

# Advanced Glaucoma - Keeping the Light at the end of the Tunnel

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## ABSTRACT

**Purpose:** To evaluate the efficacy and safety of trabeculectomy and non-penetrating deep sclerectomy (NPDS) in eyes with advanced glaucoma.

**Material and Methods:** Retrospective review of patients with advanced glaucoma submitted to surgery between January 2015 and May 2017. Absolute success was defined as postoperative intraocular pressure (IOP) <18 mmHg without application of hypotensive medications and qualified success as postoperative IOP <18 mmHg with or without hypotensive medications.

**Results:** 52 eyes were submitted to glaucoma surgery (34 NPDS and 18 trabeculectomy). The mean follow-up time was 16.2 months. 76.9% of the procedures were combined with cataract surgery. The absolute success was achieved in 82.7% of the cases and the qualified success in 96.2%. The mean IOP pre and postoperative was 22.24 and 11.93 mmHg, respectively. The mean number of preoperative hypotensive medications was 2.13 and the postoperative 0.25. The mean preoperative visual acuity was 0.42logMAR and the postoperative 0.22 logMAR. In the postoperative period, 7 cases of early hypotony, one of choroidal detachment and two of bleb cysts were recorded. Five patients required goniotomy and two selective laser trabeculoplasty for IOP control.

**Conclusions:** NPDS and trabeculectomy were effective in the treatment of patients with advanced glaucoma. There was a low rate of complications, and no cases of visual acuity decrease during the follow-up period. Control of IOP without hypotensive medications is associated with an improvement in quality of life and lower IOP fluctuations, which are crucial aspects for these patients.

**Keywords:** trabeculectomy, non-penetrating deep sclerectomy, advanced glaucoma, efficacy, quality of life.

## RESUMO

**Objetivo:** Avaliar a eficácia e segurança da trabeculectomia e esclerectomia profunda não penetrante (EPNP) em olhos com glaucoma avançado.

**Material e Métodos:** Foram revistos os casos de glaucoma avançado submetidos a cirurgia entre janeiro de 2015 e maio de 2017. O sucesso absoluto foi definido como pressão intraocular (PIO) no pós-operatório <18 mmHg sem aplicação de fármacos hipotensores oculares (FHO) e o sucesso qualificado como PIO no pós operatório <18 mmHg com ou sem colocação FHO.

**Resultados:** 52 olhos foram submetidos a cirurgia de glaucoma (34 realizaram EPNP e 18 trabeculectomia). O tempo médio de follow-up foi de 16,2 meses. 76,9% dos procedimentos foram combinados com cirurgia de catarata. Atingiu-se o sucesso absoluto em 82,7% dos casos e o sucesso qualificado em 96,2%. A PIO média pré e pós cirurgia foi 22,24 e 11,93 mmHg, respetivamente. O número médio de FHO pré cirúrgico foi 2,13 e o pós cirúrgico 0,25. A acuidade visual média pré cirúrgica foi 0.42logMAR e a pós cirúrgica 0.22 logMAR. No pós operatório registaram-se 7 casos de hipotonia precoce, um de descolamento coróideu e dois de quistos da ampola. 5 pacientes realizaram goniopunção e dois trabeculoplastia laser seletiva para controlo da PIO.

**Conclusões:** A EPNP e a trabeculectomia foram eficazes no tratamento de pacientes com glaucoma avançado. Registou-se uma baixa taxa de complicações, não se verificando diminuição da acuidade visual em nenhum dos casos. O controlo da PIO sem FHO está associado a uma melhoria da qualidade de vida e menores flutuações da PIO, aspetos fundamentais para estes pacientes.

**Palavras-chave:** Trabeculectomia, esclerectomia profunda não penetrante, glaucoma avançado, eficácia, qualidade de vida.

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## INTRODUCTION

Glaucoma is the leading cause of irreversible blindness in the world.<sup>23, 26</sup>

There is no universally accepted definition of advanced glaucoma. Regardless of the definition used, it is recognized that this group of patients presents a particular challenge for the ophthalmologist, due to their greater susceptibility for visual field and visual acuity loss.<sup>21</sup> Furthermore, the diagnostic tests are frequently more challenging and less reliable in advanced glaucoma, leading to a greater number of complementary tests to confirm disease progression.<sup>21</sup> In patients with advanced glaucoma, to avoid disease progression and further visual fields loss, the target intraocular pressure (IOP) is typically

lower. To accomplish that, the ophthalmologist has three alternatives: medical therapy, laser and surgical procedures, which can be combined.

All of these particularities dictate a closer monitoring for advanced glaucoma patients. The greater number of visits, complementary examinations, hypotensive agents and surgical procedures is associated with a higher personal and national health system financial cost, and more importantly, to a deterioration of patient's quality of life.<sup>21</sup>

Intraocular pressure fluctuation is a risk factor for visual fields progression in patients with advanced glaucoma, even with lower IOP.<sup>8</sup> In this particular group of subjects, less IOP fluctuation is expected in patients

submitted to trabeculectomy compared to patients undergoing ocular hypotensive drugs.<sup>17</sup>

The risk of visual impairment after glaucoma surgery has been described in some studies.<sup>1,13,18</sup> Visual compromise may be related to cataract, cystoid macular edema, suprachoroidal or vitreous hemorrhage, retinal detachment and uncontrolled intraocular pressure (IOP).<sup>10</sup> However, even after an otherwise uncomplicated surgery, loss of central vision has been described.<sup>1,10,13</sup> In the scientific community, this “wipe-out” phenomenon is debatable.

To date there are few publications with surgical results in patients with advanced glaucoma. The aim of the "Treatment of Advanced Glaucoma Study" a multicenter, randomized study, is to compare medical treatment with primary trabeculectomy for patients with newly diagnosed advanced glaucoma. This trial is expected to be concluded in the year 2020.

The present study was undertaken to retrospectively review the results of glaucoma surgery (trabeculectomy and NPDS) in eyes with advanced glaucoma.

## METHODS

This is a retrospective study of patients with advanced glaucoma submitted to surgery (trabeculectomy or NPDS) at the Department of Ophthalmology of Hospital Pedro Hispano (Matosinhos, Portugal) between January 2015 and May 2017.

The methodology of the study was designed in accordance with the tenets of the Helsinki Declaration.

Indications for surgery were insufficient IOP control, non-compliance to topical treatment or progression of the disease. Data recorded from each patient included age, sex, type and stage of glaucoma, number of IOP-lowering medications. Glaucoma type was defined by gonioscopy and slit-lamp examination, and advanced glaucoma was defined according to the Hodapp-Parrish-Anderson's criteria.<sup>14</sup>

All IOP measurements were performed with Goldmann applanation tonometry. Absolute success was defined as IOP < 18 mmHg 28 without glaucoma medical treatment,

and qualified success as IOP < 18 mmHg with or without ocular hypotensive agents.

The surgeries were performed by 2 surgeons.

## Pre-operative evaluation

The preoperative evaluation included: best corrected visual acuity (BCVA), anterior segment slit-lamp examination, Goldmann applanation tonometry, gonioscopy, evaluation of the ocular fundus after pharmacological mydriasis, visual fields (Humphrey visual field analyzer) and optical coherence tomography of optic disc (Optovue RTVue OCT®).

The preoperative BCVA, IOP, mean deviation (MD) of visual fields (VF) and retinal nerve fiber layer (RNFL) thickness were those evaluated at the last visit before surgery. BAVC was measured with a Snellen chart and was converted to the logMAR scale for comparison.

## Surgical technique

### NPDS

- 1- Either local anesthesia with monitored anesthesia care or general anesthesia was performed.
- 2- A 8-0 nylon traction suture was placed in the cornea adjacent to the superior limbus.
- 3- A fornix-based conjunctival flap centered at 12 o'clock was prepared, and the conjunctiva and Tenon's capsule were dissected.
- 4- Light cautery was applied as needed.
- 5- Sponges soaked in 0.2 mg/mL Mitomycin-C (MMC) were placed under the conjunctiva for 2,5 minutes, and then the subconjunctival space was carefully washed with balanced salt solution.
- 6- A 5 x 5 mm superficial (one-third-thickness) scleral flap, with a limbus-based approach, was created and dissected anteriorly until clear cornea was reached.
- 7- A smaller (4 x 4mm) deep scleral flap, with a limbus-based approach, was created, and dissection was continued anteriorly to the Schlemm's canal.
- 8- The inner wall of Schlemm's canal was carefully peeled off with forceps and the deep scleral flap excised.
- 9- An implant (AquaFlow® or Esnoper®) was placed on the exposed scleral stroma bed and secured with one 10-0 nylon suture.

- 10-The superficial scleral flap was sutured with interrupted 10-0 nylon suture.
- 11-The conjunctival flap was closed with 10-0 nylon suture.
- 12-At the end of the procedure, we checked to see if the conjunctival closure was watertight.
- 13-Cefuroxime and metilpednisolone subconjunctival injections were administered in the inferior quadrants.

## Trabeculectomy

- 1- Either local anesthesia with monitored anesthesia care or general anesthesia was performed.
- 2- A 8-0 nylon traction suture was placed in the cornea adjacent to the superior limbus.
- 3- A fornix-based conjunctival flap centered at 12 o'clock was prepared, and the conjunctiva and Tenon's capsule were dissected.
- 4- Light cautery was applied as needed.
- 5- Sponges soaked in 0.2 mg/mL Mitomycin-C (MMC) were placed under the conjunctiva for 2, to 35 minutes, and then the subconjunctival space was carefully washed with balanced salt solution.
- 6- A 5 x 5 mm half- thickness scleral flap, with a limbus-based approach, was outlined with a surgical blade, and then dissected.
- 7- A paracentesis in the peripheral cornea was performed.
- 8- Sclero-corneal tissue, including the trabecular meshwork, was then removed with microsurgical knife and Vannas scissors;
- 9- A peripheral iridectomy was performed;
- 10-The scleral flap was sutured with 10-0 nylon suture.

The 11th, 12th and 13th steps of NPDS technique were performed.

In the cases of combined surgery, phacoemulsification with intraocular lens (IOL) implantation was performed before the glaucoma surgery.

Postoperatively, all patients received a standard regimen of:

- topical antibiotic (quinolone), 5 times daily, discontinued after 2 weeks;
- topical corticosteroids (Dexamethasone phosphate 1mg/ml), 5 times daily during the first 4 to 6 weeks, and then tapered as needed.

Topical nonsteroidal anti-inflammatory was administrated during the first month after combined surgery.

Follow-up visits were scheduled at: 1 day, 1 week; 2 weeks, 1 and 3 months; after that, patients were followed within a 3-6 month-interval. Additional visits outside this regimen were scheduled according to the IOP or the presence of complications.

Postoperative laser suture lysis and associated ocular massage were conducted in a step-by-step manner until the expected target pressure was achieved. Laser suture lysis was conducted postoperatively when the IOP increased and/or the filtering bleb became more localized and flattened. Ocular massage was added routinely after laser suture lysis.

Main outcome measures of this study are BCVA, IOP, number of hypotensive medications, MD and RNFL thickness evaluated at the latest examination after surgery (range: 4 to 26 months).

The incidence of intraoperative and also of any postoperative complications such as flat anterior chamber, hypotony (defined as IOP < 5 mmHg), macular edema, choroidal detachment and status of bleb was recorded at all visits.

Statistical analysis was performed using SPSS (Version 21.0, SPSS Inc., Chicago, IL, USA). Shapiro-Wilk test was used to test for normality. Paired samples t-test was used to compare measurements before and after surgery, including mean IOP values and mean number of IOP-lowering medications. A value of  $p < 0.05$  was considered to be statistically significant.

## RESULTS

Records of 52 eyes were reviewed in this study. Demographic and baseline clinical characteristics of patients are summarized in Table 1 and 2. None of the eyes had previous glaucoma surgery.

Mean preoperative: BCVA was  $0.42 \pm 0.2$  logMAR; IOP was  $22.24 \pm 6.2$  mmHg; hypotensive medication was  $2.13 \pm 0.9$ . Average MD of the preoperative VF was

-22.79 ± 4.26 dB. Mean preoperative RNFL thickness was 66,4 ± 12,13 µm.

**Table 1** - Baseline clinical characteristics of patients undergoing glaucoma surgery for advanced glaucoma

Total (eyes)	52
Age (mean)	76,2 ± 7,2
Gender	
Male	28 (53,8%)
Female	24 (46,2%)
Type of glaucoma	
Pseudoexfoliation	20
Primary open-angle	32
BCVA (mean, LogMAR)	0.42 ± 0,2
IOP (mean, mmHg)	22.24 ± 6.2
Number of hypotensive medications (mean)	2.13 ± 0.9
VF MD (mean, dB)	-22.79 ± 4.26
RNFL thickness (mean, µm)	66,4 ± 12,13

**Table 2** - Baseline clinical characteristics of patients undergoing non-penetrating deep sclerectomy (NPDS) and trabeculectomy for advanced glaucoma.

	NPDS	Trabeculectomy	t-test
Total (eyes)	34	18	
Age (mean)	75,4 ± 6,9	77,8 ± 7,5	p = 0,094
Gender			
Male	20 (58,8%)	8 (44,4%)	
Female	14 (41,2%)	10 (55,6%)	
Type of Glaucoma			
Pseudoexfoliation	13 (38,2%)	7 (38,9%)	
Primary open-angle	21 (61,8%)	11 (61,1%)	
BCVA (mean, LogMAR)	0,43 ± 0,21	0,39 ± 0,23	p = 0,096
IOP (mean, mmHg)	21,58 ± 5,21	23,47 ± 6,73	p = 0,041
Number of hypotensive medications (mean)	1,94 ± 0,81	2,5 ± 1,21	p = 0,001
VF MD (mean, dB)	-21,9 ± 4,91	-24,85 ± 6,2	p = 0,036
RNFL thickness (mean, µm)	70,83 ± 12,62	63,33 ± 13,86	p = 0,028

**Table 3** - Show BCVA, IOP, number of hypotensive medications, success rates, VF MD and RNFL thickness after filtration surgery in our patients. Mitomycin C was used in all surgeries. Thirty four eyes had NPDS and eighteen had trabeculectomy. Most of the surgeries (76,9%) were combined with phacoemulsification and IOL implantation. There were no intraoperative complications.

n	52
Follow-up (months)	
Range	4 - 26
Mean	16,2 ± 4,8
BCVA (mean, logMAR)	0,22 ± 0,14
IOP (mean, mmHg)	11,93 ± 4,45
Number of hypotensive medications (mean)	0,25 ± 0,17
Absolute success (%)	82,7
Qualified success (%)	96,2
IOP reduction (mean, %)	46,4
VF MD (mean, dB)	-23,62 ± 5,51
RNFL thickness (mean, µm)	65.9 ± 11,24

Data from last visit after glaucoma surgery

**Table 4** - NPDS group - Preoperative and postoperative data.

	NPDS(n=34)		
	Preoperative	Postoperative	p
BCVA (mean, logMAR)	0,43 ± 0,21	0,21 ± 0,13	0,001
IOP (mean, mmHg)	21,58 ± 5,21	11,07 ± 4,1	0,001
Number of hypotensive medications (mean)	1,94 ± 0,81	0,15 ± 0,12	0,001
Absolute success (%)	88,24		
Qualified success (%)	100		
IOP reduction (mean, %)	48,7		
VF MD (mean, dB)	-21,9 ± 4,91	-22,84 ± 4,63	0,61
RNFL thickness (mean, µm)	70,83 ± 12,62	68,33 ± 10,81	0,42

**Table 5** - Trabeculectomy Group - Preoperative and postoperative data.

	Trabeculectomy (n=18)		
	Preoperative	Postoperative	
BCVA (mean, logMAR)	0,39 ± 0,23	0,24 ± 0,15	0,001
IOP (mean, mmHg)	23,47 ± 6,73	13,55 ± 5,9	0,001
Number of hypotensive medications (mean)	2,5 ± 1,21	0,47 ± 0,3	0,001
Absolute success (%)		72,2	
Qualified success (%)		89,9	
IOP reduction (mean, %)		42,3	
VF MD (mean, dB)	-24,85 ± 6,2	-25,43 ± 4,54	0,49
RNFL thickness (mean, µm)	63,33 ± 13,86	61 ± 8,54	0,31

Seidel occurred in 8 (15,4%) eyes, 4 (11,8%) after NPDS and 4 (22,2%) after trabeculectomy. Early hypotony occurred in 7 (13,5%) eyes, 3 (8,8%) after NPDS and 4 (22,2%) after trabeculectomy. These complications were successfully managed with conservative medical treatment, except one eye that needed a revision of conjunctival closure with 8-0 vicryl suture.

One (5,5%) choroidal detachment and two (11%) cases of bleb cysts occurred after trabeculectomy. The choroidal detachment was conservatively managed, and bleb cysts were successfully managed with bleb needling, with no further complications.

In the NPDS group, 5 (15,6%) eyes required Nd:YAG Laser goniopuncture for IOP control. One of this patients developed transient hypotony after this procedure. No other complications occurred.

Two (3,8%) patients (one in each group) required selective laser trabeculoplasty for IOP control.

There were no cases of postoperative flat anterior chamber, macular edema, blebitis or endophthalmitis. No patient experienced wipe-out phenomenon.

At the last follow-up visit, the mean BCVA was  $0,22 \pm 0,14$  logMAR ( $p = 0.001$ , paired t test). After a mean follow-up of 16,2 months, a significant reduction of IOP (46,4%) was achieved (from  $22,24 \pm 6,2$  to  $11,93 \pm 4,45$  mmHg postoperatively,  $p = 0.001$ , paired t test). Mean

postoperative hypotensive medications was significantly reduced  $0,25 \pm 0,17$  ( $p = 0.001$ , paired t test).

Absolute and qualified successes were achieved in 82,7% and 96,2% of the eyes, respectively.

At the last visit, the mean postoperative VF MD and RNFL thickness were  $-23,62 \pm 5,51$  dB and  $65,9 \pm 11,24$  µm, respectively. No statistically significant differences were found between VF MD and RNFL thickness values before and after glaucoma surgery (respectively,  $p = 0.56$ ,  $p = 0.35$ , paired t test).

## DISCUSSION

The goal of glaucoma treatment is to control IOP and maintain a stable visual function, with minimal impairment of our patient's quality of life.<sup>15</sup> Inherent to this strategy is the concept of the "target IOP" level, corresponding to an IOP interval which minimizes further damage to the visual field and a rate of progression unlikely to affect the quality of life of the patient. As such, it should be individualized and adjusted during the course of the disease.<sup>15, 25</sup> The greater the pre-existing glaucoma damage, the lower the target IOP should be. For advanced glaucoma damage was suggested an intraocular pressure  $\leq 12$  mmHg.<sup>31</sup>

It is important to diagnose glaucoma at an early stage to preserve the maximum visual function. The majority of patients included in this study was first diagnosed with advanced glaucoma. So our goal was no longer to protect a large field of vision, but rather a critical one, crucial for our patients quality of life and self-care. Patients in this stage of glaucoma have a high risk of further disease progression, so a 40% decrease of IOP from baseline is proposed by some authors.<sup>22</sup> To achieve this target IOP, surgical procedures are often required.<sup>24</sup> Even if advanced glaucoma could be controlled medically, the lack of compliance with medication regimens may induce significant short and long term IOP fluctuations, with a deleterious effect on the visual outcomes. Glaucoma procedures are often associated with a more effective IOP control and minimal IOP fluctuations, protecting what's left of the visual field.<sup>17</sup>

Due to a lower neuronal reserve in advanced glaucoma, the risk of visual impairment after glaucoma surgery remains a concern and has been described in some

studies.<sup>1,13,18</sup> There is no consensus in the ophthalmological community regarding the risk of immediate unexplained visual field loss (wipe-out phenomenon) after filtering procedures in patients with glaucoma.<sup>1,2,10,16,19,20,22,29</sup> It is thought that sudden, intraoperative ocular hypotony is the underlying mechanism of this phenomenon.<sup>29</sup> On the other hand, some authors<sup>2,19,20,29</sup>, with a large number of surgeries performed do not describe any case of wipe-out phenomenon.

A recent study<sup>30</sup> found that the absence of postoperative laser suture lysis is a significant risk factor for ocular hypotony after trabeculectomy. Awai M. *et al*<sup>6</sup> defends that trabeculectomy with MMC, tight sutures for the closure of scleral flaps, followed by postoperative laser suture lysis and ocular massage, reduces the risk of fixation loss in eyes with advanced glaucoma, avoiding the occurrence of hypotony and excess IOP fluctuations after surgery. We performed glaucoma surgery following this principles. In our study no patient experienced wipe-out phenomenon during the follow-up period.

Some ophthalmologists do not perform cataract surgery in patients with advanced glaucoma with low preoperative visual acuity regarding that surgery as an high risk procedure, unlikely to bring great benefit to the patient. Other groups, however, demonstrated that cataract surgery improves visual acuity and quality of life in patients with advanced glaucoma.<sup>32</sup> Different surgical options are available for patients with cataract and concomitant glaucoma. If the IOP is controlled, cataract surgery can be performed as a stand alone procedure, and glaucoma surgery postponed. After phacoemulsification pressure spikes may occur, which should be taken in account by the ophthalmologist.<sup>28</sup> Other option consists in performing glaucoma surgery first. Most patients, even those without cataract at the time of the glaucoma surgery, will need phacoemulsification in the future, especially when MMC is used.<sup>3,28</sup> But the cataract surgery performed after a filtration procedure has a risk of reducing the efficiency of first operation.<sup>9</sup> Thus, a combination of glaucoma and cataract surgeries seems a reasonable approach in these patients, many of them elderly, with comorbidities that preclude multiple surgical procedures. Other advantages of performing combined surgeries include the possible immediate increase of visual acuity and economical aspects.<sup>7</sup> In this study, combined surgery

was performed in more than three quarters of the patients, with good functional and safety profiles.

In this study we reviewed the outcome of advanced glaucoma patients submitted to trabeculectomy or NPDS. Both procedures achieved good IOP control (mean IOP reduction >40%), with overall absolute and qualified successes achieved in 82,7% and 96,2% of the eyes, respectively. Setting as the threshold for surgical success values of IOP  $\leq$  12 mmHg postoperatively, would correspond an absolute success of 51,9% and qualified success of 53,8%. We found statistically significant differences among the baseline characteristics of the patients in the different groups. That means that we can not compare the postoperative data of NPDS with trabeculectomy. However, in both groups a reduction of ocular hypotensive medications and no statistically significant disease progression during the follow-up time was noted. The safety profile was also good with both techniques, with low rate of complications and with no cases of visual acuity decrease during the follow-up period. The NPDS group presented a lower relative number of postoperative complications compared to the trabeculectomy group.

To our knowledge, in the literature there are limited published data of subjects with advanced glaucoma submitted to NPDS.<sup>4,5,12</sup> The results of our study suggest that NPDS is effective in this particular group of patients. Since this is classically a safer procedure when compared to trabeculectomy (the results of our study also indicate that), NPDS may be a valuable surgical alternative in the treatment of advanced glaucoma, providing a significant reduction in IOP and hypotensive medication with a good profile risk.

The IOP control without ocular hypotensive agents is associated with an improvement in the quality of life and lower IOP fluctuations, which may be crucial for patients with advanced glaucoma.

There are some limitations in our study such as: retrospective methodology, small sample size, variable follow-up length and differences between baseline characteristics of patients submitted to NPDS and trabeculectomy. More trials are required, with larger number of patients, longer time of follow up to confirm the conclusions suggested by this study.

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Sem conflitos de interesse.  
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