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Viscocanalostomy and combined phacoemulsification with viscocanalostomy: A five-year follow-up

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Purpose: To assess the effectiveness and safety of viscocanalostomy (VC) and phaco-viscocanalostomy (PV) surgeries in eyes with a five-year follow-up. **Methods:** Retrospective review of patients who underwent VC and PV between January 2010 and December 2012 in the Stanley Eye Unit Abergele, UK. Patients were included for the analysis if they had a full 5-year follow-up or required redo surgery in the 5-year period. Success was defined as an intraocular pressure (IOP) of <21 mmHg. The subanalysis included IOP <16 mmHg, IOP reduction >20%, and IOP reduction >30%, the complication rate, and the drop in the use of glaucoma medications post-surgery. **Results:** A total of 370 eyes from 303 patients were included for the analysis. The mean preoperative IOP was 23 mmHg ± 5.3 mmHg with an average of 3.0 ± 0.1 medications. By year 5, this was reduced to 14.3 mmHg ± 6.5 mmHg with a mean of 1.0+/- 0.9 medications; 47.8% of the eyes had an IOP of <21 mmHg by year 5 without medication with a total of 92.6% of the eyes reaching this target with medication. The main complication in this group was the perforation of the Trabeculo Descemet's Window (TDW) but this was not associated with a poorer outcome. **Conclusion:** This large data set of eyes undergoing VC surgery demonstrates the effectiveness and safety of this technique over 5 years.

Key words: Glaucoma, nonpenetrating surgery, viscocanalolstomy

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Viscocanalostomy (VC) is a nonpenetrating procedure that increases aqueous outflow at the level of the trabecular meshwork. Stegmann *et al*.[1] first described VC in 1995 in Africa as an alternative to trabeculectomy which had a relatively high failure rate at that point in the Black population. It has since gained a degree of popularity in Western countries. Compared to trabeculectomy, the resultant intraocular pressure (IOP) is typically higher.[2] This is offset, however, by a lower incidence of serious complications, such as hypotony.[2] The aim of this study was to assess the effectiveness of VC (VC) and phacoemulsification with VC surgery in a real-world setting. In this study, both the impressive sample size and the length of follow-up gives one of the most comprehensive updates on the topic, especially so in a largely Caucasian population.

Methods

This single unit retrospective cohort study included patients undergoing VC or PV between 05/01/2010 and 18/12/12. All surgeries were performed by or under the supervision of one surgeon. These patients were identified from an Intranet database retrospectively. Verbal consent was obtained from all patients for the use of their anonymized clinical data for research purposes within the clinic. The local research ethics committee and the local Research and Development Committee have approved this research and the consent procedure. As this was a tertiary referral center, the patients were excluded if they were referred back to their referring ophthalmology department. The only exclusion criteria were if the patients did not meet the follow-up criteria.

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The patients were offered VC if, despite being on maximum medical therapy, they showed evidence of progression of visual field defects on two consecutive visual field assessments (Humphrey Visual Field Analyzer, Zeiss AG, Germany), and/or IOP was poorly controlled and out of the target range for the patient. These findings were supported with the evidence of corresponding loss of retinal nerve fiber layer (RNFL) on optical coherence tomography (OCT). The patients were also offered surgery if they were intolerant of topical glaucoma medication. If visually significant lens opacities were found at the time of listing for VC, the patient was offered a combined phaco-viscocanalostomy (PV). As a retrospective study, a control arm was not included as part of the study. VC and PV surgeries were performed as described by Stegmann *et al*.[1]

The patients who had an uncomplicated surgical procedure were followed up at day 1, week 1, and month 1, then 3 monthly for a year as a rule. A YAG Goniopuncture (YAG GP) laser procedure was carried out if the IOP was too high in those eyes that did not have a perioperative perforation of the Trabeculo Descemet's Window (TDW). The follow-up after this point was dependent on clinical need. If adequate IOP control was not achieved, a pressure-lowering drop was commenced usually at the same appointment as laser treatment, and when in doubt, the patient was reassessed 4–6 weeks later and started on treatment if required.

The statistical analysis was conducted using R for Mac (R-4.0.3). Standard descriptive analysis has been used

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for the demographic and clinical descriptions of each group. The outliers have been assessed by the inspection of boxplots—values greater than 1.5 box lengths from the edge of the box have been considered as outliers. The RM -two-way (ANOVA) test revealed that the outliers have no significant effect on the result ($P > 0.5$, comparison with and without outliers), when excluding detected cases. Therefore, the cases remained in the data set. The comparisons among the groups were tested with RM-two-way ANOVA and Pearson χ^2 test, with Yates correction for conditional variables. The comparisons between the curves were performed by Wilcoxon's rank-sum test. Significance was taken at the level of $P < 0.05$.

Outcome measures

The primary outcome of the study was IOP after 5 years. Other outcome measures assessed in this study included the use of supplemental medical therapy, surgical complications, and success/failure rate.

- Success was classed as a postoperative IOP <21 mmHg without additional antiglaucoma medication after 5 years ± YAG GP.
- Qualified success was assigned if this target was met with the addition of antiglaucoma medication ± YAG GP.
- Failure was assigned if IOP was >21 mmHg or if the patients required redo surgery in the 5-year period.

To allow for benchmarking of this technique with the other studies, analyses with other definitions of success were also carried out. These included IOP <16 mmHg, reduction in IOP of >/=20%, and 30%, respectively (preoperative vs. year 5).

Results

Demographics

A total of 602 eyes of 468 patients underwent VC between January 2010 and December 2012; 370 eyes of 303 patients had a 5-year follow-up and were analyzed in the study. A high dropout rate occurred as many patients were referred back to their primary ophthalmology departments following the surgery and initial follow-up.

Of that total, 116 eyes underwent VC surgery while 254 had phacoemulsification with VC. The mean age at the time of surgery was 74 ± 9.2 years (range 41–92 years); 203 were the eyes of male patients (54%) and 167 were female patients (46%); 207 eyes operated on had primary open-angle glaucoma (POAG) (64%). The normal-tension glaucoma (NTG) was the next most common with 15.5% of the cases. The patient demographics and clinical characteristics are summarized in Table 1. Thirty eyes had previous trabeculectomies, three had previous viscocanalostomies, and two eyes had previous cyclodiode. No patients had previous minimally invasive glaucoma surgery or selective laser trabeculoplasty.

Intraocular pressure

Preoperative mean IOP was 23 mmHg ± 5.3 mmHg. Day 1 postoperative IOP was 13 mmHg ± 7.67 mmHg. By 3 months, the mean IOP had stabilized at 14.3 mmHg ± 6.5 mmHg which was maintained till year 5 at 14.3 mmHg ± 3.4 mmHg. The preoperative IOP was significantly higher than the year 5 postoperative IOP ($P < 0.001$). There is a strongly significant positive correlation between the preoperative IOP and the IOP reduction ($r = 0.808$, $P < 0.001$).

The mean IOP over 5 years is illustrated in Fig. 1.

Antiglaucoma medication

Preoperatively, the mean number of antiglaucoma medications was 3 ± 1.0 per eye. At 5 years post-surgical intervention, this had dropped to a mean of 1 ± 0.9 medication, respectively.

At 6 months the number of eyes on medication was 18 (5%). Over the next 5 years, the number of eyes requiring drops increased to 170 eyes (48%). As a rough guide, every year, 10% of the cohort needed pressure-lowering medication. This is demonstrated in Fig. 2.

Perioperative complications

The most frequent complication was intraoperative perforation of the TDW which occurred in 45 eyes (12.2%). Four eyes had a posterior capsular tear during phacoemulsification, three patients had excess bleeding documented, and two required an autoscleral patch graft to cover the buttonholes in the superficial flap. Five patients were given acetazolamide as part of their postoperative regime. Three hundred and twelve eyes (84.3%) had no documented complication. This is illustrated in Table 2.

Perforation of Trabeculo Descemet's Window

As mentioned above, perforation of the TDW was the most common complication in VC surgery (12.2%). In patients who had a perforation of TDW, their mean IOP at year 5 was 14.1 mmHg ± 2.69 mmHg compared with 14.4 mmHg ± 3.52 mmHg in patients without this complication. The difference was not statistically significant ($P = 0.136$). Similarly, the mean percentage reduction in IOP between the two groups was not statistically significant (35% vs. 37%; $P = 0.438$).

Laser goniopuncture

The number of eyes that had goniopuncture was 170 (46%). The average time to laser goniopuncture was 28 months ± 21 months (range 1–84 months).

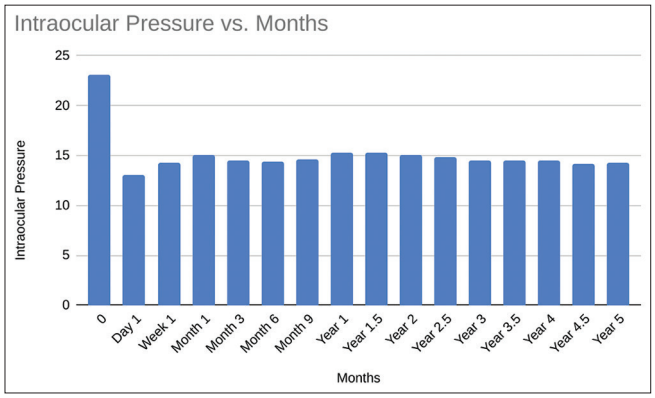

Figure 1: The mean intraocular pressure over 5 years

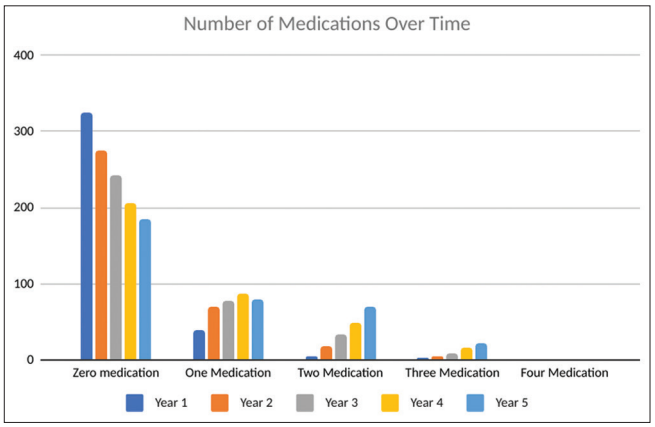

Figure 2: Number of patients on IOP-lowering medications over 5 years

Table 1: The patient demographics and clinical characteristics

			Total population	Phaco	Visco	NTG	POAG
Age (years)	Mean		74	74	73	74	74
	Standard deviation		9.2	8	11	9	8
	Maximum		92	92	92	87	90
	Minimum		41	44	41	50	44
Sex	Female	Count	203	144	59	33	126
	Male	Count	167	110	57	25	111
CDR (operated eye)	Mean		0.8	0.8	0.8	0.8	0.8
	Standard deviation		0.17	0.2	0.1	0.1	0.1
	Maximum		0.9	0.9	0.9	0.9	0.9
	Minimum		0.3	0.3	0.3	0.4	0.3
VF defect (MD in dB)	Mean		-10.88	-10.39	-11.94	-12.15	-11.10
	Standard deviation		8.522	8.22	9.10	6.50	8.86
	Maximum		12.09	9.94	12.09	1.31	12.09
	Minimum		-34.54	-32.77	-34.54	-26.22	-34.54
Glaucoma type	Glaucoma	Count	15	12	3		
	Angle recession	Count	1	0	1		
	Normotension	Count	58	39	19		
	Ocular hypertension	Count	15	15	0		
	Pigment Dispersion	Count	5	2	3		
	POAG	Count	237	157	80		
	Pseudoexfoliation	Count	23	18	5		
	Secondary glaucoma	Count	5	3	2		
	Traumatic glaucoma	Count	1	1	0		
	Uveitis	Count	10	7	3		
Type of surgery	Phaco-viscocanalostomy	Count	254			39	157
	Viscocanalostomy	Count	116			19	80

Repeat surgery

Sixteen eyes required repeat operations due to uncontrolled IOP or progression of their disease (4.3%). Two of the operations occurred in the first postoperative year. In the second year, one eye was operated on, six eyes in year 3, two in year 4, and five in year 5. Twelve of these eyes had repeat viscocanalostomies and four had trabeculectomies.

Success

Using IOP <21 mmHg as the definition of success, 177 eyes (47.8%) had an absolute success and 166 eyes (44.8%) had a qualified success where antiglaucoma medication was added in (total success 92.6%). Only 11 eyes (3%) failed to meet the criterion and an additional 16 eyes (4.3%) required a second operation. In total, a 7.7% failure rate by year 5 using this definition of success. Using the most rigorous criteria of IOP reduction of >/=30%, the success rates, and qualified success rates dropped to 35 and 64%, respectively. This is represented in Fig. 3.

Ocular hypertensives

Fifteen eyes with ocular hypertension had viscocanalostomies performed all with simultaneous phacoemulsification. This subgroup had a mean preoperative IOP of 27.8 mmHg +/- 6.4 mmHg on two medications. This reduced to 14.1 mmHg+/-2.6 mmHg ($P < 0.001$). Only one eye required one medication to control IOP after surgery.

Comparison of primary open-angle glaucoma with normal-tension glaucoma

A comparison of the success levels between POAG and NTG was made using a reduction of IOP of >/=20% (without additional medication) as per the definition of success. Fifty-eight eyes with NTG had surgery compared with 227 eyes with POAG; 48% of the eyes with POAG reached the definition of complete success versus 22% in the NTG group ($P < 0.001$).

Table 2: Perioperative complications

Complication	Count	%
Excessive bleeding noted in surgical note	3	0.8%
None	313	84.6%
Posterior capsular rent/anterior vitrectomy	4	1%
Perforation	45	13%
Scleral defect patch graft to repair button hole in scleral flap	2	0.5%

Comparison of viscocanalostomy with phacoemulsification with viscocanalostomy

A reduction of IOP of >/=20% (without medication) as a definition of success was used; 51% of VC surgery resulted in a complete success by year 5 versus 31% of the eyes which had phacoemulsification with VC ($P = 0.0035$).

Discussion

This single unit retrospective cohort study aimed to assess the long-term effects of VC in the management of glaucoma. As with all glaucoma surgeries, the success rate decreases over time.[3] The complete success rate and qualified success rate at 5 years were found to be 47.8 and 44.8%, respectively, using

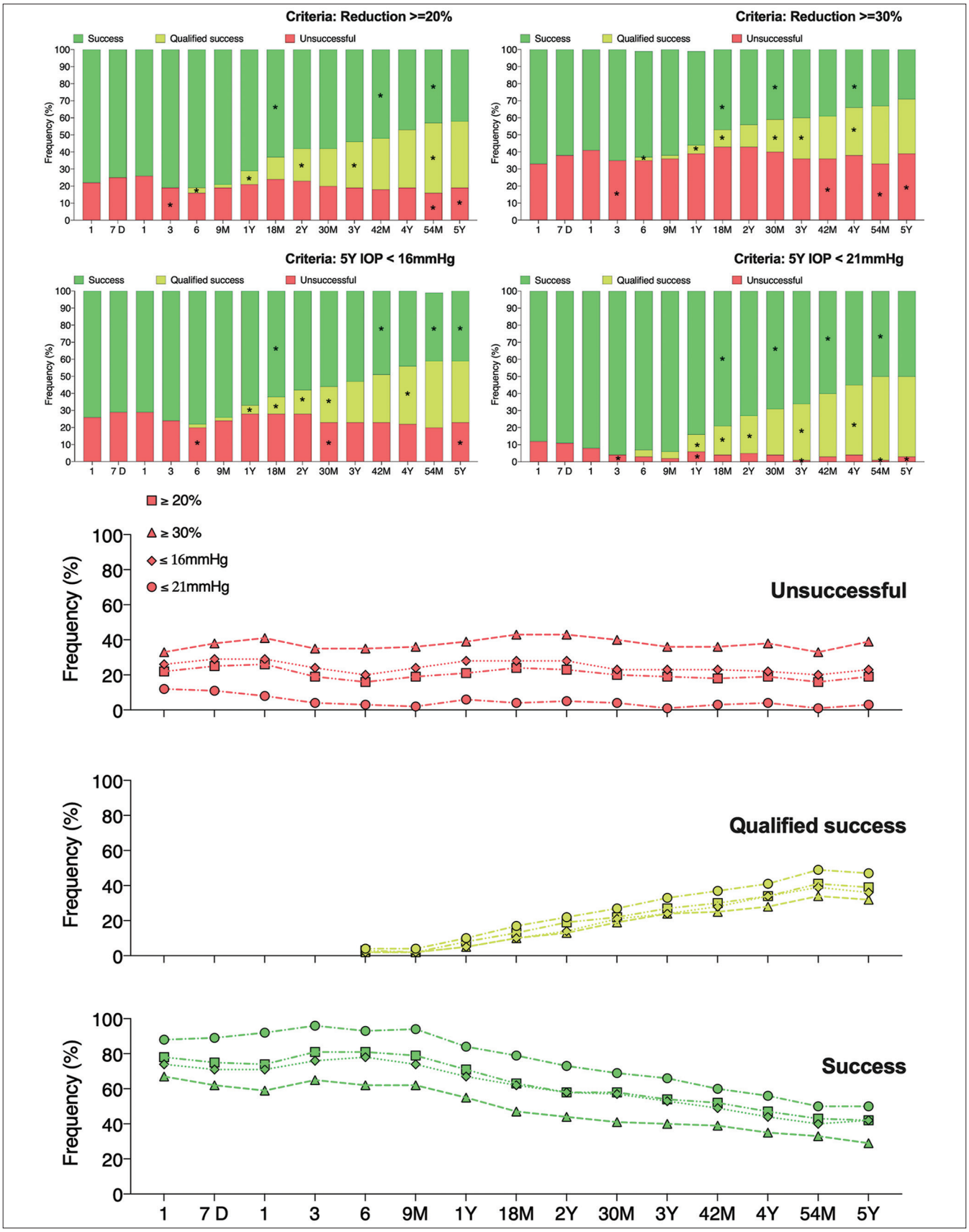

Figure 3: Success and qualified success over 5 years: IOP reduction >/=20%, >/=30%, IOP <16 and <21 mmHg, respectively

an endpoint of IOP < 21 mmHg; which results in a combined success rate of 92.6%.

The comparisons with other glaucoma studies are difficult as data sets have different starting IOPs and different definitions of success. A meta-analysis of the studies of nonpenetrating surgeries found that using <21 mmHg as an endpoint, the complete success rate was 51.1% without medication.[4] The studies in this meta-analysis had a median follow-up of 3 years. Looking specifically at studies of VC surgery with 5 years of follow-up, the results from this study are similar with the combined success rates between 82 and 90%.[5,6]

Acquiring accurate comparisons with other nonpenetrating surgeries is equally challenging. In a large study assessing results of canaloplasty over 3 years, a combined success rate (IOP </=21 mmHg) of 86.2% was achieved.[7] Looking at deep sclerectomy studies with 5 years of follow-up, the IOP reduction was between 38 and 55%.[8-10] This study achieved a mean IOP reduction of 37.8% ± 18.2%. As mentioned above, many variables differ between all these studies particularly listing IOP.

Trabeculectomy remains the benchmark to which all glaucoma surgeries are compared. The *Trabeculectomy in the 21st Century* study by Kirwan *et al*.[11] is a study somewhat comparable to this study looking at the current practice in trabeculectomy surgery in the UK. From a similar mean starting IOP of 23 mmHg ± 5.5 mmHg, a reduction by year 2 to 12.4 mmHg ± 4 mmHg, with a mean number of medications of 0.11 ± 0.4 was achieved. This compares favorably to the present study, which had a similar starting IOP of 23.07 mmHg ± 5.3 mmHg, a 5-year mean IOP of 14 mmHg ± 3.4 mmHg (with a mean number of medications of 1 ± 0.9 by the 5th year). These findings are in keeping with the other studies which demonstrate lower IOP levels following trabeculectomy versus VC.[12,13]

When looking at the complication rate in VC, the most common complication is the perforation of the TDW at 12.2%. TDW perforation is an unwanted complication. It also requires the patient to have a surgical peripheral iridectomy. In this data set, TDW perforation did not affect the IOP control and did not infer poorer outcomes. Similar results have also been shown in the previous studies.[14,15] When removing TDW perforations from the analysis, a further 14 recorded complications could be identified in the data set of 370 eyes. Penetrating procedures have been shown to have higher rates of hypotony and endophthalmitis than nonpenetrating surgeries.[16] With modern techniques, the levels of hypotony and endophthalmitis are lower but remain as not so uncommon complications in penetrating surgeries like trabeculectomy.[12,16]

An unexpected finding in this study was the higher success rate in VC versus PV. This has not been shown in the previous studies, which have shown no difference.[14,15] Also, it appears counter-intuitive as phacoemulsification alone typically decreases IOP.[17] A subanalysis of these groups showed that a higher percentage of eyes with normal-tension glaucoma were in the phacoemulsification group which might explain this unexpected finding. Similarly, in the small group of ocular hypertensive patients, there was a dramatic reduction in IOP and the number of medications used post-VC. This will be revisited by the authors when a larger data set of ocular hypertensive patients is recruited.

Conclusion

In conclusion, this retrospective cohort demonstrates that VC/PV is useful in lowering IOP and reducing the need for IOP-lowering medication. This study shows with both a large cohort and long patient follow-up period, the effectiveness of VC in the real-world setting. These operative techniques do this while maintaining a low complication rate compared to the other nonpenetrating and penetrating surgeries. While it fails to achieve as low IOP as trabeculectomy, this is offset with lower complication rates, so it might provide a more appealing option for many patients.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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