

Double blind study for Low Level Laser Therapy in patients with chronic cochlear dysfunction

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Clinical phase III study

- Prospective, randomized, double blind study
- 175 patients (72 females, 103 males)
- Mean age 51.5 ± 13.4 years
- Chronic persistent cochlear tinnitus (3 - 300 months)
- 3 treatments at time intervals of 2 weeks:

λ [nm]	Dose J/cm ²	ext. Dose [J]	Patients
Placebo	-	-	59
635	4	4 - 40	21
690	12	6 - 30	40
780	65	16 - 65	29
830	100	25 - 100	26



Evaluation

Time schedule:

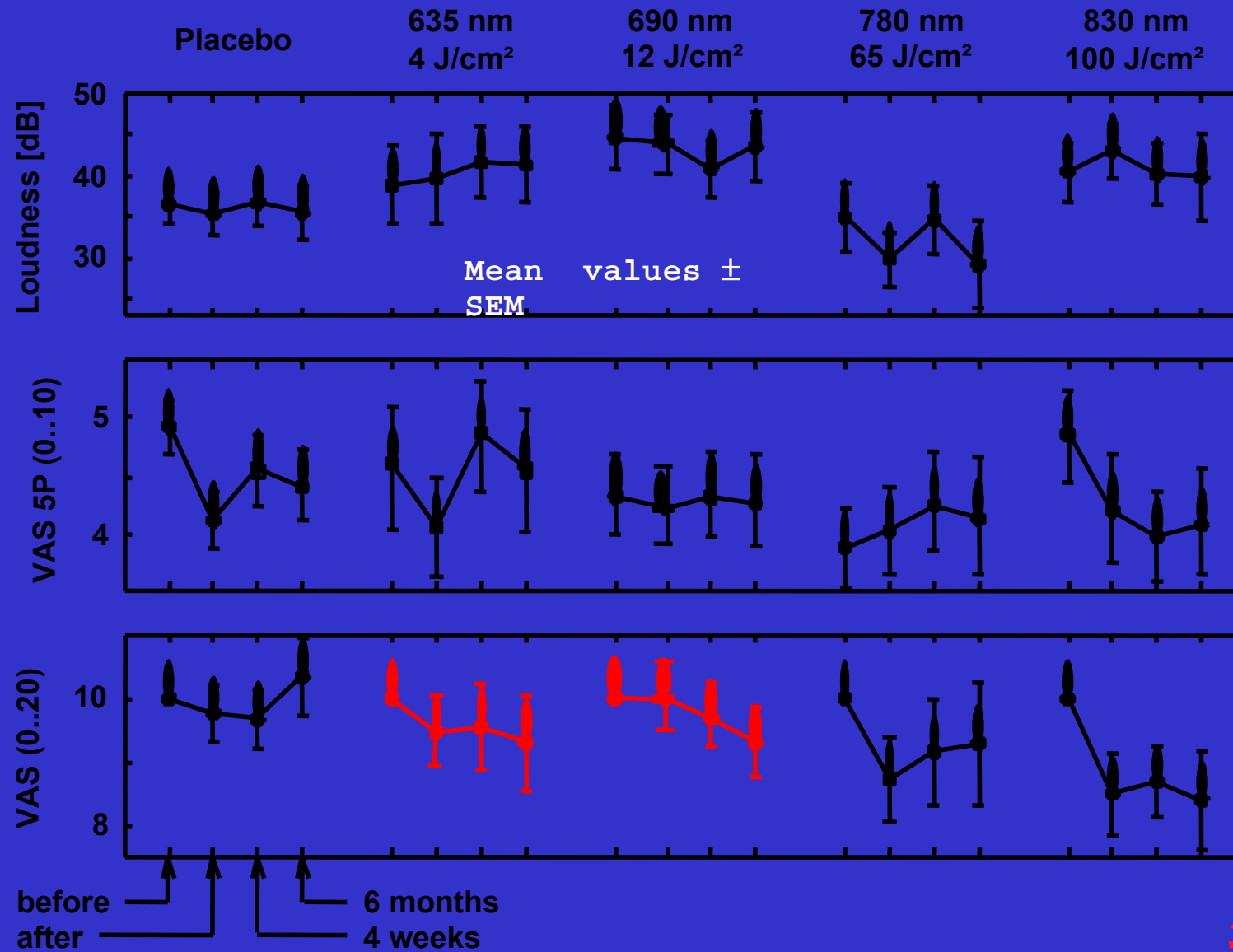
- Before first treatment
- After last treatment
- 4 weeks after last treatment
- 6 months after last treatment

Tinnitus and audiometric assessment:

- Loudness [dB] via noise matching
- VAS (visual analogue scales; 0 .. 10) for 5 parameters: loudness, inconvenience, control, disposition, stress
- Total tinnitus score VAS (tinnitus 0 .. 20, initial value: 10)
- *Goebel-Hiller-Score (not yet evaluated)*
- *Hearing threshold (not yet evaluated)*



Preliminary results



Summary

- Double blind, randomized, prospective study
- Dosimetry is specific for acoustic frequency
- No side-effects
- Tendency of tinnitus improvement at 690-830 nm (VAS 5 P) and at 635-830 nm (Total VAS score)
- Chance for possible effects at higher light doses (65-100 J/cm²)
- Significant effects for special sub groups?
- Further statistical analysis is on work



Comment

Double-blind study for low-level-laser-therapy in patients with chronic cochlear dysfunction Stefan Tauber et al.

Study

In a double-blind placebo-controlled study low-level-laser light was applied to 175 patients with chronic tinnitus. The patients received 3 single irradiations with different diode-lasers with $\lambda = 635\text{-}830\text{ nm}$ and dosages from 4 to 100 Joule / cm^2 . Irradiation was according to acoustic-specific dosimetry. Evaluation was performed before treatment and after last irradiation (immediately, 4 weeks, 6 months). Assessment of tinnitus has been performed by narrow band noise matching (NBN in dB) of tinnitus loudness. Visual analogue scales (VAS) were used for five different parameters (VAS SP 0 to 10) such as loudness, inconvenience, control, disposition and stress. Total tinnitus score (VAS 0 to 20) was evaluated, too.

Results

Low level laser therapy for chronic tinnitus has been well tolerated without side-effects. In general higher dosages caused to a stronger attenuation of tinnitus.

In comparison to placebo

- tinnitus loudness is improved by laserlight of 780 nm.
- tinnitus is attenuated by laserlight between 690 and 830 nm concerning visual analogue scales of 5 different parameters (VAS SP).
- total tinnitus score (VAS) has been improved by irradiation with laserlight of 635 up to 830 nm.

Regarding those results, **RESONANCE** offers an innovative and secure way of effective tinnitus treatment in patients with chronic tinnitus. **RESONANCE** is a new therapeutic system for chronic cochlear tinnitus without risks of side-effects.

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