A Prospective, Comparative Study between Endoscopic Cyclophotocoagulation and the Ahmed Drainage Implant in Refractory Glaucoma

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Purpose: To compare endoscopic cyclophotocoagulation (ECP) and the Ahmed drainage implant in the treatment of refractory glaucoma.

Methods: Sixty-eight eyes of 68 patients with refractory glaucoma were prospectively assigned to either ECP or Ahmed tube shunt implantation. All procedures were performed by a single surgeon. Eyes that were included were pseudophakic with a history of at least one trabeculectomy with antimetabolite, an intraocular pressure (IOP) equal to or above 35 mm Hg on maximum tolerated medical therapy, and a visual acuity better than light perception. Exclusion criteria included eyes that had had previous glaucoma drainage device implantation or a cyclodestructive procedure. Success was defined as an IOP more than 6 mm Hg and less than 21 mm Hg, with or without topical anti-hypertensive therapy.

Results: The mean follow-up was 19.82 ± 8.35 months and 21.29 ± 6.42 months, for the Ahmed and ECP groups, respectively ($P = 0.4$). The preoperative IOP, 41.32 ± 3.03 mm Hg (Ahmed) and 41.61 ± 3.42 mm Hg (ECP) ($P = 0.5$), and the mean postoperative IOP, at 24 months follow-up, 14.73 ± 6.44 mm Hg (Ahmed) and 14.07 ± 7.21 mm Hg (ECP) ($P = 0.7$), were significantly different from baseline in both groups ($P < 0.001$). Kaplan-Meier survival curve analysis showed a probability of success at 24 months of 70.59% and 73.53% for the Ahmed and ECP groups, respectively ($P = 0.7$). Complications included choroidal detachment (Ahmed 17.64%, ECP 2.94%), shallow anterior chamber (Ahmed 17.64%, ECP 0.0%), and hyphema (Ahmed 14.7%, ECP 17.64%).

Conclusion: There was no difference in the success rate between the Ahmed Glaucoma Valve and ECP in refractory glaucoma. The eyes that underwent Ahmed tube shunt implantation had more complications than those treated with ECP.

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Glaucoma treatment in patients for whom a guarded filtrated procedure has failed or has a high chance of a negative outcome is still controversial. For many years cyclodestructive procedures have been used to treat refractory glaucoma with the goal of diminishing aqueous humor production by ablating the ciliary processes.[1–8] These procedures were usually performed by a transscleral route, either by freezing the ciliary body (cyclocryotherapy)[5,9] or by coagulating the ciliary body with a laser source.[3,4,8,10] Because the surgeon is not able to assess the targets being treated, adjacent tissues may be damaged during this process, which may contribute to a relatively high rate of complication, such as pain, visual acuity reduction, inflammation, hypotony, and phthisis bulbi.[3,8,11]

Some authors have attempted to directly treat the ciliary body with an intraocular laser probe.[12] Recently, a new device that combines a laser source, endoscope, and an illumination beam in the same probe has been developed.[13] This instrument has the unique ability of simultaneous visualization and treatment of the ciliary body through a pars plana or anterior segment approach,[14] or even combined with a cataract extraction.[15,16] Additionally, Chen et al[6] have demonstrated the safety and efficacy of the endocyclophotocoagulation (ECP) for treatment of refractory glaucoma.

Glaucoma drainage implants is another modality for treatment of refractory glaucoma.[17,18] The Ahmed device (New World Medical, Inc., Rancho Cucamonga, CA) has a unidirectional valve mechanism and less hypotony was noticed in early postoperative course. It has comparable success rates to other glaucoma drainage devices for refractory glaucoma.[19–22] However, less hypotony in the early postoperative course was noticed with the Ahmed tube shunt.[19,20]

There is no gold standard for treatment of intractable glaucoma. Because of the direct approach to the ciliary body, the ECP may be a reasonable option in these eyes that is comparable to tube shunt implantation. This study was designed to compare ECP and Ahmed drainage implant in refractory glaucoma.

METHODS

This was a prospective, comparative study. All patients were recruited from the Federal University of Goiás, glaucoma clinic or Brazilian Center of Eye Surgery (CBCO), Goiânia from January 1998 to April 2000. A signed informed consent and Ethics Committee approval from the institutions were obtained before any patient enrollment.

Eyes included were all pseudophakic with an intraocular pressure (IOP) greater than or equal to 35 mm Hg on maximum tolerated therapy, with at least 1 previous trabeculectomy with antimetabolite, and a visual acuity better than light perception. Exclusion criteria included eyes that had had previous glaucoma drainage device implantation or a cyclodestructive procedure, eyes that did not perceive light, eyes that had a retinal or choroidal detachment, or eyes with a failed corneal graft.

The first eligible patient was randomized either to ECP or Ahmed drainage implantation, and then alternated consecutively with both techniques. All surgeries were performed by a single experienced surgeon (FEL). In our study, success was defined as an IOP greater than 6 mm Hg and below 21 mm Hg at 24 months of follow-up with or without maximum tolerated therapy. Failure of treatment was defined as an IOP greater than 21 mm Hg during 3 consecutive postoperative visits, IOP below 6 mm Hg for 60 days or more (hypotony), and eyes that had to undergo to another surgical intervention due to uncontrolled IOP. Patients who reached a failure end point were censored from further analyses. However, their IOP was included in the average IOP calculation at this time.

All patients underwent a thorough ophthalmic evaluation including a LogMar visual acuity,[23] slitlamp biomicroscopy, and a dilated retinal examination. An ultrasound examination was performed when the media was not clear. Demographic data such as age, sex, and race were collected for both groups. Three different physicians measured the IOP with the Goldmann tonometer in the morning, always around 10 AM. The IOP was considered as a single measure by one of the observers.

Ahmed tube shunt implantation was performed in a standard fashion. The valve's air lock was opened with a balanced salt solution injected into the tube with a 27-gauge needle, and the tube securely attached to the sclera with 7-0 silk sutures about 8 mm from the limbus in the superior temporal quadrant. The tube was positioned 2 to 3 mm into the anterior chamber, and a donor sclera patch graft covered the anterior portion of the tube at the limbus with 4 7-0 polyglactin sutures.

The ECP was done with a commercially available device (MicroProbe, ENDOOPTIKS, Little Silver, NJ) with an endoscope with a 110° field of view and a focal distance of 2 mm, camera and an 810 nm wavelength diode laser source with maximum power of 1.2W. The procedure was performed by a superior temporal pars plana incision, 3.5 mm from the limbus with power of 0.5W, continuous mode for approximately 2 seconds to produce both whitening and shrinkage of the ciliary processes. Laser power and/or duration were decreased if a "pop" was heard.[24] ECP was done to 210° of the ciliary body, corresponding to 2 to 9 hours in the right eye and from 3 to 10 hours in the left eye, including the anterior third of the pars plana. Additionally, scleral depression over the ciliary body was performed to reach the entire ciliary processes being photocoagulated. Subconjunctival injection of tobramycin and dexamethasone was performed after each procedure (ECP and Ahmed). Additionally, 0.1 mL of dexamethasone was injected in the anterior chamber. Topical antibiotics, corticosteroids, and atropine were prescribed postoperatively and tapered as the intraocular inflammation decreased.

The Wilcoxon's test was used to compare proportions, Sign's test for binary variables, analysis of variance (ANOVA - F) when the parametric tests basic assumptions were satisfied and Student's *t* test for linear variables. A Kaplan-Meier survival curve was created for both procedures and the Ahmed and ECP groups were compared with the Log-Rank test. Defining the alpha error as 0.05 and a power of 90%, the sample size necessary in each group to detect significant differences was 23. With a sample size of 34, we were able to achieve a power of 98.2%.

RESULTS

Sixty-eight patients were included in the study. Demographic data are displayed in Table 1. The average number of previous surgical procedures was 3.2 ± 2.0 and 3.1 ± 2.2 for Ahmed and ECP, respectively ($P = 0.6$). Table 2 illustrates the frequency of prior surgery with antimetabolite in both groups. Table 3 shows the glaucoma diagnosis for each group. The follow-up time was 19.82 ± 8.35 (from 2 to 24) months for the Ahmed group and 21.29 ± 6.42 (from 2 to 24) months for the ECP eyes ($P = 0.4$).

The preoperative IOP, 41.32 ± 3.03 mm Hg (Ahmed) and 41.61 ± 3.42 mm Hg (ECP) ($P = 0.5$) and the mean postoperative IOP, at 24 months follow-up, 14.73 ± 6.44 mm Hg (Ahmed) and 14.07 ± 7.21 mm Hg (ECP) ($P = 0.7$), were significantly different from baseline in both groups ($P < 0.001$) (Table 4) (Fig. 1).

TABLE 1. Demographic Data

Group	Number	Sex	Age* (mean ± SD)	Race
ECP	34	20 male, 14 female	53.76 ± 10.4	24 Caucasians, 10 Black
Ahmed	34	19 male, 15 female	56.64 ± 11.33	22 Caucasians, 10 Black, 2 Asians

*$P = 0.4$.

TABLE 2. Number of Eyes Exposed to Antimetabolites in Both Groups

Antimetabolite		Ahmed	ECP	P*
Mitomycin (MMC)	n (%)	25 (73.5)	24 (70.5)	
5-Fluorouracil (5-FU)	n (%)	4 (11.7)	3 (8.8)	F = 0.60
MMC + 5-FU	n (%)	5 (14.7)	7 (20.5)	p = 0.6

*One-way ANOVA.

The success rates at 12 (76.47% and 82.35% for Ahmed and ECP respectively, $P = 0.1$) and 24 months (70.58% and 73.52% for Ahmed and ECP respectively, $P = 0.5$) were similar between the groups. Kaplan-Meier survival curve analysis showed a probability of success at 24 months of 70.59% (19.47 ± 1.50 months) and 73.53% (21.29 ± 1.15 months) for the Ahmed and ECP groups respectively ($P = 0.7$) (Fig. 2). The Ahmed group had a greater incidence of eyes with visual acuity worsening (37.5% vs. 16%, $P = 0.001$) at 24 months postoperatively, while the ECP group had more stable eyes (60% vs. 50%, $P = 0.1$) as well as eyes with improvement in their visual acuity (24% vs. 12.5%, $P = 0.002$). The visual acuity in LogMar pre-, 0.69 ± 0.25 (Ahmed); 0.67 ± 0.24 (ECP) ($P = 0.8$), and post-operatively, 0.98 ± 0.61 (Ahmed); 0.74 ± 0.42 (ECP) ($P = 0.1$) was similar between the two groups. There was no statistical change at 24 months postoperatively compared with baseline in the ECP group (16% of eyes, $P = 0.5$), while worsening was statistically significant in eyes that had had an Ahmed tube shunt implantation (37.5% of eyes, $P = 0.03$).

The number of medications used was similar preoperatively, 3.5 ± 1.0 in the Ahmed group and 3.0 ± 1.3 in the ECP patients ($P = 0.7$) and at 24 months, 2.5 ± 1.3 (Ahmed) and 2.0 ± 1.2 (ECP) ($P = 0.3$). Complications that occurred during the study are listed on Table 5.

DISCUSSION

Refractory glaucoma is a subset of the disease where conventional treatment approaches have failed to achieve a satisfactory IOP control. Trabeculectomy typically yields lower IOP compared with Ahmed tube shunt implantation.[25] However, in some eyes the risk of premature failure usually drives the surgeon to an alternative option, such as tube shunt implants or cyclodestructive procedures.

Intraocular pressure was statistically lower in the Ahmed group compared with ECP eyes in the first week postoperatively (Table 4) (Fig. 1). The IOP rose in both groups and was equivalent at 1 month. While we found stability in the IOP in the eyes treated with ECP, the IOP continued to rise in the Ahmed group at 2 months (Table 4) (Fig. 1). This might be explained by the hypertensive period expected with drainage devices at 4 to 6 weeks postoperatively. This may be due to an increased inflammatory process at the setons plate, making

TABLE 3. Glaucoma Diagnosis in Both Groups

Diagnosis		Ahmed	ECP	P*
Neovascular	n (%)	13 (38.23)	14 (41.17)	
Pseudophakic	n (%)	10 (29.41)	10 (29.41)	F = 0.82
Associated with Penetrating Keratoplasty	n (%)	10 (29.41)	08 (23.52)	p = 0.4
Associated with Vitreo-Retinal surgery	n (%)	01 (2.9)	02 (5.88)	

*One-way ANOVA.

TABLE 4. Intraocular Pressure (± Standard Deviation) Evaluation Pre-Operatively and During the Follow-up

	Ahmed		ECP		
Period	IOP	n	IOP	n	P*
Pre-op	41.32 ± 3.03	34	41.61 ± 3.42	34	p = 0.5
7 days	5.38 ± 4.57	34	9.5 ± 5.23	34	p = 0.04
1 month	10.82 ± 7.60	34	11.38 ± 4.99	34	p = 0.4
2 months	21.88 ± 6.00	34	13.41 ± 7.11	34	p = 0.03
3 months	20.4 ± 5.70	32	13.57 ± 6.22	33	p = 0.01
4 months	16.53 ± 1.50	30	13.28 ± 3.88	32	p = 0.03
5 months	17.1 ± 5.70	30	13.64 ± 2.88	31	p = 0.08
6 months	17.78 ± 5.50	28	14.00 ± 3.62	31	p = 0.06
12 months	16.59 ± 5.37	27	15.45 ± 6.54	31	p = 0.4
18 months	14.38 ± 1.83	26	13.93 ± 5.41	29	p = 0.5
24 months	14.73 ± 6.44	26	14.07 ± 7.21	28	p = 0.7

*Independent Student's *t* test.

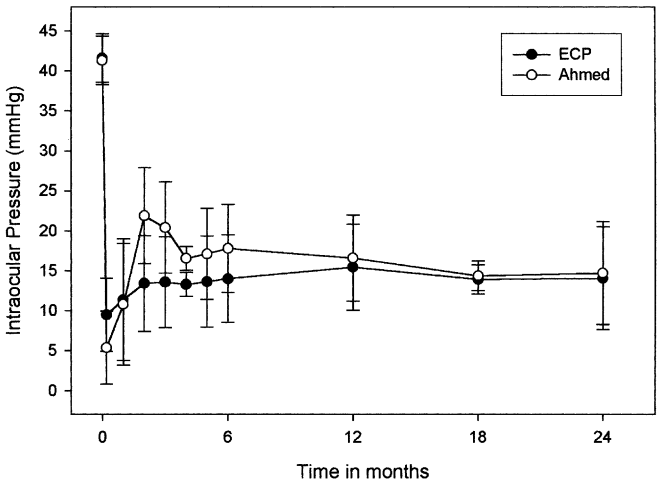

FIGURE 1. Intraocular pressure comparison between Ahmed drainage implant and Endocyclophotocoagulation.

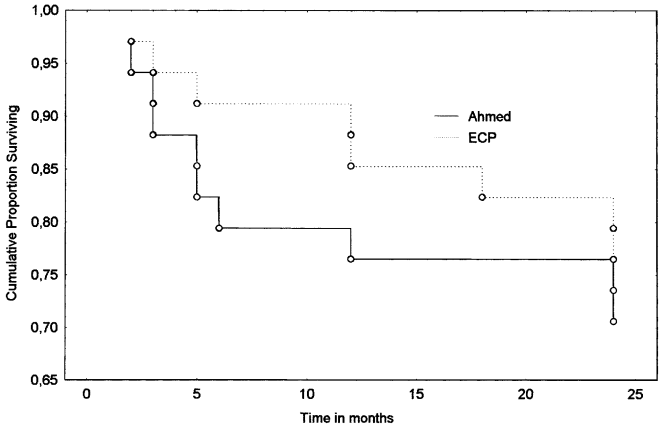

FIGURE 2. Cumulative proportion surviving (Kaplan-Meier curve) for both groups in 24 months.

difficult the aqueous flow through the dense collagen tissue in the early phase of its formation. Ayyala et al[26] compared double-plated Molteno and Ahmed tube shunts, and postulated that the hypertensive stage is inversely related to the drainage implant's plate area. Two years after surgery, the IOP was equivalent between Ahmed and ECP eyes ($P = 0.7$), and the medications used in each group was similar ($P = 0.3$).

Refractory glaucoma usually presents with advanced optic disc damage. Because IOP control is essential to preserve the visual field in eyes with glaucoma,[27] the differences in IOP during the initial months between groups might be responsible for the worsening in the visual acuity noticed in the Ahmed group ($P = 0.03$), but not observed in the eyes treated with ECP ($P = 0.5$). This disparity is important, since there were no differences in the baseline visual acuity between groups ($P = 0.8$). The visual acuity stability achieved with ECP (84% of eyes treated with ECP had improvement or stability in the visual acuity) is a substantial improvement compared with transscleral cyclophotocoagulation. In the Ahmed group, failure of the corneal graft was an important condition leading to worsening in the visual acuity and observed in only 1 patient with ECP (Table 5).

Tube shunt implantation has potential inherent complications, not observed with laser procedures, such as diplopia, tube blockage, tube exposure (2 eyes, 5.88% each), and cystic bleb formation (5 eyes, 14.7%). Furthermore, despite the presence of a valve to limit aqueous flow and therefore prevent early hypotony, eyes with Ahmed tubes had a higher incidence of hypotony-related complications, like shallow anterior chamber and choroidal detachment, which was not observed with ECP (Table 5). The presence of these complications demanded a higher number of postoperative visits in the Ahmed group. Furthermore, a higher number of procedures were necessary in this group, such as needling of the cystic bleb and anterior chamber injections of viscoelastic because of shallow anterior chamber and corneal touch. Therefore, the risk of postoperative contamination was higher in the Ahmed group. The single eye that had had endophthalmitis might be a consequence of these manipulations. The main complication in the ECP group was inflammatory precipitates in the anterior chamber. Previous studies have described higher indices (20%) compared with our results (11.76%). We believe that the anterior chamber injection of dexamethasone performed as a routine has decreased the inflammation observed in the early postoperative period, and may be included as a usual practice when performing ECP.

In our study, the eyes treated with Ahmed drainage device achieved a success rate of 76.47% at 1 year postoperatively, and 70.58% at 24 months. These results match previous studies where Ahmed tubes were placed in eyes with complicated glaucoma.[20,22,28] Similar results were also obtained in our ECP group compared with published papers.[6,7] The indices of success for eyes treated with ECP were 82.35% at 12 months postoperatively, and 73.52% at 2 years. One of the unique differences in the present study was the area of the ciliary body photocoagulated. Chen et al[6] varied the area to be treated according to the previous IOP, from 180 to 360° of the ciliary body's circumference. With ECP we can directly target the ciliary processes by a probe that combines an endoscope and laser source; thus, less tissue damage and better IOP control (less hypotony) is expected. We treated 210° of the ciliary processes because our prior experience with an extended area (260°)[7] demonstrated higher rates of ocular hypotony (18%). Even with a reduced area, one eye had persistent hypotony and another one became phthisical (2.94% each).

Although our patients were not truly randomized, they followed an alternating sequence that was established before

TABLE 5. Complications During Study

Complications	Ahmed	ECP	*P**
Choroid detachment	6 (17.64%)	1 (2.94%)	0.1
Shallow anterior chamber	6 (17.64%)	—	0.02
Hyphema	5 (14.7%)	6 (17.64%)	1.0
Cystic bleb	5 (14.7%)	—	0.05
Failure of the corneal graft	4 (11.76%)	1 (2.94%)	0.3
Tube block	2 (5.88%)	—	0.4
Corneal touch	2 (5.88%)	—	0.4
Retina detachment	2 (5.88%)	1 (2.94%)	1.0
Inflammatory precipitates in the anterior chamber	—	4 (11.76%)	0.1
Tube exposure	2 (5.88%)	—	0.4
Hypotony	—	1 (2.94%)	1.0
Endophthalmitis	1 (2.94%)	—	1.0
Phthisis bulbi	—	1 (2.94%)	1.0

*Fisher's Exact Test.

the beginning of the study, attempting to assign the same number of eyes in each group. We believe that there were no biases in the eligibility criteria, which means we did not influence the distribution of our patients. Despite a predictable series, the eyes were included arbitrarily. Therefore, the lack of randomization did not affect the study conclusion. Endocyclophotocoagulation may be a safe and efficient modality in treating refractory glaucoma compared with Ahmed tube shunt implantation. Ahmed drainage implant and ECP lower the IOP in refractory glaucoma in a similar extent ($P = 0.1$ at 12 months and $P = 0.5$ at 24 months postoperatively). However, Ahmed drainage implants had significantly more worsening of the visual acuity compared with ECP.

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REFERENCES

1. Shields MB. Cyclodestructive surgery for glaucoma: past, present, and future. *Trans Am Ophthalmol Soc*. 1985;83:285–303.
2. Lee PF, Pomerantzeff O. Transpupillary cyclophotocoagulation of rabbit eyes. An experimental approach to glaucoma surgery. *Am J Ophthalmol*. 1971;71:911–920.
3. Shields MB, Shields SE. Noncontact transscleral Nd:YAG cyclophotocoagulation: a long-term follow-up of 500 patients. *Trans Am Ophthalmol Soc.* 1994;92:271–283; discussion 283–277.
4. Simmons RB, Shields MB, Blasini M, et al. Transcleral Nd:YAG laser cyclophotocoagulation with a contact lens. *Am J Ophthalmol*. 1991;112: 671–677.
5. Bellows AR. Cyclocryotherapy for glaucoma. *Int Ophthalmol Clin*. 1981; 21:99–111.
6. Chen J, Cohn RA, Lin SC, et al. Endoscopic photocoagulation of the ciliary body for treatment of refractory glaucomas. *Am J Ophthalmol*. 1997; 124:787–796.
7. Lima FE, Carvalho DM, Beniz J, et al. Ciclofotocoagulação endoscópica em glaucomas refratários. *Rev Bras Oftal*. 1997;56:397–406.
8. Hampton C, Shields MB, Miller KN, et al. Evaluation of a protocol for transscleral neodymium: YAG cyclophotocoagulation in one hundred patients. *Ophthalmology*. 1990;97:910–917.
9. Caprioli J, Strang SL, Spaeth GL, et al. Cyclocryotherapy in the treatment of advanced glaucoma. *Ophthalmology*. 1985;92:947–954.
10. Schuman JS, Puliafito CA, Allingham RR, et al. Contact transscleral continuous wave neodymium: YAG laser cyclophotocoagulation. *Ophthalmology*. 1990;97:571–580.
11. Egbert PR, Fiadoyor S, Budenz DL, et al. Diode laser transscleral cyclophotocoagulation as a primary surgical treatment for primary open-angle glaucoma. *Arch Ophthalmol*. 2001;119:345–350.
12. Patel A, Thompson JT, Michels RG, et al. Endolaser treatment of the ciliary body for uncontrolled glaucoma. *Ophthalmology*. 1986;93:825–830.
13. Uram M. Ophthalmic laser microendoscope endophotocoagulation. *Ophthalmology*. 1992;99:1829–1832.
14. Uram M. Endoscopic cyclophotocoagulation in glaucoma management. *Curr Opin Ophthalmol*. 1995;6:19–29.
15. Uram M. Combined phacoemulsification, endoscopic ciliary process photocoagulation, and intraocular lens implantation in glaucoma management. *Ophthalmic Surg*. 1995;26:346–352.
16. Gayton JL, Van Der Karr M, Sanders V. Combined cataract and glaucoma surgery: trabeculectomy versus endoscopic laser cycloablation. *J Cataract Refract Surg*. 1999;25:1214–1219.
17. Lieberman MF, Ewing RH. Drainage implant surgery for refractory glaucoma. *Int Ophthalmol Clin*. 1990;30:198–208.
18. Melamed S. Implantation of setons in glaucoma. In: D.A. Lee, (ed.): *Management of Difficult Glaucoma.* Boston: Blackwell Scientific; 1994;401–413.
19. Coleman AL, Hill R, Wilson MR, et al. Initial clinical experience with the Ahmed Glaucoma Valve implant. *Am J Ophthalmol*. 1995;120:23–31.
20. Ayyala RS, Zurakowski D, Smith JA, et al. A clinical study of the Ahmed glaucoma valve implant in advanced glaucoma. *Ophthalmology*. 1998; 105:1968–1976.
21. Valimaki J, Tuulonen A, Airaksinen PJ. Outcome of Molteno implantation surgery in refractory glaucoma and the effect of total and partial tube ligation on the success rate. *Acta Ophthalmol Scand*. 1998;76:213–219.
22. Huang MC, Netland PA, Coleman AL, et al. Intermediate-term clinical experience with the Ahmed Glaucoma Valve implant. *Am J Ophthalmol*. 1999;127:27–33.
23. Holladay JT. Proper method for calculating average visual acuity. *J Refract Surg*. 1997;13:388–391.
24. Rebolleda G, Munoz FJ, Murube J. Audible pops during cyclodiode procedures. *J Glaucoma*. 1999;8:177–183.
25. Wilson MR, Mendis U, Smith SD, et al. Ahmed glaucoma valve implant vs trabeculectomy in the surgical treatment of glaucoma: a randomized clinical trial. *Am J Ophthalmol*. 2000;130:267–273.
26. Ayyala RS, Zurakowski D, Monshizadeh R, et al. Comparison of double-plate Molteno and Ahmed glaucoma valve in patients with advanced uncontrolled glaucoma. *Ophthalmic Surg Lasers*. 2002;33:94–101.
27. The Advanced Glaucoma Intervention Study (AGIS): 7. The relationship between control of intraocular pressure and visual field deterioration. The AGIS Investigators. *Am J Ophthalmol.* 2000;130:429–440.
28. Topouzis F, Coleman AL, Choplin N, et al. Follow-up of the original cohort with the Ahmed glaucoma valve implant. *Am J Ophthalmol*. 1999; 128:198–204.

