Title: Mapping vision loss of patients in a glaucoma backlog following the COVID-19 pandemic: A real-world analysis using the Glauc-Strat-Fast risk stratification tool.

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ABSTRACT

Introduction: Glauc-Strat-Fast is a clinical tool recommended by the Royal College of Ophthalmologists to classify glaucoma patients into strata of risk for significant future sight loss and an estimate of resource requirement. The aim of this study was to map the movement of glaucoma patients across stratification boundaries on Glauc-Strat-Fast during the COVID-19 pandemic.

Subjects and Methods: Glauc-Strat-Fast was applied to a consecutive sample of 100 primary open angle glaucoma patients in a backlog at Worcestershire Acute Hospitals NHS Trust. Stratification outcomes were compared between clinic visits prior to the COVID-19 pandemic versus the follow-up visit. Patients were stratified twice separately based on their worse eye (i.e., most affected) and better eye (i.e., least affected) according to Glauc-Strat-Fast.

Results: Amount of slippage (difference between target follow-up and actual follow-up) ranged from 2 to 32 months. There was a statistically significant average reduction in visual field mean deviation for better and worse eyes between visits ($p = <0.001$). At follow-up, no worse eyes were classified as being low risk (green), while 96 were classified as high risk (red). For better eyes, elevation of risk into the highest strata of Glauc-Strat-Fast observed a three-fold increase in patients (19 versus 56) between visits.

Discussion: This retrospective real-world analysis highlights patients' movement into the highest strata on the Glauc-Strat-Fast tool and demonstrates a significant deterioration in visual outcomes during a period of extensive appointment slippage. The findings demonstrate the utility of Glauc-Strat-Fast as a tool for improved patient management.

SUMMARY BOX

What was known before:

- The COVID-19 pandemic caused a large backlog of cases in the glaucoma service.
- Delays in glaucoma monitoring threaten outcomes relating to patients' functional vision.
- Glauc-Strat-Fast enables an understanding of individual patient risk and is useful for prioritisation and commissioning of care.

What this study adds

- Patients breaching their target follow-up time could be stratified into the highest level of risk on Glauc-Strat-Fast for both their better and worse eye.
- Effective risk stratification may help to prevent poor visual outcomes for patients in a glaucoma backlog.

INTRODUCTION

Risk stratification enables healthcare providers to identify and attribute the appropriate level of care for distinct patient subgroups. The objective is to segment patients into groups which share similar complexity and care needs, thereby allowing resources to be targeted with precision and greater efficiency. The concept of risk stratification is attractive to policymakers as it offers prospective improvements in quality and experience of care, while simultaneously reducing costs. As such, there is an increasing demand for risk stratification and predictive modelling within healthcare services, particularly in specialties responsible for large patient caseloads [1, 2].

Ophthalmology departments represent the busiest outpatient specialty in the UK [3], wherein glaucoma care absorbs significant resources with approximately one third of outpatient activity responsible for managing the condition. Glaucoma is a leading cause of visual impairment requiring ongoing monitoring by eye care professionals, typically occurring within the hospital eye services. Epidemiological modelling predicts the number of people with glaucoma will increase dramatically over the next two decades [4], creating a landscape filled with complex challenges for the hospital eye service. Soaring demand is already having an impact on the quality of healthcare service delivery in the UK. For example, a workforce census from The Royal College of Ophthalmologists found that 89% of providers reported delays in follow-up in glaucoma care [5]. A recent investigation by the Healthcare Safety Investigation Branch concluded that the hospital eye service does not have the capacity to meet demand [6], and surveillance studies have found that glaucoma patients have experienced deterioration in vision due to delays in treatment initiation or escalation, including in some cases a total loss of vision [7].

In an attempt to address the backlog of patients, new models of glaucoma care have been introduced, including an expansion of allied health professionals within glaucoma, virtual clinics, community monitoring schemes, and risk stratification of patients [8-10]. Due to being a chronic disease characterised by gradual and insidious visual loss often over several years or decades, glaucoma represents a clinical caseload where stratification based on risk may be particularly appropriate. Levels of clinical need across the glaucoma spectrum are not equivalent. Patients may be at low risk of vision loss due to a range of clinical factors, some patients will require more careful observation, and some will have a rapidly progressing form of the disease requiring close monitoring with proactive and timely interventions.

Glauc-Strat-Fast is a clinical tool for classification of patients with glaucoma into strata of risk for significant future sight loss and an estimate of resource requirement [11]. The tool enables an understanding of individual risk and can improve clinical services through effective prioritisation and commissioning of care and was designed to reflect the complexities of

glaucoma management, progression and vision loss. The tool was developed by a worldwide team of glaucoma specialists led by Prof Peter Shah, Ms Freda Sii, Mr Imran Masood, Prof Graham Lee, Mr James Kirwan and Mr Simon Dulku, centred at the Birmingham Institute of Glaucoma Research at the Institute of Translational Medicine at University Hospitals Birmingham, UK. The team first published the tool in the Medical Defence Union Journal [12], and thereafter many iterations have been developed, leading to the version described in this report which is recommended by the Royal College of Ophthalmologists and the UK and Éire Glaucoma Society (UKEGS) for use in the NHS glaucoma clinics. Glauc-Strat-Fast has recently been validated in eyes with ocular hypertension and open angle glaucoma [13], and has also been mapped to the relevant competencies across the glaucoma care pathway spanning primary and secondary care [14]. The purpose of this real-world study was to examine visual outcomes of patients within a glaucoma backlog in the hospital eye services, and to determine movement of patients between stratification boundaries on the Glauc-Strat-Fast tool.

METHODS

A database of all glaucoma cases under the care of one of the authors (TS) on a backlog list at Worcestershire Acute Hospitals NHS Trust was created. Worcestershire Acute Hospitals provide hospital-based services from three main UK sites - the Alexandra Hospital in Redditch, Kidderminster Hospital and Treatment Centre, and Worcestershire Royal Hospital in Worcester, serving a population of ~600,000. The UK glaucoma backlog worsened during the COVID-19 pandemic, as regular outpatient attendances were deferred [15-16]. At Worcestershire Acute Hospitals NHS Trust, staff were redeployed and ophthalmology services were restricted to emergencies. Consequently, glaucoma patients breached their recommended follow-up schedule, including those stratified to be most at risk of visual disability according to Glauc-Strat-Fast. The lead clinician (TS) in the Worcester Department of Ophthalmology approached PS and wider team at University Hospitals Birmingham as they have extensive experience in developing and implementing the Glauc-Strat-Fast patient stratification system.

Stratification: Glauc-Strat-Fast uses a red/amber/green system, with red patients being at highest risk of severe visual loss and needing the highest levels of time and resources. The cut-offs used for each boundary (worse eye mean deviation [MD] visual field loss in dB) are: Green 0 to -4 dB / Amber -4 to -8 dB / Red <-8 dB. The mean deviation is conventionally used in the clinic and in clinical trials; it is a summary measure of the overall reduction in visual field sensitivity relative to a group of healthy age-matched observers with more negative values indicating more vision loss. Traditional strata for mild, moderate and advanced glaucoma using MD have referred to 0

to -6 dB, -6 to -12 dB and <-12 dB, respectively, for example, in the Hodapp-Parrish-Anderson classification system [17]. However, through extensive consultation with over 100 global glaucoma specialists, a consensus was reached that most clinicians would now consider that the cut off for advanced stage disease should be lowered to -8 dB from -12 dB [11]. In the Glauc-Strat-Fast tool patients are assigned plus factors and red flags for high-risk phenotypic features and co-morbidities that increase complexity including systemic conditions, mental/physical disabilities, socio-economic deprivation, and lifestyle circumstances such as the need for transport. (Figure 1.). The tool also acknowledges diagnosis, stage of disease, complexity of disease, rate of disease progression, life expectancy, ocular and systemic comorbidities, dependency and socio-economic deprivation.

<Figure 1 here>

Figure 1. Glaucoma risk stratification tool 'Glauc-Strat-Fast'. **Key:** OHT = ocular hypertension; dB = decibels; VF = visual field; mmHg = millimetres of mercury; IOP = intraocular pressure.

A total of 3,342 glaucoma cases were identified as being in a backlog by members of the clinical care team (OS; TS). The backlog parameters were defined using the ophthalmic service guidance for performance reporting by the Royal College of Ophthalmologists which refers to 'within 25%' as the recommended indicator for measuring delays in follow-up [18]. A calculation was applied to the glaucoma service at Worcestershire Acute Hospitals NHS Trust to derive the number of patients with primary open angle glaucoma (POAG) exceeding their 25% recommended follow-up. The calculation used the time period between the last appointment and the target appointment and the time period between the last appointment and the actual date to establish the extent of the delay, and whether the delay exceeded 25% of the planned timescale. From this group, a consecutive sample of 100 POAG patients who were eligible to be stratified according to Glauc-Strat-Fast were invited for assessment by the clinical care team. Eligible patients were those previously diagnosed with POAG with at least 2 visual function measurements (Snellen visual acuity and Humphrey visual field) included in their electronic medical record prior to the COVID-19 pandemic. This was to ensure that the visit prior to the pandemic was not the patient's first hospital attendance or their first time performing the visual field test. POAG patients were selected as this cohort does not share the same complexities as other glaucoma types such as secondary or pseudoexfoliative glaucoma. At the follow-up study visit, these measurements were repeated. Snellen visual acuity was converted to logarithm of the minimum angle of resolution (logMAR) units, where higher scores are indicative of poorer vision. Where very low vision was recorded (count fingers (CF) and hand motion (HM)), logMAR numerical values were imputed in

line with recognised conversion methods [19]; for this study, CF and HM were valued as 1.9 and 2.3 logMAR, respectively.

Analysis: The amount of slippage between appointments was calculated for each patient. Slippage was defined as the amount of delay beyond the suggested appointment date. Extent to which patients breached their follow up time was calculated as the difference between the requested appointment date and actual appointment date in months (i.e., slippage). For example, where a patient was scheduled to be seen in 6-months and was followed up in 12-months, the extent of slippage was calculated to be 100% (6-months). Visual function measurements were compared between the two clinic visits (i.e., prior visits versus follow-up visit). Average change in measurements between the prior and follow-up visits were analysed using Wilcoxon sign rank test and categorical variables were compared using Pearson's χ^2 . Differences in MD scores across the three strata of Glauc-Strat-Fast were analysed using the Kruskal-Wallis test. All analyses were performed using SPSS 27.0 and data were plotted using RStudio ggplot2 packages.

RESULTS

Average age of patients was 79 (± 9.1) years and 54 were male. All patients had a diagnosis of primary open angle glaucoma. The majority of patients (98%) identified as White British. Baseline demographics are summarised in Table 1. Using the first recorded visual field in each series, average total duration of follow-up prior to the pandemic was 9.7 (± 6) years. At the prior clinic visit, median visual field MD for the worse eye was -8.6 dB [IQR -3.7 to -16.2] indicating moderate to severe visual loss. Target follow-up time after the prior visit ranged from 6 weeks to 12 months (median = 6 months, interquartile range = 4 to 6 months). Amount of slippage ranged from 2 to 32 months (median = 8 months, interquartile range = 6 to 12 months).

Age (years)		79 (± 9.1)
Sex	Male	54
	Female	46
Ethnicity	White British	98
	Asian/Asian British	2
Ocular comorbidity	Clinically significant cataract	4
	Retinal vein occlusion	5
	Age-related macular degeneration	15
	Other retinal problem	6

Table 1. Patient demographics

All patients were stratified twice separately based on their worse eye (i.e., most affected) and better eye (i.e., least affected) according to Glauc-Strat-Fast. Table 2 shows average visual acuity and visual field measurements for the better and worse eye at both visits.

	Prior visit	**Follow-up**	**p-value**
Mean deviation (dB)			
Better eye	-2.6 [-0.9 to -5.4]	-8.6 [-4.3 to -16.5]	<0.001*
Worse eye	-8.6 [-3.7 to -16.2]	-20.9 [-13.6 to -29.3]	<0.001*
Visual acuity (logMAR)			
Better eye	0.0 [-0.1 to 0.0]	0.2 [0.0 to 0.2]	<0.001*
Worse eye	0.0 [0.0 to 0.2]	0.3 [0.2 to 0.8]	<0.001*

Table 2. Median [IQR] measurements between prior clinic visit and follow-up with significance as determined by Wilcoxon sign rank test. * denotes statistical significance.

A statistically significant average reduction in visual field mean deviation for the better and worse eye between visits was observed (Wilcoxon sign rank test; p = <0.001). Similarly, a statistically significant worsening in LogMAR visual acuity was found for both eyes (Wilcoxon sign rank test; p = <0.001). When reverting to Snellen measurements, 40% of patients experienced a drop in visual acuity: 25% dropped one line; 9% dropped 2 lines; 6% had dropped >2 lines.

As patients move between and cross boundaries within the Glauc-Strat-Fast tool based on worse eye MD, this change can be visualised in the Jones-Shah plot (Figure 2). The plot was designed for the purpose of displaying individual patient visual field MD scores mapped to the red-amber-green classifications according to Glauc-Strat-Fast. MD scores were significantly different on average between strata (Kruskal Wallis test; p = <0.001). At follow-up, no eyes could be classified as low risk (green), 4 were moderate (amber), and 96 were high risk (red), and MD scores were significantly different between strata (Kruskal Wallis test; p = <0.001).

<Figure 2 here>

Figure 2. Jones-Shah plot stratification according to worse eye MD of 100 patients on Glauc-Strat-Fast between clinic appointments

As shown in Figure 3, stratification determined by better eye MD at the prior visit identified 21 patients as low risk, 14 as moderate risk, and 48 as high risk. MD scores were statistically significantly different between strata at the prior visit (Kruskal-Wallis test; p = <0.001) and follow-up visit (Kruskal-Wallis test; p=0.018). At the prior visit, 67 patients were classified into

the lowest level of risk (green), 14 patients were moderate risk (amber), and 19 were high risk (red). At follow-up, proportions of patients in each strata were 19, 25, and 56, respectively. The elevation of risk into the highest strata of Glauc-Strat-Fast (red) observed a three-fold increase in patients (19 versus 56) between the two clinic appointments. Figures 2 and 3 display scores for individual patients, therefore enabling a visualisation of the full distribution of measurements between both time points. The plots provide an overall summary of the profile of each strata of Glauc-Strat-Fast and allows for sub analysis of the associated clusters.

<Figure 3 here>

Figure 3. Jones-Shah plot of stratification according to better eye MD of 100 patients on Glauc-Strat-Fast between clinic appointments

At the prior visit, all patients were capable of performing the Humphrey visual field test in at least one eye, and 97% could perform the test bilaterally. In other words, three patients were perimetrically blind in one eye at the prior visit. Perimetrically blind patients are those with significantly reduced visual functioning to the point where standard perimetric testing cannot be performed to produce meaningful results. In line with previous research and for analysis purposes, perimetric blind eyes were assigned a MD value of -30 dB. [20]. By the follow-up visit, 19 patients were considered perimetrically blind in at least one eye, and one additional patient was bilaterally perimetrically blind.

'Only eye' patients are those with extensive vision loss in their worse seeing eye; thus, relying principally on the healthier contralateral eye for visual functioning. The definition of only eye can be used in different ways. Here, only eye status was based on a visual function parameter (worse eye MD <-20 dB). Of the 100 patients in this analysis, 13 were considered to have an 'only eye' at the prior visit, rising to 52 patients at follow-up (χ^2; p = <0.001).

Although it is not possible to reliably establish a rate of visual field progression based on only two measurements, we performed a simulation in an attempt to contextualise the findings alongside a frequently used progression threshold. A decline in MD of greater than or equal to 1 dB/year has been considered by several studies as the criterion for rapidly progressive disease [21-23]. In this study, rate of progression was estimated by calculating the difference in worse eye MD between the prior and follow-up visit, divided by the total number of months between the two visits (requested follow-up time + slippage). This gives an average deterioration per month which was multiplied by 12 to predict the annual loss. Using this method, median (IQR) change between

the two appointments was -8.9 dB (-4.5 to -13.3) over an average time period of 10 ± 6 months. When comparing our data to the clinically significant glaucomatous progression thresholds, 91 patients would fall within the parameters of fast progression. While the use of linear models is an acceptable approach to analyse slopes for MD [24], it is appreciated that some patients in clinic may demonstrate stepwise visual field progression, such as patients with significant visual field loss being more likely to progress at a faster rate [25].

Discussion

The glaucoma backlog was amplified by the COVID-19 pandemic, affecting the way patients accessed healthcare services, resulting in many individuals breaching their recommended follow-up times. Our real-world study provides a snapshot of patients' movement between levels of risk strata on Glauc-Strat-Fast during a period of significant hospital delays. Stratification provides an opportunity to prioritise patients based on their level of risk, and judicious implementation of a validated instrument such as Glauc-Strat-Fast can help to improve glaucoma services by identifying patients requiring closer and more frequent monitoring.

Predictive modelling suggests over 28 million operations were cancelled or postponed globally during the peak 12 weeks of the first wave of the pandemic [26]. Ophthalmology departments were significantly impacted by delays in services. For example, the number of referrals for neovascular age-related macular degeneration dropped by over 70% compared to the previous year [27], and retrospective analysis suggests there was a significant loss in visual function due to inconsistent intravitreal injection delivery of treatment [28]. In our study, average time elapsed between the recommended follow-up and actual follow-up was 8 months. Visual functioning, as determined by visual acuity and visual field MD had deteriorated in both eyes between patients' clinic visits. The Getting It Right First Time (GIRFT) ophthalmology report recommends glaucoma pathways include adoption of risk stratification processes, and for adoption to be used consistently across the sector [29]. GIRFT is a national programme designed to improve medical care within the NHS by reducing unwarranted variations, and the 2020 report acknowledges only a small proportion of providers are actively stratifying glaucoma patients according to their risk of visual disability, and tailoring clinical provision accordingly. In glaucoma care, managing patients according to risk could allow ophthalmologists to focus primarily on higher risk caseloads, while lower risk patients may be seen less frequently, or could be monitored by accredited allied health professionals. Services led by non-medical professionals are emerging and showing to be safe and effective [30, 31]. Yet several barriers to widespread implementation of glaucoma service improvements remain, primarily due to rigid organisational processes, despite policy emphasis on encouraging innovation at this level [32]. The pandemic provided an opportunity to tackle this inertia as a rapid scale up in patient prioritisation was

required through necessity. This study gives insights into the utility of Glauc-Strat-Fast by evidencing the poor visual outcomes observed among patients at a time where stratification could not easily be achieved.

Visual field measurements had significantly declined at follow-up, and the proportion of patients stratified in the highest level of risk based on MD had increased to 56 and 96 for better eye and worse eye, respectively. The proportion of patients stratified into the highest level of risk (red) at follow-up is striking and indicative of significant decline in vision between clinic visits. These findings are similar to previous research examining MD change between pre and post pandemic which suggested a higher proportion of patients with early glaucoma progressing between appointments, whereas those with moderate or advanced glaucoma did not progress [33]. It is noteworthy that the sample used in our study may not be wholly representative of the national trends across glaucoma clinics during the pandemic. For example, the extent of worse eye visual field damage at the prior visit was significant -8.6 [IQR -3.7 to -16.2] dB. It is well established that rates of glaucomatous progression are highly variable [34], whereby patients with more advanced disease are more likely to progress at a faster rate [25]. Yet, the change in MD among patients in this study appears to be significantly faster than those reported in other studies, albeit these studies using clinical data prior to the pandemic era [21, 25, 35]. The results provide a snapshot of the detrimental impact of the pandemic on glaucoma clinical services. Notwithstanding, the research team reflected on preceding issues which may have exacerbated the poor visual outcomes observed in the study. For example, the lead clinician (TS) identified poor management on behalf of the clinical commissioning group (CCG) in the years prior to the pandemic, such as inconsistent planning for management of low risk glaucoma (i.e., hospital or community based systems), withdrawal of funding for glaucoma nurse practitioners, and limited investment in the glaucoma service.

While it is sobering to appreciate the number of patients losing vision during the pandemic, it is important to consider specific local factors which may have contributed to these findings, besides simply analysing the amount of slippage between clinic appointments. For example, evidence suggests the pandemic period was associated with a worsening in chronic disease self-management [36], and some glaucoma patients showed a decline in adherence to anti-glaucoma medications [37]. Moreover, despite stable levels of adherence, a reduced regularity in the timings of eye drop instillations was also reported. One study identified barriers to glaucoma medication adherence during the pandemic including non-availability of medications, financial difficulties, perceived inefficacy of drops, lower socioeconomic status, and stress due to the pandemic [38]. In addition, poor health literacy may be associated with decreased successful drop instillation [39]. Studies relating to glaucoma and mental health indicate a high proportion of

anxiety and depression during the pandemic, with poorer mental health being linked to worse self-management behaviours [40, 41]. In other words, challenges with mental health may have caused a reduced prioritisation of eye health or diminished self-efficacy in people with glaucoma. Self-efficacy is one of the key constructs of social cognitive theory which can be used to understand health behaviours in glaucoma [42]. For instance, some patients may not have an active role in their healthcare and thus assume no action is required from them if they are not contacted by their care team. In addition, to some extent the pandemic cultivated distrust in modern medicine and healthcare professionals, largely due to frequently changing recommendations, conflicting messages and conspiracy theories [43], which may have had implications for how patients perceived their condition. Finally, material deprivation is known to affect eye health outcomes [44]; thus the demography of our sample may partly explain the poor visual outcomes observed in this study.

The significance of our findings can be considered in relation to the impact on the patients themselves. Patients with visual field loss rate their vision-related quality of life significantly lower than those with preserved visual functioning [45], and several studies have observed a significant relationship between visual field loss and vision-related quality of life [46-52]. Loss of vision between visits had caused some patients to become effectively 'only eye' patients. Only eye patients are those with severe vision loss from causes including trauma, surgical complications and advanced disease, or may have long-standing poor visual function from dense amblyopia. Our analysis showed the number of patients considered as only eye increased from 13 to 52 between the prior and follow-up visit. Becoming an only eye patient presents exceptional physical, emotional and psychological challenges. For example, patients report greater difficulties in completing activities of daily living and describe emotional distress due to uncertainty around the prognosis relating to their residual vision [53]. In addition, only eye patients represent a more complex caseload and often require greater clinical resources [54, 55]. Our findings demonstrate the implications of the pandemic on the glaucoma service, with significant consequences for patients' visual outcomes and in turn, quality of life.

Risk stratification and scoring algorithms in glaucoma can help to guide clinical care teams when tackling high volumes of patients and significant appointment slippage. One study during the pandemic used a large collaborative data repository from electronic health records for triaging glaucoma patients. Patients were assigned a risk score based on COVID-19 morbidity, disease severity and glaucoma progression, which was used to calculate which appointments could be safely postponed and rescheduled by balancing the risks of glaucomatous progression with potential risk of acquiring COVID-19 [56]. The algorithm, combined with clinical judgement, provided a source of additional information to aid appointment scheduling. Stratification models

such as scoring algorithms and Glauc-Strat-Fast can be adopted as elegant tools to assist clinical decision making. The pandemic highlighted what can be done for patient management in extremis and has triggered the need for a rapid scale-up of innovative approaches to addressing the glaucoma backlog.

Our study has some limitations. We simply report the average change in clinical measurements retrospectively between two appointments. Our approach, therefore, does not account for measurement variability on, for example, the visual field test, which is known to become more variable among those with severe glaucomatous damage [57]. This obviously differs from an in-depth analysis of visual field progression using a continuous series of measurements over time. However, the intention of this study was to provide a real-world exploratory insight into movement between stratification boundaries and patterns in clinical outcomes among patients significantly breaching their recommended follow-up schedule during the pandemic. Our reporting of average scores also does not take into account some subtle nuances within the data. For example, poorer scores at follow-up may partly be explained by patients becoming worse test-takers after a prolonged period of not completing these measures, or may reflect patients' anxieties around returning to clinics for the first time since the pandemic began. Due to the real-world nature of this study, a further limitation is the reliance on retrospective clinical data extracted from records of a relatively small cohort of patients, as well as the limited generalisability of the sample. For example, the majority of patients were Caucasian with few patients included from minority ethnic communities, who may be at an elevated risk of glaucoma or may differ in their eyecare experiences and behaviours [58, 59].

In conclusion, while decision making amid a crisis will invariably be complex and challenging, this retrospective analysis shows the extent of patients' movement into the highest strata on the Glauc-Strat-Fast tool and demonstrates a significant deterioration in visual outcomes during a period of extensive appointment slippage. The results highlight the value of the Glauc-Strat-Fast tool, particularly when managing a protracted backlog, and underpin the clinical need for effective patient risk stratification in the glaucoma service.

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