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HairMax LaserComb laser phototherapy device in the treatment of male androgenetic alopecia: A randomized, double-blind, sham device-controlled, multicentre trial.

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BACKGROUND AND OBJECTIVE: The use of low levels of visible or near infrared light for reducing pain, inflammation and oedema, promoting healing of wounds, deeper tissue and nerves, and preventing tissue damage has been known for almost 40 years since the invention of lasers. The HairMax LaserComb is a hand-held Class 3R lower level laser therapy device that contains a single laser module that emulates 9 beams at a wavelength of 655 nm (+/-5%). The device uses a technique of parting the user's hair by combs that are attached to the device. This improves delivery of distributed laser light to the scalp. The combs are designed so that each of the teeth on the combs aligns with a laser beam. By aligning the teeth with the laser beams, the hair can be parted and the laser energy delivered to the scalp of the user without obstruction by the individual hairs on the scalp. The primary aim of the study was to assess the safety and effectiveness of the HairMax LaserComb laser phototherapy device in the promotion of hair growth and in the cessation of hair loss in males diagnosed with androgenetic alopecia (AGA).

METHODS: This double-blind, sham device-controlled, multicentre, 26-week trial randomized male patients with Norwood-Hamilton classes IIa-V AGA to treatment with the HairMax LaserComb or the sham device (2 : 1). The sham device used in the study was identical to the active device except that the laser light was replaced by a non-active incandescent light source.

RESULTS: Of the 110 patients who completed the study, subjects in the HairMax LaserComb treatment group exhibited a significantly greater increase in mean terminal hair density than subjects in the sham device group ($p < 0.0001$). Consistent with this evidence for primary effectiveness, significant improvements in overall hair regrowth were demonstrated in terms of patients' subjective assessment ($p < 0.015$) at 26 weeks over baseline. The HairMax LaserComb was well tolerated with no serious adverse events reported and no statistical difference in adverse effects between the study groups.

CONCLUSIONS: The results of this study suggest that the HairMax LaserComb is an effective, well tolerated and safe laser phototherapy device for the treatment of AGA in males.

PMID: 19366270 [PubMed - indexed for MEDLINE] globe by pursuing additional international medical device registrations and further establish the credibility of the HairMax LaserComb® in the global marketplace".