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Comprehensive Laser Rehabilitation Therapy of Tinnitus: Long-Term Double Blind Study in a Group of 200 Patients in 3 Years

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Abstract

Definition of tinnitus records that it is an auditory perception for which there is no objective sonic source from the outer environment. Our original study, published in Laser Partner Clinixperience No. 4/2000, has been regarded as a classical tinnitus work. It unambiguously confirmed clinical experience of our predecessors, presented with a high amount of personal enthusiasm (Shiomi, Wilden) but, unfortunately, not much based on statistics. However, recently our study has gained corroboration by originally slightly sceptical medical authorities obtaining statistically almost identical results. Our study has been published more than two years ago. With the time passing by we have been under the impression that the results might be even better than those obtained during several-months therapy in the original cohort of patients. This impression led to a decission that a new comparison with a larger group of patients, than the original forty in our basic study, and followed in a longer time horizon, might be of a certain interest. We were wondering whether our clinical observations, confirmed by personal experience of other clinics, would also find an adequate correlate in statistical expression.
A model protocol as well as instruction photographs are attached to the paper.

Introduction

For our New Study the patients registered in our clinic due to tinnitus for more than three years were chosen. With regard to maximum objectiveness, the patients who had finished attendance due to unknown reasons were included in the "no-effect" group, although we are well aware that a part of them finished the treatment because of various other reasons (such as time cunsuming engagements, problematic transport, family reasons). In a small group of 5 patients we tried to check the objective reasons by a phone query, and indeed, 2 patients gave other reasons whilst 3 patients had finished attendance due to unsatisfactory or no result of procedures. Even though it is interesting for us to have another little group of 6 patients visiting our clinic for check ups and for a series of therapies despite (after a year and more) zero effect of procedures. In a part of this group (in 3 patients) a certain subjective improvement (up to less than 50 per cent relief) can be noticed after a long attendance (2 - 3 years). There is certainly a point at issue, to what an extent this subjective improvement can be regarded as an objective one, whether these patients have not settled down to their complaint... It is a problem of little numbers, definitely not having any influence over the total figure, however, from a clinical point of view we consider this observation interesting... It should be also mentioned that, in general, compliance of patients suffering from tinnitus is excellent, which may be caused by the level of their subjective tribulations leading to a craving to get rid of it.

Materials and Methods

We have evaluated in total 200 patients visiting our clinic since 1997 till now for tinnitus, followed till 2001, i.e. at least for 3 years. With our approval 8 patients, who were totally free of tinnitus after a short period of treatment, were crossed off and finished attendance earlier. In this respect we have an odd case history of a female patient, who was relieved of her several years lasting lateralized tinnitus after a single mobilization of distal C vertebra (note that entire 8.8 per cent of patients in our original study were relieved of tinnitus only by mere physiotherapy procedures aimed at axial skeleton - there really exists an often disputed diagnosis of vertebrally conditioned tinnitus).
As it can be seen above, patients, who finished the therapy due to reasons unknown, have been incorporated in the group "therapy with no effect".
Evaluated group of patients was chosen at random from the whole number of our patients with tinnitus, the main condition being particularly regular attendance during the period of the last three and more years. In all the patients a subjective tinnitus had been diagnosed, i.e. an organic cause of this condition could not be straightly determined by examinations (meaning that especially patients with dg. neurinomus statoacusticus or another organic cause, such as a tumor or a head injury with a positive finding by NMR, CT or EEG, were excluded). In this respect we are well aware that some dubitation could be seen in possible atherosclerotic changes of veins, especially of carotid veins and a. vertebrales, which might also be regarded as an organic cause of tinnitus. However, with almost a hundred-per-cent level of incidence in population of higher age categories it is rather difficult to call these changes a pathology.

Table 1 - Age groups of followed patients

Age	0 - 15	15 - 25	25 - 35	35 - 45	45 - 55	55 - 65	65 - 75	75 +	Total
Male	2	3	9	11	23	28	32	4	112
Female	0	4	7	16	19	25	16	1	88
Total	2	7	16	27	42	53	48	5	200

Our group (New Group) of patients consisted of 112 males and 88 females (in comparison with our previous study there was an interesting shift towards higher share of males, according to our opinion this more corresponds with the level of distribution of tinnitus within population in relation to work anamnesis and hobbies).
Average age was 64 years, ranging within the limits of 15 and 98 years. This meant a shift towards higer categories of age, probably corresponding with the incidence of tinnitus within the population, and maybe also due to the fact that our activities have been covered by media, mainly by those focussed on seniors, and thus new patients could have appeared on the basis of media influence.
Level of subjective complaints was evaluated according to, nowadays almost classical, three scales:

1. Percentage scale (complaints evaluated 100 per cent at the beginning of therapy, according to the level of relief decreased to 80, 70 per cen, possible acceleration of problems goes up to 110, 120 per cent, no tinnitus equals 0 per cent),
2. Five-grade scale - analogous to pain scales (I = no tinnitus, V = tinnitus limiting all activities, II, III and IV = clearly defined complaints)
3. Graphic scale (patient marking 0 to 10, accompanied by a simple graphics showing face grimaces according to his/her amount of subjective hardship).

This combination has proven more than suitable for evaluating such a subjective suffering as tinnitus. Particularly nowadays, when most clinical studies are aimed at evaluation of "quality of life" of individual patients, this combination appears a good criterion to measure such a most valuable state. Above mentioned combination can also make a serious processing possible, with regard to different social, economic, expressive, cultural and intelectual qualities of individual patients.
In order to simplify the effect of therapy as much as possible the results were divided in four groups:

1. Patients with no effect of comprehensive therapy (or even with aggravated condition, however we can say that no patient has reported a setback of tinnitus after the therapy)
2. Less than 50 per cent relief as far as subjective evaluation of the patient is concerned
3. More than 50 per cent relief as far as subjective evaluation of the patient is concerned
4. No more tinnitus, patient free of the disease.

This evaluation is identical with our previous study, and it enabled us to compare easily the results of both studies.

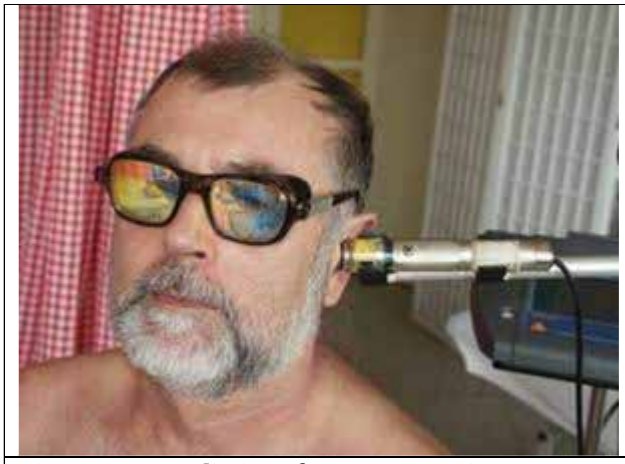
Therapy

LLLT - Physiotherapy aimed at the initial organ of hearing:

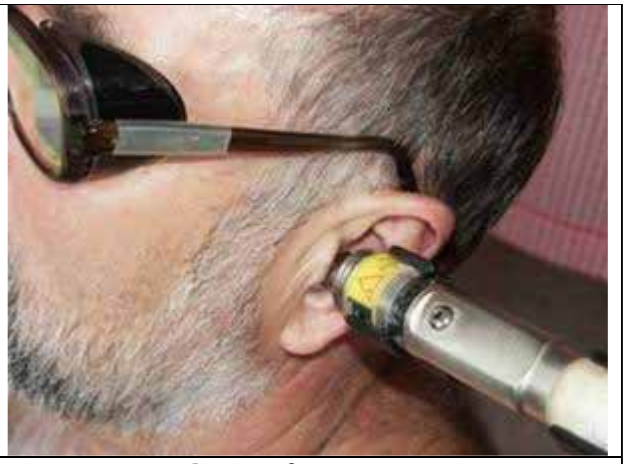
There is no need to discuss necessary parameters of laser probes used. We need an infrared laser beam with a sufficient power output (we have been using an IR 300 mW laser probe, we also tried using a 450 mW probe but a part of our patients reported a subjectively unpleasant thermic effect in the area of application). On the other hand, we pay maximum attention to irradiation of a sufficient dosage of energy.
In our clinic we use the following techniques of LLLT application:

1. application on meatus acusticus externus - in the direction of the axis of the auditory duct - continuous beam 50 J/cm^2 followed by 25 J/cm^2, frequency modulation of 5 Hz,
2. irradiation of processus mastoideus - directed on the center, the vector of the beam in the direction of counter-lateral orbit, continuous beam 90 J/cm^2 , followed by 45 J/cm^2 with 5 Hz pulse frequency.

Modulation of 5 Hz we use due to assumed potenciation of stimulative effect of non-invasive laser.
We strictly appeal to maintain the direction of the vector of aiming the beam - in fact the target structure of the helix is a shape of several square milimeters. It might be the reason why, when compared with other laser devices with the same output parameters, therapy with Maestro/CCM probes has proved rather successful due to their characteristic diffusion of the emitted beam, increasing probability of hitting desired target structures (difference of prognostic level of success between hitting the target with a shotgun or with a rifle - thanks to ass. prof. Horak for his witty comparison). LLLT has been applied on 100 per cent of our patients.
Attendance was scheduled so that the first series of 8 - 10 procedures in total, twice a week, be a complex consisting of medication, rehabilitation therapy of axial skeleton, and LLLT. In the interval of 2 - 3 months further courses of therapy follow, usually consisting of 5 - 6 therapies, once a week, always as a series of LLLT procedures. Therapy of axial skeleton is added when necessary (often not necessary in case of regularly exercising patients, instructed properly in the course of the first series). Medication with Egb 761 continuing in the long term, most of the patients after several months of therapy with a reduced dosage 1 - 0 - 1 tablets, in the order of at least several more months. A part of the patients in the cycle between procedures has noticed a possibility to titrate medication according to immediate subjective complaints - it means they keep to regular dosage 1 - 0 - 0, when tinnitus accelerates switching to 1 - 1 - 0, or even to 1 - 1 - 1 tablets. Possible episodes of accelerated tinnitus usually abate quickly then. In case of long term stabilized patients we plan clinical check ups at least twice a year, always connected with mobilisation of acute blockades of distal C vertebra. Inviting patients for these check ups always in the spring and fall has proved successful.
We have noticed one rather substantial phenomenon of LLLT: so far no side effect has been reported. On the other hand, there is an interesting clinical finding in a certain group of patients (6 patients = 3 per cent), an acceleration of tinnitus after the first few LLLT procedures. Positive aspect of this phenomenon is that these patients have always belonged in the group with a massive effect of the therapy (more than 50 per cent relief, or even free of tinnitus at all). This clinical observation has been personally confirmed by other authors working at tinnitus treatment with the use of LLLT (Wilden).

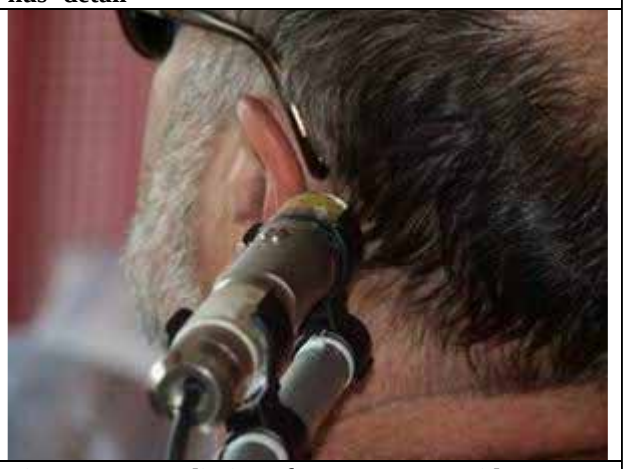


Picture 3 – Irradiation of Meatus Acusticus Externus



Picture 4 – Irradiation of Meatus Acusticus Externus -detail

Picture 5 – Irradiation of Procesus Mastoideus



Picture 6 – Irradiation of Procesus Mastoideus

Placebo LLLT

Due to persistently appearing theories on the effect of LLLT of tinnitus being a mere placebo we have created a minor group of 31 patients in order to confirm or exclude this hypothesis. In the course of three months attendance these patients underwent medication therapy as well as physiotherapy of axial skeleton with classical rehabilitation techniques in the same extent as all the other patients did. Instead of a functional laser source these patients were treated with a probe not emitting laser beam, although there was acoustic as well as visual signalization of operation. Among all other physiotherapeutic devices a non-invasive laser is extremely suitable to perform a placebo test, since its application on a patient is not connected with any subjective feelings nor phenomenons (in contradiction to electrotherapy, for instance). As we work with an IR wavelength, it was possible to arrange a double blind study, for the fact whether the therapist works with a device emitting laser beam or with a placebo unit was not even known to the therapeutic personnel.
The results - unambiguously confirming that there is no placebo involved in LLLT - are summarized in Table 2. The outcome is undoubtedly statistically significant.

Table 3 - Comparison of clinical effect of - 6 months vs. 3 years vs. placebo

EFFECT OF THERAPY	Original Group (31 patients - 6 months)	New Group (200 patients - 3 years)	Placebo Group (31 patients - 3 months)
No effect	19.4 %	16.0 %	25.8 %
Less than 50 per cent reliéf	19.4 %	15.0 %	48.4 %
More than 50 per cent reliéf	35.5 %	43.0 %	25.8 %
No more tinnitus	25.8 %	26.0 %	0.0 %

Statistical comparison

Courtesy: Mr. Arnost Komarek, Biostatistisch Centrum, Katholieke Universiteit Leuven, Belgium.

Statistical comparison of the two groups, differing from each other by the length of therapy was done with the use of χ^2 test of homogenity of two multinomic separations, confirming whether distribution of monitored population into groups according to the effect of therapy is equal for both groups, i.e. after 6 months and 3 years of therapy.

Expressed in mathematical terms, let us suppose that the effect of therapy in both studied populations (6 months vs. 3 years) is directed by multinomic division, i.e. that a given person belongs with a certain probability (based on population) to one of the four groups according to the effect of therapy. It will be statistically tested whether the probability of participation in individual groups is equal in both populations. We can pronounce an alternative hypothesis, that the probability to belong at least to one group according to the therapy is different in populations studied.

For the calculation of testing statistics it is necessary to calculate expected frequencies, i.e. frequencies which could be monitored under a hypothesis that the length of therapy has no influence on the effect. Higher differences between relative and expected frequency testify against the hypothesis of zero influence of the length of therapy.

Table 4 - Monitored relative occurrence

EFFECT OF THERAPY	Original group 6 months / 31 patients	New group 3 years / 200 patients
No effect	19.4 %	16.0 %
Less than 50 per cent reliéf	19.4 %	15.0 %
More than 50 per cent reliéf	35.5 %	43.0 %
No more tinnitus	25.8 %	26.0 %

Table 5 - Expected absolute occurrence

EFFECT OF THERAPY	Original group 6 months / 31 patients	New group 3 years / 200 patients
No effect	5.11	32.91
Less than 50 per cent reliéf	4.84	31.18
More than 50 per cent reliéf	13.03	83.98
No more tinnitus	8.06	51.94

Table 6 - Monitored absolute occurrence

EFFECT OF THERAPY	Original group 6 months / 31 patients	New group 3 years / 200 patients
No effect	6	32
Less than 50 per cent reliéf	6	30
More than 50 per cent reliéf	11	86
No more tinnitus	8	52

The χ^2 test statistics, which is in the case of zero hypothesis directed by χ^2 division with 3 grades of loose in the first group is:

$\chi^2 = 0.88$.

Monitored p value equals 0.83, which is rather a high level and thus it can be stated that the difference between the two groups with different duration of therapy is not statistically significant.

Discussion

1. Patients with no effect of Comprehensive Laser Therapy: the figure will definitely be higher by the number of patients who finished the therapy due to reasons other than zero effect of treatment. We ourselves had been expecting a higher decrease of representation of this group and therefore we were rather surprised by the result. However, it is quite logical that in the course of three years there are more patients who finish the attendance of therapeutic procedures due to other reasons than due to zero effect of procedures. In the particular group of patients it

these are listed in New Group. This number correlate rather well even with correction of 2 patients (of total 5 patients) contacted by phone. Should we try to take these patients into account, the results in the table would look even better. Despite of this, we have left the numbers as it is, in the name of objectiveness.
2. Almost identical number of patients with less than 50 per cent relief in the Original and New Groups. Decrease in this cohort of patients has been caused by shifting the patients to "no-effect" group (however erased from the evidence due to other reasons), but particularly by moving them to "more than 50 per cent relief", or even to "no more tinnitus" group.
3. The most significant, and most pleasant fact of the New Group is the shift in terms of positive effect on tinnitus, evaluated by the patients as more than 50 per cent relief or even as no more tinnitus.

Conclusion

After three years of clinical monitoring 200 patients after Comprehensive Laser Therapy (medication, rehab physiotherapy aimed at axial skeleton and LLLT) of tinnitus have been evaluated with the following results:

1. 16 per cent of patients with no effect (however, approximately one third of this group may have finished attendance due to other reasons than in direct relation to the results of therapy, attendance finished sua sponte by the patient),
2. 15 per cent of patients marking their relief of tinnitus as less than 50 per cent alleviation (evaluation through combination of three different scales), having in mind especially the criterion of "quality of life",
3. 43 per cent of patients, the biggest group consisting of patients evaluating their relief of tinnitus within mentioned scales as more than 50 per cent,
4. 26 per cent of patients are totally free of tinnitus.

We had expected a shift in the statistics towards better values in terms of subjective patients evaluation of improvement after a longer time of systhematic therapy. However, from the point of view of statistical significance, expressed in exact tests, there was no statistically significant shift. Despite of this, our study confirms a correctly created complement of therapeutic care of tinnitus patients, especially thanks to high level of success of this therapy in terms of the level of relief of patients, thus improving their "quality of life". This goal should always be our priority.

Model protocol

PRE-EXAMINATION EVALUATION	**Co-peration between specialists**	• neurology • nose-ear-throat • rehabilitation (or physiotherapy)
EXAMINATION PART	**Gathering anamnesic data**	Acoustic trauma in the anamnesis (regardless to one-time episode or a chronic burden)
		Abuse of potentially ototoxic medicaments (especially antibiotics, total anesthesia)
		Ocurrence of tinnitus in family anamnesis
	Evaluation of the level of subjective suffering	Percentage scale
		Five-grade scale
		Ten-grade scale with graphics showing mimics
	Clinical examination	Thorough otoneurological examination
		Thorough examination of axial skeleton
		Nystagmus
		Blood pressure
	Technical means of examination	Audiogram + masking of tinnitus
		CT/NMR
		X-ray of C vertebra
		ENG
		Tinnitogram
	Lab tests	Especially detection of diabetes mellitus
		Lipide metabolism disorders
	Functional pathology of axial skeleton	Patients should always be examined by a specialist on myoskeletal medicin

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THERAPY	**Medication**	Preferably indicated by an ENT specialist: vasoactive medication, antihistaminics, nootropics
		Good experience with Gingko biloba preparations: Egb 761, Tanakan, Tebokan pills
		Frequent changing of the scheme of medication not suitable
	Rehab therapy	Aimed at the axial skeleton
		Physiotherapy focussed on analgesia and relaxation of muscle spasms (DD currents by Bernard, interferential currents, pulsed magnetic field (these techniques applied on distal parts of neck vertebra).
		Traction therapy – horizontal tractions, preferrably devices with pulsed modulation
		Mobilization (manipulation) of current functional blockades.
		Therapeutic physical exercise, techniques aimed at distal parts of neck vertebra, postizometric relaxation activities, automobilization activities
	LLLT	Basic requirements on the device: IR (830nm), power output 250 mW - 400 mW
		Possibility of a head rest, adjustable stand holding the probe in required position, therapy lasts about 15 minutes on one ear
		Non-contact in a milimeter distance
		Irradiation points: • procesus mastoideus aiming in the direction of contra-lateral orbit • meatus acusticus externus in the direction of the acoustic duct.
		• Mastoideus: 90 J/sq cm – cw, followed by 45 J/sq cm – pulsed 5 Hz. • Duct: 50 J continuous + 25 J, 5 Hz.
		• 2 – 3 times a week • 8 - 10 applications in total • 4 – 6 weeks break • following series may be to cut to 5 – 6 therapies, once a week • minimum 5 series in total