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THERAPEUTIC ADVANCES in
Ophthalmology

Original Research

Impact of minimally invasive glaucoma surgery on the ocular surface and quality of life in patients with glaucoma

Ther Adv Ophthalmol

2023, Vol. 15: 1–10

DOI: 10.1177/25158414231152765

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Abstract

Background: Minimally invasive glaucoma procedures are emerging as clinically effective and safe glaucoma management approaches; however, evidence regarding quality-of-life outcomes is limited.

Objectives: To explore the impact of minimally invasive glaucoma surgery (MIGS) combined with phacoemulsification on patient-reported outcomes and clinical parameters related to ocular surface disease in people with glaucoma.

Design: Retrospective observational study.

Methods: Fifty-seven consecutive patients were examined prior to undergoing iStent combined with phacoemulsification with or without adjunctive endocyclophotocoagulation and at 4-month follow-up.

Results: At follow-up, on average patients returned statistically significantly improved scores on glaucoma-specific (GQL-15, $p < 0.001$; GSS, $p < 0.001$), general health (EQ-5D, $p = 0.02$) and ocular surface PROMs (OSDI, $p = 0.001$). Patients were using fewer eye drops on average after MIGS compared with before surgery (1.1 ± 0.9 *versus* 1.8 ± 0.8; $p < 0.001$). Undergoing MIGS was associated with improved tear film break-up time ($p < 0.001$) and reduced corneal fluorescein staining ($p < 0.001$).

Conclusion: This retrospective audit shows quality of life and clinical parameters related to the ocular surface are improved following MIGS combined with phacoemulsification in patients previously treated with anti-glaucoma therapy.

Keywords: minimally invasive glaucoma surgery, ocular surface, quality of life

Received: 8 April 2022; revised manuscript accepted: 5 January 2023.

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Introduction

Glaucoma is an optic neuropathy that results in structural damage to the optic nerve and progressive loss of the visual field. This condition is associated with elevated intraocular pressure (IOP), which is the only modifiable risk factor for disease progression.[1] Several randomised clinical trials have demonstrated the benefit of lowering IOP.[2–5] Thus, all current glaucoma management strategies rely on sustainably stabilising IOP to within a target range to prevent visual field damage.[6]

Typical treatment pathways in glaucoma commence with medical therapy, widening to laser or incisional surgery if adequate IOP reduction is not achieved. Topical glaucoma medications have the potential problems of ocular surface disease, poor compliance and difficulty administering drops.[7,8] Trabeculectomy primarily remains the treatment of choice for patients with progressing moderate/advanced primary open-angle glaucoma.[9] However, the procedure is associated with side effects, some of which pose a threat to sight, such as endophthalmitis, persistent hypotony and choroidal detachment.[10] In trabeculectomy, a scleral flap is created through a penetrating procedure to allow aqueous humour to drain into a conjunctival bleb. Many minimally invasive

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glaucoma surgery (MIGS) devices are currently available, and the published literature in this rapidly evolving area in surgical glaucoma management demonstrates a good safety profile while also reducing medication burden, improving ocular surface comfort and potentially deferring or negating the need for filtering surgery.[11–17] In 2012, the US Food and Drug Administration (FDA) approved the first MIGS implantable device, the iStent® Trabecular Micro-Bypass Stent (Glaukos, Laguna Hills, CA, USA), for treatment of mild-to-moderate open-angle glaucoma, which is performed in combination with phacoemulsification.[18] Randomised prospective studies suggest patients may achieve target IOP using iStent, without the requirement of adjunctive medications.[19–21] The iStent Inject® W is a second-generation trabecular micro-bypass stent made of biocompatible, medical-grade titanium. A comprehensive review of the procedure is described elsewhere.[22] Briefly, the mechanism of action involves an *ab interno* implantation of two preloaded trabecular micro-bypass stents with a single entry. When implanted into the trabecular meshwork, the device allows aqueous humour to flow from the anterior chamber into Schlemm's canal. The combined triple procedure of two iStent injects®, phacoemulsification and endoscopic cyclophotocoagulation (ECP) is referred to as ICE2. ECP is applied to the ciliary process using a standard power setting of 0.25 W and titrated until a desired reaction was achieved. ICE2 offers superior IOP-lowering cumulative effects compared with iStent and phacoemulsification alone,[23] and is a cost-effective approach to glaucoma management.[24]

While a growing body of evidence is emerging regarding the clinical efficacy of MIGS, fewer efforts have been directed at establishing the patient-centred outcomes associated with these devices. As described by Samuelson *et al.*,[25] the trials that led to the approval of iStent used patient-reported outcomes as exploratory endpoints rather than primary trial endpoints. Patient-reported outcome measures (PROMs) are instruments derived from standardised, validated questionnaires that are used to measure perceived health status, functional status, or health-related quality of life. Asking a patient directly is an effective way to ascertain how they feel about their condition and how it might be affecting their well-being.[26] Yet, there is limited evidence regarding the impact of MIGS on patient-reported outcomes. This is significant given the severe and heterogeneous impact glaucoma may impose on routine daily activities and quality of life.[27–29]

The aim of this investigation was to conduct an exploratory evaluation of changes in quality of life following internal MIGS using iStent combined with phacoemulsification, with or without adjunctive ECP, and measure the extent to which the procedure reduces complaints related to ocular surface discomfort.

Methods

Patients attending outpatient clinic appointments, who were listed for MIGS, or already on a waiting list to undergo MIGS at Queen Victoria Hospital, NHS Foundation Trust, East Grinstead were recruited. The study followed a retrospective observational design and eligible patients were identified consecutively by members of the clinical care team. Surgery was performed by a single surgeon between July 2016 and May 2020. Clinical criteria to list patients for MIGS combined with cataract surgery were: treated (on topical medication or previous selective laser trabeculoplasty) ocular hypertension or mild glaucoma patients,[30] with visually significant cataracts. ECP was added for those with moderate glaucoma or when further IOP reduction was deemed clinically necessary (18 of 57 eyes). Combined procedures were all completed during a single surgical encounter. Patients provided consent for undergoing surgery. The findings were reported following the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) checklist for cohort studies.

The study duration was 4 months. All patients attended a baseline visit 2–4 weeks prior to surgery at which point PROMs were administered. PROM data collection did not include a medication washout protocol, ensuring changes in quality of life and ocular surface comfort were not impacted by medication modification effects. Clinical measurements at this visit included Snellen visual acuity, IOP using Goldmann Applanation Tonometry (GAT), Oxford Corneal grading scheme, tear film break-up time (TBUT) and tear film osmolarity using Tear Lab. Osmolarity was the first test performed, with Tearlab® Osmolarity System, where a tear sample is collected from the eye, touching the reader tip in the line of moisture on top of the lower

eyelid (before instillation of any drops). TBUT was the second parameter to be measured at slit-lamp examination, with instillation of one drop of non-preserved 2% sodium fluorescein by the examining doctor. TBUT was defined as the time (in seconds) between the opening of the eyelids and the first appearance of a growing micelle. The slit-lamp magnification was set at 10×, and the background illumination intensity was kept constant. The Oxford grading scale was then completed where the severity of corneal staining is divided into one of six groups from 0 (*absent*) to 5 (*severe*). The examiner compared the overall appearance of the corneal staining with a reference figure, simulating the pattern of staining encountered in dry eye disease. Following that, IOP was then measured after installing one drop of 0.5% proxymetacaine hydrochloride non-preserved with GAT.

All measurements were taken for the operated eye and repeated 4 months post-operatively. All patients underwent cataract surgery combined with trabecular bypass surgery with the iStent inject® W (Glaukos, San Clemente, CA, USA) which involved implanting two preloaded trabecular micro-bypass stents. This was combined, when clinically appropriate, with endoscopic cyclophotocoagulation (Beaver-Visitec International, Waltham, MA, USA).

In addition to baseline and follow-up eye examinations, all patients completed PROMs, which were all performed by the same investigator, pre- and post-operatively, to enable data on ocular and functional complaints to be systematically captured. The PROMs used were as follows.

European Quality of Life in 5 Dimensions (EQ-5D) is a classification of general health status.[31] The EQ-5D assesses five attributes: mobility, self-care, usual activity, pain and discomfort, and anxiety and depression. Each dimension has five possible outcomes: no problems, slight problems, moderate problems, severe problems or extreme problems / inability to complete. Five-digit codes were translated into a single health state score using an existing scoring system that is generated from a UK population sample. The EQ-5D is the most commonly used general health PROM and is recommended in the National Institute for Health and Care Excellence (NICE) guidelines for health economic analysis in the United Kingdom.[32]

Glaucoma Quality of Life-15 (GQL-15) is a disease-specific measure designed to assess the impact of glaucoma on vision-related quality of life.[33] The GQL-15 has four subscales: central and near vision, peripheral vision, mobility, and glare or dark adaptation. Scoring is based on 5-point Likert-type scales in which a response of 5 denotes *severe difficulty* and 1 indicates *no difficul*ty.

Glaucoma Symptom Severity Scale (GSS) is a 10-item measure of ocular complaints that are often associated with glaucoma treatment: burning/smarting/stinging, tearing, dryness, itching, soreness/tiredness, feeling of something in the eye, blurry/dim vision, hard to see in daylight, hard to see in dark places and halos around lights. For each patient, a 5-level score is generated ranging from 0 (*complaint present and very bothersome*) to 4 (*complaint absent*). The final score is an unweighted average of all 10 items.[34]

Ocular Surface Disease Index (OSDI) is a 12-item instrument designed to provide a rapid measurement of the severity of ocular surface symptoms and their impact on functioning.[35] Responses are rated on a scale of 0–4 (0 = *none of the time*, 1 = *some of the time*, 2 = *half of the time*, 3 = *most of the time*, 4 = *all the time*). The overall composite score is calculated based on responses to the three subscales: vision-related function, ocular symptoms and environmental triggers. Scores range from 0 to 100, where higher scores indicate greater problems.

Data analysis

Ocular surface measurements and responses on PROMs were compared between baseline and 4-month follow-up visit. The overall study group ($N = 57$) was not disaggregated by treatment type for the main analysis. In other words, 39 patients undergoing iStent inject® W combined with phacoemulsification and 18 patients undergoing ICE2 were analysed together. A sub-analysis on self-reported changes in ocular surface discomfort was performed between the two treatment groups. In cases of missing PROM items, data imputation was used. Missing items were coded using the average value for the measure, allowing for a complete data set for analysis. The average change in parameters between baseline and follow-up was analysed using paired *t* tests or Wilcoxon signed-rank test. One-way analysis of

Table 1. Median [IQR] scores pre and post MIGS on ocular surface parameters and significance as determined by Wilcoxon signed-rank test.

	Baseline ($N = 57$)	4-month follow-up ($N = 57$)	*p* value
Tear lab osmolarity	298 [294–306.5] mOsm/L	300.5 [294–310.5] mOsm/L	0.38
TBUT	4 [3.75–5] s	6 [5–7] s	<0.001*
Oxford Scale	1 [1–2]	1 [0–1]	<0.001*
logMAR VA	0.2 [0.1–0.3]	0.1 [0.0–0.1]	<0.001*
IOP	18.0 (4.2) mmHg	14.0 (4.6) mmHg	<0.001*

Mean (SD) shown for baseline and follow-up and significance determined by paired *t* test. IOP, intraocular pressure; TBUT, tear film break-up time; VA, visual acuity.
*Statistical significance.

variance (ANOVA) on ranks was used to compare OSDI outcomes among medication groups. Comparison between patients undergoing iStent *versus* ICE2 was performed using Mann–Whitney *U* test. Due to the exploratory nature of this investigation, no sample size calculation was used, and therefore findings should be interpreted as descriptive statistics. All analyses were performed using SPSS 27.0, and data were plotted with RStudio using the ggplot2 packages.

Results

Sixty-three patients were enrolled with an average age of 77 ± 7.8 years. Six patients were excluded from the analysis: three due to missing PROM data, one patient was followed up at a different unit, one patient had endophthalmitis and one patient was deceased. A total of 57 eyes of 57 patients (27 females) were included. All patients had a diagnosis of open-angle glaucoma with mild-to-moderate visual field loss as determined by Humphrey Field Analyser (Carl Zeiss Meditec, Dublin, CA, USA). The average visual field damage in the worse eye prior to surgery was −3.18 dB [interquartile range (IQR): −7.13 to −1.47 dB]. At the time of recruitment, patients were using on average 1.8 (± 0.8) anti-glaucoma medications.

As shown in Table 1, a statistically significant mean reduction in IOP between baseline and follow-up was observed (18.0 *versus* 14.0 mmHg; $p < 0.001$). Scores on the Oxford Scale for grading ocular surface staining were lower on average compared with baseline ($p < 0.001$). TBUT increased from 4 (IQR: 3.75–5) to 6 (IQR: 5–7) s ($p < 0.001$). Osmolarity did not change significantly over time. Tear osmolarity was 298 (IQR: 294–306.5) mOsm/L at baseline and reached 300.5 (294–310.5) mOsm/L at 4-month follow-up ($p = 0.38$).

On average, patients returned improved scores after surgery on all PROMs in the study (Figure 1). As shown in Table 2, median EQ-5D Index score at 4 months post-surgery was 1.0 (IQR: 0.837–1.0) compared with 0.848 (IQR: 0.768–1.0) at baseline ($p = 0.02$). For GQL-15, where lower scores are indicative of improved glaucoma-related quality of life, a statistically significant difference was observed between baseline and follow-up [18 (IQR: 16–20) *versus* 16 (IQR: 15–18); $p < 0.001$]. Responses on the GSS composite score were, on average, statistically significantly improved between baseline and follow-up ($p = < 0.001$) and for both the symptom subscale ($p < 0.001$) and function subscale ($p < 0.001$). Patients also reported, on average, statistically significantly improved ocular surface comfort according to responses on the OSDI between baseline and follow-up ($p = 0.001$).

Data relating to drop status at 4-month follow-up were available for 82.5% ($N = 47$) of patients. On average, patients were using fewer eye drops

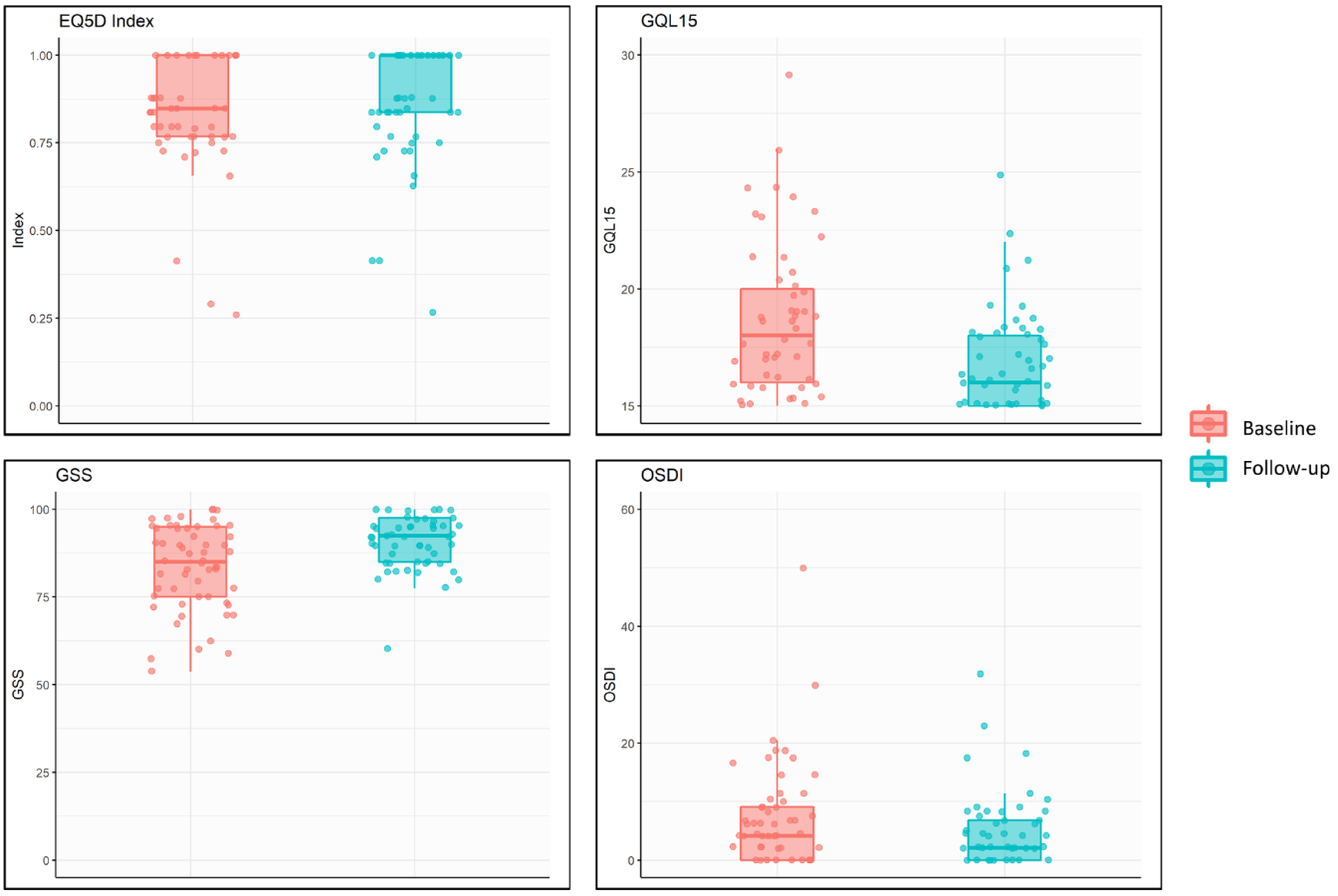

Figure 1. Boxplots showing distribution of scores between baseline (red) and 4-month follow-up (blue).
Each point represents an individual patient response. Boxplots give median, interquartile range, and 5th and 95th percentiles (whiskers). For EQ-5D Index and GSS, higher scores indicate better outcomes. For GQL15 and OSDI, lower scores indicate better outcomes.

compared with before surgery (1.1 ± 0.9 *versus* 1.8 ± 0.8; $p < 0.001$). Over one-quarter (27.7%) were drop-free at 4-month follow-up. On average, the greatest improvement in responses on the OSDI were among patients who were drop-free at 4 months (mean change = 2.4 ± 7.4), compared with patients on one drop (2.2 ± 6.8) or two or more drops (2.3 ± 6.8); however, differences between these groups were not statistically significant (Kruskal–Wallis test; $p = 0.21$) (Figure 2).

A sub-analysis comparing change in OSDI scores between patients undergoing iStent + phacoemulsification ($N = 39$) and those undergoing the ICE2 triple procedure with adjunctive ECP ($N = 18$) showed no statistically significant differences between groups (mean change = 2.3 ± 6.3 *versus* 2.1 ± 6.1, Mann–Whitney U test; $p = 0.87$).

Discussion

The field of MIGS is a rapidly evolving area in the glaucoma treatment paradigm, with numerous studies highlighting promising clinical outcomes. Until recently, the MIGS research landscape has been almost entirely committed to establishing the efficacy and safety profile of the procedures,[36] with only recently emerging studies addressing patient-reported outcomes.[25] Our findings demonstrate that, on average, the iStent procedure with phacoemulsification with or without combined ECP leads to statistically significantly improved patient-reported outcomes at 4 months post-surgery.

Previous randomised controlled trials have demonstrated negligible changes in PROMs between glaucoma treatment groups,[5,37] likely because commonly used non-disease-specific measures

Table 2. Median [IQR] scores at baseline and 4-month follow-up on PROMs and significance as determined by Wilcoxon signed-rank test.

	Baseline ($N = 57$)	4-month follow-up ($N = 57$)	*p* value
EQ-5D Index	0.848 [0.768–1.0]	1.0 [0.837–1.0]	0.02*
GQL-15	18 [16–20]	16 [15–18]	<0.001*
GSS	85 [75–95]	92.5 [85–97.5]	<0.001*
Symptom subscale	85.4 [70.8–91.7]	91.7 [83.3–100]	<0.001*
Function subscale	87.5 [81.3–100]	100 [87.5–100]	<0.001*
OSDI	4.2 [0–9.1]	2.1 [0–6.8]	0.001*

Scores for Symptom (six items) and Function (four items) subscales of GSS are given in addition to composite score.
EQ-5D, European Quality of Life in 5 Dimensions; GQL, glaucoma quality of life; GSS, Glaucoma Symptom Severity Scale; OSDI, Ocular Surface Disease Index.
*Statistical significance.

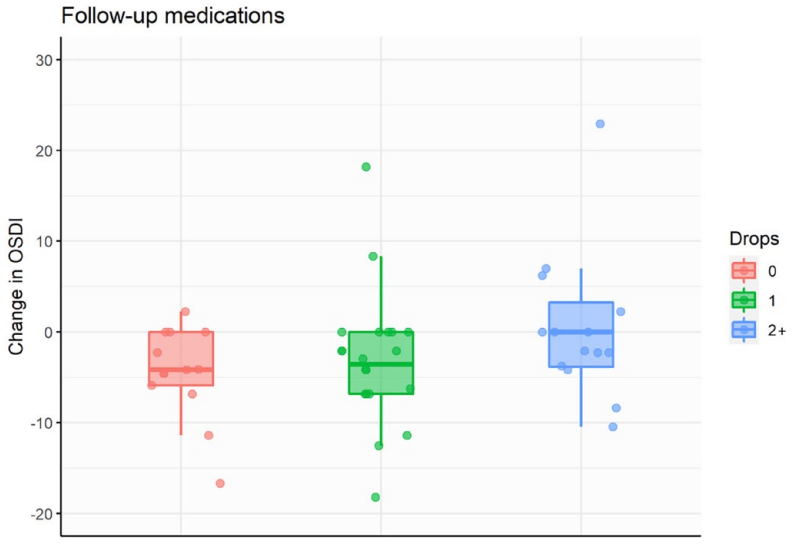

Figure 2. Boxplots showing distribution of change in scores on OSDI based on drop status.
Groups are based on drop status at 4 months and include drop-free (red), one drop (green), and two or more drops (blue). Negative scores (lower than 0) indicate improvement from baseline.

are insensitive to disease-related changes in people with mild-to-moderate glaucoma. The statistically significant improvements in PROM scores detected over a relatively short follow-up are therefore striking. This outcome is likely to partly be explained by the removal of visually significant concomitant cataract in combination with MIGS. The presence of cataract is associated with poorer quality of life in people with glaucoma,[38] and removal of cataract typically results in improved self-reported visual function.[39] As described previously,[25] improvements in patient-reported

outcomes following MIGS will largely be driven by cataract outcomes. As such, our findings raise important questions regarding the indications for use of MIGS in pseudophakic eyes, as surgery may yield smaller, less prominent self-reported improvements in quality of life. Yet, it remains encouraging that in addition to improvements in self-reported visual functioning, patients also reported better ocular surface comfort and fewer glaucoma-related ocular symptoms. In addition to lens opacity, factors relating to disease severity, extent of visual field loss and anatomical variables must be balanced with the patient's visual needs when deciding on surgical approach.

The minimally invasive procedures in this study resulted in a significant reduction in the number of eye drops required 4 months post-operatively. This finding aligns with previous studies highlighting reduced drop dependence following MIGS.[40] At 4-month follow-up, there were no significant differences in self-reported ocular surface complaints between patients who were drop-free, compared with those on one, or two or more medications. It is noteworthy, however, that a previous study exploring preference elicitation in glaucoma indicated reduced number of IOP-lowering drops was regarded with relatively little importance compared with other aspects of visual functioning, such as maintaining indoor and outdoor mobility and driving capacity.[41] These findings provide further justification for incorporation of outcome measures that capture a range of glaucoma-related challenges, including functioning, well-being, visual perception and treatment burden.

Our results suggest patients undergoing MIGS when previously treated using anti-glaucoma therapy leads to increased TBUT and decreased corneal fluorescein staining after 4 months. These findings indicate that reduced exposure to glaucoma medications can improve tear film stability and the overall health of the ocular surface following MIGS. There was no change in tear osmolarity after 4 months. Elevated osmolarity is a central mechanism of ocular surface damage.[42] However, our results are consistent with previous studies that observe a non-significant change in tear osmolarity among glaucoma patients switching from preserved to preservative-free medications.[43] The limited change in tear osmolarity between baseline and follow-up is likely due to the average measurements at both time points being much lower than the diagnostic cut-off for hyperosmolarity of scores in excess of 316 mOsm/L.[44] Moreover, tear osmolarity readings are prone to significant variation, and the practicality of using this technique for diagnosis of mild dry eye has been questioned.[45]

This study has a number of limitations. Due to the exploratory nature, we did not use a sample size calculation to determine the number of patients required to detect clinically relevant treatment effects. Rather, our aim was to assess outcomes in a real-world sample of consecutive patients attending the Queen Victoria Hospital glaucoma clinic. Previous studies in ophthalmology have demonstrated PROMs to have ceiling/floor effects, particularly in cases where patients have early-stage disease with minimal visual disability.[37] As such, a power calculation using PROM-derived estimates would likely demand a substantial sample size, attracting significant study costs. Nevertheless, this article provides useful data to help inform statistical power in future studies in the area of MIGS and quality of life. The design of our study did not allow for a comparison between the study population with a control group, which can be considered a limitation; however, a previous trial has already demonstrated the superior IOP reduction and safety profile of iStent with phacoemulsification compared with phacoemulsification alone.[19] Clinical and PROM measurements were taken by a clinical fellow who was not masked to the treatment outcomes of each patient; however, the risk of bias was minimised by the statistical analysis being performed by a member of the research team who was independent of the clinical care team. A further limitation is the limited follow-up period and that data were collected at only two time points. To fully understand the costs and benefits of MIGS, long-term follow-up in tandem with meaningful analysis is a priority.[46] It would be interesting, for example, to establish how PROM scores are affected in cases of repeated surgeries, where functional outcomes are likely to be less directly impacted by cataract removal. Our patients had relatively early visual field damage at the time of surgery; thus, equivalent outcomes may not be replicated among patients with more complex or advanced stage disease. Moreover, surgery was performed on the most-affected eye. However, PROM scores are likely to be driven by the least-affected or 'better' eye.[47,48] As such, our study cannot ascertain the role of MIGS when treating the healthier contralateral eye.

Our results demonstrate an average improvement in PROM scores following MIGS combined with phacoemulsification. PROMs are increasingly being used as outcome measures in ophthalmic clinical trials.[4,5] In some cases, PROMs are mandated by governing bodies such as NICE to enable cost-utility analyses. However, self-reported measures do not always correlate well with clinical measures of visual function, and individuals with a similar ophthalmological profile may report markedly dissimilar quality of life experiences.[49] As such, it is difficult to establish a meaningful change in PROM score following clinical intervention. Methods such as an anchor-based approach, which relate changes in PROM scores to an external, usually clinical indicator of health status, may be useful for interpreting meaningful changes in PROMs.[50] Understanding methods to calculate meaningful changes in quality of life remains an emerging area of investigation in the field. There is scope for PROM data to be used in conjunction with a more objective assessment of visual disability, such as performance-based measures,[51] as a means of identifying meaningful adverse or beneficial treatment effects.

To summarise, much of the evidence in support for MIGS has not been anchored in patient-oriented methodology. The guidelines of the European Glaucoma Society state that the goal of care for people with glaucoma is to promote well-being and quality of life.[52] Thus, studies to define patient-reported outcomes following MIGS are of high priority. This study provides evidence to support improved patient-reported outcomes and ocular surface parameters following MIGS. Glaucoma patients undergoing MIGS also benefit from reduced medication reliance and improved IOP control. The growing potential and clinical application of MIGS necessitate a clearer understanding of patient perspectives, and our findings begin to answer increasingly important questions relevant to MIGS device development and evaluation.

Declarations

Ethics approval and consent to participate

The study followed the Tenets of Helsinki Declaration, and was approved as an audit by Queen Victoria Hospital Clinical Research and Audit Department (ID: QVH503; Date: 07/05/2020), which also waived the need for consent for participation.

Consent for publication

Not applicable.

Author contributions

Lee Jones: Data curation; Formal analysis; Investigation; Visualization; Writing – original draft.

Natalia Maes: Data curation; Investigation; Methodology; Project administration; Writing – review & editing.

Umair Qidwai: Data curation; Investigation; Methodology; Project administration; Writing – review & editing.

Gokulan Ratnarajan: Conceptualization; Funding acquisition; Methodology; Resources; Supervision; Writing – review & editing.

Acknowledgements

None.

Funding

The authors received no financial support for the research, authorship and/or publication of this article.

Competing interests

The authors declared the following potential conflicts of interest with respect to the research, authorship and/or publication of this article: Dr Ratnarajan is a consultant for Glaukos and Beaver-Visitec. This was an independent study.

Availability of data and materials

Not applicable.

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