

Laser light - a new, non invasive treatment for Erectile Dysfunction: a placebo-controlled, single blinded pilot study

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--- See picture illustrations below ---

Background: In vitro and animal studies have shown that the application of laser light may induce vasorelaxation, which is the event that produces penile erection. The hypothesis was that application of laser light to the vascular bed of the penis might restore erectile function.

Purpose: To prove this hypothesis, a specifically designed device, emitting laser light, was externally applied to the penis of patients with erectile dysfunction (ED). This study has been conducted to prove the efficacy and safety of laser therapy for the treatment of ED.

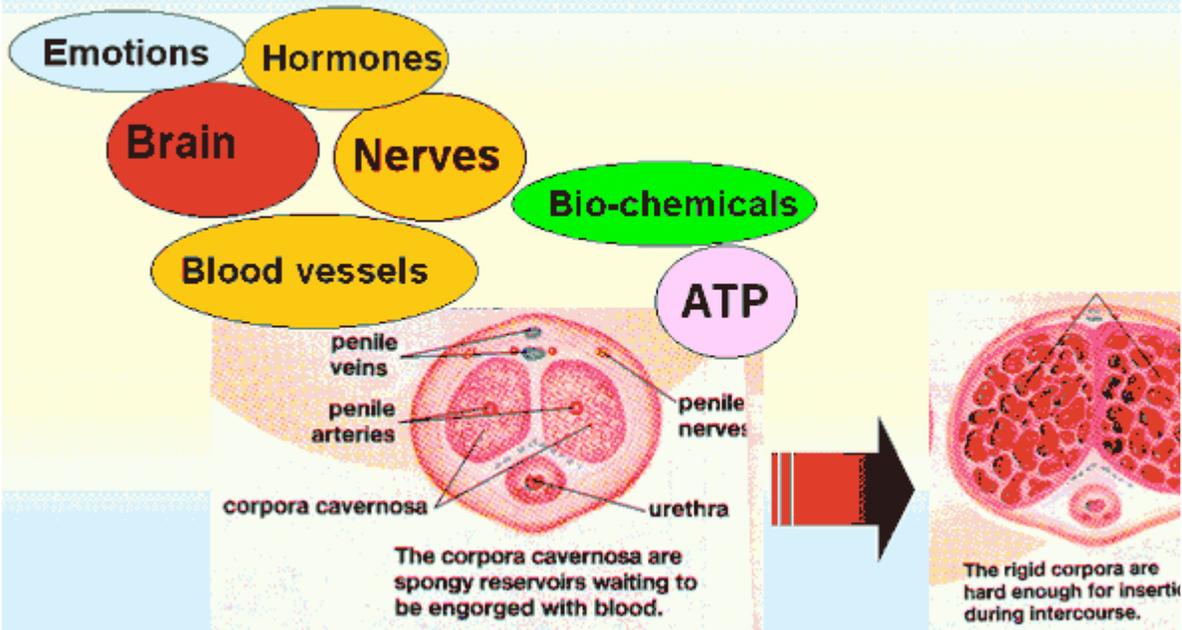
Material and Methods: 44 volunteers were randomly assigned to treatment with placebo or 808 nm GaAlAs laser light. 39 patients completed all treatments and follow up visit: 18 patients in the treatment group (A) and 21 in the placebo group (B). The treatments were delivered for 19 minutes, twice a week, total of 6 treatment sessions. The laser unit has 2 rows of 5 treatment points each and the unit is applied on the dorsal aspect of the penis, every row corresponds to the corpus cavernosum of the penis. Treatment is given for 20 minutes, twice a week, 6-8 times. Power of each diode is 150 mW. Questions 3 and 4, as well as the Erectile Function Domain from the International Index of Erectile Function (IIEF) assessed the improvement in ED.

Results: The baseline median values for questions 3 and 4 were identical in both groups - 2.0. In group B the median remained 2.0 after the treatment for question 3 and 4 while in group A it increased by 1.5 to 3.5 (for question 3 - $p=0.0536$; for question 4 - $p=0.03$). Median Erectile Function domain score (question 1-5 and 15) was 14 in group B and decreased to 12. In group A baseline score was 13 and it increased to 20.5 after treatment ($p=0.02$). Many patients in the treatment group reported occurrence of morning erections. Improvements were usually reported after the 4th or 5th treatment sessions. There were no adverse effects as a result of the treatment.

Discussion and Conclusion: The treatment performed by the laser parameters used in this study has showed improvement in ED. The improvement duration in average was of 6 month. Further studies are needed for optimization of treating parameters: wavelength, dose and sessions.

--- See pictures below ---

Erection - a complex process



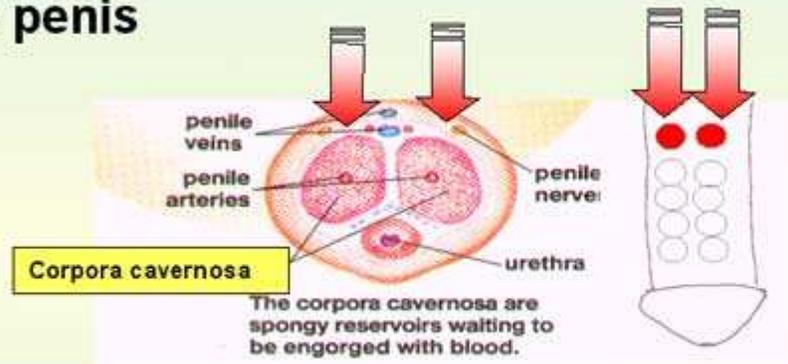
Nerve stimulation relaxes and dilates the smooth muscles walls of the blood vessels in the corpora

UPTIMUM (a patented device, method and technology)



Technology Principle

- Applying low power laser energy by “scanning the penis



- Treatment Head allows efficient energy transfer to the Corpora Cavernosa
- Treatment schedule: 6-8 treatments / 20 minutes each

Presumed laser mechanism of action on smooth muscle

