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What is the Efficacy of "Soft" and "Mid" Lasers in Therapy of Tendinopathies?

A Double-Blind Study

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Summary. The efficacy of "athermic" lasers (HeNe $\lambda = 632.8$ nm and IR diode $\lambda = 904$ nm) in the treatment of tendinopathies was investigated in a randomized double-blind study. On 10 consecutive days, 64 patients (32 therapy, 32 placebo) were treated for 15 minutes each with a switched-on or switched-off laser under otherwise identical conditions. The extent of movement in involved joints (neutral 0 method) and rating on a pain scale for resting pain, movement pain, and pressure pain before treatment, after treatment, and 2 weeks after conclusion of therapy, as well as infrared thermography, served to check therapy. After the end of therapy, a significant reduction ($P = < 0.001$) of 50% was shown for resting pain as well as reductions of 30% for movement and 30% for pressure pain. This result was identical in the therapy group and in the placebo group. There was also no indication of a different result of therapy between the therapy and placebo groups with regard to the thermographic control and the extent of movement. The breakdown of the data in terms of age, sex, and duration of disease did not provide any indications of different results for placebo or therapy. It was striking that the patients who reported sensations during or after the treatment (irrespective of whether pleasant or unpleasant) had a greater reduction of pain than the patients without sensations. This laser therapy thus did not show any effect above and beyond that in the untreated group in our double-blind clinical study.

Various manufacturers offer "athermic" lasers (low-power lasers) for treatment of a large number of clinical pictures in the most diverse specialist disciplines of medicine. More rapid "cure" and speedy freedom from pain are mostly promised, and these are documented with numerous references to case reports in the literature. The proponents of this form of therapy explain the mechanism of action as a "direct effect" (key word: "biostimulation") of laser light on certain cell structures, which is not specified in detail, and refer to studies on frequency-specific mechanisms of excitation and absorption of electromagnetic radiation in cell cultures [11, 15, 17]. All manufacturers emphasize that this is a direct effect of laser light and not the result of local hyperthermia. In the orthopedic field, good results are assured for rheumatic diseases, arthroses, sport injuries, tendinopathies, etc.

The instruments on the market can be subdivided into two groups:

1. Helium-neon (HeNe) laser, $\lambda = 632.8$ nm, visible spectrum range, "red light"; continuous emission, continuous wave output 1–10 mW.

2. Infrared laser (gallium-aluminum-arsenic = GaAlAs), $\lambda = 904$ nm, nonvisible spectrum range, near infrared; pulsed emission – from 600 imp/s up to 5000 imp/s, impulse length less than 200 ns, effective continuous wave output between 1 and 30 mW, impulse peak outputs up to 70 W (manufacturer's specifications).

The HeNe laser is offered mainly for "laser acupuncture," for "laser stimulation therapy," and to promote wound healing. In addition, it serves as a visible target laser in the infrared (IR) laser with the objective of illuminating an area similar to that reached by the invisible IR radiation. The IR laser is frequently but incorrectly credited with a greater depth of penetration (see Discussion), and it is ac-

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cordingly offered for therapy of more deeply situated diseases. Clever in terms of advertising psychology, but misleading, the manufacturers of IR lasers mostly report the impulse peak performance as being up to 70 W; it is expressly emphasized here that the effective output of these instruments is always in the mW range, and this is necessarily the case, since otherwise very much more stingent regulations will have to be observed by manufacturers and users. The designation "mid" laser is misleading: these are also "soft" lasers with an effective output of a few mW/cm^2. Since the pause duration in this pulsed laser is up to 10^4 times as long as in the impulse laser of about 100 ns, even here there is a value of only a few mW for the effective output. An extra designation for these pulsed lasers (mid lasers, i.e., lasers with "middle" energy) is misleading and unjustified. The output density (i.e., output per irradiated surface area) is once more reduced by a simple divergent lens system or mechanical device ("scanner") for the illumination of a larger area (exception: "laser acupuncture"). The extremely low output density (less than 1 mW/cm^2) also explains the designation "athermic" laser. The tissue warming is so minimal that it cannot be detected by sensory nerves or by measurement techniques. The substantially greater technical problems at high outputs will not be dealt with here.

A survey of the literature on this topic reveals that a large number of references are cited (several hundred by one manufacturer alone [9]), but hardly any randomized double-blind studies to demonstrate clinical efficiency and which meet recognized biometric norms are to be found [7, 8, 14, 16]. Since this method of treatment is becoming increasingly more widespread, it appeared to us to be urgently necessary to carry out a study to demonstrate clinical efficiency.

Patients and Methods

We were able to include 64 patients (32 women, 32 men) aged between 17 and 76 years, mean 47.05 years, with the confirmed diagnosis of tendinopathy in a randomized double-blind study. Patients with multiple degenerative orthopedic diseases or additional neurological diseases were not included in the study. In all, we treated 41 patients with an epicondylopathy of the radial or ulnar humerus and 23 patients with other tendinopathies. Without knowledge of the person or the diagnosis, we randomly assigned 32 patients each to the therapy or the placebo group. The groups were equivalent with regard to age (therapy: 17–76 years, mean 46.5 years; placebo: 18–73 years, mean 48.4 years), sex distribution, and duration of the condition before laser therapy. All patients were examined before treatment, after the tenth treatment, and 2 weeks after conclusion of the treatment by one and the same doctor who was not informed as to whether the patient belonged to the therapy or to the placebo group.

Resting, movement, and pressure pain and, with irritation of joints, also the extent of movement according to the neutral 0 method, as well as pleasant, unpleasant, or no sensations during of after the laser treatment were reported by means of a standardized investigation plan. Resting pain, movement pain, and pressure pain were rated according to a simple scale:

0 = no pains
1 = little pains
2 = severe pains
3 = intolerable/very severe pains

In superficially situated tendinopathies, infrared telethermography was additionally performed with side comparison before, directly after, and 2 weeks after conclusion of the laser treatment. We did not give the patients pharmacotherapy or any physical therapy for the period of their participation in the study. In addition, they were urgently requested not to take any drugs on their own during the laser treatment.

In the therapy group, the patients were treated ten times for 15 min/day on consecutive days, with a pause at the weekend in accordance with the manufacturer's specifications. The distance between the laser and the skin was about 10 cm, and the skin was depilated and cleansed with 70% alcohol before each treatment. Regular checks were carried out in the patients of the therapy group with a simple IR detector to ensure that IR light was emitted. In addition, we measured skin temperatures during the treatment in 16 patients.

The HeNe laser beam (10 mW in accordance with manufacturer's specifications) was centered on the main point of pain reported by the patient, illuminating an area of about 4 cm^2. The IR laser beam (GaAlAs laser, $\lambda = 904$ nm, pulsed emission with 1200 impulses/s, impulse length less than 200 ns, effective power output up to 30 mW, according to the manufacturer's specifications) coupled with this should give a power density of up to 7.5 W/cm^2. The patients were informed about possible dangers (eyes) and had to wear laser-protection glasses during the entire treatment.

In the placebo group, the procedure was identical, with the sole exception that neither the HeNe laser nor the IR laser were turned on. Beeping and flashing lights at the beginning and end of the treatment were manipulated by the treating physician in such a way that the patient had to gain the impression of an actual treatment. Attention was paid to skin cleaning, wearing of the protective glasses, and informing the patient of dangers. Reference to the invisibility of the IR laser radiation was always sufficient as an explanation for the treatment situation.

The statistical analysis of the results of therapy was carried out with the paired Student's t-test.

Results

In accordance with our measurements in the therapy group, the laser instruments investigated here are properly designated as "athermic". We were able to detect no raised temperature during treatment either in infrared telethermography or with laid-on temperature sensors. It is thus very probable that local warming is to be ruled out as a mechanism of action (resolution of the temperature measurement $\Delta T = 0.1$°C).

Thermography exclusively registers the skin temperature, so that only superficially situated tendino-

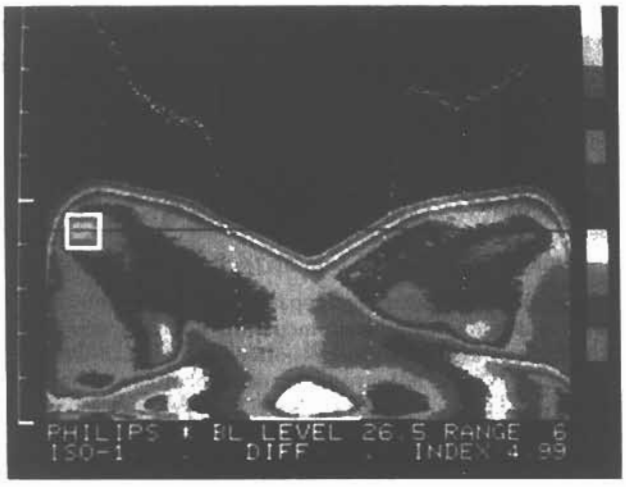

Fig. 1. Thermography of a radiohumeral epicondylopathy

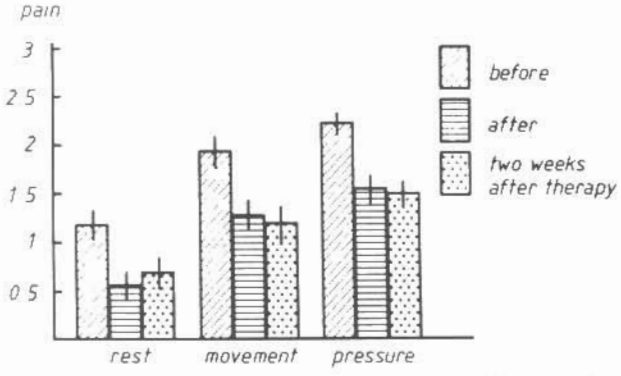

Fig. 2. Reduction of pain in therapy group according to scale

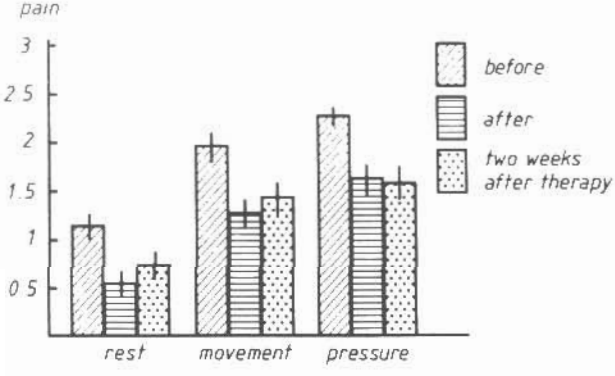

Fig. 3. Reduction of pain in placebo group according to scale

pathies are accessible. Thermography therefore cannot be used in the region of the shoulders or the hips. We applied this method above all in epicondylopathies, achillodynias, and other superficially situated tendinopathies without a thick covering of soft tissue (Fig. 1).

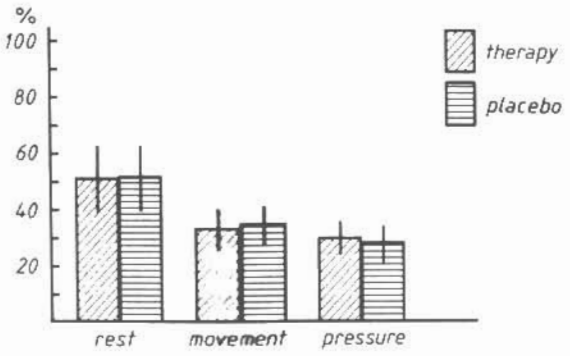

Fig. 4. Comparison of two groups with respect to percentage of pain reduction

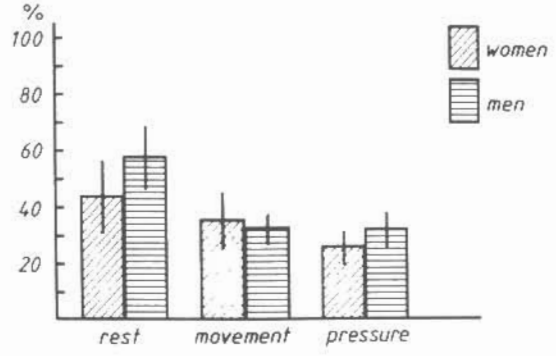

Fig. 5. Comparison of women and men with respect to percentage of pain reduction

Overall, 43 patients with superficial findings were investigated thermographically. Local warming at the point of pain before the beginning of therapy was shown for 41 patients in the side comparison and was compared with that for subjects in a 0 series under defined investigation conditions. In two patients hyperthermia was not found despite a superficially located tendinopathy. Directly after ten treatments, the ratio was 33:10, and 2 weeks after conclusion of treatments 35 findings were hyperthermic and eight nonhyperthermic. In three patients with a marked hyperthermia before and after therapy, surgery was performed later. Twelve weeks after operation, hyperthermia could no longer be detected in the side comparison in all patients who were free of pain. It is crucial that there was no thermographic difference between the therapy and the placebo group with regard to degree and decline of hyperthermia.

The statistical analysis of the pain scale showed that a significant reduction ($P < 0.001$) had occurred both in resting pain and in movement and pressure pain. There was no difference between the therapy group and the placebo group (Figs. 2, 3) with regard to this pain reduction.

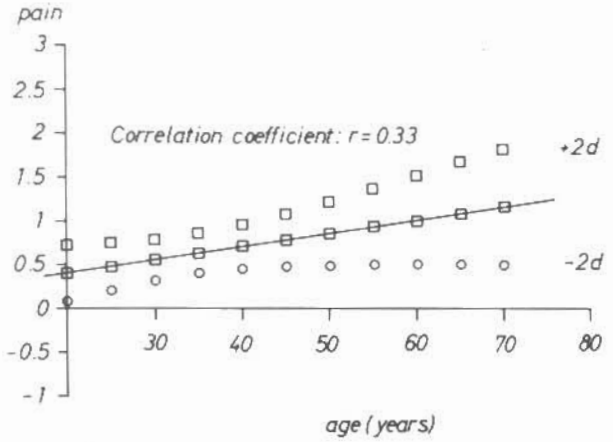

Fig. 6. See text

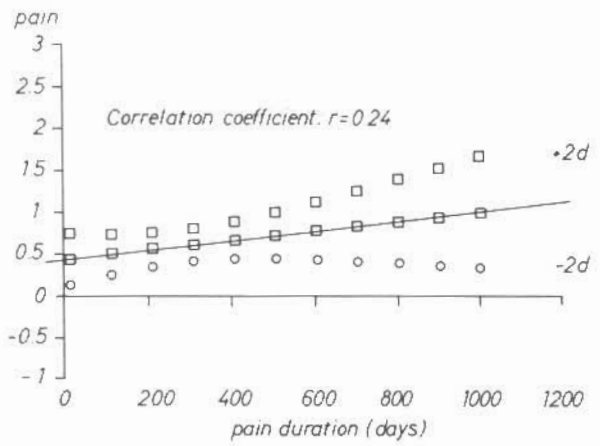

Fig. 7. See text

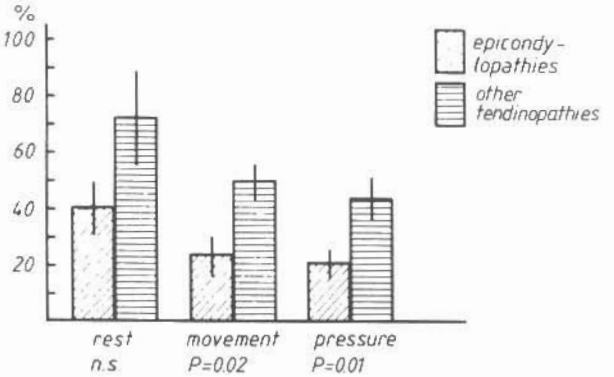

Fig. 8. Comparison of epicondylopathies and other tendinopathies with respect to percentage of pain reduction

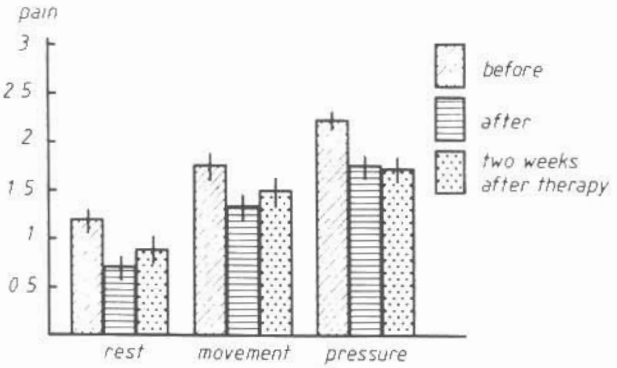

Fig. 9. Assessment of pain according to scale in 41 epicondylopathies before and after therapy

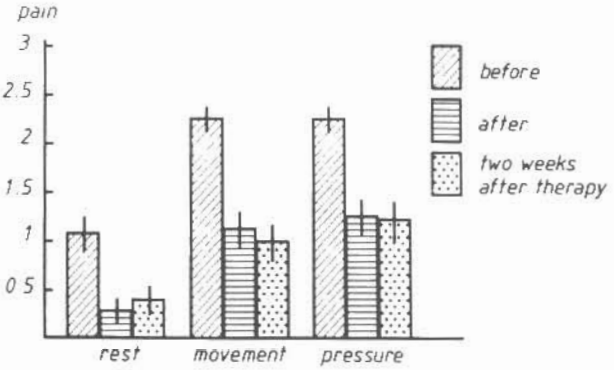

Fig. 10. Assessment of pain according to scale in 23 tendinopathies before and after therapy

Figure 4 illustrates this result once more with a direct comparison between therapy and placebo. Marked pain reduction of 50% for resting pain and of about 30% each for movement and pressure pain after therapy was found, but the results were identical for patients treated and those not treated with laser. Expressed in absolute figures, 23 patients were improved, four unchanged, and five worse in the therapy group after conclusion of the treatment; in the placebo group 26 had improved, three were unchanged, and three had deteriorated; i.e., the laser therapy did not have any effect on the result of treatment. Further statistical analysis of the pain scales revealed that the result of therapy was not sex specific (Fig. 5). The degree of pain reduction correlated neither with the age of the patients ($r = 0.33$) nor with the duration of disease ($r = 0.24$) (Figs. 6, 7).

The extent of movement measured according to the neutral 0 method for extension/flexion and pronation/supination in the epicondylopathies likewise did not show any significant differences for the therapy or placebo groups. The non-epicondylopathies showed a significantly better reduction of pain than the epicondylopathies – again, irrespective of placebo or therapy (Figs. 8–10). The report of sensations during therapy allowed subdivision into three groups: patients without sensations ($n = 25$) responded least well to the treatment; the others

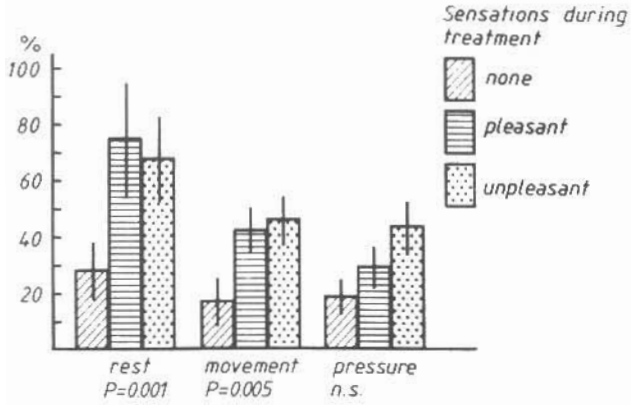

Fig. 11. Sensations reported during treatment as related to percentage of pain reduction

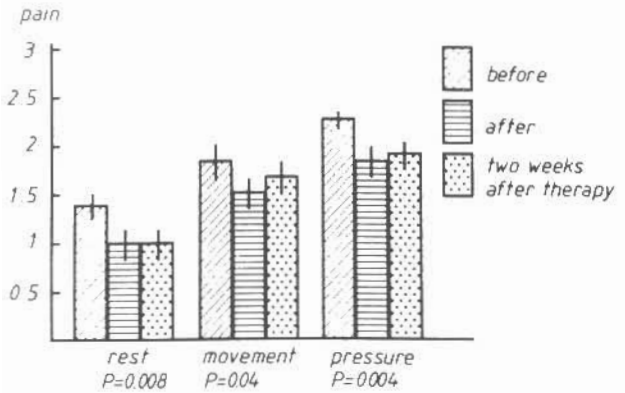

Fig. 12. Assessment of pain according to scale in 25 patients who felt no sensations during therapy

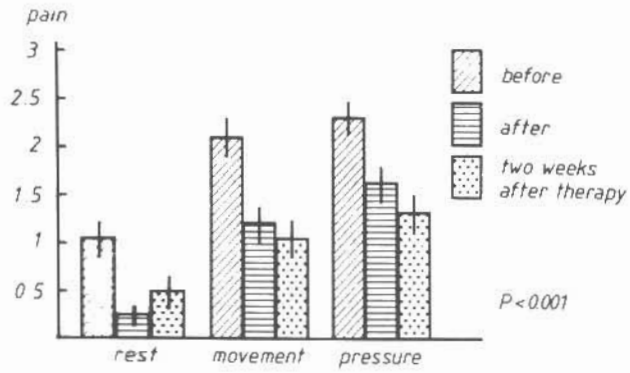

Fig. 13. Assessment of pain according to scale in 19 patients who experienced pleasant sensations during therapy

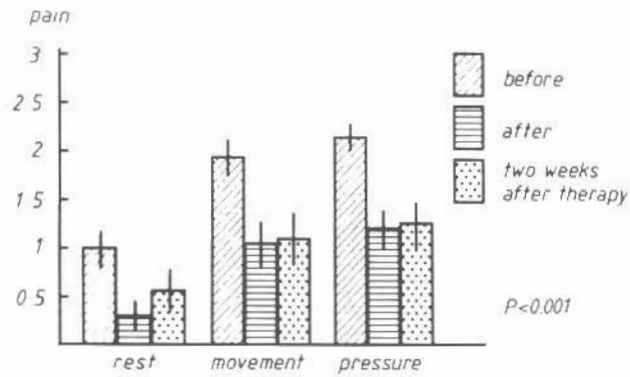

Fig. 14. Assessment of pain according to scale in 20 patients who experienced unpleasant sensations during therapy

showed a significantly higher percentage of pain reduction, irrespective of whether pleasant or unpleasant sensations had been felt. This also applied regardless of whether the patients belonged to the therapy or to the placebo group (Figs. 11–14).

Discussion

First of all, it is to be emphasized that we did not find any differences in the extent of pain reduction between the therapy group and the placebo group. The results of measurements in accordance with the neutral 0 method for extension/flexion or pronation/supination (epicondylopathies) and the thermographic controls likewise did not show any significant difference that might have pointed to a greater success in the therapy group or in the placebo group. Thus, an effect of IR or HeNe laser in treatment of tendinopathies above and beyond the placebo effect was not observed. There was no doubt a reduction of pain in the patients, and the thermogram in some cases indeed showed a reduction of the hyperthermia in the region of superficially situated tendinopathies, but there are sufficient obvious explanations for these effects. First and foremost, and doubtless even elicited by the word "laser" and intensified by a futuristic design of the instruments, there is an appreciable placebo effect. In addition, the patients are often highly motivated by the long duration of the disease to use what is in some cases the last chance of conservative therapy in hopes of being able to avoid an operation. During the laser treatment, the patients are consciously or unconsciously concerned with sparing and immobilizing their diseased joints, and in addition they are not exposed daily to the damaging agent "sport". However, how does the large number of reports of success arise?

For better appraisal of these often uncritically listed case reports, we refer to the description of our results without comparison with the placebo group. The average alleviation of pain in our therapy group (50% for resting pain and 30% for movement and pressure pain) shows good agreement with the values

specified by the manufacturers. However, this result is identical with that for the placebo group. The quality of the ostensibly double-blind studies which are obligingly distributed by the manufacturers of the mid laser instruments may be termed at least doubtful [9, 14, 16]. In some cases, the authors have corrected their initially positive appraisal [18]. In the meantime, we have been able to gather clinical experience with various "athermic" lasers and have seen no essential physical, technical, or clinical medical differences. With the same wavelength of $\lambda = 904\,\text{nm}$ or $\lambda = 632.8\,\text{nm}$ and, by definition, dispensing with high-output densities (otherwise these instruments will no longer be "athermic") as well as dispensing with monochromasy and coherence, a high consistency of the instruments is automatic. It remains to be stated with regard to the "fundamental studies" [11, 15, 17] that to our knowledge, biological excitation mechanisms, which would be present only at $\lambda = 632.8\,\text{nm}$ or $\lambda = 904\,\text{nm}$, have not been demonstrated. In purely theoretical terms, normal sunlight is likely to be far more advantageous, since this would entail presentation of all the possibly biologically active frequencies, not only two.

The concept of the allegedly deep penetration of laser light also requires clarification. In penetration into homogeneous tissue, electromagnetic waves undergo an exponential attenuation. For such attenuation processes there are precise concepts, e.g., the half-value depth d 1/2; i.e., at a depth of penetration of d 1/2, only half of the initial intensity is present. For $\lambda = 633\,\text{nm}$, $d\,1/2 = 0.8\,\text{mm}$, for $\lambda = 904\,\text{nm}$, $d\,1/2 = 1.2\,\text{mm}$ [9]. It can be readily estimated from this that even at a depth of about 1 cm only 0.1% of the initial intensity, which is very low anyway, is present. The effect of the "athermic" lasers, if present at all, is already restricted in purely theoretical therms to the uppermost layers of the skin. It is to be emphasized once more that we were unable to detect any effects of "athermic" laser therapy in our clinical double-blind study above and beyond the effects in our placebo group. Our results show that the therapy of tendinopathies with "athermic" lasers is not effective, at least in clinical practice.

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