National Electronic Glaucoma Surgery and Visual Field Preservation Audit: Feasibility Report

A report commissioned from The Royal College of Ophthalmologists National Ophthalmology Database Audit by the Healthcare Quality Improvement Partnership

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National Electronic Glaucoma Surgery and Visual Field Preservation Audit: Feasibility Report

This feasibility study was commissioned by HQIP as part of a National Ophthalmology Audit with The Royal College of Ophthalmologists as the Audit Provider.

Executive Summary

Glaucoma accounts for approximately 10% of people registered as sight impaired or severely sight impaired in the UK. In people over 40 years in the UK the prevalence of glaucoma is approximately 2%, with a further 3% to 5% of people having risk factors or equivocal signs of possible glaucoma. In England and Wales this amounts to approximately half a million individuals with glaucoma and three quarters of a million people at risk of developing glaucoma, generating a service demand of approximately two million clinical visits annually. The only known effective treatment for glaucoma is lowering of intraocular pressure (IOP), regardless of the pre-treatment pressure. Once treatment has commenced lifelong chronic disease monitoring is necessary to maintain disease control, with treatment escalations as necessary. Vision loss from glaucoma cannot be recovered and treatment is aimed at preservation of remaining sight. Most patients are treated with eye drops alone, laser treatment and surgery are however necessary in a proportion of affected individuals.

This report includes two feasibility studies for possible national glaucoma audits based on data collected using electronic medical record systems (EMR) as part of routine care and computerised visual field tests that are linked to EMRs.

Part 1 addresses glaucoma surgery, trabeculectomy, which is the most frequently undertaken glaucoma surgical procedure, during the 2015-2016 year there were 5,438 NHS funded trabeculectomy operations. This surgery is reserved for people whose eyes are more severely affected by glaucoma and remains the most effective IOP lowering treatment.

Part 2 addresses visual field preservation in five large glaucoma care delivery centres. The lowering of IOP through all available methods is directed towards the ultimate goal of preservation of sight which is measured

clinically by means of a (computerised) visual field (VF) test. The 'average' value of the visual field sensitivity is used here to evaluate the extent of visual damage and its speed of progress through time.

Findings

The surgical study involving around 9,000 operations has highlighted a number of key challenges which would need to be overcome for a meaningful national audit to be feasible. These include:

- High levels of missing data
    - A proportion of EMR enabled centres are currently not using the EMR throughout the patient pathway. This arises due to mixed use of EMR and paper record systems where surgery is recorded on the EMR but pre- and post-operative outpatient data are recorded in paper notes only. Fully implementing the EMR for both theatre and outpatient use would address this issue.
    - Missing historic data from patient visits which took place prior to the local implementation of the EMR.
- Lack of integration of visual field data with clinically collected EMR data
    - Visual field testing measures glaucoma damage to vision and as such is fundamental to understanding success or otherwise of long term treatment. Many centres currently do not fully utilise the EMR functionality which provides for integration of visual field data with clinical EMR data. Long term surgical success in terms of preservation of vision could therefore not be assessed for the majority of centres which forced a reliance of the proxy measure, IOP lowering, which itself was subject to high levels of missing data.

Within the limitations note above there were a number of important positive messages which emerged from the exercise:

- A substantial majority of patients undergoing surgery experience a clinically meaningful reduction in IOP of around 8mmHg
- Pressure reduction on average is maintained, with relatively minor attrition, over at least five years
- Stringent composite criteria for success and partial success (glaucoma drops needed post-operatively) demonstrated that only around a quarter of operations fail at one year against strict success criteria
- A tentative risk prediction model with an encouraging C-Stat of 0.8 has been derived for case complexity adjustment
- A feasible 'proof of concept' methodology for a national audit has been demonstrated.

Visual field (VF) preservation is the most important clinical metric in terms of avoidance of sight loss in glaucoma. The VF study demonstrates that it is feasible to extract large volumes of VF data from multiple sites for aggregation. The five sites chosen for this study were all EMR enabled and known to run large glaucoma services with aggregated electronic VF databases. Few sites have VF databases with data from multiple field machines gathered into a single database suitable for analysis in this way. Whilst accepting that these selected sites are ahead of most sites in terms of electronic working, there were encouraging positive messages derived from this approach, including:

- Most VF were of good quality, only one in 20 being deemed unreliable by accepted criteria
- It was possible to identify eyes with VF damage at presentation and to assess the speed of VF progression in serial tests from the same individual
- A novel metric was used to predict years of sight loss based on the patient's VF status, the speed of progression of VF loss and their residual life expectancy
- It is feasible to derive metrics for process (frequency of VF testing) and effectiveness of VF preservation (speed of progression of loss, loss of sight years) as candidate metrics for future comparative centre level audits.

These high level metrics for blindness avoidance are novel and provide new opportunities for future service assessments in terms of the most important aspect of glaucoma care, i.e. preservation of sight.

Feasibility for a National Audit of Glaucoma

These complementary approaches to auditing outcomes in glaucoma each appear to be feasible in terms of their methodologies. The two main limitations for both approaches are completeness of collection of relevant data in EMR systems as a by-product of routine clinical care and lengthy follow-up required for long-term treatment benefits. For the clinical data relevant to the surgical audit this problem is probably a greater challenge as resolving it would require not only implementation of EMR systems to collect the necessary data, but also full use of the EMR throughout the patient pathway and back entry of historic clinical data on large numbers of patients. A more focussed back entry for surgical patients only might be a compromise option where centres were specifically interested in auditing their surgical outcomes. Aggregation of visual field data from multiple field testing machines is most easily achieved through implementation of an EMR which hosts the aggregated visual field data. Alternative options could include separate data extractions from individual machines with subsequent aggregation into a single database but this option would be time consuming and carry significant cost if applied to many glaucoma services, in particular if these were delivered in different settings such as outreach clinics.

National Electronic Glaucoma Audit Feasibility Report

1. Background

Glaucoma is an acquired optic neuropathy with characteristic optic nerve head excavation called cupping and corresponding nerve fibre pattern visual field defects. Glaucoma accounts for approximately 10% of people registered as sight impaired or severely sight impaired in the UK. Glaucoma takes many clinical forms, the most prevalent in the UK being Chronic Open Angle Glaucoma (COAG). Approximately two thirds of patients with COAG have elevated intraocular pressure (IOP) with the remaining one third without evidence of elevated eye pressure (IOP above 21 mmHg). In people over 40 years in the UK the prevalence of glaucoma is approximately 2%, with a further 3% to 5% of people having risk factors or equivocal signs of possible glaucoma. In England and Wales this amounts to approximately half a million individuals with glaucoma and three quarters of a million people at risk of developing glaucoma, generating a service demand of approximately two million clinical visits annually. Primary Angle Closure Glaucoma (PACG) is less common than COAG in Caucasians but more common in far eastern races.

The only known effective treatment for glaucoma is lowering of IOP, regardless of the pre-treatment pressure. Once treatment has commenced lifelong chronic disease monitoring is necessary to maintain disease control, with treatment escalations as necessary. Vision loss from glaucoma cannot be recovered and treatment is aimed at preservation of remaining sight. Most patients are treated with eye drops alone, laser treatment and surgery are however necessary in a proportion of affected individuals. Treatment escalations are required for patients when the disease is poorly controlled as evidenced by progression of visual field loss or optic nerve damage, or an unacceptable IOP level. Initial treatment is generally deemed effective if a pressure reduction of 25% to 30% has been achieved and the pressure is below 21 mmHg. For patients requiring ongoing follow-up and/or treatment at regular intervals, recent studies by both the Royal National Institute of Blind People and The Royal College of Ophthalmologists identified that many centres may not have adequate capacity and furthermore there is no standard NHS metric for capturing information related to these delays. Delays to follow-up monitoring visits have been associated with vision loss in people with glaucoma.

In 2014, The Healthcare Quality Improvement Partnership (HQIP) commissioned a National Ophthalmology Audit which included three feasibility studies for electronic audits. These were for glaucoma, to include trabeculectomy surgery and visual field (VF) preservation, for age-related macular degeneration (AMD)

treatment and for retinal detachment surgery in addition to the main focus of the National Audit which was for cataract surgery. These additional studies were commissioned in order to assess the feasibility of undertaking national audits in the three conditions based purely on data extracted from specialty specific electronic medical record systems (EMRs).

2. Context of the Feasibility Studies

The National Ophthalmology Database Audit is primarily concerned with publishing comparative cataract surgical results for named surgeons (excluding trainees) and named centres (including trainees) and sits within the National Clinical Audit and Patient Outcomes Programme (NCAPOP). The main cataract surgical audit and the three feasibility studies are based on routine clinical care data which is extracted from specialty specific Electronic Medical Record (EMR) systems. By far the most widely used system is the Medisoft EMR, with the OpenEyes EMR currently contributing cataract surgery data from a single very large centre, with a small number of bespoke local databases also providing data. The remit of the feasibility studies is to investigate the feasibility of the use of data derived exclusively from EMRs to assess the potential for future full scale national audits in one or more of these three topics. This report is based on multicentre data collected as a by-product of routine clinical work using the Medisoft EMR.

The audit provider is The Royal College of Ophthalmologists (RCOphth) which has engaged a number of subcontractors to deliver various elements of the audit. The brief from the audit commissioners included a requirement that these audits should build on the work of The RCOphth National Ophthalmology Database project which previously extracted, aggregated and analysed EMR derived data and published surgical benchmarks for a number of high volume ophthalmological procedures. A small working group based at The RCOphth obtains permissions and coordinates the work in conjunction with the 'NOD Delivery Unit' based in Cheltenham, the EMR providers Medisoft and OpenEyes, and a web design company. The NOD Delivery Unit forms the 'engine room' of the audit where the extracted data are aggregated and analysed following extraction by the EMR providers. The Medisoft EMR cataract module and optometric data return tools are provided by the audit as needed to allow currently paper based centres to collect data as part of routine clinical activity. The national audit is overseen by a RCOphth based multi-professional steering committee with Patient and Public Involvement (PPI) which reports via the Informatics and Audit Sub-committee to the Professional Standards Committee and ultimately to the College Council. Regular contract review meetings are held with the audit commissioners.

3. Aims of the Glaucoma Feasibility Audit

The National Audit tender for the glaucoma feasibility study included two important aspects of glaucoma care, trabeculectomy surgery to reduce IOP and visual field testing:

- *Aim 1*: To assess the feasibility of auditing the outcomes of trabeculectomy surgery in multiple EMR enabled centres
- *Aim 2*: To assess the feasibility of auditing visual field testing for glaucoma in five large EMR enabled centres in terms of frequency of visual field testing and lifetime visual field preservation.

4. Stakeholder Engagement

During 2015 a Delphi exercise was undertaken to identify the audit outcomes regarded by experts as being of importance for a possible future national glaucoma audit. This was led by the specialist glaucoma advisor on the National Ophthalmology Database Audit Steering Committee, Professor Anthony King. Members of the UK and Eire Glaucoma Society (UKEGS) were invited to participate in a Delphi exercise using an electronic survey. From a mailing list of 174 members, 64 agreed to take part, of whom 40 (67%) completed both rounds of the Delphi exercise. The main findings of the survey are summarised in Table 1.

Table 1. Delphi Question: When measuring national glaucoma treatment outcomes what data is it important and practical to collect?

Outcome	Median	Agreement	IPRAS	Disagreement index
IOP	9	Important	8.3	0.0
Visual Field	9	Important	7.6	0.1
Treatment related complications / adverse events	9	Important	7.6	0.1
Anatomical progression (optic disc / RNFL)	8	Important	6.9	0.3
Visual acuity	8	Important	6.9	0.3
Need for further glaucoma surgery	8	Important	6.9	0.3
Loss of driving licence	8	Important	6.2	0.2
Certification of visual impairment (due to glaucoma)	8	Important	6.9	0.3
Hypotony	8	Important	5.4	0.4
Number of medications	7.5	Important	6.9	0.3
Vision related quality of life e.g. NEIVFQ-25	7	Important	4.6	0.7
Glaucoma related quality of life e.g. GAL-9 (Glaucoma activity limitation 9)	7	Important	4.7	0.2
Experience of care e.g. patient experience questionnaire	7	Important	3.9	0.5
Information of costs (staff cost, drug cost, intervention cost etc.)	7	Important	3.9	0.5
Loss of visual field by a fixed amount e.g. 5dB	7	Important	5.4	0.4
Loss of visual field to a fixed level e.g. Hodapp Parrish Anderson criteria for advanced field loss (stage 4)	7	Important	4.6	0.7
Ocular discomfort e.g. OSDI (Ocular Surface Disease Index)	6.5	Unsure	4.6	0.2
Number of hospital visits over defined follow-up period	6	Unsure	3.9	0.5
General Health quality of life e.g. EQ5D / SF-6D	6	Unsure	3.9	0.5

Part 1 - Trabeculectomy Surgery Audit

Trabeculectomy surgery is the most frequently undertaken surgical procedure for uncontrolled glaucoma. During the 2015-2016 NHS year 5,438 trabeculectomy operations were undertaken in England (NHS Digital hospital episode statistics, C60.1). The procedure involves creation of a fistula for controlled drainage of aqueous humour from the anterior eye to a space under the conjunctiva referred to as a bleb, and is the recommended standard surgical procedure. NICE found this surgery to be the most cost effective method of IOP lowering but in view of the surgical risks did not recommend it as first line treatment except where glaucoma was advanced at presentation, in which case it should be considered. The treatment is therefore reserved for progressive or advanced disease or excessively high and otherwise uncontrollable IOP.

5. Methodology

5.1 Data Extraction from EMRs

The data for these analyses was initially extracted from the Medisoft EMR in autumn 2015 with supplementary extraction in to resolve a number of issues in the original extraction. Trabeculectomy surgery data were extracted from 33 NHS centres covering the period from initial installation of the EMR (which varied by centre) up to 31 March 2015. The data files for analysis included:

- Patient details
- Operative data (Indications for surgery, operative procedures, anaesthesia, cataract surgery details and trabeculectomy surgery specific data)
- Ocular co-pathology
- Diagnosis
- Injections
- Visual acuity
- Intraocular pressure measurements
- Biometry measurements
- Operative complications
- Post-operative complications
- Medications

5.2 Inclusion and Exclusion Criteria for the Trabeculectomy Feasibility Audit

- Include all first trabeculectomy operations undertaken on adult patients (18 or older)
- Include eyes previously treated with topical, systemic or laser therapy for lowering IOP
- Exclude eyes which have previously undergone glaucoma drainage surgery except for deep sclerectomy, canalostomy, viscocanalostomy, minimally invasive glaucoma surgery (MIGS)
- A patient may contribute two eyes to the audit
- As failure can be reported at the surgeon level, a valid surgeon identifier and grade was required

NHS hospitals use the Medisoft EMR in a variety of ways. Some centres use the EMR for the entirety of the glaucoma care pathway, including for outpatient monitoring visits, pre- and post-operative assessments and surgery, while others use the EMR for recording surgery only. With this in mind, a key element to assessing the feasibility of a national electronic glaucoma audit is data completeness.

5.3 Feasibility Study Candidate Outcome Metrics for Consideration

A range of data items of relevance to assessing the feasibility of a trabeculectomy audit were identified based on expert opinion and the Delphi responses. These are listed in Appendix 1.

5.4 Surgical Case Complexity

Reporting surgical success or failure rates provides a limited insight into the performance of individual surgeons as their case complexity is likely to vary. In order to better accommodate variations in case complexity risk models for surgical success and partial success would be needed. Parameters for model construction were therefore defined with a view to exploring the data for predictors of success versus failure. A model referring to a one year post-operative time point for a set of composite success versus failure criteria was planned.

5.41 Composite outcome definition for case complexity analyses

- Success
    - IOP <18 and >=30% reduction and
    - No drops and
    - No failure criteria
- Partial Success
    - As for success except on drops
- Failure (if any of these exist then classified as a failure)
    - IOP >=18 or
    - IOP <30% reduction or
    - NPL or
    - LogMAR VA drop =>0.5 (unless subsequent VA recovery) or
    - bleb revision or
    - further glaucoma surgery (trab, tube, cyclodiode)

Note: If bleb revision or further surgery at any time following index trabeculectomy then failure is defined for all future points in time. Bleb needling with or without augmentation does not imply failure unless other criteria apply. Thresholds of 18 mmHg and 30% reduction could be varied.

Inclusion and exclusion criteria for case complexity analyses are listed in Appendix 2.

5.5 Statistical Analysis

All analyses were conducted using STATA version 11, (StataCorp. 2009. Stata Statistical Software: Release 11. College Station, TX: StataCorp LP). Centre participation was affirmed by agreement from the Trust Caldicott Guardian and Clinical Lead for Ophthalmology.

6. Results

6.1 Operations

In total 9,541 Trabeculectomy operations were recorded on The RCOphth NOD. The first operation was recorded in the 2000-2001 NHS year and the last in the 2014-2015 NHS year. The number of trabeculectomy operations recorded increased over the 15-year period and from the 2010 NHS year, more than 1,000 trabeculectomy operations were recorded per NHS year, Figure 1. The increasing number of trabeculectomy operations over the 2000's reflects the pattern of EMR adoption within centres. Figure 2 illustrates the time points for each of the operations undertaken at each centre. Sparse dots towards the left illustrate slow EMR adoption in many centres, with continuous activity for some centres towards the right side as confluent dots form an uninterrupted line. Of the 33 centres contributing trabeculectomy data, 27 had recorded less than 500 trabeculectomy operations and 11 centres had recorded less than 100 operations, Figure 3.

The 9,541 trabeculectomy operations recorded on The RCOphth NOD were performed in 9,428 eyes. Of these, 427 (4.5%) eyes were excluded from analysis. Reasons for exclusion were as follows:

- 65 operations were performed on patients aged <18 years
- 338 eyes had a record of a previous trabeculectomy operation prior to implementation of the EMR at the centre
- One eye had a record of previous surgery that included tube or bleb prior to implementation of the EMR at the centre
- 23 operations had no valid surgeon identifier recorded. This is a historic issue within one contributing centre which has been rectified for future extractions.

9,000 First Trabeculectomy operations were eligible for analysis, with 101 repeat operations recorded which are of relevance for certain post-operative results (e.g. repeated surgery implies failure of the first trabeculectomy). The 9,000 first trabeculectomies were performed on 4,429 (49.2%) left eyes and 4,571 (50.8%) right eyes of 7,537 patients.

Figure 1: The number of trabeculectomy operations recorded per NHS year.

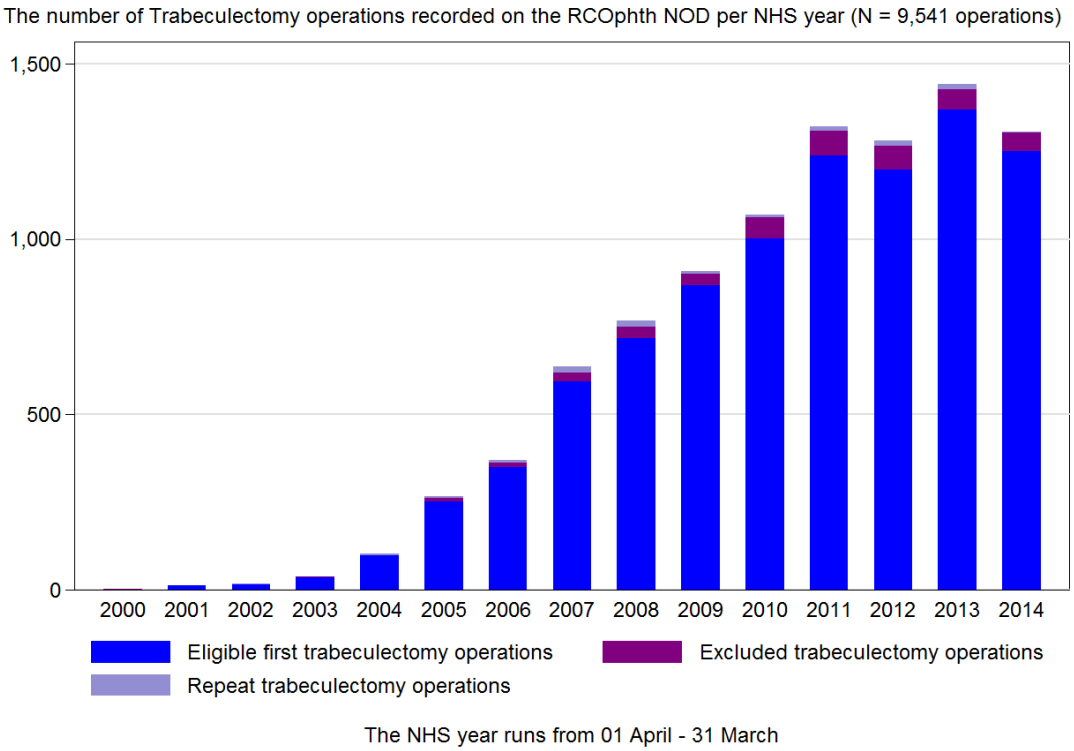


Figure 2: Distinct dates of trabeculectomy surgery in each participating centre.

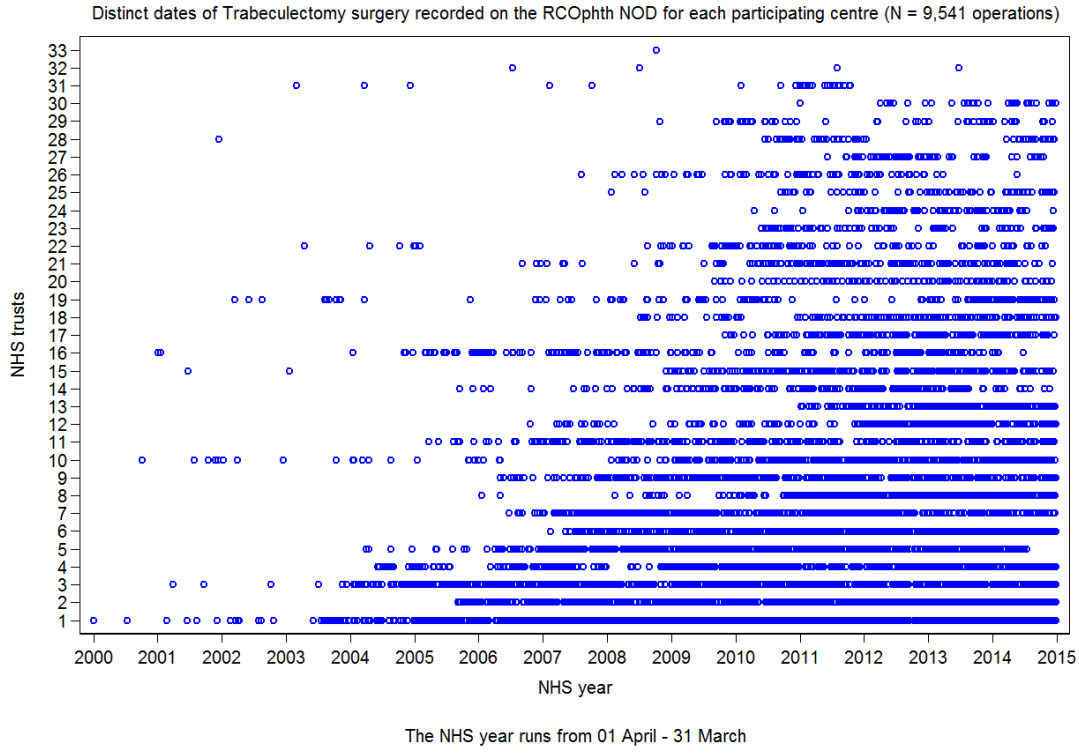
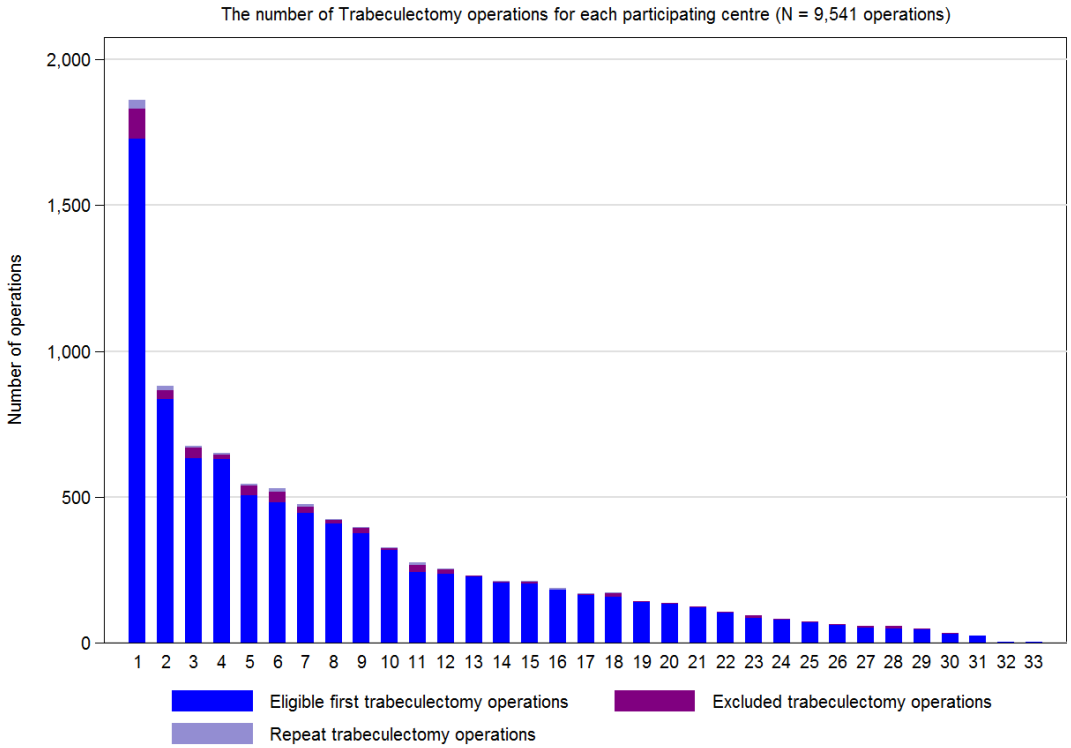


Figure 3: The number of trabeculectomy operations per participating centre.



6.2 Surgeons

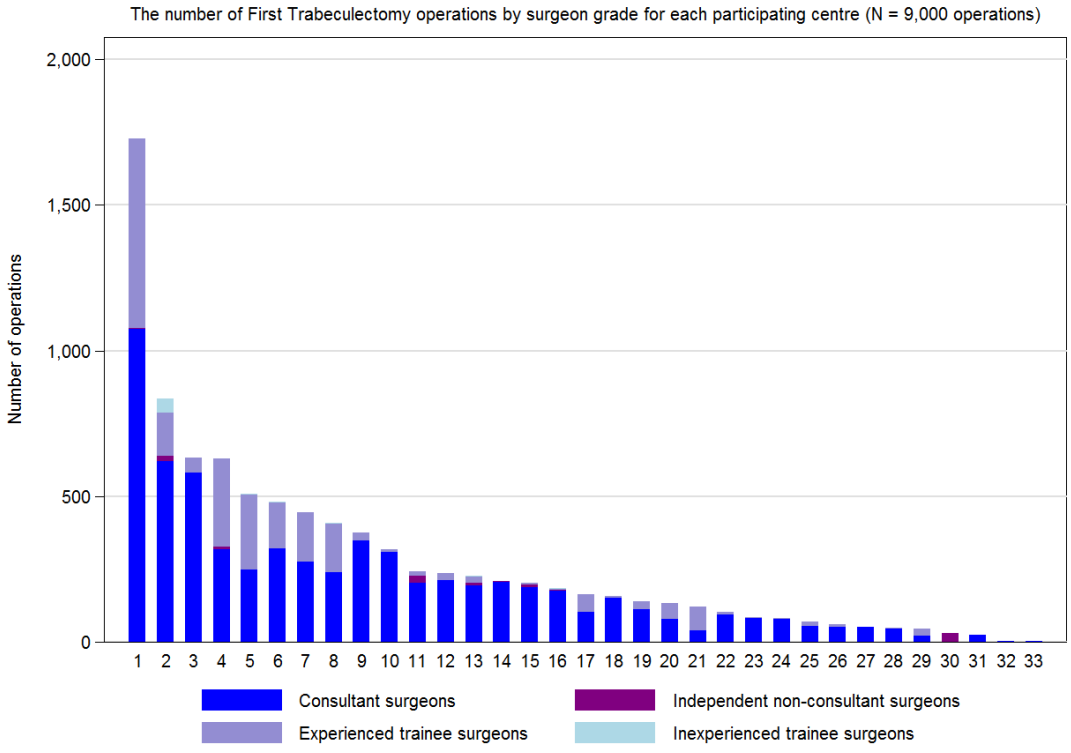
379 Surgeons performed the 9,000 first trabeculectomy operations with 16 surgeons having performed surgery at more than one grade.

The number of surgeons and operations at each surgeon grade were:

- 132 consultant surgeons performed 6,536 (72.6%) operations
- 18 independent non-consultant surgeons performed 110 (1.2%) operations
- 238 experienced trainee surgeons performed 2,298 (25.5%) operations
- Seven less experienced trainee surgeons performed 56 (0.6%) operations

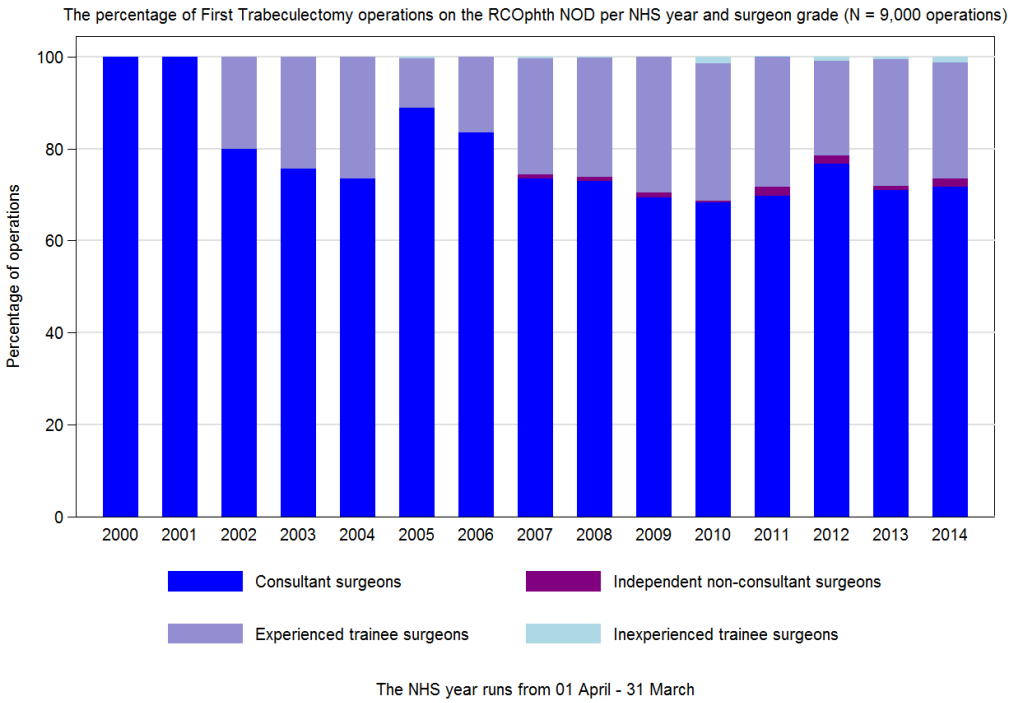
The number of first trabeculectomy operations performed by each grade of surgeon in each participating centre varied between the centres, Figure 4.

Figure 4: The number of first trabeculectomy operations by each grade of surgeon in each participating centre



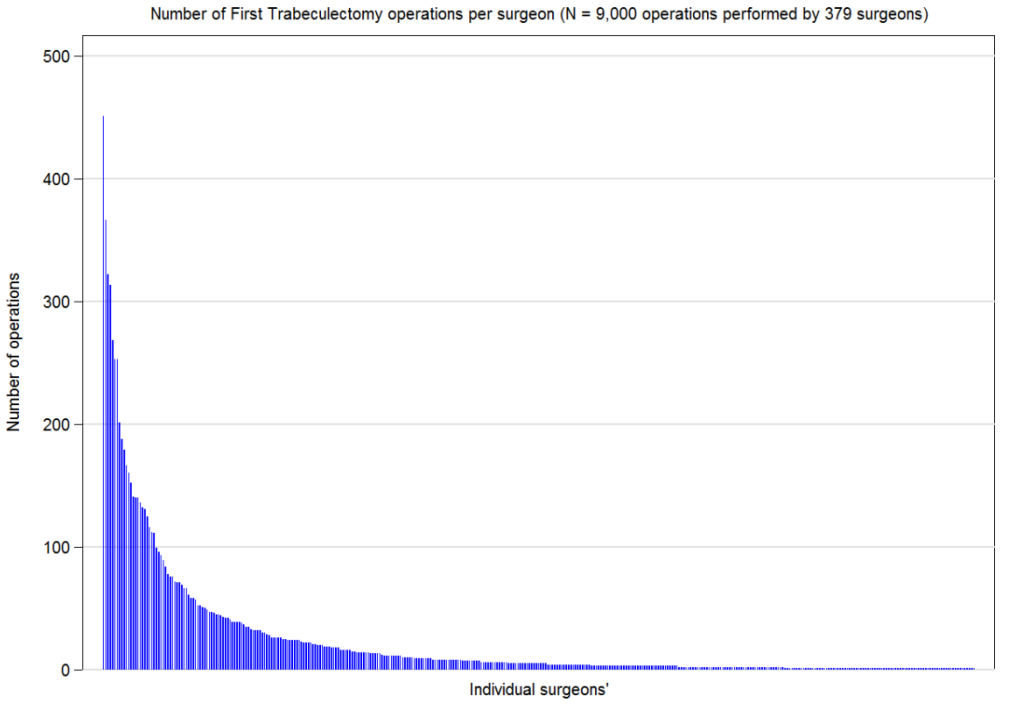
The proportion of first trabeculectomy operations for each surgeon grade varied between the NHS years, and consultant surgeons performed >60% of operations in each NHS year, Figure 5.

Figure 5: The percentage of first trabeculectomy operations performed by each grade of surgeon by NHS year



The median number of first operations per surgeon was five (IQR 2 – 20) and 244 (64.4%) of surgeons had fewer than 10 operations on The RCOphth NOD, Figure 6

Figure 6: The number of first trabeculectomy operations for each surgeon

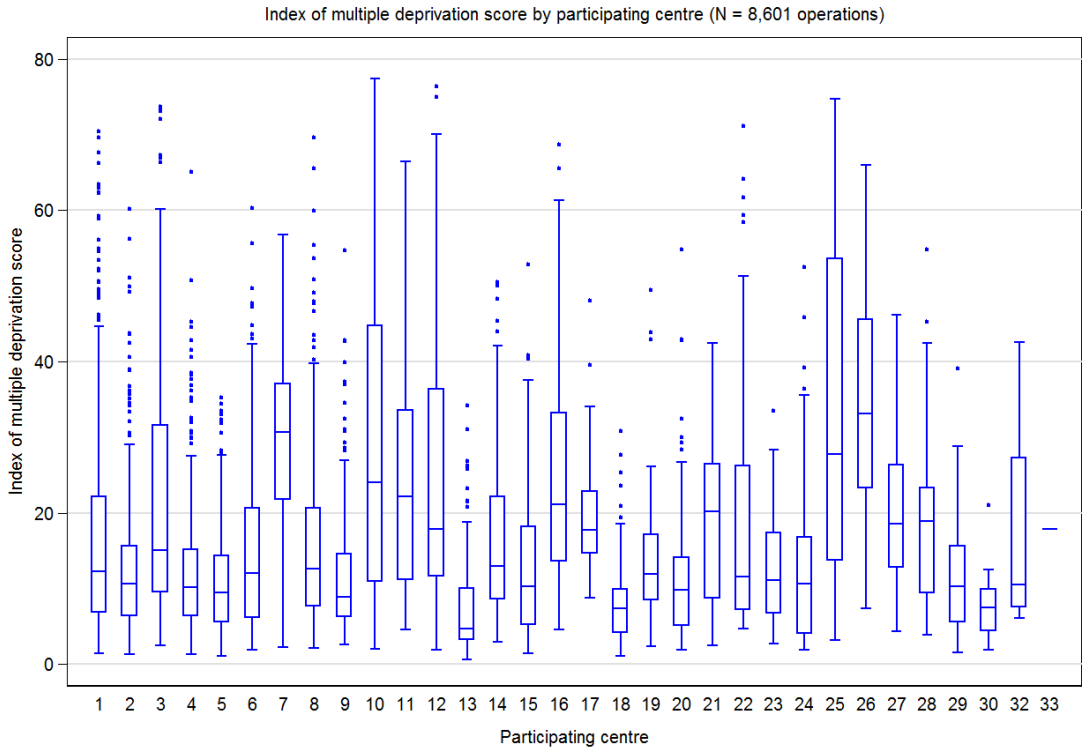


6.3 Patients

The 9,000 first trabeculectomy operations were performed on 7,537 patients where 1,463 patients had surgery to both their eyes and four patients had simultaneous bilateral surgery. For 8,962 of these operations, 83.3% were performed on the first eye to be treated with the median age for first and second treated eyes being virtually identical. For 30 eyes the status of whether they were first or second treated eyes could not be determined and eight eyes (four patients) underwent bilateral simultaneous surgery. Of the 1,460 patients undergoing surgery in both eyes, the median time between the first and second eyes being treated was eight months (range; one day – 8.9 years). Of the 7,537 patients, 3,753 (49.8%) were men, 3,773 (50.1%) were women and the gender was not stated for 11 (0.1%) patients. The ethnicity was recorded as Caucasian for 4,793 (63.6%) patients, UK ethnic minorities for 355 (4.7%) patients and not stated for 2,389 (31.7%) patients. The index of multiple deprivations (IMD) score was calculable for 8,601 (95.6%) eyes overall. Within centres the percentage of eyes where an IMD score could not be calculated was <11% for all except centre 33 where none were calculable. From the 2007 NHS year onwards <6% of operations had a non-calculable IMD score. Overall there was considerable variation in IMD score between centres,

Figure **7**.

Figure 7: Box and whisker plot of the patient's IMD score for each participating centre.

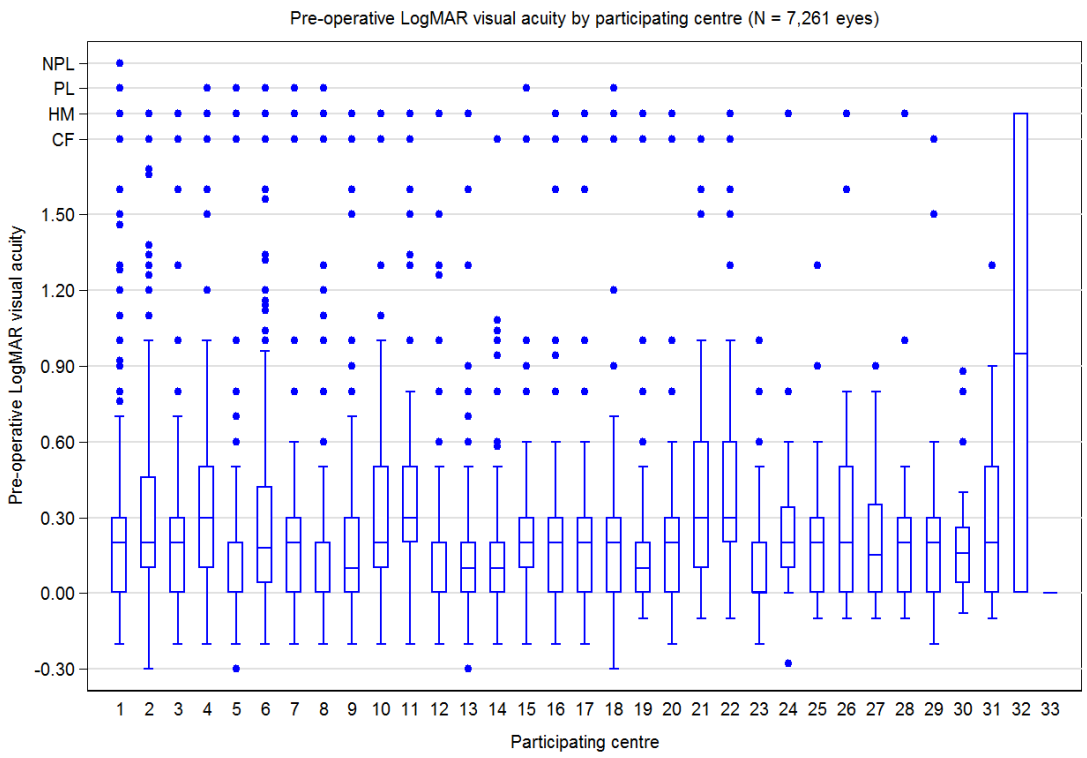


6.4 Pre-operative Status

6.41 Pre-operative Visual Acuity

For the 9,000 First Trabeculectomy operations the pre-operative VA was recorded for 7,261 (80.7%) eyes. The percentage of eyes with a missing pre-operative VA varied between centres and seven centres had >30% of treated eyes with a missing pre-operative VA. The percentage of operations each year with a missing pre-operative VA was <25% since the 2008 NHS year. The pre-operative best VA measurement was CDVA for 3,870 (53.3%) eyes, UDVA for 1,243 (17.1%) eyes and PHVA for 1,495 (20.6%) eyes. For 653 (9.0%) eyes the best VA measurement was equal for at least two assessment types. The median pre-operative VA was 0.20 LogMAR (IQR; 0.00 – 0.30 LogMAR) where 83 (1.1%) had CF, 100 (1.4%) eyes had HM, 16 (0.2%) eyes had PL and one (<0.1%) eye had NPL. The pre-operative VA was 0.30 LogMAR or better for 5,685 (78.3%) eyes, 0.60 LogMAR or better for 6,572 (90.5%) eyes and 1.00 LogMAR or better for 6,948 (95.7%) eyes. Since the 2008 NHS year the pre-operative VA has been fairly stable, but varied between the contributing centres, Figure 8. No difference in pre-operative VA was evident for deciles of IMD score or between eyes for those 1,096 patients who had both eyes undergo First Trabeculectomy surgery.

Figure 8: Box and whisker plot of pre-operative visual acuity for each participating centre.



6.42 Pre-operative Co-pathology

The presence of one or more ocular co-pathology was recorded for 1,410 (15.7%) First Trabeculectomy surgery eyes as presented by surgeon grade in **Table 2**. The percentage of operations performed in eyes with an ocular co-pathology was <30% for each NHS year since the 2002 NHS year. The percentage of operations performed in eyes with an ocular co-pathology varied between participating centres where 18 centres had >20% of operations performed in eyes with an ocular co-pathology and two centres had no eyes with a recorded ocular co-pathology, but these were the two centres with the fewest operations, Figure 9. The most frequently recorded ocular co-pathologies were previous cataract surgery, uveitis / synaechiae and high myopia which were present in 9.3%, 2.6% and 2.2% of operated eyes respectively. No other individual ocular co-pathology was present in >2% of eyes except for unspecified other which included 12 eyes with optic nerve / CNS disease, 10 eyes with no fundal view / vitreous opacities, and four eyes with inherited eye diseases.

Figure 9: The percentage of First Trabeculectomy operations with an ocular co-pathology by participating centre.

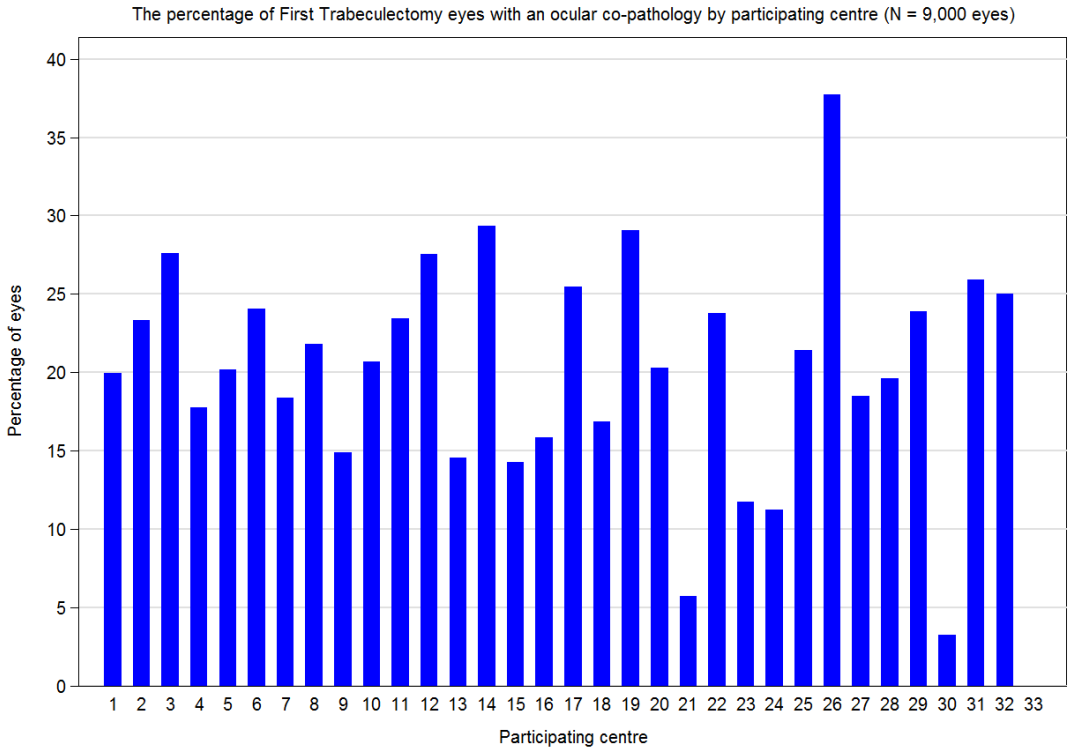


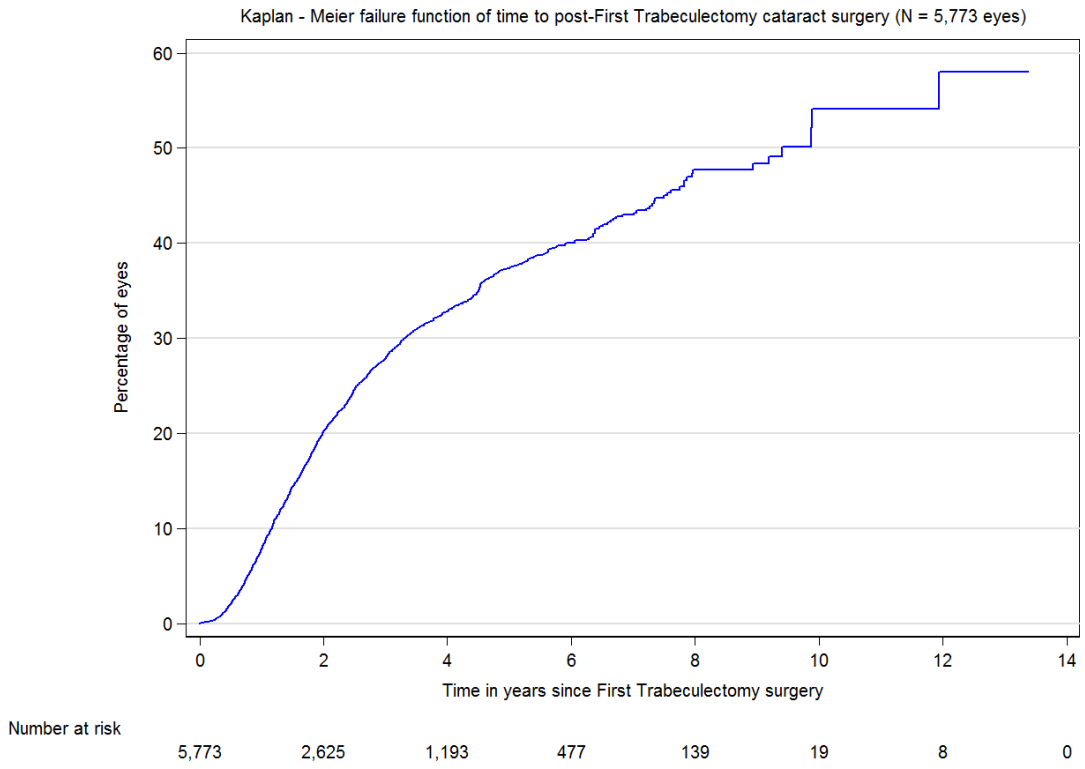
Table 2: Recorded Ocular Co-pathologies for First Trabeculectomy operation by grade of surgeon

Co-pathology, n (column %)	Consultant surgeons	Independent non-consultant surgeons	Experienced trainee surgeons	Inexperienced trainee surgeons	Overall
Number of operations	6,536	110	2,298	56	9,000
No. of recorded ocular co-pathologies					
0	5,098 (78.0)	95 (86.4)	1,878 (81.7)	51 (91.1)	7,122 (79.1)
1	1,059 (16.2)	13 (11.8)	334 (14.5)	4 (7.1)	1,410 (15.7)
≥2	379 (5.8)	2 (1.8)	86 (3.7)	1 (1.8)	468 (5.2)
Recorded ocular co-pathology					
Previous cataract surgery	630 (9.6)	5 (4.5)	201 (8.7)	3 (5.4)	839 (9.3)
Uveitis / Synaechiae	180 (2.8)	2 (1.8)	50 (2.2)	0 (0.0)	232 (2.6)
High myopia	153 (2.4)	1 (0.9)	44 (1.9)	0 (0.0)	198 (2.2)
Age related macular degeneration	131 (2.1)	0 (0.0)	29 (1.3)	0 (0.0)	160 (1.8)
Pseudoexfoliation / Phacodenesis	106 (1.6)	3 (2.7)	33 (1.4)	1 (1.8)	143 (1.6)
Previous vitrectomy	107 (1.6)	1 (0.9)	31 (1.3)	1 (1.8)	140 (1.6)
Other retinal pathology	105 (1.6)	0 (0.0)	21 (0.9)	0 (0.0)	126 (1.4)
Diabetic retinopathy	104 (1.6)	0 (0.0)	19 (0.8)	0 (0.0)	123 (1.4)
Corneal pathology	85 (1.3)	0 (0.0)	19 (0.8)	0 (0.0)	104 (1.2)
Other macular pathology	68 (1.0)	1 (0.9)	17 (0.7)	0 (0.0)	86 (1.0)
Brunescent / White cataract	50 (0.8)	0 (0.0)	9 (0.4)	0 (0.0)	59 (0.7)
Amblyopia	40 (0.6)	1 (0.9)	18 (0.8)	0 (0.0)	59 (0.7)
*Unspecified other	213 (3.3)	3 (2.7)	43 (1.9)	1 (1.8)	260 (2.9)

6.43 Lens Status

Of the 9,000 First Trabeculectomy operations, 839 (9.3%) were performed in eyes that had previously undergone cataract surgery 1,478 (16.4%) were performed in eyes that had combined cataract + trabeculectomy surgery and a further 910 (10.1%) eyes had no follow-up data recorded.
In total 5,773 eyes were eligible for post-trabeculectomy cataract surgery analysis where 1,293 (22.4%) had cataract surgery and 4,480 (77.6%) did not. The six month, one year, three years, five years and 10 years rates of post-trabeculectomy cataract surgery were 2.1%, 7.8%, 27.9%, 37.5% and 54.2% respectively, Figure 10. Only one cataract operation was performed more than 10 years after the First Trabeculectomy surgery and no difference in the post-trabeculectomy cataract surgery rates was observed between the grade of surgeons, p = 0.7285.

Figure 10: Kaplan-Meier failure graph for time to post-trabeculectomy cataract surgery



6.44 Pre-operative Intraocular Pressure (IOP)

Of the 9,000 First Trabeculectomy eyes, 4,824 (53.6%) eyes had a pre-operative IOP measurement and 4,176 (46.4%) did not. The percentage of eyes with a missing pre-operative IOP varied between centres and nine centres had >80% of treated eyes with a missing pre-operative IOP and two centres had 100% missing pre-operative IOP Figure 11. Except for the 2002 NHS year, the percentage of operations with a missing pre-operative IOP was >40% for each NHS year.

The median pre-operative IOP was 20 mmHg (IQR; 16.3 – 24 mmHg) while the mean and standard deviation were 21.2 and 6.9 mmHg respectively. The distribution of pre-operative IOP was fairly consistent across surgeon grades and the pre-operative IOP was <10 mmHg for 12 (0.2%) eyes, <14 mmHg for 395 (8.2%) eyes, <18 mmHg for 1,690 (35.0%) eyes and <21 mmHg for 2,747 (56.9%) eyes. None of the eyes had a pre-operative IOP of <5 mmHg, Table 3. The pre-operative IOP was fairly stable across years but varied between the contributing centres Figure 12. No difference in pre-operative IOP was evident between deciles of IMD score.

Figure 11: The percentage of eyes with a missing pre-operative IOP for each participating centre.

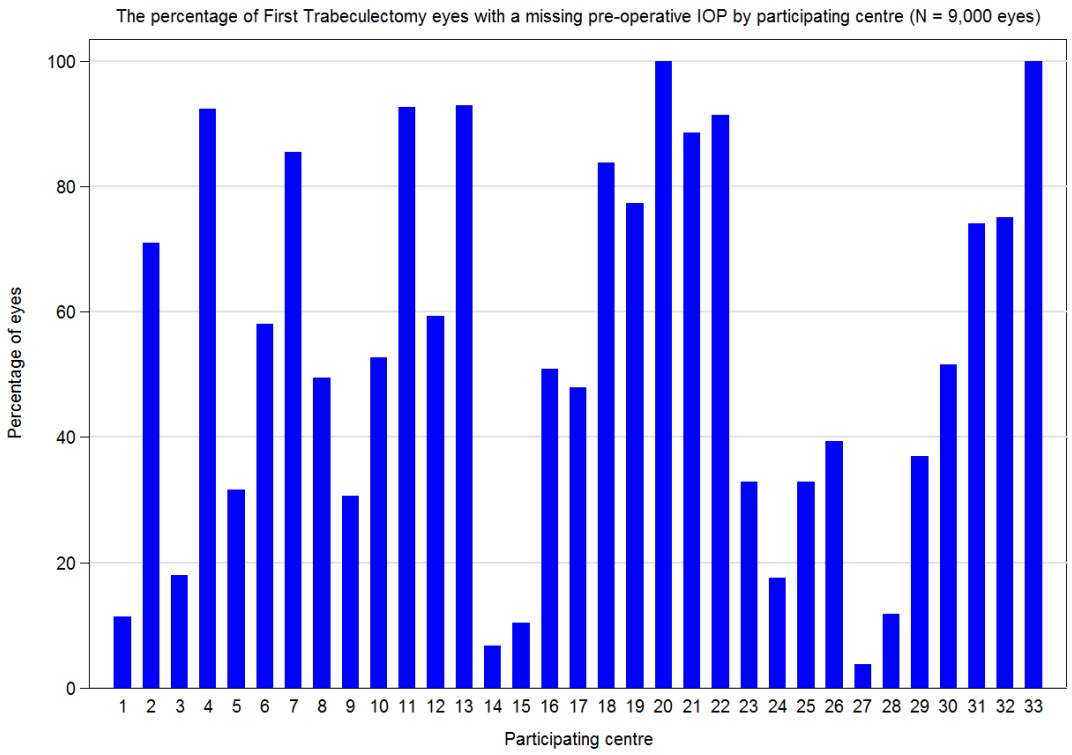


Figure 12: Box and whisker plot of pre-operative IOP for each participating centre.

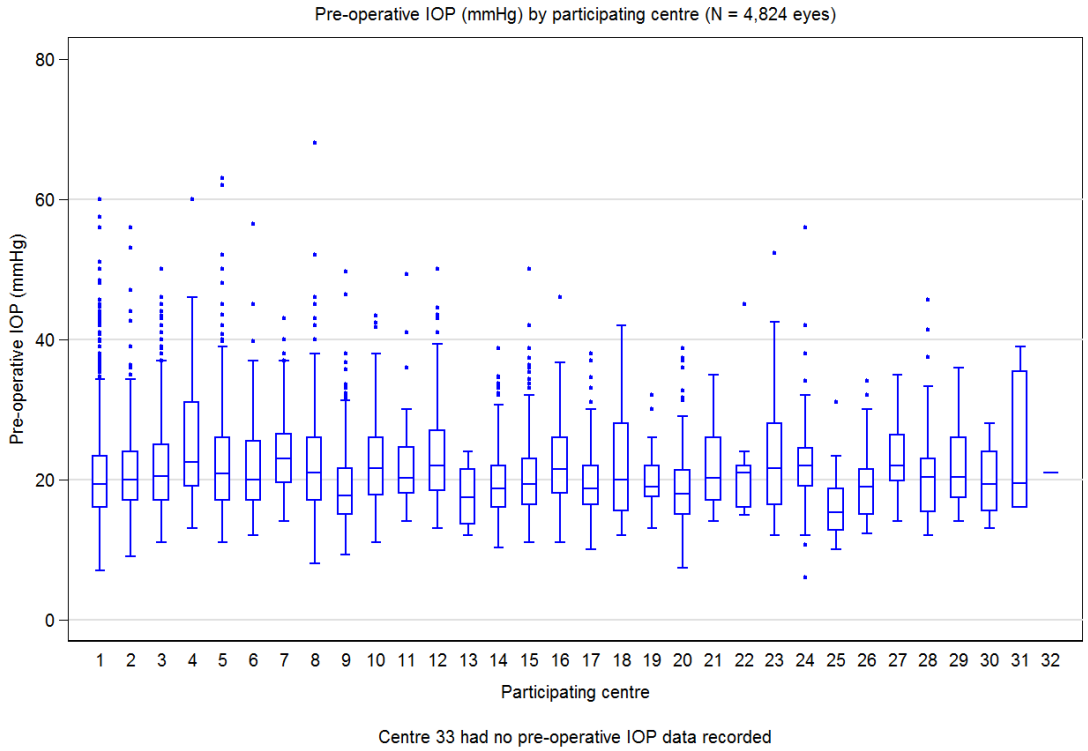


Table 3: Pre-operative IOP for First Trabeculectomy operations by grade of surgeon

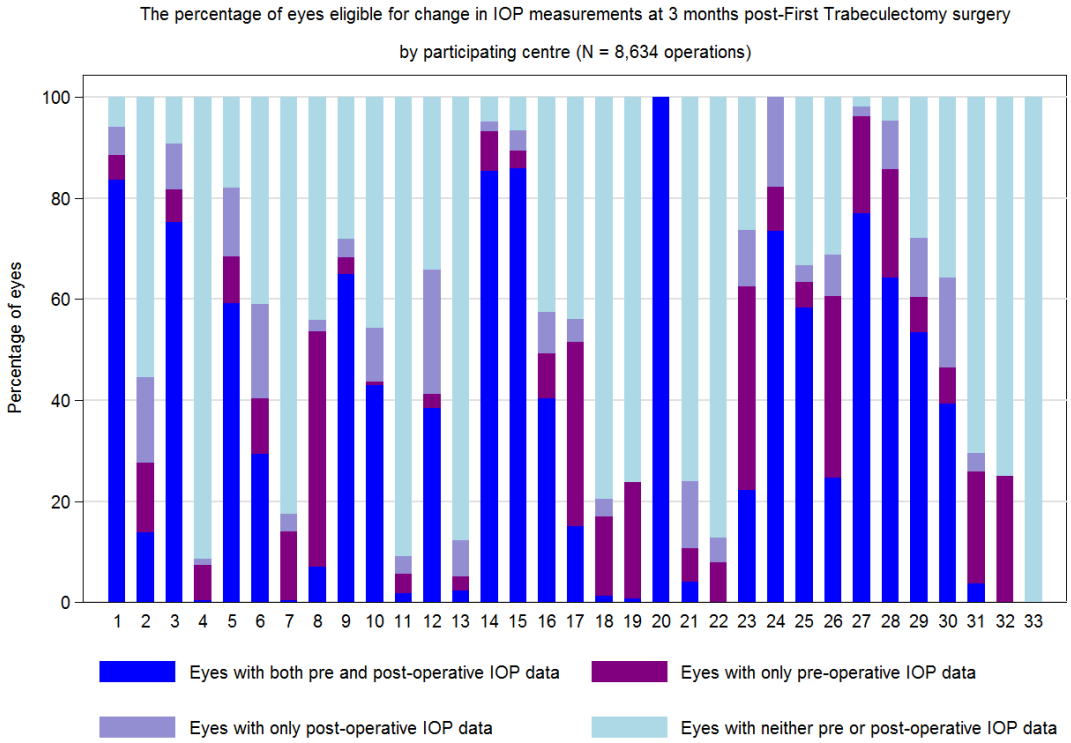
Pre-operative IOP	Consultant surgeons (N = 6,536)	Independent non-consultant surgeons (N = 110)	Experienced trainee surgeons (N = 2,298)	Inexperienced trainee surgeons (N = 56)	Overall (N = 9,000)
Number of eyes with a missing IOP	2,975 (45.5)	73 (66.4)	1,094 (47.6)	34 (60.7)	4,176 (46.4)
Number of eyes with an IOP	3,561 (54.5)	37 (33.6)	1,204 (52.4)	22 (39.3)	4,824 (53.6)
Summary estimates (mmHg)					
Mean	21.2	22.4	20.9	20.8	21.2
Median	20.0	20.7	19.3	19.7	20.0
Standard deviation	6.9	7.4	6.8	5.4	6.9
Inter-Quartile Range	16.3 – 24.3	16.7 – 26.3	16.3 - 24	17 - 24	16.3 – 24
Range	6 – 68	13 – 49.3	9 - 63	13 – 34	6 - 68
Number of eyes where the IOP is:					
<5 mmHg	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
<10 mmHg	11 (0.3)	0 (0.0)	1 (<0.1)	0 (0.0)	12 (0.2)
<14 mmHg	291 (8.2)	1 (2.7)	102 (8.5)	1 (4.5)	395 (8.2)
<18 mmHg	1,221 (34.3)	12 (32.4)	451 (37.5)	6 (27.3)	1,690 (35.0)
<21 mmHg	1,991 (55.9)	20 (54.1)	723 (60.0)	13 (59.1)	2,747 (56.9)
<25 mmHg	2,729 (76.6)	26 (70.3)	938 (77.9)	17 (77.3)	3,710 (76.9)
<30 mmHg	3,173 (89.1)	32 (86.5)	1,085 (90.1)	20 (90.9)	4,310 (89.3)

7. Post-operative Ocular Status

7.1 Post-operative Intraocular Pressure (IOP) three months post-surgery

From the 9,000 eyes undergoing First Trabeculectomy surgery, 366 (4.1%) had less than three months potential follow-up. Of the 8,634 eyes with sufficient follow-up the three months post-operative IOP was missing for 4,227 (49.0%) eyes. The percentage of eyes with a missing three months post-operative IOP varied between centres, where six centres had <25% of treated eyes with a missing three month post-operative IOP, 16 centres had >60% of treated eyes with a missing three month post-operative IOP and two centres had no three month post-operative IOP data recorded, Table 4 and Figure 13. The percentage of operations each NHS year with a missing three month post-operative IOP did decrease over the study period, but was >40% for each NHS year, and the variation across the age groups in the percentage of eyes with a missing three months post-operative IOP was statistically significant (p = 0.000).

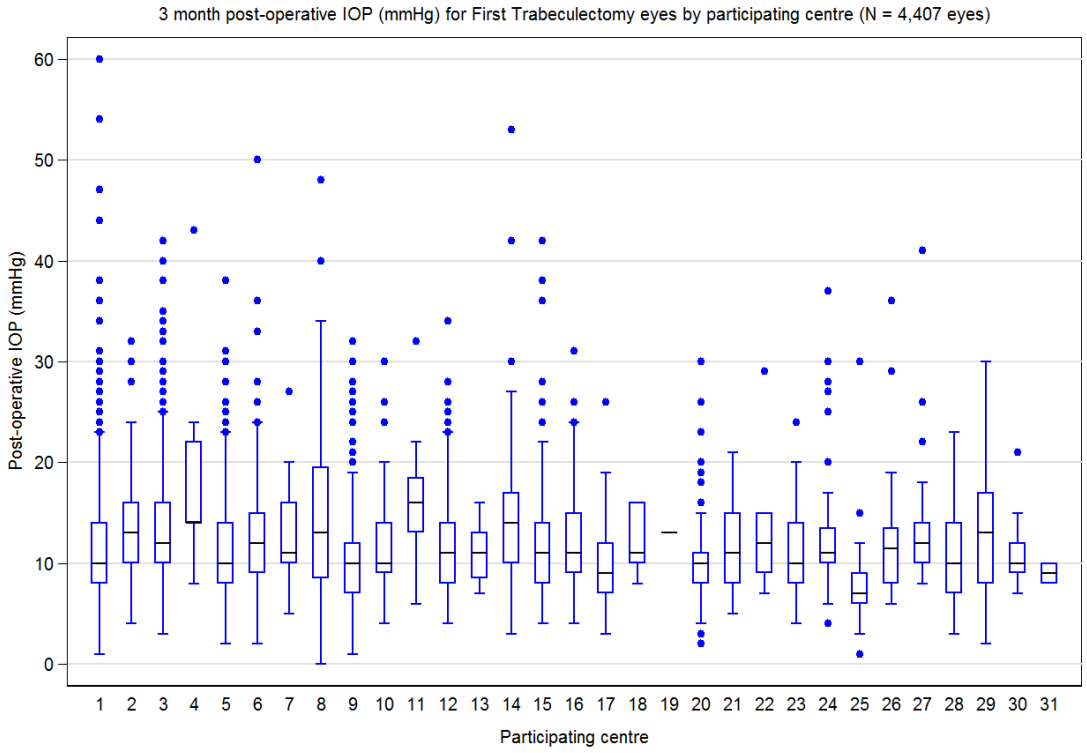
Figure 13: The percentage of eyes with IOP data pre-operatively and at three months post-First Trabeculectomy surgery by participating centre



From 4,407 First Trabeculectomy surgery eyes with sufficient potential follow-up and a three month post-operative IOP, the IOP was fairly consistent since the 2007 NHS year. There was considerable post-operative IOP variation between the participating centres, Figure 14, but not for deciles of IMD score.

The three months post-operative IOP was <5 mmHg for 182 (4.1%) First Trabeculectomy surgery eyes, <10 mmHg for 1,441 (32.7%) eyes, <14 mmHg for 2,980 (67.6%) eyes, <18 mmHg for 3,796 (86.1%) eyes and <21 mmHg for 4,110 (93.3%) eyes.

Figure 14: Three months post-operative IOP measurements for First Trabeculectomy surgery eyes by participating centre (one-month to six months IOP data window)

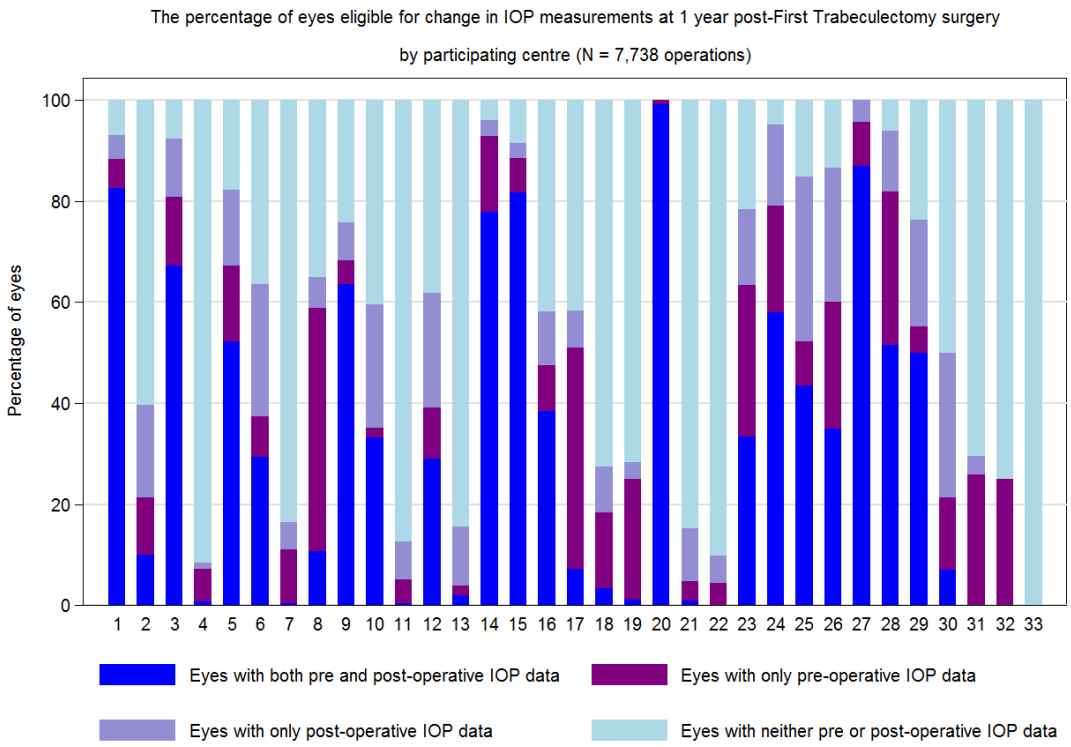


7.2 Post-operative Intraocular Pressure (IOP) one year post-surgery

From the 9,000 eyes undergoing First Trabeculectomy surgery, 1,262 (14.0%) had less than one year potential follow-up. Of the 7,738 eyes with sufficient potential follow-up the one year post-operative IOP was missing for 3,735 (48.3%) eyes. The percentage of eyes with a missing one year post-operative IOP varied between centres, where six centres had <25% of treated eyes with a missing one year post-operative IOP, 15 centres had >60% of treated eyes with a missing one year post-operative IOP and two centres had no one year post-operative IOP data recorded, Table 4 and Figure 15.

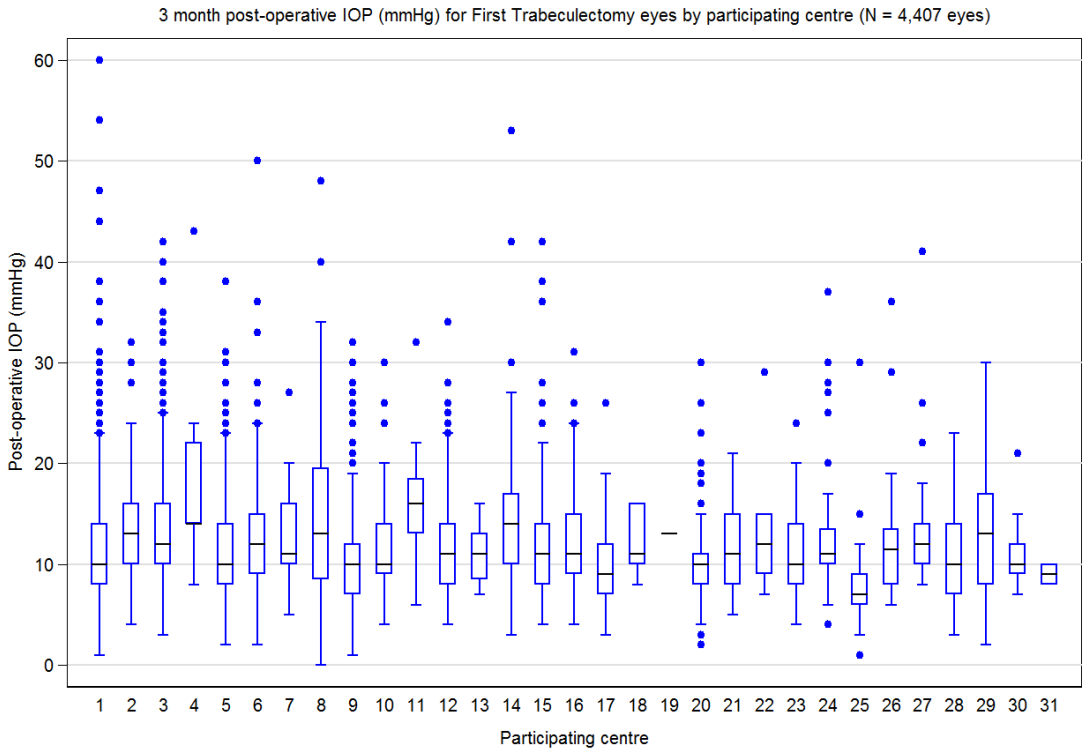
The percentage of operations each NHS year with a missing one year post-operative IOP was >40% in every NHS year, and the variation across the age groups in the percentage of eyes with a missing one year post-operative IOP was statistically significant (p = 0.000).

Figure 15: The percentage of eyes with IOP data pre-operatively and at one year post-First Trabeculectomy surgery by participating centre



From 4,003 First Trabeculectomy surgery eyes with sufficient potential follow-up and a one year post-operative IOP, the IOP has been fairly consistent since the 2007 NHS year. There was considerable variation between the participating centres, Figure 16 but not for deciles of IMD score. The one year post-operative IOP was <5 mmHg for 99 (2.5%) First Trabeculectomy surgery eyes, <10 mmHg for 1,066 (26.6%) eyes, <14 mmHg for 2,531 (63.2%) eyes, <18 mmHg for 3,465 (86.6%) eyes and <21 mmHg for 3,780 (94.4%) eyes.

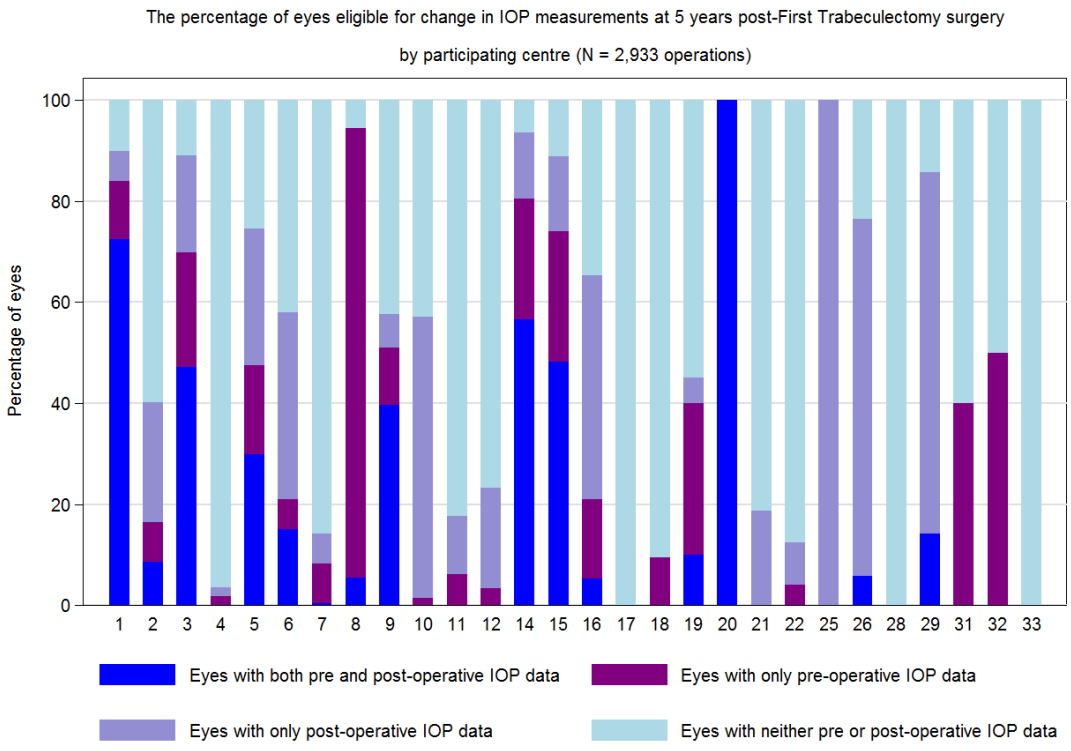
Figure 16: One year post-operative IOP measurements for First Trabeculectomy surgery eyes by participating centre (+/- 6 months data window).



7.3 Post-operative Intraocular Pressure (IOP) five years post-surgery

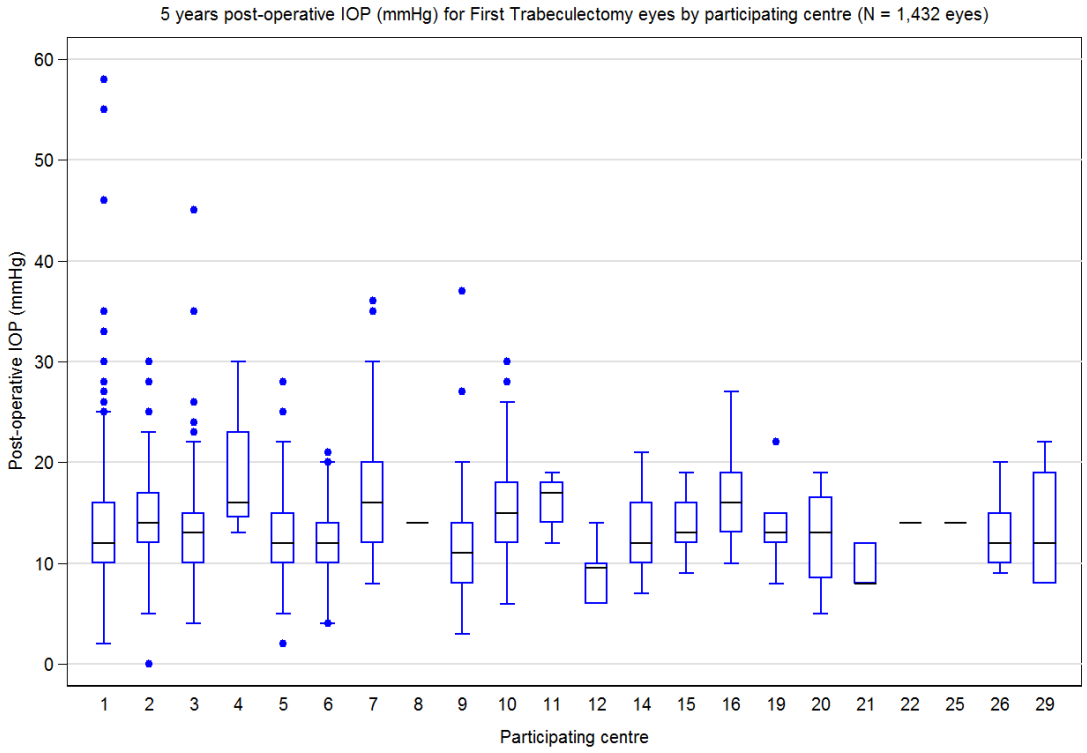
From the 9,000 eyes undergoing First Trabeculectomy surgery 6,067 (67.4%) had less than five years potential follow-up. Of the 2,933 eyes with sufficient potential follow-up the five year post-operative IOP was missing for 1,501 (51.2%) of eyes. The percentage of eyes with a missing one year post-operative IOP varied between centres, where three centres had <25% of treated eyes with a missing five year post-operative IOP, 15 centres had >60% of treated eyes with a missing five year post-operative IOP, six centres had no five year post-operative IOP data recorded and a further five centres had none of the operations with sufficient potential follow-up for five year post-operative IOP analysis, Table 4 and Figure 17. The percentage of operations each NHS year with a missing five year post-operative IOP was >40% in every NHS year, and the variation across the age groups in the percentage of eyes with a missing five year post-operative IOP was statistically significant (p = 0.000).

Figure 17: The percentage of eyes with IOP data pre-operatively and at five years post-First Trabeculectomy surgery by participating centre



From 1,432 First Trabeculectomy surgery eyes with sufficient potential follow-up and a five year post-operative IOP, the IOP varied between participating centres, Figure 18 but not for NHS year and deciles of IMD score. The five year post-operative IOP was <5 mmHg for 26 (1.8%) First Trabeculectomy surgery eyes, <10 mmHg for 266 (18.6%) eyes, <14 mmHg for 786 (54.9%) eyes, <18 mmHg for 1,198 (83.7%) eyes and <21 mmHg for 1,348 (94.1%) eyes.

Figure 18: Five years post-operative IOP measurements for First Trabeculectomy surgery eyes by participating centre (+/- one year data window).



7.4 Cumulative Frequencies for post-operative Intraocular Pressure (IOP) at three months, one year and five-years post-surgery

The cumulative frequencies for post-operative IOP indicate that on average IOP gradually rises between three months and five years, Figure 19.

Figure 19: Cumulative frequency of three months, one year and five years post-operative IOP for First Trabeculectomy surgery eyes.

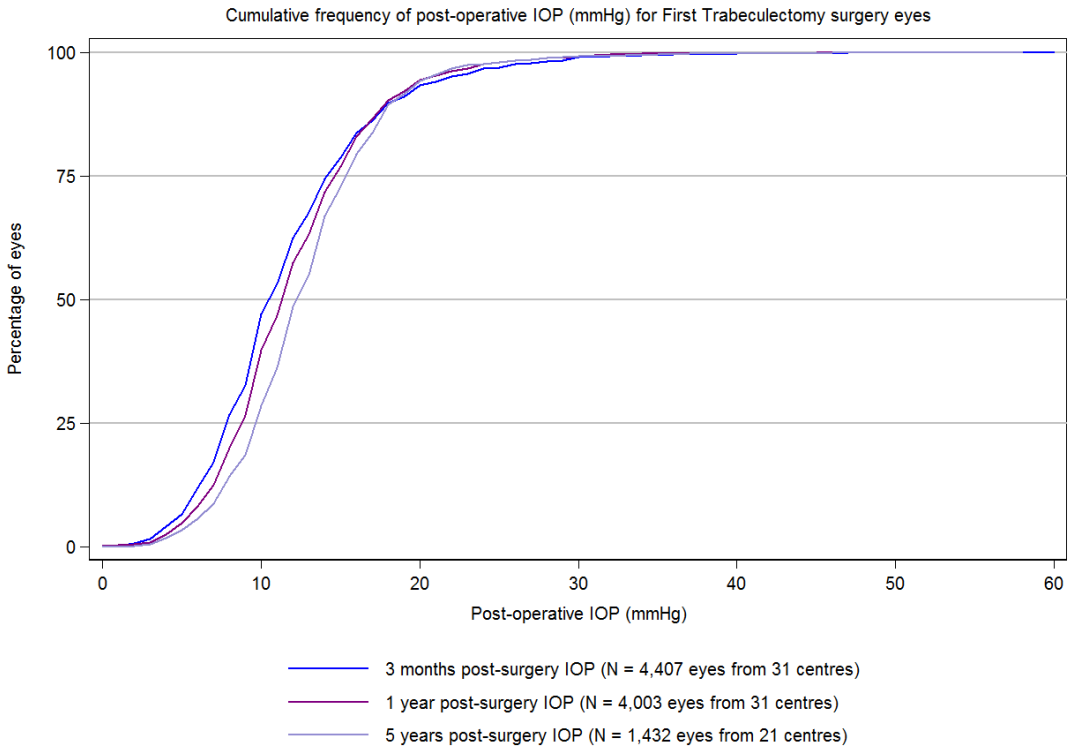


Table 4: Missing post-operative IOP by participating centre and time period.

Missing post-operative IOP	3 Months post-surgery		1 year post-surgery		5 years post-surgery	
Centre	N eligible	% missing	N eligible	% missing	N eligible	% missing
1	1,678	10.7	1,577	12.6	796	21.7
2	813	69.4	714	71.7	304	67.8
3	624	15.7	595	21.3	375	33.6
4	589	98.3	507	98.0	225	98.2
5	506	27.1	471	32.9	204	43.1
6	454	52.0	401	44.4	133	48.1
7	435	96.1	400	94.0	204	93.6
8	381	90.6	325	83.1	18	94.4
9	359	31.5	334	29.0	149	53.7
10	298	46.3	259	42.5	70	44.3
11	230	94.8	213	92.0	113	88.5
12	211	37.0	189	48.1	30	80.0
13	212	90.6	153	86.3	0	N/A
14	206	12.6	198	19.2	46	30.4
15	198	10.1	175	15.4	27	37.0
16	183	51.4	177	50.8	95	50.5
17	159	80.5	139	85.6	4	100.0
18	147	95.2	120	87.5	21	100.0
19	130	99.2	92	95.7	40	85.0
20	129	0.0	112	0.9	4	0.0
21	121	82.6	105	88.6	16	81.3
22	102	95.1	91	94.5	24	91.7
23	72	66.7	60	51.7	0	N/A
24	79	8.9	62	25.8	0	N/A
25	60	38.3	46	23.9	0	N/A
26	61	67.2	60	38.3	17	23.5
27	52	21.2	46	8.7	0	N/A
28	42	26.2	33	36.4	1	100.0
29	43	34.9	38	28.9	7	14.3
30	28	42.9	14	64.3	0	N/A
31	27	92.6	27	96.3	5	100.0
32	4	100.0	4	100.0	2	100.0
33	1	100.0	1	100.0	1	100.0

8. Post-operative Ocular Status

8.1 Intraocular Pressure (IOP) change from baseline to three month post-operatively

Of the 4,824 eyes with a pre-operative IOP measurement 3,709 eyes had sufficient follow-up and a three months post-surgery IOP measurement for a change in IOP at three months analysis. Of these the median IOP change was -8.3 mmHg (reduction) (IQR; -13 to -4.3 mmHg, reduction). In total 3,337 (90.0%) eyes had a reduction in IOP, 49 (1.3%) had no change in IOP and 323 (8.7%) had an increase in IOP, Table 5. In each NHS year since the 2003 NHS year the majority of eyes experienced a reduction in IOP at three months post-surgery with the median IOP reduction being stable from the 2007 year onwards, Figure 20. Some variation was observed between contributing centres, Figure 21 with only three of the 30 centres having <80% of eyes with a reduction in IOP at three months post-surgery Figure 22.

Figure 20: Median change (reduction) in IOP from pre-operatively to three months post-operatively

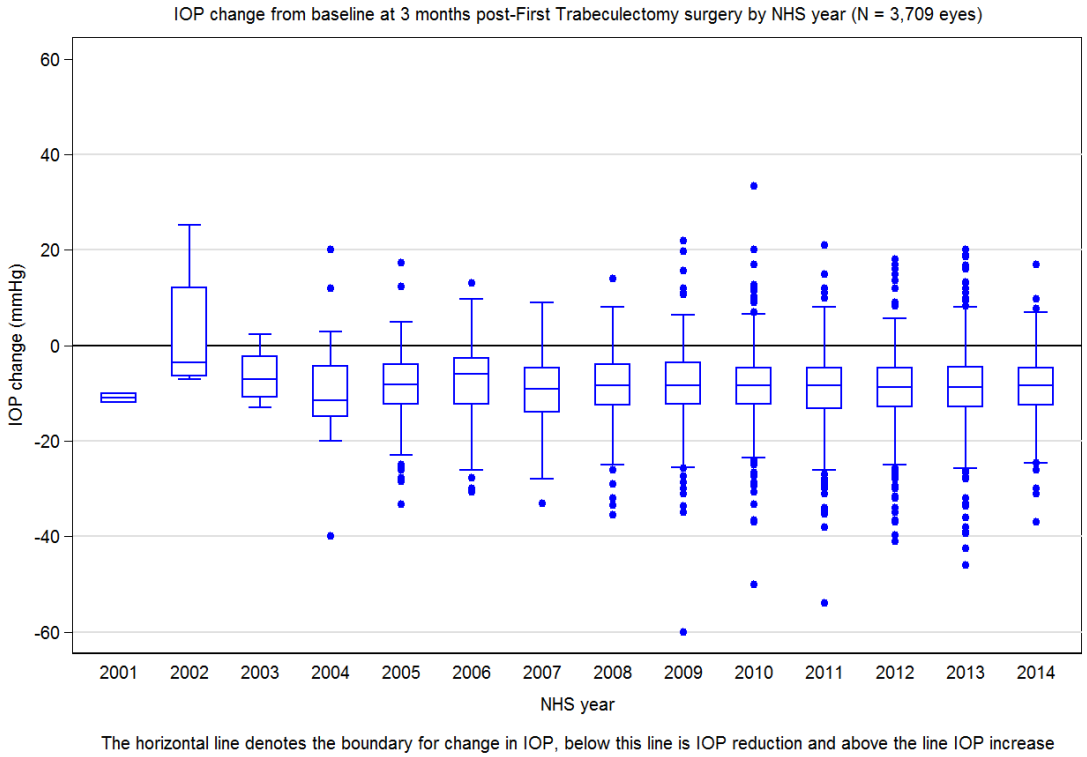


Figure 21: Change in IOP between pre-operative baseline and three months post-operatively

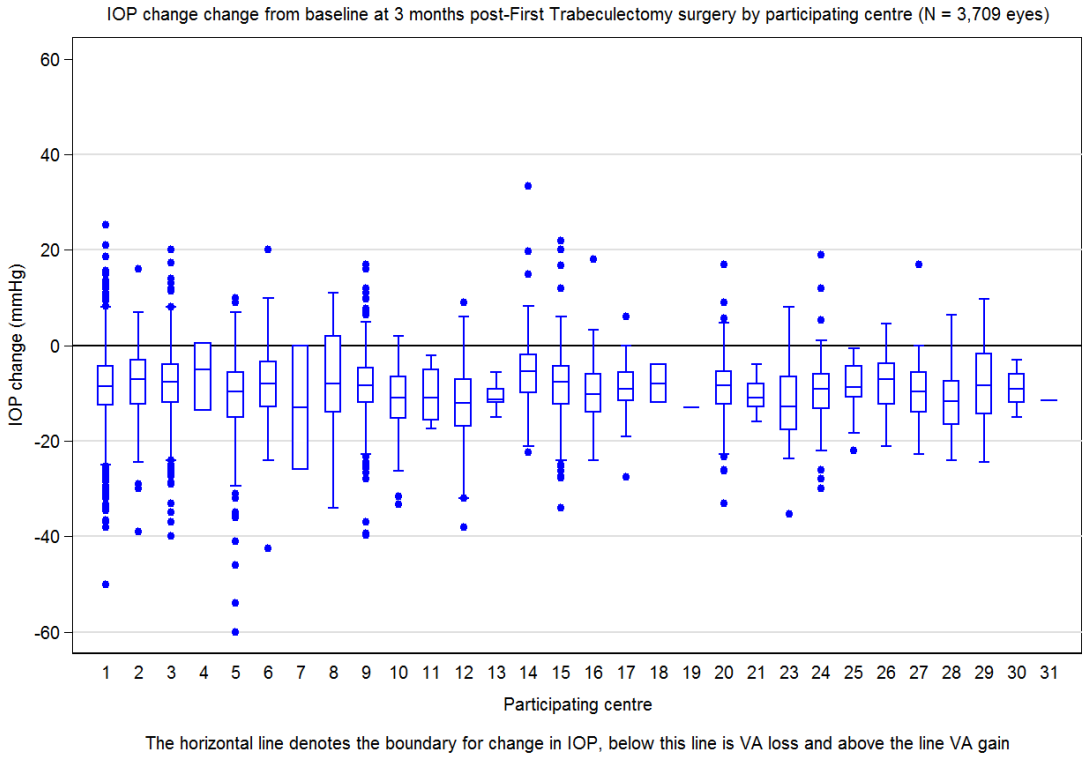
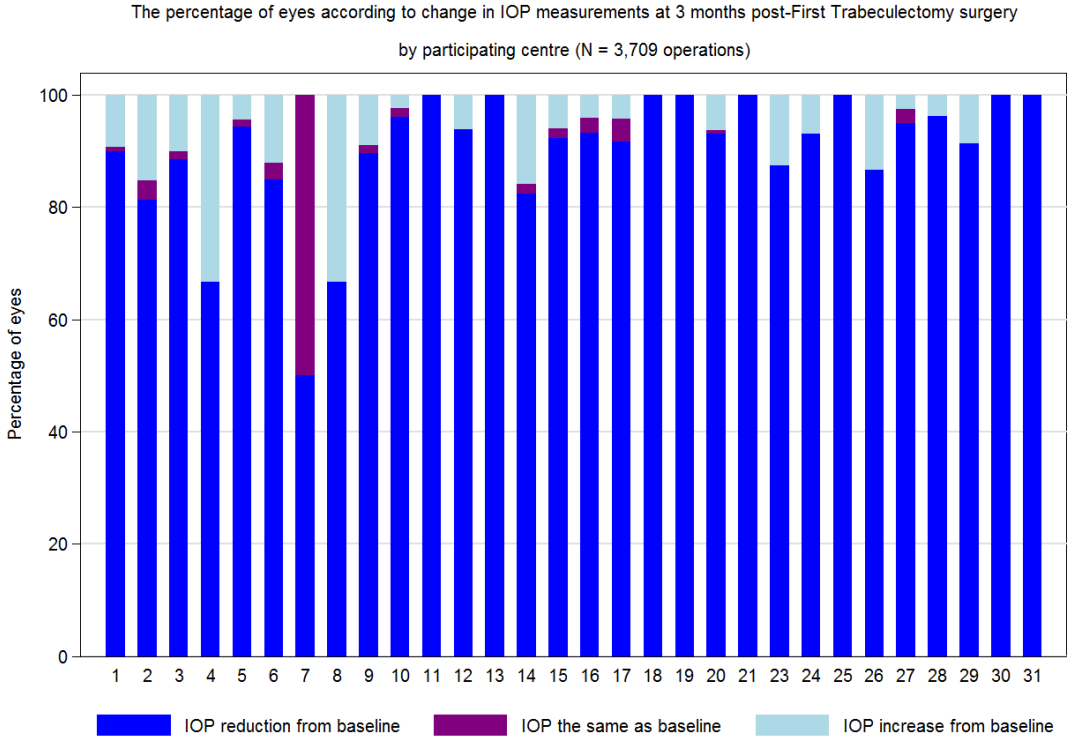


Figure 22: Change in IOP between pre-operative baseline and three months post-operatively



8.2 Intraocular Pressure (IOP) change from baseline to one year post-operatively

Of the 4,824 eyes with a pre-operative IOP measurement 3,201 eyes from 29 centres had sufficient follow-up and a one year post-surgery IOP measurement for change in IOP at one year analysis. From 2007 on the change in IOP by year was stable, Figure 23. Overall the median IOP change was -8.0 mmHg (reduction) (IQR; -12.3 to -0.7 mmHg, reduction) with 2,908 (90.8%) eyes having a reduction in IOP, 42 (1.3%) no change in IOP and 251 (7.8%) an increase in IOP, Table 5. Some variation was observed between contributing centres, Figure 24 with only three of the 29 centres having <80% of eyes with a reduction in IOP at one year post-surgery Figure 25.

Figure 23: One year post-First Trabeculectomy surgery change in IOP by NHS year

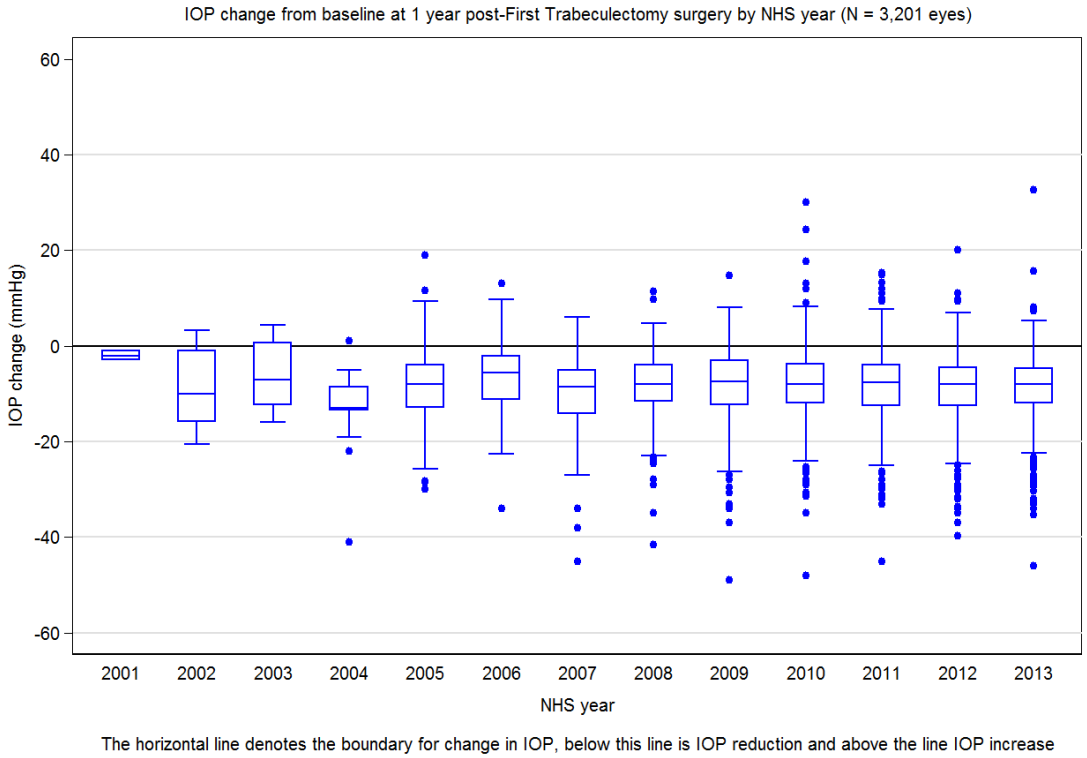


Figure 24: One year post-First Trabeculectomy surgery change in IOP by participating centre

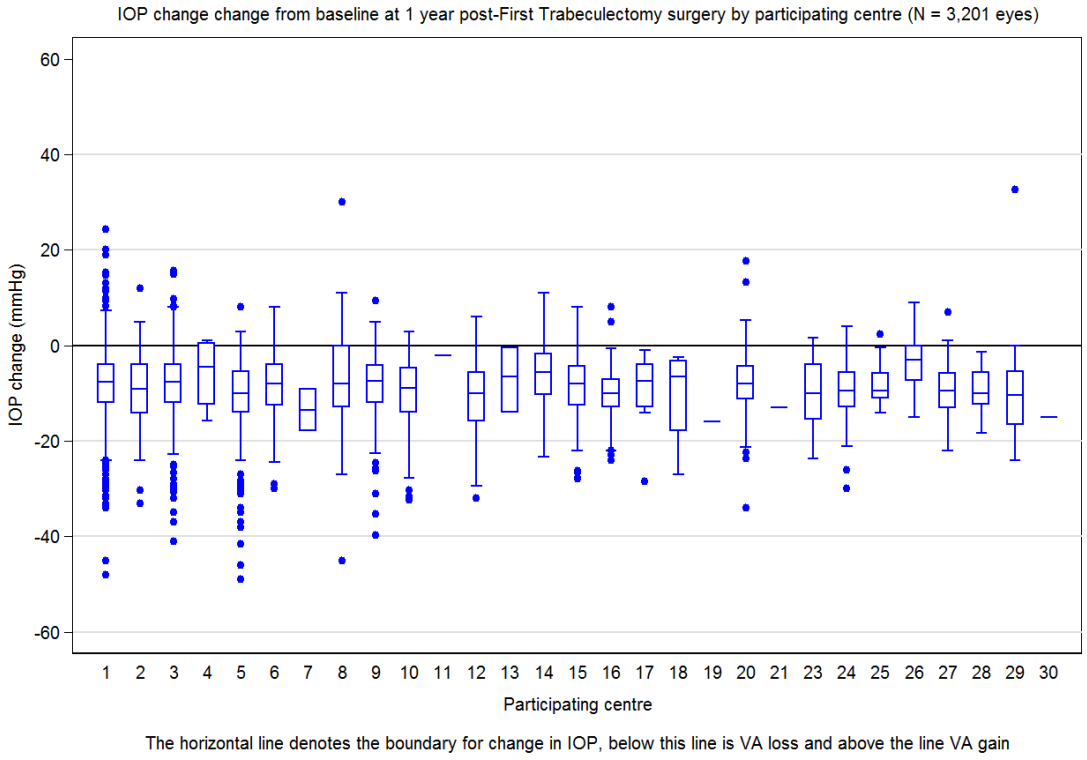
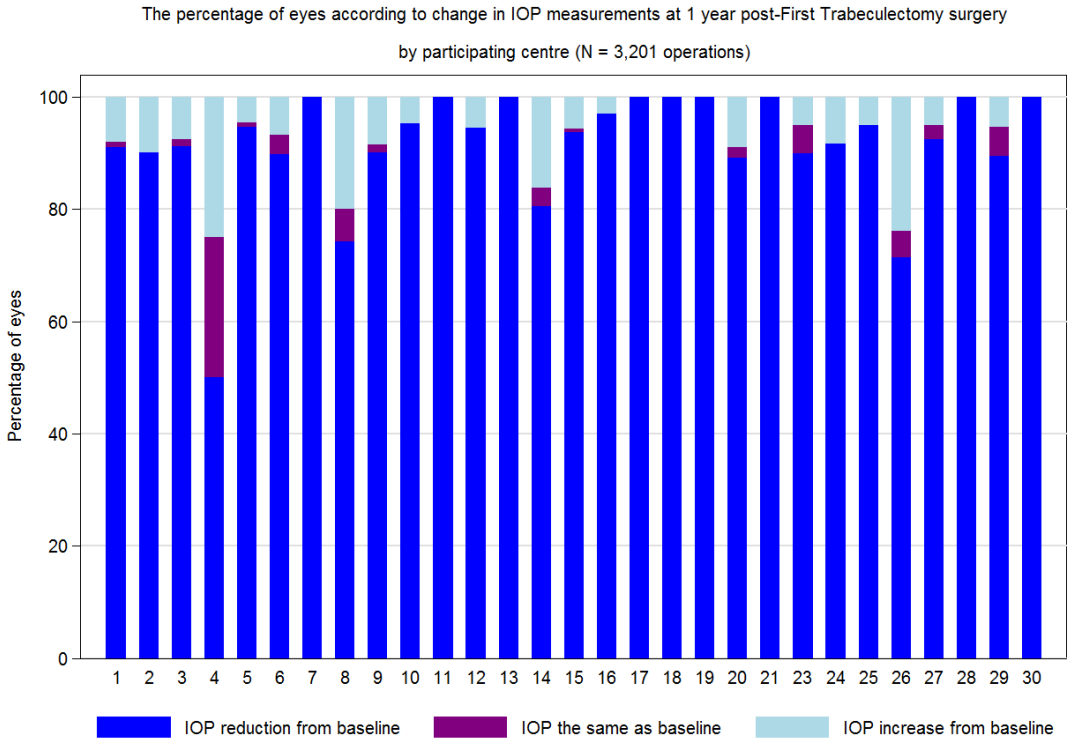


Figure 25: Change in IOP between pre-operative baseline and one year post-operatively



8.3 Intraocular Pressure (IOP) change from baseline to five years post-operatively

Of the 4,824 eyes with a pre-operative IOP measurement only 976 eyes from 15 centres had sufficient follow-up and a five-year post-surgery IOP measurement. The median reduction in IOP across all centres was -7.3mmHg. In total 864 (88.5%) eyes had a reduction in IOP, 20 (2.0%) had no change in IOP and 92 (9.4%) had an increase in IOP, Table 5. Some variation was observed between contributing centres with five of the 15 centres having <80% of eyes with a reduction in IOP at five-years post-surgery Figure 26. In view of the high levels of missing IOP data at five years, Table 4 and Figure 17, further inter-centre comparisons were not made.

Figure 26: Change in IOP between pre-operative baseline and five-years post-operatively

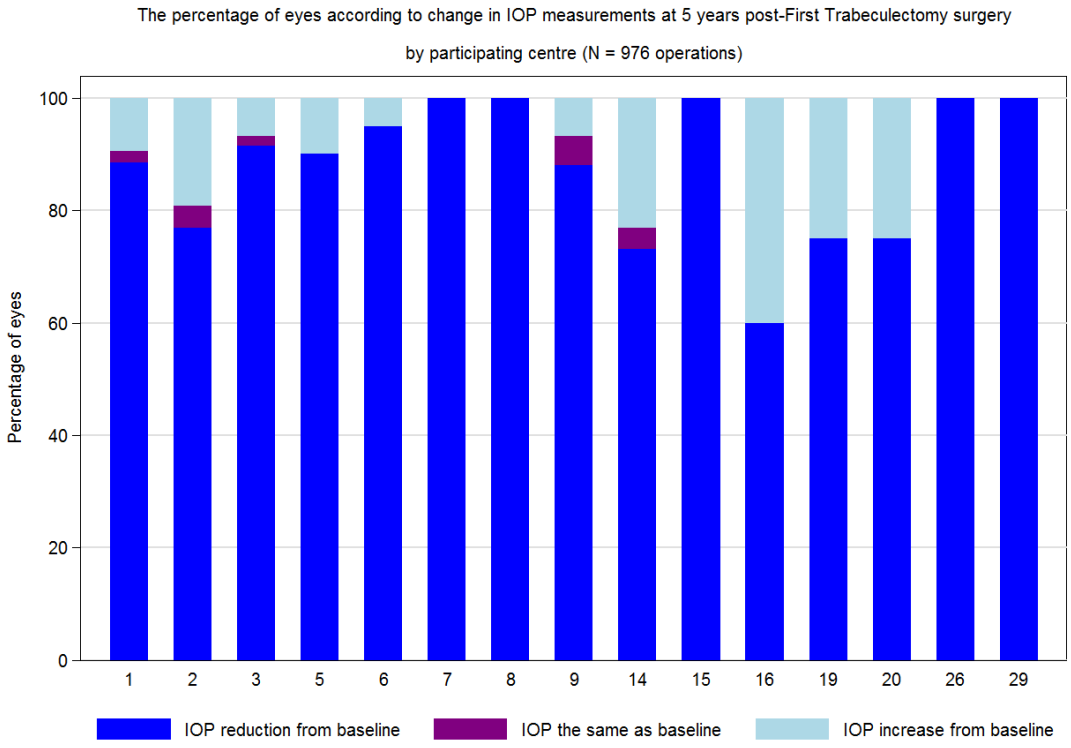


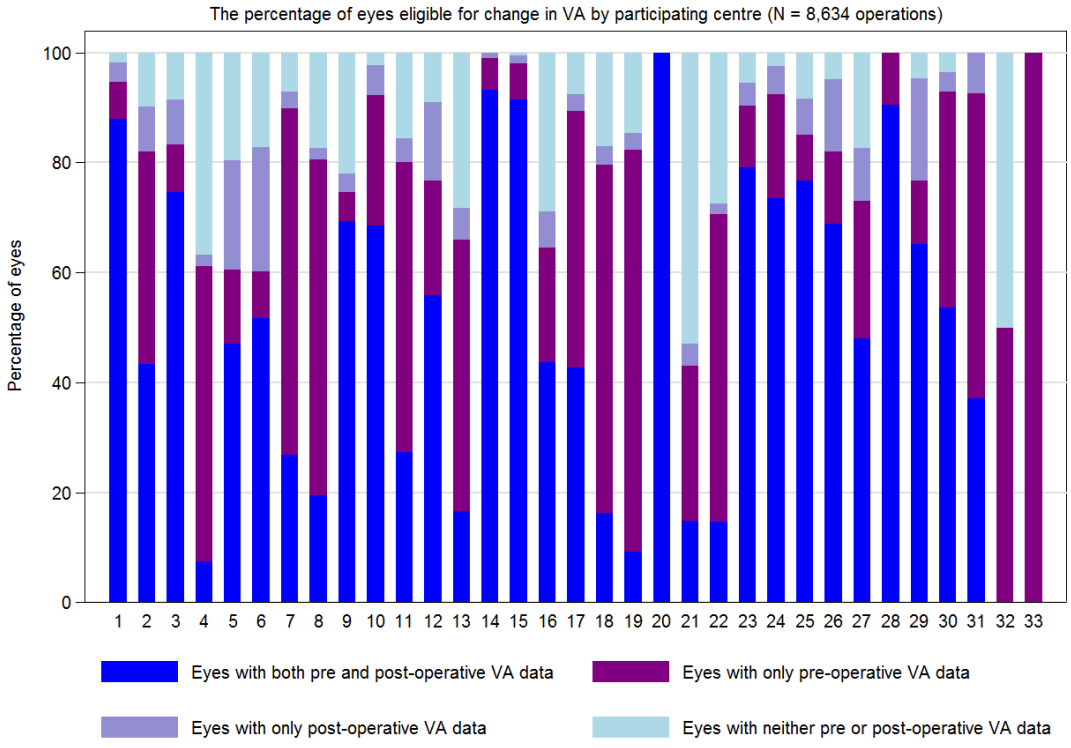
Table 5: Change in IOP by follow-up period and age at First Trabeculectomy surgery

N (column%) unless stated otherwise	3 Months post-surgery	1 year post-surgery	5 years post-surgery
N	3,709	3,201	976
Median	-8.3	-8.0	-7.3
Inter Quartile Range	-13.0 - 4.3	-12.3 – 4.0	-11.7 - -3.3
With IOP reduction	3,337 (90.0)	2,908 (90.8)	864 (88.5)
No change in IOP	49 (1.3)	42 (1.3)	20 (2.0)
With IOP increase	323 (8.7)	251 (7.8)	92 (9.4)
% with 30% reduction	70.2	67.0	61.5
% with 50% reduction	42.1	36.8	29.5
Age at First Trabeculectomy surgery			
<70 years (n)	1,638	1,429	459
% with 30% reduction	71.7	67.9	60.8
% with 50% reduction	43.5	37.5	30.1
70 – 74 years (n)	637	575	182
% with 30% reduction	72.4	67.8	62.1
% with 50% reduction	45.2	38.6	28.6
75 – 79 years (n)	709	616	198
% with 30% reduction	67.1	65.1	58.1
% with 50% reduction	39.5	33.0	27.8
80 – 84 years (n)	518	418	114
% with 30% reduction	69.1	67.7	70.2
% with 50% reduction	40.2	39.5	33.3
85 – 90 years (n)	175	143	21
% with 30% reduction	63.4	61.5	57.1
% with 50% reduction	35.4	31.5	23.8
≥90 years (n)	32	20	2
% with 30% reduction	68.8	70.0	50.0
% with 50% reduction	34.4	30.0	0.0

8.4 Visual Acuity (VA) loss from baseline to three months post-operatively

Of the 9,000 First Trabeculectomy operations, 8,634 operations were performed in eyes where the patient had at least three months potential follow-up and of these, 4,709 (54.5%) had both a pre and post-operative VA measurement. The median change in VA was 0.00 LogMAR (IQR; 0.20 loss to 0.10 gain) The percentage of eligible eyes that had pre and post-operative VA data, pre-operative VA data only, three month post-operative VA data only or no data varied dramatically between centres. VA data for pre- and post-operative periods are shown in Figure 27 for each centre. The VA data collection windows were: pre-op between one year prior to surgery and the day of surgery with the measurement closest to the day of surgery used. Post-op between one month and one year post-surgery with the measurement closest to three months post-surgery used. These were chosen to optimise data capture by means of sufficiently wide data collection windows without extending too far forward to avoid possible impacts of co-morbidities.

Figure 27: VA data before and three months after First Trabeculectomy surgery for 32 centres.

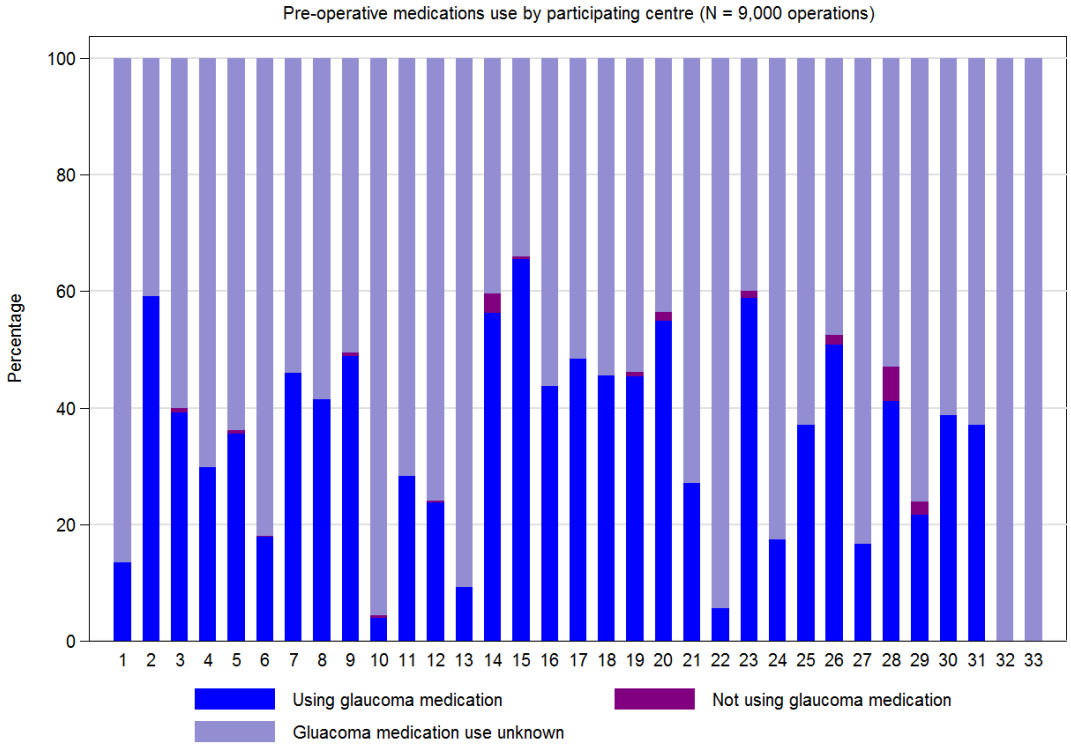


9. Glaucoma Medications

9.1 Pre-operative Medication Use

Reporting of pre-operative medication use varied between NHS years and for the last three NHS years approximately 40% of operations have been performed in eyes where the patient/eye was reported as using pre-operative medications. Recorded pre-operative medication use varied considerably between participating centres, where 14 centres had >40% of operations and six centres >50% of operations where the patient/eye was recorded as using pre-operative medication. The pre-operative medication status was unknown for all operations performed in two centres; these were the two centres with the fewest operations, Figure 28.

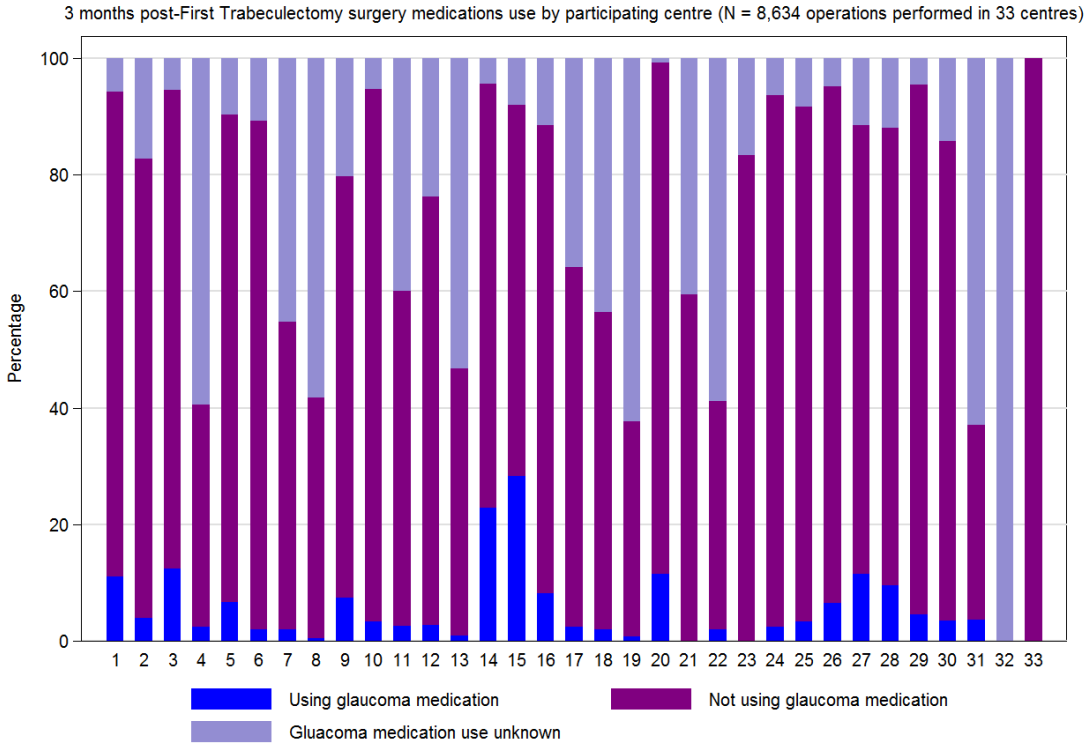
Figure 28: Reported pre-operative medication use by participating centre.



9.2 Post-operative Medication Use

From 8,634 eyes with the potential for three months post-First trabeculectomy surgery follow-up, 6,149 (71.2%) eyes were recorded as not using any glaucoma medications, 583 (6.8%) were recorded as using a glaucoma medication and the glaucoma medication status was unknown for 1,902 (22.0%) eyes. Recorded three months post-First Trabeculectomy surgery glaucoma medication usage varied considerable between centres, Figure 29.

Figure 29: Three months post-First Trabeculectomy surgery medication use by participating centre



From 7,738 eyes with the potential for one year post-First trabeculectomy surgery follow-up, 4,522 (58.4%) eyes were recorded as not using any glaucoma medications, 896 (11.6%) were recorded as using a glaucoma medication and the glaucoma medication status was unknown for 2,320 (30.0%) eyes. Recorded one year post-First Trabeculectomy surgery glaucoma medication usage varied considerable between centres, Figure 30.

From 2,933 eyes with the potential for five years post-First trabeculectomy surgery follow-up, 977 (33.3%) eyes were recorded as not using any glaucoma medications, 456 (15.5%) were recorded as using a glaucoma medication and the glaucoma medication status was unknown for 1,500 (51.1%) eyes. Recorded five years post-First Trabeculectomy surgery glaucoma medication usage varied considerable between centres, Figure 31.

Figure 30: One year post-First Trabeculectomy surgery medication use by participating centre

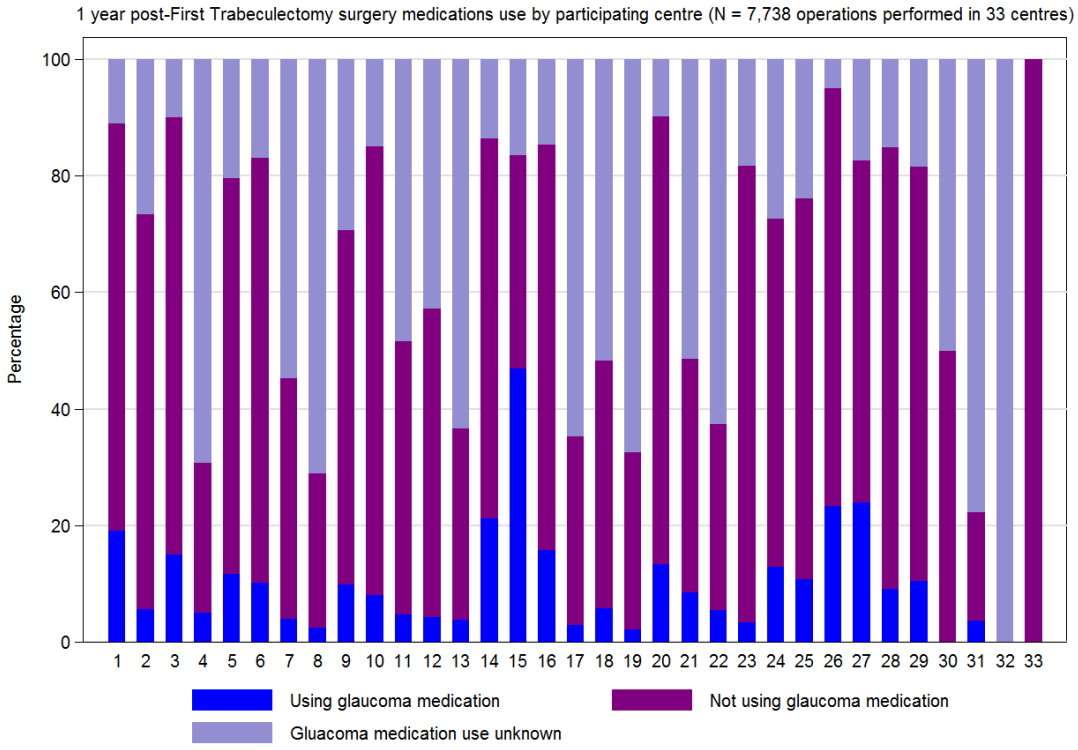
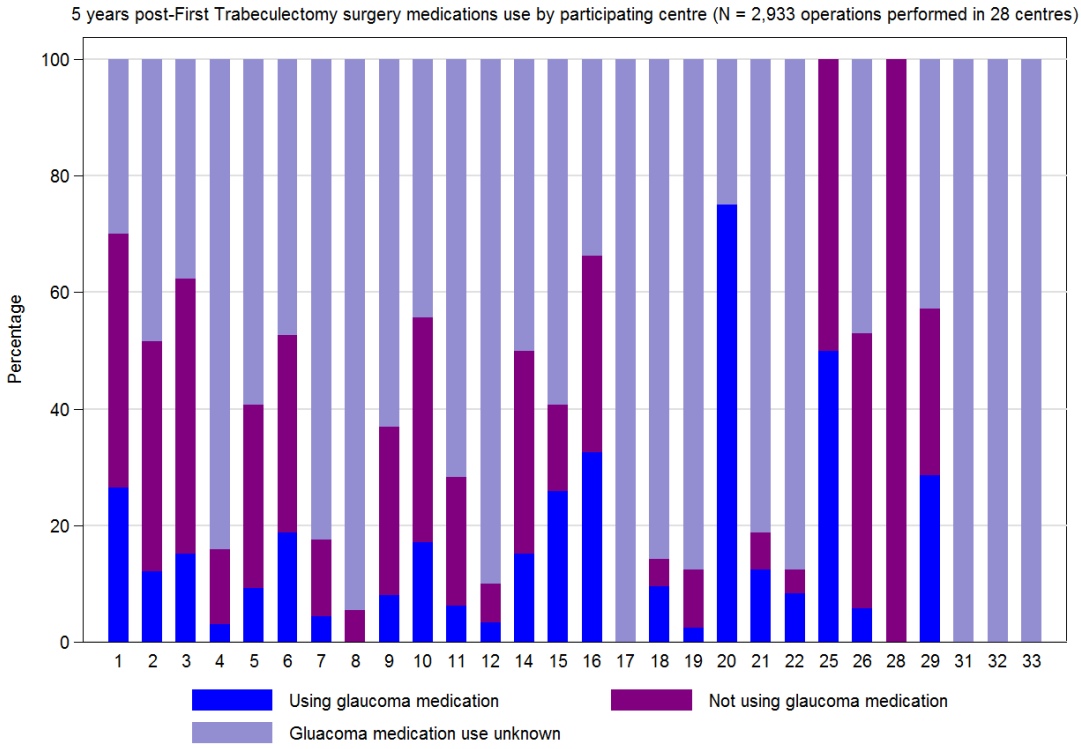


Figure 31: Five years post-First Trabeculectomy surgery medication use by participating centre



At each post-operative time point plus pre-operatively, the most frequently used type of glaucoma eye drop was a prostaglandin analogue / prostamide, followed by beta blockers and carbonic anhydrase inhibitors, and some eyes were using more than one medication or medication class, Table 6.

Both recorded post-operative medication use and the percentage of eyes where the use was unknown varied considerably between participating centres at each post-operative time point.

Due to the high proportions of unknown data for medication usage, particularly pre-operatively, no results for change in medication use are provided.

Table 6: Pre-operative and post-operative medication use

Post-operative medication, n (column %)	Pre-operative	3 months	1 year	5 years
Number of operations	9,000	8,634	7,738	2,933
Pre-operative medication status				
Not using any glaucoma medication	30 (0.3)	6,149 (71.2)	4,522 (58.4)	977 (33.3)
Using Acetazolamide only	293 (3.3)	86 (1.0)	146 (1.9)	43 (1.5)
Using glaucoma eye drops only	2,365 (26.3)	445 (5.2)	653 (8.4)	389 (13.3)
Using Acetazolamide + eyes drops	322 (3.6)	42 (0.5)	75 (1.0)	22 (0.8)
Using glaucoma medicine, drug unknown	10 (0.1)	10 (0.1)	22 (0.3)	2 (<0.1)
Unknown	5,980 (66.4)	1,902 (22.0)	2,320 (30.0)	1,500 (51.1)
Eyes drop classes				
Beta blockers	1,730 (19.2)	247 (2.9)	373 (4.8)	220 (7.5)
Prostaglandin analogues / prostamides	2,115 (23.5)	345 (4.0)	496 (6.4)	321 (10.9)
Adrenergic agonists	736 (8.2)	83 (1.0)	134 (1.7)	106 (3.6)
Carbonic anhydrase inhibitors	1,685 (18.7)	240 (2.8)	350 (4.5)	214 (7.3)
Cholinergic agonists	128 (1.4)	87 (1.0)	144 (1.9)	30 (1.0)
Number of classes				
0	323 (3.6)	6,245 (72.3)	4,690 (60.6)	1,022 (34.8)
1	628 (7.0)	198 (2.3)	306 (4.0)	148 (5.1)
2	770 (8.6)	115 (1.3)	158 (2.0)	103 (3.5)
3	947 (10.5)	123 (1.4)	183 (2.4)	107 (3.7)
≥4	342 (3.8)	51 (0.6)	81 (1.0)	53 (1.8)
Unknown	5,990 (66.4)	1,902 (22.0)	2,320 (30.0)	1,500 (51.1)

10. Surgical Outcome

10.1 Outcome Definitions

A composite definition for success, partial success and failure was used for construction of a surgical outcome prediction model for case complexity adjustment:

- Success
    - IOP <18 and >=30% reduction and no drops and no failure criteria
- Partial Success
    - As for success but on glaucoma drops
- Failure (if any of these exist then surgery classified as a failure)
    - IOP >=18 or
    - <30% reduction or
    - NPL or
    - VA drop =>0.5 unless subsequent VA recovery or
    - bleb revision or
    - further drainage / glaucoma surgery
        - trabeculectomy; drainage tube; cyclodiode

Note:

- MD drop >=10dB in a relatively brief period following surgery would be regarded as a failure criterion but VF data unavailable for this analysis
- Bleb revision or further surgery at any time indicates failure for all time points going forward
- The success criteria for IOP <18mmHg and >=30% IOP reduction may be excessively stringent

10.2 Outcomes at one year post-operatively

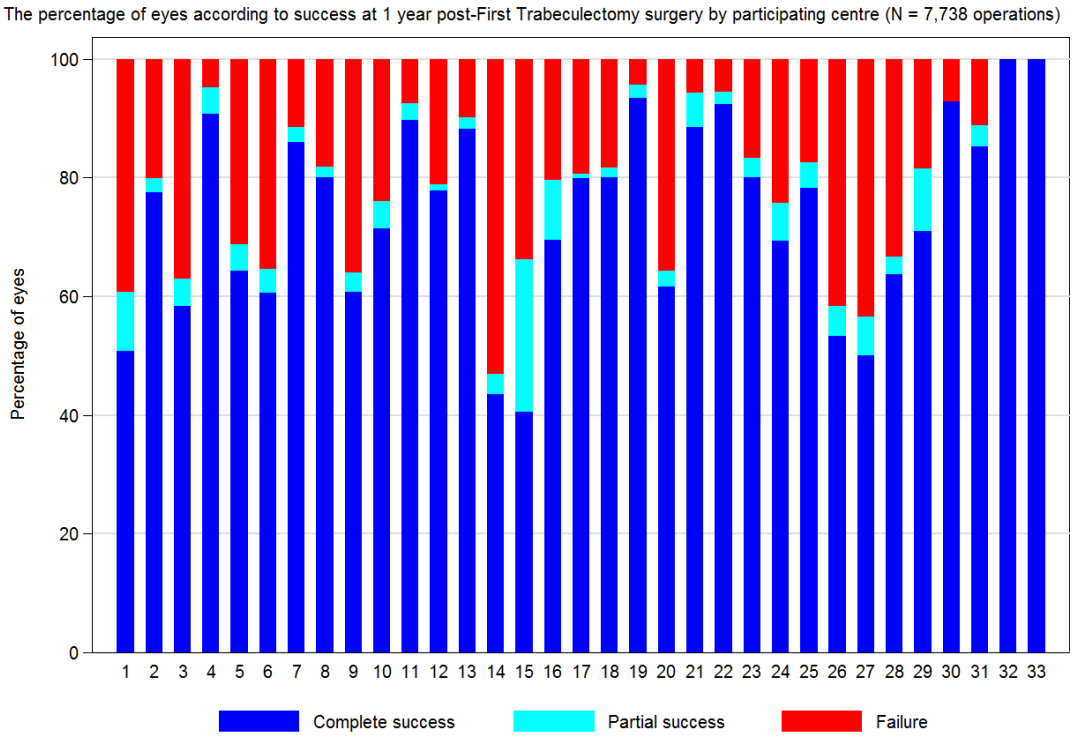
Due to time constraints, surgical outcome was assessed at the single time point of one year post-operatively. From the 9,000 eligible for analysis First Trabeculectomy surgery eyes, 1,262 (14.0%) did not have the potential for one year's follow-up. From 7,738 eyes with at least one year's potential follow-up, at one year post-First Trabeculectomy surgery complete success was achieved for 5,263 (68.0%) eyes, partial success for 417 (5.4%) eyes and failure was experienced by 2,058 (26.6%) eyes. The proportion of eyes with each level of surgical failure differed between the grades of surgeons, although the proportions were very similar for consultant surgeons and experienced trainee surgeons who between them performed the majority of operations, Table 7.

Table 7. One year post-First Trabeculectomy surgery surgical failure

Failure at 1 year post-First Trabeculectomy surgery, N (row %)	Complete success	Partial success	Failure	Total
Consultant surgeons	3,790 (67.3)	298 (5.3)	1,544 (27.4)	5,632
Independent non-consultant surgeons	69 (80.2)	3 (3.5)	14 (16.3)	86
Experienced trainee surgeons	1,370 (69.2)	116 (5.9)	495 (25.0)	1,981
Inexperienced trainee surgeons	34 (87.2)	0 (0.0)	5 (12.8)	39
Total	5,263 (68.0)	417 (5.4)	2,058 (26.6)	7,738

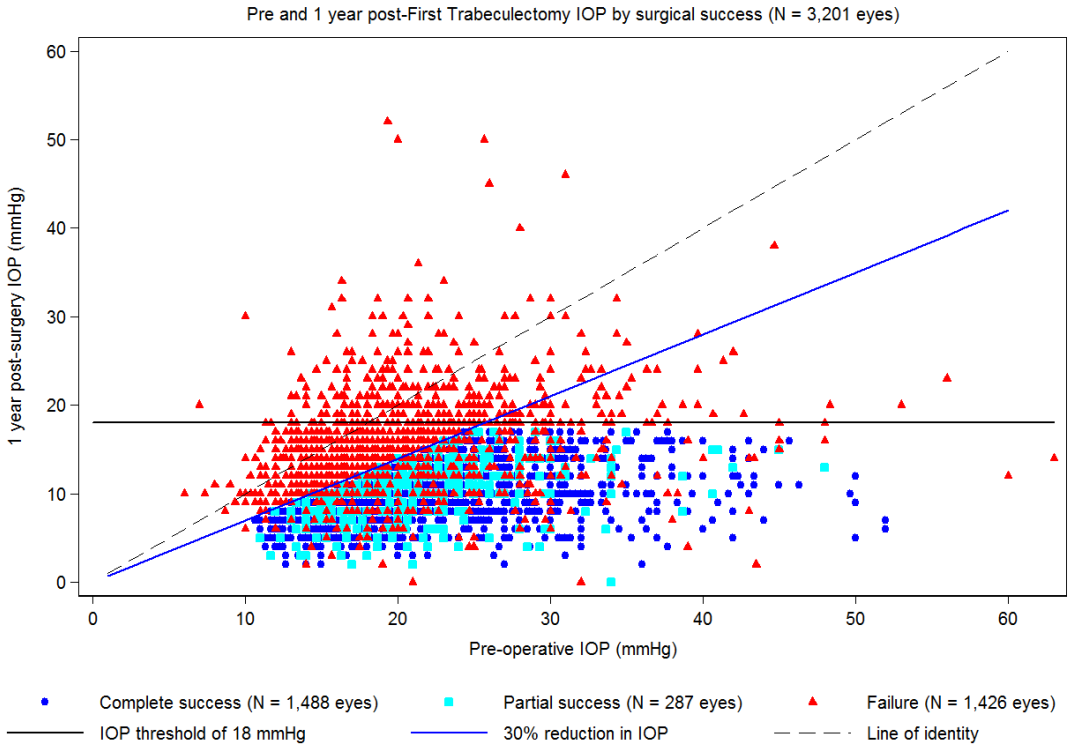
Based on these criteria the proportion of eyes with each level of surgical failure at one year post-First Trabeculectomy surgery varied between participating centres, Figure 32.

Figure 32: The percentage of eyes according to surgical failure status at one year post-First Trabeculectomy surgery by participating centre



For those 3,201 eyes where both pre- and post-operative IOP values were available the 30% IOP reduction criterion could be rigorously applied. This additional stringency of definition reduced the sample size and the number of otherwise successful operations such that overall 46% were successful, 9% were partially successful and 45% were failures at one year, Figure 33.

Figure 33: Pre-operative and one year post-operative IOP according to surgical failure status at one year post-First Trabeculectomy surgery.



10.3 Risk model for failure

To illustrate proof of concept, a pilot investigation of a risk model for surgical outcome was undertaken. The outcome of interest was failure (which included partial success or failure) versus complete success. Briefly, complex and secondary glaucoma's were excluded and a number of uncommon co-morbidities collapsed into a single category. Where potential predictor variables were missing in high proportions these were either excluded (e.g. axial length with around half missing) or in the case of dichotomous variables, where reasonable, assumptions inferred about absence. Candidate covariates that were significant at the 10% level from univariate χ^2 tests were fitted to the model, these were; surgeon grade, patient's gender and diabetic status, previous ocular surgery, pre-operative glaucoma eye drop use, cataract status, conjunctiva incision, type of suture and antimetabolite used during surgery, the presence/absence of diabetic retinopathy, high myopia, other retinal pathology or previous vitrectomy, post-operative intravitreal injections and post-operative bleb manipulation. Variables retained in the resulting logistic regression multi-variable model are in Table 8 (C-Stat = 0.81).

It should be emphasised however that this model is presented simply as an illustration and that there are a variety of issues with the model which would need to be addressed prior to any implementation as a working tool for surgical case complexity adjustment. Issues include small numbers of recorded operations for many surgeons (e.g. of the 341 individual surgeons, 232 surgeons had performed <10 operations and 314 surgeons <50 operations), high levels of missing data for certain variables, time dependency of certain variables, choice of criteria for success (those adopted may be overly stringent). As a proof of concept however this exercise has value in demonstrating the feasibility of developing this approach for glaucoma surgery in the future. With this in mind, the model has been applied to the results for surgeons and centres for illustrative purposes.

Table 8: One year post-First Trabeculectomy surgery surgical failure model estimates

Model C-Stat (AUROC) = 0.81	Odds ratio	Coefficient	p-value	95% confidence interval for the coefficient
Constant	N/A	-2.106	0.00	-2.642 to -1.571
Other retinal pathology	1.852	0.616	0.040	0.030 to 1.203
Post-operative Intravitreal Injection	2.457	0.899	0.019	0.150 to 1.648
Post-operative bleb manipulation	87.001	4.466	0.000	4.093 to 4.839
Cataract status				
No record of cataract surgery	REF	0	N/A	N/A
Cataract surgery before trabeculectomy surgery	1.843	0.612	0.000	0.280 to 0.943
Combined cataract + trabeculectomy surgery	0.839	-0.176	0.389	-0.576 to 0.225
Cataract surgery after trabeculectomy surgery	2.623	0.964	0.000	0.607 to 1.321
Conjunctiva incision				
Fornix based	REF	0	N/A	N/A
Limbal based	2.211	0.794	0.002	0.280 to 1.307
Other	1.065	0.063	0.974	-3.724 to 3.851
Unknown	0.181	-1.712	0.391	-5.627 to 2.203
Suture type				
Releasable only	REF	0	N/A	N/A
Fixed only	2.006	0.696	0.001	0.283 to 1.109
Both releasable and fixed	1.567	0.449	0.052	-0.004 to 0.903
Unknown	3.903	1.362	0.496	-2.554 to 5.278
Antimetabolite				
None	REF	0	N/A	N/A
5-fluorouracil	1.975	0.681	0.032	0.059 to 1.303
Minutes with mitomycin C	1.582	0.459	0.050	<-0.001 to 0.917

10.4 Unadjusted trabeculectomy surgery results for surgeons and centres at one year post-operatively

Based on the definition for failure or partial success of surgery (i.e. not fully successful) results are presented for surgeons and centres. Figure 34 illustrates unadjusted rates for surgeons and Figure 35 for centres.

Figure 34: Unadjusted for case complexity one year post-First Trabeculectomy surgery failure graph

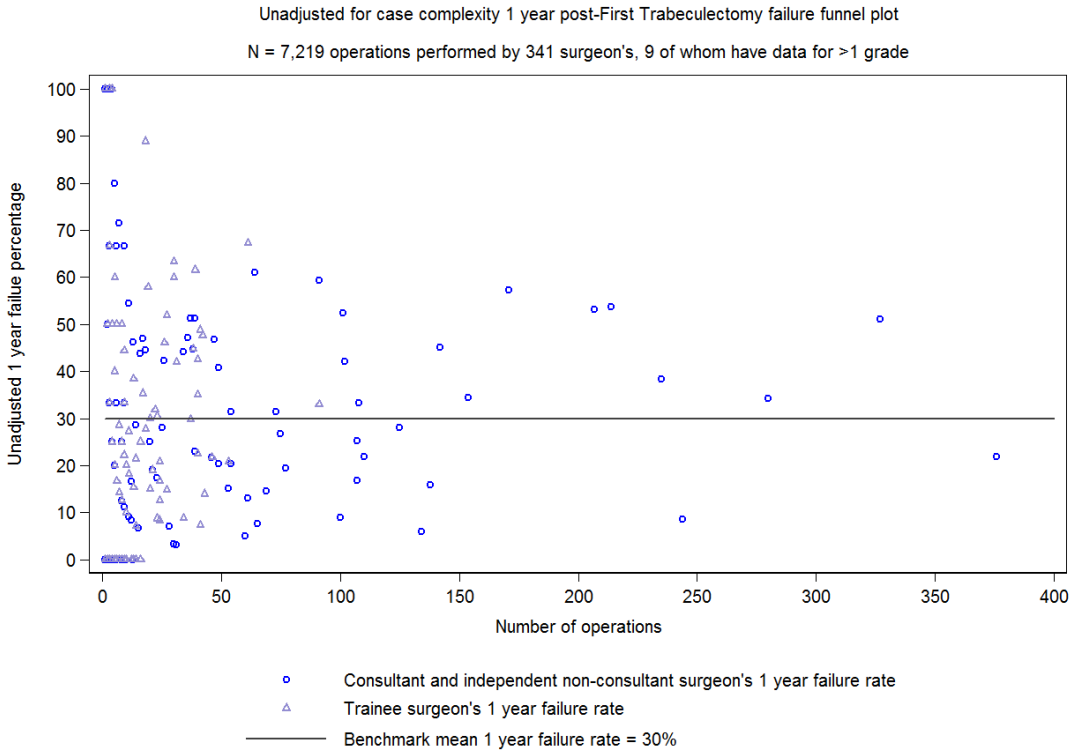
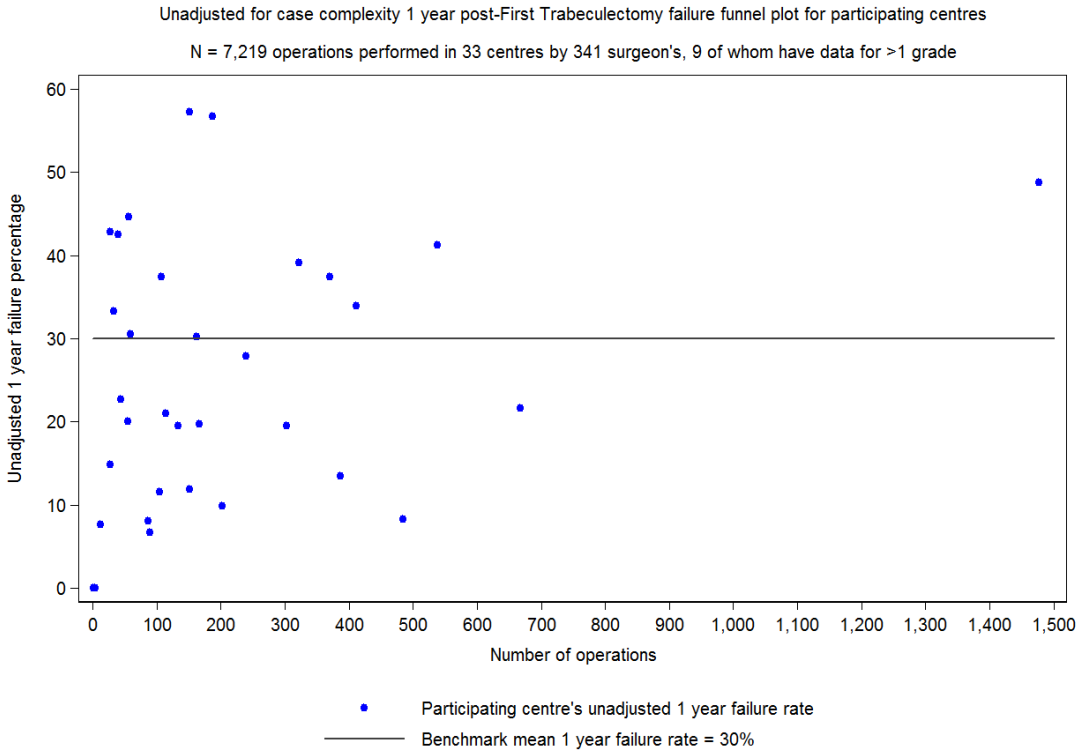


Figure 35: Unadjusted for case complexity one year post-First Trabeculectomy surgery failure graph for participating centres



10.5 Case complexity adjusted trabeculectomy results for surgeons and centres at one year post-operatively

Based on the definition for failure or partial success of surgery (i.e. not fully successful) results are presented for surgeons and centres. Figure 36 illustrates case complexity adjusted results for surgeons and Figure 37 results for centres.

Figure 36: Adjusted for case complexity one year post-First Trabeculectomy surgery failure graph

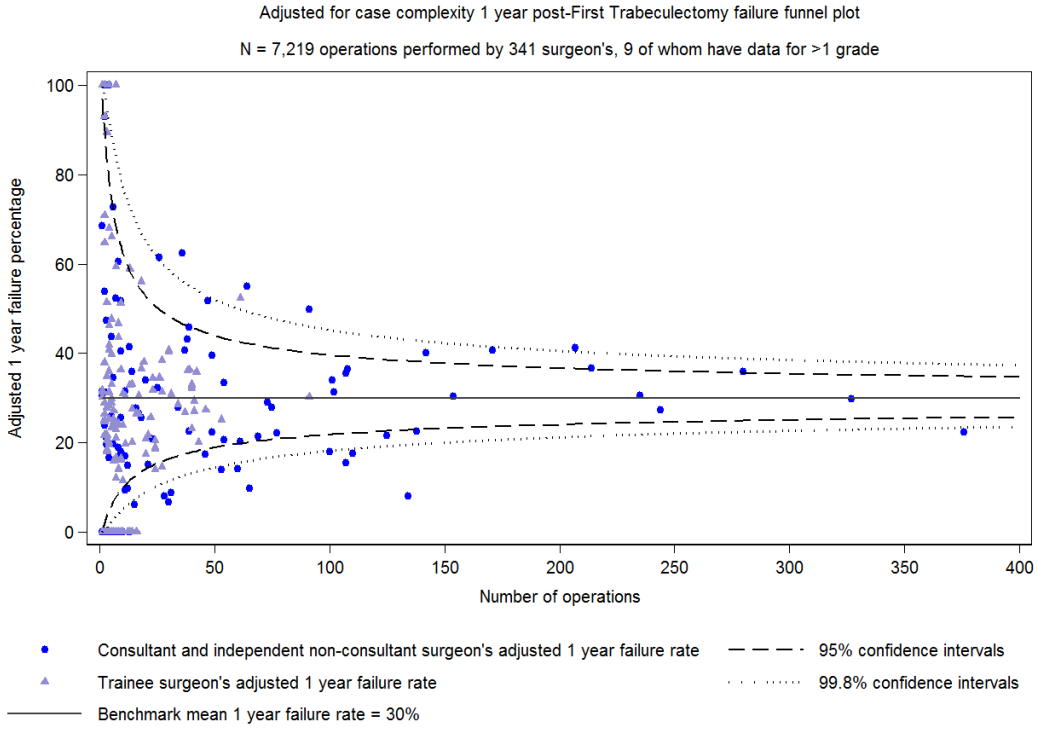
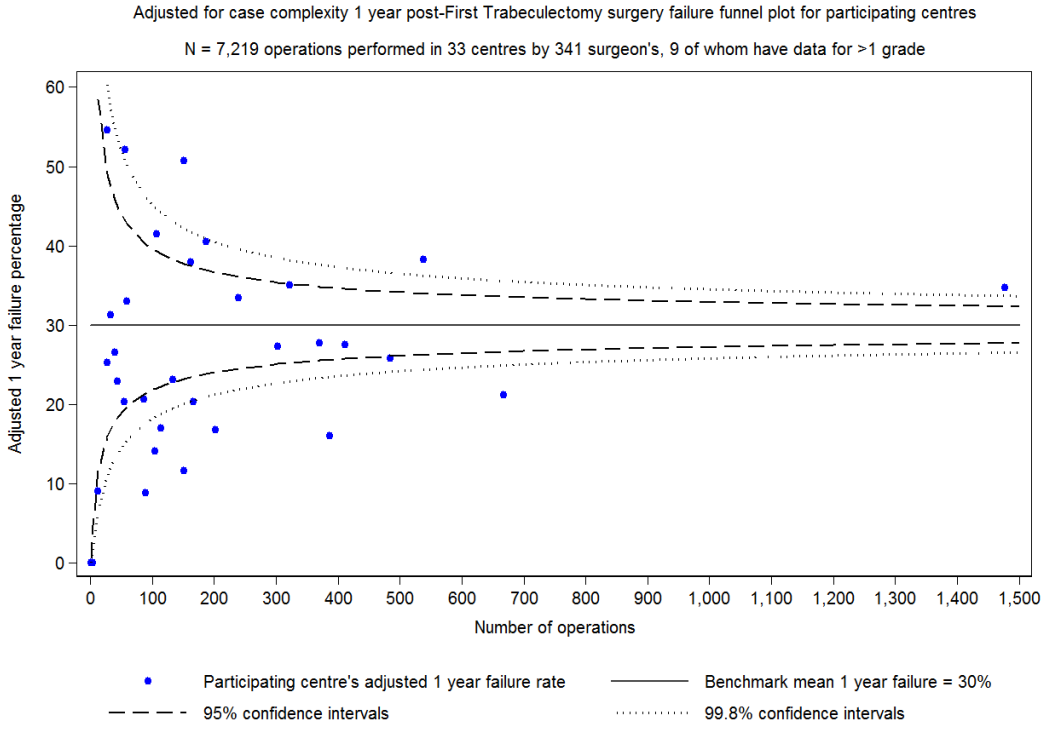


Figure 37: Adjusted for case complexity one year post-First Trabeculectomy surgery failure graph for participating centres



11. Conclusions for the Trabeculectomy Surgery Audit

11.1 Missing data

Significant issues with missing data have been identified. These reflect the variety of ways in which the EMR is used in practice. It should be pointed out that glaucoma is a long term chronic condition and patients attend hospital services over many years. Moving from paper based records to electronic records therefore presents a significant challenge in terms of back entry of historic data. One large glaucoma service employed two technicians for two years to enter back data for over 14,000 glaucoma patients going back 10 years. This aspect of glaucoma care represents a non-trivial barrier to adoption of an EMR. Where centres use an EMR partially, e.g. for recording surgery, but continue with paper notes in outpatient clinics the EMR extractable data around the surgical event is partially or entirely absent. In order to preserve vision, the primary purpose of the surgery is to lower IOP. In these analyses, overall IOP data were available for only around half of operated eyes pre-operatively and post-operatively at three months, one year and five years. Pre- to post-operative change in IOP data were available for around 43% at three months and one year and around 33% at five years. These figures result from the variable use of the EMR in different centres, a few centres having high levels of data completeness but many having low or extremely low levels of data completeness.

11.2 Effectiveness of surgery

Based on the available information it would appear that good levels of IOP reduction, around 8mmHg, are being achieved and maintained over a five-year period. Based on fairly stringent composite criteria, overall around a quarter of operations were deemed to have failed for one reason or another at one year, although when the subgroup with fuller data completion was examined separately this reduced to a bit over half of operations being successful at one year.

11.3 Risk model and adjustment of outcomes for case complexity

As a proof of concept exercise a risk adjustment model has been derived and applied to outcomes for surgeons and centres. This illustrates the feasibility of the approach although despite an encouraging C-Stat of >0.8 the model would require further work and data completeness would need to improve in order to apply this methodology across many centres in a comparative audit.

Part 2 – Visual Fields Audit

12. Background

Glaucoma is characterised by optic nerve damage with corresponding visual field loss. A whole population screening programme for glaucoma has been found to not be cost-effective and there is no existing national glaucoma detection strategy. In the UK, the vast majority of glaucoma cases are opportunistically identified by community optometrists during the course of routine eye examinations. Automated perimetry has been widely used in glaucoma clinics for more than 20 years and large historical archives of digital visual field (VF) records are readily available. We therefore test the feasibility of using large archives of VF records to audit aspects of health service delivery in glaucoma clinics and this is the main aim of Part 2 of this report. A clinically useful summary measure of overall visual field damage, relative to visually healthy age-matched controls, from automated perimetry is the mean deviation (MD) which ranges from approximately 0 dB for a normal field to -30 dB for complete blindness.

Rates (or speed) of visual field (VF) loss among glaucoma patients can only be determined by observation of individuals over time. Rate of VF loss (dB/year) is a straightforward concept. For example, an eye diagnosed with an MD of -8 dB will take 12 years to reach a level of significant VF impairment (MD of -20 dB) if they progress at a rate of -1 dB/year. This is an oversimplification because impactful localised central and binocular VF loss is sometimes not best measured by a single perimetric summary index like MD. These calculations are however clinically useful when managing a patient over time, especially when decisions need to be made about intensifying treatment. Average rates of field loss and proportion of eyes with rapid progression can act as pointers to the effectiveness of a service to a community in terms of avoidance of glaucoma blindness. Prospective and retrospective studies have derived estimates of average rates of VF loss in groups of patients yielding estimates for median rate of MD loss that vary considerably from -0.05 to -0.62 dB/year. Progression rates for individual patients may however be masked by seemingly reassuring ‘whole service’ averages. Critically important in glaucoma care is preservation of a sighted lifetime and the risk of blindness within a person’s lifetime can be summarised using a novel loss metric (called *Loss of Sight Years* [LSY]) which combines the field loss progression rate and the patient’s expected lifetime to indicate the expected number of years of blindness which lie ahead for the patient.

13. Methods

Visual field data were extracted from the Medisoft EMR system in November 2015 and transferred to The Royal College of Ophthalmologists' National Ophthalmology Database (RCOphth NOD). VF test data were extracted from five contributing NHS Trusts and combined with elements of the clinical data held by The RCOphth NOD. The specialist VF analyses were subcontracted to City, University London. All patient data were anonymised and securely held on the university database. No other clinical data was used in this study apart from patient's age, gender and the dates of the VF examinations.

13.1 Inclusion and Exclusion Criteria

13.11 Visual field type

To focus on measurements that are most widely used when monitoring VF status in the clinic only VFs recorded on the Humphrey Visual Field Analyzer (HFA, Carl Zeiss Meditec, Dublin, CA, USA) using a Goldmann size III stimulus with a 24-2 test pattern acquired with the Swedish Interactive Testing Algorithm (SITA Standard or SITA Fast) were included.

13.12 Glaucoma eligibility

The glaucoma study population was defined as patients with measurable VF loss in at least one eye at presentation (first clinic visit) thereby attempting to exclude people at risk of future glaucoma (known as glaucoma suspects) and people with normal visual fields and raised eye pressure (ocular hypertension, i.e. a risk factor for possible future glaucoma). It is important to state that many patients would likely have had clinical features suggestive of glaucoma that we also excluded at this point (i.e. glaucoma suspects), but this approach will detect the majority of people whose sighted future lifetime may come under threat. HFA mean deviation (MD) is a standard measure of the overall severity of a VF detect, relative to healthy peers, with more negative values indicating greater VF loss. Patients were only included if they had a VF with a MD flagged as outside the 95% normative limits by the HFA VF analysis software. This criterion had to be satisfied for the first two visits to the clinic to improve the precision of the estimate of an individual likely to have glaucomatous VF loss. These criteria can be used as a proxy for patients in glaucoma clinics who are receiving routine care.

13.2 Candidate Metrics used for Service Assessment

A series of parameters, some novel, were used to characterise and estimate aspects of patient management in the clinics. These included:

- age at presentation
- reliability of visual fields
- stage of glaucoma at presentation
- speed of visual field loss
- loss of sight years
- frequency of visual field testing

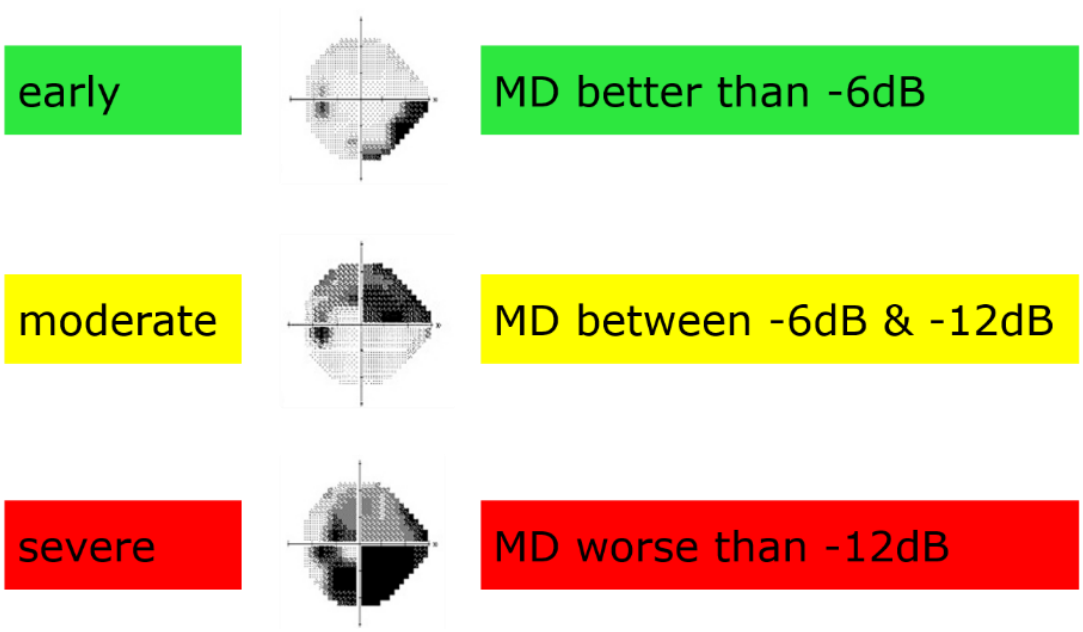
13.21 Reliability of VF measurements taken

Test reliability parameters are recorded during VF tests; the clinically most useful measure is false positives (FP). HFA flags these errors with an unreliability message (when there are more than 15% FP errors). Percentage of VFs considered as unreliable due to FP errors was therefore determined for each centre. This represents a proxy measure of the percentage of VFs which would be discarded in clinical practice.

13.22 Glaucoma severity classification

MD in the worse eye (the one with the more negative value) at the second clinic visit was taken as the surrogate of detectable VF severity at 'diagnosis'. These values were taken from a widely used criterion for summarising disease stages in glaucoma, Figure 38. It is important to note that this is the worse (most affected) eye for each patient, chosen because this would likely be the most 'detectable' glaucomatous eye.

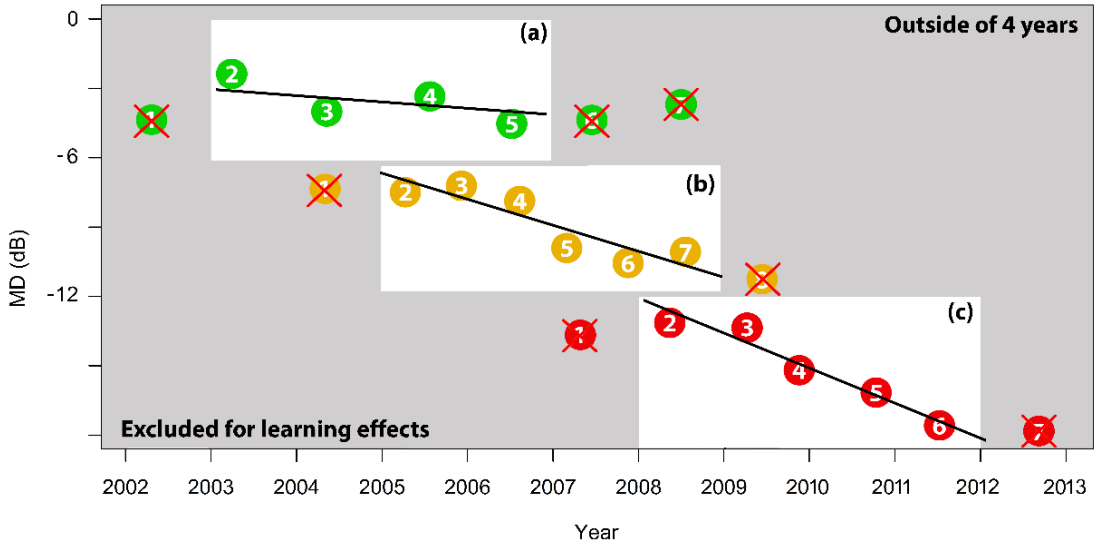
Figure 38: Examples of visual fields from different patients stratified by disease severity. Figure taken from Boodhna et al., 2015.



13.23 Speed (rate) of visual field loss in clinics

To determine the rate of progression, eyes with short follow-up (less than four years or less than five examinations) were excluded. The first VF examination in each series was then removed from further analysis to account for perimetric learning effects. Precision of estimating the rate of MD loss (dB/year) using simple linear regression varies enormously by the length of follow-up. We attempted to control for this by only calculating the rate within a fixed four-year period (window) from the baseline test, Figure 39. Each series had to have at least three examinations within this period. Eyes with longer follow-ups were not excluded, this fixed 'window' was important for comparison of rates across the study period because those diagnosed at the start of the period would have had much longer follow-up than those towards the end of the study period. Rates of MD loss (dB/year) for all eyes were recorded such that comparison between clinical sites could be made. Eyes were stratified to determine the relationship between age and severity of MD loss at the second visit with rates of VF loss.

Figure 39: A schematic illustrating the VF series inclusion criteria and method for calculating rates of MD loss (dB/year) for three example eyes detected in 2001 (a), 2003 (b) and 2006 (c).



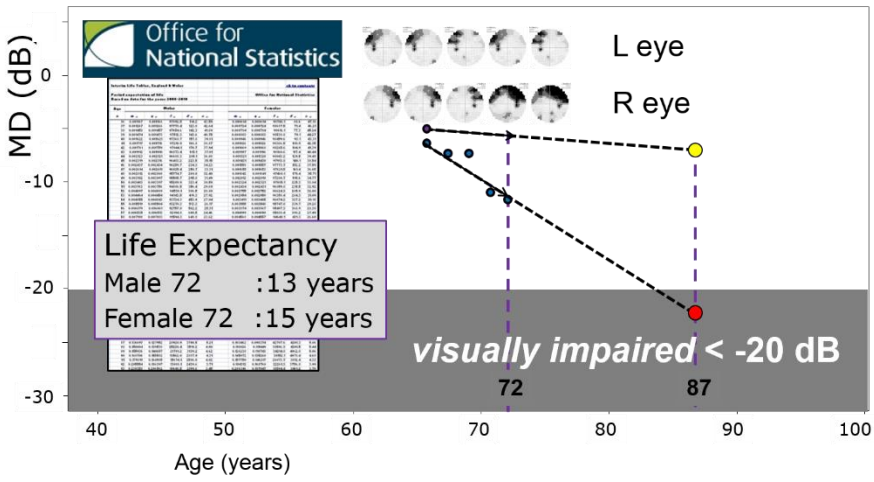
Eyes were excluded if there were < five VF examinations or <four years of follow-up. The first VF in each series was omitted to account for perimetric learning effects. Rate was calculated from linear regression of the baseline VF and the series of exams that fell within a four-year period after it (white window). So, for example, for series (a) the sixth and seventh recorded VFs fall outside this window and are not used in the calculation. This ensures that all rates are estimated with equivalent precision allowing for comparisons over time. A minimum of three VFs were required to be in this four-year window. Figure taken from Boodhna et al., 2015.

13.24 Estimated 'risk' of Visual Field (VF) loss blindness in clinics

It is important to consider the VF loss in both eyes when evaluating the visual disability a patient may suffer over the course of their lifetime. Loss of Sight Years (LSY) is a novel parameter, linked to actuarial data, which estimates the number of years that a patient will have bilateral VF loss worse than MD of -20dB in their predicted remaining lifetime. To calculate LSY, the rate of progression was assumed to remain constant for the remainder of a patient's expected lifetime. Median residual life expectancies, based on age and gender, were collected from the UK Office of National Statistics (Office of National Statistics, 2012). Using rate of progression for each eye, the age at which each patient will reach an MD of -20 dB in both eyes is predicted. LSY is then calculated as the number of years between the patient's expected age of bilateral visual impairment and the patient's expected age of death. LSY is

given as a whole number in years. An illustration of this is shown in Figure 40. For each patient we determined whether LSY would be predicted to be longer than three years. We then calculated the percentage of patients in each centre with this attribute. All statistical analyses were carried out using open-source programming language, R.

Figure 40: A schematic illustrating the analysis conducted in this study. Visual field series from the left and right eyes of a patient were used to estimate a linear rate of loss in each eye (dB/y). The patient's median life expectancy was obtained from the UK Office of National Statistics[1], and was used to predict the MD of each eye at expected time of death. In this illustration, the right eye was anticipated to progress into the visual impairment stage by the end of the patient's life. However, given that the left eye is progressing less quickly and has less VF damage at the outset, this patient would be unlikely to experience bilateral visual impairment in their remaining patient's lifetime. This 'patient' would therefore have an LSY of zero.



13.25 Frequency of visual field testing in clinics

A simple metric for the frequency of examination during the four-year follow-up period was also calculated. The average interval (in months between VF tests) was calculated for each patient and the distribution of this metric was determined for each centre.

[1] Office of National Statistics
https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/lifeexpectancies/datasets/nationallifetablesunitedkingdomreferencetables

14. Results

14.1 Visual field tests

The aggregated database of extracted visual field tests contained 591,449 VFs from 73,119 patients, Table 9.

Table 9: Total number of visual fields and patients per centre. Each centre is represented by a specific colour (red, orange, green, blue and purple for each of the five centres, respectively). This colour coding for the centres is used going forward in this report.

	Centre 1	Centre 2	Centre 3	Centre 4	Centre 5
Number of Patients	3 382	8 320	27 837	18 278	15 302
Number of VFs	15 924	63 614	283 661	110 349	117 901
Date range for the data	April 2000 – March 2015	April 2000 – March 2015	April 2000 – March 2015	April 2000 – March 2015	May 2000 – March 2015

Following exclusion of ineligible VF test types the initial field set was reduced to 570,545 VFs from 71,404 patients.

14.11 Visual field tests classified as from patients with glaucoma

Application of the inclusion and exclusion proxy criteria for glaucoma resulted in a total of 221,154 VFs from 25,579 patients. This reduced number of patient records (37% of the total VFs), reflects the fact that many of the recorded VFs were from sequences of follow-ups or referrals of glaucoma suspects.

14.12 Visual fields for those classified as having glaucoma

Based on their second recorded VF, median (interquartile range) MD was, -6.5 (-12.0, -4.0) dB with the number of examinations median (interquartile range) in the four-year period being five (four, six). Overall, the median time interval between VF tests was seven (three, 11) months. These summary measures are described for each centre in Table 10.

14.13 Patients with glaucoma

Age median (interquartile range) of patients classified as having glaucoma was 72 (62; 80) years. Individuals were stratified, into age categories as: younger patients (<60 years, n = 5,219) and older patients (> 80 years, n = 5,744). All others were considered to be 'average' age patients (n = 14,616).

Table 10: Summary of number of visual fields and patients per centre after inclusion criteria (medians with interquartile range).

	Centre 1	Centre 2	Centre 3	Centre 4	Centre 5
Number of Patients	1,364	2,354	11,532	5,676	4,654
Number of VFs	7,813	19,654	121,939	36,011	35,737
Sex (% men)	46.5	46.6	46.7	48.4	44.4
% of unreliable VFs	3.7	4.0	4.4	3.8	4.5
Median Age (years)	76 (68, 82)	72 (62, 80)	72 (62, 80)	73 (63, 80)	70 (59, 78)
Median MD (IQR) at presentation (dB)	-8.3 (-14.7, -4.7)	-6.6 (-12.3, -3.8)	-6.6 (-12.0, -4.1)	-6.3 (-12.1, -3.9)	-5.8 (-11.0, -3.7)
Median Time (IQR) interval (months)	9 (6, 13)	9 (6, 12)	7 (5, 10)	11 (7, 14)	9 (6, 13)

Patients from Centre one were on average older than patients from the other four centres. Centre five had younger patients. Patients within Centre one were also found to have a generally worse MD values than patients from the other four centres.

14.14 Reliability of Visual Fields (VF) measurements

Percentage of unreliable VFs is shown for each centre in Table 10. The proportion of unreliable tests was not significantly differently between centres (p = 0.12, Chi-squared test).

14.15 Stage of Visual Fields (VF) loss at presentation

Patients with MDs better than -6 dB, between -6 dB and -12 dB or worse than -12 dB were categorised as having early (n = 11,814), moderate (n = 7,328), or advanced/severe (n = 6,437) VF loss, respectively.

The overall percentage of eyes presenting with early (48%), moderate (28%) or severe (24%) VF loss is shown in Figure 41 and by centre in Figure 42. Centre one was found to have the highest percentage of cases severe VF loss at presentation (34%).

Figure 41: Waffle plot estimating the percentage of eyes presenting with early (green), moderate (yellow) or severe (red) VF loss based on the mean deviation at the second visit.

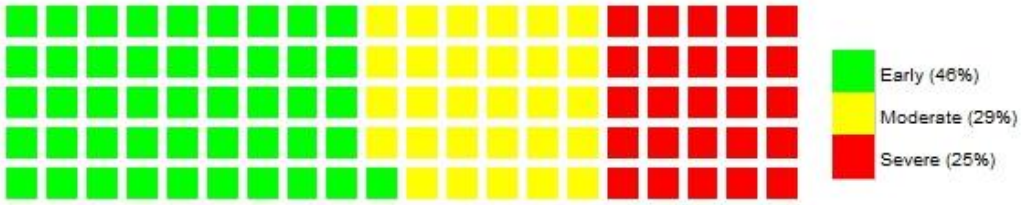
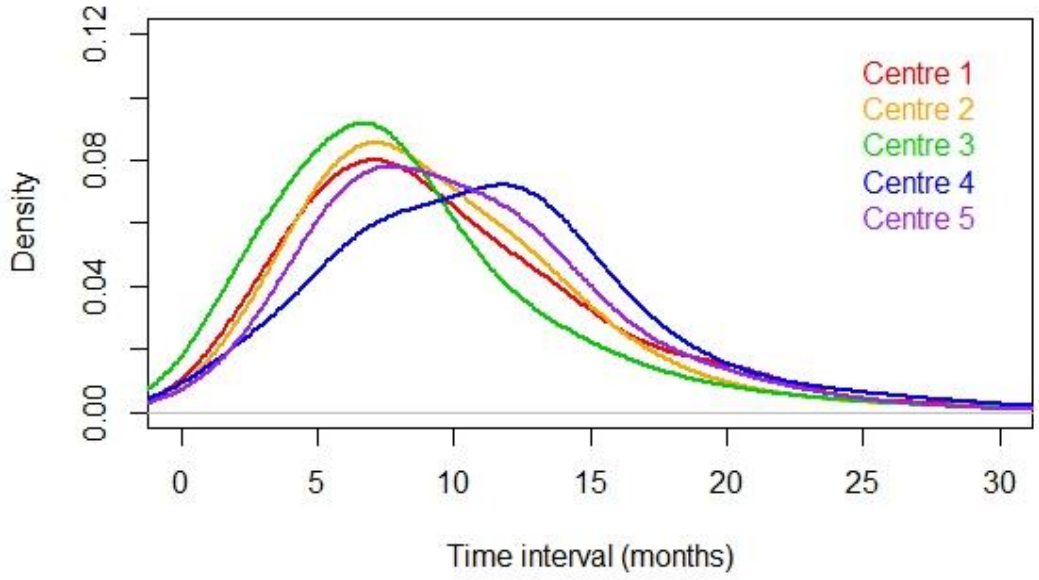


Figure 42: Waffle plots estimating the percentage of eyes presenting with early (green), moderate (yellow) or severe (red) VF loss based on the mean deviation at the second visit stratified per centre.

14.16 Frequency of visual field testing

The distribution of the time interval in months between VF tests is shown in Figure 43 and was summarised in Table 10. Centre four had a noteworthy longer median time interval between VF tests (11 months) compared to the other centres. The distributions of time intervals of VF testing were found to be significantly different between centres ($p < 0.001$; Kruskal-Wallis test).

Figure 43: Density plot showing the distribution of times interval between VF tests in months for stratified by centre.

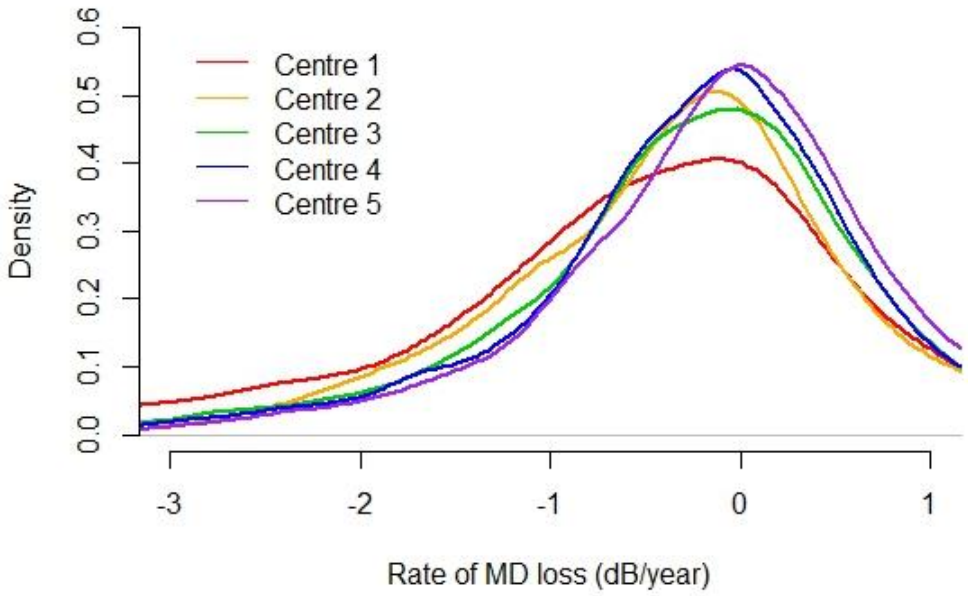


14.17 Speed (rate) of Visual Field (VF) loss in clinics

Older patients (> 80 years) were found to progress faster than younger patients (<60 years). Patients with moderate (-6, -12 dB) and severe (< -12 dB) VF loss, were found to progress more rapidly than patients with early VF loss (> -6 dB). The rates of MD loss for each centre are represented as

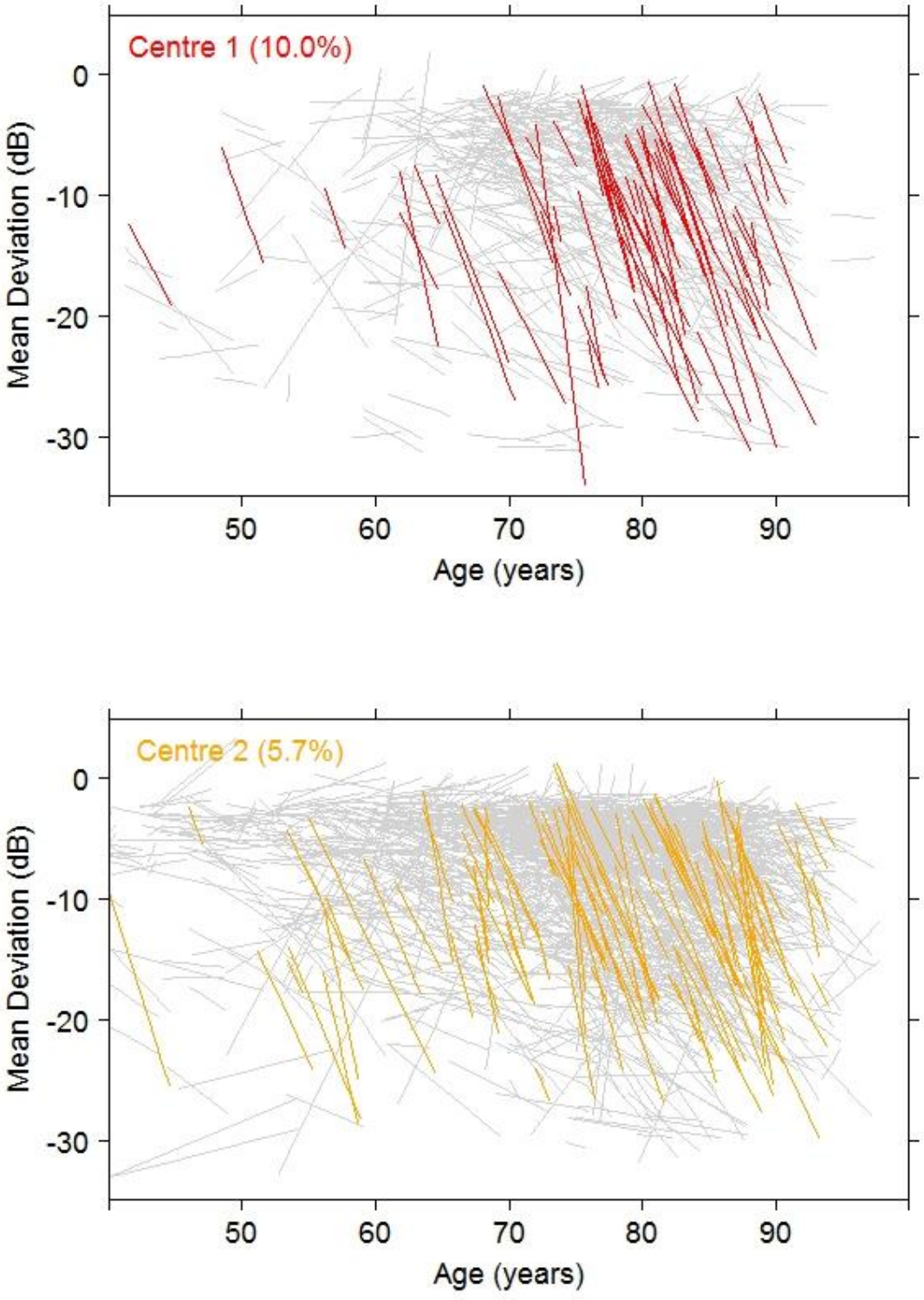
distributions in Figure 44. Centre one had more rapidly progressing patients than the other centres but the patients in this centre were older on average.

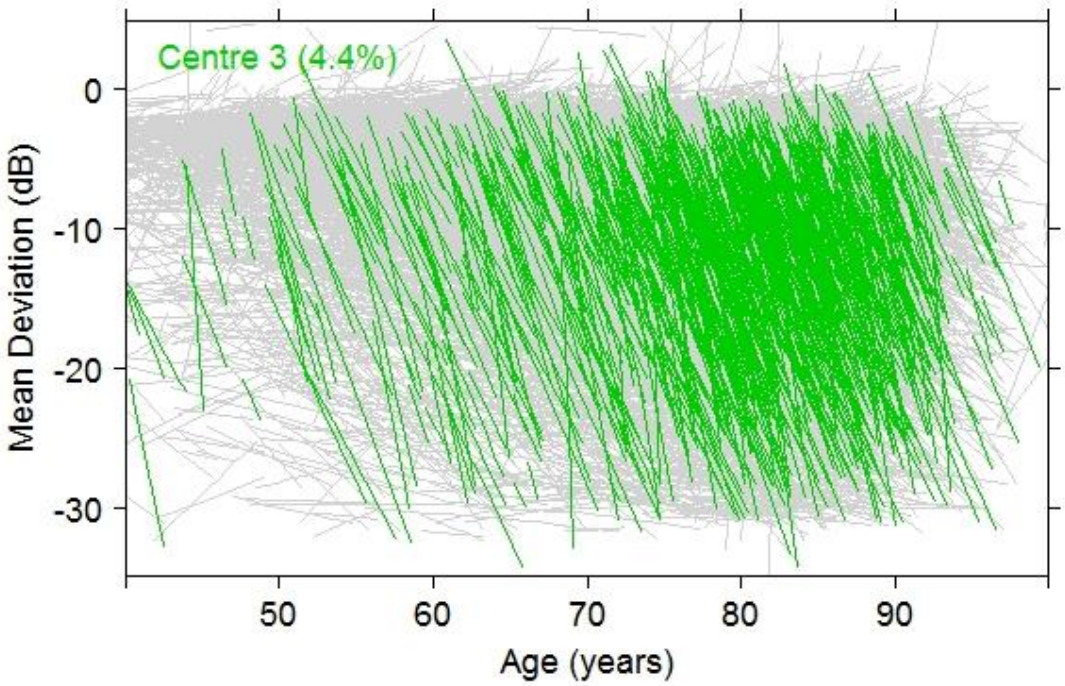
Figure 44: Density plot showing the distribution of rates of MD loss in the worst eyes for each patient stratified per centre.

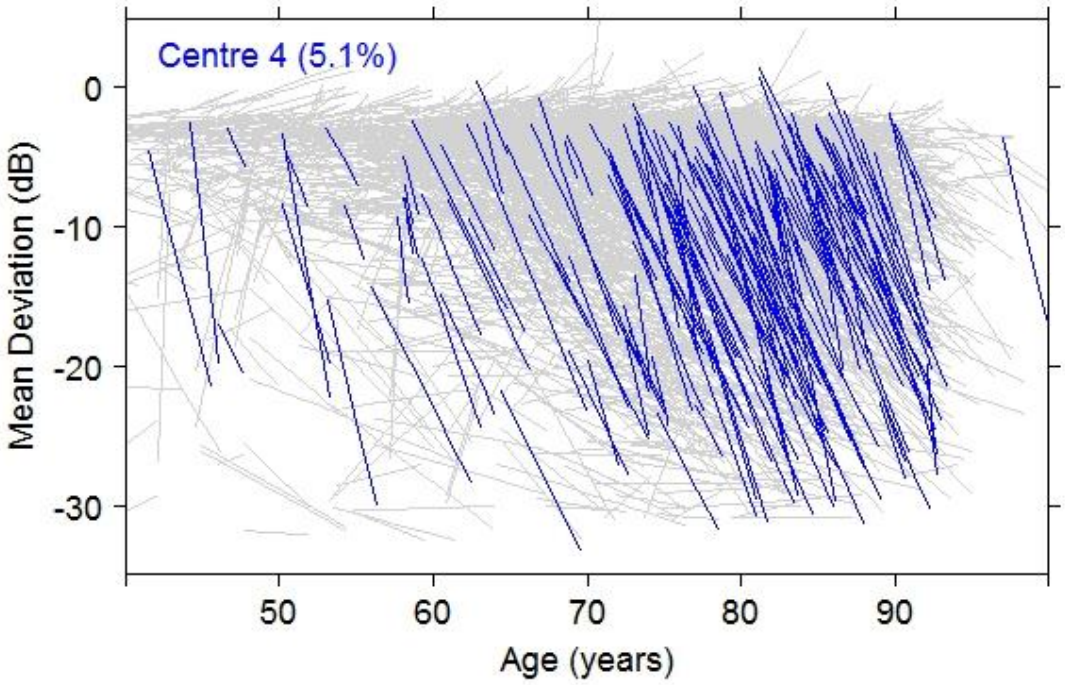


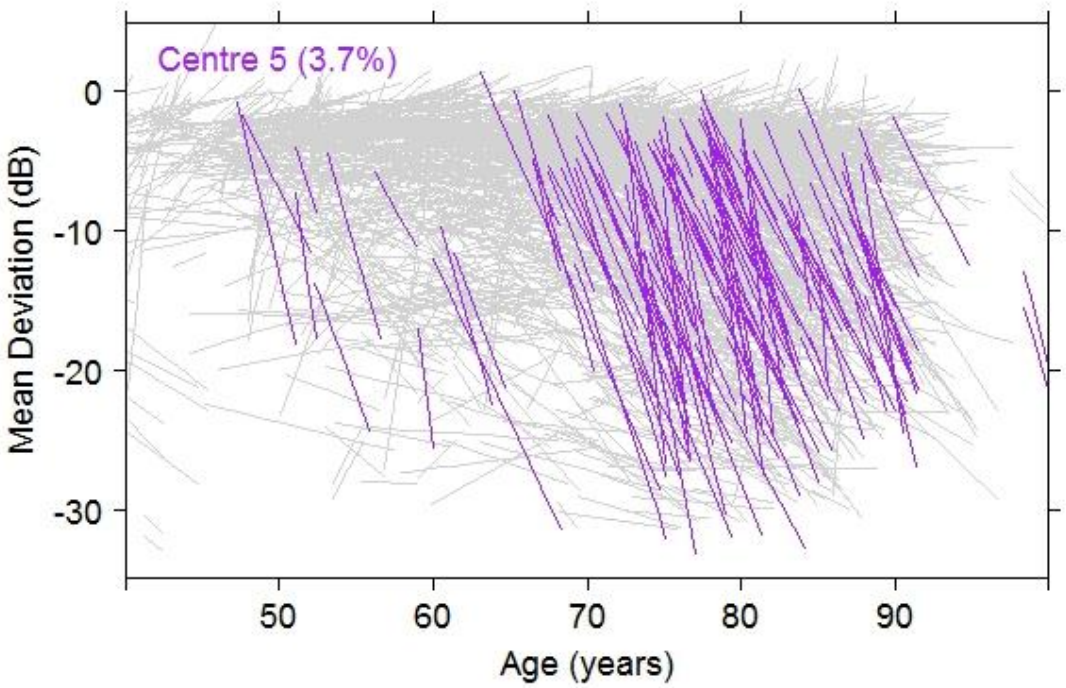
Speed of progression for every eye in each centre is shown in a series of Hedgehog Plots Figure 45. Each line represents an eye with size indicating length of follow-up and location of the line is aligned to the patient's age (x-axis) and severity of initial loss (y-axis); steeply declining lines indicate rapidly changing eyes. Eyes with VF loss of worse than 2dB/year are highlighted in colour for each centre and the percentage is given in the graphic.

Figure 45: Hedgehog plots showing speed of visual field progression for all patients within each centre. The graphic highlights eyes with a VF loss of more than 2dB/year.




Centre 3 (4.4%)
Mean Deviation (dB)
0
-10
-20
-30
50
60
70
80
90
Age (years)


Centre 4 (5.1%)
Mean Deviation (dB)
0
-10
-20
-30
50
60
70
80
90
Age (years)



14.18 Loss of sight years

Overall, 10.6% of all patients were estimated to have LSY of more than three years in their predicted lifetimes. The results stratified by centre are shown in Table 11.

Table 11: Results of the LSY for each centre.

	Centre 1	Centre 2	Centre 3	Centre 4	Centre 5
% Patients with LSY > 3 years	15.5	11.8	10.4	11.0	9.2

15. Conclusions for the Visual Field Audit

15.1 Data completeness and quality

It is not possible to determine the completeness of inclusion of all people with glaucoma from these studies. However, individuals with glaucoma attend clinics serially as observation through time is a fundamental element of glaucoma care. People with significant glaucoma would have visual field loss and the methods used here should have detected a high proportion of people at risk of vision loss from progressive glaucoma. The reliability of the visual fields is encouraging; most of the fields in these analyses were reliable with less than one in 20 VF tests being unreliable overall and little variation between sites.

15.2 Comparative Analyses

The metrics employed have demonstrated differences between sites which are relevant to local service provision. Centre one patients were older at presentation and presented with worse VF loss suggesting possible difficulty with accessing the service. Centre four had longer median periods between visual field testing, suggesting possible delays to follow-up appointments. Despite this possibility, progression of visual field loss was not faster in Centre four compared with other centres. Progression of field loss was worse in Centre one which may be a reflection of later presentation and older age at presentation. Importantly however, the loss of sight years was worse in Centre one with just over 15% of patients expected to become severely sight impaired for a period of three or more years prior to death. This compares unfavourably with the other sites where this metric ranged between 12% and 9%. This observation underlines the importance of early detection of glaucoma for prevention of avoidable blindness. Although this aspect of glaucoma care may lie beyond the immediate control of secondary care it does highlight a need for better service integration between primary community and secondary hospital eye care.

16. Feasibility of a National Audit for Glaucoma

This glaucoma audit feasibility study directly addresses the three highest stakeholder rated (median score 9/10) aspects of glaucoma care, i.e. IOP, visual field and (surgical) treatment related complications / adverse events. In all, seven of the 10 highest stakeholder rated (>7/10) aspects of care have been addressed within elements of the audit. A further two of these 10 have been indirectly addressed (CVI and driving) through other metrics. The only aspect of care in the top 10 rated items which it has not been possible to assess has been anatomical progression (optic disc / RNFL), Table 1.

16.1 Trabeculectomy Surgery

Current usage of EMR systems in the centres contributing to this feasibility study is variable which imposes major challenges to a national glaucoma surgery audit. Surgical event data may be recorded but the pre- and post-operative data which is needed to understand the patient context around the surgery is poorly recorded in many centres. This issue has imposed numerous limitations on the meaningfulness and representativeness of the results presented in Part 1 of this report. For centres with high levels of data completeness a national audit of trabeculectomy surgery would however be feasible following statistical refinement of the risk model for case complexity adjustment.

16.11 Recommendations for improving the feasibility of a national glaucoma surgery electronic audit

- EMR enabled centres should be encouraged to extend the use of their EMR to encompass the entire patient pathway
- Historic data for existing patients should be entered retrospectively to provide a clinically usable EMR tool simultaneously facilitating electronic auditing
- Data quality should be emphasised locally, e.g. confirmation of current glaucoma diagnosis and recording of clinical findings and medications at each visit
- Centres without any EMR should consider available EMR options with a view to implementation of a suitable system which collects relevant structured data in accordance with established datasets
- Outreach and community services should access the central EMR database in order that patient data does not become dispersed across sites or alternative providers. NICE recommend that full data should be available at each visit for safe patient care
- Visual field machines should be connected to the EMR in order to ensure that visual field data are available for auditing long term success of surgical intervention, i.e. preservation of vision

- Optic disc imaging devices should be connected to the EMR to facilitate quality decision making in regard to needs for possible escalation of treatment, including surgery if indicated
- Software auditing tools should be included within the EMR system for local audit purposes
- Agreed standard datasets should be available for extraction from the EMR for National Audit purposes.
- A data subset in the form of a minimum audit dataset would potentially permit data entry via a simplified data collection system (e.g. a web based data collection tool) for interim use by paper based centres in advance of full EMR implementation.

16.2 Visual Field Preservation

In the five centres included in Part 2 of this study it has been shown that it is feasible to audit the quality of glaucoma care at a high level through analysis of visual field databases from EMR enabled centres. This approach, which is outcome focussed, is a potentially useful method for assessing blindness prevention from glaucoma in secondary care centres. Visual field testing technology is standardised in the UK NHS and although in many centres the electronic visual fields tests will be distributed across several visual field testing machines it is feasible to aggregate these fields into a central database located in each centre for central analysis. Ideally such a central field database would reside within a specialty specific EMR implementation serving both clinical and quality assurance needs. Secondary benefits from such an approach would include the ability to more easily detect patients whose field loss is progressing rapidly in order to intensify their treatment as well as detection of those patients whose visual fields are stable who may require less intensive monitoring once field stability has been documented. By shifting the focus towards those in most need, scarce health services resources can be more effectively utilised. In the current NHS digital environment, a variety of challenges would need to be overcome in order to extend this audit approach into a national audit of vision preservation in people with glaucoma.

16.21 Recommendations for improving the feasibility of a national glaucoma visual fields electronic audit

- EMR enabled services should have centralised visual field databases integrated into the EMR with visual field data accessible within the EMR for clinical purposes
- EMR software tools should be available for local audit purposes
- EMR visual field databases should be accessible for data extraction for national audits

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It is with deep regret that we note the death of our friend and colleague Robert Johnston, who sadly died in September 2016. Without his inspirational vision, determination and career long commitment to quality improvement in ophthalmology this work would not have been possible.

Appendix 1. Feasibility Study Candidate Outcome Metrics for Consideration

- Pre-op data completeness
  - % eyes for surgery with a pre-op IOP
  - % eyes for surgery with a pre-op VA
  - % eyes for surgery with pre-op initial MD
  - % eyes for surgery with a pre-op MD
  - % fellow eyes with a pre-op IOP
  - % fellow eyes with a pre-op VA
  - % fellow eyes with pre-op initial MD
  - % Fellow eyes with a pre-op MD
  - % centres where any pre-op glaucoma meds recorded for >70% op eyes
- Post-op data completeness
  - % eyes with a post-op IOP
    - 3/12 post op
    - 12/12 post op
    - 60/12 post op
  - % eyes with a post-op VA
    - 3/12 post op
  - % eyes with a post-op MD
    - 12/12 post op
    - 60/12 post op
- Data completeness for assessing change in status pre-op to post-op
  - % surgery eyes with Change of IOP data
    - % eyes with both pre-op IOP and post-op IOP at each of the post-op IOP points 3/12, 12/12, 60/12
  - % surgery eyes with Change of MD
    - % eyes with both pre-op MD and post-op MD at each of the post-op MD points 12/12, 60/12
  - % Surgery eyes with MD trajectory (if Time > 18/12) and change of trajectory
    - Pre-op trajectory
    - Post-op trajectory
    - Trajectory difference (pre- minus post-op)
  - % surgery eyes with Change of VA data
    - % eyes with both pre-op VA and post-op VA at 3/12
- Number of trabeculectomies undertaken
  - Per Centre across years
  - Per Surgeon for all years
  - Per Surgeon per year (date from first trabeculectomy recorded by a given surgeon)
- Where data available then report results for pre-op, post-op, and change, for patients with COAG (exclude secondary glaucomas and primary angle closure glaucoma) noting
  - Pre-op and post-op continuous variables
    - Mean (SD) pre-op IOP or Median (IQR)
  - Pre- and Post op IOP also to be expressed as
    - % eyes below 21,
    - % eyes below 18,
    - % eyes below 14,
    - % eyes below 10
    - % eyes below 5

    - IOP change parameters to be expressed for relevant time points as
        - mmHg change
        - % change from baseline
        - % eyes with 30% drop IOP
        - % eyes with 50% drop in IOP
        - IOP Before – after bubble plot
    - MD change – effectiveness of vision preservation
        - Pre-op MD to 12/12 post-op MD and pre-op to 60/12 post-op MD
        - MD change bubble plots
        - Change in MD trajectory pre- to post-op
        - MD Trajectory Before – after bubble plot
- Safety and unfavourable outcomes
    - VA worse by a trebling or worse of the visual angle (e.g. 6/6 to 6/18; or in LogMAR a drop of 0.5 or more) from pre-op to 3/12 and 12/12 post op
    - % eyes with MD drop of 10db from pre-op to 12/12 post op
    - % eyes post op with HM or worse vision
    - % eyes below five with 0.5 LogMAR VA drop pre- to post-op
    - % eyes endophthalmitis
    - % Bleb revision
    - % Bleb leak
    - % Blebitis
    - % Further trab(s)
    - % Further glaucoma drainage surgery (e.g. tube)
- Eye drop use (including centres only where pre-op eye drop use is recorded for >70% patients)
    - Topical medication load – effectiveness of surgery in reducing this
        - Number of glaucoma meds pre-op (drops and Dx separately)
        - Number of glaucoma meds post-op at 12/12 and 60/12 (drops and Dx separately)
        - Reduction in number of drops at 12/12 and 60/12

It should be noted that it was not possible to report on all these candidate items due to data availability and time constraints.

Appendix 2. Inclusion and exclusion criteria for case complexity analyses

- Eyes included in the model
  - Trabeculectomies for COAG, including diagnoses of POAG, NTG, pseudo-exfoliative glaucoma, pigmentary glaucoma
  - Age over 18 years at time of surgery
- Eyes excluded from the model
  - Diagnosis of secondary glaucoma (except Pigmentary and Pseudoexfoliative)
  - Diagnosis of Uveitis
  - Diagnosis of congenital glaucoma
  - Diagnosis of narrow angle glaucoma or primary angle closure or acute angle closure (basically all the narrow angle sub-types)
  - Previous YAG PI
  - Valid surgeon identifier and grade
- Candidate indicator variables for model construction for case complexity analyses
  - Age
  - Gender
  - SES (IMD)
  - Surgeon grade
  - 1st 2nd eye undergoing trab
  - Previous deep sclerectomy, canalostomy, viscocanalostomy, MIGS at any time prior to index trab
  - Previous cataract surgery at any time prior to index trab
  - Previous vity at any time prior to index trab
  - Previous any eye operation at any time prior to index trab
  - IVI ***not*** for infection (i.e. anti-vegF or steroid drugs)
    - Prior to trab
    - Subsequent to trab analysed separately
  - Combined phako-trab
  - Subsequent phako within observation period (may impact trab function at longer time points e.g. 60/12)
  - MMC use at surgery
  - 5-FU use at surgery
  - Limbal or fornix based conj flap
  - Releasable or fixed sutures
  - Bleb needling with or without augmentation – 5FU / MMC
  - AL < 20mm
  - Pre-surgery glaucoma eye drops use
  - High myopia
  - AMD
  - Diabetic Retinopathy status
  - Corneal pathology
  - Other retinal pathology
  - Psuedoexfoliation / phacodenesis
  - Unspecified other ocular co-pathology
  - Diabetic status

Appendix 3. Interpreting the Trabeculectomy Results Graphs

1. Among the results there are 8 types of graphs. The labelling of centres is a ranking of the total number of operations contributed by each centre for all years, so that centre one is the centre that contributed the highest number of operations and centre 33 the least.
2. Bar charts – the horizontal axis consists of the categorical element, either deciles of IMD score, NHS year or contributing centre. For stacked bar charts the horizontal axis category is sub-divided by another category, for these graphs the vertical height of each bar indicates the quantity of interest for that bar chart as read from the vertical axis.
3. Box and Whisker plots – the spread for the variable of interest is shown for each of the contributing centres. Within the box, the central line is the median or 'middle' value and the outlines represent the inter quartile range (25% and 75% centiles). The horizontal lines above and below the box (whiskers) terminate at the values corresponding to ±1.5 times the IQR. Extreme values are the dots beyond that.
4. Funnel plots – The spread of dots on these look like a funnel going from left to right. Each dot represents a result for a surgeon or centre as read off the vertical axis (proportion or rate). The funnel effect results from increasing statistical precision as the numbers get higher going along the horizontal axis. Some of the plots have lines on them showing what is expected. A result above the top line (3 standard deviations) would be deemed unacceptably high, a dot between the lines is deemed a bit on the high side but not alarmingly so.
5. Scatter plots – these display as a point the measurements corresponding to the values on the x-axis and y-axis. The scatter plot for IOP also contains a diagonal line of identity and a line for 30% reduction.
6. Kaplan-Meier graphs – These display the Kaplan-Meier estimate of failure by time t, where the number at risk underneath displays the number in the sample still at risk of failure at specified time points.
7. Waffle plot – these display the percentage of a group with a quantity of interest, i.e. the percentage of eyes according to severity of visual field loos. Each box represents 1% of the sample.
8. Density plots – these illustrate the distribution of rates of vision loss (MD loss) similarly to a histogram plot but without grouping values into 'bins'.
9. Hedgehog plots - these illustrate the speed of vision loss as the downward slope through time mapped to the relevant age of the patient.

Appendix 4. Glossary

Abbreviation	Description
%	Percentage
<	Less than
>	Greater than
CDVA	Corrected Distance Visual Acuity
CF	The ability to count fingers
COAG	Chronic open angle glaucoma
dB	Decibels
EMR	Electronic Medical Record
FP	False Positive
HFA	Humphrey Field Analyser
HM	The ability to distinguish hand movements
HQIP	Healthcare Quality Improvement Partnership
IMD	Index of Multiple Deprivation
IOP	Intraocular Pressure
IQR	Inter Quartile Range
LogMAR	An eye chart comprising of rows of letters which can be used to estimate visual acuity
LSY	Loss of Sight Years
MD	Mean Deviation or Mean Defect
NCAPOP	National Clinical Audit and Patient Outcomes Programme
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NOD	National Ophthalmology Database
NPL	No Perception of Light
PACG	Primary Angle Closure Glaucoma
PHVA	Pin Hole Visual Acuity
PL	Perception Light
PPI	Patient and Public Involvement
RCOphth	The Royal College of Ophthalmologists
RNFL	Retinal Nerve Fibre Layer

S251 exemption	Approval for exemption from section 251 of the NHS Health and Social Care Act 2006 which allows for certain uses of patient identifiable data
UDVA	Uncorrected Distance Visual Acuity
UK	United Kingdom
UKEGS	UK and Eire Glaucoma Society
VA	Visual Acuity
VF	Visual Field

Appendix 5. List of Figures

Appendix 6. List of Tables