Selective Laser Trabeculoplasty for the Management of Open-Angle Glaucoma in St. Lucia

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Objective: To evaluate the efficacy of selective laser trabeculoplasty (SLT) for the treatment of primary open-angle glaucoma in an African-derived population in the developing world.

Methods: Sixty-one subjects from St. Lucia with medically treated primary open-angle glaucoma underwent a 30-day washout, followed by bilateral 360° SLT. Intraocular pressure (IOP) was measured 1 hour, 1 week; and 1, 3, 6, 9, and 12 months after SLT.

Results: Mean (SD) IOP with medical therapy was 17.3 (5.0) mm Hg and 17.5 (4.0) mm Hg in the right and left eyes, respectively, and increased to 21.4 (3.6) mm Hg and 21.1 (3.5) mm Hg, respectively, after washout. Both eyes demonstrated a prompt and sustained IOP response to SLT therapy. Intraocular pressure dropped significantly by the first week and remained in the range of 13 to 14 mm Hg without medical therapy through 12 months in patients deemed successful. The mean IOP reductions from baseline ranged from 7.3 to 8.3 mm Hg (34.1%-38.8%) in right eyes and from 7.6 to 8.2 mm Hg (36.0%-38.9%) in left eyes through 12 months. The 12-month Kaplan-Meier survival rate (≥10% IOP reduction from postwashout baseline) was 77.7%, and 93% of successful subjects experienced IOP levels less than with-medication values. Most subjects reported moderate photophobia for 2 to 3 days after SLT; only 1 received anti-inflammatory therapy. Five eyes of 3 subjects had IOP spikes between 5 and 10 mm Hg that resolved without treatment.

Conclusions: The magnitude and duration of IOP reduction are clinically relevant in individuals from St. Lucia of African descent. If repeatable, SLT could be a powerful tool for reducing glaucoma-related blindness in this population.

to therapy and tachyphylaxis associated with chronic β-blocker therapy—issues not specific to the developing world—may further diminish the efficacy of medical therapy. Incisional surgical interventions are impractical for several reasons. There are few, if any, trained glaucoma surgeons in these regions. Medical mission-based surgery is infeasible given the intensive and prolonged postoperative care that glaucoma surgery requires. Additionally, black race is a well-established risk factor for glaucoma filtration surgery failure even under optimal conditions. A surgical trial conducted in St. Lucia (albeit in the pre-antimetabolite era) suggested that guarded trabeculectomy was inadequate to control glaucoma in St. Lucia and that a full-thickness procedure would likely be required; mitomycin-C–augmented trabeculectomy in black patients in Dominica fared significantly better, although with higher rates of potentially blindness complications such as bleb leak and infection.

Is there a role for trabeculoplasty in the developing world? The Glaucoma Laser Trial characterized the safety and efficacy of argon laser trabeculoplasty (ALT) in the management of OAG, and subsequently ALT was shown to be effective in African-derived Caribbean individuals with glaucoma, producing IOP reductions of 6 to 7 mm Hg that endured for 12 or more months in most patients when used as an adjunct to medical therapy. Despite these findings, trabeculoplasty has not had widespread application in the developing world for several reasons: minimal availability and portability of argon-based laser platforms in this region, the transience of its effect on IOP, and the potential safety concerns of repeat ALT, which include significant and sustained IOP elevations.

Selective laser trabeculoplasty (SLT) is equally safe and effective as ALT, more portable than argon-based laser platforms, and a recent published study suggested that SLT may be safe and effective when repeated after the initial treatment effect wanes. Selective laser trabeculoplasty meets many of the criteria necessary for viable application in the developing world: the treatment is fast, safe, and minimally invasive, and no postoperative medications or evaluations are strictly necessary; the equipment is portable; and the incremental cost of treatment is small once the equipment and expertise are on-site. Selective laser trabeculoplasty has also not been widely applied to glaucoma management in the developing world, likely for all the reasons previously enumerated here for ALT and also because—unlike the argon laser system—the SLT system is a dedicated device with a single indication.

There remains unmet need for a safe, effective, and cost-effective therapy for glaucoma patients in the African-derived developing world. Selective laser trabeculoplasty may be a part of the solution to the developing world’s burgeoning glaucoma burden. To our knowledge, there are no published reports describing the efficacy of SLT therapy in people of African descent to date. Herein, we report the 12-month results of a prospective cohort study designed to evaluate the role of SLT as the sole treatment for OAG in St. Lucia.

This was a prospective, interventional cohort study conducted in St. Lucia in accordance with the tenets of the Declaration of Helsinki. The protocol was reviewed and approved by ethics committees at West Virginia University and in St. Lucia. All participants provided written informed consent.

African-derived individuals from St. Lucia aged 40 years or older with confirmed primary OAG being treated with 1 topical IOP-lowering medication were eligible to participate. Subjects were prescreened for eligibility (age, diagnosis, and number of medications taken) from the clientele of 2 eye clinics in St. Lucia, one in the northern city of Castries and the other in the southern city of Vieux Forte. All subjects who met screening criteria underwent a comprehensive examination including visual acuity, Perkins tonometry, gonioscopy, pachymetry, slitlamp examination, Humphrey Matrix frequency-doubling perimetry, and dilated fundoscopic examination. Qualifying participants had open angles and glaucomatous optic discs (excavation, diffuse or focal thinning, or notching of the neuroretinal rim; visible nerve fiber layer defects; or asymmetry of the vertical cup-disc ratio of >0.2 between eyes) with or without typical glaucoma defects on reliable Humphrey Matrix perimetry. All qualifying subjects underwent a 30-day washout of current IOP-lowering medication. To qualify for washout, the visual acuity was 20/400 or better in the worse eye, iridocorneal angles were open, the cup-disc ratio did not exceed 0.8 in either eye, and visual field loss did not encroach within the central 10°. Following washout, subjects underwent 2 IOP assessments 2 hours apart on the same day. Subjects whose washout IOP was ≥35 mm Hg or less at both points received bilateral 360° SLT treatment in a single session following a single application of brimonidine 0.2% in each eye. The Selecta SLT system (Lumenis) and the Latina lens were used. Selective laser trabeculoplasty power was continuously adjusted through each procedure to produce tiny champagne bubbles with every second or third shot. The entire circumference of the angle was treated, with approximately 25 spots placed per quadrant. No anti-inflammatory medications were used postoperatively. Subjects were instructed to not take any IOP-lowering medications and were reexamed 1 hour, 1 week, and 1, 3, 6, 9, and 12 months after SLT therapy. All IOP assessments were obtained by a single technician using a single Perkins tonometer at the same time of day (within 1 hour) for each patient. Two IOP measurements were obtained at each point and averaged, with the tonometer dial positioned on 10 mm Hg before each measurement.

The minimum success criterion was specified a priori as a 10% reduction in IOP from baseline after washout. At each visit after the 1-week assessment, subjects failing to meet this criterion in either eye underwent a second assessment within 2 days. Subjects failing to meet the 10% reduction criterion in the same eye(s) on both of these assessments were deemed failures. Failing subjects restarted topical medical therapy or, if failing after a minimum of 6 months of IOP control, were offered repeat 360° SLT in the failing eye(s).

The goal of this study was to achieve estimates of the magnitude and duration of IOP reduction following SLT therapy to establish the viability of SLT in people of African descent and to inform the design of future studies. In the absence of a control or comparator group, statistical analysis was planned to be descriptive in nature. Mean (SD) IOP at each planned visit, IOP reductions from baseline (after washout) at each post-SLT visit, and the cumulative probability of success at 12 months were planned outcome measures. As no statistical comparisons were planned, a formal power and sample size calculation was not performed. Enrollment was planned to take place...
A total of 82 prescreened subjects were evaluated for participation. Of these, 64 subjects met the eligibility criteria and underwent 30-day washout of topical IOP-lowering medications. After washout, 61 subjects met final eligibility criteria (1 had IOP exceeding 35 mm Hg after washout, 1 restarted medical therapy by nonstudy personnel during the washout period, and 1 withdrew consent) and underwent bilateral 360° SLT therapy. All were individuals from St. Lucia of African descent, 69% (42 of 61) were women, and their mean (SD) age was 61.5 (9.7) years. No subjects withdrew or were lost to follow-up through 12 months of follow-up. One subject died of unrelated causes, 1 underwent cataract surgery in 1 eye, and 1 restarted IOP-lowering medications by nonstudy personnel during the 12-month study; all contributed data up to the time of these events. Overall, 58 of the remaining 60 subjects were examined at 12 months; 2 subjects were off the island at the time.

Mean (SD) IOP before washout was 17.3 (5.0) mm Hg in right eyes and 17.5 (4.0) mm Hg in left eyes. Most subjects were being treated with a β-blocker (61%), with a smaller number treated with a prostaglandin analogue (30%) or other drugs (9%). After washout, the mean (SD) IOP increased to 21.4 (3.6) mm Hg and 21.1 (3.5) mm Hg in right and left eyes, respectively. Baseline ocular characteristics and SLT parameters are provided in Table 1. Table 2 provides the IOP response profile through 12 months after SLT therapy among patients still controlled with SLT alone. The IOPs of failing patients were included in the visit at which each failed, but they were dropped from subsequent visits once patients restarted medical therapy or received repeat SLT. Mean IOP in both eyes demonstrated a prompt and sustained response to SLT therapy, dropping significantly by the first week and remaining in the 13 to 14 mm Hg range without any use of topical IOP-lowering medical therapy through 12 months of follow-up (Figure 1). The mean IOP reductions from baseline across visits (months 1, 3, 6, 9, and 12) ranged from 34.1% to 38.8% (7.3-8.3 mm Hg) in right eyes and from 36.0% to 38.9% (7.6-8.2 mm Hg) in left eyes.

Survival analysis with 10% or greater IOP reduction in both eyes without the need for IOP-lowering medications as the success criterion revealed a 12-month survival rate of 77.7% (Figure 2). By the completion of the 12-month visit, 13 subjects had failed to achieve at least a 10% IOP reduction in both eyes at 1 or more visits (4, 3, and 6 subjects at months 3, 6, and 9, respectively, demonstrating an initial nonresponder rate of 7% at month 3 and 11% at month 6), 3 were censored (1 each for death, cataract surgery, and reintiation of medical therapy), and 2 were not examined at month 12. Among the 13 failures, 5 failed at IOPs that were lower than their prewashout IOP (with treatment); this occurred because washout IOP in these cases was lower than with-therapy IOP, which was likely a manifestation of spontaneous IOP variability. Of these 13 failures, only 4 failed in both eyes for a total of 17 failed eyes (13.9% of 122 total eyes). Among the 43 patients who remained successes through month 12, 40 (93.0%) had a mean IOP reduction in both eyes of at least 20% from baseline, 29 (67.4%) had a mean IOP reduction of at least 30%, 22 (51.2%) had a mean IOP reduction of at least 40%, and 7 (16.3%) had a mean IOP reduction of at least 50% from baseline while taking no medications 12 months after a single SLT treatment (Figure 3). At month 12, 40 of the 43 successfully controlled patients had IOP that was equal to or lower than their prewashout IOP while taking medication. Spikes in IOP in excess of 5 mm Hg 1 hour after SLT were seen in 5 eyes of 3 subjects. None of these spikes exceeded 10 mm Hg and all resolved by the week 1 visit without treatment. Nearly all subjects (59 of 61, 96.7%) reported 2 to 3 days of moderate photophobia immediately following SLT when evaluated at the week 1 visit. Only 1 subject sought evaluation for photophobia and received a 3-day course of topical nonsteroidal anti-inflammatory drug therapy; the photophobia was resolved by the week 1 visit.

Reduction of IOP—whether by medication, laser procedures, or surgical interventions—effectively reduces the risk for glaucoma-related vision loss in mixed populations that are largely of European extraction but do contain some people of African descent (although results in this subset are infrequently reported separately from the entire sample).24–26 Medical therapy is available in St. Lucia, but the ineffectiveness of primary medical therapy in preventing glaucoma-related vision loss in this setting is established by the nation’s high (16%) 10-year incidence of glaucoma-related blindness in the generic β-blocker era. This ineffectiveness is likely attributable to some combination of nonadherence, tachyphylaxis, and inability to pay for medical therapy. Primary incisional surgical intervention is also impractical for numerous reasons: the high rate of complications, lack of local expertise in glaucoma surgery techniques, cost, and relatively lower success rates in blacks vs white patients. Laser tra-
beculoplasty has not been systematically explored as a therapeutic option for this population. In this article, we report the 12-month IOP-lowering profile of SLT monotherapy in African-derived individuals from St. Lucia.

The Advanced Glaucoma Intervention Study demonstrated that people of African descent in the developed world respond well to ALT.

Our data support that the same is true of SLT in people of African descent living in the developing world. In the current study, a single SLT treatment produced mean IOP reductions in the range of 33% to 40% (7-8 mm Hg) without the need for medical therapy for at least a year in most patients (>75%) treated. Interestingly, a handful of subjects had lower IOP after washout of IOP-lowering medications compared with before washout. Five of the 13 failures occurred at IOP levels that were lower than their prewashout with medication IOP. The average IOP reduction with SLT was significantly greater than that provided by medical therapy at every point after the 1-week assessment. The mean IOP in the patients still controlled at 12 months was 13 mm Hg in both eyes, and 93% of these patients had lower IOP 12 months after SLT than they did on medical therapy prewashout. Subjects in the Collaborative Initial Glaucoma Treatment Study assigned to medical therapy experienced mean IOP reductions of approximately 35% over 5 years with essentially stable mean visual field scores throughout follow-up. Similarly, the subset of subjects in the associative analysis of the Advanced Glaucoma Intervention Study who consistently had IOP less than 18 mm Hg (and a mean IOP of 12.3 mm Hg) also manifested overall visual field stability through 6 years of follow-up. These observations from major clinical trials support that both the absolute and relative IOP reductions produced by SLT in our cohort should reason-

### Table 2. IOP at Each Period and Change From Baseline by Eye Among Patients Deemed Successes at Each Period

<table>
<thead>
<tr>
<th>Period</th>
<th>IOP Before Washout</th>
<th>Change From Baseline IOP</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Right Eye</td>
<td>Left Eye</td>
</tr>
<tr>
<td>Before washout (n = 61)</td>
<td>17.3 (4.0)</td>
<td>17.5 (4.0)</td>
</tr>
<tr>
<td>After washout (n = 61)</td>
<td>21.4 (3.6)</td>
<td>21.1 (3.5)</td>
</tr>
<tr>
<td>Hour 1 (n = 61)</td>
<td>21.0 (4.2)</td>
<td>20.4 (4.0)</td>
</tr>
<tr>
<td>Month 1 (n = 61)</td>
<td>13.5 (3.4)</td>
<td>12.9 (3.1)</td>
</tr>
<tr>
<td>Month 3 (n = 59)</td>
<td>14.0 (3.5)</td>
<td>13.2 (3.2)</td>
</tr>
<tr>
<td>Month 6 (n = 55)</td>
<td>13.8 (3.7)</td>
<td>13.5 (3.7)</td>
</tr>
<tr>
<td>Month 9 (n = 51)</td>
<td>14.1 (3.4)</td>
<td>13.4 (3.7)</td>
</tr>
<tr>
<td>Month 12 (n = 43)</td>
<td>13.1 (3.3)</td>
<td>12.9 (3.1)</td>
</tr>
</tbody>
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**Abbreviation:** IOP, intraocular pressure.
Bilateral 360° SLT in a single session was very well tolerated by all subjects. Because no subject in this study was lost to follow-up through 12 months, the characterization of safety issues was comprehensive; this follow-up rate is attributable to the local community’s support for this initiative, which included reminder phone calls and volunteered transportation for subjects to attend study visits. Five eyes of 3 patients (5 of 122, 4.1%) manifested IOP spikes greater than 5 mm Hg but less than 10 mm Hg that resolved within a week without treatment. In a study by Latina and colleagues, 25% of eyes that underwent 180° SLT manifested a 5 mm Hg or greater IOP spike within the first 2 hours. Eyes that underwent 360° SLT in various studies have exhibited acute IOP spikes of 5 mm Hg or greater at rates ranging from 4.5% to 27%.20,31,32 Our observed IOP spike rate is at the low end of this range. In contrast, all but 2 patients reported moderate photophobia commencing the day after SLT and lasting 2 to 3 days. Only 1 of the 59 affected subjects required treatment, and all reported resolution of symptoms by the week 1 assessment. This was unexpected and not consistent with our experience performing SLT on African American patients nor with the published literature on SLT safety.33 The etiology of this symptom is not immediately clear. The most likely explanation is acute iridocyclitis following SLT. Unfortunately, a slitlamp was not available for the week 1 assessment (it was allocated to another clinician at the time of our week 1 evaluation; this scheduling conflict was owing to Hurricane Tomas striking St. Lucia on October 30, 2010, necessitating that we delay the start of this study by 1 month such that our presence overlapped that of another eye care team) so this hypothesis cannot be addressed in the current data set; a formal evaluation of this hypothesis is planned for the next treated cohort.

The magnitude of the IOP increase after washout of IOP-lowering medications was modest, at 3.5 to 4.5 mm Hg. Most patients were taking β-blockers or prostaglandin analogues, which would be expected to produce greater average IOP reductions than we observed. This relatively small medication effect is likely explained both by nonadherence to therapy and tachyphylaxis to chronic β-blocker therapy. Additionally, timolol may be less effective in black than white patients,34,35 thus perhaps the smaller than expected increase in IOP observed after washout is consistent with the demographics of our cohort. The washout IOP of this population (21.4 mm Hg in right eyes and 21.1 mm Hg in left eyes) is entirely consistent with the mean IOP reported by Mason and colleagues6 among treatment-naive patients with OAG in the original St. Lucia Eye Survey (21.1 mm Hg in right eyes and 21.3 mm Hg in left eyes). This level of IOP is entirely capable of producing progression to blindness in this population. In their follow-up study, Wilson and colleagues reported a 16% 10-year incidence of unilateral or bilateral blindness in this population, with mean follow-up IOP of 21.0 mm Hg in both eyes.

Our ultimate goal is to apply the lessons from this and subsequent studies to untreated or undertreated patients with OAG throughout the African-derived developing world. We hoped to show that SLT was a reasonable alternative to medical therapy in patients who otherwise would not receive medical therapy. We elected to use a convenience sample of diagnosed and medically treated patients for this study because to identify and enroll treatment-naive patients would have been extremely costly and time consuming. This is a ubiquitous practice in the evaluation of IOP-lowering therapies; to our knowledge, there are no phase 3 regulatory studies of topical IOP-lowering medications that included a requirement that all subjects be treatment naive at enrollment. Our subjects underwent washout and establishment of untreated IOP at baseline. There is no obvious reason to expect that our results would differ from those obtained when SLT is offered to treatment-naive patients, particularly given that our sample’s washout IOP was identical to the mean IOP of treatment-naive patients with glaucoma in the prior St. Lucia glaucoma studies.6,7 We did not set out to establish that SLT is preferred over medical therapy or that patients who can afford and are controlled with medical therapy should undergo SLT as replacement therapy, although our data would support further inquiry along these lines because SLT reduced IOP significantly better than medical therapy for most patients in this cohort. A comparative cost analysis of medications vs SLT in this setting is impractical at present as the long-term duration of effectiveness of SLT has not yet been established.

We considered inclusion of a control group. An untreated control group was rejected as unethical. A control group that received topical medical therapy was a consideration, but this method was rejected as it minimized what is likely a very important distinction between efficacy and effectiveness. This difference—that the IOP reduction seen in a group of patients who receive free drug, free care, and frequent monitoring within a clinical trial (efficacy) is likely greater than that seen when the same drug is used in routine clinical practice (effectiveness)—is generally disregarded in the developed world but is likely clinically significant in a setting where medical therapy is not widely affordable, thus nonadherence is likely high. Alternatively, a control group that received a prescription for medical therapy and no assistance in filling the prescription would be the methodologically appropriate control group to achieve the goals of this study in this setting. We did not include such a control group to ensure that all consenting subjects could potentially benefit from participation, a design feature that was deemed essential to garnering local support and adequate enrollment.

The criticism that a minimum 10% reduction from baseline is of limited clinical significance warrants justification. There are 2 distinct issues here. The first is a human subjects protection issue: what is the threshold for declaring failure and advancing therapy so as not to leave these study subjects undertreated in the interest of science? The second is a public health issue: what is the minimum degree of IOP reduction needed to justify offering primary SLT to untreated and underserved African-derived populations?

Our methodological justification for a 10% threshold for these study subjects is as follows. Our intention was
to set a threshold that approximated medical therapy, with the belief that if SLT worked slightly less well than medications, it should not be disregarded as a viable therapy in an untreated population. We assumed most patients would be taking β-blocker therapy, and while the IOP-lowering profile of β-blockers is known, we could not accurately account for possible nonadherence and tachyphylaxis a priori, thus we could not anticipate the extent to which IOP might increase after washout. The 10% level was selected as a preliminary threshold during study planning, with the intent to revise the threshold if necessary prior to laser treatment based on the observed IOP change in the study cohort after washout of IOP-lowering medications. The observed mean (SD) increase in IOP after washout was 4.1 (4.6) mm Hg in right eyes and 3.7 (4.6) mm Hg in left eyes, such that medical therapy reduced IOP by 19% and 17.5% in right and left eyes, respectively, from untreated washout IOP. If a 20% threshold had been selected as the success criterion, most patients would likely have been considered failures, even if SLT reduced IOP equivalently to (or even marginally better than) medical therapy. A 15% threshold was considered. This would require the declaration of failure if IOP were a mere 0.5 mm Hg higher than with medical therapy (15% vs 17.5%, or 0.5 mm Hg in a sample with washout IOP of approximately 21 mm Hg). We would not necessarily consider SLT valueless in this population if it were on average 0.5 mm Hg less effective than medical therapy. Thus, the a priori 10% threshold was reviewed but not revised after washout. In our data set, 40 of the 43 subjects still controlled at month 12 (65.6% of the 61 subjects overall) had IOP reductions in excess of 20% from untreated baseline at this point; of the remaining 3 who had IOP reductions between 10% and 20% at month 12, 2 had IOP at this point that was less than their IOP with medical therapy at the start of the study.

This is not to say that an average 10% reduction in IOP is adequate to justify the development of a public health initiative to offer primary SLT widely throughout the African-derived developing world. If we had found a mere 10% mean IOP reduction in this preliminary study, it is unlikely that we would pursue this approach as a viable intervention in this setting. However, our data demonstrate that SLT in this population reduces IOP by an average of 40% in most patients for at least 12 months. Approximately 75% experienced adequate IOP control with no additional therapy 12 months after initial SLT, and 93% of those had better IOP reduction after SLT than they did when taking medical therapy. But not every patient achieves adequate IOP reduction after SLT, as one-quarter of the subjects did not achieve adequate IOP control with SLT. While SLT will clearly not be the answer for every patient with glaucoma, the magnitude and duration (to date) of response observed in this cohort are more than adequate to justify further exploration of this treatment modality as a partial solution to the African-derived developing world’s burgeoning glaucoma burden. Knowing what we know now, a higher success threshold (minimum 20% IOP reduction from postwashout baseline) should be used to guide the advancement of therapy (restarting medical therapy or repeating laser therapy) in future studies.

Before the results of this study can be translated into a population-based public health initiative, several key questions must first be addressed. How long might the IOP reduction from initial SLT persist and can SLT be safely repeated when it does wear off? We do not yet know the mean duration of effect of SLT in this population because too few patients in this cohort have reached failure at the 12-month mark. At 12 months, three-quarters of patients continued to do well without the need for medical therapy. Regarding repeatability of SLT, to our knowledge, the only peer-reviewed published data to date is from Hong and colleagues, who reported that success of second SLT (≥20% IOP reduction) was comparable to that of first SLT in a retrospective analysis. No ethnicity data were provided in that study, shedding no light on the repeatability of SLT in people of African descent. More recently, Berezina and colleagues reported that repeat 360° SLT reduced IOP from prerepeat baseline by a significant amount for 30 months; however, by month 36, IOP was statistically similar to prerepeat baseline. Approximately 25% of the patients in this retrospective analysis were African American but their results were not reported separately.

A second key question is whether the results observed in individuals from St. Lucia are unique to this closed population or will generalize to other African-derived populations within the developing world. We plan to conduct a study of similar design to the current study in an ethnically similar yet geographically distinct population to confirm the external validity of our St. Lucia findings. If both repeatability and generalizability of SLT can be demonstrated in this population, our goal is to develop a public health initiative structured around a mobile glaucoma laser program to serve the treatment needs of this region.

Submitted for Publication: July 23, 2012; final revision received September 24, 2012; accepted October 22, 2012. Published Online: January 24, 2013. doi:10.1001 /jamaophthalmol.2013.1706
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Conflict of Interest Disclosures: Dr Realini is a member of the Lumenis speakers’ bureau.
Funding/Support: This study was funded in part by the American Glaucoma Society. Lumenis Inc provided the selective laser trabeculoplasty system at no cost.
Previous Presentation: This study was presented in part at the American Glaucoma Society Annual Meeting; March 1, 2012; New York, New York.


