

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

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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 transferred on the whole. D) If LLLL is administered in sufficiently high dosages to the inner ear (cochlea),

it is possible to obtain and document medicinally significant biostimulative effects.

**Introduction**  
According to a study of the university of Cologne<sup>1)</sup> 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 papers<sup>2)</sup>

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 appropriate 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 quality 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<sup>3)4)</sup> and the penetration capacity of LLLL into the inner ear <sup>5)</sup>, 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**  
include examinations of the therapy of inner ear diseases

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* ( $\bar{x}$ )	duration of disease* ( $\bar{x}$ )
patients	cases	left	right	male	female		
348	402	46.5%	53.5%	57.5%	42.5%	56.9 years	5.9 years

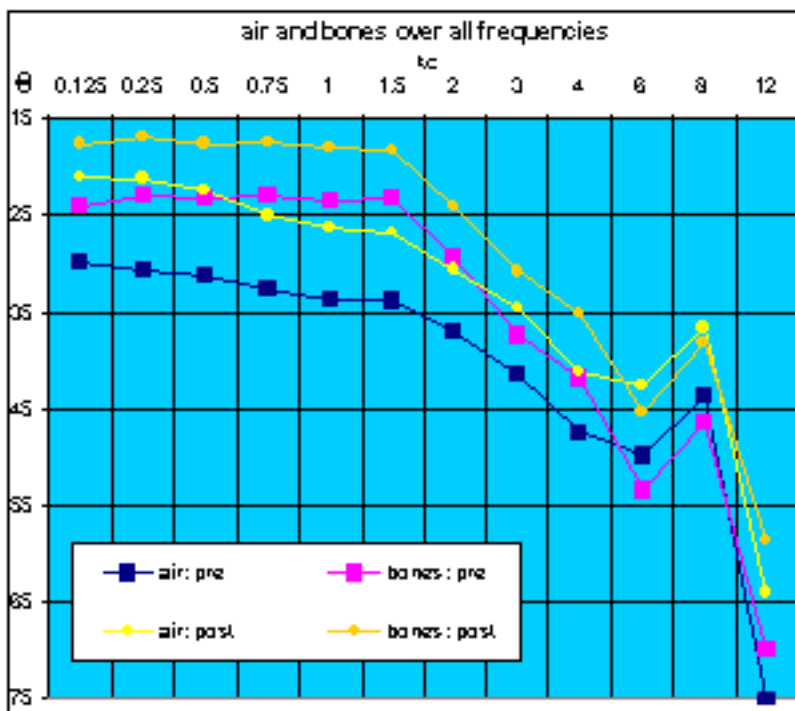
  

tinri- tus*	period of time		treatment	treat- ment	energy
	from	until	phase ( $\bar{x}$ )	ment ( $\bar{x}$ )	quantity ( $\bar{x}$ )
97.3%	24.06.96	09.02.99	61.5 days	11.8 hours	6723 joule

\* 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.

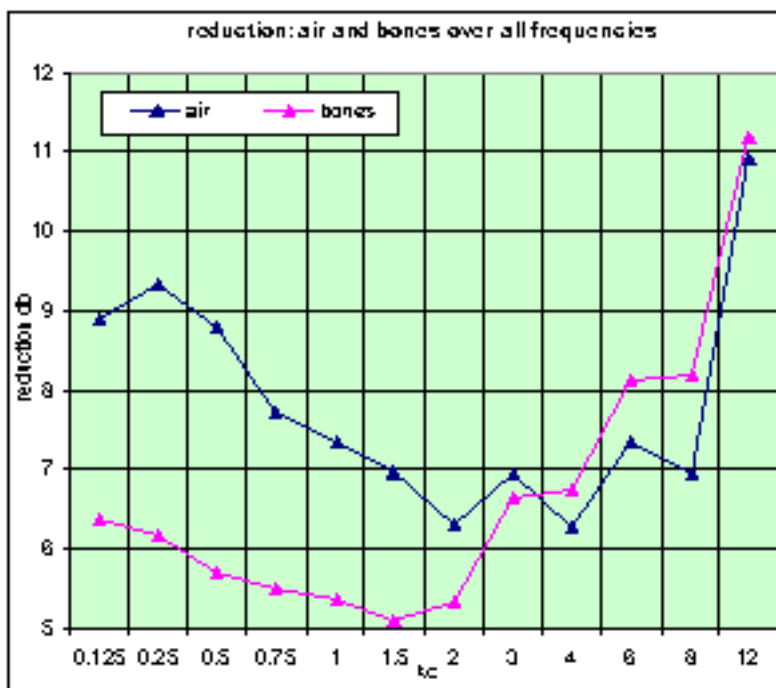
**Fig. 1**



(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**



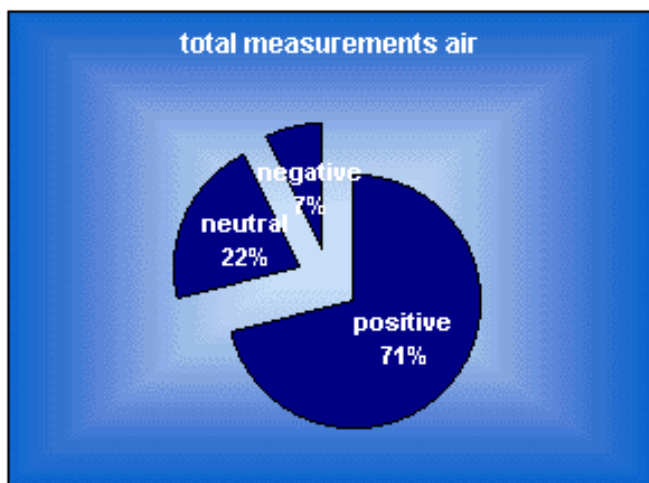
(For underlying table compare appendix, table 1)

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).

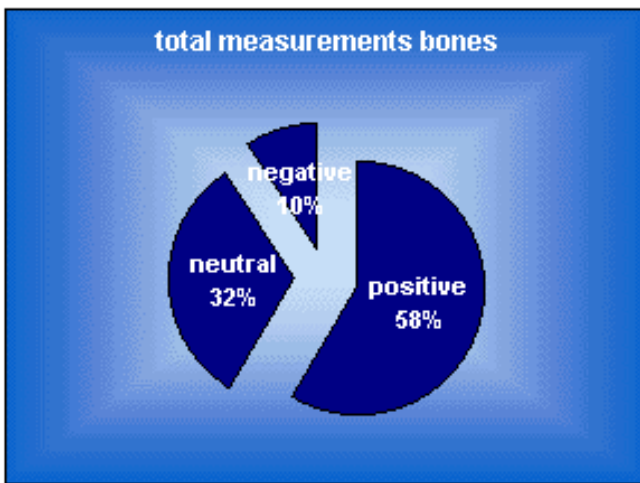
The average reduction (*improved hearing*) of the sound pressure necessary for the perception of sounds within a given frequency totals a mean value of 7.2 db over all frequenciesair(*air* = 7.8 db; *bones* = 6.7 db). Altogether, this corresponds with an average amelioration of the hearing capacity of <20.6 %(*air* = 20.5%;*bones* = 20.6%); for further figures compare appendix, table 1.

**Fig. 3a**



air	number
positive	3431
neutral	1046
negative	347
total	4824

**Fig. 3b**



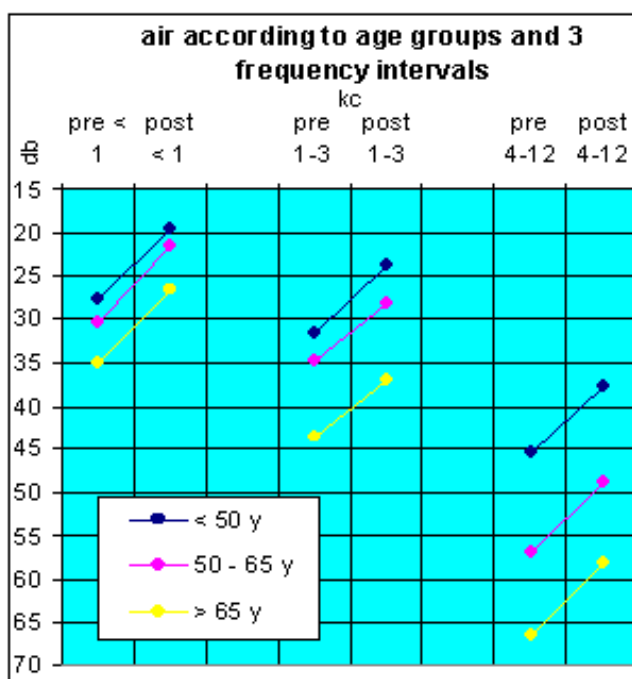
bones	number
positive	2817
neutral	1545
negative	462
total	4824

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

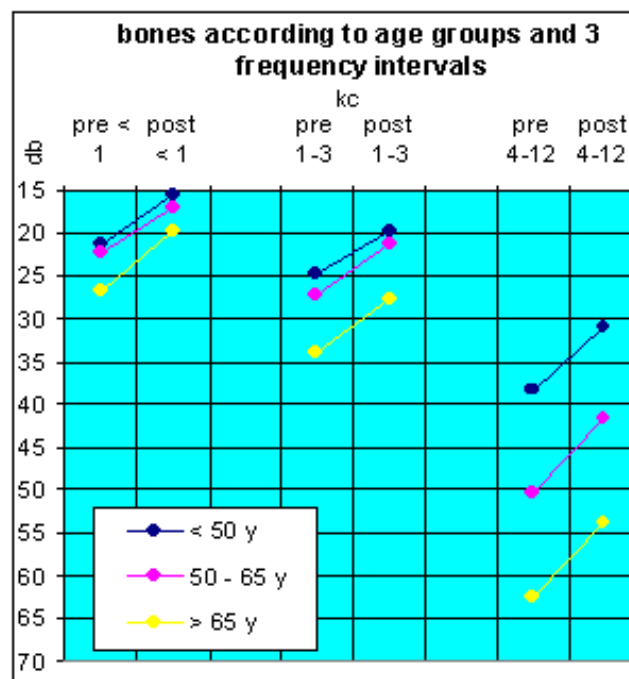
age grouping	cases		disease	time-	treatment	treatment	energy quantity(j)
	number	age(̄)	(̄)	t.us	phase(̄)	(̄)	
<50y	116	37.9 y	36y	98.1%	62days	120 hours	644 jule
50-65y	169	59.1 y	55y	97.6%	62days	120 hours	666 jule
>65y	117	72.4 y	89y	94.9%	41 days	114 hours	709 jule

Fig. 4a



(For underlying table compare appendix, table 2)

Fig. 4b



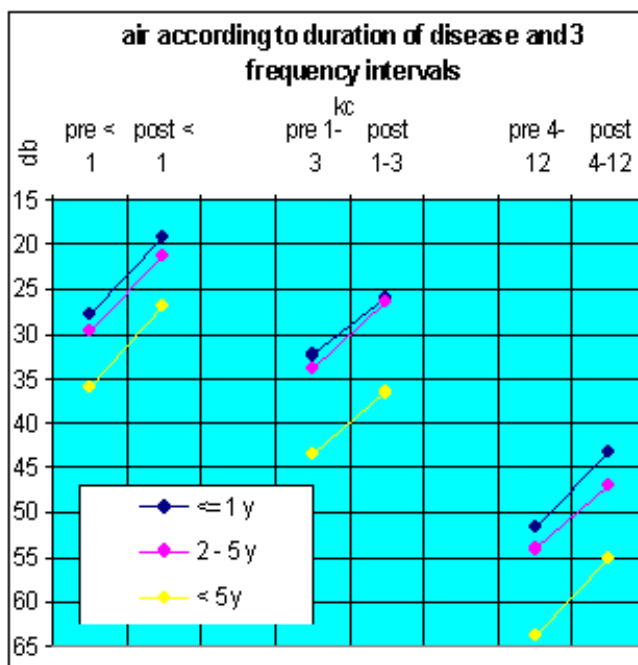
(For underlying table compare appendix, table 2)

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 conduction 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 transferred energy. However, this seems to be biologically plausible as well.

## Grouping according to duration of the disease and 3 frequency intervals

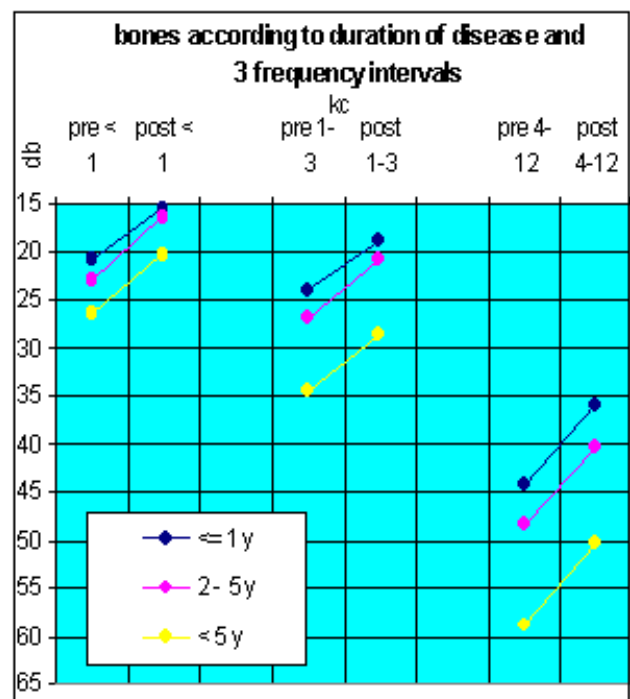
duration of disease grouping	cases		disease (@)	treatment time (@)	treatment phase(@)	treatment (@)	energy quantity(@)
	number	age(y)					
≤1y	145	53.9y	0.6y	97.9%	64days	121hours	6292joule
2-5y	124	55.4y	3.0y	95.2%	66days	11.6hours	6757joule
>5y	133	60.6y	14.5y	93.9%	54days	11.8hours	7161joule

Fig. 5a



(For underlying table compare appendix, table 3)

Fig. 5b



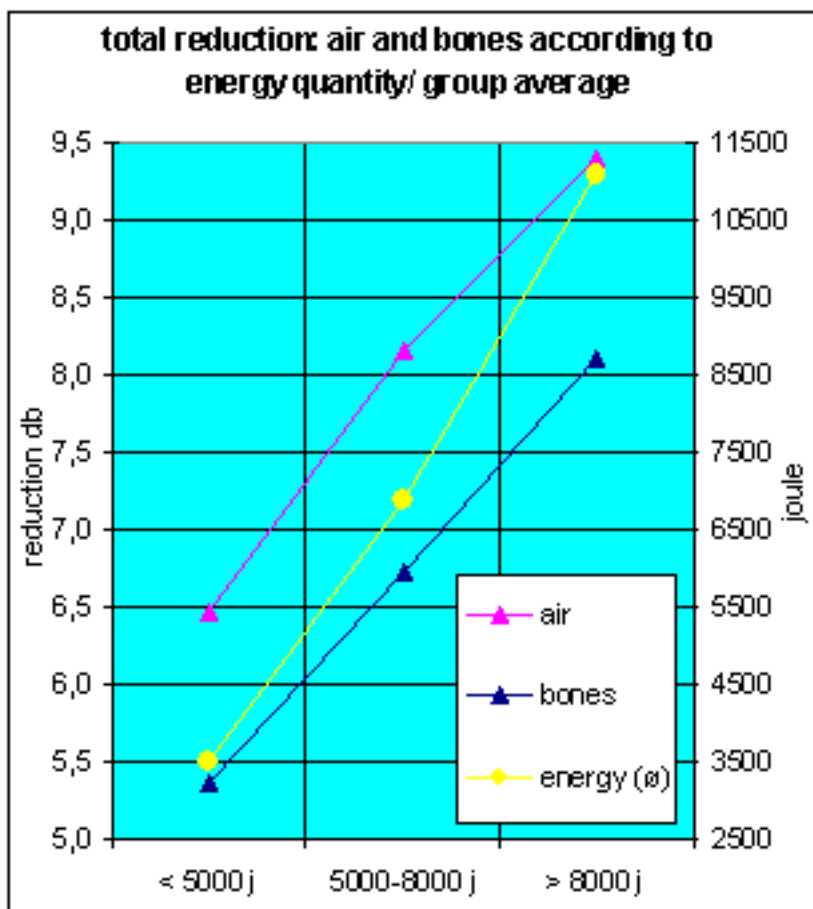
(For underlying table compare appendix, table 3)

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 transferred 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 transferred 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 LLL 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 transferred energy.

### Grouping according to energy quantity and 3 frequency intervals

energy quantity grouping	cases		disease (ø)	time-tus	treatment phase(ø)	treatment (ø)	energy quantity(ø)
	number	age (ø)					
<5000joule	118	55,6	52 y	96,6%	32 days	100 hours	3499 joule
5000-8000 joule	205	57,8	56 y	97,1%	34 days	105 hours	6886 joule
>8000joule	79	56,3	79 y	98,7%	177 days	180 hours	11091 joule

Fig. 6a



(For underlying table compare appendix, table 4)

The grouping of the readings according to energy quantities reveals a clear correlation between the total quantity of the transferred energy and the therapeutical results that were obtained. The larger the quantity of transferred 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

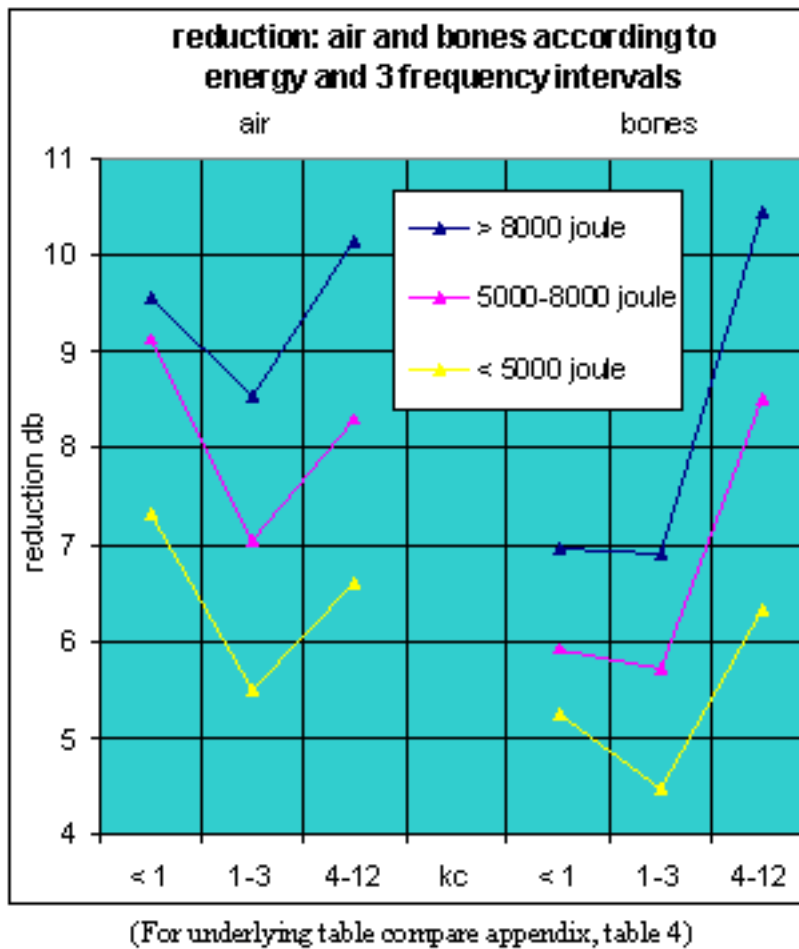


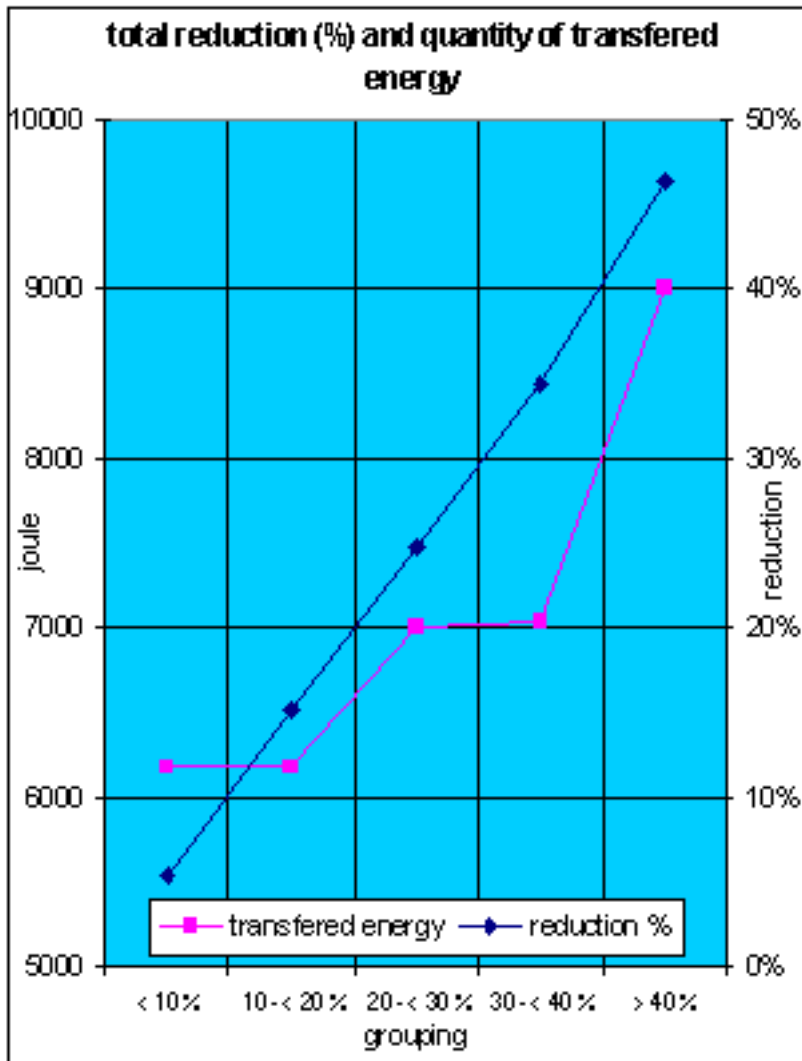
Fig. 6b clearly shows the correlative (*parallel*) connection between the total quantity of transferred energy and the total reduction.

### Grouping according to relative total reduction and evaluation of correlation coefficients

reduction%	cases		class	time	treatm	treat	energy	reduction%
	number	age(%)						
<10%	68	57.7y	75y	97.1%	55days	115h	616j	5.4%
10-<20%	132	59.1y	72y	95.2%	51days	114h	616j	15.2%
20-<30%	138	55.8y	4.8y	97.0%	64days	119h	700j	24.8%
30-<40%	44	52.2y	3.5y	100.0%	66days	11.7h	790j	34.3%
≥40%	25	51.4y	5.1y	100.0%	110days	149h	900j	46.4%
correlation coefficient *	-0.68	-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 transferred energy (6188 j) results in the lowest relative reduction (5.4 %), whereas the largest quantity of transferred 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 transferred energy*) thus confirms the observations implied by the foregoing groupings according to age, duration of the disease and total quantity of transferred 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 medicinally 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<sup>6)</sup> 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 transferred energy in the course of the treatment phases or per unit; in the latter case further technological developments on the part of the laser industry are indispensable, though.

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