Diode Laser Transscleral Cyclophotocoagulation as a Primary Surgical Treatment for Primary Open-angle Glaucoma

Peter R. Egbert, MD; Seth Fiadoyor, MD; Donald L. Budenz, MD; Patience Dadzie, RN; Sally Byrd, MD

Objectives: To evaluate the feasibility of diode laser transscleral cyclophotocoagulation (TSCPC) as a primary surgical treatment for primary open-angle glaucoma and to compare 2 laser energy settings used for treatment.

Methods: In a prospective clinical trial in Cape Coast and Accra, Ghana, 1 eye of each of 92 patients with primary open-angle glaucoma was treated by diode laser TSCPC as a primary surgical treatment. Eyes were randomly assigned to receive treatment by 20 applications of either 1.5 W applied for 1.5 seconds or 1.25 W applied for 2.5 seconds.

Results: Seventy-nine (86%) of 92 patients completed 3 months of follow-up; follow-up was 13.2±6.0 months (mean±SD). Intraocular pressure decreased in 53 (67%) of the 79 eyes. The drop in intraocular pressure was 20% or more in 37 eyes (47%) and final intraocular pressure was 22 mm Hg or less in 38 eyes (48%). An atonic pupil was a previously unreported complication that arose in 27 (28%) of 92 eyes. There were no serious complications of hypotony, phthisis bulbi, or sympathetic ophthalmia. Visual acuity decreased in 18 (23%) of 79 eyes treated by TSCPC and in 10 (23%) of 47 fellow eyes treated only with glaucoma medications. There was no difference in outcomes between the 2 laser energy settings.

Conclusions: Diode laser TSCPC is a practical, rapid, well-tolerated procedure that may provide a modest and variable lowering of intraocular pressure. The treatment, used with conservative energy levels applied to the eye, seems to have few serious complications, although a previously unrecognized complication of atonic pupil needs further evaluation. A moderate variation in laser energy settings does not influence the results of treatment.


DIODE LASER transscleral cyclophotocoagulation (TSCPC) has been used successfully for the treatment of refractory glaucoma, including those eyes in which other surgical treatments have failed.1-5 Transscleral cyclophotocoagulation has not been specifically studied for the primary surgical treatment of primary open-angle glaucoma (POAG), although its use has been proposed,6 because of the fear of vision loss after destructive procedures on the ciliary body.

In the black population of West Africa, glaucoma is the major cause of irreversible blindness. Long-term medical treatment is not feasible in most regions, however, because of the long distances patients must travel for treatment, and because of the high expense and low availability of medications. Glaucoma is often considered to be a surgical problem in these regions. In Ghana, we have shown that trabeculectomy with antimetabolites is an effective treatment for POAG.7-9 Unfortunately, Ghana, like many developing countries, has a shortage of both ophthalmologists comfortable with glaucoma surgery and resources for eye care, so that trabeculectomy cannot be offered to every glaucoma patient. Because a simple, rapid, and inexpensive surgical procedure for glaucoma would be of great benefit, contact diode laser TSCPC offers attractive attributes—the procedure is quick, easy to learn, and does not require a complicated, sterile operating room. In addition, the laser is solid state, reliable, compact, and portable.

We performed a prospective trial of TSCPC for the primary surgical treatment of POAG in 2 outpatient clinics in Ghana. Our primary goal was to evaluate the feasibility of diode laser TSCPC as a primary treatment of POAG in developing countries. A second goal was to determine, by a prospective randomized trial,
PATIENTS AND METHODS

After approval of the study by the institutional review board of each clinic, patients with glaucoma were invited to participate in the study. Inclusion criteria were being older than 20 years and having a diagnosis of POAG. Patients were excluded if they had previous glaucoma surgery, including argon laser trabeculoplasty, cataract extraction, or any other ocular surgery, or if they had no light perception. Most patients had been diagnosed as having glaucoma only a few days or weeks before treatment and had been using glaucoma medications for a short time.

All treatments were performed in 2 outpatient clinics in Ghana between February and August 1997. The Cape Coast Christian Eye Clinic is located in the coastal city of Cape Coast and the Emmanuel Eye Clinic is in Accra, the country’s capital. Both clinics have developed a reputation for treating glaucoma and their patients come from a wide geographical area. Trabeculectomies are performed on patients with glaucoma when possible, but many patients are managed with glaucoma medications because trabeculectomies cannot be performed in sufficient numbers.

Glaucoma was diagnosed based on elevated intraocular pressure (IOP) and glaucomatous optic disc cupping. Most patients came to the clinic for examination because of a loss of central visual acuity and were found to have very advanced glaucoma. Ocular examination included uncorrected visual acuity and visual acuity with glasses, if available; slitlamp examination; IOP by Goldmann applanation or Tonopen (Mentor O & O Inc, Norwell, Mass); gonioscopy; and dilated fundus examination. Visual field examinations were not performed.

After a thorough explanation of the procedure, informed consent was obtained from all patients. One eye of each patient was chosen for treatment on clinical grounds (often the eye with worse glaucoma). The other eye received the best available conventional treatment, including glaucoma medications or trabeculectomy with antimetabolites. Four surgeons (P.R.E., S.F., D.L.B., and S.B.) performed the treatment. An OcuLight SLx diode laser (IRIS Medical Instruments, Mountain View, Calif) with a handheld G-probe (IRIS Medical Instruments) was used as described by Kosoko et al. After retrobulbar anesthesia, the anterior edge of the footplate was placed at the corneoscleral limbus and the probe was pressed firmly on the conjunctiva so that the laser beam was roughly parallel to the visual axis. The conjunctiva was kept moist with balanced salt solution. Twenty applications were given in each eye and spaced evenly over 360°. Care was taken to avoid areas of intense conjunctival pigmentation because they were subject to conjunctival burns. In this case, the remaining applications were placed closer to each other to maintain a total of 20. The probe was cleaned with alcohol and used for 4 treatments.

We randomly assigned patients to receive 1 of 2 energy settings. After the retrobulbar anesthesia and just before treatment, a nurse tossed a coin to determine the settings.

Group 1 received a treatment of 1.5 W applied for 1.5 seconds (2.25 J), and group 2 received 1.25 W applied for 2.5 seconds (3.125 J). With 20 applications, each eye received a total of either 45.0 J or 65.5 J. The power was not adjusted for the occurrence of “pops.” These 2 laser parameters were selected to have different ratios of power to time of exposure, with a moderate difference in total energy following a small pilot study of several combinations of settings. In the pilot study, there was a tendency for eyes treated with higher energies to have excessive postoperative iritis (P.R.E., unpublished data, 1997). At the end of the procedure, 4 mg of dexamethasone phosphate was injected subconjunctivally and 1% atropine solution was applied. The patient then applied topical atropine twice daily and steroid drops 4 times daily for at least 3 weeks or until iritis resolved. Any glaucoma medications were stopped after the treatment but restarted as needed.

The change in IOP was the principal outcome of interest both for establishing overall efficacy and for comparing group 1 with group 2. However, some patients had relatively normal preoperative IOP of 22 mm Hg or less because of medications; in these patients the principal outcome was a reduction of medications. Secondary outcome measures were changes in visual acuity and complications. Patients were seen at 1 day, 1 week, 3 weeks, and then every 2 to 3 months after treatment. Patients who failed to keep appointments were contacted by mail when possible and, in some cases, by clinic personnel traveling to the patient’s residence. Each examination included review of symptoms, number of glaucoma medications, visual acuity, IOP, and slitlamp examination. The examiners were not masked to the treatment.

Retreatments were done at the discretion of the follow-up ophthalmologist if the first treatment failed to decrease the IOP. Retreatment recapitulated the original laser parameters but was limited to 15 applications over 270°.

Patients were not included in the outcome analysis of IOP unless they completed at least 3 months of follow-up. We found that IOP varied during the first 2 months after treatment because of iritis and the use of atropine and steroids, but by 3 months these influences were absent. If the treated eye had another glaucoma operation or a cataract extraction, the last preoperative IOP was recorded and follow-up was terminated.

An increase or decrease in visual acuity was considered to be an increase or decrease of 2 or more lines on the Snellen chart or 1 category of visual acuity if a patient was unable to read the eye chart.

χ² Tests were used for the categorical variables, and a nonpaired 2-sided t test for continuous variables.
There was no difference in preoperative IOP between patients who completed the follow-up and those who did not (P = .42) or between the clinics that did the treatment (P = .85).

CHANGE IN IOP

The results refer to the 79 treated eyes of 79 patients who completed at least 3 months of follow-up (Table 2). The follow-up lasted 13.2±6.0 months (mean±SD) (range, 3-26 months). The Figure shows IOP before treatment and at the last follow-up examination. Intraocular pressure decreased in 53 (67%) of the eyes; the drop in IOP was 20% or more in 37 eyes (47%) and 30% or more in 24 eyes (30%). No eye developed an IOP lower than 10 mm Hg. The mean±SD pretreatment IOP was 29.0±8.9 mm Hg (range, 17-66 mm Hg), and at the last examination after treatment IOP decreased to 25.7±10.3 mm Hg (mean±SD)(range, 10-66 mm Hg) (P = .02). The IOP varied with time in individual eyes, going both up and down from 1 visit to another. One explanation for this variation was the poor compliance with taking medications.

Intraocular pressure decreased more in eyes with a high pretreatment IOP than in those with a low pretreatment IOP (regression coefficient, 0.72; P <.001). We also looked at clinically relevant subsets of the total treated group: eyes with pretreatment IOP greater than 22 mm Hg and eyes with a pretreatment IOP of 22 mm Hg or less, which were treated in an attempt to eliminate glaucoma medications (Table 2). A 20% decrease in IOP occurred in 32 (54%) of 59 eyes in the former group, but in only 3 (15%) of 20 eyes in the latter (Table 2).

Two eyes had an increase in IOP of more than 20 mm Hg that we cannot fully explain, although both patients had failed to continue taking glaucoma medications. One patient was a 31-year-old man whose fellow eye had no light perception and who had an IOP of 47 mm Hg without medications. The treated eye went from an IOP of 24 mm Hg before treatment with medications to 54 mm Hg after treatment without medications. The second patient was an 85-year-old woman whose fellow eye had a trabeculectomy with an IOP of 14 mm Hg. The treated eye had a pretreatment IOP of 25 mm Hg while taking medications and 66 mm Hg after treatment without taking medications.

In 32 patients, the fellow eye (the eye not receiving TSCPC) had a trabeculectomy; in 47 patients the fellow eye was treated with medications only. In these 47 patients, a comparison was made between the eye treated

| Table 1. Preoperative Data for All Patients |

| Age, y, mean ± SD (range) | 60.9 ± 12.9 (21-86) | 61.2 ± 12.1 (31-86) | 60.6 ± 13.5 (21-85) |
| Sex, No. (%) | | | |
| Men | 56 (61) | 26 (55) | 30 (67) |
| Women | 36 (39) | 21 (45) | 15 (33) |
| IOP,‡ mm Hg, mean ± SD (range) | 29.3 ± 8.9 (16-66) | 29.4 ± 9.9 (19-66) | 29.1 ± 8.1 (16-50) |

* Laser settings, 1.5 W, 1.5 seconds.
† Laser settings, 1.25 W, 2.5 seconds.
‡ IOP indicates intraocular pressure.

| Table 2. Results After Treatment for Patients Completing at Least 3 Months of Follow-up |

| Pretreatment IOP* | Total | ≤22 mm Hg | >22 mm Hg | P |
| No. of eyes | 79 | 20 | 59 | .09 |
| Follow-up, mo, mean ± SD | 13.2 ± 6.0 | 15.0 ± 5.0 | 12.6 ± 6.3 | .09 |
| No. (%) of eyes with 20% decrease in IOP | 37 (47) | 3 (15) | 32 (54) | .002 |
| Decrease in IOP, mm Hg, mean ± SD | 3.3 ± 12.0† | −1.85 ± 6.7‡ | 5.0 ± 13.0 | <.001 |
| No. (%) of eyes with final IOP =22 mm Hg | | | |
| Total | 38 (48) | 13 (65) | 25 (42) | .08 |
| Not using glaucoma medications | 11 (14) | 2 (10) | 9 (15) | >.25 |
| No. of glaucoma medications, mean ± SD | | | |
| Before treatment | 1.8 ± 0.92 | 2.0 ± 0.9 | 1.7 ± 0.9 | >.25 |
| After treatment | 1.3 ± 1.18 | 1.6 ± 1.2 | 1.2 ± 1.2 | >.25 |

* IOP indicates intraocular pressure.
† P = .02.
‡ Minus sign indicates an increase in IOP from baseline.
with TSCPC and the fellow eye treated with medications only (Table 3). The fellow eyes had a small mean increase in IOP.

There was no significant difference between the effect of the 2 laser settings on IOP (Table 4). At the last examination after treatment, neither the mean IOP, the change in IOP from baseline, nor the percentage of eyes having a 20% reduction in IOP was significantly different between the 2 groups.

Several other variables were examined as possible predictors for the success of treatment. Only pretreatment IOP was a positive predictor as described above. Neither age, sex, number of “pops,” treating clinic, nor postoperative atomic pupil had a significant effect on the decrease in IOP (P > .25 for each when used as a single predictor in a standard linear model test).

**RETREATMENTS**

Only 16 (20%) of 79 eyes were re-treated (7 in group 1 and 9 in group 2). Fourteen of those eyes had 1 retreatment and 2 had 2 retreatments (Table 5). Using a 20% decrease in IOP as a measure of success, none of the re-treated eyes was a success before retreatment, but 9 (57%) of 16 were a success after retreatment. (By this measure, 28 [44%] of 63 eyes not re-treated were a success.)

**CHANGES IN VISUAL ACUITY**

Visual acuity at the last follow-up examination was compared with visual acuity before treatment. Eighteen (23%) of 79 eyes had a decrease in visual acuity, 55 (70%) had no change, and 5 (6%) had an increase. In 1 eye the visual acuity after treatment was not recorded. Two eyes progressed to no light perception (both were limited to hand motions before treatment). In the subset of 19 eyes that had relatively good pretreatment visual acuity (20/60 or better), only 1 (5%) had a decrease in visual acuity. For comparison, a change in visual acuity was also tabulated for fellow eyes in patients who did not have a trabeculectomy. One fellow eye progressed to no light perception. There was no significant difference in visual acuity change between the fellow eyes and the eyes receiving TSCPC (Table 3).

**MEDICATIONS**

Eleven (14%) of 79 eyes had a final IOP of 22 mm Hg or less without medications. In the 20 eyes with an IOP of 22 mm Hg or less before treatment that were treated in an attempt to eliminate medications, only 2 eyes (10%) were receiving no medications at the last examination while maintaining IOP at less than 22 mm Hg.

**COMPLICATIONS**

Complications were studied in all 92 treated eyes. Acceptance of the procedure was good—most patients liked the idea of a laser and found the procedure less frightening than an operation, such as trabeculectomy. Most patients experienced mild to moderate pain for a few days, but none complained of severe pain. Mild iritis was always seen the day after treatment and severe iritis occurred in 2 eyes, which resolved with topical steroids within 6 to 8 weeks. Transient conjunctival burns were common. A hyphema occurred during treatment in 3 eyes but resolved in each case by the next day. There were no cases of hypotony, phthisis bulbi, or sympathetic ophthalmia during the follow-up period.

An atomic pupil was noted in 27 (29%) of the 92 eyes (13 from group 1 and 14 from group 2) and may have been present more often because we did not prospectively look for this characteristic. The change ranged from

### Table 3. Comparison of Eyes Treated by Diode Laser TSCPC With the Fellow Eye in the Same Patients* (n = 47)

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Group 1</th>
<th>Group 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean ± SD of follow-up, mo</td>
<td>3.3 ± 1.5</td>
<td>3.4 ± 1.6</td>
</tr>
<tr>
<td>% of eyes with decrease in IOP</td>
<td>79%</td>
<td>79%</td>
</tr>
<tr>
<td>Mean ± SD of IOP, mm Hg</td>
<td>2.7 ± 1.0</td>
<td>2.7 ± 1.0</td>
</tr>
</tbody>
</table>

*The fellow eye received medications only in 47 of the 79 patients with 3 months or more of follow-up (excluding 32 patients whose fellow eye had a trabeculectomy). The eyes of these 47 patients are compared.

IOP indicates intraocular pressure; TSCPC, transscleral cyclophotocoagulation.

†Minus sign indicates an increase of IOP from baseline.

‡Data on visual acuity were missing from 3 patients.

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In this prospective study of diode laser TSCPC for the treatment of POAG in eyes that had not had any previous surgery, we set out to determine if TSCPC could play a role in the treatment of POAG in developing countries. The treatment was, as hoped, quick and relatively simple to apply. The laser was reliable even in face of the tropical heat and humidity of Ghana. Patient acceptance of the treatment was excellent and patients found the procedure less frightening than trabeculectomy. The procedure seems safe in that no major complications were recognized, but the effect of TSCPC on IOP was unpredictable.

The extent of IOP reduction after treatment was modest and varied from eye to eye. With a mean follow-up of 13.2 months, IOP was reduced 20% or more in 47% of the eyes, and final IOP was 22 mm Hg or less in 48%. Yet, the IOP in other eyes remained unchanged or increased. We cannot explain this variation in full, although a reasonable contributing factor is the erratic use of glaucoma medications. Preoperative IOP was a significant predictor of success: IOP was reduced more frequently in eyes with high than with low initial IOP. A 20% IOP reduction occurred in 57% of eyes with a pretreatment IOP greater than 22 mm Hg and in only 15% of eyes with a pretreatment IOP of 22 mm Hg or less. One goal of this study was to determine if patients with relatively normal IOP could stop taking glaucoma medications after treatment. We found that TSCPC generally does not allow discontinuation of medications in this group. Just 10% of patients with a pretreatment IOP of 22 mm Hg while taking medications were able to stop medications and still maintain an IOP of 22 mm Hg or less.

It is important to recognize that retreatments with diode laser TSCPC have been shown to be effective in other studies and have been used in as many as 49% to 62% of eyes. Spencer and Vernon11 have advocated considering TSCPC as a course of treatment in which multiple sessions are routine. We retreated only 20% of eyes in our study and found that 57% of these had a final reduction in IOP of at least 20%. If more eyes that had not responded to the initial treatment had been re-treated, our final success rate probably would have been higher. It may be that repeated treatments are necessary to achieve optimal results.

We randomized treatment between 2 energy levels, with different ratios of power and duration of application, because the most appropriate laser energy settings are not known. There was no difference in outcomes between the 2 settings. Krott et al12 also failed to find a correlation between energy applied during TSCPC and outcome. Within certain limits, the laser energy settings may not be as crucial to results as other undetermined variables, such as probe position and angle, or variation in the anatomy of individual eyes. Bloom et al11 have recommended transillumination to identify the position of the pars plicata of the ciliary body, but it has not been shown whether this technique improves results.

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We are aware of no other studies that have specifically looked at diode laser TSCPC as the primary surgical treatment for POAG. There are a few retrospective studies of TSCPC for refractory glaucoma of various types that have included results for POAG; these studies report variable results with success rates for POAG that are usually higher than we found in our study.3,10,11,13,14 Aside from being retrospective, these studies differed from ours in several other key ways—the patients were not African, the eyes often were previously operated on, the treatment energies were usually higher, and retreatments were more frequent.

In an earlier study, using the same population in Ghana, we examined trabeculectomy with intraoperative antimetabolites as a treatment of POAG.74 Intracocular pressure was reduced to less than 21 mm Hg in 73% to 93% of eyes with a mean follow-up of 10 months. Diode laser TSCPC, as applied in the current study, does not match those results. In terms of complications, TSCPC causes more immediate iritis than trabeculectomy, but avoids the occasional flat chamber. Late follow-up of trabeculectomy with antimetabolites in the same population showed a 2% incidence of hypotony6 and no endophthalmitis. We do not have data to compare cataract formation or vision change between the 2 procedures.

We used conservative amounts of laser energy in the treatment because there is little information on the complications associated with diode laser TSCPC in black patients or in POAG. Both the energy per application and the number of applications were at or below the lower range given in most other treatment studies. We thought it was important to minimize complications in patients who had not had other surgery and potentially had other forms of treatment available for their eyes. Serious complications did not occur; there were no cases of hypotony (the lowest IOP was 10 mm Hg), phthisis bulbi, or sympathetic ophthalmia.

Some eyes lost vision—visual acuity decreased in 23% of patients. There is a strong concern that TSCPC can lead to loss of central vision from cystoid macular edema or other causes. On the other hand, we have noticed in our clinical practice in Ghana that patients with advanced glaucoma often lose vision rapidly as a consequence of the natural progression of the disease. After diode laser TSCPC, it is difficult to ascertain whether loss of vision results from treatment or from the natural progression of glaucoma. We attempted to answer the question by looking at the data in 2 ways. First, the treated eyes that had relatively good visual acuity (20/60 or better) before treatment were studied—these eyes presumably had less risk for rapid loss of visual acuity from glaucoma than eyes with worse pretreatment visual acuity. Only 1 (5%) of 19 of these eyes lost visual acuity after TSCPC. Second, we looked at the vision change in the
fellow eyes. The fellow eyes that had treatment by medications only, with no TSCPC, lost vision at the same rate as the eyes treated by TSCPC. Precise conclusions cannot be drawn from comparisons of the treated and untreated eyes because treatment was not randomly allocated between the eyes. However, the vision loss in fellow eyes is consistent with the idea that many of the study patients had advanced glaucoma and were at risk to lose vision from the natural progression of glaucoma. Some may also have had maturation of cataracts.

An unexpected complication was the atonic pupil that was observed in 29% of treated eyes. Pupil abnormalities have not been reported before except for one mention of a “localized iris shrinkage with pupillary distortion” and “atrophy of the iris root” by Mueller et al.13 Atonic pupils may not have been recognized before because the vast majority of eyes that have been treated with diode laser TSCPC have either had neovascular glaucoma, which often causes poorly reactive pupils, or have had previous intraocular operations that distorted the iris. Two cases of neurotrophic corneal defects have been seen following diode laser TSCPC, which suggests that corneal sensory nerves can be damaged.15 Perhaps the parasympathetic nerve supply to the iris sphincter was damaged in our cases. It will be important to monitor patients’ symptoms and any loss of accommodation to evaluate the clinical significance of this finding.

This study has limitations. Because all of the patients were black Africans and most had very advanced glaucoma, our results may not apply to other populations. Only 79 (78%) of 92 treated patients completed the 3-month follow-up necessary to evaluate treatment results, and more patients failed to return for later examinations. Although this is a good follow-up rate for studies in developing countries, the patients who did not return could have had different results than those who completed the follow-up. Also, longer follow-up could reveal loss of effect or more complications. The use of glaucoma medications was not constant, which makes it difficult to gauge the effect of TSCPC alone on IOP.

In conclusion, the role of diode laser TSCPC in the management of POAG in developing countries warrants further study. It fulfilled some of its expectations as a practical, rapid, and easy-to-learn primary surgical treatment for POAG. The treatment, used with conservative energy applied to the eye, seems to be free from serious complications, although a previously unrecognized complication of atonic pupil needs further evaluation. There was no difference in the outcome of the 2 laser energy settings used.

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Corresponding author and reprints: Peter R. Egbert, MD, Stanford University Medical Center, Room A 157, Stanford, CA 94305-5308 (e-mail: egbert@stanford.edu).

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