Tinnitus

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Combined non-invasive laser - Egb 761 therapy of chronic tinnitus

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The treatment of patients with chronic tinnitus is very problematic and therefore otologists are trying to discover more suitable courses of therapy. In this study we wanted to evaluate the outcome of using a combination of EGb 761 and soft laser therapy.

We examined 120 patients with an average duration of tinnitus of 10 years. The patients underwent pure-tone audiometry, speech audiometry and objective audiometry tests. The intensity and frequency of tinnitus was also determined. EGb 761 was administered 3 weeks before starting soft laser therapy. Patients underwent 10 sessions of laser therapy, each lasting for 10 min. An improvement in tinnitus was audiometrically confirmed in 50.8% of patients.

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Transmeatal cochlear laser (TCL) treatment of cochlear dysfunction: a feasibility study for chronic tinnitus.

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Low-level-laser-therapy (LLLT) targeting the inner ear has been discussed as a therapeutic procedure for cochlear dysfunction such as chronic cochlear tinnitus or sensorineural hearing loss. Former studies demonstrate dose-dependent biological and physiological effects of LLLT such as enhanced recovery of peripheral nerve injuries, which could be of therapeutic interest in cochlear dysfunction. To date, in patients with chronic tinnitus mastoidal and transmeatal irradiation has been performed without systematic dosimetric assessment. However, light-dosimetric studies on human temporal

bones demonstrated that controlled application of laserlight to the human cochlea depends on defined radiator position within the external auditory meatus. This feasibility study first presents a laser application system enabling dose-controlled transmeatal cochlear laser-irradiation (TCL), as well as preliminary clinical results in patients with chronic cochlear tinnitus. The novel laser TCL-system, consisting of four diode lasers (lambda=635 nm-830 nm) and a new specific head-set applicator, was developed on the basis of dosimetric data from a former light-dosimetric study. In a preliminary clinical study, the TCL-system was applied to 35 patients with chronic tinnitus and sensorineural hearing loss. The chronic symptoms persisted after standard therapeutic procedures for at least six months, while retrocochlear or middle-ear pathologies have been ruled out. The patients were randomised and received five single diode laser treatments (lambda=635 nm, 7.8 mW cw, n=17 and lambda=830 nm, 20 mW cw, n=18) with a space irradiation of 4 J/cm2 site of maximal cochlear injury. For evaluation of laser-induced effects complete otolaryngologic examinations with audiometry, tinnitus masking and matching, and a tinnitus-self-assessment were performed before, during and after the laser-irradiation. The first clinical use of the TCL-system has been well tolerated without side-effects and produced no observable damage to the external, middle or inner ear. Changes of tinnitus loudness and tinnitus matching have been described. After a follow-up period of six months tinnitus loudness was attenuated in 13 of 35 irradiated patients, while two of 35 patients reported their tinnitus as totally absent. Hearing threshold levels and middle ear function remained unchanged. Further investigations by large double-blind placebo-controlled studies are mandatory for clinical evaluation of the presented TCL-system and its therapeutic effectiveness in acute and chronic cochlear dysfunction.

Hyperacusis treatment with a combination of laser therapy. pulsed electromagnetic field therapy and reactive oxygen specimen control.

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In a clinical study, at Audio Laser-Kliniken, 26 hyperacusis patients with 42 "hyperacusick" ears were measured using audiometry before and after therapy. There were 7 patients/13 ears returning by random to the clinic 4-6 months after finished therapy for a long time follow up. 10-20 treatments (twice a week) per patient were performed.

The LASER light effect per session varied between 206.7-513.6 J per ear. 810-830 and 635-650 nm wavelength was administrated via meatus. Pulsed Electromagnetic Field Therapy was also used and Reactive Oxygen Specimen were measured and controlled by an additional intake of antioxidants per os. The average pain threshold improvement was for all 245 hyperacusis observations 17.02 dB. The mean value was 16.90 dB. The average improvement was 22.84 dB for 74 long time follow up observations (4-6 months after therapy). Until now there hasn't been any known potent therapeutic method improving hyperacusis.

Patients with grave hyperacusis seem to have the largest dB-improvements from this therapy. The combined set of therapies in this study should be a first choice therapy for all hyperacusis patients.

Report on more than eight years of low level laser therapy of chronic inner ear diseases.

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The IXX Annual Meeting of The American Society for Laser Medicine and Surgery, Lake Buena Vista, Florida. April 16-18, 1999. Lasers in Surgery and Medicine. Supplement 11, 1999.

348 patients (402 ears) were treated with low level laser. Most patients had tinnitus. This study, however, only reports on the objective outcome of the audiometry, taken before and after therapy. The hearing capacity of the patients was improved in all frequency sectors (average value = 20.6%). The best db-reductions were obtained in the low frequencty sector (11.7 db) and in the high frequency sector (14.6 db). There was a close correlation between the improvement of the hearing capacity and the age of the patients and the duration of their disease. In conclusion it can be stated that if LLLT is administered in sufficiently high dosages to the inner ear (cochlea), it is possible to obtain and document significant biostimulative effects.

ON THE EFFECTIVENESS OF LOW LEVEL LASER LIGHT (LLLL) IN THE INNER EAR

Examined by pre- and posttherapeutical audiometry courses of air and bone conductions
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(db = decibel; j = joule; kc = kilocycle; nm = nanometer)

ABSTRACT

A) The objective of the study was the documentation of the biostimulative effects of LLLL in high energetical dosages (measured in j) by audiometry changes of a statistically relevant number of patients. B) The energy was transmitted with 3 laser diodes with a wave length of 830 nm and 3 diodes with a wave length of 635 nm; it was administered via meatus and mastoid. The examination and therapy included 348 patients and 215 right and 187 left inner ear organs (cochlea). 171 organs were female, 231 were male. Their average age at the beginning of the therapy was 56.9 years; the average duration of their disease was 5.9 years. 97.3 % suffered from tinnitus. The examination started on 24 june 1996 and ended on 9 february 1999. The average treatment phase lasted 61.5 days. The average duration of the therapy was 11.8 hours; the average quantity of the transmitted energy was 6732 j. Before

every therapy series with LLLL the patients actual hearing capacity (air and bone conductions) was examined by audiometry. At the end of each therapy series their hearing capacity was examined by the same method for a second time. The statistical analysis consisted of the arithmetical evaluation of a mean value of all test data over 12 frequencies as far as air and bone conductions were concerned, the drawing up of frequency intervals (low = 0.125, 0.25, 0.5 and 0.75 kc, middle = 1, 1.5, 2 and 3 kc, and high = 4, 6, 8 and 12 kc) and the grouping of the patients according to age, duration of the disease, quantity of the transmitted energy and the relative total reduction of the necessary sound volume in db. In cases of deafness 125 db were used as an auxiliary numeric value. C) The hearing capacity of the patients was ameliorated in all frequency sectors (average value = 20.6 %). The best db-reductions were obtained in the low frequency sector (9.3 db) and in the high frequency sector (11.2 db). There was a close (and biologically plausible) correlation as far as the amelioration of the hearing capacity and the age of the patients and the duration of their disease were concerned; this correlation was the higher, the more energy was transfered on the whole. D) If LLLL is administered in sufficiently high dosages to the inner ear (cochlea), it is possible to obtain and document medicinically significant biostimulative effects.

Introduction

According to a study of the university of Cologne[1)] by 2030 every second German will be suffering from impairments of the inner ear. Even at the present time, the number of people all over the world, who are inflicted with long-standing impairments or acute diseases of the inner ear, amounts to millions. The basic diagnostic for the documentation of the functional quality of the cochlea is the audiometry. The correlation of organopathological examinations of the cochlea and pathological audiometry results is illustrated by scientific papers2)

The audiometry belongs to the diagnostical standard equipment of medical offices and acousticians and is universally being used as a basic diagnostic by trade operative associations and industrial medicine for the purpose of examinations and appraisements. This is why it seemed approriate to use this method, which is both economical and easy on the patient, to verify the biostimulative effects of LLLL on the inner ear.

Nowadays, the prevailing measures to give therapy to patients with a reduced hearing capacity are the administration of non-specific medicaments that stimulate the blood circulation respectively the utilization of technical equipment such as sound amplifiers (hearing aids) or - in severe cases - electronically operated artificial inner ear appliances.

At present, a therapy that ameliorates the biological qualitiy of the sensory cells of the cochlea and thus increases the hearing capacity is being cold-shouldered by the overwhelming majority of physicians.

Although the manifold clinical and experimental studies of the international low level laser literature[3)] include examinations of the therapy of inner ear diseases [4)] and the penetration capacity of LLLL into the inner ear [5)], so far there was no statistical inquiry about the therapy with high dosages of LLLL, which is backed up by a sufficient amount of audiometrical data and takes into account a statistically relevant number of patients respectively inner ear organs.

Material and methods

The data of this study were collected from patients, whose further treatment - within the scope of conventional therapies - was predominantly regarded as futile when they started the low level laser therapy (LLLT). The patients all received an out-patient treatment, which consisted exclusively of a monotherapy. They were advised to take reasonable prophylactic measures against noise during (and after) the therapy. Possibly existing medicamentous or masker therapies were discontinued. Patients with hearing aids were advised to reduce the adjustments according to their improving hearing quality.

Basic data of the study

number		side		gender		age*	duration of
patients	cases	left	right	male	female	(ø)	disease* (ø)
348	402	46.5%	53.5%	57.5%	42.5%	56.9 years	5.9 years

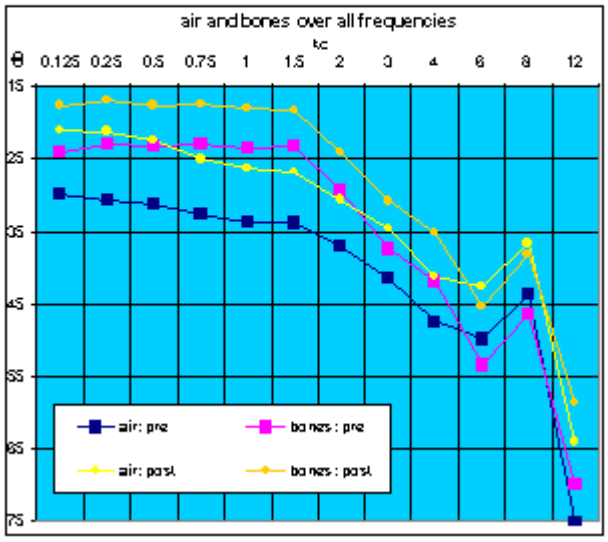
tinni-	period of time		treatment	treat-	energy
tus*	from	until	phase (ø)	ment (ø)	quantity (ø)
97.3%	24.06.96	09.02.99	61.5 days	11.8 hours	6723 joule

* at the beginning of the treatment

The energy was transmitted by 3 laser diodes with a wave length of 830 nm und 3 diodes with a wave length of 635 nm; it was administered via meatus and mastoid. The statistical analysis consisted of the arithmetical evaluation of a mean value of all audiometrical data over 12 frequencies as far as air and bone conductions were concerned, the drawing up of frequency intervals (low = 0.125, 0.25, 0.5 and 0.75 kc, middle = 1, 1.5, 2 and 3 kc, and high = 4, 6, 8 and 12 kc and the grouping of the patients according to age, duration of the disease, quantity of the transmitted energy and the relative total reduction of the necessary sound volume in db. In cases of deafness 125 db were used as an auxiliary numeric value.

Results

Fig. 1



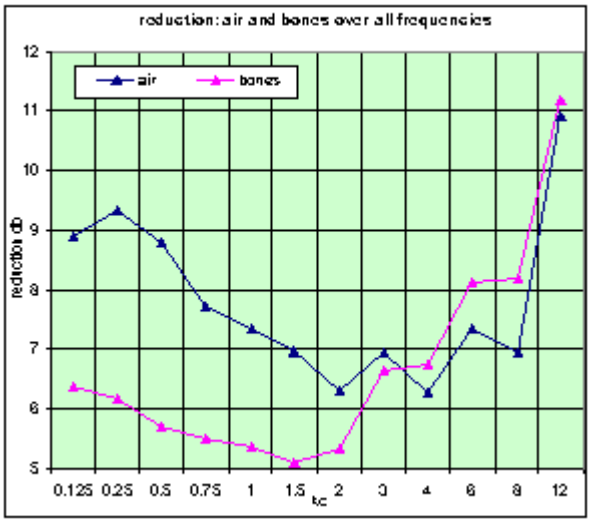
(For underlying table compare appendix, table 1)

In the case of the initial audiometrical results (*pretherapeutical findings*) the evaluation of the mean value of all readings reveals a clearly reduced average course of the hearing curves of the air and bone conductions over all frequencies, with low points in the frequency sector around 6 kc and the frequency sector around 12 kc (*sensorineural hardness of hearing, oblique descension*).

As expected, the bone conduction is situated above the air conduction in all frequencies. Occasional intersections of the air and bone conductions are only to be found in the frequency sector between 6 and 8 kc; this phenomenon, which is known from individual audiometries and can be observed on the mean curve, is due to an increasing loss of the differentiation capacity of the cochleas sensory cells within the range of higher-grade biological quality reductions of the organ of Corti.

In the case of the final audiometrical results (*posttherapeutical findings*) the evaluation of the mean value of all readings reveals a clearly and symmetrically ameliorated average course of the hearing curves of the air and bone conductions over all frequencies as compared with the pretherapeutical course (*amelioration of the sensorineural hardness of hearing with a reduction of the oblique descension*). As expected, the bone conduction is once again situated above the air conduction in all frequencies; the intersection phenomena in the frequency sector between 6 and 8 kc show a downward tendency.

Fig. 2



(For underlying table compare appendix, table 1)

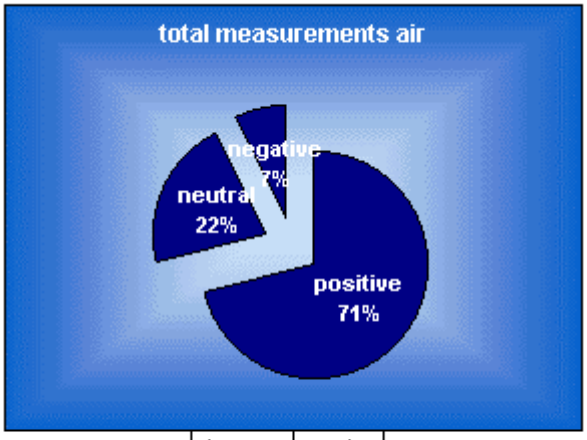
The diagram of the average total reduction (db) of the air and bone conductions shows a significant amelioration of the hearing capacity in the low and high frequency sector and a more pronounced amelioration of the air conduction as compared with the bone conduction in the lower frequency sector.

Clinically, this can be interpreted to the effect that, apart from its general therapeutical value, the LLLL also exerts a positive influence on the widespread sound conduction disturbances in this frequency sector, which are indicated by degenerative changes of the middle ear (for instance, otosclerotic processes.)

The highest reduction is to be found in the low frequency sector *(9.3 db when there are 0.25 kc in the air conduction; 6.4 db when there are 0.124 kc in the bone conduction)* and in the high frequency sector *(10.9 db when there are 12 kc in the air conduction; 11.2 db when there are 12 kc in the bone conduction).*

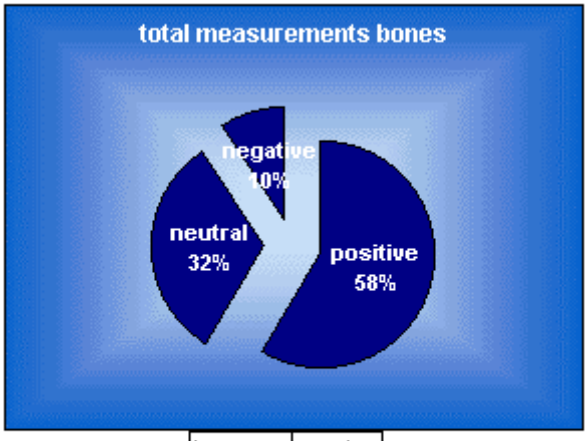
The average reduction (*improved hearing*) of the sound pressure necessary for the perception of sounds within a given frequency totals a mean value of 7.2 db over all frequenciesair(*air = 7.8 db; bones = 6.7 db).* Altogether, this corresponds with an average amelioration of the hearing capacity of<20.6 %*(air = 20.5%;bones = 20.6%)*; for further figures compare appendix, table1.

Fig. 3a



air	number
positive	3431
neutral	1046
negative	347
total	4824

Fig. 3b



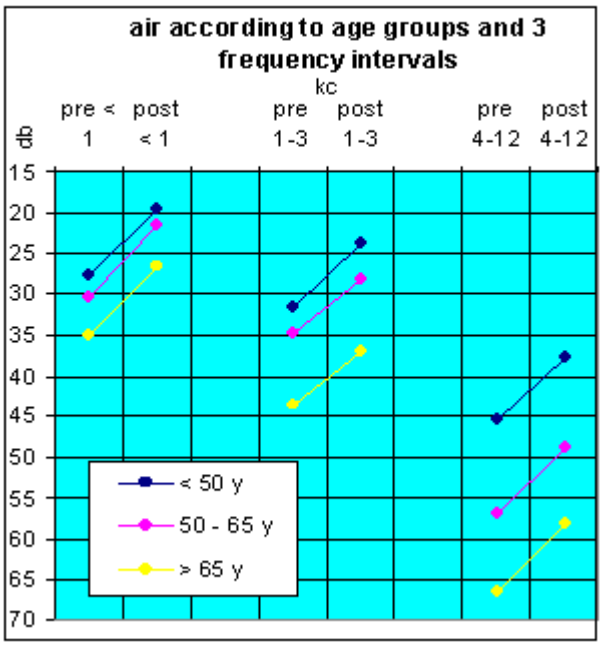
bones	number
positive	2817
neutral	1545
negative	462
total	4824

The comparison of all pre- and posttherapeutical readings over all frequencies reveals statistically highly significant results in the case of the air and bone conductions.
The values of the air conduction, which are slightly higher as those of the bone conduction, indicate that the LLLL has additional positive therapeutical effects on the sound conducting structures of the middle ear.

Grouping according to age and 3 frequency intervals

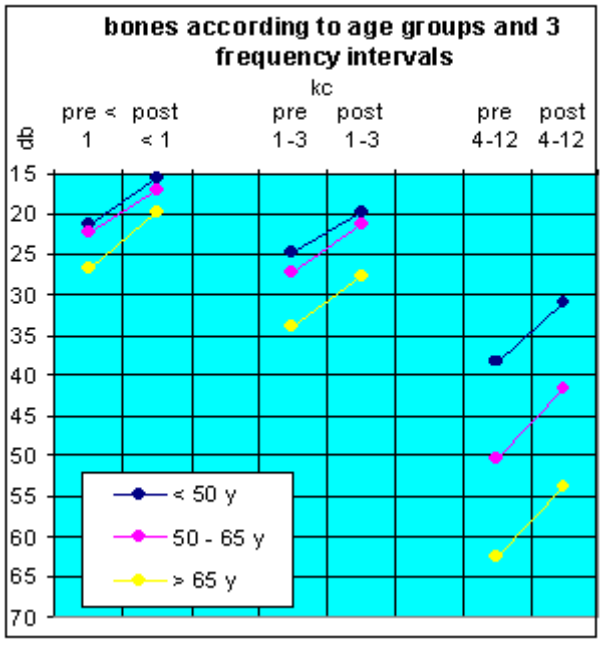
age grouping	cases		disease (ø)	tinni-tus	treatment phase(ø)	treatment (ø)	energy quantity(ø)
	number	age(ø)					
≤50y	116	37.9 y	3.6y	99.1%	62 days	12.0 hours	6444 joule
50-65y	189	59.1 y	5.5y	97.6%	62 days	12.0 hours	6666 joule
≥65y	117	72.4 y	8.9y	94.9%	41 days	11.4 hours	7094 joule

Fig. 4a



(For underlying table compare appendix, table 2)

Fig. 4b



(For underlying table compare appendix, table 2)

The grouping of the readings according to age groups and 3 frequency intervals results in findings that are biologically plausible as far as both the air and the bone conductions is concerned. In other words, the patient group with the highest average age (72.4 years) finds itself in the most disadvantageous starting position; the patient group with the lowest average age (37.9 years) finds itself in the most advantageous starting position.

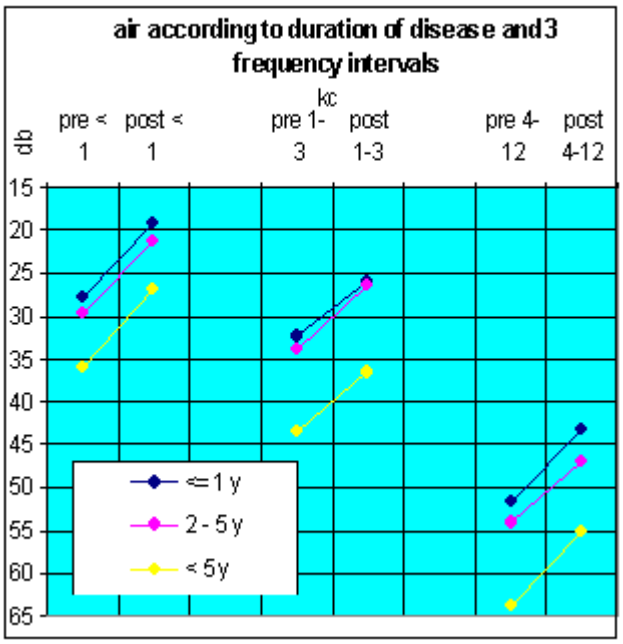
This applies to all 3 frequency intervals. The data also show that - in spite of the respective starting position - all age groups profit from the biostimulative effects of the LLLL in a relatively equal way. This holds good for both the air and the bone conduction.

If one takes into consideration the energy quantity (j) transmitted in order to reach these results, it is obvious that the eldest age group needs the largest quantity of transfered energy. However, this seems to be biologically plausible as well.

Grouping according to duration of the disease and 3 frequency intervals

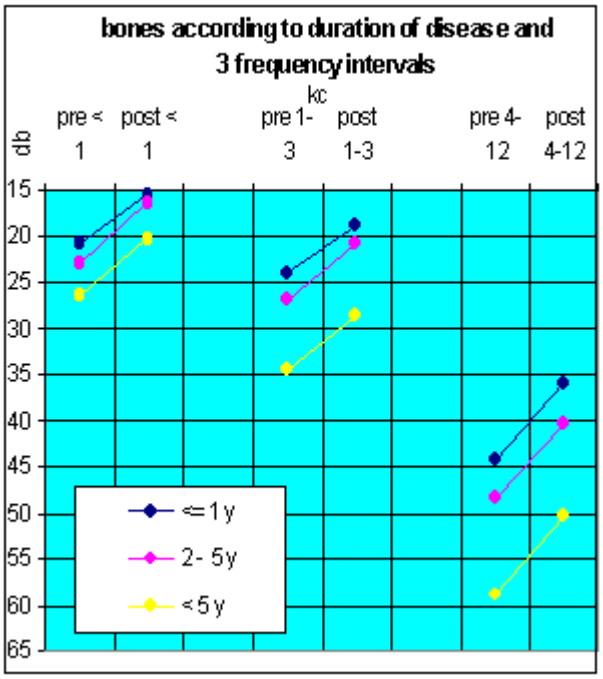
duration of disease grouping	cases		disease (ø)	timi-lus	treatment phase (ø)	treatment (ø)	energy quantity (ø)
	number	age (ø)					
<=1 y	145	53.9 y	0.6 y	97.9%	64 days	12.1 hours	628 joule
2-5 y	124	55.4 y	3.0 y	95.2%	66 days	11.6 hours	675 joule
>5 y	133	60.6 y	14.5 y	98.9%	54 days	11.8 hours	716 joule

Fig. 5a



(For underlying table compare appendix, table 3)

Fig. 5b



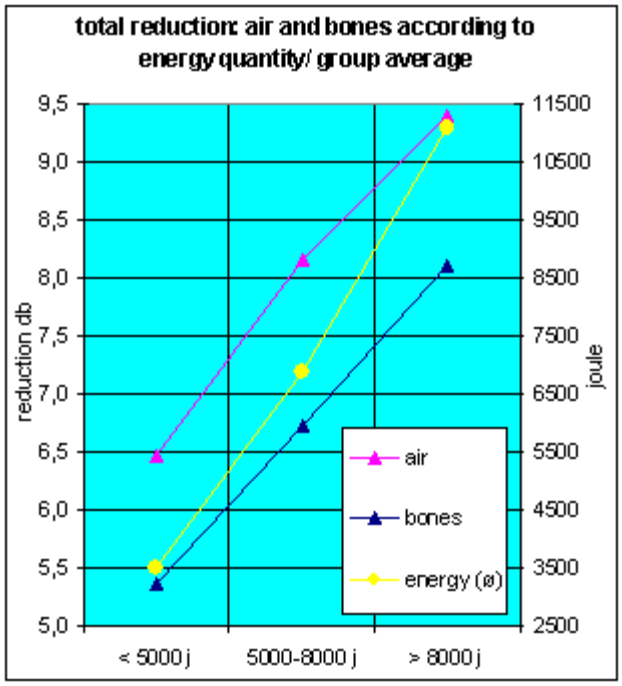
(For underlying table compare appendix, table 3)

As to the grouping of the readings according to the duration of the disease and 3 frequency intervals, the patient group with the shortest duration of the disease (0.6 years) has the best initial values and obtains the best final results with the smallest quantity of transfered energy. The patient group with the longest duration of the disease (14.5 years) has the poorest initial values and furthermore needs the largest quantity of transfered energy. This holds good for both the air and the bone conduction over all frequencies. At the same time, a detailed analysis of the data reveals that - in spite of the respective duration of the disease - all patient groups profit from the biostimulative effects of the LLLL in a relatively equal way. It has to be emphasized, though, that once again the most difficult patient group (*average duration of the disease 14.5 years*) needed the largest quantity of transfered energy.

Grouping according to energy quantity and 3 frequency intervals

energy quantity grouping	cases		disease (ø)	tinnitus	treatment phase (ø)	treatment (ø)	energy quantity (ø)
	number	age (ø)					
<5000 joule	118	55.6	5.2 y	96.6%	32 days	100 hours	3489 joule
5000-8000 joule	205	57.8	5.6 y	97.1%	34 days	105 hours	6886 joule
>8000 joule	79	56.3	7.9 y	98.7%	177 days	180 hours	11091 joule

Fig. 6a



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The grouping of the readings according to energy quantities reveals a clear correlation between the total quantity of the transfered energy and the therapeutical results that were obtained. The larger the quantitity of transfered energy, the higher the db-reductions that could be observed. This applies to both the air and the bone conduction in all 3 frequency intervals.

Fig. 6b

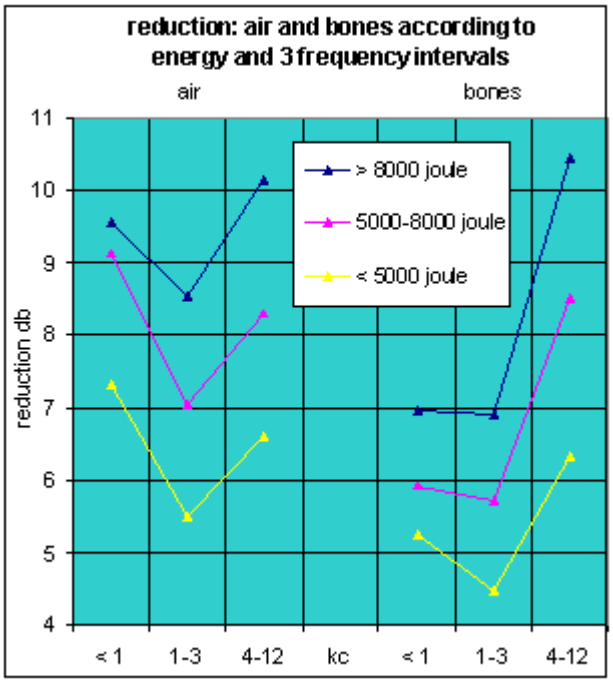

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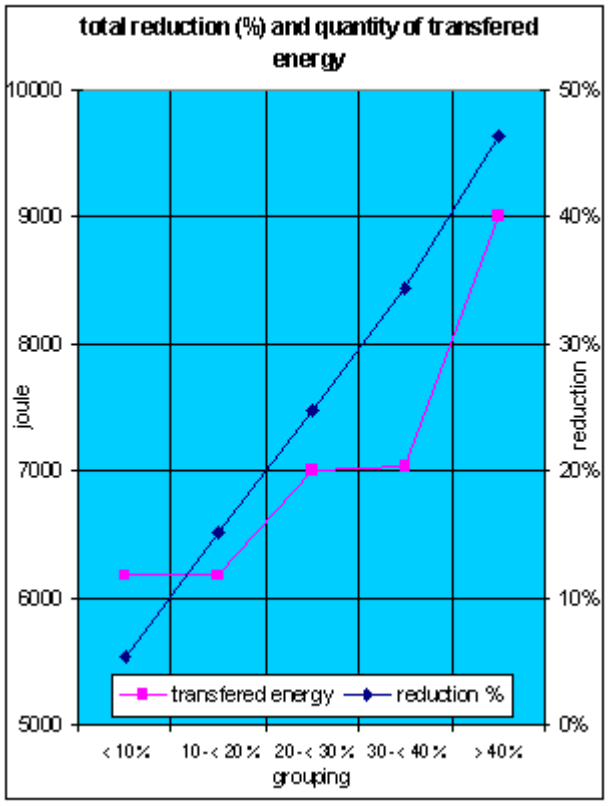
Fig. 6b clearly shows the correlative (*parallel*) connection between the total quantity of transfered energy and the total reduction.

Grouping according to relative total reduction and evaluation of correlation coefficients

reduction % grouping	cases number	cases age (ø)	disease (ø)	tirri-tus	treatment phase (ø)	treat-ment (ø)	energy quantity (ø)	reduction % (ø)
<10%	68	57.7 y	7.5y	97.1%	55 days	11.5 h	6183 j	5.4%
10-<20%	132	59.1 y	7.2y	96.2%	51 days	11.4 h	6180 j	15.2%
20-<30%	138	55.8 y	4.8y	97.0%	64 days	11.9 h	7012 j	24.8%
30-<40%	44	52.2 y	3.5y	100.0%	65 days	11.7 h	7040 j	34.3%
>=40%	25	51.4 y	5.1 y	100.0%	110 days	14.9 h	9107 j	46.4%
correlation coefficient *		-0.29	-0.77		0.86	0.79	0.91	

* of the column in relation to the last column (reduction %)

Fig. 7



(For underlying table see above)

Even if expressed in percentages, the mean values of the respective groupings demonstrate that the smallest amount of transfered energy (6188 j) results in the lowest relative reduction (5.4 %), whereas the largest quantitity of transfered energy (9007 j) brings about the highest relative reaction (46.4 %).

The highest correlation coefficient of 0.91 (*relative total reduction in relation to total quantity of transfered energy*) thus confirms the observations implied by the foregoing groupings according to age, duration of the disease and total quantity of transfered energy.

In the whole course of the therapy no side effects whatsoever could be observed.
In some of the cases, however, the LLLT of the inner ear organ presented in this paper caused specific individual reactions such as temporary vertigo respectively the disappearance of an existing otogenic vertigo, the momentary appearance respectively disappearance of a sensation of pressure in the ear and changes respectively the reduction or disappearance of a prevailing dysacusia and/or tinnitus, which had to be interpreted correctly with regard to the patient.

Conclusions

If LLLL is transmitted to the inner ear (cochlea) in sufficiently high dosages, it is possible to obtain

and document medicinically significant biostimulative effects.

In this respect, the results of the study at hand not only refer to the fundamental working model of the cellular energy transfer[6] from 1998, which was based on quantum mechanics, but confirm its conclusions as well, namely, that cellular regeneration processes do take place, if the mitochondria in question are stimulated to an increased production of adenosine triphosphate (*ATP*) by sufficiently large quantities of LLLL.

To what extent subsequent LLLTs lead to additional organic betterments (on average > than 20.6 %) is left up to future studies. The same applies for an augmentation of the total quantity of the transfered energy in the course of the treatment phases or per unit; in the latter case further technological developements on the part of the laser industry are indispensable, though.

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Laser therapy in the combined treatment of hyperacusis, a prospective clinical study.

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Abstract

Patients suffering from hyperacusis were treated twice a week with a combination of therapeutic laser, pulsed electromagnetic field and the control and adjustment of Reactive Oxygen Species (ROS). 245 observations in 42 ears on 26 patients were measured before therapy and after 10-20 therapeutic sessions. One group was evaluated in short-term follow-up (immediately after therapy), another group was evaluated in long-term follow-up (4-6 months after therapy). The average improvement for the pain thresholds was 17.02 dB. An average improvement of 10 dB or more was obtained in 40 ears. In the long-term follow-up group the average result was 22.84 dB and in the short-time follow-up group it was 14.50 dB. All ears improved. Between 177-504 J of laser light was administrated via meatus acusticus. The pulsed electromagnetic field applicator generated a magnetic field of a maximum of 100 µT and it was placed behind the ear, over the area of the mastoid bone. ROS were measured and controlled by administrating different sorts of antioxidants such as Ginkgo biloba.

[Low-energy laser radiation in the combined treatment of sensorineural hearing loss and Meniere's disease]

[Article in Russian]

Pal'chun VT, Lapchenko AS, Kadymova MI, Kucherov AG.

59 patients with neurosensory hypoacusis and 45 with Meniere's disease underwent helium-neon laser intra- or supravascular radiation of blood. The treatment proved effective in acute neurosensory hypoacusis and Meniere's disease. In chronic neurosensory hypoacusis the effect was insignificant.

Comprehensive therapy of patients suffering from tinnitus.

Prochazka M, Tejnska R.

37 patients suffering from tinnitus (age 18-86 years) were treated in three ways: 1. Rehabilitation: mobilisation, physical training, physiotherapy. 2. Same as 1 but with placebo laser added. 3. Same as 1 but with functional laser added. Laser used was 830 nm 300 mW. 2-3 treatments per week were given, total 10 treatments. Treatment protocol: 90 J/cm2 CW on mastoideus, 45 J/cm2 5 Hz on mastoideus, 50 J/cm2 CW on acoustic duct, 25 J/cm2 5 Hz on acoustic duct. Tebokan Egb 761 ginko medication was added to treatment. Results were classified as no effect/less than 50% relief/more than 50% relief/no more tinnitus. The percentwise outcome for the three groups was: 1. 29.4/44.1/17.6/8.9 2. 25.8/48.4/25.8/0 3. 19.4/19.4/35.5/25.8

Auris Nasus Larynx. 1997; 24 (1): 39-42.

Promising results using LLLT for tinnitus and inner ear diseases

Shiomi et al. used a 40 mW GaAlAs laser in a group of 38 patients suffering from tinnitus, resistant to several medical therapies for more than six months. 21.6 J was given each time through the auditory meatus toward the cochlea. Ten treatments or more were given. Only 26% of the patients reported improved duration, but 58% had reductiont of loudness and 55% reduced annoyance. The authors conclude: ”Laser therapy seemed to be worth trying on patients with intractable tinnitus”. Editorial note: The results can be improved if much higher doses are given. Dr. Lutz Wilden of Bad Füssing, Germany reported on his 6 years of experience at a recent lecture before the members of the Swedish Laser Medical Society (Stockholm, May 1998). Dr. Wilden is using three different lasers. One is directed through the meatus, two are positioned over the mastoid. Total dosage 2000-4000 (sic) joules per treatment (60 minutes per session, 30 minutes per ear). Doses may seem very high, but the thick bone behind the ear absorbs about 95% of the energy before reaching the inner ear. For more info, see http://home.t-online.de/gbl-hc/ez.

TINNITUS AND VERTIGO - A CASE FOR THE DENTIST?

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The correlation between tinnitus/vertigo and cranomandibular disorders (CMD) has been known for quite some time, yet few dentists seem to be aware of this. It is not natural for the dentist to ask, nor for the patient to inform the dentist about such a situation since it does not appear to be a dental indication. However, quite a number of tinnitus/vertigo patients will be releived of their symptoms if a proper CMD treatment is performed. Low level lasers have been used to treat tinnitus patients with reasonable success, if sufficient

energy and suitable treatment technique is used. These lasers have also proved themselves successful in the treatment of CMD. It is obvious, therefore, that low level laser therapy is an appropriate treatment modality for the yet undefined subgroup of tinnitus/vertigo patients with a CMD background. Laser therapy will reduce pain levels, ease muscular spasms and revert the vicious circle. In some cases laser therapy alone will produce astonishing results, in others it has to be combined with traditional occlusal stabilisation procedures. It is important for doctors to be aware of this subgroup of tinnitus patients since traditional therapies, and even laser therapy of the inner ears, will be ineffective if the CMD is not diagnosed and treated. This presentation will look at the literature documentation for laser therapy of tinnitus/vertigo.

Light dosimetry and preliminary clinical results for low level laser therapy in cochlear dysfunction.

Beyer W et al.

The light distribution inside the cochlear windings produced by irradiation of the tympanic membrane was quantitatively measured ex vivo for wavelengths of 593, 612, 635, 690, 780 and 805 nm by means of video dosimetry. The transmission of light across the tympanic cavity and the promontory depends strongly on the wavelength. Spatial intensity variations of a factor of 10 and more inside the cochlear windings have been measured. The clinical study was performed with 30 patients suffering from chronic permanent tinnitus. 5 irradiations within 2 weeks each with a space irradiation of 4J/cm2 were applied at the cochlear position to be treated. Diode lasers of 635 or 830 nm, 15 patients each, were used. During and after irradiation there was no significant change of hearing. However, 40% of the patients reported a slight to significant attenuation of the tinnitus loudness of the treated ear. There was no difference between the two wavelength groups. A double blind controlled study is in preparation.

Otology & neurotology 2002; 23 (3): 296-300.

Transmeatal low-power laser irradiation for tinnitus.

Nakashima T, Ueda H, Misawa H et al.

To evaluate effectiveness of 60mW laser irradiation in the treatment of tinnitus. Prospective, randomised double-blind study. This investigation included 68 ears in 45 patients with disabling unilateral or bilateral tinnitus. The active or placebo laser treatment was administered trans-meatally once a week for 6 minutes. Laser irradiation was performed four times during a 4-week period. A questionnaire was administered to evaluate the loudness, duration, quality, and annoyance of tinnitus before and after irradiation. The loudness and pitch match for tinnitus were obtained, and distortion product otoacoustic emissions were also examined.: No significant difference was observed between the active and placebo laser groups with regard to outcome of loudness, duration, quality, and annoyance of tinnitus. In one patient who received active laser treatment, acute hearing deterioration occurred after the third irradiation. Transmeatal low-power laser irradiation with 60 mW is not effective for the treatment of tinnitus.

Lasers Med Sci. 2003;18(3):154-61.

Transmeatal cochlear laser (TCL) treatment of cochlear dysfunction: a feasibility study for chronic tinnitus.

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Low-level-laser-therapy (LLLT) targeting the inner ear has been discussed as a therapeutic procedure for cochlear dysfunction such as chronic cochlear tinnitus or sensorineural hearing loss. Former studies demonstrate dose-dependent biological and physiological effects of LLLT such as enhanced recovery of peripheral nerve injuries, which could be of therapeutic interest in cochlear dysfunction. To date, in patients with chronic tinnitus mastoidal and transmeatal irradiation has been performed without systematic dosimetric assessment. However, light-dosimetric studies on human temporal bones demonstrated that controlled application of laserlight to the human cochlea depends on defined radiator position within the external auditory meatus. This feasibility study first presents a laser application system enabling dose-controlled transmeatal cochlear laser-irradiation (TCL), as well as preliminary clinical results in patients with chronic cochlear tinnitus. The novel laser TCL-system, consisting of four diode lasers (lambda=635 nm-830 nm) and a new specific head-set applicator, was developed on the basis of dosimetric data from a former light-dosimetric study. In a preliminary clinical study, the TCL-system was applied to 35 patients with chronic tinnitus and sensorineural hearing loss. The chronic symptoms persisted after standard therapeutic procedures for at least six months, while retrocochlear or middle-ear pathologies have been ruled out. The patients were randomised and received five single diode laser treatments (lambda=635 nm, 7.8 mW cw, n=17 and lambda=830 nm, 20 mW cw, n=18) with a space irradiation of 4 J/cm2 site of maximal cochlear injury. For evaluation of laser-induced effects complete otolaryngologic examinations with audiometry, tinnitus masking and matching, and a tinnitus-self-assessment were performed before, during and after the laser-irradiation. The first clinical use of the TCL-system has been well tolerated without side-effects and produced no observable damage to the external, middle or inner ear. Changes of tinnitus loudness and tinnitus matching have been described. After a follow-up period of six months tinnitus loudness was attenuated in 13 of 35 irradiated patients, while two of 35 patients reported their tinnitus as totally absent. Hearing threshold levels and middle ear function remained unchanged. Further investigations by large double-blind placebo-controlled studies are mandatory for clinical evaluation of the presented TCL-system and its therapeutic effectiveness in acute and chronic cochlear dysfunction.

The Role of LLLT in Treatment of Tinnitus

Laser Partner, 26.2.2002

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Abstract

Comprehensive laser rehabilitation therapy of tinnitus has proven successfull and beneficial for treatment of this widespread civilization disease. Its long-term results are convincing, bringing significant relief to 36 per cent of patients and even leaving remarkable 26 per cent of patients without any symptoms (see Miroslav Prochazka, Ales Hahn: Comprehensive Laser Rehabilitation Therapy of Tinnitus: Long-Term Double Blind Study on a Group of 200 Patients in 3 Years, Laser Partner No. 51/2002). With the results mentioned above we can really speak about a breakthrough. This study brings an additional overview of the role of LLLT (Low Level Laser Therapy) in the treatment. Our results enable us to pinpoint laser as the leading element in the overall therapy of tinnitus.

Introduction

Tinnitus is an auditory perception apearing without an objective sonic source from the outer environment. Tinnitus can be subjective (heard only by the patient) and objective (sound can be even heard also by others). Our study, however, deals with patients suffering from subjective tinnitus only. According to literature, fifteen per cent of entire population have experienced at least a tinitus episode some time, its incidence and severity rising with age up to approx. eighty-five per cent of population older than 60.

Our clinic has been treating tinnitus for more than 5 years. We have published three studies on this particular issue, and we are of the opinion that our results are being followed in several countries (Brasil, Cyprus, Sweden, Switzerland, Slovakia, Turkey, Japan, Germany etc.) and implemented in numerous clinics with significant results. Studies published by these clinics show results which are almost identical with our experience.

Our last study on a group of 200 patients in the course of three years was finalized in February 2002 and published in June 2002. Since there have always been efforts to evaluate an exact role of LLLT in treatment of tinnitus, apart from medication and physiotherapeutic manipulation of neck vertebra as an integral part of the comprehensive therapy, we have decided to create a separate group of patients to be treated only with laser. This was only possible thanks to our vast experience and long involvement in tinnitus treatments.

Materials and methods

Our group consisted of 72 patients, 49 males, 23 females, age ranging between 16 to 92 years. The age and sex is given in Table 1.

SEX / AGE	16 - 20	21 - 30	31 - 40	41 - 50	51 - 60	61 +
Male	2	4	6	9	13	15
Female	0	1	4	5	6	7
Total	2	5	10	14	19	22

Prior to the application of LLLT, all the patients underwent the following pre-therapy examination:

1. Anamnesis (aimed especially at the fact whether tinnitus was caused by an acoustic trauma, as well as at genetic predisposition)

2. Subjective evaluation of suffering

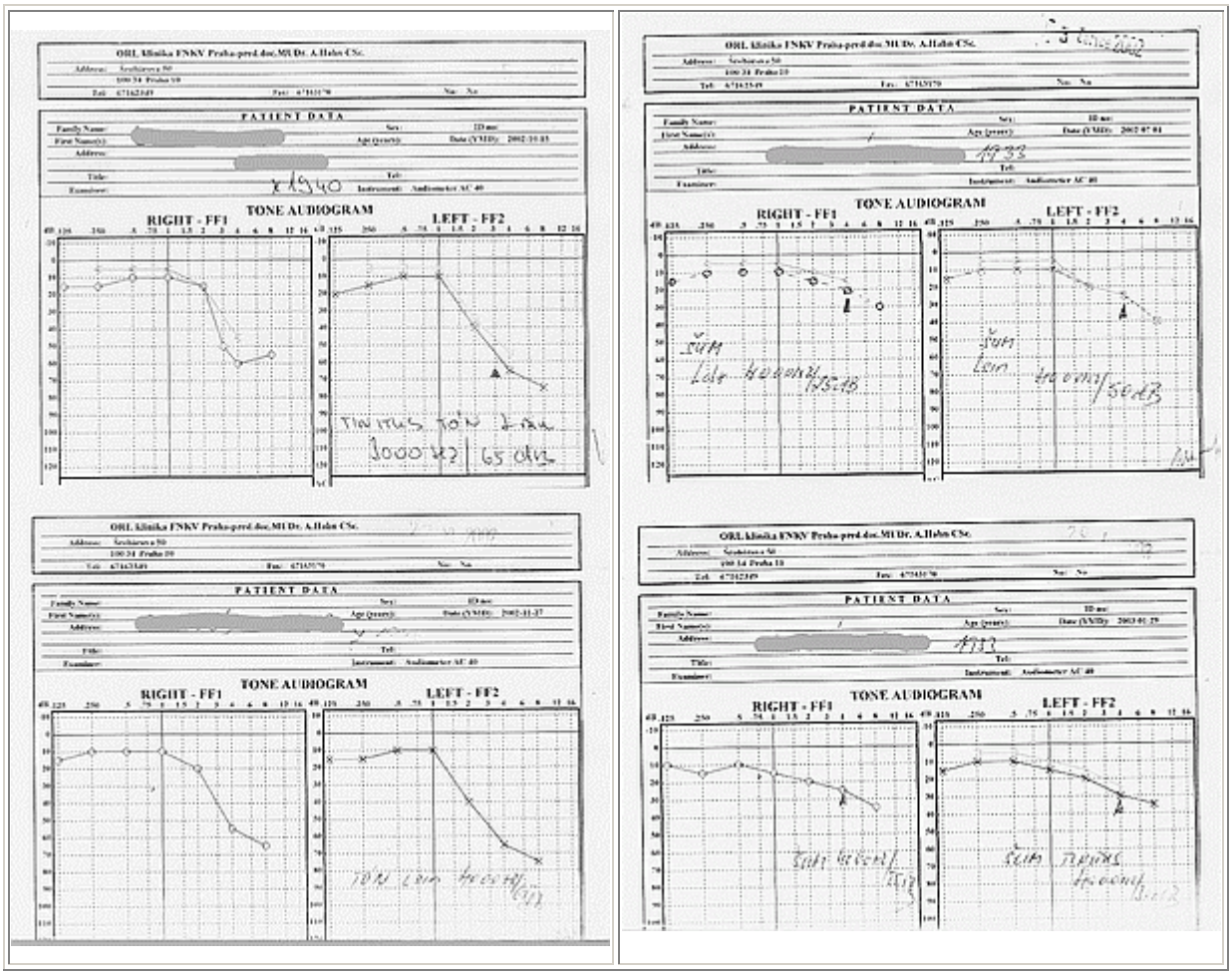
3. Clinical examination (otoneurology, axial skeleton, nystagm, blood pressure)

4. Technical examination (audiogram, x-ray of neck vertebra, ENG, tinnitometry)

5. Laboratory testing

Audiograms were taken in all the patients prior to the therapy. After the therapy audiograms were taken in 62.5 per cent, i. e. 45 patients, showing a slight improvement. Audiogram provides only for numeric range of perception of frequency of sounds, however it does not give us an objective evaluation of quality of hearing. Furthermore, the patients do not see the main improvement in a wider range of frequency of sounds, this remains usually on a similar level, but the main benefit is the absence of the additional burdening sound caused by tinnitus. Therefore the patients can better analyze sounds in general, their hearing is “refreshed” as they usually describe the result of the therapy.

Typical audiograms of patients with tinnitus before and after therapy shown on Picture 1.



MAESTRO/CCM device (manufactured by MediCom, Prague) was used for the study, with an infrared laser probe (830 nm) and power output 300 mW. The following application dosages and frequency modulations were applied on the following points:

1. meatus acusticus externus - in the direction of the axis of the auditory duct - continuous beam 50 J/cm2 followed by 25 J/cm2, frequency modulation of 5 Hz (Picture 2),

2. processus mastoideus - directed on the center, the vector of the beam in the direction of counter-lateral orbit, continuous beam 90 J/cm2 , followed by 45 J/cm2 with 5 Hz pulse frequency (Picture 3).

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.

Picture 2:

Irradiation of meatus acusticus externus

Picture 3:

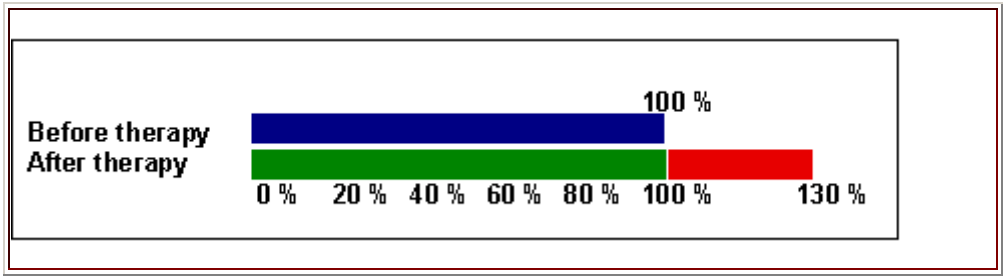
Irradiation of processus mastoideus

At the beginning, attendance was scheduled to 10 procedures in total, twice a week. Having completed the first series, patients returned after 2 - 3 months for another two series, each consisting of 5 - 6 therapies, once a week.

Evaluation

Level of subjective complaints was evaluated according to three scales:

- Percentage scale - complaints evaluated 100 per cent at the beginning of therapy (Blue), according to the level of relief decreased (Green) to 80, 70 etc. per cent, possible acceleration of problems (Red) goes up to 110, 120 etc. per cent, no tinnitus equals 0 per cent



- Five-grade scale - analogous to pain scales, reaching from Gr. I = No tinnitus to Gr. 5 = tinnitus interfering all activities

Grade I = No tinnitus

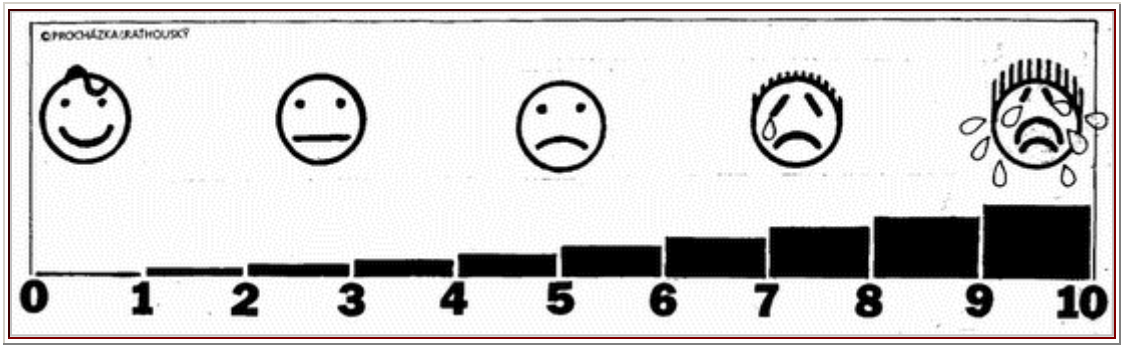
Grade II = No interfering sound perceived during the day, only in evenings, causing no discomfort

Grade III = Interfering sound perceived during the day, interrupting drowse only

Grade IV = Interrupting drowse and sleep, interfering sound causing discomfort during the day

Grade V = Unbearable discomfort, interfering all activities

- Graphic scale - Patient marking 0 to 10, accompanied by a simple graphics showing face grimaces according to his/her amount of subjective hardship.



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
2. Less than 50 per cent relief
3. More than 50 per cent relief
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.

Results

The results obtained are shown in Table 2.

Result	Patients	Per cent
No effect	15	20.8
Less than 50 % relief	19	26.4
More than 50 % relief	22	30.6
No more tinnitus	16	22.2

Total	72	100

It was interesting to compare our latest results (LLLT only) with those of our previous studies, i. e. our study made in 1998, long-term study between 1999 - 2001, and the initial study aimed at LLLT only. Comparison is contained in Table 3.

Result	1998	1999 - 2001	LLLT only
No effect	19.4 %	16.0 %	20.8 %
Less than 50 % relief	19.4 %	15.0 %	26.4 %
More than 50 % relief	35.5 %	43.0 %	30.6 %
No more tinnitus	25.8 %	26.0 %	22.2 %

Discussion

Hippocratic Oath orders us to treat patients to the best of our knowledge and ability. Since our long-term experience in comprehensive treatment of tinnitus has been based on the triad of physiotherapeutic manipulation, medication, and LLLT, we were at a loss whether we would not harm our patients in a way, giving them only a part of the treatrment, mere LLLT. We have to declare, that we have selected patients during the introductory examination, sorting out patients whose x-ray indicated a possibility of tinnitus caused by vertebral blockades. On the other hand, this selection led to a more pure evaluation of the role of LLLT in the treatment of tinnitus, leaving out both a possible cause and a corresponding treatment.

We have been positively surprised that in general the ratio of individual four groups remained similar. The number of patients with no effect of LLLT slightly increased (by 4.8 per cent when compared to the long-term study, by 1.4 per cent in comparison to the original study of 1998). This is obviously caused by the absence of medication and physiotherapy, showing their supportive efect.

In the group evaluating improvement as less than 50 per cent the leading role of LLLT can be evidenced best. More than one-fourth of all patients (26.4) report improvement after therapy performed with LLLT only, which is a result better than those in both previous studies (19.4 and 15.0) .

Impressive results have also been obtained in the last two groups , when we imagine more than one half of all patients reporting significant and/or total relief of tinnitus (30.6 + 22.2 = 52.8 per cent).

Conclusion

22.2 per cent patients suffering from tinnitus never more after treatment with therapeutic laser is a great success of LLLT. It only confirms the leading role of LLLT within comprehensive laser rehabilitation therapy of tinnitus. On the other hand we must stress the necessity to apply the two remaining parts of our therapeutic triad as well, since medication and physiotherapeutic manipulation are integral parts of the general care of our patients, and we should not deprive the suffering of the means and methods capable of bringing them more relief, which we are aware of.

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