

# Early results of modified nonpenetrating deep sclerectomy and phacoemulsification in the treatment of open angle glaucoma and cataract

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**PURPOSE.** *To study the outcome and control of intraocular pressure (IOP) of a combined modified nonpenetrating deep sclerectomy (NPDS) without use of implants and phacoemulsification in patients with primary open angle glaucoma (POAG) and cataract.*

**METHODS.** *Prospective series of 14 eyes in 14 patients with medically uncontrolled POAG and cataract with significant visual impairment undergoing a modified NPDS and phacoemulsification. The surgery was designed to utilize all four mechanisms of outflow track of aqueous of NPDS without the use of scleral implant and a standardized postoperative management and early Nd:YAG laser goniopuncture at 4 weeks. All patients underwent clinical assessment before and after surgery at day 1, day 7, weeks 2, 3, and 4, and then at 2, 3, and 6 months postoperation. Surgical outcome was assessed in terms of IOP, visual acuity, and the incidence of complications.*

**RESULTS.** *IOP decreased significantly from a preoperative value of  $21.71 \pm 3.81$  mmHg (mean  $\pm$  SD) to a postoperative value of  $13.14 \pm 3.73$  mmHg (mean  $\pm$  SD) ( $p < 0.05$ , paired  $t$  test) at 6 months. The number of antiglaucoma eyedrops needed for control of IOP decreased from  $3.28 \pm 0.91$  to zero after operation at 6 months follow-up. The change in IOP pre and post laser goniopuncture was noted with no complication or fluctuation in anterior chamber depth. Visual acuity ranged from finger counting to 6/18 with Snellen chart at 6 meters preoperatively to 6/36 to 6/9 postoperatively. There were no intraoperative complications. There was one recessed conjunctival wound at 1 week. No other postoperative complication was noted.*

**CONCLUSIONS.** *Modified NPDS without scleral implant with early Nd:YAG laser goniopuncture and phacoemulsification for treatment of patients with POAG and cataract is a safe and effective procedure with complete success at 6 months. (Eur J Ophthalmol 2009; 19: 72-9)*

**KEY WORDS.** *Nonpenetrating trabecular surgery, Scleral implants, Goniopuncture, Open angle glaucoma, Intraocular pressure*

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## INTRODUCTION

Surgical management of glaucoma has evolved over the last 40 years from unpredictable full thickness drainage to safer guarded fistula operation as in trabeculectomies (1, 2). Though trabeculectomies stand the test of time to remain one of the most commonly performed operations with success for glaucoma patients, there remained a significant portion of early and late postoperative complica-

tions reported in various series despite refinement of the techniques (3-5).

In recent years, nonpenetrating glaucoma surgery developed as a new filtering surgery without opening the internal trabecular structures and hence a better safety profile compared with trabeculectomies (6-8). Various studies reported similar success rate to trabeculectomies and lower rate of complications, namely, flat anterior chamber, hyphema, choroidals, and cataract. However, similar to tra-

beculectomies, there remain variations in techniques, e.g., use of antimetabolites, use of different types of scleral implants intraoperatively, or the application of laser goniopuncture postoperatively (9-11). These variations in techniques may mean that direct comparison across series may be difficult. Recent evidence favors the use of antimetabolites and scleral implant with higher absolute success rate and lower long-term intraocular pressure (IOP) when compared with those not using the two adjunctive treatments. However, the currently available implants are mostly costly, and this may have a major financial implication in the management of glaucoma patients especially when large numbers of patients are involved (12-14).

Though there is no study comparing success of nonpenetrating deep sclerectomy (NPDS) with or without goniopuncture reported so far, there are reports of better success rate in case series including larger portion of patients receiving postoperation goniopuncture (10, 15). This was also shown in a recently published article indicating that earlier goniopuncture led to a much higher complete success rate when goniopuncture was performed within 3 months postoperation (16).

We report a modified method of NPDS into a staged operation of initial NPDS utilizing all four mechanisms of aqueous drainage inherent to the NPDS by Mermoud and Shaarawy (17). This surgery was followed by further augmentation of the flow of aqueous and IOP control by utilizing the subconjunctival filtering bleb mechanism by means of goniopuncture carried out in the standard timing of performance at 4 weeks after the operation. In this way, we take the advantage of the very low risk profile in the early postoperative phase, followed by the enhanced outflow and hence a better outflow drainage and bleb formation at a later stage when early complications from conventional trabeculectomy are avoided. No implant of any type was used and the postoperative management is standardized.

## METHODS

A consecutive case series of adult primary open angle glaucoma patients with cataract significantly impairing vision who are indicated for glaucoma surgery were recruited from January to May 2007 with operation of the modified NPDS and phacoemulsification performed. Criteria for inclusion in the study were presence of cataract with

significant visual impairment with best-corrected visual acuity (BCVA) less than 6/18 on Snellen chart at 6 meters and primary open angle glaucoma with inadequate control of IOP with maximal tolerable medical therapy or disease progression in terms of deterioration of visual field (VF) with medical control. Patients with previous history of trabeculectomies or other intraocular surgeries were excluded. Patients with previous laser trabeculoplasty were excluded. Before operation, all patients underwent BCVA assessment (Snellen chart at 6 meters), biomicroscopy slit lamp examination, applanation tonometry with Goldmann tonometer, and visual field assessment. All patients undergoing surgery were examined with detailed gonioscopy ensuring that the area of planned NPDS had accessible trabeculum and was free from obstruction by peripheral anterior synechiae before operation. After operations, all patients were monitored in scheduled visits at day 1, week 1, week 2, week 3, week 4, and at 2, 3, and 6 months, respectively, with BCVA assessment and IOP measurement. The morphology of the drainage bleb as well as any complications were recorded at every visit. Nd:YAG laser goniopuncture was performed at week 4 visit. All patients received only topical treatment and Nd:YAG laser goniopuncture postoperatively; no needling or antifibrotics or suture lysis were employed in all cases to avoid heterogeneous postoperative management. Approval was obtained from the department ethics committee and was conducted according to the Declaration of Helsinki. Written consent was obtained from all patients. Statistical analysis was performed using the Student *t* test for paired data and  $p < 0.05$  was considered significant. Kaplan Meier survival curves for success rates under three different success criteria of postoperative IOP  $\leq 21$  mmHg and  $> 6$  mmHg, IOP  $\leq 18$  mmHg and  $> 6$  mmHg, and IOP  $\leq 15$  mmHg and  $> 6$  mmHg without glaucoma medications were noted.

## *Surgical technique*

All operations were performed by a single experienced glaucoma surgeon (N.S.Y.) under local anesthesia. A corneal traction suture was placed in the nasal cornea to enhance exposure. A fornix based conjunctival flap was created and hemostasis was achieved with minimal wet-field electrocoagulation cautery. A superficial scleral flap, 1/3 of the estimated total scleral thickness (300  $\mu$ m), measuring 4 mm was created with a 15 degree slit knife (Alcon, Fort Worth, TX) and a 55 degree crescent knife

(Beaver, Becton Dickinson Surgical Systems, Franklin Lakes). The flap was dissected forward into clear cornea for at least 1.5 mm ensuring a large corneo-Desemet membrane for ease of performance of later YAG laser goniopuncture.

Mitomycin C (MMC) 0.4 mg/mL antimetabolites were used in all cases. MMC was applied with a cellulose sponge placed both below the scleral flap as well as in the subconjunctival space on top of the scleral flap. The exposure was for a specific period of time of 2 minutes followed by irrigation with balanced salt solution.

Phacoemulsification was performed using a separate 3.0 mm clear corneal wound. Sodium chondroitin sulfate-sodium hyaluronate (Healon GV) was injected to fill the anterior chamber and a capsulorhexis forceps was used to create a 5.0 mm continuous curvilinear capsulorhexis.

Phacoemulsification was performed using the stop and chop technique with the Legacy 20000 machine (Alcon). Cortical remnants were then aspirated, the capsular bag filled with sodium chondroitin sulfate-sodium hyaluronate (Healon GV), followed by the implantation of a foldable IOL via the 3.0 mm corneal wound. IOL model used was AR40e (AMO acrylic foldable lens) in all cases. Viscoelastic was then aspirated and replaced with balanced salt solution. The phacoemulsification wound was then closed with one 10-0 nylon stitch. A total of 0.5 mL of 1% acetylcholine chloride (Miochol<sup>®</sup> CIBA Vision) was injected intracamerally to constrict the pupil. The surgery was followed by dissection of the deep scleral flap up to 90% of the total scleral thickness and was continued towards the limbus to expose the sclerocorneal trabecular meshwork. The dissection was extended at least 1 mm into clear cornea. Special care was taken to create a large enough trabeculo-Desemet membrane (TDM) complex without microperforation. The juxtacanalicular trabecular membrane was removed together with the inner wall of Schlemm's canal with the aid of the trabecular forceps (Huco, Switzerland). At this stage, aqueous humor was seen percolating through the thin TDM. If percolation was inadequate, further stripping of the membrane was performed. The deeper flap was excised with the Vannas scissors flushed to the dissection made into the cornea taking care not to apply excessive traction on this deep flap to avoid breaking the very fragile TDM complex. With the achievement of adequate percolation of aqueous, no implant was put underneath the scleral flap.

The superficial scleral flap was closed loosely with 10-0 nylon and the conjunctiva was closed with 8-0 Polyglactin 910 (Vicryl).

The operated eyes were patched with neomycin and polymyxin sulfates and dexamethasone ointment (Maxitrol<sup>®</sup>) overnight. All patients were prescribed 1% prednisolone acetate eyedrops six times per day (Pred Forte), 0.5% levofloxacin eyedrops four times a day (Cravit), and ointment Maxitrol during the first 3 months of the postoperative period. Patients were put on 1% pilocarpine QID for the operated eyes for the initial 6 weeks to keep the iris taught and prevent iris plug to the inner TDM complex; this aimed to prevent the obliteration of the flow by percolation of aqueous through the TDM complex. All patients were reviewed on the first postoperative day and they were monitored in scheduled visits at week 1, week 2, week 3, week 4, and at 2, 3, and 6 months, respectively, with best visual acuity, biomicroscopy slit lamp examination, and IOP measured by Goldmann applanation. Any postoperative complications were specifically looked for and noted; morphology of the drainage bleb was recorded at every visit. Nd:YAG laser goniopuncture was performed at week 4 visit using the YAG Trokel single mirror lens (Ocular Instruments, Bellevue, WA). Detailed gonioscopy examination was performed before the laser procedure to ensure a well exposed TDM complex and iris are held taut with topical pilocarpine; this is to prevent any possible complication of peripheral iris sticking onto the TDM complex during the drop in pressure and hence a creation of pressure gradient during the laser procedure. This examination is very important as the drainage function of the NPDS would be hampered if peripheral iris sticks onto and blocks inner filtration window. Applanation tonometry by Goldmann applanation and slit lamp examination was performed before and after the Nd:YAG goniopuncture. The change in IOP and AC depth and AC inflammatory reaction was noted before and after the Nd:YAG laser goniopuncture procedure.

### *Outcome criteria*

The surgical outcome was assessed in terms of IOP, visual acuity, and the incidence of complications. Complete success was defined as IOP  $\leq 21$  mmHg and  $> 6$  mmHg without additional glaucoma medication, qualified success as IOP  $\leq 21$  mmHg and  $> 6$  mmHg with additional glaucoma medication, and failure as IOP  $> 21$  mmHg re-

quiring oral glaucoma treatment or surgery for IOP control or IOP <6 mmHg. Eyes with no light perception or phthisical eyes were also classified as failures. Two more stringent criteria of success were also defined with upper limit of IOP set at 18 mmHg and 15 mmHg. Results were displayed as Kaplan Meier curve for the three success criteria.

## RESULTS

There were a total of 14 eyes in 14 patients in this prospective case series. Demographic data of the patients are shown in Table I. The mean age at time of surgery was 68.2 years (range from 50 to 82 years old). All were Chinese, with 5 male and 9 female patients. The mean preoperative IOP was  $21.71 \pm 3.81$  mmHg (range 16 to 28 mmHg), and was reduced significantly to mean postoperative IOP at 6 months of  $13.21 \pm 3.58$  mmHg (range 6 to 19 mmHg) ( $p < 0.05$ ). The number of medications decreased from  $3.28 \pm 0.91$  preoperatively to  $0.0 \pm 0.0$  postoperatively. The preoperative visual acuity ranged from finger counting to 6/18 and the postoperative visual acuity ranged from 6/36 to 6/9 at 6 months follow-up. There was no patient with loss of any lines of visual acuity, and there were 10 out of 14 eyes demonstrating two or more lines of improvement in visual acuity. There were no intraoperative complications. Early postoperative complications included one recessed conjunctival wound edge at 1 week postoperation visit, yet there remained a diffuse bleb with no leakage noted. Most patients devel-

oped a low diffuse bleb which extended two to three clock hours. There was no shallow anterior chamber, hyphema, hypotony, or infection in the postoperative period. No late complications were noted.

The IOP preoperation and in the 6-month period after operation are displayed in Figure 1.

The changes in IOP before and after laser goniopuncture at week 4 visits are displayed in Figure 2.

Intraoperative and postoperative complications are displayed in Figure 3.

Kaplan Meier survival curve of patients with complete success at the three success criteria of IOP  $\leq 21$  mmHg and  $> 6$  mmHg, IOP  $\leq 18$  mmHg and  $> 6$  mmHg, and IOP  $\leq 15$  mmHg and  $> 6$  mmHg are displayed in Figure 4.

## DISCUSSION

The use of NPDS in treating open angle glaucoma has been reported with comparable success rate to trabeculectomies with much lower complications so far (6-8). Most case series and comparative studies were performed either comparing use of NPDS with implant with results of conventional trabeculectomy or in comparing the results of NPDS using different models of scleral implant to keep the scleral lake for longer period of time. Some studies also reported results of case series with heterogeneous group of patients, some with and some without scleral implant. This may make comparison of actual success of different methods difficult. We thus modi-

TABLE I - DEMOGRAPHIC CHARACTERISTICS

| Characteristics                                 | Values                                 |
|---|--|
| Age, yr, mean $\pm$ SD                          | 68.21 $\pm$ 8.07                       |
| Female  | 9                                      |
| Male  | 5                                      |
| Chinese   | 14 (100%)                              |
| Right eye                                       | 6                                      |
| Left eye  | 8                                      |
| Preoperative IOP (mm Hg), mean $\pm$ SD         | 21.71 $\pm$ 3.81                       |
| Preoperative medications, mean $\pm$ SD         | 3.29 $\pm$ 0.91                        |
| Preoperative VF (mean deviation), mean $\pm$ SD | 11.03 $\pm$ 9.33                       |
| Preoperative VF (CPSD), mean $\pm$ SD           | 5.43 $\pm$ 3.41                        |
| Preoperative BCVA (range in Snellen)            | Finger counting to 6/18                |
| Preoperative gonioscopy                         | 6 Shaffer grade 3<br>8 Shaffer grade 4 |

IOP = intraocular pressure; VF = visual field; BCVA = best-corrected visual acuity.

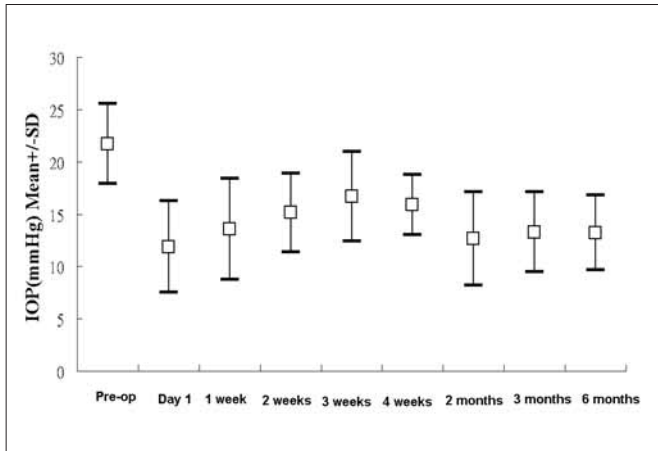


Fig. 1 - Intraocular pressure before operation and in the 6-month period after operation.

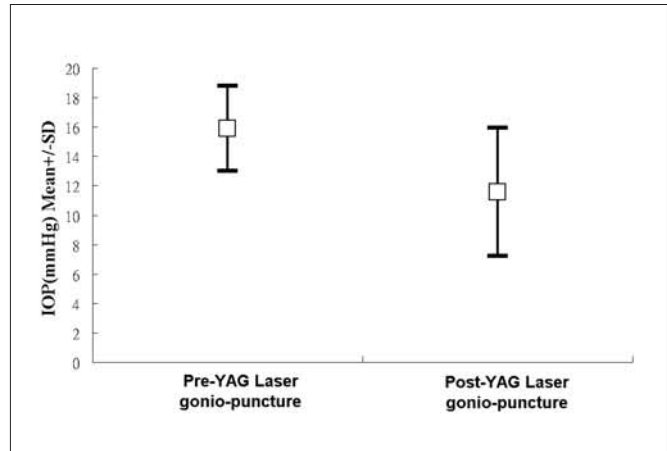


Fig. 2 - Changes in intraocular pressure before and after laser gonio-puncture at week 4 visit.

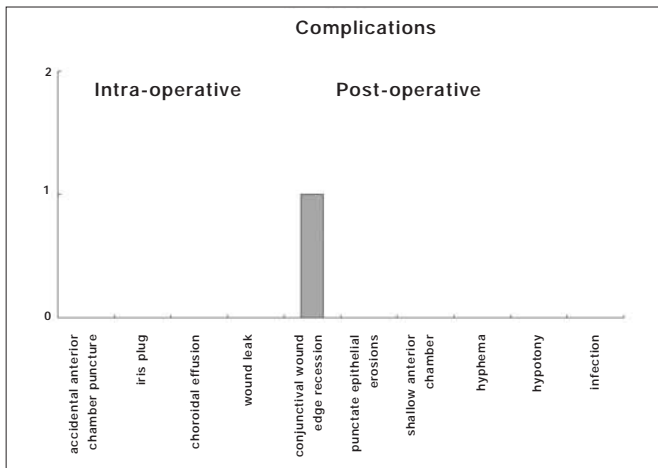


Fig. 3 - Intraoperative and postoperative complications.

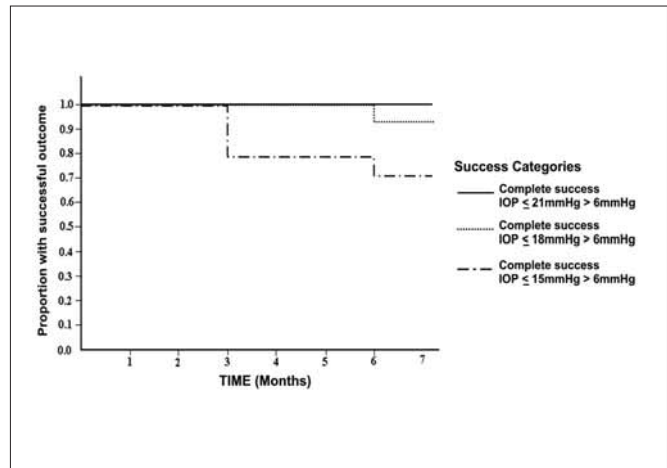


Fig. 4 - Kaplan Meier survival curve for the three success criteria.

fied the technique as a standardized method and report the results herein.

Since NPDS involved deroofting of the Schlemm's canal and removal of the inner wall of the Schlemm's canal together with the juxtacanalicular trabeculum (the main part of resistance in outflow of aqueous), percolation of aqueous thus achieved via the thin TDM complex is important. Previous experience with NPDS operation showed there are four mechanisms of aqueous humour resorption after passage through the trabeculo-Descemet membrane in this operation (17); namely, subconjunctival filtering bleb, intrascleral filtering bleb, subchoroidal passage, and episcleral drainage via Schlemm's canal ostia. We hence modify the surgery into a staged operation of initial NPDS

utilizing all four mechanisms, and then further augment the flow and IOP control by utilizing the subconjunctival filtering bleb mechanism. The initial NPDS targets at aqueous percolation into the scleral lake and then into the subconjunctival space to keep a shallow diffuse subconjunctival bleb; the scarring in this layer is prevented by both the intraoperative use of MMC and the film of aqueous that keep percolating in the initial weeks after the operation. This is followed by more profuse aqueous outflow by opening up the inner TDM complex with Nd:YAG laser gonio-puncture before either the scleral lake or the subconjunctival space scar down. In this way, we take the advantage of the very low risk profile in the early phase postoperation especially on postoperative shallow anteri-

or chamber, choroidal effusions, hypotony, and hyphema. This is followed by the enhanced outflow and hence better outflow drainage and bleb formation without the fear of complications at this later stage when early complications from conventional trabeculectomy are avoided.

Since we aim at a long term bleb formation for the persistent mechanisms of drainage of aqueous in this case, we would like to keep the scarring in the subconjunctival space minimal. For a bleb to develop in the postoperative period, the most important factors include, first, continuous percolation of drainage of aqueous from inside the eye through the guarded fistula as in trabeculectomy or through the TDM complex as in NPDS, and second, intact conjunctival wound edges without leakage throughout the postoperative course and hence a persistent layer of aqueous in the subconjunctival space separating the layers of conjunctiva, tenon, and sclera. With the use of antimetabolites MMC, it is well known that leakage at the conjunctival wound edge is more common. These leakages are sometimes healed by decreasing the aqueous flow by aqueous suppressants and hence lowering the intra-bleb pressure to break open the leakage and hence offering an opportunity for the conjunctival wound edge to adhere. For NPDS, the constant controlled flow of aqueous through the TDM complex into the intrascleral lake and then into the subconjunctival space creates a low intra-bleb pressure and hence less chance of leakage despite the use of MMC in modified NPDS also. This is the case in one of our patients who developed recessed conjunctival wound edge at the limbus 1 week after the operation and yet no leakage was noted when a shallow diffuse bleb developed.

Another advantage of this modified method lies in the saving of intrascleral implant to keep the scleral lake open by mechanical barrier. There are studies demonstrating that the use of collagen implant in NPDS enhances success rate, provides significantly lower IOP levels, and lowers the need for postoperative medications. However, scleral implants currently available in the market such as SK gel (reticulated hyaluronate), aqua flow collagen implant, and other implants used are expensive; this may have cost implications in terms of glaucoma treatment offered to our patients especially when we are offering this treatment to a large number of patients. In our series, we modify our technique to prevent scarring in the initial weeks after surgery and to obliterate the scleral lake created. We treated the surgical site with MMC both on top of and under the scleral flap during the operation, which

in turn helps to prevent scarring in both these potential spaces by inhibiting the fibroblasts. Further, the aqueous percolation which is well achieved intraoperatively helps to keep the channel of flow patent as far as the TDM complex keeps functioning. Good intraoperative hemostasis is also important to prevent any bleeding or blood pooling in the intrascleral lake that may lead to scarring; selection of the site to perform the NPDS intraoperatively to avoid the emissary veins is also recommended. Further augmentation of aqueous drainage from anterior chamber to sclera lake and then to subconjunctival space by the Nd:YAG laser goniopuncture also ensures that the sclera lake is remaining open. There is a rising trend in the IOP postoperatively in the first 4 weeks postoperation, possibly due to decrease in flow in the entire drainage route. The Nd:YAG goniopuncture performed in week 4 demonstrated that the IOP went back to a lower range and was sustained until 6 months postoperation. The hypothetical possibility of sticking of peripheral iris to the inner TDM complex was also successfully prevented with the use of acetylcholine intraoperatively and pilocarpine used postoperatively in the early 6 weeks follow-up. Though this method does not replace the mechanical effect in keeping the scleral lake open with the means of a scleral implant which usually lasts more than 6 months, the earlier use of goniopuncture has been shown in a recently published article to markedly enhance the control of eye pressure (16), hence early goniopuncture utilized in our modified technique may help to maintain a similar IOP control despite the non-use of the scleral implant.

With this understanding in mind, we would like to suggest cases with healthy iris and pupil sphincter that respond well to pilocarpine and acetylcholine to be selected. For the later stage of planned Nd:YAG goniopuncture, to ensure a guaranteed access of the Nd:YAG laser to this TDM complex created intraoperatively, the TDM must be large enough.

Because of the very stable anterior chamber depth, minimal inflammation, and lower fluctuation of IOP postoperatively, all patients enjoyed good visual acuity throughout the postoperative period even in the early phase postoperation.

The results indicate that this technique of modified NPDS together with a staged Nd:YAG laser goniopuncture may be a promising surgical option for primary open angle glaucoma. This may be further extended to angle closure glaucoma, combined with phacoemulsification as indicated by a previous reported study that selected cases with

accessible trabeculum especially in the superior angle planned for operation (18).

There are minimal variations in the technique used in this modified technique performed by a single experienced glaucoma surgeon (N.S.Y.) on the part of NPDS and the staged Nd:YAG goniopuncture. This eliminates possible variability in surgical technique that makes direct comparison with other series difficult.

Our series has limitations. This is not a large case series, and though it documents a favorable course after this modified NPDS with staged Nd:YAG laser goniopuncture, the follow-up is too short to note for the long-term success of this drainage path thus created. However, as most trabeculectomy series reported found that most of the scarring in the subconjunctival space and thus the problem with proper drainage bleb formation occurs in the first few months after operation, this may shed some light as to the long-term promising effect of this operation. The patients were kept under pilocarpine in the first 6 weeks after operation; pilocarpine, besides being a pupil constricting agent used in these patients, may also increase the outflow of aqueous via the conventional pathway. According to pharmacologic studies of pilocarpine, it was shown that 2% pilocarpine being used QID may have increased outflow and hence effect on IOP in human study; however, the dosage we use is much lower and we noted no change of IOP after pilocarpine was stopped at 6 weeks postoperatively (19). Third, the outcome chosen to assess success of surgical intervention for glaucoma treatment, including IOP, visual acuity, and complications, was not ideal in our study. Other parameters to determine

glaucoma damage, e.g., optic nerve head morphology and visual field loss, would add more information. Yet the criteria analyzed in our study allowed comparison with previous reported series of NPDS surgery.

## CONCLUSIONS

Many years after the invention of conventional Cairns trabeculectomy (1), glaucoma surgeons are still looking for the best surgical options that offer the best safety profile and long-term IOP control for their patients. Combined phacoemulsification and modified NPDS without scleral implant with early Nd:YAG laser goniopuncture is a safe and effective procedure with complete success at 6 months in our series. Further study with randomized controlled trial and longer term follow-up is needed to prove or disprove the application of this modified NPDS as a surgical option for our patients.

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