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Randomized clinical trial evaluating mETDRS versus normal or high-density micropulse photocoagulation for diabetic macular edema.

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Abstract

PURPOSE: To compare modified Early Treatment Diabetic Retinopathy Study (mETDRS) focal/grid laser photocoagulation with normal-density (ND-SDM) or high-density (HD-SDM) subthreshold diode-laser **micropulse** photocoagulation for the treatment diabetic macular edema (DME).

METHODS: A prospective, randomized, controlled, double-masked clinical trial with patients with previously untreated DME and best corrected visual acuity (BCVA) worse than 20/40 and better than 20/400. Patients were randomized to receive either mETDRS focal/grid photocoagulation (42 patients), ND-SDM (39 patients), or HD-SDM (42 patients). Before treatment and 1, 3, 6, and 12 months after treatment, all patients underwent ophthalmic examinations, BCVA, color fundus photography, fluorescein angiography, and optical coherence tomography (OCT).

RESULTS: At 12 months, the HD-SDM group had the best improvement in BCVA (0.25 logMAR), followed by the mETDRS group (0.08 logMAR), whereas no improvements were seen in the ND-SDM group (0.03 logMAR). All groups showed statistically significant progressive reduction of central macular thickness (CMT) throughout the study ($P < 0.001$). The HD-SDM group exhibited the greatest CMT reduction (154 μm), which was not significantly different from that of the mETDRS group (126 μm; $P = 0.75$).

CONCLUSIONS: At 1 year, the clinical performance of HD-SDM was superior to that of the mETDRS photocoagulation technique, according to the anatomic and functional measures of improvement used in this investigation. A rationale for this

treatment modality as a preferable approach is suggested, and the precise role of subthreshold **micropulse** laser treatment may become more defined as experience grows, guided by optimized treatment guidelines and more comprehensive trials. (Clinicaltrials.gov number, NCT00552435.).

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