

CO₂ laser-assisted sclerectomy effective, easy to learn

The procedure was analyzed in patients with primary open-angle glaucoma and pseudoexfoliation glaucoma.

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Clinicians can become adept at a simplified sclerectomy procedure for glaucoma after performing it only a few times, according to a co-author of a study on the technique.

Ehud I. Assia, MD, said that CO₂ laser-assisted sclerectomy surgery (CLASS) is also significantly safer than manual non-penetrating filtration surgery.

“The main advantage of CLASS is that it is a non-penetrating procedure in most cases,” Assia said. “The laser does very effectively what surgeons may find technically challenging using the manual technique. Leaving a very thin tissue of only a few microns requires high skills and considerable experience.”

CLASS includes CO₂ laser ablation of thin scleral tissue layers to achieve aqueous humor percolation and can be performed alone or coupled with cataract surgery. The procedure is performed in Europe, Asia, South and Central America, and Canada. In the U.S., it is in the FDA approval pipeline.

“The CLASS technique is quite easy to learn, and surgical technique is mastered after only a few cases,” Assia said.



Ehud I. Assia

“Any surgeon who can do a flap can utilize the CLASS technology. ... CLASS is intended for open-angle cases. However, successful operations were reported also in narrow-angle eyes,” he said.

About the study

The technique’s safety and efficacy were tested in a single-arm, open-label study Assia co-authored. The study included 108 eyes of 108 patients diagnosed with primary open-angle glaucoma or pseudoexfoliation glaucoma.

All of the patients were included in the study’s safety analysis, and 97 were included in the efficacy analysis. The mean patient age was 69.3 ± 12.8 years. The mean preoperative IOP was 25.8 ± 5.4 mm Hg.

The procedure was considered a complete success if IOP was reduced at least 20% to between 5 mm Hg and 18 mm Hg with no dependence on medication or need for further surgery. Qualified success was defined as the same conditions with or without medications at 1, 2 and 3 years after surgery.

During each surgery, a 5 mm × 5 mm scleral flap was created at the limbus and into the clear cornea. The surgeon repeatedly applied laser over Schlemm's canal to ablate the thin layers of sclera.

Ablation stopped when aqueous percolation occurred. The percolating aqueous absorbed the laser energy and kept it from the rest of the scleral tissue.

Results

Mean postoperative IOP decreased to 13.5 ± 3.8 mm Hg, 13.5 ± 4.1 mm Hg, 13 ± 3.1 mm Hg and 14.2 ± 2.9 mm Hg at 6 months, 1 year, 2 years and 3 years, respectively. At the same respective postoperative time points, the mean percent IOP decrease was $45.8\% \pm 16.8\%$, $45.1\% \pm 19.5\%$, $46.8\% \pm 15.5\%$ and $42.5\% \pm 14.4\%$.

Complete success was achieved in 60.2%, 57.9% and 47.8% of patients at 1, 2 and 3 years, respectively. In the same time frame, qualified success was seen in 79.6%, 91.2% and 84.8% of patients.

Concerning safety, the authors reported five perforations (4.6% of patients) due to over-ablation of the scleral tissue. The authors listed 11 different complications related to the procedure. Early bleb leak and iris incarceration were the most common, with each affecting nine patients.

Noa Geffen, MD, the study's lead author, presented 5-year postoperative results at the European Society of Cataract and Refractive Surgeons meeting in Barcelona in September 2015. The results at the 5-year follow-up were very similar to the 3-year results, Assia said. Mean IOP was measured at 14.3 mm Hg at the 5-year mark.

The qualified success rate at 5 years was 86.4%, slightly higher than at 3 years. – *by Joe Green*

Reference:

Geffen N, et al. *J Glaucoma*. 2016:doi:10.1097/IJG.0000000000000437.

For more information:

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Disclosure: Assia reports he is the inventor of the CLASS technology and has a financial interest in IOptima. The study was supported in part by grants from IOptima.