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Comparative Outcomes of the Molteno3 and Baerveldt Glaucoma Implants

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Purpose: To compare outcomes between 2 nonvalved glaucoma drainage devices (GDDs) used to treat refractory glaucoma or in patients with neovascular/uveitic glaucoma likely to be poorly responsive to less aggressive therapies.

Design: Retrospective, nonrandomized, multicenter comparative study.

Participants: A total of 117 eyes from 117 patients.

Methods: Retrospective chart review of patients who underwent implantation of the Baerveldt (BGI) (Abbott Medical Optics, Abbott Park, IL) or the Molteno3 glaucoma implant (MGI) (Molteno Ophthalmic Limited, Dunedin, New Zealand). Noninferiority of the MGI versus the BGI was tested with Cox and mixed-effects regression models. Interventions in each group were analyzed with chi-square tests.

Main Outcome Measures: The primary outcome was time until device failure, defined as intraocular pressure (IOP) >21 mmHg or a reduction <20%, hypotony, reoperation for glaucoma, or loss of light perception. Secondary outcomes were intraoperative time, postoperative IOP, number of IOP-lowering medications, and visual acuity (VA).

Results: The MGI could not be deemed noninferior to the BGI with regard to time until device failure (hazard ratio [HR], 0.83; confidence interval [CI], 0.41−1.65). The MGI was noninferior to the BGI when comparing postoperative IOP, a difference of −0.40 mmHg (95% CI, −1.74−0.93). The MGI needed 2% fewer medications (ratio of 0.98, 95% CI, 0.79−1.22), but noninferiority could not be claimed. With regard to VA, the MGI's mean was 0.10 logarithm of the minimum angle of resolution (logMAR) higher (95% CI, −0.01−0.21), but noninferiority testing was again inconclusive. Intraoperative time for the MGI was 15.7 minutes shorter versus the 350 mm^2 plate size BGI ($P < 0.001$) and 4.3 minutes shorter versus the 250 mm^2 plate size BGI ($P = 0.32$). More patients in the MGI group needed secondary operative management (11%, $P = 0.03$).

Conclusions: The MGI was noninferior to the BGI in lowering IOP. Differences in time until device failure, VA outcomes, and medication use were inconclusive. The MGI required more secondary operative interventions. The MGI required less time to implant than the BGI's 350 mm^2 plate size implant. Overall, the use of both GDDs is justifiable to lower IOP when more conservative management has failed. *Ophthalmology Glaucoma 2020;3:40-50 © 2019 by the American Academy of Ophthalmology*

Supplemental material available at www.ophthalmologyglaucoma.org.

Glaucoma remains a prevalent disease and is projected to affect more than 110 million people by 2040.[1] Despite ongoing research, the only proven treatment for glaucoma remains lowering intraocular pressure (IOP).[2,3] Medical management and less-invasive therapies such as laser trabeculoplasty can slow the progression of optic nerve damage or visual field loss by controlling IOP, but a subset of patients will fail to respond. Even in the age of microinvasive glaucoma surgery, adequate IOP control may require more aggressive surgical management including placement of glaucoma drainage devices (GDDs).[4]

Despite the long history of GDD use, there is no clearly superior device.[5] A number of prospective studies have compared both nonvalved and valved GDDs and found lower long-term failure rates and fewer additional medication requirements in nonvalved devices after the initial perioperative period.[6–9] However, these same studies showed that nonvalved devices have higher rates of perioperative hypotony in addition to higher long-term rates of complications that threatened vision or needed further operative interventions.[10] Because of these conflicts, a better understanding of potential differences between competing devices may help surgeons select which GDD to implant.

Both the Baerveldt glaucoma implant (BGI; BG-103-250 with 250 mm^2 plate size [B250] and BG-101-350 with 350 mm^2 plate size [B350]; Abbott Medical Optics, Abbott Park, IL) and Molteno3 glaucoma implant (MGI; Molteno3 SS [185 mm^2] and Molteno3 SL [245 mm^2]; Molteno Ophthalmic Limited, Dunedin, New Zealand) are nonvalved shunts with unique geometries and implantation idiosyncrasies. To our knowledge, there are few studies comparing only nonvalved GDDs. Studies that do were noted to

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investigate device size without taking into consideration inherent design and implantation differences between manufacturers.[11] Most survival analyses of the MGI have evaluated outcomes of the device in isolation,[12,13] but do show good efficacy in line with that of other devices like the BGI. Of note, the MGI's end-plate in the subconjunctival space is smaller in surface area than the BGI's. The BGI's design (especially the larger B350 device) sometimes requires manipulation of and implantation under the extraocular muscles, which may increase rates of postoperative diplopia.[14] We hypothesize that this manipulation also leads to increased intraoperative time. Larger end-plate surface area was also thought to result in better long-term management of IOP; however, the paradigm has recently shifted.[15] Instead, increasingly large end-plates failed to lead to better IOP control and may cause more iatrogenic injury during surgical implantation.[16] Because of this, we hypothesize that the MGI's smaller surface area and unique geometry in conjunction with a less complex surgical implantation lead to shorter intraoperative time in addition to noninferior time until failure, IOP control, medication use, and visual outcomes when compared with the BGI. These factors may also affect differences in postoperative complications requiring in-office intervention or operative management.

Methods

Study Design

We conducted a retrospective, nonrandomized comparative study using data obtained from electronic health records in patients seen at Barnes-Jewish Hospital in St. Louis, Missouri; St. Louis Veterans Affairs Healthcare System; and the University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania. We hypothesized that the MGI is noninferior to the BGI in terms of glaucoma treatment outcomes and required less time to implant. For intraoperative time, a superiority hypothesis was used, whereas a noninferiority paradigm was used for the remaining comparisons, using the BGI as the standard against the MGI. Such a paradigm is necessary because a nonsignificant *P* value from a standard/superiority test does not give us evidence of similarity. Nonsignificance may emerge from low statistical power (due to small sample size, high variance, or both) or from a true lack of difference between the 2 groups. To appropriately test if the MGI is at least as good as BGI, noninferiority tests are required.

Patients

Patients who had placement of an MGI or BGI from January 1, 2015, to June 30, 2017, were selected and data collected until the most recent follow-up at the time of chart review. To maintain statistical independence in patients who underwent placement of bilateral GDDs, we only evaluated 1 eye of each patient, choosing the eye with longest follow-up when both were present. Reasons for placement of the GDD were left to the discretion of the surgeon. Patients undergoing phacoemulsification of a cataract at the time of GDD placement were included. Exclusion criteria included prior GDD in the same eye, additional interventions at the time of GDD implantation (e.g., goniosynechialysis, diode cyclophotocoagulation, angle procedures), follow-up less than 90 days, and a pars plana or sulcus approach for the tube tip.

Institutional Review Boards at each institution independently approved this study (Barnes-Jewish Hospital, St. Louis, MO; Veterans Affairs Medical Center, St. Louis, MO; University of Pittsburgh, Pittsburgh, PA). All aspects of this study adhered to the tenets of the Declaration of Helsinki. All participants provided informed consent.

Surgical Methods

Implantation of GDDs was performed by attending ophthalmologists and residents or glaucoma fellows under direct supervision of attending ophthalmologists. All attending ophthalmologists were glaucoma specialists. If indicated, phacoemulsification of cataract was performed first followed by GDD placement combined into 1 operative procedure. Implantation technique was not standardized and left to the discretion of each surgeon. Because nonvalved tubes require restriction of aqueous flow onto the end-plate in the postoperative period to prevent hypotony, surgeons used 1 of 2 maneuvers. The first involves ligating the tube with absorbable suture near the plate and then fenestrating the tube anterior to the suture allowing some aqueous flow. The second involves stenting the lumen of the tube with a polypropylene or nylon suture (called a "ripcord") that is then removed after the GDD's end-plate has developed its fibrotic capsule. Both techniques were used in patients in this study.

Data Collected

Data for each eye were obtained via retrospective chart review with particular attention given to IOP, visual acuity (VA, measured in Snellen and converted to logarithm of the minimum angle of resolution [logMAR] for statistical analysis),[17] glaucoma diagnosis, IOP-lowering medications used preoperatively and postoperatively, and intraoperative time. The IOP was measured in millimeters of mercury by Goldmann applanation tonometry. The number of medications was calculated on the basis of the number of drug classes used. Because data were collected retrospectively, there was no study protocol setting predefined follow-up intervals, so patient visits were classified into periods per World Glaucoma Association recommendations.[18] For patients with more than 1 visit in any given period, only the visit closest to the "ideal date" was used in the analysis except for determining intervention and complication rates. These end points used all available data points up until failure for reoperation, removal of the device, or loss of LP vision.

Outcome Measures

The primary outcome was days from surgery to failure of the implant. Failure was defined, in consonance with the Ahmed Baerveldt Comparison Study,[19] as any of the following: IOP >21 mmHg or a decrease $<20\%$ on 2 consecutive visits after 90 days, IOP ≤ 5 mmHg on 2 consecutive visits after 90 days, removal of the device, loss of light perception vision, or reoperations for failure. Secondary outcomes were intraoperative time, mean postoperative IOP, number of medications, and VA. The latter 3 outcomes were evaluated in a longitudinal, repeated-measures fashion, thus analyzing them throughout the entire follow-up period. Given the important difference in surgical implantation techniques between the B350's larger plate and the smaller B250, the size of this implant was also considered in the intraoperative time model.

Additionally, information regarding in-office and operative procedures was analyzed to understand further postoperative treatment needs. These procedures were broken into 2 main criteria: those related to intrinsic device failure and those related to transient problems. Operative management related to intrinsic

Table 1. Patient Demographics

	Baerveldt (Abbott Medical Optics, Abbott Park, IL)	Molteno3 (Molteno Ophthalmic Limited, Dunedin, New Zealand)	P Value
Patients, N	77	40	
Concomitant phaco, N (%)	21 (27.3)	10 (25.0)	0.97
Female gender, N (%)	31 (40.3)	14 (35.0)	0.72
Age (yrs), mean (± SD)	65.6 (±11.6)	65.4 (±13.5)	0.94
Race			0.26
Asian	2 (2.6)	1 (2.5)	
Black	27 (35.1)	19 (47.5)	
Native American	0 (0.0)	1 (2.5)	
White	48 (62.3)	19 (47.5)	
Right eye, N (%)	40 (51.9)	19 (47.5)	0.79
Lens type, N (%)			0.12
Phakic	34 (44.2)	19 (47.5)	
Posterior chamber IOL	41 (53.2)	17 (42.5)	
Anterior chamber IOL	1 (1.3)	0 (0.0)	
Aphakic	1 (1.3)	4 (10.0)	
Glaucoma type, N (%)			0.13
Primary open-angle	49 (63.6)	23 (57.5)	
Combined mechanism	9 (11.7)	5 (12.5)	
Chronic angle-closure	3 (3.9)	3 (7.5)	
Pigmentary	8 (10.4)	0 (0.0)	
Neovascular	1 (1.3)	2 (5.0)	
Uveitic	3 (3.9)	2 (5.0)	
Secondary to trauma	2 (2.6)	0 (0.0)	
Pseudo-exfoliation	2 (2.6)	2 (5.0)	
Unspecified/other	0 (0.0)	3 (7.5)	
Surgeon level of training			
Fellow/resident, N (%)	61 (79.2)	40 (100.0)	0.005

IOL = intraocular lens; SD = standard deviation.
Comprehensive patient demographics of study population.

device failure was considered "reoperation for failure." These failures were due to unsatisfactory therapeutic action of the GDD requiring further interventions such as trabeculectomy, laser procedures, or additional GDDs. Transient problems were further subcategorized into in-office interventions and operative interventions.

Statistical Analysis

Cox regression was used to assess time until failure, and the noninferiority margin for the hazard ratio (HR) was set a priori at 1.05. This indicates the MGI is considered noninferior if its rate of failure is no more than 5% greater than the BGI's rate, which was deemed a clinically insignificant difference. This model included only the implant type as its sole explanatory variable.

Mixed-effects regression was used to model the intraoperative time and the other longitudinal, postoperative outcomes (IOP, medication use, and VA). For the intraoperative time, a random effect was used to account for the different surgeons performing the surgeries, and the linear regression model also included the implant type, size (for the BGI only), and whether phacoemulsification was done concomitantly or not. The models for the postoperative outcomes included a random effect to account for repeated measures from the same patient plus terms for implant type, preoperative levels of the outcome variable, and number of days from surgery. In the case of IOP and VA, a linear regression was used with the noninferiority margins set at 1 mmHg and 0.2 logMAR (or 10 Early Treatment Diabetic Retinopathy Study lines). To properly model medication count, we used a Poisson regression and set a priori the noninferiority margin at 1.10. This indicates the MGI cohort is noninferior to the BGI if it used $\leq$10% more medications than the BGI.

For intraoperative time, we tested the significance of the coefficient for implant type with a 2-sided t test with $\alpha = 0.05$ using Kenward-Rogers degrees of freedom.[20] For all outcomes tested for noninferiority, 95% Wald confidence intervals (CIs) were drawn and noninferiority determined in case they were entirely under the noninferiority margin.[21,22] Subsequent calculations of associated P values were determined with $\alpha = 0.025$ in a 1-sided test. For mixed effects linear regression, a t test on the coefficient using Kenward-Rogers degrees of freedom was planned. For mixed effects Poisson regression, the coefficient is tested with a z-test.

Finally, the proportion of patients requiring nonfailure-related interventions were compared using (Egon Pearson's) chi-square test with $\alpha = 0.05$.[23,24] As in similar studies,[6] once a GDD was determined to reach failure criteria due to reoperation for glaucoma, device removal, or loss of light perception, future data points were excluded from further analysis in the case of IOP and medications. When analyzing VA, no censoring was performed. Compiled data were analyzed and figures were generated with R (R Foundation for Statistical Computing, Vienna, Austria).

Results

In total, 117 eyes from 117 patients underwent placement of a BGI or MGI. Comprehensive patient demographics and outcome variables are described in Tables 1 and 2, respectively. There

Table 2. Postoperative Outcomes and Intraoperative Time

	Baerveldt	Molteno3	Noninferiority Margin	Noninferiority *P* Value*	Method	Conclusion
HR for failure (95% CI)	Reference	0.83 (0.41–1.65)	1.10	0.2098	Cox regression	Inconclusive
IOP, mmHg						
Overall postoperative,† mean	17.0	16.6	1.00	0.0203	ME linear regression	Molteno noninferior
Baseline, mean ± SD	23.6±7.2	22.8±8.1				
1-yr follow-up, mean ± SD	14.0±4.0	13.3±4.2				
Glaucoma medications						
Incidence rate ratio‡ (95% CI)	Reference	0.98 (0.79–1.22)	1.05	0.2687	ME Poisson Regression	Inconclusive
Baseline, mean ± SD	3.4±1.0	3.3±0.8				
1-yr follow-up, mean ± SD	2.1±1.41	2.0±1.43				
VA, logMAR						
Overall postoperative,† mean	0.60	0.70	0.20	0.0362	ME Linear Regression	Inconclusive
Baseline, mean ± SD	0.38±0.45	0.60±0.66				
1-yr follow-up, mean ± SD	0.42±0.49	0.64±0.67				
Intraoperative time	B250	B350	Molteno3	Superiority *P* Value	ME Linear Regression	
Minutes, mean	59.8		55.5	0.3240		Inconclusive
Minutes, mean		71.3	55.5	0.0003		Molteno Superior

B250 = 250 mm^2 plate size Baerveldt glaucoma implant; B350 = 350 mm^2 plate size Baerveldt glaucoma implant; CI = confidence interval; HR = hazard ratio; IOP = intraocular pressure; logMAR = logarithm of the minimum angle of resolution; ME = mixed effects; SD = standard deviation; VA = visual acuity.
Analysis of primary and secondary outcomes with statistical parameters and methods of analysis.
*α set at 0.025 in 1-sided noninferiority tests.
†Calculated by taking into account all measurements across the entire follow-up.
‡Incidence rate ratio can be interpreted as the number of medications in the MGI group divided by the BGI group, across all follow-up.

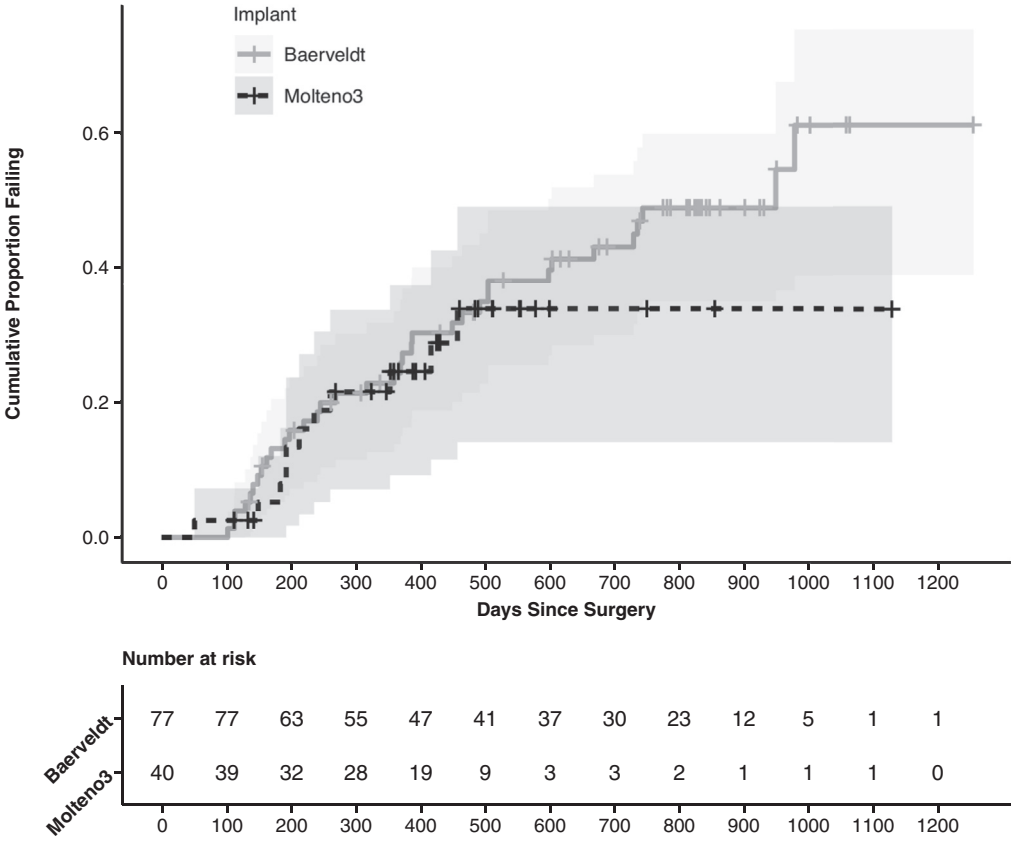

Figure 1. Kaplan–Meier survival plot of both the Molteno3 and Baerveldt in days since surgery.

were no significant differences in baseline patient demographics or underlying ocular pathology when comparing the BGI and MGI groups, although the BGI (N = 77) was implanted more frequently than the MGI (N = 40) and the baseline VA for the MGI was worse than the BGI. All MGIs were implanted by a resident or fellow under the supervision of an attending versus 79.2% of the BGIs.

Differences in time until failure between both GDDs were graphically compared with Kaplan–Meier survival curves as depicted in Figure 1 and numerically compared in a Cox regression model, which estimated the HR at 0.83 (95% confidence interval [CI], 0.41–1.65), a nonsignificant result as shown in Table 2.

Overall rates of failure were 45.5% for the BGI and 27.5% for the MGI when looking at all visits. At year 1, the failure rate was

Table 3. Failures and Interventions

	Baerveldt (N = 77)	Molteno3 (N = 40)	
Patients with ≥1-yr follow-up, N (%)*	64 (83.1)	32 (80.0)	
Failures by year 1, N (%)	17 (28.3)	6 (27.3)	
Follow-up in days, median (max)	528 (1254)	362 (940)	
Reason for failure, N (%)	35 (45.5)	11 (27.5)	
IOP > goal†	26 (33.8)	8 (20.0)	
Hypotony‡	4 (5.2)	1 (2.5)	
Reoperation for glaucoma§	5 (6.5)	2 (5.0)	
Loss of light perception vision	0 (0.0)	0 (0.0)	
Eyes with interventions, N (%)‖			**P Value**
In-office procedures	5 (6.5)	5 (12.5)	0.2724
Operative procedures	4 (6.5)	7 (17.5)	0.03124

IOP = intraocular pressure.
Differences in failure outcomes in patients undergoing placement of glaucoma drainage device and overall intervention rates.
*Defined as patients with any visit after postoperative day 272 (1 year mark as recommended by World Glaucoma Association surgical trial guidelines).
†IOP >21 mmHg or <20% reduction below baseline on 2 consecutive visits after 90 days.
‡IOP ≤5 mmHg on 2 consecutive visits after 90 days.
§Additional glaucoma surgery requiring a return to the operating room.
‖Procedures not associated with failure of the device (anterior chamber paracentesis, tube shortening, tube tie-off).

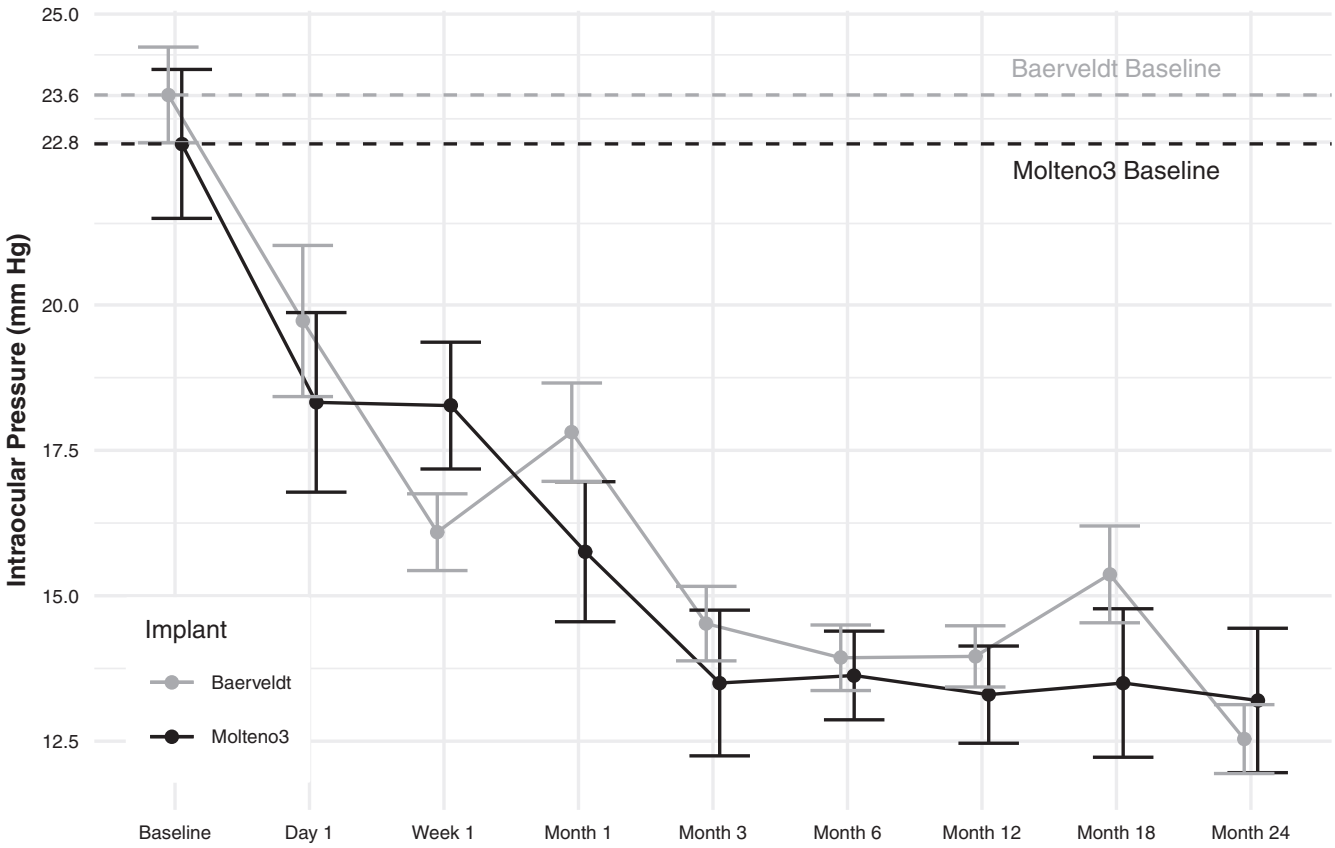

Figure 2. Intraocular pressure (IOP) over time in both the Molteno3 and Baerveldt. Eyes are censored from further analysis after date failure criteria is met. **Error bars** represent standard error. Follow-up time point binning defined by World Glaucoma Association recommendations.

20.6% versus 16.7% for the BGI and MGI, respectively. The BGI had longer median follow-up at 528 days versus 362 days for the MGI (Table 3). Elevated IOP was the most common cause of failure (26 eyes [33.8%] in the BGI and 8 [20.0%] in the MGI, Table 3). Failure due to persistent hypotony was rare in both implants (4 eyes [5.2%] in the BGI and 1 in the MGI [2.5%], Table 3). There were no failures for loss of light perception vision.

As shown in Table 3, the number of patients requiring reoperation for failure was 6.5% and 5.0% for the BGI and MGI groups, respectively. For nonfailure-related interventions, the MGI group had a higher relative number of patients needing operative intervention compared with the BGI, which was statistically significant. Overall, 17.5% of MGIs needed operative intervention versus 6.5% in the BGI. The number of in-office interventions was not statistically different between the 2 groups (6.5% and 12.5% for the BGI and MGI, respectively). Mean IOP differences between the 2 GDDs were studied in a repeated-measures fashion, with our model eliciting a difference of −0.40 mmHg (95% CI, −1.74−0.93) in favor of the MGI. Given that our noninferiority margin was set at 1 mmHg, this is a significant result claiming noninferiority of the MGI over the BGI when it comes to reducing overall IOP over the entire follow-up ($P = 0.0203$). Figure 2 highlights the mean IOP over time, which demonstrates the final effect of both GDDs is not seen until around the postoperative month 3 visit (which likely reflects the opening of the tube ligature at ∼6 weeks). Reduction in IOP was sustained in both devices over time. Most patients still needed to use at least 1 pressure-lowering medication at their last recorded follow-up visit, although at year 1, 54.5% required fewer medications with the MGI and 63.3% for the BGI.

The mean number of IOP-lowering drug classes was studied with a Poisson regression, also in a repeated-measures fashion, resulting in an incidence rate ratio of 0.98 (95% CI, 0.79−1.22). The incidence rate ratio, in this context, represents the multiplier of the mean number of medications used in the MGI group in relation to the BGI group. For example, if this number is 2.0, this means that those in the MGI group used twice as many medications, on average, across the entire follow-up. Because our CI is practically centered on 1.0 and wider than our noninferiority margin of 1.05, this is a nonsignificant result for either noninferiority or superiority in either direction.

Mean baseline VA (measured in converted logMAR) was 0.38 (∼20/50) in the BGI and 0.59 (∼20/80) in the MGI (Table 2). Mean VA at years 1 and 2 was, respectively, 0.42 and 0.41 (both ∼20/50) for the BGI and 0.65 and 0.61 for the MGI (20/90 and 20/80, respectively). Mean VA across the entire follow-up (Fig 3) was similar between the 2 devices, with a mean difference of 0.10 (95% CI, −0.01−0.21, Table 2). Considering a noninferiority margin of 0.2 logMAR and $\alpha = 0.025$, this is an

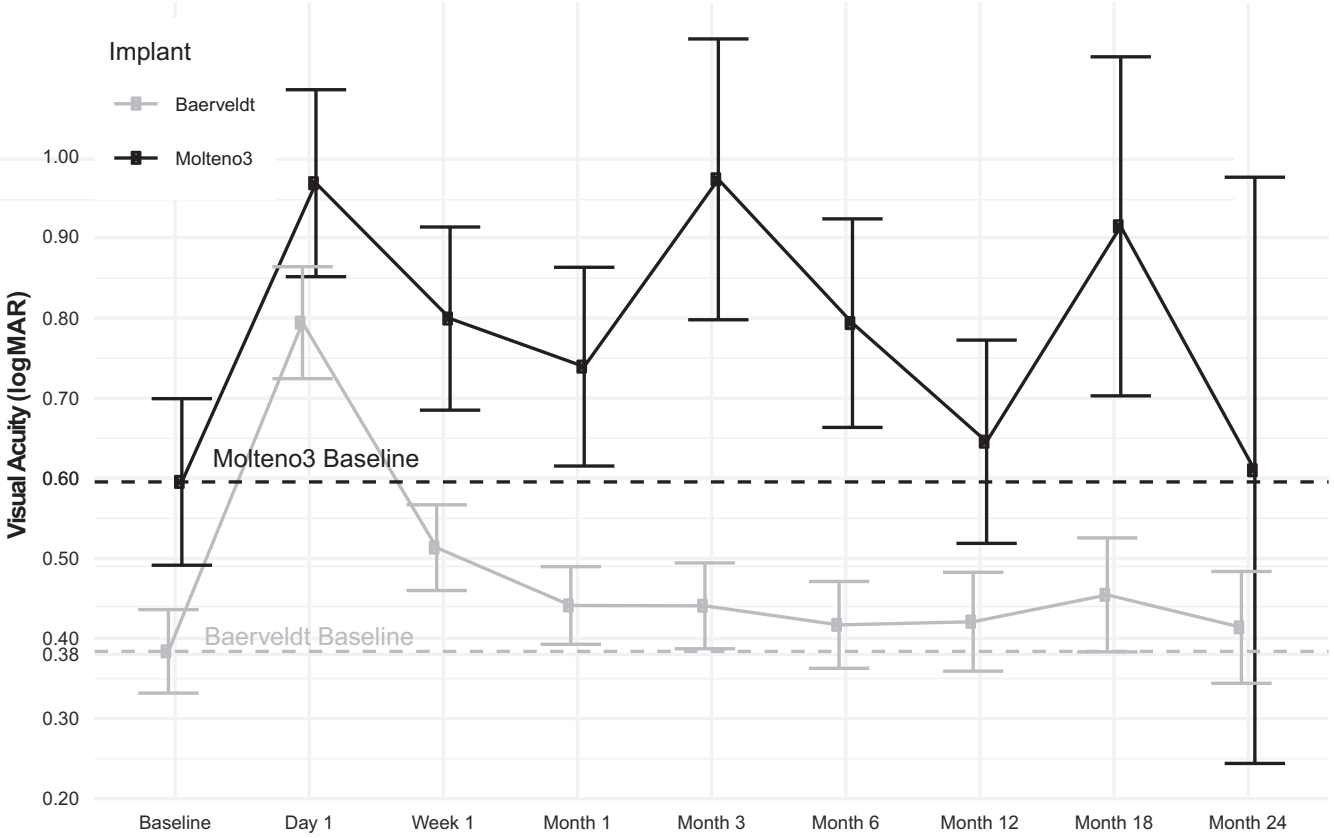

Figure 3. Visual acuity (VA) measured in logarithm of the minimum angle of resolution (logMAR) over time in both the Molteno3 and Baerveldt. Lower logMAR represents better Snellen VA. Follow-up time point binning defined by World Glaucoma Association recommendations.

inconclusive result ($P = 0.0355$). Finally, the MGI required 15.7 minutes less to implant than the B350 ($P < 0.001$) versus only 4.3 minutes less between the MGI and B250 ($P = 0.32$, Fig 4).

Discussion

This study evaluated outcomes of patients who underwent placement of the MGI or BGI at 1 of 3 tertiary care medical centers to guide surgeon selection of nonvalved GDDs. Our study was inconclusive regarding the noninferiority of the MGI over the BGI with respect to time until failure. We found that the MGI is noninferior in controlling IOP (Table 2). We were not able to conclude noninferiority with regard to medication use or VA outcomes. The MGI required significantly less time to implant than the B350. It was also slightly faster to implant than the BGI 250, but this difference was not statistically significant. The MGI did require more operative postsurgical interventions, although in-office interventions were not significantly different (Table 3).

Both the MGI and BGI were effective at lowering IOP in line with similar studies looking at GDD outcomes.[6,8] Given the MGI is noninferior to the BGI when assessing IOP reduction, it is important to determine whether there are other outcome measures that may guide the use of either device. Complications of GDD placement seen in our study population, principally hypotony and elevated IOP, are managed and considered differently. These complications were the most common cause of failure, which is not unexpected given elevated IOP or hypotony often precedes the decision to perform additional surgery.

Early postoperative hypotony was noted in both the MGI and BGI in equal numbers (Appendix 1, available at www.ophthalmologyglaucoma.org). At our institutions, the BGI was the predominate GDD used before 2015 at what would become our earliest date of data collection and experience with the MGI was comparatively limited. The MGI required significantly more operative interventions than the BGI for events like early and late postoperative hypotony and tube tip mispositioning (Table 3, Appendix 1, available at www.ophthalmologyglaucoma.org). The MGI was always performed by a trainee (under supervision), which may account for the greater need for intervention versus the BGI. In-office or operative interventions to correct this hypotony did not seem to affect the end results as described by our outcome measures.

Management of postoperative elevated IOP differs early and late in the follow-up period.[25] The most common cause of early postoperative IOP elevation was retained OVD, which was typically managed with anterior chamber paracentesis (Appendix 1, available at

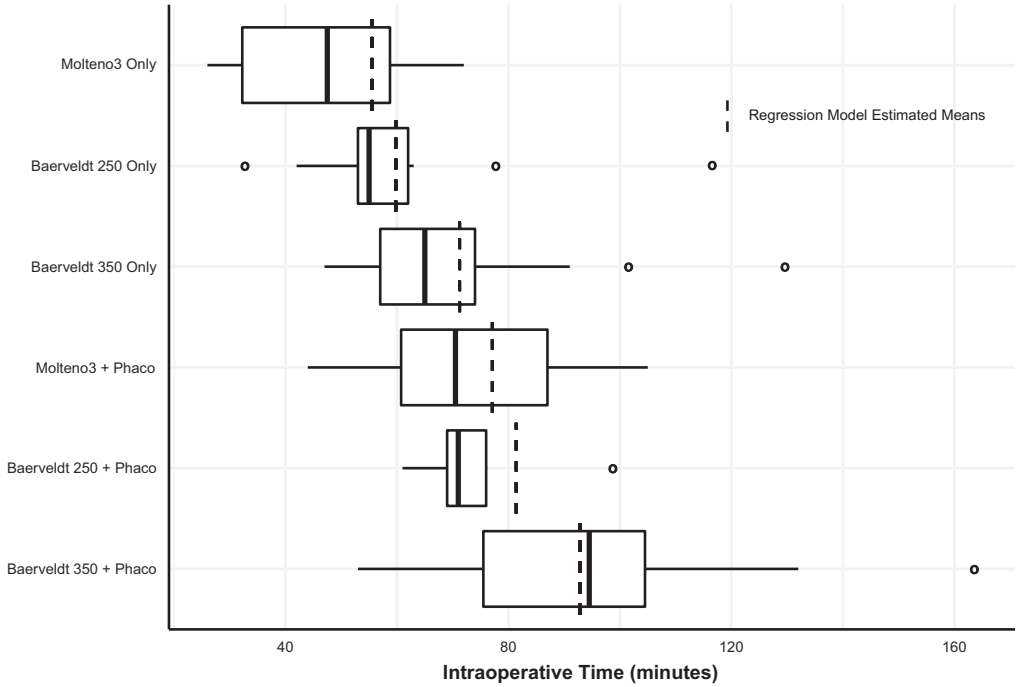

Figure 4. Box plot of intraoperative time for both the Molteno3 (Molteno Ophthalmic Limited, Dunedin, New Zealand) and Baerveldt (Abbott Medical Optics, Abbott Park, IL) with and without phacoemulsification of cataract (stratifying for both plate sizes of the Baerveldt device). **Error bars** represent standard error. **Dotted vertical line** represents estimated mean from the linear regression model. **Outliers** display as points outside error bars.

www.ophthalmologyglaucoma.org). Early IOP elevation is not uncommon and was not considered a failure criterion within 90 days of surgery. Late IOP elevation is likely due to inadequacy of the GDD to maintain outflow and is the most common cause of GDD failure in our study. This usually necessitated other interventions including diode cyclophotocoagulation or a second GDD. Interestingly, the MGI had a lower proportion of failures due to both hypotony and elevated IOP, although the shorter average length of follow-up for the MGI between the 2 groups may explain this difference.

Postoperative VA in the MGI and the BGI was assessed across the entire follow-up in our linear regression model. Those receiving the MGI had a mean logMAR 0.10 higher than the BGI, but also a considerably worse baseline VA (0.60 vs. 0.38, respectively). No conclusive claims can be made regarding the noninferiority of the MGI over the BGI. Figure 3 highlights the differences in VA via logMAR over the follow-up period. As would be expected, VA worsens in the immediate postoperative period then typically rebounds to preoperative levels. The MGI seemed to take longer to recover postoperative VA versus the BGI. The reason for this is unclear but could reflect inherent differences in the preoperative study populations. For example, as stated, baseline mean VA was worse in the MGI population, likely affecting postoperative VA.

Intraoperative time was significantly less in patients undergoing placement of an MGI compared with the B350 by approximately 16 minutes on average, even accounting for surgeries with concomitant phacoemulsification and controlling for the surgeon (Fig 4). We do not include this outcome to suggest the MGI will always be faster to implant than the B350 or that it is inherently easier to place, but instead use it to highlight a potentially important difference between the 2 devices during placement. Rates of diplopia were not assessed in our study, but the BGI has been shown to induce diplopia in patients in other studies (especially with inferonasal placement).[14,26] Most studies describing diplopia after MGI implantation were in pediatric patients or in patients receiving an older, double plate−style MGI (all MGIs used in our study used the single-plate design).[27–29] The MGI's design obviates the need for manipulation of the extraocular muscles or placement of the plate under muscles, unlike the B350. The B250 often does not require extraocular muscle manipulation, likely accounting for the similar implantation times.

Both the MGI and BGI were successful in lowering the number of IOP-lowering medications needed postoperatively (Table 2 and Fig 5). Most patients still needed to use some medications after surgery, but, at year 1, 54.5% and 63.3% of the MGI and BGI groups, respectively, required less. Our analysis was not able to claim noninferiority of the MGI over the BGI in terms of medication use, but the 2 rates seem similar in our model, with the incidence rate ratio at 0.98 (CI, 0.79−1.22). Graphically, the trend seems to show an uptick in usage in the MGI group, but the wide error bars in Figure 5 also denote the great variance in those measurements. Longer-term studies with larger sample sizes are imperative in teasing out differences between the 2 devices.

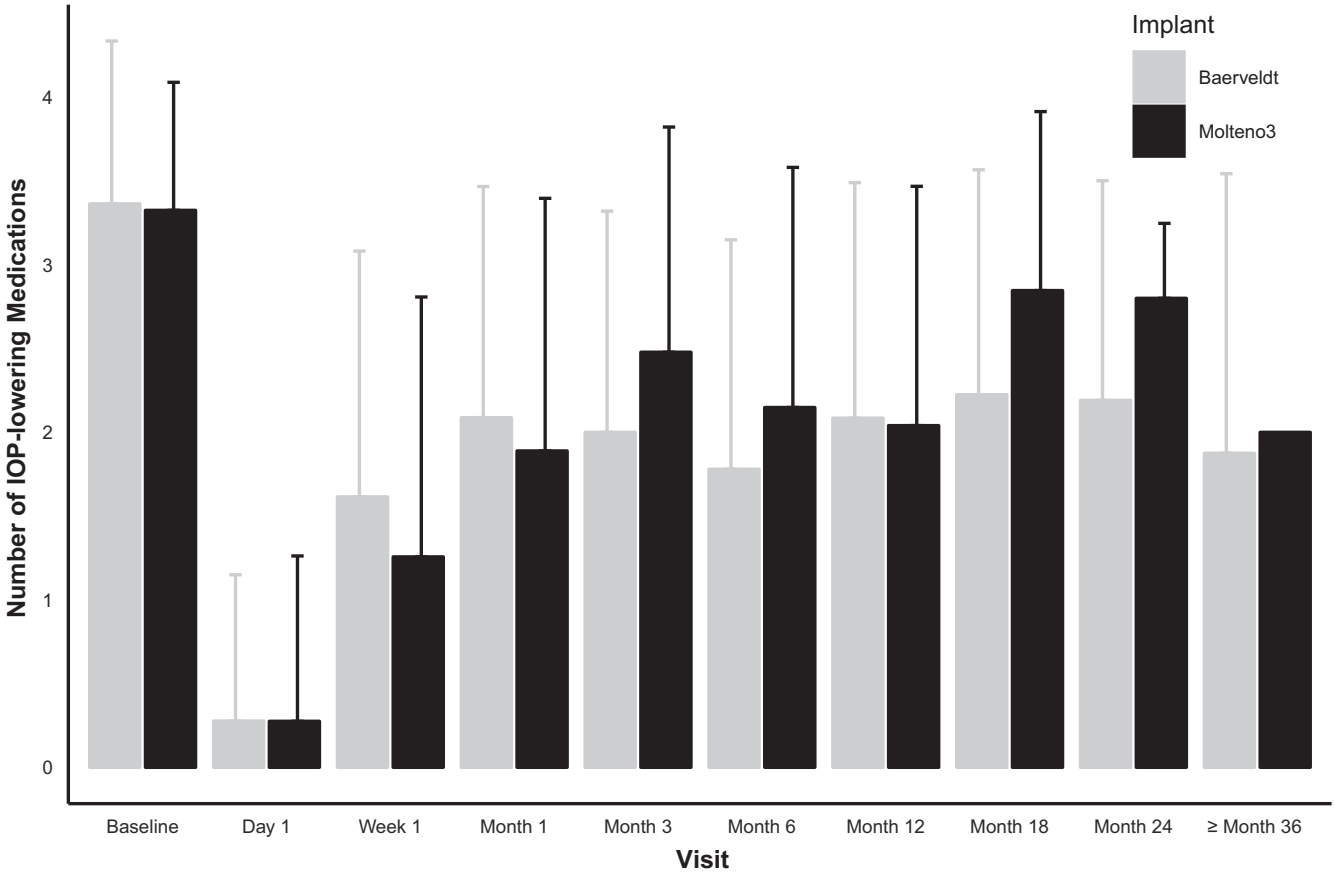

Figure 5. The intraocular pressure (IOP)-lowering medication use at different follow-up time points. Follow-up time point binning defined by World Glaucoma Association recommendations.

Study Limitations

Limitations of this study include inter-surgeon variability, differences in surgical technique, variable follow-up, small sample size, and the biases inherent to a retrospective study. Our statistical model accounted for differences in intraoperative time between surgeons; however, the MGI was placed more often by trainees than the BGI. Of note, 1 attending physician at 1 institution only implants the BGI (of whom 16 of 26 did not involve a trainee). All other GDDs (both BGI and MGI) were implanted by trainees under the supervision of attending physicians. Two of our senior authors were also attending surgeons represented in this study and chose the GDD to implant for their respective cases, which may be a potential source for bias. We were not able to reliably categorize differences in surgical technique, such as the number of tube fenestrations used, because documentation of this in operative reports was inconsistent. These discrepancies are a potential source of bias. Although all patients had at least 90 days of follow-up, the MGI group's median length of follow-up was less than the BGI's. The BGI was more commonly implanted at the beginning of the study period as our surgeons began to use the MGI. This likely influences the median length of follow-up more heavily. Our statistical models were robust for this difference in follow-up times. All these limitations would be important to address in a future prospective, controlled, and randomized study.

In conclusion, the BGI and MGI are similar devices that lower IOP by the same physical principles. The MGI was noninferior in reducing IOP over time, but all other noninferiority tests were inconclusive in this experiment. A closer look at the CIs and effect sizes do suggest an absence of large differences. Patients receiving the MGI required more operative interventions than with the BGI. The MGI's design may lead to shorter intraoperative times, especially if compared with the larger B350. Overall, the use of the BGI or MGI is justifiable to lower IOP when more conservative management has failed.

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Footnotes and Financial Disclosures

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No animal subjects were used in this study.

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Data collection: Dixon, Margolis, Palko, Mortensen, Conner, Sheybani

Analysis and interpretation: Dixon, Moulin, Sheybani

Obtained funding: N/A

Overall responsibility: Dixon, Moulin, Margolis, Palko, Sheybani

Abbreviations and Acronyms:
BGI = Baerveldt glaucoma implant; **B350** = Baerveldt glaucoma implant model BG-101-350−350 mm^2 plate size; **B250** = Baerveldt glaucoma implant model BG-103-250−250 mm^2 plate size; **CI** = confidence interval; **GDD** = glaucoma drainage device; **HR** = hazard ratio; **IOP** = intraocular pressure; **logMAR** = logarithm of the minimum angle of resolution; **MGI** = Molteno3 glaucoma implant; **VA** = visual acuity.

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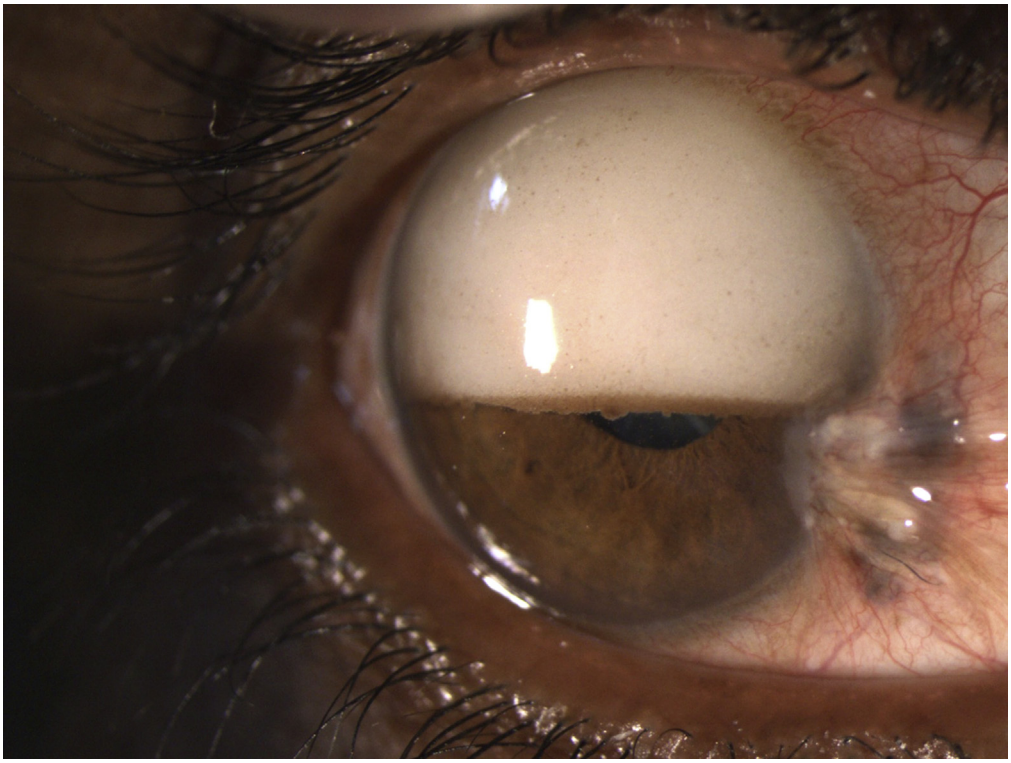
Pictures & Perspectives



Silicon Oil−Induced Glaucoma

A 38-year-old man presented to the glaucoma clinic with loss of vision in his right eye 6 years after undergoing vitreoretinal surgery following traumatic retinal detachment. His visual acuity was no perception of light and intraocular pressure 28 mmHg. Anterior segment showed emulsified silicon oil globules occupying slightly more than half of the anterior chamber and covering the pupil. Optic nerve head showed total cupping with disc pallor. The patient was diagnosed with silicon oil−induced glaucoma, but no intervention was done in view of painless blind eye. The patient was informed about his visual prognosis, and then sent for rehabilitation services. (Magnified version of the Figure is available online at www.ophthalmologyglaucoma.org).

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