CO_2 Laser-assisted Sclerectomy Surgery, Part II: Multicenter Clinical Preliminary Study

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Purpose: To evaluate the efficacy of CO_2 laser-assisted sclerectomy surgery (CLASS) in primary and pseudoexfoliative open-angle glaucoma.

Materials and Methods: Patients for primary filtration surgery underwent CLASS with a CO_2 laser system (OT-134-IOPtiMate, IOPtima Ltd., Ramat Gan, Israel). This self-controlled system gradually ablates and removes scleral layers until percolating fluid absorbs the energy, attenuating further tissue ablation. Intraocular pressure (IOP) was measured at baseline, 1, 2, 4, and 6 weeks, and 3, 6, and 12 months, respectively. Complete success was defined as $5 \leq IOP \leq 18$ mm Hg and 20% IOP reduction with no medication at a 12-month endpoint visit, and qualified success as the same IOP range with or without medication.

Results: Thirty of 37 patients completed 12 months of follow-up. Mitomycin C was used in 25 procedures (83.3%). The mean baseline IOP of 26.3 ± 7.8 mm Hg (mean ± SD) dropped to 14.4 ± 3.4 and 14.3 ± 3.1 mm Hg at 6 and 12 months, respectively, with 42.4% and 40.7% IOP reduction at 6 and 12 months, respectively ($P < 0.001$). Complete success was achieved by 76.7% and 60% of the patients at 6 and 12 months, respectively, whereas qualified success was achieved by 83.3% and 86.6% of the patients at 6 and 12 months, respectively. Complications were mild and transitory with no sequela.

Conclusions: Short-term and intermediate results suggest that CLASS may become a simple, safe, and effective means of choice for the treatment of open-angle glaucoma.

Key Words: glaucoma, filtration, nonpenetrating deep sclerectomy, laser surgery

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The pioneering work of Krasnov[1] in 1969 and the various modifications that succeeded it[2–8] have led to the development of a filtration procedure known as the nonpenetrating deep sclerectomy (NPDS). Conventional trabeculectomy has so far remained the gold standard for glaucoma surgery, despite its potential vision-threatening complications, including shallow or flat anterior chamber, hypotony, infection, choroidal hemorrhage, and malignant glaucoma.[9] NPDS is known to have a higher safety profile compared with trabeculectomy[10] but one of the main drawbacks of the procedure is its technical difficulty. The procedure requires dissection of 2 scleral flaps; superficial and deep, unroofing of the Schlemm canal and exposure of the juxtacanalicular trabeculum, all of which are essential for allowing effective fluid percolation.[6] Inadvertent perforation of the thin trabecular membrane during these manual manipulations is a frequent complication, occurring in 30% to 50% of the cases during the early stages of the learning curve,[7,11] whereas, in contrast, if the tissue is not cut deep enough, effective filtration may not be achieved.

CO_2 laser-assisted sclerectomy surgery (CLASS) procedure offers a potential alternative to the manual NPDS procedure for the management of medically uncontrolled glaucoma. The characteristics of the CO_2 laser, when used specifically to ablate the sclera, are elaborated in part I of this study. The unique characteristics of this laser were used to develop the simplified CLASS procedure, in which inadvertent perforations are unlikely.[12,13] The CO_2 laser effect ceases once aqueous starts to percolate preventing perforation. When used in conjunction with a micromanipulating system, the OT-134 (IOPtiMate; IOPtima Ltd., Ramat Gan, Israel), it can be used to achieve effective fluid percolation in a minimal or noninvasive procedure. The OT-134 also offers a scanning mode that further facilitates precisely controlled tissue ablation.

Experimental studies in animal eyes and in human cadaver eyes[12] confirmed that the novel CLASS technique is a relatively simple operation with a short learning curve. After preclinical trials using the OT-134, as described in the first part of this study, we evaluated the safety and efficacy of the CLASS technique in the clinical trials described here.

MATERIALS AND METHODS

This was a prospective, nonrandomized, noncomparative, multinational, multicenter clinical research study, conducted in accordance with the Declaration of Helsinki with the approval of the human research committee of the participating medical centers, with applicable regulations pertaining to good clinical practice. All participating patients or their legal guardians signed an informed consent document before the study was started. The clinical trials were carried out in Mexico city, Mexico (Drs Carrasco and Turati), in Madanapelee, India (Drs Thomas and Naveen), and in Moscow, Russia (Dr Anisimova).

Eligible candidates were adults (aged 18 years or above) of both sexes, with primary open-angle glaucoma or pseudoexfoliative glaucoma in the eye scheduled for surgery. The clinical diagnosis was based on the findings of glaucomatous optic neuropathy and of reliable and reproducible evidence of visual field defects typical of glaucoma. The criteria for glaucoma diagnosis were an open-angle and glaucomatous appearance of the optic nerve head, including thinning or notching of the neuroretinal rim accompanied by localized or diffuse retinal nerve fiber layer loss, cup/disc ratios being higher vertically compared with horizontally, and accompanied by correlated

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typical glaucomatous visual field loss. Primary filtration surgery was indicated in each participant, all of whom were on maximal tolerated ocular hypotensive medications and had an intraocular pressure (IOP) in the study eye of 18 mm Hg or higher, as measured with a Goldmann applanation tonometer during 3 consecutive visits over a 90-day period before enrollment. In addition, inclusion criteria were a phakic or pseudophakic study eye with a Shaffer angle wider than grade 2, no associated ocular disorders other than cataract, and no earlier surgical or laser intervention in the study eye other than clear corneal incision cataract surgery.

Patients with a history of an earlier intraocular surgery but clear corneal cataract extraction, a history of ocular laser procedures, or with a history of severe eye trauma were excluded from the study. Patients with any media opacity, which may interfere with optic nerve evaluation, and patients with a pupillary dilation diameter of < 2 mm, a best-corrected visual acuity of 20/200 or less in the fellow eye, known allergy to the study medications, with severe systemic disease or disabling conditions, or pregnant or nursing women were excluded from the study. Data from patients, who were followed up for less than 6 months, were excluded from the study.

The patients underwent a baseline examination within 2 weeks before surgery, and 1 day, 1, 2, 4, and 6 weeks, and 3, 6, and 12 months after surgery. Baseline examination included refraction, best-corrected visual acuity measured with a Snellen chart, comprehensive biomicroscopy, IOP assessment with a calibrated Goldmann applanation tonometer (average of 3 repeated measurements taken at the same time of the day $\pm$ 1 h), and fundus examination including optic disc evaluation. The patients also underwent gonioscopy, assessment of central corneal thickness (average of 3 repeated measurements), and 3 consecutive threshold 24-2 Humphrey perimetry tests, the last of which was carried out within 2 weeks before surgery.

Complications, both intraoperative and postoperative (early, through day 7, and late, beyond 1 wk), were classified according to severity and their relationship to the studied device. In addition, the incidence of intraoperative macroperforations, defined as perforations accompanied by iris prolapse or anterior chamber shallowing or both, was recorded.

Surgical Technique

All the operations were performed under subconjunctival anesthesia with 2% lidocaine without epinephrine. A 5.5-mm superior fornix-based incision was made and the Tenon capsule was dissected to expose the sclera. A partial thickness (one-third to one-half) rectangular limbal-based 5×5-mm superior scleral flap was dissected at the limbus into the clear cornea. The desired scanning area and the shape were set, the laser beam was focused, and the area to be treated was verified with a red laser (HeNe)-aiming beam (Fig. 1A). The CO_2 laser beam was then applied over an area that included the Schlemm canal until the outer wall of the canal was ablated and a scleral bed was formed. The residual charred tissue was wiped away with a BSS damp Weck-Cel sponge and ablation was continued until sufficient percolation was achieved along a region of at least 3 mm in length (Figs. 1B–D). The scleral flap was repositioned and secured with 2 interrupted 10-0 nylon sutures and a high-molecular weight ophthalmic viscosurgical device (Healon 5; Abbott Medical Optics, Santa Ana, CA) was applied beneath the flap. The conjunctiva was adequately secured with 10-0 nylon buried sutures (2 to 4), and the eye was patched with antibiotic and steroid ointments.

The application of mitomycin C (MMC) and its concentration were left to the surgeon's discretion. The

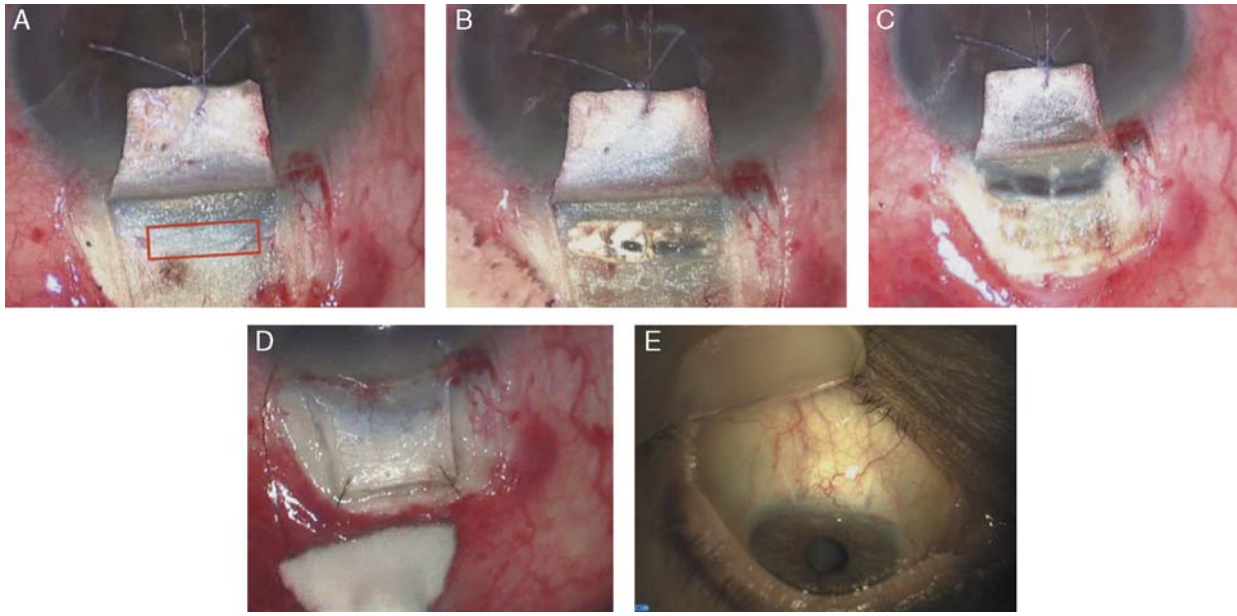

FIGURE 1. Surgical steps: (A) a carbon dioxide laser beam is applied under a scleral flap. Red aiming beams indicate the area to be ablated. When the lateral anterior dots are positioned at the surgical limbus (transition of transparent to gray zones) the ablated area will include the Schlem canal. B, Percolating aqueous is beginning to be seen at the ablated area. C, The desired surgical endpoint is achieved, percolation without scleral perforation. D, The superficial flap is sutured to its original position. E, Postoperative image of the conjunctival bleb 1 month later in the patient.

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patients were treated postoperatively with prednisolone acetate 1% drops (Pred Forte; Allergan, Irvine, CA) 6 times daily for 4 weeks and with moxyfloxacin 0.5% drops (Vigamox; Alcon Laboratories, Fort Worth, TX) 4 times daily for 2 weeks.

Surgeons working on their first cases with the CLASS procedure were permitted to convert to conventional trabeculectomy at any stage of the operation.

Postoperative Analysis

"Complete success" was defined as IOP values measured at the 6-month visit and 12-month endpoint, ranging between 5 and 18 mm Hg and IOP reduction $\geq 20\%$ compared with baseline IOP without additional hypotensive medication or repeat filtration surgery. The same finding, but also including patients who required hypotensive medications postoperatively, was defined as "qualified success." Failure was defined as an IOP value < 5 mm Hg and > 18 mm Hg, IOP reduction of $< 20\%$ compared with baseline IOP, severe loss of vision, or the need to undergo additional glaucoma surgery other than goniopuncture or needling. Goniopuncture and needling were not considered to be failures or adverse events, as both are commonly used as normal postoperative interventions that are required to maintain or augment the operative results of glaucoma surgeries.[13–15] The number of hypotensive medications being used by each patient at the time of the 6-month and the 12-month visits was compared with the baseline situation.

Statistical Methods

Continuous variables were summarized in terms of the mean, median, standard errors, and minimum and maximum values. Categorical variables were derived from frequency counts and percentages.

The 95% confidence intervals (CIs) were calculated for the mean IOP measurements and for the success rates at 6-month follow-up and the 12-month endpoint. A paired *t* test was used to determine the significance of the changes in IOP. All the tests applied were 2 tailed, and a *P* value of ≤ 0.05 was considered significant. The data were analyzed using the SAS software (SAS Institute, Cary, NC).

RESULTS

Between December 2007 and June 2008, 37 consecutive patients (37 eyes) who met the inclusion/exclusion criteria were enrolled in the study. Demographic data and baseline information on the recruited patients are summarized in Table 1.

Five patients were excluded from the performance analysis; in 4 cases because of inappropriate size and configuration of the manually performed scleral flap (too deep, causing perforation, or too small). In 1 of these 4 cases the ablation zone was larger than the dissected flap, and in the other 3 cases the surgeons opted to convert to conventional trabeculectomy. One patient was excluded as he underwent laser treatment (iridectomy) before this procedure, a major violation of the protocol. Moreover, this patient had Fuch endothelial dystrophy leading to corneal decompensation, which was another protocol violation. Although all 5 patients were excluded from the performance analysis, those who had received at least partial laser treatment were included in the safety analysis.

All the patients were followed in the prospective prescribed manner apart from 1 patient who was lost to follow-up 6 weeks after the procedure and another patient who died, 4 weeks after the procedure, from causes unrelated to the glaucoma surgery (complications of long-standing severe diabetes mellitus).

MMC was used in 25 patients (83.3%), of which 15 patients at a concentration of 0.02% for 2 minutes and 10 patients at a concentration of 0.04% for 1 minute. Shallow diffuse blebs were observed in all the cases (Fig. 1E).

Safety Analysis

Data on all 37 enrolled patients were used in the analysis of safety outcomes. No device malfunctions occurred. There were no device-related macroperforations. Four cases of microperforation, defined as small trabeculo-Descemet holes with no loss of depth of the anterior chamber, and no iris prolapse, were recorded. The anterior chamber remained deep and stable in all cases.

Mild transitory complications were recorded in some of the 30 patients who were included in the final analysis. These included 4 cases of superficial punctuate keratitis, microhyphema (1 case), infectious conjunctivitis (1 case), wound dehiscence (1 case), and wound leaks (2 cases, both at 1 surgical center in which the surgeon did not suture the scleral flap in half of the procedures, including those 2 cases). All complications resolved spontaneously or with conservative treatment in 1 month after the surgery. None of these ill effects was attributed specifically to the laser treatment. One patient developed choroidal detachment 1 week postoperatively; this was treated by drainage and was completely resolved.

Performance Analysis

The preoperative IOP of 26.3 ± 7.8 mm Hg (mean ± SD) dropped to 14.4 ± 3.4 mm Hg at 6 months and 14.3 ± 3.1 mm Hg at 12 months postoperatively (Fig. 2), yielding average IOP reductions at 6 and 12 months of 11.9 ± 7.4 mm Hg (42.4%) and 11.6 ± 8.4 mm Hg (40.7%), respectively ($P < 0.001$). Kaplan-Meier survival curves for probability of CLASS success are presented in Figure 3. The patterns of IOP reduction were similar at all 3 surgical

TABLE 1. Demographic Details and Baseline Data

Race No. (%)	Age (y), Mean ± SD (min-max)	Male Patients (%)	Diagnosis No. (%)	C/D Mean ± SD (min-max)	CCT (μm), Mean ± SD (min-max)
Hispanic, 14 (37.8%); Indian, 13 (35.2%); Caucasian, 10 (27%)	63.9 ± 11.8 (29.7–84.2)	21 (56.8)	POAG- 28 (75.7%) PEXG- 9 (24.3%)	0.8 ± 0.1 (0.4–1.0)	542.8 ± 32.9 (486–611)

CCT indicates central corneal thickness; C/D, cup-to-disc ratio; PEXG, pseudoexfoliative glaucoma; POAG, primary open-angle glaucoma.

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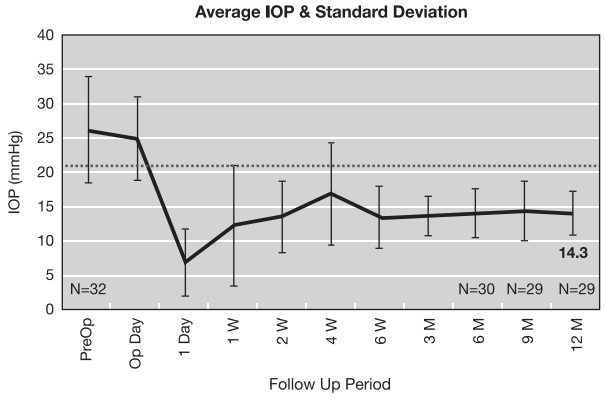

FIGURE 2. Cumulative intraocular pressure (IOP) ± SD measurements of 33 patients taken from the preoperative stage up to 12 months postoperatively. Average IOP reduction at 12 months = 41%. Dashed line indicates preoperative IOP level minus 20%.

centers in Asia (India), America (Mexico), and Europe (Russia) (Fig. 4). Defining success as $5 \leq IOP \leq 18$, and 20% IOP reduction, the complete success rates after 6 and 12 months were 76.7% (95% CI, 0.58-0.90) and 60% (95% CI, 0.40-0.77), respectively, whereas qualified success were 83.3% (95% CI, 0.65-0.94) and 86.6% (95% CI, 0.69-0.96), respectively.

The complete success rates after 12 months with and without MMC were 68.2% and 42.9%, respectively, not showing statistically significant difference ($P = 0.375$), whereas the rates of qualified success were 95.5% and 71.4%, respectively, not showing statistically significant difference either ($P = 0.136$).

The preoperative use of hypotensive medications per patient dropped from an average of 2.5 ± 1.3 to 0.1 ± 0.4 at 6 months and 0.6 ± 0.9 at 12 months ($P < 0.001$) (Fig. 5).

Eight needling procedures were carried out in 7 patients between 1 and 4 weeks (mean, 3.8 wk) after surgery. Two patients needed to undergo YAG laser goniopuncture procedures, carried out 2 and 4 weeks after the initial surgery.

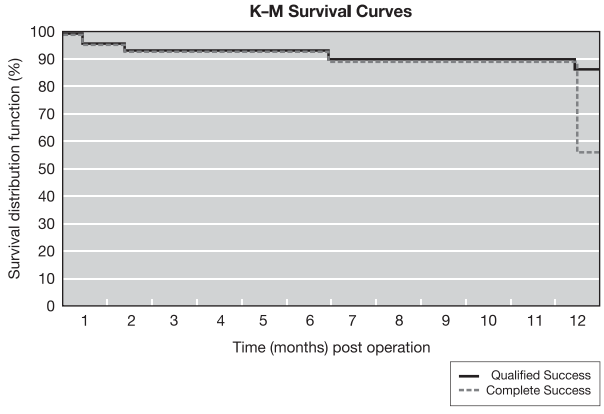

FIGURE 3. Kaplan-Meier survival curves for probability of CO_2 laser-assisted sclerectomy surgery success. Solid line indicates qualified success and dashed line indicates complete success.

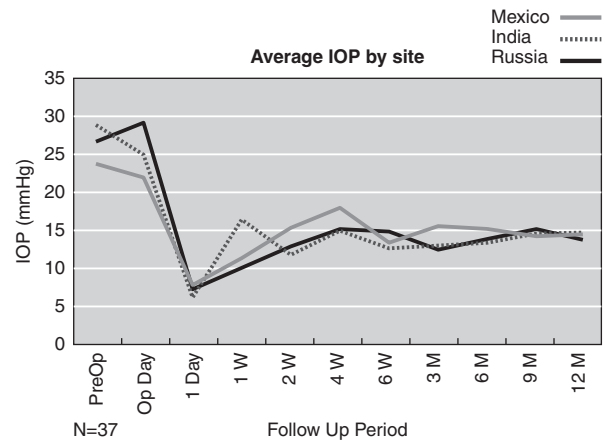

FIGURE 4. Intraocular pressure results at each of the participating surgical centers. The intraocular pressure patterns are almost identical in the 3 centers in the 3 different continents.

DISCUSSION

Nonpenetrating filtration surgery is a promising surgical procedure for open-angle glaucoma treatment. A review of the literature shows contradictory findings, however, with some studies describing NPDS as superior[2–4] and others as similar or inferior-to-standard trabeculectomy.[16–18] Despite its possible advantages, mainly its higher safety profile compared with those of other filtration procedures, many surgeons are reluctant to use this procedure. A meta-analysis of the results of manual NPDS[19] showed that a mean IOP of 21 mm Hg or lower at a mean follow-up of 31.3 months was achieved by 48.6% of patients without any implant or antimetabolite medications, by 68.7% of patients with an implant, and by 67.1% of patients on use of antimetabolites. The use of laser technology to improve surgical accuracy is therefore a highly appealing option.[12]

The CO_2 laser is most commonly used in laser-assisted operations.[20] It has been used for tissue dissection in filtration procedures using either a continuous wave or a rapid superpulse mode.[21] The CLASS technique is convenient because the microdissection is performed under direct microscopic observation, and the safety profile is high as the anterior chamber is not penetrated.

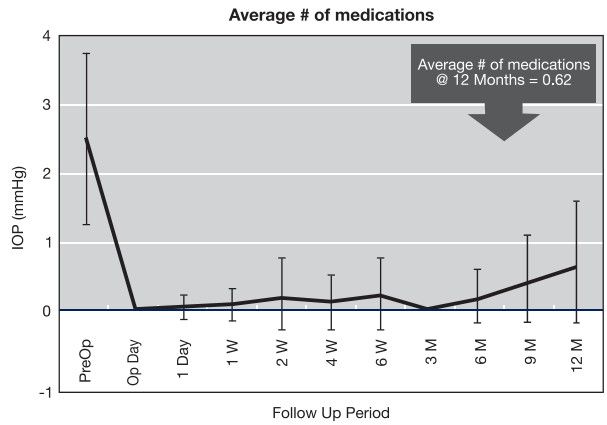

FIGURE 5. Average number of hypotensive medications ± SD from the preoperative stage up to 12 months postoperatively.

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The CO_2 laser has certain qualities that confer significant advantages when it is used specifically to facilitate deep sclerectomy filtration surgeries. These include photoablation of dry tissues, coagulation of bleeding vessels, and almost complete absorption of the laser energy by even minute amount of water. As the emitted radiation is readily absorbed by the percolating aqueous humor, the trabecular meshwork is effectively protected from the laser energy when percolation takes place. Thus, perforation of the thin trabeculo-Descemet membrane during deep sclerectomy, which is the most frequent intraoperative complication of manual NPDS, is substantially minimized.[7,11]

The feasibility and safety of the earlier CO_2 laser prototype (model OT-133) for CLASS procedure were examined in experimental models[12] and in a clinical trial.[22] Although the results were usually satisfactory, localized heating and tissue photocoagulation resulted in several cases in early fibrosis and adhesions, with consequent failure of the filtration. The improved version (OT-134) provides faster scanning, higher power focused laser beam, evenly distributed over the scanned area with some beam overlap to ensure uniform, effective ablation with minimal coagulative thermal damage to adjacent tissues. The energy is deposited using a scanner, which rapidly scans the focused laser beam across the treatment zone. The scanner is designed to move the focused beam such that the dwell time of the focused beam at each point is less than the thermal relaxation time, the characteristic heat conduction time is constant in the tissue. The laser energy absorbed by the sclera locally heats the tissue above evaporation temperature, causing local vaporization of the sclera at the laser deposition area. It has been shown in a preclinical study (part I of this study) that the lateral walls of the ablation zone showed a thin layer of thermal damage, 200 to 250 μm thick, whereas the thermal damage was minimal or absent at the bottom of the ablation zone.

No malfunctions of the laser device were recorded and there were no device-related intraoperative problems or serious postoperative complications. The recorded complications were mostly mild and transitory, and did not include macroperforations. Microperforations were suspected in some cases, but this did not interfere with the safety or efficacy of the surgical outcome and might even have improved filtration. The simplicity of performance is an appealing advantage, as it obviates the prolonged learning curve characteristic of manual NPDS, and thus can be confidently performed by surgeons with a wide range of experience in filtration surgery. The surgeon does not need to manually dissect layers of sclera and the drainage system or locate the orifice of the Schlemm canal, as in manual NPDS techniques. Instead, the surgeon gradually ablates an area, which is easily identified by the use of simple landmarks (aiming dots of the scan pattern positioned on the surgical limbus). Once fluid is seen percolating, the natural drainage apparatus is clearly visible and the emerging fluid prevents further damage and perforation of the remaining thinned tissue.

The efficacy of the CLASS procedure was at least comparable with that reported in a series of studies using the manual NPDS.[19] No implants were used in this study and MMC was used in 73.5% of the patients. The results of this study may be further improved by the use of scleral implants, such as hydrogel, reticulated hyaluronic acid, or autologous scleral implants.[6,7,19,22–24]

The limitations of this study include the absence of a control group and the limited follow-up period (12 mo). Longer-term follow-up is required to further evaluate and substantiate the safety and long-term efficacy of the CLASS, and to assess its usefulness in a wider spectrum of indications. Despite these limitations, the results are sufficiently promising to suggest that the CLASS is a simple surgical procedure to perform, which appears to be relatively safe and effective in the short and intermediate term.

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