Trabecular Microbypass Stent and Phacoemulsification in African American Patients With Open-angle Glaucoma: Outcomes and Effect of Prior Laser Trabeculoplasty

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Precis: In African American patients with glaucoma, iStent/phacoemulsification lowered intraocular pressure and reduced glaucoma medication usage for up to 1 year, even in patients with prior selective laser trabeculoplasty (SLT).

Purpose: Currently, no studies have examined the outcomes of a trabecular microbypass stent and phacoemulsification in African American patients. Here, the authors investigate whether iStent/phacoemulsification decreases intraocular pressure (IOP) and/or medication usage in African American patients with glaucoma. They are also interested in whether prior SLT would affect outcomes of iStent/phacoemulsification.

Patients and Methods: A multicenter, retrospective case series of eyes that underwent iStent/phacoemulsification between 2013 and 2017 with up to 1-year follow-up. Eyes with a confirmed diagnosis of glaucoma in African American patients were included. Eyes with neovascular glaucoma or closed angle glaucoma and eyes that underwent previous incisional glaucoma surgery were excluded.

Results: Eighty-nine eyes were included in the study and data for 66 eyes were available at postoperative year 1 (POY1). IOP decreased from 18.3 ± 5.7 mm Hg to 15.9 ± 4.6 (P < 0.001) and glaucoma medication usage decreased from 1.9 ± 1.1 to 1.1 ± 1.1 (P < 0.001) at POY1. Eyes that underwent prior SLT experienced less of a decrease in IOP when compared with eyes without prior SLT, but IOP at POY1 was not significantly different between these groups. Both groups had a similar reduction in medication usage. The most common complications were IOP spikes on postoperative day 1 and microphlymas.

Conclusions: In this cohort, there was a significant decrease in IOP and medication usage 1 year after iStent/phacoemulsification. iStent/phacoemulsification is an effective and safe treatment option in African American patients with glaucoma.

Key Words: glaucoma, iStent and phacoemulsification, African American patients

Glaucoma is the leading cause of irreversible vision loss worldwide. African Americans (AA) have almost 3 times the prevalence of glaucoma when compared with white Americans.1,2 At the time of presentation, AA patients are more likely to present with advanced visual field loss, increased cup to disc ratio, and experience blindness up to 10 years before white patients.3-5 Currently, the only known therapy for glaucoma is to decrease intraocular pressure (IOP), which can be achieved through topical medications, laser therapy, and/or surgery. AA patients have variable outcomes with some of these procedures and as of now, there are little data to show that tube shunts, ExPRESS shunts (Alcon, Ft. Worth, TX), and canaloplasty are more efficacious than a trabeculectomy.6,7 Even after the introduction of antimetabolites, several studies have found increased rates of filtration failure in AA patients undergoing trabeculectomy.7,8-10 Another study found that trabeculectomy with ExPRESS shunt was as effective as a trabeculectomy in AA patients after 1 year while requiring fewer postoperative interventions.11 There remains an important need to continue studying outcomes of IOP-lowering surgeries, particularly in AA patients.

One procedure that has yet to be studied in AA patients is the trabecular microbypass iStent (Glaukos, San Clemente, CA), one of the Minimally Invasive Glaucoma Surgeries. It is a biocompatible implant-grade titanium, ab-interno, heparin-coated device that is placed in the trabecular meshwork. The iStent was approved by the Food and Drug Administration when combined with phacoemulsification for use in patients with mild to moderate glaucoma and has been shown to be safe with minimal surgical complications.12 Two meta-analyses of studies comparing combined iStent and phacoemulsification to phacoemulsification alone found that the former caused a significantly larger reduction in IOP and the number of glaucoma medications used postoperatively.13,14 However, the studies included in these meta-analyses were mixed population studies, which included predominantly white patients. To our knowledge, this is the first study to evaluate the outcomes of iStent exclusively in AA patients.

Selective laser trabeculoplasty (SLT; Lumenis, Yokneam, Israel) is a 532-nm Q-switched, frequency-doubled Nd:YAG laser that delivers a 3 nanosecond pulse to the trabecular meshwork.15 It is an in-office, outpatient procedure with short recovery time. Glaucoma providers can use SLT as a primary or adjunctive intervention to control IOP.15,16 Klamm et al17 found that prior SLT treatment did not negatively affect outcomes in combined phacoemulsification and trabeculectomy cases. To our knowledge, no study has evaluated the outcomes of iStent/phacoemulsification in patients with prior SLT.

In this study, we aim to evaluate the effect of iStent/phacoemulsification on IOP, visual acuity, and number of...
glaucoma medications in AA patients with glaucoma. We also compared these outcomes in patients who had SLT before iStent/phacoemulsification and patients without prior laser therapy. Given the increased severity of disease and risk of treatment failure in AA patients, this work is necessary to help evaluate the effectiveness of iStent in this population.

PATIENTS AND METHODS

This is a retrospective, observational case series of combined phacoemulsification and trabecular microbypass (iStent) surgeries performed at University Hospital (Newark, NJ), Jersey City Medical Center (Jersey City, NJ), and Duke University Eye Center (Durham, NC). The investigators obtained institutional review board approval at their respective institutions for this study. Patient records were anonymized and de-identified before analysis. The surgeries were performed between January 2013 and August 2017 by experienced glaucoma surgeons (L.H., A.K., and S.W.). The indication for iStent/phacoemulsification was mild/moderate glaucoma, or ocular hypertension treated with glaucoma medications and/or SLT, with the presence of a cataract. The surgeons assessed the patients and performed the surgeries on patients they thought were appropriate candidates. As per Food and Drug Administration regulations at the time of the surgeries, there was 1 first-generation iStent placed in each eye during a combined procedure with phacoemulsification. Eyes included in the study were from self-identified AA patients with glaucoma who underwent combined iStent/phacoemulsification. Patients with neovascular glaucoma or closed-angle glaucoma were excluded. Patients with previous incisional glaucoma surgery were excluded as well. Treatment success was defined as eyes having a 20% reduction in IOP or if there was a reduction in at least 1 glaucoma medication at postop year 1 compared with preoperative values. We also compared IOP and medication usage in eyes that underwent SLT (laser group) versus eyes that did not undergo SLT (no laser group) before iStent/phacoemulsification.

At each visit, patients underwent a slit-lamp examination with applanation tonometry to measure IOP and had their medications reviewed. Patients had 1 to 2 preoperative visits and follow-up dates were scheduled for 1 day [postoperative day (POD) 1 to 4], 1 week (POD 5 to 10), 1 month [postoperative week (POW) 3 to 5], 3 months (POW 9 to 16), 6 months [postoperative month (POM) 4 to 8], and 1 year (POM 8 to 16) after surgery. Preoperative IOP was based on the average of the last 2 IOP measurements before surgery and in cases where there was only 1 preoperative recording, that was used as the baseline. Primary outcomes included IOP and number of anti-glaucoma medications. Combination glaucoma medications such as dorzolamide/timolol, brinzolamide/brimonidine, and brimonidine/timolol were counted as 2. Eyes that underwent secondary IOP-lowering procedures including trabeculectomy/ExPRESS, Ahmed (New World Medical, Rancho Cucamonga, CA)/Retisert (Bausch + Lomb, Laval, Quebec, Canada), and SLT in the iStent/phacoemulsification postoperative time period were censored from the study after these secondary interventions.

Statistical Analysis

The mean and SD were calculated for IOP and number of antiglaucoma medications. Paired t tests were used to compare values at postoperative to preoperative time points. Simple linear regression was used to evaluate the relationship between baseline IOP and absolute reduction in IOP at postoperative year 1 (POY1). Independent t tests were used to compare between the laser and no laser groups. P < 0.05 was considered statistically significant. Microsoft Excel was used for statistical analysis.

RESULTS

Patient Demographics

A total of 89 eyes (75 patients) were included in this study and 66 of 89 (74%) eyes had data available at POY1. The age range was 51 to 97 years (mean 75.0 ± 9.0). About 57 of 89 (64%) eyes included were from female patients. All patients were self-identified as being AA. A total of 74 of 89 (83%) eyes had primary open-angle glaucoma (POAG). The other eyes had pseudoxefoliative glaucoma (n = 1), ocular hypertension (n = 5), normal-tension glaucoma (n = 2), narrow-angle glaucoma (n = 2), uveitic glaucoma (n = 1), and mixed mechanism glaucoma (n = 4). Three eyes were noted to have a phacomorphic effect. The 3 eyes with a phacomorphic effect and the 2 eyes with narrow-angle glaucoma had no iridotrabecular contact or synechial closure.

IOP and Medications

Baseline (preoperative) IOP was 18.3 ± 5.7 (Table 1). On POM3, IOP decreased to 15.9 ± 4.7, which was significantly lower than the baseline IOP (P = 0.001, n = 76 eyes). The decrease in IOP was maintained until POY1 (15.9 ± 4.6, P = 0.001, n = 66 eyes). This represents a 2.4 mm Hg reduction or a 13% decrease in IOP at POY1. There were 47 of 66 (71%) eyes that had the same or a lower IOP on POY1 when compared with baseline IOP. Patients with a higher preoperative IOP experienced a larger decrease in IOP at postoperative year 1 (Fig. 1). Simple linear regression showed that baseline IOP accounted for about 35% of the variation in the reduction in IOP after 1 year (P < 0.001).

Glucoma medication usage decreased from a mean of 1.9 ± 1.1 to 1.1 ± 1.1 medications (P < 0.001, n = 66 eyes) at POY1 (Table 1). Mean medication usage was lower at all postoperative time points when compared with baseline medications. At POY1, 33 of 66 (50%) eyes had no change in the number of glaucoma medications at POY1 relative to baseline and 32 of 66 (48%) were taking ≥ 1 less medication. There was 1 eye at POY1 with a recorded IOP but no information on medication. There

| TABLE 1. Intraocular Pressure and Number of Glaucoma Medications Taken Preoperatively and at All Postoperative Visits |
|--------------------------------------------------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|
| Eyes (n) | Preoperative | POD1 | POW1 | POM1 | POM3 | POM6 | POY1 |
| IOP (mean ± SD) | 18.3 ± 5.7 | 17.9 ± 6.5 | 16.9 ± 6.8 | 16.9 ± 6.0 | 15.9 ± 4.7 | 15.8 ± 4.6 | 15.9 ± 4.6 |
| Paired t test | 0.599 | 0.645 | 0.044 | 0.001 | < 0.001 | < 0.001 | < 0.001 |
| No. medications | 1.9 ± 1.1 | 0.6 ± 0.9 | 0.6 ± 0.9 | 0.8 ± 1.0 | 1.2 ± 1.2 | 1.2 ± 1.2 | 1.1 ± 1.1 |
| Paired t test | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 | < 0.001 |

IOP indicates intraocular pressure; POD, postoperative day; POM, postoperative month; POW, postoperative week; POY, postoperative year.
were 25 of 66 eyes (38%) on 0 glaucoma medications at POY1 compared with 9 of 91 eyes (10%) at baseline.

After 1 year, 48 of 66 (73%) eyes had success with treatment (≥20% reduction in IOP or took ≥1 fewer glaucoma medication compared with preoperative values).

**Laser Trabeculoplasty Subanalysis**

We included 37 eyes that underwent SLT (34 eyes had it once and 3 eyes had it twice), an average of 39.2 ± 31.5 months before the iStent/phacoemulsification. When compared with baseline values, these eyes experienced a 1.2 mm Hg decrease in IOP at POY1 (17.5 ± 4.1 to 16.3 ± 4.0; 7% decrease; paired t test compared with baseline IOP  P=0.137), whereas the no laser group experienced a 3.3-mm Hg decrease (18.8 ± 6.6 to 15.5 ± 5.1; 18% paired t test compared with baseline IOP  P<0.001) (Table 2). The no laser group had a lower IOP at POY1 compared with the laser group, but the values were not significantly different from each other (independent t test  P=0.456). Of note, both groups experienced a similar reduction in glaucoma medication at all postoperative time points (Table 2). Using the same definition of treatment success as above, at POY1, 20 of 30 (67%) eyes in the laser group had success with treatment compared with 28 of 36 (78%) in the no laser group.

**Safety and Best Corrected Visual Acuity**

Visual acuity improved from 0.4 logMAR (20/50) at baseline to 0.1 (20/25). At POY1, only 2 eyes dropped ≥2 Snellen lines. Seventeen eyes had an IOP spike (>21 mm Hg) on POD1, and all but 1 of those eyes had normal pressures (≤21 mm Hg) over the next 2 visits (Table 3). The 1 eye that had elevated IOP at subsequent visits was found to have the iStent covered by peripheral anterior synechiae. Furthermore, 10 eyes had dispersive microhyphemas, all of which resolved without sequelae by POW1, with the exception of 1 patient in which it cleared on POM1 (IOP in this patient was normal on POW1 and POM1). Of the eyes with microhyphemas, only 1 eye had an IOP ≥21 mm Hg on POD1, which resolved on POM1 (information for the POW1 visit was not available).

For secondary procedures, from the time of surgery to 1 year postoperatively, 1 eye received a YAG capsulotomy, 3 eyes had YAG to the iStent, 1 eye received SLT, 2 eyes received a trabeculectomy with EXPRESS shunt, and 1 eye had an Ahmed/Retisert after the iStent placement (Table 3).

**TABLE 2.** Intraocular Pressure and Number of Glaucoma Medications Taken Preoperatively and Postoperatively for Eyes With and Without SLT Prior to iStent/Phacoemulsification

|                      | Preoperative | POD1 | POW1 | POM1 | POM3 | POM6 | POY1 |
|----------------------|--------------|------|------|------|------|------|------|
| No laser group, n (eyes) | 52           | 51   | 35   | 49   | 43   | 38   | 36   |
| Laser group, n (eyes)    | 37           | 37   | 32   | 34   | 33   | 31   | 30   |
| IOP no laser group       | 18.8 ± 6.6   | 18.1 ± 7.7 | 17.2 ± 8.3 | 16.0 ± 5.7 | 15.9 ± 4.8 | 15.0 ± 4.6 | 15.5 ± 5.1 |
| IOP laser group          | 17.5 ± 4.1   | 17.7 ± 4.6 | 16.7 ± 4.9 | 18.1 ± 6.2 | 17.1 ± 4.4 | 16.6 ± 4.5 | 16.3 ± 4.0 |
| Independent t test       | 0.256        | 0.775 | 0.755 | 0.123 | 0.058 | 0.143 | 0.456 |
| Glaucoma medications no laser group | 1.9 ± 1.1 | 0.6 ± 0.9 | 0.5 ± 0.7 | 0.9 ± 1.0 | 1.1 ± 1.2 | 1.2 ± 1.2 | 1.0 ± 1.1 |
| Glaucoma medications laser group | 1.9 ± 1.0 | 0.5 ± 0.9 | 0.8 ± 1.0 | 0.7 ± 1.0 | 1.2 ± 1.1 | 1.3 ± 1.2 | 1.2 ± 1.0 |
| Independent t test       | 0.985        | 0.746 | 0.312 | 0.585 | 0.639 | 0.886 | 0.366 |

IOP indicates intraocular pressure; POD, postoperative day; POM, postoperative month; POW, postoperative week; POY, postoperative year; SLT, selective laser trabeculoplasty.
Of note, the eye with the Ahmed/Retisert had a preoperative IOP of 37 mm Hg while on 4 medications. In the eyes that received the trabeculectomy with ExPRESS shunt, 1 underwent SLT once and the other underwent SLT twice before iStent/phacoemulsification.

**DISCUSSION**

We found that combined iStent/phacoemulsification resulted in a 2.4 mm Hg (13%) decrease in IOP and a 42% decrease in glaucoma medication use after 1 year. Eyes that did not undergo prior laser therapy experienced a greater decrease in IOP (18%) when compared with the laser group (7%), but the POY1 IOP values were not significantly different. Both groups experienced similar decreases in medication usage after 1 year. There was a favorable safety profile in this cohort. To our knowledge, this is the first study that specifically investigates outcomes of iStent in AA patients.

Previous studies found that eyes that underwent iStent/phacoemulsification experienced an 18% to 22% decrease in IOP after 12 months. In our study, IOP was significantly lower 12 months after surgery compared with baseline IOP, albeit less so than these previous studies. One of those studies mentioned having 6% of eyes included from black patients and the other 2 studies did not mention demographic information. Another study, which included 39.5% of patients of African descent, found a 16% decrease in IOP 6 months after iStent/phacoemulsification. Possible reasons as to why the IOP decrease was lower overall in our cohort is that we included patients who underwent prior laser therapy, which was possibly selected for patients with more advanced glaucoma. Also, the laser group may have selected for patients with more advanced glaucoma. Eyes in the laser group experienced a 1.2 mm Hg decrease in IOP 1 year after iStent/phacoemulsification while taking 0.8 fewer medications. Therefore, iStent may be considered as a treatment option in eyes with and without prior SLT.

Medication compliance is one of the cornerstones of effective glaucoma treatment. Friedman and colleagues compared patients taking <75% of their glaucoma medications at baseline. They found that among other factors, being AA was associated with less adherence to glaucoma medications. Some patients undergo SLT before incisional surgery, which makes it important to study how that would impact the outcomes of future interventions. We found that patients with prior SLT experienced a smaller decrease in IOP at POY1 when compared with the no laser group, but there was no difference between the IOP at POY1 between the 2 groups. The laser group had a lower baseline IOP, which may explain the smaller decrease. Also, the laser group may have selected for patients with more advanced glaucoma. Eyes in the laser group experienced a 1.2 mm Hg decrease in IOP 1 year after iStent/phacoemulsification while taking 0.8 fewer medications. Therefore, iStent may be considered as a treatment option in eyes with and without prior SLT.

Limitations to this study include that it is retrospective in nature, there is no control group, the parameters of laser therapy were not available, data regarding the severity of the disease were not available, there was no glaucoma medication washout, patients self-reported race, and that we included patients with non-POAG types of glaucoma. Also, there was no repeated measures analysis or statistical adjustment for both eyes of patients being included in the study. Glaucoma is typically a disease that lasts for life therefore longer-term studies are needed in the future to investigate whether this decrease in IOP and medication usage is sustained. Furthermore, not all patients followed-up to 1 year, which may have affected the final IOP. We had 66 of 89 (77%) eyes follow-up at 1 year, with the remainder being lost to follow-up, which is typical for these retrospective studies.

Our study showed that AA patients experience a significant decrease in IOP and number of medications used after undergoing iStent/phacoemulsification placement.
Undergoing SLT before the iStent/phacoemulsification dampens the decrease in IOP, but the decrease in medication usage is similar to patients without before SLT. It is a relatively safe procedure and allows for more invasive treatments to be done in the future if needed. Future work includes a retrospective comparison of eyes from non-AA patients and a prospective study that includes a control arm of AA patients that undergo phacoemulsification alone.

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