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Clinical science

Impact of visit schedule on estimated success rates in glaucoma surgical studies

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ABSTRACT

Aims To evaluate how different methods of managing multiple visits within predefined time windows affect intraocular pressure (IOP)-based success rates in glaucoma surgery studies.

Methods We applied literature-based high IOP failure criteria to two cohorts of 934 and 1760 eyes undergoing trabeculectomy and deep sclerectomy (DS) with median follow-up of 41.4 months and 45.4 months, respectively. Failure was defined by IOP thresholds, loss of light perception, hypotony requiring revision or additional IOP-lowering surgery. Visits were grouped into guideline-based windows and six visit-managing strategies were applied to all visits, mean, lowest, highest, median and closest IOP to the recommended time point. We calculated Kaplan-Meier success rates for each visit-managing strategy. Visual field (VF) analysis was conducted on patients in the trabeculectomy cohort with ≥4 VFs in ≥2 years post-surgery.

Results For the 21 mm Hg threshold, 5-year success was highest with the lowest IOP (trabeculectomy: 54.8%; DS: 74.5%), followed by closest IOP (trabeculectomy: 46.7%; DS: 67.6%), the median (trabeculectomy: 46.9%; DS: 69.1%) and mean IOP (trabeculectomy: 46.3%; DS: 68.6%). Success rates were lower with peak IOP (trabeculectomy: 39.3%; DS: 60.4%) and all visits IOP (trabeculectomy: 38.8%; DS: 61.0%). In the VF subset, eyes classified as failures demonstrated significantly faster mean deviation (MD) progression than those classified as successes although substantial overlap in the distribution of MD rates persisted between groups under every strategy.

Conclusions Visit-managing strategies influence reported success rates. None of the evaluated approaches achieved a clear separation in VF progression rates, underscoring the inherent limitations of IOP-threshold-based classifications.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Glaucoma surgery success is usually defined using recommended intraocular pressure (IOP) thresholds and preferred follow-up time points, but follow-up schedules vary widely in clinical studies.

⇒ Current guidelines do not specify how to manage multiple IOP measurements within recommended time windows, leaving a key methodological step unstandardised.

WHAT THIS STUDY ADDS

⇒ Different strategies for managing multiple visits within the same time window yield significant differences in estimated surgical success rates, failure risks and times to failure, even with identical datasets and IOP criteria.

⇒ Across all strategies, IOP-based classifications showed limited separation in visual field progression, highlighting the imperfect relationship between pressure thresholds and functional outcomes.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Standardising visit-handling strategies may improve comparability and interpretability of glaucoma surgical outcomes.

⇒ Future guidelines and trials should define and report visit-management strategies and consider outcomes beyond IOP thresholds, such as visual field progression, to reflect true clinical benefit.

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INTRODUCTION

Current guidelines for the design and reporting of glaucoma surgical studies recommend intraocular pressure (IOP)-based endpoints as the primary outcome.[1 2] These guidelines advocate predefined upper and lower IOP thresholds to define surgical success or failure, based on the assumption that IOPs above or below certain values increase the risk of disease progression or hypotony-related complications, respectively. However, previous studies[3 4] from our group have shown that the selection and definition of these thresholds are highly heterogeneous across studies, and even small variations in their values can substantially alter reported success rates. Moreover, these thresholds correlate only weakly with clinical outcomes: high IOP thresholds are poor surrogates for postoperative visual field (VF) progression, frequently misclassifying eyes with moderate or fast progression as surgical successes, while low thresholds are only marginally associated with hypotony-related complications, as most patients with numerical hypotony remain asymptomatic.

Beyond defining IOP criteria, current guidelines also recommend preferred follow-up time points and allowable visit windows. Yet, in both

retrospective studies and prospective trials, patients are often seen more frequently than specified intervals, especially after the first postoperative year, when World Glaucoma Association (WGA) guidelines[1] recommend annual visits. How the data from additional visits within these time windows are managed is rarely standardised or explicitly reported. The impact of this variability is unknown but may compromise the consistency and reliability of reported surgical success rates.

In this study, we examined how different approaches to handling multiple visits within predefined time windows affect IOP-based success rates, using two large cohorts of patients who underwent trabeculectomy or deep sclerectomy.

METHODS

Patients' cohorts

We analysed two large retrospective clinical datasets comprising patients who underwent either trabeculectomy or non-penetrating DS. Details regarding clinical settings, surgical techniques and collected variables have been described previously.[3 4]

The trabeculectomy cohort included patients treated at the Glaucoma Division of the Stein Eye Institute, UCLA, between 1999 and 2022. Surgeries were performed or directly supervised by one of five attending surgeons using a standardised technique.[5–7] The use of this dataset was approved by the institutional review board (IRB) of the University of California, Los Angeles. The study was conducted in accordance with the principles of the Declaration of Helsinki and complied with the Health Insurance Portability and Accountability Act. The requirement for written informed consent was waived by the IRB.

The DS cohort included patients treated at Calderdale and Huddersfield NHS Foundation Trust (2001–2014) and Gloucestershire Hospitals NHS Foundation Trust (2014–2020), all under the care of a single surgeon (NA). A consistent surgical technique was applied throughout.[8–11] All procedures were either performed or supervised by the consultant surgeon. This dataset, based on anonymised retrospective data, did not involve direct patient interaction or identifiable information. According to UK regulations, such analyses are categorised as clinical audits or service evaluations and do not require IRB review. The study adhered to the Declaration of Helsinki, the UK Data Protection Act, and the National Institute for Health Research (NIHR) guidelines. Data access was approved by the respective Caldicott Guardians responsible for information governance at both institutions.

We included a broad range of preoperative, intraoperative and postoperative variables. Preoperative data encompassed demographic characteristics, visual acuity, IOP, number of glaucoma medications, central corneal thickness, VF mean deviation (MD), glaucoma diagnosis, lens status and history of ocular surgery. Intraoperative variables included whether the procedure was standalone or combined with another ocular surgery. Postoperative data included IOP, number of medications, visual acuity, postoperative complications, revision surgeries and subsequent glaucoma procedures. Follow-up was censored at the time of listing for further glaucoma surgery. Both eyes were included if eligible, but only the first eligible procedure per patient was considered if multiple surgeries occurred. Eyes lacking preoperative IOP data were excluded, as success rates could not be calculated in these cases. No additional inclusion or exclusion criteria were applied.

VF subset

Postoperative VF data were available for a subset of trabeculectomy eyes. We included eyes with a minimum of four qualifying postoperative VF examinations and at least 2 years of follow-up after surgery. Qualifying tests were performed with the Humphrey Field Analyzer (Carl Zeiss Meditec) using 24–2 or 30–2 programmes, size III stimulus, and SITA standard or fast algorithms. Only reliable tests were retained, defined by a false-positive rate <15%, without exclusion based on fixation losses or false-negative responses.

Success criteria

For this study, we used four IOP composite criteria to define high IOP failure, including: (A) IOP>21 mm Hg or <20% of IOP reduction from baseline, (B) IOP>18 mm Hg or <20% of IOP reduction, (C) IOP>15 mm Hg or <25% of IOP reduction and (D) IOP>12 mm Hg or <30% of IOP reduction.

Failure was defined as follows: IOP above predetermined cutoffs in two consecutive visits after 3 months from surgery, loss of light perception, hypotony revision surgery, further IOP-lowering glaucoma surgery or ciliodestructive procedures.

To assess the impact of visit handling strategies on estimated surgical success, we applied six distinct approaches for managing multiple IOP measurements within each predefined time window:

- All visits: each IOP value recorded within the time window was individually assessed against the failure criteria, without averaging or summarising.
- Closest IOP: only the IOP value from the visit closest to each scheduled time point was used.
- Mean IOP: the arithmetic mean of all IOP values within the window.
- Median IOP: the median of all IOP values within the window.
- Max IOP: the highest IOP value recorded within the time window.
- Minimum IOP: the lowest IOP value recorded within the time window.

Time windows were defined following the recommendations of the WGA[1] and are summarised in online supplemental table 1. Success rates were estimated separately for each threshold and for each visit handling strategy. By varying only the visit handling strategy, their influence on success rates across different IOP-based failure definitions was estimated.

Statistical analysis

All statistical analyses were conducted using R (R Foundation for Statistical Computing, Vienna, Austria). A two-tailed p value of less than 0.05 was considered indicative of statistical significance. Snellen visual acuity measurements were converted to the logarithm of the minimum angle of resolution (logMAR) format. Continuous data were expressed as either mean±SD or median with IQR, while categorical data were summarised using frequencies or percentages.

Kaplan-Meier survival analysis was used to estimate the cumulative incidence of surgical failure according to various IOP-based definitions. To adjust for clustering at the patient level, we used robust SE estimates derived from the infinitesimal jackknife method.[12] Each IOP threshold criterion was analysed independently.

We performed clustered Cox proportional hazards regression using robust SEs to account for inter-eye correlation to evaluate differences in the risk of failure with varying handling strategies. The reference level in the model consisted of patients whose

follow-up visits adhered to the guideline-recommended schedule (ie, closest visit to the recommended interval).

Agreement between different visit management strategies in classifying failure at 5 years was evaluated using Cohen's kappa statistic. Interpretation of kappa values followed conventional thresholds: 0.00–0.20 (slight agreement), 0.21–0.40 (fair agreement), 0.41–0.60 (moderate agreement), 0.61–0.80 (substantial agreement) and ≥0.81 (almost perfect agreement).[13]

We used UpSet plots to visualise the number of eyes categorised as failure at the 5-year mark by various visit management strategies according to the different IOP thresholds. The UpSet plots[14] are an alternative to Venn diagrams and allow visualisation of the number of eyes failed as detected by each criterion alone and by their intersections with other criteria.

For the VF analysis, IOP-based success classifications were recalculated to match the time frame of available VF data. Rates of MD progression were estimated using linear mixed-effects models with random intercepts and random slopes. MD at each visit was modelled as a function of time from surgery (years), success/failure status according to each visit-management strategy and their interaction. The interaction term quantified differences in progression rates between eyes classified as success and failure. Separate models were fitted for each visit-management strategy across the different IOP thresholds.

RESULTS

Patient cohorts

We included 934 eyes from 766 patients in the trabeculectomy cohort and 1760 eyes from 1381 patients in the DS cohort. The median (IQR) follow-up periods were 41.4 (19.3–74.8) months for the trabeculectomy cohort and 45.4 (20.9–79.5) months for the DS cohort. Trabeculectomy patients had significantly more visits per time window compared with DS patients (online supplemental figure 1, p<0.001 at all time points). Characteristics of these patients are provided in previous publications[11] and detailed in online supplemental table 2.

Figure 1 shows Kaplan-Meier success rates for criterion A (IOP≤21 mm Hg and ≥20% IOP reduction) in the trabeculectomy and DS cohorts. In both groups, 5-year success was highest when using the lowest IOP value (trabeculectomy: 54.8%; DS: 74.5%), followed by the closest IOP to the recommended time point (trabeculectomy: 46.7%; DS: 67.6%), the median (trabeculectomy: 46.9%; DS: 69.1%) and mean IOP (trabeculectomy: 46.3%; DS: 68.6%) within a time window around the recommended time point. Success rates were lower when using peak IOP (trabeculectomy: 39.3%; DS: 60.4%) and IOP from all available visits (trabeculectomy: 38.8%; DS: 61.0%). Compared with IOP of the closest visit to the recommended interval (figure 2), the risk of failure was significantly lower when using the visit with the lowest IOP value (trabeculectomy HR: 0.84; DS HR: 0.78; both p<0.001), and significantly higher when using the visit with the highest IOP (trabeculectomy HR: 1.28; DS HR: 1.28; both p<0.001) or IOPs from all available visits (trabeculectomy HR: 1.41; DS HR: 1.34; both p<0.001). No significant differences in failure risk were observed with median or mean IOP values in either group (all p≥0.38).

The median (95% CI) time to failure in the trabeculectomy cohort was shortest when using all visits (35.2 (29.1 to 34.4) months), followed by maximum IOP (38.9 (35.5 to 47.3) months), mean IOP (50.3 (47.3 to 67.6) months), median IOP (52.5 (47.3 to 69.3) months), closest IOP (56.4 (47.3 to 68.6) months) and minimum IOP (76.8 (67.7 to 92.7) months). Median failure time for the DS cohort could not be estimated for criterion A, as success rates remained above 50% throughout available follow-up.

Pairwise Cohen's κ values for 5-year success (figure 3) across the six visit-managing strategies ranged from 0.71 to 0.98, indicating substantial to almost perfect agreement between methods. UpSet plots (online supplemental figure 2) showed that the vast majority of eyes classified as failures were consistently identified by all six visit-managing strategies. The smaller subsets of disagreement primarily involved strategies using max IOP and all available visits, either alone or in combination with closest, mean or median IOP. These patterns suggest that discrepancies were limited and largely driven by managing strategies more prone to flagging failure.

Similar results were found for other IOP criteria for success rates (online supplemental figure 3), median time to failure (online supplemental table 3), failure risk (online supplemental figure 4), level of agreement (online supplemental figure 5) and overlap in eyes classified as failures, as visualised in UpSet plots (online supplemental figure 2).

VF subset

A total of 339 eyes from 303 patients in the trabeculectomy cohort met eligibility criteria for the VF analysis. Eyes had a median (IQR) of 7 (5–11) postoperative VFs over a median follow-up of 6.2 (4.2–8.1) years, with the first postoperative VF performed at a median of 6.5 (4.9–9.5) months after surgery. Compared with the full trabeculectomy cohort (online supplemental table 4), the VF subset had better visual acuity, was slightly younger and had less advanced glaucoma, although the latter two differences were not statistically significant; all other baseline characteristics were comparable. The overall median (IQR) postoperative MD slope was −0.36 (−0.74 to −0.09) dB/year.

Figure 4 and online supplemental table 5 show the distribution of postoperative VF progression rates between eyes classified as surgical success or failure according to the six visit-handling strategies for criterion A. Across all visit-management strategies and IOP thresholds, eyes classified as failures exhibited

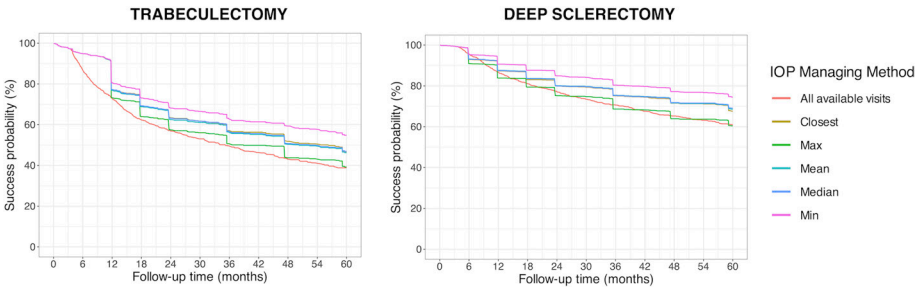

Figure 1 Kaplan-Meier curves showing the cumulative probability of success based on criterion A (IOP≤21 mm Hg and ≥20% IOP reduction) using six different visit-managing strategies in the trabeculectomy (left panel) and deep sclerectomy (right panel) cohorts. IOP, intraocular pressure.

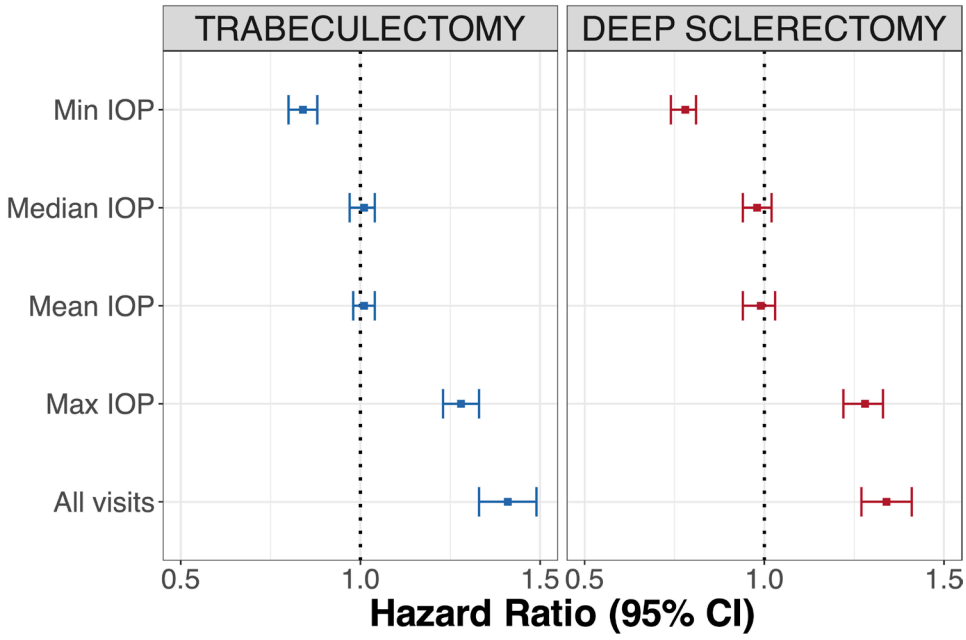

Figure 2 Forest plot illustrating the risk of failure according to six visit-managing strategies based on criterion A (IOP≤21 mm Hg and ≥20% IOP reduction). The reference group is the closest IOP, which estimates success rates using only the IOP value from the visit closest to each scheduled time point. Dots and horizontal bars indicate HRs and corresponding 95% CIs. IOP, intraocular pressure.

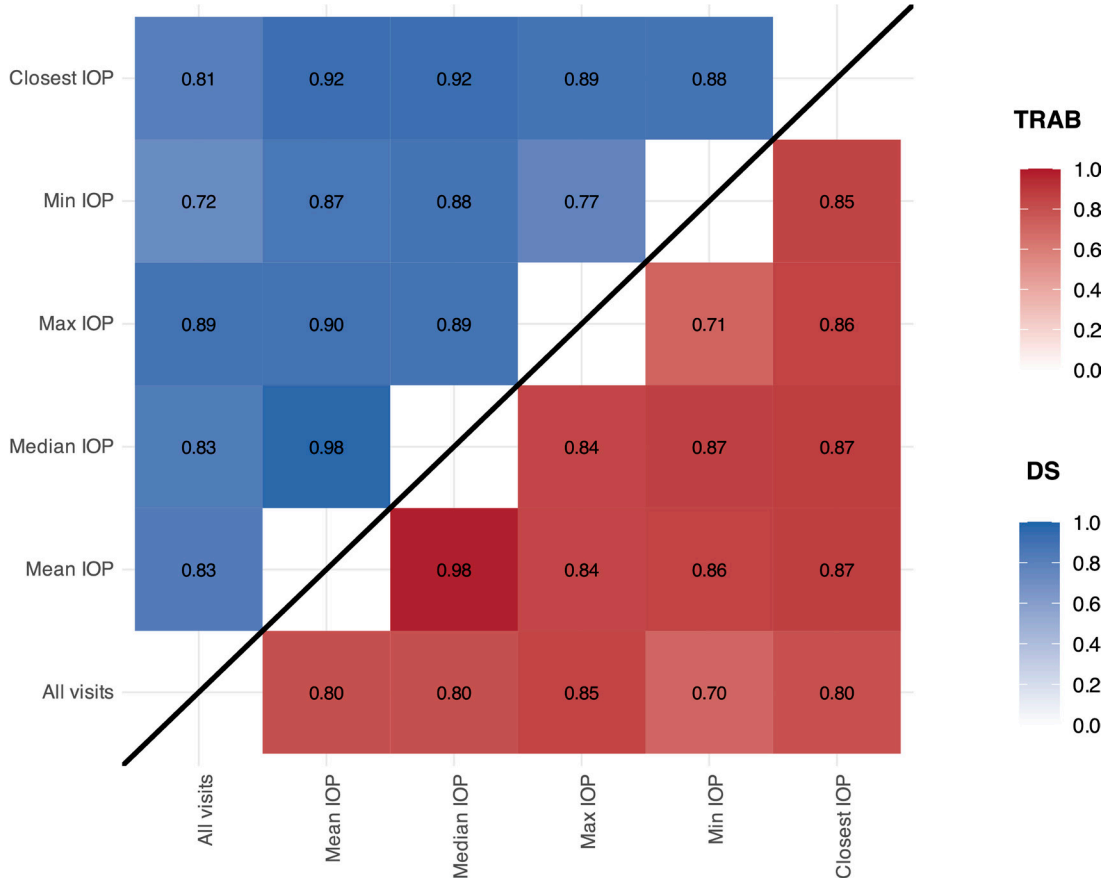

Figure 3 Heatmap illustrating the level of agreement between visit-managing strategies in classifying failure at 5 years based on criterion A (IOP≤21 mm Hg and ≥20% IOP reduction) in the trabeculectomy and deep sclerectomy cohorts. Agreement was measured using Cohen's κ, with darker colours indicating stronger agreement. DS, deep sclerectomy; IOP, intraocular pressure; TRAB, trabeculectomy.

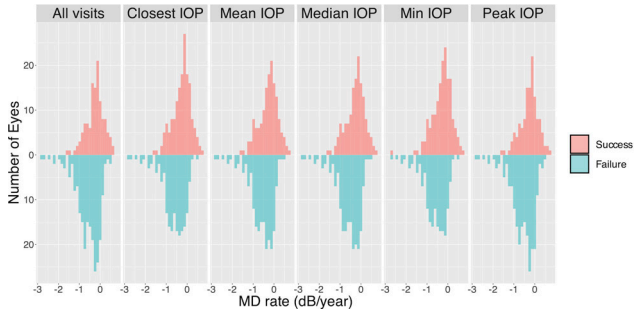

Figure 4 Distribution of visual field mean deviation (MD) progression rates (dB/year) in eyes classified as success or failure according to each visit-management strategy under criterion A (IOP≤21 mm Hg and ≥20% reduction from baseline). IOP, intraocular pressure.

significantly faster MD progression compared with those classified as successes. However, there was substantial overlap in the distribution of MD slopes between the success and failure groups under every strategy. This pattern was consistent irrespective of the method used to handle multiple IOP measurements. Similar results were found for other threshold criteria for failure (online supplemental figure 6 and tables 6-8).

DISCUSSION

The WGA[1] and, more recently, the European Glaucoma Society[2] and the American Academy of Ophthalmology[15] have issued documents to guide clinicians in defining success and failure of glaucoma procedures. These guidelines recommend composite criteria based on IOP thresholds, typically requiring two or more consecutive visits above or below predefined cutoffs, along with preferred follow-up intervals. However, in clinical studies, patients are often seen more frequently than time points recommended by research guidelines, and current guidelines provide no specific direction on how to manage multiple visits within the same time window. In this study, we examined how six different visit-managing strategies affect IOP-based surgical success rates in two large cohorts of trabeculectomy and DS patients. Despite using identical datasets and failure definitions, varying the visit-managing approach led to differences in estimated success rates and median time to failure detection.

Success rates were lowest and the failure risk highest when using peak IOP or all available visits within each time window, whereas the minimum IOP led to the highest success rates and lowest failure risk. Approaches using all visits or the peak IOP are more vulnerable to single outlier measurements or transient IOP fluctuations that may not reflect true long-term surgical outcomes. A single postoperative spike or measurement error can trigger failure classification even if subsequent visits show adequate control. Moreover, isolated high IOP readings often prompt interventions, such as restarting medication, suture lysis, releasable suture removal, needling or ripcord removal, which frequently restore IOP control and prevent persistent failure. The conventional requirement for confirmation of failure at two consecutive visits partly mitigates, but does not eliminate, this issue. Conversely, using minimum IOP may present an overly favourable picture, as it selectively captures the lowest pressure while ignoring intervening periods of inadequate control, potentially underestimating failure risk. Metrics such as mean or median IOP provide more balanced and stable estimates by smoothing out short-term variability. Strategies that incorporate multiple measurements within a time window may be influenced not only by the actual IOP level but also by visit intensity. For example, postoperative IOP elevation often prompts additional visits to confirm the measurement, intensify treatment, perform postoperative manoeuvres and reassess IOP control after treatment escalation. In this setting, the median is likely more appropriate than the mean, as it is less sensitive to isolated high or low IOP values and therefore less prone to distortion by outlier measurements.

Our findings confirm that absolute success rates cannot be interpreted in isolation. Small changes in the IOP criterion itself can markedly affect reported success rates[3]; however, even applying the same exact criterion with different visit-managing strategies can lead to substantially different estimates. This is also a direct consequence of interpreting an outcome subject to intrinsic variability, such as IOP as a hard outcome event analogous to death. This means that the absolute failure rate can be directly modified by varying the frequency of postoperative visits; more visits result in a higher chance of observing an IOP above a specific threshold. Most published studies do not explicitly describe how multiple visits are managed, limiting comparability across the literature. These observations underscore the need for standardised definitions and reporting practices.

Despite differences in estimated success rates, none of the visit-management strategies achieved a clear separation in the distribution of VF progression rates. This limitation appears inherent to IOP-threshold-based classifications rather than attributable to any specific method of handling multiple visits. These findings reinforce the concept that, although operationally convenient, IOP-based definitions represent imperfect surrogates for long-term disease control. They highlight the need to incorporate more robust and clinically meaningful endpoints, such as VF progression rates, which directly reflect disease control rather than relying solely on arbitrary IOP thresholds prone to variability, real and methodological, and not tightly connected to true patient outcomes.

This study has limitations. We did not address whether alternative visit-managing strategies would alter results in randomised controlled trials comparing treatments. Although we observed a high level of agreement among strategies, certain approaches, particularly those based on maximum IOP or all available visits, consistently yielded higher failure rates and shorter median times to failure. These differences could affect statistical power and potentially influence whether a clinically meaningful difference between treatment arms achieves statistical significance. In addition, the actual number of postoperative visits differed between cohorts and might itself have influenced estimated success rates, as more frequent follow-up increases the likelihood of detecting IOP excursions; however, despite these differences in visit intensity, the overall pattern of results across visit-managing strategies was consistent in both cohorts. Trabeculectomy and DS are both established surgical approaches for glaucoma management.[10 16–18] This study does not aim to compare the efficacy of these procedures directly. Caution is warranted in interpreting differences between the groups, as the trabeculectomy cohort had a higher prevalence of known risk factors for surgical failure, including non-white ethnicity, secondary glaucoma, lower preoperative IOP and prior ocular surgeries involving glaucoma, cornea or retina. Additional unmeasured differences may also exist and would be best evaluated in the context of a randomised controlled trial.

In conclusion, the method used to manage multiple IOP measurements within predefined time windows can meaningfully affect reported surgical success rates in glaucoma studies. Standardising visit-managing approaches and incorporating explicit definitions into study protocols would improve

transparency, comparability and the reliability of IOP-based outcome reporting. None of the evaluated approaches, however, achieved a clear separation in VF progression rates, underscoring the inherent limitations of IOP-threshold-based classifications.

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Contributors AR conceived and designed the study, supervised data analysis, interpreted the results and drafted the manuscript. DK, SWJ and EM contributed to data collection and data management. GM and FO contributed to statistical methodology and critical interpretation of the analyses. NA and JC contributed to study design, data acquisition and critical revision of the manuscript for important intellectual content. LR and SDC contributed to study supervision and manuscript revision. All authors reviewed and approved the final version of the manuscript and agree to be accountable for all aspects of the work. AR is the guarantor of this work and accepts full responsibility for the integrity of the data and the accuracy of the analysis. During the preparation of this work, the authors used ChatGPT5.0 in order to improve the readability and language of the manuscript. After using this tool/service, the authors reviewed and edited the content as needed and take full responsibility for the content of the publication.

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Patient consent for publication Not applicable.

Ethics approval This study involves human participants. The use of the US cohort was approved by the UCLA Institutional Review Board (#11-1436). For the UK cohort, this dataset, based on anonymised retrospective data, did not involve direct patient interaction or identifiable information. According to UK regulations, such analyses are categorised as clinical audits or service evaluations and do not require IRB review.

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