Journal of the Colleges of Medicine of South Africa
ISSN: (Online) 2960-110X

Single treatment selective laser trabeculoplasty in a Southern African resource-constrained context

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Dates:
Received: 20 Aug. 2024
Accepted: 06 Nov. 2024
Published: 17 Jan. 2025

How to cite this article:
Pons EJ, Pons JJ, Grossman ES, Louw D, Werbeloff M. Single treatment selective laser trabeculoplasty in a Southern African resource-constrained context. J Coll Med S Afr. 2025;3(1), a118. https://doi.org/10.4102/jcmsa.v3i1.118

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Background: In a resource-constrained environment, selective laser trabeculoplasty (SLT) is an attractive option. This study's primary objective is to report real-world outcomes in terms of reduction in intraocular pressure, reduction in topical treatment and further surgery required.

Methods: A retrospective case series of consecutive patients who received SLT between 01 January 2017 and 31 December 2018 was conducted. Patient data were captured for up to 21 months.

Results: In all, 59 eyes of 36 patients were analysed. The mean patient age was 57.8 years (± 10.0). Sixty four per cent of the patients had SLT on both eyes. 83% of the patients were black ethnicity or of mixed race ethnicity. There was a significant and sustained intraocular pressure reduction (median reduction = 25.8%, IQR = 5.3%, 40.4%) from pre-SLT to 10–15 months (Wilcoxon T = 27.5, p = 0.002). The Kaplan-Meier survival analysis estimated that 60% of patients required no treatment escalation for up to 21 months. Neither cup-disc ratio nor pre-treatment intraocular pressure were found to be a predictive factor of treatment success or failure (p = 0.675 and p = 0.128).

Conclusion: The results of this study support the use of SLT for patients with not only mild to moderate glaucoma but also advanced glaucoma in a Southern African, resource-limited context. The results demonstrate ongoing benefit for these patients up to 21 months following a single treatment.

Contribution: This research provides, for the first time, long-term data from a low-resourced setting on the use of SLT in the treatment of glaucoma in Eswatini.

Keywords: glaucoma; community eye health; selective laser trabeculoplasty; sub-Saharan Africa; Eswatini.

Introduction

Providing an eye-care service that is equipped to offer effective glaucoma care is most challenging in resource-limited settings such as Eswatini.[1] This study reports on data from a regional eye hospital in Eswatini, which implements selective laser trabeculoplasty (SLT) as a once-off intervention to improve glaucoma control.

Glaucoma is known to be the leading cause of irreversible blindness in sub-Saharan Africa.[2,3,4,5] It is well known that patients of African ethnicity present with more advanced and more aggressive disease at a younger age with higher intraocular pressures (IOP) than other groups.[3,6,7] This is further compounded by delayed presentation because of a lack of awareness and poor access to medical facilities.[8,9,10,11] Providing adequate treatment to control the disease process is also impeded by high medication costs and a lack of expertise.[4,10] This vulnerable patient population requires a unique management strategy for optimal glaucoma control.[9,11]

The Good Shepherd Hospital Eye Clinic (GSHEC) is a regional eye centre providing eye-care services as well as attending patients from neighbouring countries. Twelve per cent of all outpatient consultations (1000 outpatient consultations per month) and 10% of all surgeries performed at GSHEC are glaucoma related (unpublished data).

At GSHEC, the management of open angle glaucoma (OAG) involves early surgery or as ab initio treatment (see Appendix 1). While surgery is a definitive treatment option, a once-off intervention to improve glaucoma control is very attractive in a resource-limited setting.[8]

Selective laser trabeculoplasty is a particularly attractive treatment option as it can be performed on an outpatient basis, is associated with a very low complication rate and can delay incisional surgery. However, cost and uncertainty around its effect in the African setting remain the major drawbacks to its routine use.[12]

There is little research on the use of SLT in African patients, with only seven research publications originating from the African continent.[13,14,15,16,17,18,19] Only three of the publications studied the effect of SLT for a duration of more than 6 months,[13,15,16] and only two studies included patients with advanced glaucoma.[13,16] At GSHEC, a robust record-keeping system facilitates research. This study (further referred to as the Eswatini study), enabled us to capture real-world data describing the clinical outcomes of patients who underwent SLT in this setting.

Research aims

The aim of this study was to report on the outcomes of patients who had received SLT at GSHEC in Eswatini.

Research objectives

Primary research objective: To analyse the response to a single treatment of SLT by documenting:

- Intraocular pressure reduction over set intervals according to World Glaucoma Association (WGA) convention at Post-Operative Month (POM) 1–2 (15–60 days), POM 3–4 (61–122 days), POM 5–9 (123–256 days), Post-Operative Year (POY) 1 (257–456 days), POM 18 (457–639 days), POY 2 (640–913 days), POY 3 (> 913 days).
- The number of pre- and post-intervention glaucoma medications over the same intervals after initial intervention.
- Any further incisional surgery required following the initial intervention and at what time interval.

Secondary research objective: Analysis of any potential predictive factors for successful treatment.

Research methods and design

This was a retrospective, non-comparative, observational case series of participants who had undergone SLT at GSHEC between 01 January 2017 and 31 December 2018.

Consecutive participants, diagnosed with OAG or Ocular Hypertension (OHT), were identified from the laser registry who received SLT. Diagnosis was made based on cup-disc-ratio (CDR), gonioscopy and IOP alone, as no automated perimetry or optical coherence tomography was available during the study. Intraocular pressure was measured using rebound tonometry (iCare) or Goldmann Applanation Tonometry. Basic demographic data, including sex and ethnicity, as well as clinically relevant information, were obtained from hospital records. Participants who had undergone previous SLT or filtration surgery were excluded. The indication for SLT was at the discretion of the treating ophthalmologist or medical officer under supervision with reference to the local glaucoma treatment guidelines (Appendix 1).

A single laser machine (OptoSLT, Optotek) was used for all participants included in this study (frequency-doubled Q-switched Nd:YAG laser [532 nm]) and gonio lens (1:1 magnification). A standard procedure was in use, which was as follows: A pre-operative dose of pilocarpine 2% is given 30 min prior. Delivery of 75–125 shots is evenly interspaced along the trabecular meshwork for 360°. Energy level starting at 0.4 mJ for heavily pigmented eyes (or 0.8 for less pigmented eyes) and increasing by 0.1 mJ until micro-bubble threshold is observed or until micro-bubbles are noticed ('champagne bubbles') where the energy is then decreased by 0.1 mJ. Participants were given a stat dose of apraclonidine 0.1% and prednisolone acetate 1% immediately after the procedure and an IOP check 30 min thereafter.

Post-intervention data

The study followed the guidelines of the WGA.[20] As a result, the following information was captured:

- Intraocular pressure at subsequent visits.
- Follow-up measurements grouped into intervals as defined previously.
- Time of commencement of adjunctive glaucoma medications and number of agents added.
- Recording of any complications or vision loss as a result of the intervention.
- Data capture beyond March 2020 was disrupted because of the outbreak of COVID-19.

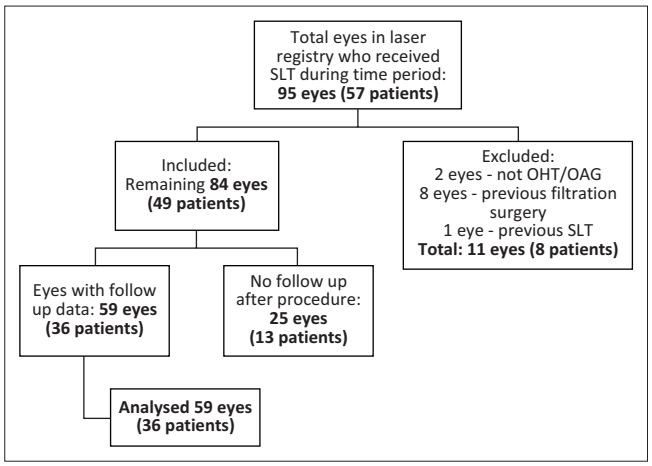
The reduction in IOP after SLT was evaluated by percentage as per the WGA guidelines.[20] Time to failure was analysed in the form of a Kaplan-Meier curve. Treatment escalation or surgical failure was defined by any one of the following scenarios:

- The need to increase the number of glaucoma medications after SLT.
- An increase in IOP above baseline at any follow-up interval.
- Progression to filtration surgery: either offered or performed.

Where necessary, decisions were made on a case-by-case basis (see Appendix 2). Patients for whom no data were available in the follow-up period of the study were considered censored.

Data analysis

Percentages were calculated for categorical demographic variables, and means or medians and standard deviations or interquartile ranges were calculated, as appropriate, for changes in IOPs and other continuous variables following normality analyses. Because of substantial clustering of



SLT, selective laser trabeculoplasty; OHT, ocular hypertension; OAG, open angle glaucoma.

FIGURE 1: Flow chart illustrating inclusion and exclusion process.

the data with a strong intraclass correlation of 0.77, inferential statistics were conducted at patient level as single level analyses on a randomly selected single eye of each participant using Stata 18 (StataCorp LLC).[21,22]

Ethical considerations

Ethical approval to conduct this study was obtained from the Eswatini Health and Human Research Review Board (No. EHHRRB142/2022) and the Walter Sisulu University Faculty Health Sciences Research Ethics & Biosafety Committee (No. 137/2022). The protocol for this study was approved by the management of Good Shepherd Hospital.

Results

The inclusion and exclusion criteria are summarised in Figure 1.

Most patients were male (68%). There were approximately equal proportions of right and left eyes (49% right eyes). Open angle glaucoma was the most common diagnosis (73%). Approximately half of the participants (51%) had a cup-to-disc ratio greater than 0.8 and 56% were on two or more glaucoma agents. This demonstrates a substantial representation of participants with more advanced and aggressive glaucoma (Table 1). Because of the lack of objective measures of glaucoma severity, CDR and IOP are later discussed as predictors of response to SLT.

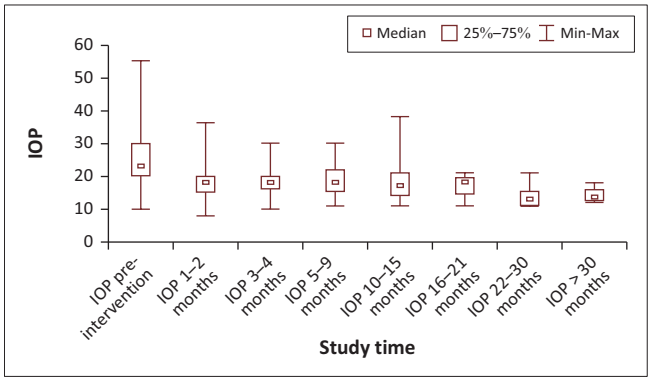
Reduction in intraocular pressure

On analysis of the 34 eyes of patients who had no medication change and no filtration surgery, the median IOPs over the six-time points showed a decreasing trend (Figure 2), with a reduction of 25.8% (IQR = 5.3%, 40.7%) from pre-SLT to 10–15 months. At pre-intervention, the median IOP of all eyes was 23.0 mmHg (IQR = 20 mmHg, 30 mmHg) with mean 24.7 mmHg 95% confidence interval (CI) (22.7, 26.8), while at the 10–15-month interval, the median IOP was 17.0 mmHg (IQR = 14.0 mmHg, 19.5 mmHg) with mean 17.8 mmHg 95% CI (16.0, 19.6). Compared to pre-SLT levels, IOPs at

TABLE 1: Demographic data.

Demographics (total eyes N = 59)	Eyes	
	n	%
Eye		
Right eye	29	49
Left eye	30	51
Sex		
Male	40	68
Female	19	32
Diagnosis		
OAG	43	73
OHT	14	24
NTG	2	3
CDR category		
CDR ≤ 0.5	16	27
0.5 ≤ CDR ≤ 0.8	12	20
0.8 < CDR	30	51
unrecorded	1	2
Pre-intervention number of topical agents		
0	6	10
1	20	34
2	17	29
3	16	27
Ethnicity		
Asian people	6	10
Black people	26	44
Caucasian people	2	3
Mixed race people	23	39
Unrecorded people	2	3

OAG, open angle glaucoma; OHT, ocular hypertension; NTG, normal tension glaucoma; CDR, cup-to-disc ratio.



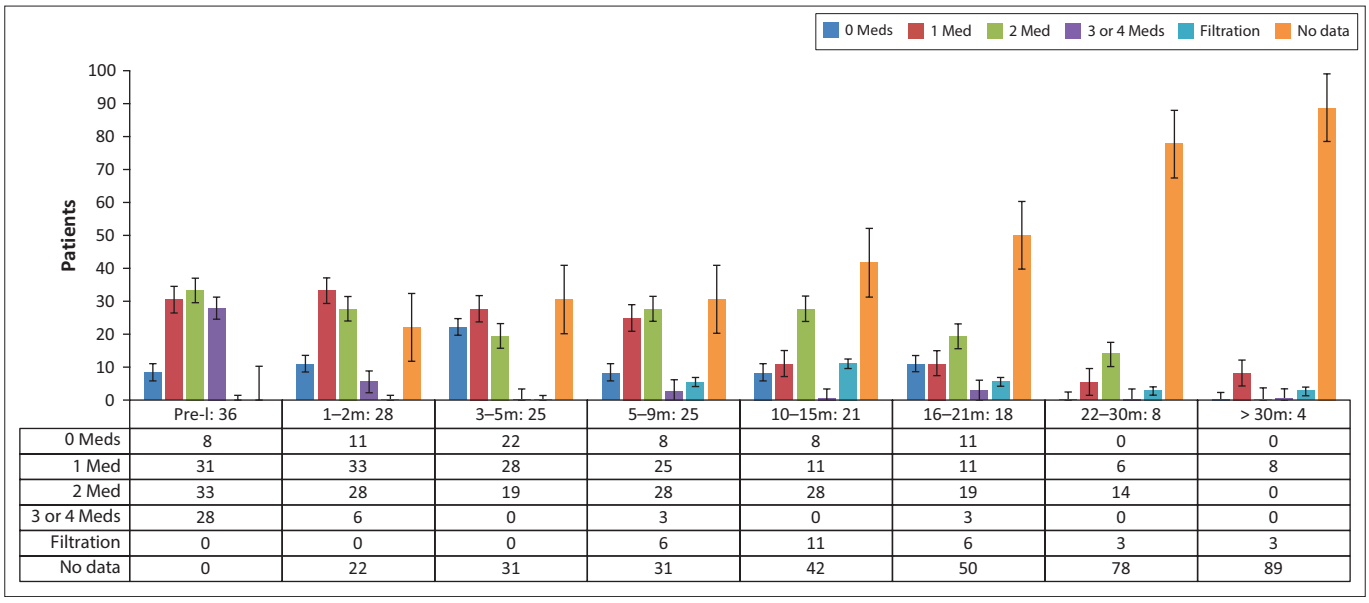
IOP, intraocular pressures.

FIGURE 2: Intraocular pressures of eyes over time intervals.

12 months were reduced by more than 20% in 56% of the eyes. This success rate improved to 71% of eyes when the criterion was relaxed to an IOP reduction greater than 10% over the 12-month period. At patient level (considering one randomly selected eye for patients with both eyes treated), there was a significant and sustained IOP decrease (Wilcoxon T = 27.5, n = 21 patients, p = 0.002).

Changes in medication

Beyond 16–21 month follow-up, half (50%) of the participants did not return (Figure 3). Results beyond this point should be treated with caution because of data attrition. The median number of medications pre-SLT and at 10–15 months were 2.0 at both these time intervals. Before receiving SLT, 8%



	Pre-I: 36	1–2m: 28	3–5m: 25	5–9m: 25	10–15m: 21	16–21m: 18	22–30m: 8	> 30m: 4
0 Meds	8	11	22	8	8	11	0	0
1 Med	31	33	28	25	11	11	6	8
2 Med	33	28	19	28	28	19	14	0
3 or 4 Meds	28	6	0	3	0	3	0	0
Filtration	0	0	0	6	11	6	3	3
No data	0	22	31	31	42	50	78	89

Pre-I, pre-Intervention; m, month; Meds, medicine.

FIGURE 3: Bar chart showing the percentage of total participants by number of medications and filtration over time (n = 36).

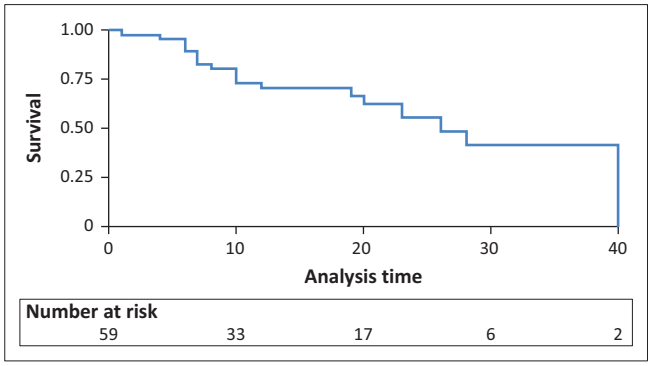


FIGURE 4: Kaplan-Meier Survival Curve (n = 59).

of the patients were taking no medications, 31% were taking one, 33% were taking two, 25% were taking three, and 3% were on four medications. After excluding patients who had undergone filtration surgery, medication data were available for 17 patients at 10–15 months. Of these patients, 18% were taking no medications, 24% were taking one, and 59% were taking two, with no patients on more than two. Pairwise medication differences were not significant (Wilcoxon T = 12.5, p = 0.126).

Kaplan-Meier survival curve over time

A Kaplan-Meier survival curve was used to demonstrate treatment outcomes for the 59 eyes of the study (Figure 4).

At 21 months following SLT, 60% of the patients had not experienced a failure event (Figure 4). Attrition increased beyond 21 months. A total of 6 eyes required filtration surgery during the study time period.

Intraocular pressure and cup-to-disc ratio as predictors of response

A significant correlation was found between pre-intervention IOP and SLT response (r = 0.70, p = 0.002); however, this was influenced by an outlying point with pre-IOP = 55 and 12-month post-IOP = 38. Excluding this point, the correlation was not significant (r = 0.13, p = 0.128). Glaucoma disc cupping was also not found to be a significant predictor of a greater than 10% IOP reduction (p = 0.675).

Other predictors of selective laser trabeculoplasty response

Patient age was not found to be significantly correlated with 12-month post-operative IOP (r = 0.04, p = 0.889) after omitting patients whose medications had been increased and those who had required filtration. Glaucoma diagnosis (normal tension glaucoma [NTG], OAG, or OHT) was also not found to be significant (p = 0.262).

Complications

No complications after SLT were documented in the form of a significant IOP increase at the standard 30 min IOP check immediately after the procedure. No additional medication such as steroids or analgesia was prescribed following SLT to suggest that the patients had required treatment for severe side effects or complications.

Discussion

The outcomes of this study are in keeping with the findings of the Glaucoma and Ocular Hypertension (LiGHT) trial[23] and to the West Indies Glaucoma Laser Study (WIGLS) trials,[24] both considered the leading studies on SLT efficacy and SLT in patients of African origin, respectively. This Eswatini study provides data on SLT beyond 12 months in African patients, demonstrating no treatment escalation in 60% of participants at 21 months follow-up.

However, just 56% of eyes had an IOP reduction of greater than 20%. Because of the wide variability of both patient demographics and reporting methods, it is challenging to compare these results to that of other studies. A study by

Realini et al., described a study population that has some similarity to this report, as they included patients with more advanced glaucoma.[25] Approximately only 50% of the patients in the medication group could be adequately controlled after receiving SLT.[25] The South African study by Goosen, Visser and Sartorius demonstrated much higher success rates, finding that 85% – 95% of patients responded with an IOP reduction of 20% or more; however, the study population may not be comparable.[16] Finally, Philippin et al. reported that 61% of their study population had a successful IOP reduction at 12 months; but here, success was based on more stringent target values as laid out in their methodology.[13]

This variability in response among different study populations brings up the issue of predictability in SLT. The Eswatini study included a large proportion of patients with more advanced glaucoma compared to other similar studies, a sub-group of glaucoma patients that are not traditionally offered SLT. Fifty-one per cent of patients studied had a CDR of 0.8 or greater and more than half of the patients were on two or more topical agents (28% on three to four agents). This unique patient sample presented the opportunity to analyse CDR and higher pre-intervention IOP as predictors of treatment success with SLT. Fisher's exact test demonstrated no significant relationship between CDR and SLT response in this study ($p = 0.675$ and $p = 1.000$, respectively). This certainly encourages the use of SLT across the spectrum of patients with glaucoma. Analysis of additional potential predictive factors (IOP before intervention, age, and ocular diagnosis) also demonstrated no significant relationship to the reduction in IOP. These findings are in keeping with the results of the WIGLS 2 Trial.[26]

The reduction in topical agents in this study was modest compared with similar studies such as Goosen et al.[16] The modest reduction is most likely an indication of the increased proportion of participants with high risk glaucoma and as a result, inadequate glaucoma control. The median baseline IOP for the Eswatini study was 23 mmHg (most participants already on topical medication), which is markedly higher than any other African study apart from Philippin et al. (26.5 mmHg).[13] For comparison, Realini et al. and Goosen et al. reported a mean baseline IOP of 21.7 mmHg and 19.9 mmHg, respectively.[16,25] Based on the pre-intervention IOP, participants from the Eswatini study would be classified as inadequately controlled on topical medication alone.[27] For this reason, SLT was used as adjunctive therapy as opposed to monotherapy in this patient population.

Remarkably, of the 49 participants who were included in this study, 25% (13 participants) were lost to follow-up immediately after receiving the intervention. The long travel distances, which often include a border crossing in this context, may explain poor patient adherence. These patients often require an escort because of poor vision and may become despondent with the cumulative costs each month.[28] This, together with the high proportion of at-risk participants described in this study, only serves to confirm that in this setting, patients with glaucoma require a therapeutic option not entirely dependent on their ability to follow-up. While it is clear that SLT may not be sufficient as monotherapy for these patients, the results of this study strongly support extending this treatment option to all glaucoma patients, including those at risk of vision loss.

Strengths and limitations

The limitations of the study are inherent to the low-resourced setting in which the study took place. Clinical decision making was dependent on IOP and change in CDR alone, in the absence of corneal pachymetry, automated visual fields testing and optical coherence tomography. Because of the retrospective design of the study, no standardised criteria could be used to select patients for the intervention; this was again at the discretion of the treating clinician. There is also inherent limitation on the detection of adverse events and treatment complications because of the retrospective nature of the study.

Despite these limitations, this study demonstrates a true reflection of the challenges of managing glaucoma, especially in Africa. It allowed for the inclusion of patients routinely excluded from most clinical trials on SLT, such as advanced glaucoma.

Summary and relevance for clinical practice

In summary, this study reported on the outcomes of single treatment SLT in a specific resource-constrained Southern-African setting. The results were in keeping with international landmark studies as well as with other studies carried out on the African continent. This study contributes valuable information on the use of SLT in patients with advanced glaucoma and higher initial IOP. As demonstrated by the increasing patient attrition in this study, a treatment option that is independent of patient attendance and barriers to follow-up, would be invaluable. While SLT is not a cure for glaucoma, a single treatment may be beneficial and protective for patients. Certainly in Africa, many of the most vulnerable glaucoma patients present with markedly elevated IOPs and advanced optic nerve damage at diagnosis. It is important to find solutions, which allow the inclusion of these patients so that they too can benefit from evidence-based research.[12] The outcomes of this study recommend the continued use of SLT in patients with OAG and OHT at GSHEC, and additionally, encourage the inclusion of patients with more advanced disease. Further prospective research is needed to assess the effectiveness of SLT as a treatment option for glaucoma in similar resource-limited settings.

Conclusion

The results of this study support the use of SLT for patients with not only mild to moderate glaucoma, but also advanced glaucoma, in a Southern African, resource-limited context, and demonstrate ongoing benefit for these patients for up to 21 months following a single treatment.

Acknowledgements

The author would like to thank Good Shepherd Hospital, the Ministry of Health in Eswatini and the Ethics Review Board of Eswatini (Ethics Health & Human Research Review Board) for making this research possible.

This article is partially based on the author's dissertation entitled 'Outcomes of selective laser trabeculoplasty in glaucoma patients treated at Good Shepherd Hospital Eye Clinic, Eswatini: A retrospective study' towards the degree of Master of Medicine in the branch of Ophthalmology, Walter Sisulu University, South Africa, with supervisor D. Louw, received 8 December 2023, unpublished.

Competing interests

The authors declare that they have no financial or personal relationships that may have inappropriately influenced them in writing this article.

Authors' contributions

E.J.P., J.J.P., E.S.G. and M.W. designed the study. Data were collected by E.J.P. M.W. analysed the data. E.S.G., D.L., M.W. and E.J.P. edited the manuscript and all authors reviewed and commented on the final draft.

Funding information

This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors.

Data availability

Raw data were generated at Good Shepherd Hospital Eye Clinic, Eswatini. Derived data supporting the findings of this study are available from the corresponding author, E.P., upon request.

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Appendices starts on the next page →

Appendix 1: Good Shepherd Hospital Eye Clinic glaucoma treatment guidelines

Good Shepherd Hospital Eye Clinic, Eswatini Dr J Pons Sunday, July 14, 2019

GSHEC Glaucoma severity definitions		Mild	Moderate	Severe	Phthysis B
	IOP	< 25	25 to 40	IOP > 40	Pain
	CDR	< 0.5	0.5 to 0.8	CDR > 0.8	Full
	VF (In the absense of HVFA)	No loss	Some loss	Affects ADL	NPL
Glaucoma Management Stepwise approach:					
	1 Glaucoma medication	Compliant patient			
	SLT	Yes			
	Repeat SLT		After 6 months		
	Goniotomy 23G/Kahook	At time of Cataract surgery			
	GATT		Yes		
	2 Glaucoma medications		Yes		
	MMC Trabeculectomy		Yes		
	3 Glaucoma medications			Yes	
	Ahmed Valve/in sulcus if pseudophakic		Failed Trab/ other CI to Trab		
	Cyclo Cryo/Diode CP			No/mild pain	
	Retrobulbar CPZ				If painful
Key:	Preferred				
	Preference				

IOP, intraocular pressure; CDR, cup-disc-ratio; SLT, selective laser trabeculoplasty; NPL, no perception of light; VF, visual field; HVFA, Humphrey Visual Field analysis; MMC, mitomycin C; GATT, gonio-assisted transluminal trabeculotomy; CP, cylophotocoagulation; CPZ, chlorpromazine; CI, contra-indicated; Trab, trabeculectomy.

Appendix 2

Rules Used to make consistent decisions for Kaplan Meier Survival Curve
Rule 1 applied: Medication change is compared to baseline not previous interval
Rule 2 applied: Where time-specific data not captured, approach is conservative: use lower limit of time interval
Rule 3 applied: When medication is transiently increased within first 0–3 months and thereafter decreased, this does not constitute failure
Rule 4: IOP not sustained above pre-intervention
Rule 5: When medication reduces and IOP increases, this is not a reason for failure in terms of IOP

IOP, intraocular pressure.

FIGURE 1-A2: Rules to govern decisions for Kaplan-Meier survival curve.