



Cover Letter

February 05, 2025

To: editor of clinical trial

Topic: Cover letter for Submission of protocol for registration in clinical trial.

Dear Sir/Madam,

I wish to register an article entitled **“Deep sclerectomy with scleral bed fenestration versus trabeculectomy in medically uncontrolled primary open angle glaucoma.”**

This article is co-authored by:

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All authors have contributed significantly and all are in agreement with the content of the manuscript.

The authors declare that there is no conflict of interests regarding the publication of this article.

On behalf of all contributors, I'm Nosaiba Essam Ahmed , will correspond with the journal from this point onward.

Thank you,

Yours' sincerely,

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Title of the study

**Deep sclerectomy with scleral bed fenestration versus
trabeculectomy in medically uncontrolled primary open angle
glaucoma.**

Protocol of Thesis Submitted to the Faculty of Medicine

Minia University

In Partial Fulfillment of the requirement for Doctorate Degree (M.D) in
Ophthalmology By:

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Introduction:

Glaucoma is an optic neuropathy that is characterized by progressive structural and functional deterioration of the optic nerve (1)

Glaucoma is the second leading cause of blindness worldwide, although it is the most common cause of irreversible vision loss in the whole world (2)

In 2013, the number of people (aged 40-80 years) diagnosed with glaucoma worldwide was 64.3 million, increasing to 76.0 million in 2020 and expected to reach 111.8 million in 2040 (2)

Primary open angle glaucoma is the commonest subtype of glaucoma. The number of persons diagnosed with POAG was estimated 52.68 million in 2020 and expected to be 79.76 million in 2040 (3).

In primary open angle glaucoma vision preservation remains the aim of treatment through correcting the only treatable risk factor in glaucoma which is the intraocular pressure. This can be achieved by different modalities including medical, laser or surgical methods (4)

In many cases medical and laser therapy can provide an effective IOP control, while surgery is still indicated when they fail to lower IOP sufficiently, or if the patient is not compliant to those methods of treatment (5).

Surgeries done for treatment of POAG are variable, including penetrating surgeries & non penetrating surgeries (6)

The example of penetrating surgeries is the trabeculectomy (both conventional or with modifications as application of mitomycin) & while examples of non-penetrating surgeries are multiple as deep sclerectomy, canaloplasty, gonioscopy-assisted transluminal trabeculotomy, goniotomy with kahook dual blade, or I stent implantation (7).

Trabeculectomy is a filtration procedure that reduces IOP by creating a connection between the anterior chamber & the subconjunctival space after excision of a part of the trabecular meshwork. Unfortunately, although it



reduces IOP effectively it is associated with a higher incidence of complications as hypotony, lost anterior chamber or suprachoroidal effusion (8).

Therefore, non-penetrating glaucoma surgeries as deep sclerectomy have been developed to improve the safety of the conventional filtering procedures(9).

Deep sclerectomy prevents the sudden hypotony that occurs in penetrating surgeries by creating progressive filtration of aqueous humor without perforating the eye through the preservation of the thin trabeculo-Descemet membrane (5)

Nevertheless, many authors think that deep sclerectomy is less effective than trabeculectomy for intraocular pressure reduction ,hence adding a new modification to deep sclerectomy is needed to increase its efficacy(10)



Aim of The Study

- ❖ The purpose of this study is to compare between deep sclerectomy with scleral bed fenestration & trabeculectomy as regard the efficacy (in IOP control) & the safety to the eye in medically un controlled primary open angle glaucoma patients.



Patients and Methods

❖ **Study design:**

It is a prospective, interventional, , randomized, parallel-group case control study.

❖ **Study Population:**

Study participants: will be 60 eyes of 60 patients with medically uncontrolled primary open angle glaucoma ,30 of whom will be subjected to trabeculectomy, while the other 30 will undergo deep sclerectomy with scleral bed fenestration.

Ethical approval:ⁱ

The study will be conducted after being approved from the institutional review board of faculty of medicine in Minia university and according to the tenets of the Declaration of Helsinki 2006. Therefore all patients in the study will be informed about the study details & they will sign an informed consent.

❖ **Place of the study:** The study will be conducted in Minia University Hospital.



Inclusion criteria:

- ❖ 1. Patients above 40 years old.
- ❖ 2. Primary open angle glaucoma patients who are uncontrolled on maximally tolerated medical therapy.
- ❖ 3-Phakic (with clear lens or visually insignificant cataract) patients.

Exclusion criteria:

- ❖ 1. Patients with any other type of glaucoma except for primary open angle glaucoma.
- ❖ 2. Patients who received previous laser therapy for glaucoma as laser trabeculoplasty.
- ❖ 3. Patients with severe ocular surface diseases as ocular cicatricial pemphigoid and severe dry eye
- ❖ 4. Previous ocular surgeries.
- ❖ 5. Patients with significant cataract.



❖ Ophthalmic examination:

All patients will be subjected to the following:

(A)History:

- ❖ Complete medical history
- ❖ Family history of primary open angle glaucoma.
- ❖ History of medications especially topical antiglaucoma drugs (number of bottles, duration of treatment, & presence of any of side effects of these drops) also history of any systemic medications that may affect the IOP as systemic beta blockers for hypertension, in addition, the patient should be asked about the intake of any systemic or topical steroids exclude steroid induced glaucoma.
- ❖ History or previous ocular interferences.

(B)pre-operative examination:

All patients will undergo a comprehensive ocular examination including:

- ❖ Uncorrected visual acuity (UCVA).
- ❖ Best corrected visual acuity (BCVA) by log MAR scale.
- ❖ Intraocular pressure by Goldman & air puff tonometers.
- ❖ Corneal pachymetry using pentacam to correlate IOP values with the corneal thickness.
- ❖ Anterior segment examination using slit-lamp biomicroscopy (sun kingdom, China).
- ❖ Gonioscopic examination using Goldmann 3 mirror contact gonio lens for anterior chamber angle assessment



- ❖ Fundus biomicroscopy using a +78 D condensing lens for assessment of optic disc changes.
- ❖ Optical coherence tomography of the optic nerve head by (Optovue Inc. Fairmont, CA).
- ❖ Visual field examination with Humphrey visual field analyzer.

(C) post-operative examination:

1-IOP is measured with Goldmann applanation tonometry & correlating the results with corneal pachymetry using pentacam.

- The schedule of IOP measurement will be done as follows: preoperatively one week before the surgery & postoperatively after 1 month, 3 months & then 6 months.

2-Postoperative assessment of the eye after both of the glaucoma surgeries:

- ❖ Slit lamp examination:
 - To assess the anterior chamber as regarding its depth (whether normal or shallow & if there is any irido corneal touch) & its content to exclude hyphemia.
 - Also, to assess the morphology of the bleb especially after trabeculectomy whether it diffuse, thin & avascular or not.
- ❖ IOP measurement by air puff (to exclude hypotony or IOP rise in early postoperative period as due to trapped methyl particles).
- ❖ Siedle test to exclude leakage in case of hypotony.



- ❖ Fundus or US examination to exclude suprachoroidal detachment or hemorrhage if there is hypotony or increased IOP.

3- Optical coherence tomography of the optic nerve head (OCT ONH) will be done to the patients 3months & 6 months post operatively with comparing its parameters to their values taken preoperatively to detect the rate of glaucomatous progression after the two types of surgeries.

-The OCT ONH parameters that will be measured are:

- ❖ Optic disc cupping.
- ❖ Retinal nerve fiber layer thickness in the four quadrants.
- ❖ Average total ganglion cell complex thickness.



Statistical Analysis:

- ❖ Data obtained will be collected & compared preoperatively and postoperatively for both groups who underwent the two types of glaucoma surgeries mentioned before.
- ❖ Results will be analyzed using IBM SPSS.
- ❖ P value < 0.05 will be considered significant.



References

1. Mélik Parsadaniantz S, Réaux-le Goazigo A, Sapienza A, Habas C, Baudouin C. Glaucoma: a degenerative optic neuropathy related to neuroinflammation? Cells. 2020;9(3):535.
2. Study VLEGotGBOD. Global estimates on the number of people blind or visually impaired by glaucoma: A meta-analysis from 2000 to 2020. Eye. 2024;38(11):2036.
3. Zhang N, Wang J, Li Y, Jiang B. Prevalence of primary open angle glaucoma in the last 20 years: a meta-analysis and systematic review. Scientific reports. 2021;11(1):13762.
4. Pantalon A, Feraru C, Tarcoveanu F, Chiselita D. Success of primary trabeculectomy in advanced open angle glaucoma. Clinical Ophthalmology. 2021:2219-29.
5. Correia Barbosa R, Gonçalves R, Bastos R, Alves Pereira S, Basto R, Viana AR, et al. Trabeculectomy Vs Non-penetrating Deep Sclerectomy for the Surgical Treatment of Open-Angle Glaucoma: A Long-Term Report of 201 Eyes. Clinical Ophthalmology. 2023:1619-27.
6. Díaz-Barreda MD, Sánchez-Marín I, Boned-Murillo A, Pérez-Navarro I, Martínez J, Pardina-Claver E, et al. Modification of Corneal Biomechanics and Intraocular Pressure following Non-Penetrating Deep Sclerectomy. Journal of Clinical Medicine. 2022;11(5):1216.
7. Barbosa RC, Gonçalves R, Bastos R, Pereira SA, Basto R, Viana AR, et al. Trabeculectomy Vs Non-penetrating Deep Sclerectomy for the Surgical Treatment of Open-Angle Glaucoma: A Long-Term Report of 201 Eyes. Clinical Ophthalmology (Auckland, NZ). 2023;17:1619.
8. Oh LJ, Wong E, Lam J, Clement CI. Comparison of bleb morphology between trabeculectomy and deep sclerectomy using a clinical grading scale and anterior segment optical coherence tomography. Clinical & Experimental Ophthalmology. 2017;45(7):701-7.
9. Kalala A, Gillmann K, Mermoud A. Prospective evaluation of penetrating deep sclerectomy in advanced open-angle glaucoma: filtration surgery adapted to resource scarcity in developing countries. Journal Français d'Ophtalmologie. 2020;43(3):228-36.
10. Dada T, Sharma A, Midha N, Angmo D, Gupta S, Sihota R. Efficacy of trabeculectomy combined with limited deep sclerectomy versus

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trabeculectomy alone: a randomized-controlled trial. Journal of Glaucoma.
2021;30(12):1065-73.
