test, which indicates a lessening of the symptoms. In the individual intensity symptoms there are varying differences in the course of the therapy. Acute complaint conditions become continuously less severe to the point of no complaints. Chronic conditions become milder in their individual intensity.

In the overall efficacy assessment 93.3% of investigators and 89.7% of patients gave a verdict of “very good” and “good”. “No effect” was the verdict of 2.6% of investigators and 3.8% of patients. In the matter of tolerance assessment 91.1% of investigators and 89.8% of patients adjudged it “very good” and “good”. 3.9% of investigators and 5.1% of patients judged the tolerance to be “bad”.

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