Abstract

Purpose
To evaluate the safety and efficacy of CO2 laser–assisted deep sclerectomy surgery (CLASS) in patients with open angle glaucoma.

Methods
A prospective single–arm, nonrandomized clinical investigation for the evaluation of technology. 43 eyes of 33 consecutive patients diagnosed with either primary open angle glaucoma, pseudoxfolliation glaucoma or secondary glaucoma of ocular trauma and uveitis who were the candidates for glaucoma filtration surgery were included. The average age of the patients was 43.3 ± 17y. Laser–assisted deep sclerectomy using a CO2 laser system was performed in all patients. A 1/3 to 1/2 thickness of scleral flap was created, cut off part of Tenon's Capsule for some younger patients. Anti–fibrotic material of 0.04% mitomycin C or 5–FU for 120 seconds were applied under the scleral flap and under the conjunctiva. A CO2 laser with a beam–manipulating system was used to achieve deep scleral lake (reservoir) and for unroofing of Schlemm’s canal zone. Visual acuity, complete ophthalmologic examination, and intracocular pressure (IOP) were measured and documented at baseline, 1 day, 1 week and at 1, 3, 6, and 12 months. Complete success was defined as $5 \leqslant \text{IOP} \leqslant 21$ mmHg with no medication at the 12 month endpoint visit. Qualified success was defined as a similar IOP reduction with medication.

Results
The preoperative IOP of 31.67 ± 9.24 mmHg (mean ± SD) dropped to 14.11 ± 3.42 mmHg at 6 months and 17.46 ± 3.85 mmHg at 12 months postoperatively. The complete success rate after 12 months was 61.5%, whereas qualified success was 92.3%.

Conclusion
CLASS procedure is a safe and effective procedure for open–angle glaucoma patients.