Original Article

Preliminary Trabeculectomy results using the Moorfields Safer Surgery Technique in Malta

Matthew Fenech, Adrian Mifsud, Francis Carbonaro

Abstract

Purpose: To review the results of the Moorfields Safer Surgery System (MSSS) for trabeculectomy, recently introduced in Malta.

Methods: Patient files were reviewed from data collected over an 18 month period, from Mater Dei Hospital. Files of all patients undergoing primary trabeculectomy with a minimum of 12 months follow up data available were reviewed. Primary outcome measure of success was defined as a 30% drop in final post-operative intraocular pressure (IOP) at 1 year. The secondary outcome measure of success was a final post-op IOP of less than 21mmHg. Unqualified success was defined as a satisfactory IOP without the need of anti-glaucoma medication, while qualified success was defined as a satisfactory IOP in those patients requiring anti-glaucoma medication.

Results: 43 eyes (mean age = 66.2 yrs ± 11.7) were analysed. The mean pre-operative IOP was 27.0mmHg ± 4.6. The mean post-op IOP at one year was 15.3mmHg ±2.7. Unqualified success for the primary outcome measure was achieved in 64.1% of patients while the qualified success was achieved in 82.1%. Unqualified success for the secondary outcome measure was achieved in 72.7%, while a qualified success of 94.8% was obtained. There was a 6.8% failure rate.

Conclusions*:* The results from this first review using the Moorfields safe surgery system for Trabeculectomy surgery in the Maltese islands compares well to the current literature.

Key Words

5- Fluorouracil, Malta, Mitomycin, Moorfields safer surgery, Trabeculectomy

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Introduction

Trabeculectomy was first described over forty years ago by Sugar in 1961[1],further promoted by Cairns and Philips in 1986.[2-3] It is currently the most commonly performed operation for uncontrolled glaucoma.[4] The procedure has undergone various alterationsover the years, the main one being that described by Peng Khaw, commonly known as the Moorfields Safer Surgery System (MSSS).[5]

The aim of this study was to determine whether the MSSS, recently introduced to Malta by the senior author (FC), was resulting in outcomes which were safe and satisfactory when compared to larger international reviews. Advancements in today's contemporary trabeculectomy techniques include the likes of antifibrotic agents like 5-fluorouracil (5-FU) and Mitomycin–C (MMC), the use of adjustable or releasable sutures, the application of an intensive post-operative treatment regimen and the implementation of glaucoma fellowship programmes,[6] all of which have led to reduced post-operative complications and improved surgical outcomes.[4]

We set out to review the outcomes of the MSSSS in Malta in patients with a minimum of 12 months follow up.

Methods

Ethical approval was obtained through the ethics department at Mater Dei Hospital Malta. The study adhered to the Declaration of Helsinki. All the trabeculectomies were performed by one single consultant surgeon (FC) between 19th of November 2013 and the 5th of March 2016 *(n=43)*.

A retrospective review was performed over a period of 3 months. The data collected in this study (FCAR) was subsequently compared to other published studies.

A total of 43 eyes from 39 patients were used in this study. Demographic data, the duration and number of antiglaucoma medications being used, best corrected visual acuity (BCVA) pre-operatively and 12 months post-operatively, the aetiology of glaucoma and the intra-ocular pressure pre-operatively and 12 months post-operatively were recorded.

Exclusion criteria included previous trabeculectomy attempts, any other prior glaucoma surgery, follow up period of less than 12 months and patients undergoing a combined surgical procedure.

Failure rate was defined as the necessity for cyclodiode, revision of surgery or progression to tube surgery.

Standardised surgical approach

The surgical approach used in all cases was that described by Khaw as part of the MSSS, with the aim of improving posterior aqueous flow accompanied by more diffuse drainage blebs. Such success was achieved by applying Mitomycin-C in the subconjunctival space and the application of releasable sutures to the scleral-flap.[7]

Trabeculectomies were performed by the same consultant ophthalmic surgeon in order to eliminate any variability in results that would have been obtained had several different consultants contributed to the study.

Outcome measures

Outcome measures vary from study to study, making it difficult to compare results directly. Primary outcome measure of success was defined as a 30% drop in final post-op IOP at 1 year. The secondary outcome measure of success was a final IOP less than 21mmHg. Unqualified success was defined as a satisfactory IOP of less than 21mmHg without the use of IOP-lowering drops, while qualified success was defined as a satisfactory IOP with concurrent use of IOP-lowering drops. Failure was defined as unsatisfactory IOP of greater than 21mmHg, whereby further treatment such as diode laser or tube surgery was required.

Results

43 eyes of 39 patients were reviewed, all undertaking trabeculectomy surgery at Mater Dei Hospital, Malta. The mean age of patients was 66.2 years (SD 11.7). The predominant glaucoma type was primary open angle glaucoma (POAG), occurring in 59.5%, while 16.7% had pseudo-exfoliation (PXF), 7.1% had primary angle closure glaucoma (PACG) or rubeotic glaucoma, with the remainder comprising of congenital, chronic open angle and phacomorphic (Figure 1).

The mean number of topical mediations used pre-operatively was 2.73 (Figure 2). A total of 71.4% of patients were on 3 or more topical medications pre-operatively. Furthermore, 9.5% of patients were on oral anti-glaucoma medication (Diamox, Duramed Pharmaceuticals Inc, Cincinnati), USA) prior to surgery. The mean number of topical medications used post-operatively was 1.25 (Figure 3).

Early complications occurring in the first 2 post-operative weeks occurred in 47.6% of patients. 14.3% of patients experienced loss of more than 1 line of Snellen visual acuity over 1 year (Table 1). Late complications were considered to be those that occurred more than 2 weeks post operatively. A comparative assessment of the complications observed in our cohort to those observed in a selection of other studies may be seen in Table 2.

The mean pre-operative IOP was 27.0 +/- 4.6mmHg. Mean post-op IOP was 15.3mmHg ± 2.7. Comparison of pre-op and post-op IOP shows a mean reduction of 11.7mmHg (Figure 4).

Unqualified success for the main outcome measure was achieved in 64.1% of patients while qualified success was achieved in 82.1%. Unqualified success for the secondary outcome measure was achieved in 72.7%, with a qualified success of 94.8% (figure 5) being seen. A failure rate of 6.8% was observed.

***Figure 1**: Percentage distribution of type of glaucoma*

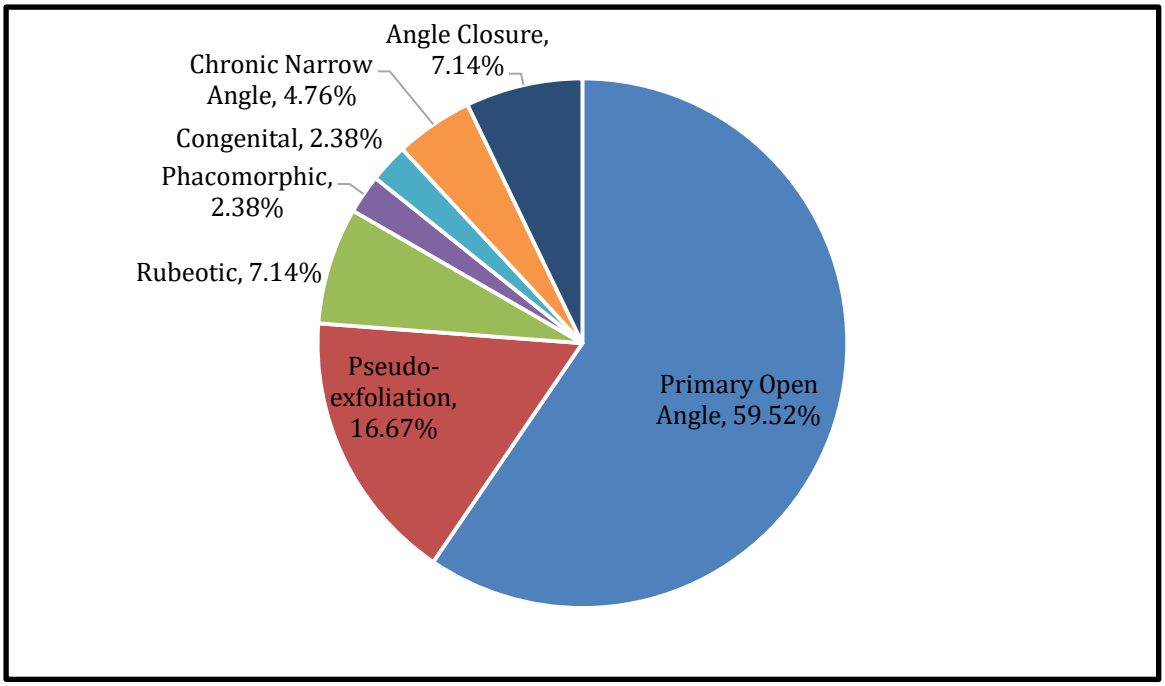


***Figure 2:** IOP lowering regimen (drops) pre-op*

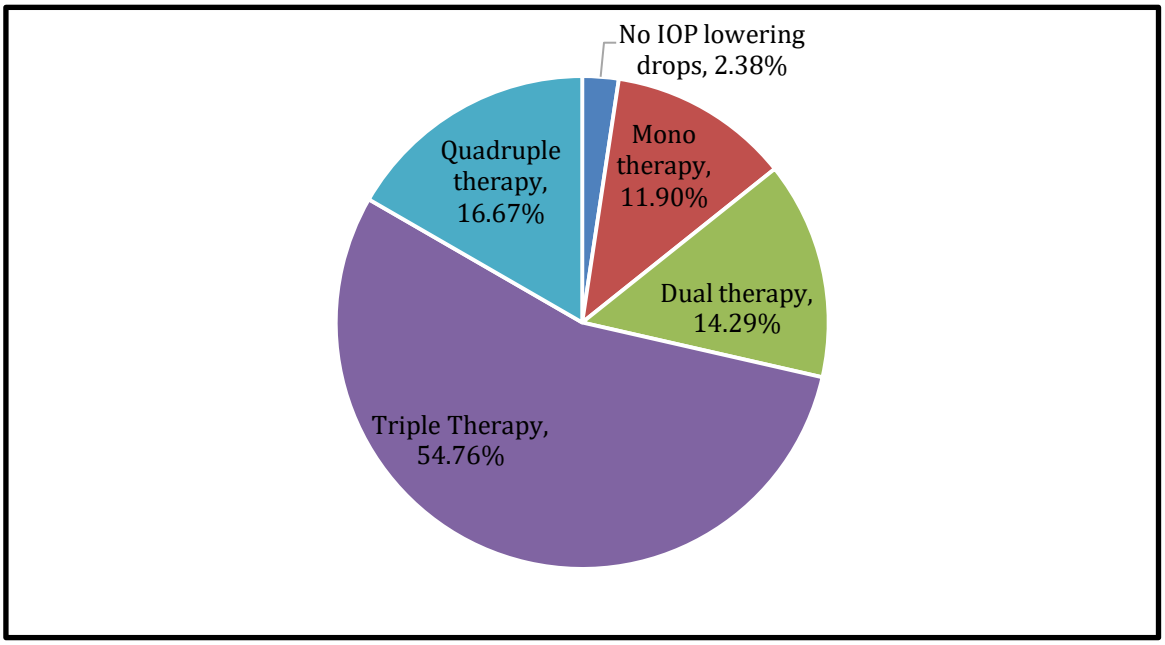


***Figure 3**: IOP lowering regimen (drops) post-op*

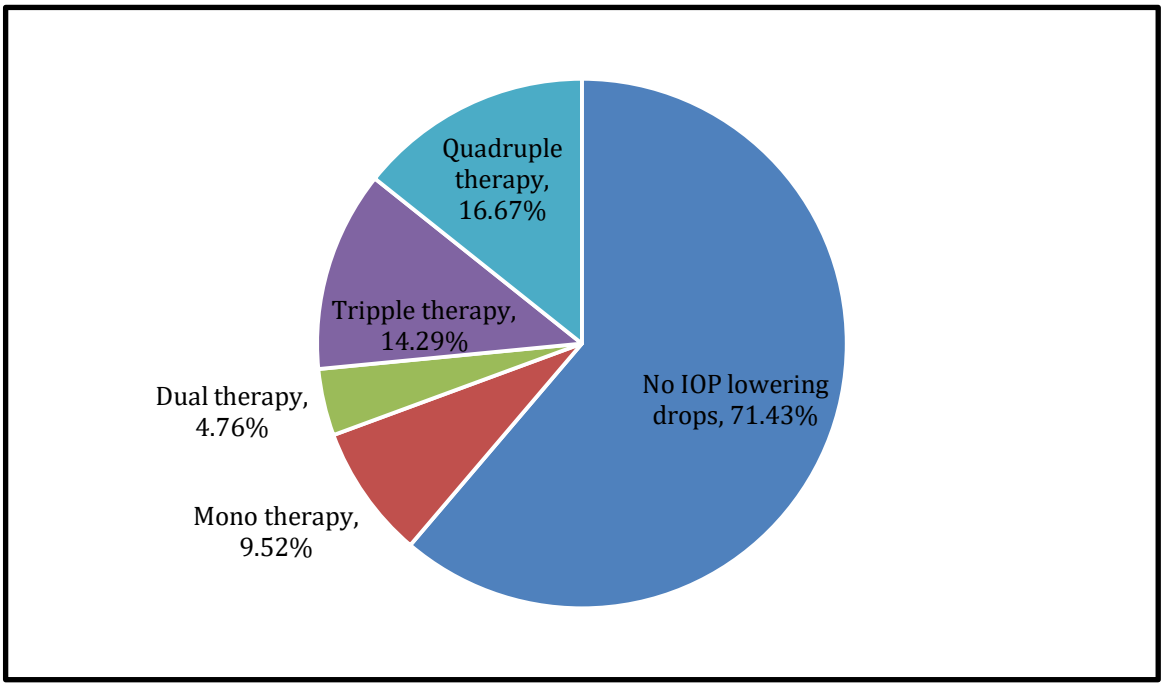


***Table 1:** Early complications occurring within 2 post-operative weeks and late complications after 2 post-operative weeks*

Post-operative complications	
Early complications - <2 weeks	**Current study (%)**
• Hyphaema	26.19
• Hypotony	9.52
• Choroidals	4.76
• Shallow anterior chamber	2.38
Late complications - >2 weeks	
• Loss of >1 line of Snellen visual acuity	14.3
• Cataract	11.9
• Corneal ulceration	4.76
• Macular oedema	2.38
• Retinoschisis	2.38

Table 2: *Comparison of the post-operative complications between the current study other published studies. (CBIITS; Collaborative Bleb-related Infective Incidence and Treatment Study, TNTG; Trabeculectomy in Normal Tension Glaucoma Study, NST; National Survey on Trabeculectomy study, SESTS; Southeast Scotland trabeculectomy surevy*

		Post-operative complications; Study comparison				
Complication	Current study	Kirwan et al.	CBIITS	TNTG study	NST study	SESTS study
Early						
Hyphaema	11.9	6	2.7	3.6	20.2	3.6
Hypotony	9.52	3	1.3	2.3	24.3	17.8
Shallow AC	2.38	0.9	3.1	23.9	23.4	0.8
Late						
Cataract	11.9	N/a	N/a	3.6	20.2	3.6
Loss of >1 Snellen line of visual acuity	14.3	N/a	N/a	18.8	10.9	N/a
Endophthalmitis	0	0.5	0.97	0	0.2	0
Cystic Blebs	2.38	7.7	0.36	N/a	3.4	N/a

Figure 4: *Comparison of mean pre-op IOP and mean post-op IOP between the FCAR study and other published studies*

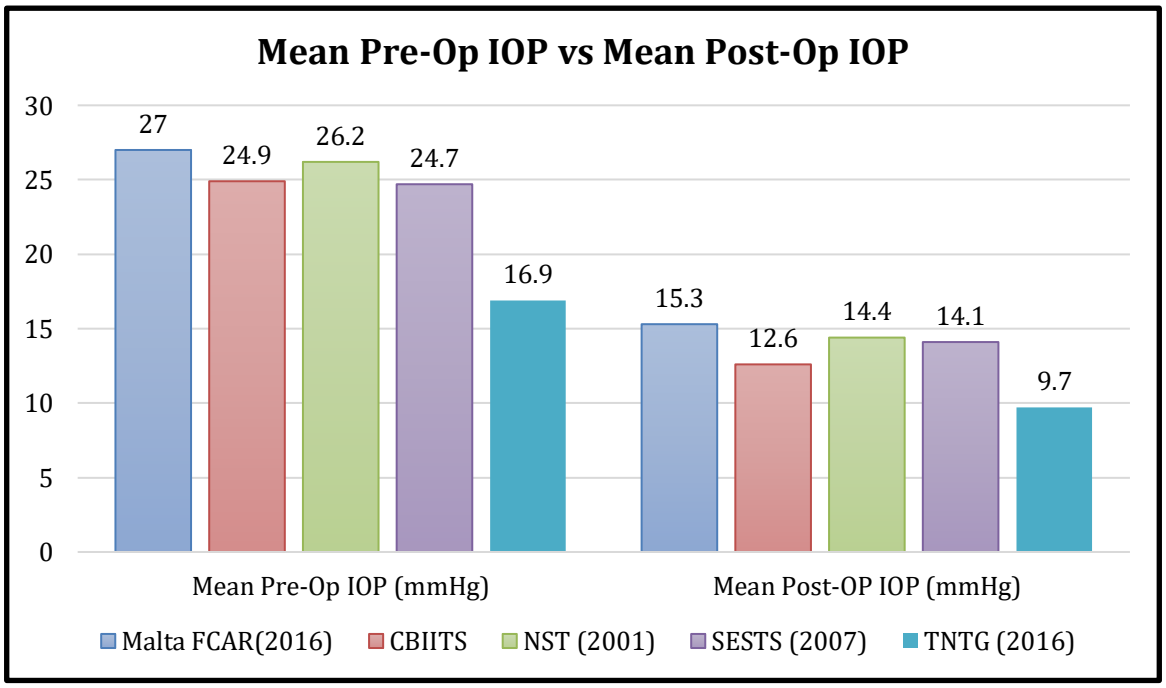
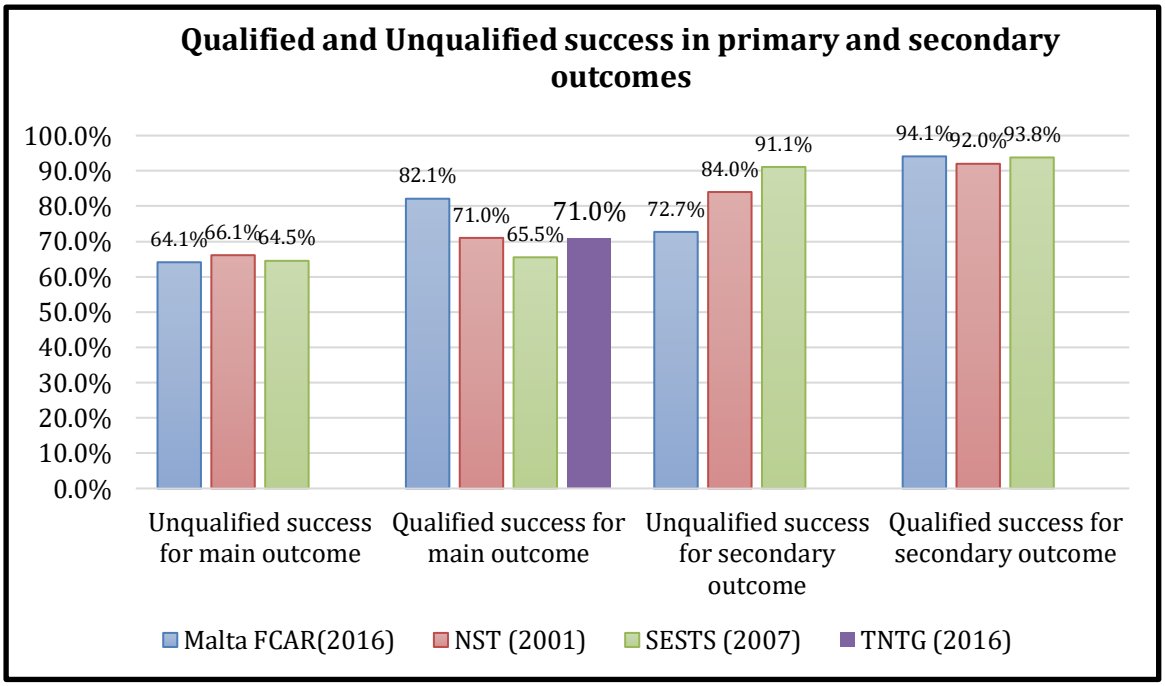


Figure 5: *Comparison of unqualified and unqualified success rates in the primary and secondary outcomes between the FCAR study and other published studies*



Discussion

Our study set out to assess current practices of trabeculectomy in Malta, by comparing the outcomes and results 1 year post operatively with the results obtained in similar studies. Unfortunately, although sseveral studies evaluate the effect of trabeculectomy using the MSSS, it is difficult to compare the surgical results because there are small differences in the success criteria and patient demographics. Studies that included only surgical-naive subjects seemed to show results that were better than those subjects who had a surgical history.[7]

The UK National Survey of Trabeculectomy (NST) study[8] and the Southeast Scotland Trabeculectomy Survey (SESTS) [9] recruited patients who were IOP lowering agents prior to surgery, whilst our study also recruited patients who were not on IOP lowering agents. This may have contributed to our qualified success rates being higher than the other two studies. Furthermore, the TNTG study[10] does not discuss the number of IOP lowering drugs used pre-operatively or post-operatively.

Oral acetazolamide was used in 9.1% of patients in our study. This rate is higher than that found in the NST study, while the rate was significantly lower than that found in the SESTS study. Furthermore, our patients were operated at a more advanced stage of glaucoma. This may explain why our unqualified success rates for the secondary outcome measure were lower than the comparative studies. The starting IOP was also higher in our cohort and this would contribute to the lower success rate for the secondary outcome.

Cohort selection as mentioned earlier may strongly impact the ability to compare results between studies. The TNTG study for instance only considered patients suffering from normal tension glaucoma. As a result, the pre-operative IOP and the post-operative IOP were destined to be lower. That being said, the post-operative change in IOP is also lower in the TNTG study. The lack of data on the number of pre-operative and post-operative IOP lowering drugs makes the comparison of secondary outcome measures between our cohort and the TNTG study impossible.

16.8% of patients in our cohort had complicated glaucoma. This compares closely to the 18% of cases in the SESTS study. Conversely, the NST study only included patients with POAG, PXF, PDS and NTG, whilst the TNTG study only considered patients with normal tension glaucoma, with a pre-operative IOP of <21mmHg. The Collaborative Bleb-Related Infection Incidence and Treatment Study (CBIITS)[7] on the other hand

excluded patients with normal tension glaucoma and refractory glaucoma secondary to neovascularization.

Conjunctival surgery is in itself a risk factor for failure of trabeculectomy surgery[5,11]. The NST study excluded patients who had previous surgery involving the bulbar conjunctiva. Our study only excluded patients that had previously undergone glaucoma surgery and not those patients whose surgery involved any disruption of conjunctival tissue. The TNTG study only excluded patients who had previously undergone combine cataract and filtration surgery. Furthermore, the CBIITS study included patients who had previously undergone filtration surgery.

A look at the complication rates within our study would show that early or late complications occurred in 66.7% of patients involved. Early complications were more common than late complications, occurring in 47.61% and 19.04% respectively (Table 1).

The rate of early complications compares favourably with 53.9% and 46.6% observed in the SESTS and NST studies respectively. It was postulated that the higher rate of early complications in the SESTS study may be due to the greater use of anti-metabolites compared to the NST study. This is also apparent in our study, with a higher rate of early complications when compared to the NST study, with 100% of patients within our cohort were given MMC during the procedure. The lower overall complication rate in the TNTG study may be pinned to the fact that all patients in the TNTG study cohort were cases of normal tension glaucoma. Hyphaema rate sin our study were higher than average. This may stem from the fact that our study cohort included a lot of patients suffering from diabetes mellitus. Furthermore, the CBIITS study makes it clear that neovascular glaucoma cases were excluded from the cohort.

Interestingly, hypotony was not so common amongst our complications, occurring in 9.52%. This is most likely due to the fact that adjustable sutures were used in our study and the TNTG study as part of the MSSS technique, as opposed to the conventional suture technique used in SESTS and NST. Adjustable sutures allow for tighter closure of the flap.[14] Furthermore, the use of a small sclerostomy punch and a fornix-based conjunctival flap help to further prevent hypotony.[15-17] Intra-operative hypotony is also reduced by the use of continuous intra-operative infusion .[18]

Also of note is the fact that no bleb leaks were reported in our study. This is a well documented early complication of trabeculectomy surgery. The answer may again lie in the technique adopted. By applying the MSSS, round-bodied needles are used as opposed to spatulated ones, allowing any conjunctival holes to close more spontaneously.[14]

Endophthalmitis was not noted in our study. This was not the case with the SESTS and NST study. It is possible that our cohort was not large enough to cater for the low incidence rate of endophtahlmitis. Furthermore, the positioning of the filtration bleb, which is ideally placed under the upper lid, coupled with the shift from limbus-based incisions to fornix-based incisions, dramatically reduces the rates of blebitis and endophthalmitis.[17]

Our study has several limitations. Firstly, the study is retrospective in nature, relying on case note documentation. The retrospective nature of the study did not allow for the adjustment of confounding factors such as age or sex. The sample size used in our study was relatively small. Demographic data of the qualified and unqualified success groups in both primary and secondary outcomes was not compiled. It is therefore difficult to attribute statistical significance to the results obtained.

A follow up of 1 year was chosen for pragmatic reasons, to be able to compare to the results obtained in the SETS and NTS studies. However, it is likely that success rate will decrease with longer follow-up. The TNTG study made use of a 4-year follow-up period, being able to assess the long-term impacts of filtration surgery using the MSSS approach. Our study could be further extended by another 3 years to assess whether the results obtained accurately compare to those within the TNTG study.

Measuring post-operative IOP was the only indicator of success or failure of filtration surgery in our cohort. The use of a single digit as a therapeutic aim for filtration surgery may be misleading. It may be worthwhile extending the follow-up period in our cohort and assessing outcomes and success in terms of the preservation of visual fields or the structural integrity of the optic nerve head and nerve fibre layer, as was undertaken in the TNTG study.[10,18]

Tube surgery has recently been implemented in

the Maltese islands. A comparison study similar to the TVT study would prove to be beneficial and could provide further knowledge on the differences that may exist in the safety and efficacy outcomes of both approaches[19] Furthermore, a four-year follow-up on the cohort used in this study would provide a lot of information on the long-term success and survival of trabeculectomy using MSSS here in Malta. Data will continue to be collected so as to monitor success rates over two and four year periods.

References

1. Sugar, AS. *Experimental trabeculectomy in glaucoma*. Am J Ophthalmol.1961:51: 623-7
2. Cairns, JE. *Trabeculectomy. Preliminary report of a new method*. Am J Ophthalmol.1968; 66(4):673-9.
3. Phillips CI. *Trabeculectomy 'ab externo'*. Trans Ophthalmol Soc UK. 1969; 88: 681-691.
4. Broadway DC, Clark A. *The Norwich Trabeculectomy Study: Long-term Outcomes of Modern Trabeculectomy with Respect to risk Factors for Filtration Failure.* J Clin Exp Ophthlamol, 2014; 5(371)
5. Khaw, P.T. *Trabeculectomy Technique*, in *Glaucoma Today*. 2005, Surgical Pearls.
6. Kamal DS, Jayaram H, Strouthidis NG. *Trabeculectomy for normal tension glaucoma; outcomes using the Moorfields Safer Surgery technique*. Br J Ophthalmol. 2016; 100(3);332-8.
7. Sugimoto Y, Mochizuki H, Ohkubo S, Higashide t, Sugiyama K, Kiuchi Y. *Intraocular Pressure Outcomes and Risk Factors for Failure in the Collaborative Bleb-Relted Infection Incidence and Treatment Study*. Ophthalmology. 2015; 122(11): 2223-33
8. Edmunds B, Thompson JR, Salmon JF, Wormald RP. *The National Survey of Trabeculectomy. III. Early and late complications.* Eye (Lond), 2002; 16(3):297-303.
9. Cackett P, Vallance J, Cobb C, Devlin H, Simpson A, Sanders R. *South-East Scotland trabeculectomy survey.* Eye (Lond), 2007; 21(1):46-51.
10. Kirwan JF, Lockwood AJ, Shah P, Macleod A, Broadway DC, King A,et al. *Trabeculectomy in the 21st century: a multicenter analysis.* Ophthalmology. 2013; 120(12): 2532-9.
11. Shaarawy T. *Glaucoma surgery: taking the sub-conjunctival route.* Middle East Afr J Ophthalmol. 2015; 22(1): 53-8
12. Gessesse GW, Damji KF. *Advanced Glaucoma; Management Pearls*. Middle East Afr J Ophthalmol. 2013; 20(2);131-41
13. Bunce C, Membrey W, Poinoosawmy D, Hitchings R. *Glaucoma surgery with or without adjunctive antiproliferatives in normal tension glaucoma: 1 intraocular pressure control and complications*. Br J Ophthalmol. 2000; 84(6):586–90.
14. Dhingra S, Khaw P.T. *The moorfields safer surgery system.* Middle East Afr J Ophthalmol. 2009; 16(3): 112-5.
15. Kuroda U, Inoue T, Awai-Kasaoka N, Shobayshi K, Kojima S, Tanihara H. *Fornix-based versus limbal-based conjunctival flaps in trabeculectomy with mitomycin C in high-risk patients.* Clin Ophthalmol. 2014; 8: 949-54.
16. Alwitry A, Patel V, King A.W. *Fornix vs limbal-based trabeculectomy with mitomycin C.* Eye (Lond). 2005; 19(6): 631-6.
17. Gracitelli CP, Abe RY, Tatham AJ, Rosen PN, Zangwill LM, Boer ER et al. *Association between progressive retinal nerve fiber layer loss and longitudinal change in quality of life in glaucoma*. JAMA Ophthalmol. 2015;133 (4): 384–90
18. Gedde SJ, Heuer DK, Parish RK. *Review of results from the Tube Versus Trabeculectomy (TVT) Study*. Curr Opin Ophthalmol. 2017; 21(2): 123-8