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Nonpenetrating deep sclerectomy: a 6-year retrospective study

Y. LACHKAR, J. NEVERAUSKIENE, M.-N. JEANTEUR-LUNEL, H. GRACIES, M. BERKANI, M. ECOFFET, J. KOPEL, G. KRETZ, P. LAVAT, M. LEHRER, F. VALTOT, P. DEMAILLY

Glaucoma Institute, Foundation Hospital Saint-Joseph, Paris - France

PURPOSE. *Nonpenetrating trabeculectomy, also called nonpenetrating deep sclerectomy (NPDS), is a filtering surgery where the internal wall of Schlemm's canal is excised, allowing subconjunctival filtration without actually entering the anterior chamber. This technique was developed to minimize the complications of trabeculectomy. The authors investigated its safety and efficacy in a retrospective noncomparative study.*

METHODS. *A total of 258 eyes (179 patients, mean age 61.4±11.56 years) with uncontrolled open angle glaucoma with prior medical therapy were treated. NPDS with a biocompatible collagen device (157 eyes) sutured to deep scleral bed or with the use of a 5-fluorouracil sponge (90 eyes) were analyzed. The main outcome measure was postoperative intraocular pressure (IOP) with an average follow-up of 54.4±17.07 months (range 1-85). Efficacy was determined 1 month, 3 months, and every 6 months after the procedure for 6 years.*

RESULTS. *Mean preoperative IOP was 24.47±5.92 mmHg. Mean postoperative IOP was 14.44±5.31 mmHg (average lowering of the IOP was 38.94±23.81%) at 1 month, 15.16±4.57 mmHg (35.73±21.35%) at 3 months, 15.87±4.24 mmHg (32.45±20.52%) at 6 months, 16.32±4.53 mmHg (29.96±23.69%) at 12 months, 17.12±4.45 mmHg (26.51±23.93%) at 18 months, 16.77±4.44 mmHg (28.18±21.73%) at 24 months, 16.43±4.15 mmHg (28.89±23.69%) at 30 months, 16.34±4.12 mmHg (30.05±21.61%) at 36 months, 16.16±4.01 mmHg (30.06±22.55%) at 42 months, 15.71±3.74 mmHg (32.49±19.08%) at 48 months, 15.61±3.48 mmHg (31.26±21.01%) after 5 years, and 15.81±3.79 mmHg (33.73±20.9%) after 6 years. YAG goniopuncture was performed in 47.3% of cases with a mean follow-up of 12±13 months. These goniopunctures were effective in lowering IOP after a long-term follow-up (24 months). Additional 5-fluorouracil injections were used in 7% of cases. Visual field (Octopus or Humphrey mean defect and corrected loss variance or loss variance) was not modified (p<0.01). Number of preoperative glaucoma medications was 2.01±0.58 and number of postoperative glaucoma medications was 0.85±0.92. Complications were peroperative microperforations in 27 eyes (10.5%), shallow anterior chamber in 2 eyes, hyphema in 2 eyes (0.8%), cataract in 5 eyes (2%), and dellen in 1 eye (0.4%). No cases of endophthalmitis or choroidal detachment were found. After surgery, 23 eyes (8.9%) required a new filtering surgical procedure, and diode laser cyclophotocoagulation was necessary in 2 eyes (0.8%). The probability success rate, defined as an IOP lower than 21 mmHg, was 66.46% (Kaplan Meier) at 60 months off all glaucoma medications and 80.32% with medical or new surgical treatment.*

CONCLUSIONS. *NPDS appears to be an effective and safe filtering procedure for lowering IOP and could be an alternative to trabeculectomy in open angle glaucoma with the advantage of having fewer complications. (Eur J Ophthalmol 2004; 14: 26-36)*

KEY WORDS. *Deep sclerectomy, Glaucoma, Nonpenetrating glaucoma surgery*

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INTRODUCTION

Glaucoma is the second leading cause of vision loss after cataract. The number of people with primary glaucoma worldwide in the year 2000 has been estimated at nearly 66.8 million, with 6.7 million having bilateral blindness.

Trabeculectomy has remained the mainstay of surgical treatment of glaucoma since its introduction by Cairns (1), and is considered the standard filtration operation for glaucoma. In this procedure, aqueous humor is drained from the anterior chamber into the subconjunctival space through a sclerectomy, which involves a full-thickness penetration of the globe under a partial-thickness scleral flap. This flap is utilized to modulate aqueous flow in order to minimize the risk of postsurgical complications such as infections or overfiltration and hypotony.

Nonpenetrating deep sclerectomy (NPDS) is a promising alternative to standard trabeculectomy. Advantages may be cited for recommending this procedure, including avoidance of prolonged hypotony and less inflammation postoperatively. Associated with an undisturbed anterior chamber is more rapid recovery of visual acuity (VA). A peripheral iridectomy is typically part of a trabeculectomy, but is not performed in nonpenetrating filtration surgery. Earlier studies have described the short- and medium-term tonometric results of NPDS, but there is little information about long-term outcomes.

The purpose of this study is to evaluate the effectiveness of NPDS with or without collagen implant in patients with open angle glaucoma (OAG) who had their first NPDS after maximum tolerated medical treatment, and to examine the relationship of intraocular pressure (IOP) and visual function with long-term follow-up.

MATERIALS AND METHODS

Patient selection

The charts of all consecutive phakic patients who underwent their first NPDS between January 1993 and December 1997 were reviewed. Eligibility criteria were a diagnosis of primary OAG, age older than 30 years, and a minimum follow-up of 2 years after surgery (with at least three visual fields available during this period and at least one baseline preoperative field). Coexisting retinal or neurologic disease that may have affected the visual field was a criterion for exclusion. Primary OAG was further defined as the presence of a reproducible visual field defect consistent with glaucoma and the appearance of the optic disc with a pretreatment IOP of 22 mmHg or more and an open angle with no signs of secondary causes of glaucoma.

Indications for surgery, while the patient was undergoing maximally tolerated medical therapy, were as follows: 1) IOP that in the examiner's opinion placed the patient at high risk for glaucomatous progression, 2) worsening of the visual field as judged by the examining physician, and/or 3) deterioration of the optic disc as judged by the examining physician.

For each patient, the following data were collected: age at the time of surgery; sex; race; the eye to undergo surgery; preoperative VA; mean of the last three IOP readings recorded during the 3 months preceding NPDS; baseline preoperative visual field(s); prior argon laser trabeculoplasty (LTP), if any, and the date it was performed; length of prior medical treatment and type and number of medications used; date of surgery; and perioperative and postoperative complications. Additionally, we recorded the VA, IOP, medications used, and any complication or concurrent problem that may have affected the VA or visual field for each postoperative visit. We also noted the date, technique, and complications of cataract extraction or other filtering surgery after NPDS.

Surgical technique

Surgical procedures were performed by eight surgeons participating in this study using local peribulbar anesthesia.

A 7-0 superior peripheral corneal traction silk suture or a suture in the superior rectus muscle was used. A limbus based conjunctival flap was dissected superiorly, and the sclera was exposed.

A superficial scleral flap (5 mm wide and 6 to 7 mm long) with one third of thickness was dissected anteriorly into the clear cornea using a no. 69 Beaver blade (Alcon Surgical, Fort Worth, TX).

The technique of NPDS with collagen implant

A second triangular, deep scleral limbic base flap was dissected and excised leaving only a thin layer of deep sclera over the ciliary body and the sclera. Anteriorly, the dissection was made downwards to remove Schlemm's canal (SC) and juxtacanalicular trabecula (inner part of SC). Excision of the corneal stroma was performed more anteriorly down to Descemet's membrane. This allowed aqueous humor to percolate through the thin trabeculo-Descemetic membrane. The collagen implant (Staar Surgica AG, Nidau, Switzerland) was then secured to the deep sclera by placing a 10/0 nylon suture at the midpoint of the triangular bed. The rectangular scleral flap was then closed with two 10/0 monofilament nylon sutures. The conjunctiva was sutured with 8/0 vicryl continuous suture.

The technique of NPDS with application of 5-fluoruracil (without collagen implant)

The surgical sponge was trimmed and soaked in 5-fluoruracil (5-FU) 50 mg/ml and then applied between the superficial scleral flap and the deep scleral plane, taking care to avoid contact between the cut conjunctival edge and the sponge. The sponge was left in place for 5 minutes. Following this the sclera was thoroughly irrigated with 20 ml balanced salt solution.

After removing SC and juxtacanalicular trabecular meshwork, the superficial scleral flap was not sutured. The conjunctiva was sutured with 8/0 vicryl continuous suture.

Postoperatively, patients were treated with topical antibiotics, corticosteroids, and/or nonsteroidal anti-inflammatory medications for 3 to 4 weeks. No bandage was required. Postoperative follow-up was done on an ambulatory basis on days 1, 3, 8, 14, 30, 60, and 90, and every 6 months.

When the filtration through the trabeculo-Descemetic membrane was suspected to be insufficient because of flat filtration bleb and/or elevated IOP, Nd:YAG laser goniopuncture was performed at the site of surgery.

Goniopuncture was performed using a LASAG 15 gonioscopy contact lens (CGA1) (Lasag, Thun, Switzerland) at the site of the trabeculo-Descemetic membrane using the free running Q-switch mode with an energy ranging from 2 to 7 mJoules (from 2 to 15 burns). After the laser treatment, all patients were treated with topical prednisolone acetate 3 times a day for 3 days.

If there were signs of bleb failure within the first 21 postoperative days, additional subconjunctival 5-FU injections (5 mg via a 30-gauge needle into the bleb) were given.

The criteria for surgical outcome were defined as follows. Surgical success was defined as an IOP greater than 5 mmHg and less than 22 mmHg, with or without the use of antiglaucoma medications and at least a 30% reduction. Complete success was defined as IOP of 21 mmHg or less without medications. Qualified success required antiglaucoma medications, ocular massage, or needle revision of the deep sclerectomy (DS0) site, or Nd-YAG laser goniopuncture to achieve the target pressure (IOP of 21 mmHg or less). Surgical failure was defined as IOP of 22 mmHg or more while receiving maximally tolerated antiglaucoma medications or the need for subsequent glaucoma surgery.

Visual field evaluation

Automated perimetry (G1, 32 programs of Octopus, Interzeags, or 24-2 threshold tests of Humphrey Field Analyzer) was used to monitor visual field status. The same visual field program was used to examine each eye during follow-up. We used mean defect (MD), corrected pattern standard deviation (CPSD), or corrected loss variance (CLV) to analyze visual fields.

Statistical methods

The nonparametric Wilcoxon signed rank test was used to compare IOP. Long-term success rate was analyzed with the Kaplan-Meier survival curve.

RESULTS

General characteristics

Table I shows the preoperative characteristics of our patient population. A total of 258 eyes (130 right eyes, 128 left eyes) from 179 patients (mean age 61.4±11.56 years) (83 women, 96 men) were eligible.

A total of 253 eyes (98.0%) received long-term (>1 year) medical treatment before surgery. For one patient no documentation regarding the length of preoperative medical treatment was available. Four eyes (1.6%) were known to have short length (<1 year) of medical therapy before NPDS. The usual preoperative therapeutic regimen consisted of a beta-blocker, a miotic, alpha 2 agonist, and an oral or local car-

TABLE I - PREOPERATIVE CHARACTERISTICS OF THE PATIENT POPULATION

Characteristics	Value
No. of patients	179
men	96
women	83
No. of eyes	258
right	130
left	128
Age (yr)	
range	30-82
mean ± SD	61.4±11.56
Preoperative visual acuity	
range	0.1-1.25
mean ± SD	0.68±0.29
No. of preoperative medications	
mean ± SD	2.01±0.58
Prior ALT, no. of eyes (%)	
yes	100 (38.75%)
no	158 (61.25%)

SD = Standard deviation; ALT = Argon laser trabeculoplasty

TABLE II - MEAN (±SD) IOP AND AVERAGE LOWERING OF IOP IN PERCENT AT EVERY POSTOPERATIVE VISIT FOR ALL OF THE STUDY EYES

Time after NPDS (mo)	No. of eyes	Mean IOP ± SD	Average lowering of IOP ± SD
1	257	14.44±5.31	38.94±23.81
3	254	15.16±4.57	35.73±21.35
6	254	15.87±4.24	32.45±20.52
12	251	16.32±4.53	29.96±23.69
18	247	17.12±4.45	26.51±23.93
24	245	16.77±4.44	28.18±21.73
30	234	16.43±4.15	28.89±23.69
36	216	16.34±4.12	30.05±21.61
42	196	16.16±4.01	30.06±22.55
48	178	15.71±3.74	32.49±19.08
60	129	15.61±3.48	31.26±21.01
72	52	15.81±3.79	33.73±20.9

NPDS = Nonpenetrating deep sclerectomy; IOP = Intraocular pressure; SD = Standard deviation

TABLE III - PROBABILITIES OF SUCCESS (Kaplan-Meier survival analysis) WITH MEDICATIONS FOR 258 EYES AFTER NPDS

Duration of follow-up (mo)	IOP 6-15 mmHg (%)	IOP 6-18 mmHg (%)	IOP 6-21 mmHg (%)
1	61.6	87.2	99.6
3	56.9	78.8	98.8
6	46.3	76.9	98.4
12	40.9	76.4	97.5
24	37.8	69.9	96.5
36	41.0	72.8	90.7
48	47.5	80.4	86.1
60	50.9	79.8	80.3

bonic anhydrase inhibitor used alone or in combination. Mean number (±standard deviation (SD)) of preoperative mediations was 2.01 (±0.58). Mean preoperative IOP (±SD) was 24.47 mmHg (±5.92).

Before surgery, argon laser trabeculoplasty (ALT) was used in 100 eyes (38.75%); amongst these 100 eyes, ALT 360° was performed in 94 eyes (36.4%) and ALT 180° in 6 eyes (2.3%).

Intraocular pressure

IOP decreased from a mean (±SD) preoperative value of 24.47 mmHg (±5.92) to 15.81 mmHg (±3.79) at the last postoperative visit for all of the study eyes. Table II shows the mean (±SD) IOP and average lowering of IOP as percentage at every postoperative visit for all of the study eyes. Table III presents probabilities of success with medications at different IOP values.

Patients were followed for 1 to 85 months (average follow-up was 54.4±17.07 months). Ninety-six eyes (37.2%) did not undergo any further (laser or incisional) surgery, and had no complications.

A total of 25 eyes (9.7%) underwent additional glaucoma surgery due to either evidence of further glaucomatous damage or unacceptably high IOP. Among these 23 eyes, 2 had transscleral diode laser cyclophotocoagulation. Fifteen eyes underwent repeat NPDS with mitomycin C. Eight remaining eyes had a trabeculectomy. The average number of medications (±SD) used decreased from 2.01 (±0.58) before

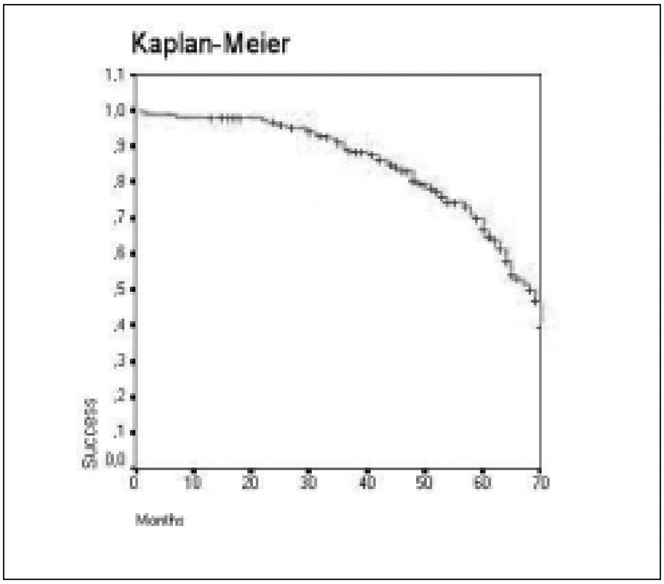

Fig 1 - *Probability success rate defined with Kaplan-Meier method without treatment.*

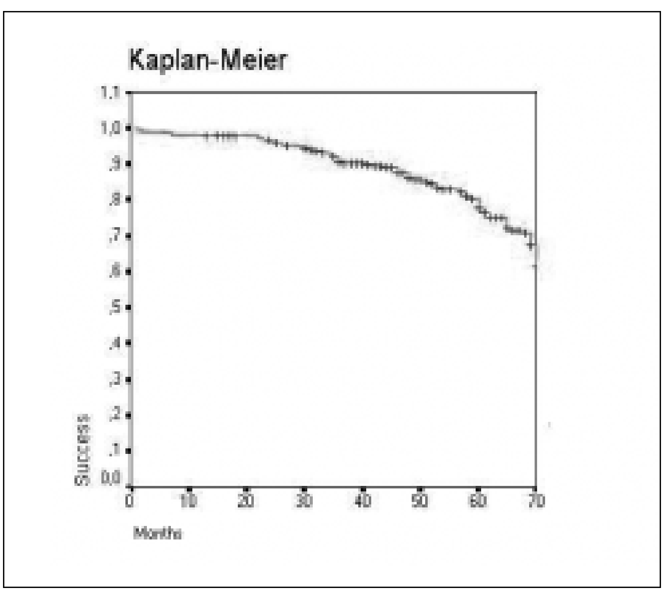

Fig 2 - *Probability success rate defined with Kaplan-Meier method with treatment.*

surgery to 0.84 (±0.8) at the last follow-up. Cataract occurred in 3 eyes (1.2%).

The probability success rate, defined with the Kaplan-Meier method as an IOP lower than 21 mm Hg, was 66.46% at 60 months without treatment (Fig. 1) and 80.32% with medical or new surgical treatment (Fig. 2). However, if the more stringent criteria are applied there is a steady drop-out as more eyes fail to survive, until at 60 months 50.9% of eyes maintain an IOP < 15 mmHg (Tab. III).

Visual acuity

The mean (±SD) VA changed from 0.68 (±0.29) to 0.60 (±0.31) at the last follow-up (p<0.01). At the last follow-up, VA was within 1 line or better than preoperative levels in 220 of 259 eyes.

In four eyes, significant VA loss was attributed to worsening glaucoma. For all other patients, VA loss could be explained by development or progression of cataract. Seventeen patients underwent cataract extraction.

Visual field

Visual field (Octopus, Humphrey) MD, PSD, or CLV indices were not modified. Preoperative MD and CLV were 8.25 and 23.08, respectively, and postoperative MD and CLV at 60 months were 24.73 and 7.78 (p<0.01). Only four patients showed evidence of deterioration in the visual field in the presence of good IOP control.

Surgical complications

The NPDS was associated with collagen device (CD) in 157 (60.9%) eyes and with adjunctive use of 5-FU (50 mg, 5 minutes) in 90 (34.9%) eyes. No major intraoperative complications were encountered. Table IV shows the complications and additional treatment in the follow-up period. Of 179 patients (258 eyes) who had NPDS, 27 (10.5%) had a microperforation of Descemet window at the time of surgery without conversion to trabeculectomy. Of these cases, 2 eyes (0.8%) had flat or shallow anterior chambers and 2 eyes (0.8%) had hyphema. One patient (0.4%) had dellen.

Nd:YAG goniopuncture was used in 47.3% of cases at 1 to 59 months postoperatively; among these 128 eyes, goniopuncture was used in 32 eyes (12.5%) in the early postoperative period and in 96 eyes (37.1%) in the late postoperative period.

Argon laser iridoplasty was used in 25 eyes (9.7%): for treatment of goniosynechiae after NPDS in 16 eyes and for treating iris prolapse after goniopuncture in 9 eyes. Bleb encapsulation was noted in 18 (7.0%) eyes.

TABLE IV - INTRAOPERATIVE, EARLY, AND LATE POSTOPERATIVE COMPLICATIONS AND CHARACTERISTICS OF POSTOPERATIVE FOLLOW-UP OF NONPENETRATING DEEP SCLERECTOMY (NPDS)

Complications and characteristics of treatment	No. (%) of eyes
Intraoperative	
Microperforation of Descemet	27 (10.5)
Early (within 2 months)	
Hyphema	2 (0.8)
Shallow/flat anterior chamber	2 (0.8)
Dellen	1 (0.4)
Subconjunctival 5-FU	18 (7.0)
Nd:YAG goniopuncture	32 (12.5)
Iris prolapse after goniopuncture	9 (3.5)
Goniosynechiae	16 (6.2)
Revision of NPDS and trabeculectomy	1 (0.4)
Late	
Nd:YAG goniopuncture	96 (37.1)
Endophthalmitis	-
Progressive cataract	3 (1.2)
Reoperation	
NPDS with mitomycin C	15 (5.8)
Trabeculectomy	8 (3.1)
Transscleral diode laser	
Cyclophotocoagulation	2 (0.8)

FU = 5-fluoruracil solution

In all cases additional subconjunctival 5-FU injections into the bleb were given. There were no complications traditionally associated with a trabeculectomy, including Tyndall, formations of the posterior synechiae, choroidal detachment, or endophthalmitis.

DISCUSSION

Recently, there has been renewed interest in nonpenetrating glaucoma surgery. The first results of a case series of nonpenetrating deep sclerectomy were reported in 1972 by Krasnov (2). In this procedure, the lumen of Schlemm's canal was externalized for 2 hours under a limbus-based conjunctival flap. There was no control group. The complications of the procedure were not described. The success rate (IOP < 19 mmHg) was estimated to be 83% of cases. In 1984, Zimmerman and co-authors (3) performed nonpenetrating deep sclerectomy ("nonpenetrating trabeculectomy") in 28 eyes with glaucoma associated with aphakia. After preparing a fornix-based conjunctival flap, a superficial partial-thickness scleral flap was dissected into clear cornea. A second deeper flap was then dissected forward to the canal of Schlemm, and was excised. The superficial scleral flap was then loosely approximated and the conjunctival incision was closed. At 1 year postoperatively, mean IOP was 17.5 mmHg, and 65% of these eyes required antiglaucoma medications. In 1990, Fyodorov et al (4) modified this technique utilizing a collagen drainage device placed under the scleral flap.

More than in conventional trabeculectomy, the success of this mode of antiglaucomatous surgery is linked to the intraoperative anatomic outcome (5-11). Most importantly, removing the outer wall alone does not address the disease of primary open-angle glaucoma. Reducing resistance to outflow can be achieved

TABLE V - NONPENETRATING DEEP SCLERECTOMY: CLINICAL RESULTS (listed by length of follow-up)

Authors	No. eyes	Follow-up (yr)	Implants or 5-FU	Preop. IOP (mmHg)	Postop. IOP (mmHg)	% Success	Goniopuncture (%)	Complications (%)	Perforations (%)
Bas et al (14)	34	5.3	No	25.64±7.28	15.31±4.28	92	NA	8	26
Sanchez et al (12)	86	9.7	CD	26.9±8.8	14±308	NA	15	3	NA
	82	9.7	No	25.8±8.5	17.8±803	NA	15	1	NA
Hamard et al (28)	27	11	5-FU	23.5±501	15.5±2.9	57.3	40.7	0	7.4
	15	11	CD	22.6±6.9	16.2±3.9	66	33	0	0
Sourdille et al (31)	72	13.8	SK gel	26.3±5.22	15.4±3.1	NA	NA	0	9.7
Massy et al (32)	50	14.2	No	24.32±7.21	14.86±4.59	81	24	4	14
Mermoud et al (15)	44	14.4	CD	26.7±7.3	14±3.5	69	23	0	10
Demailly et al (11)	148	20	CD	23.3±5.2	16.1±4.7	68	34.6	1	9.45
	55	20	5-FU	24.1±6.3	15.8±4.6	69	32.4	0	16.3
Karlen et al (33)	100	36	CD	27.8±8.6	14±3.5	44.6	41	0	3.1
Shaarawy et al (29)	105	43.2	CD	26.8±7	11.8±3	63	NA	0	NA
Dahan and Drusedau (34)	86	46	No	30.4±6.1	15.35±4.05	NA	NA	1.1	NA
Current study	157	60	CD	24.47±5.92	15.72±5.1	75	47.3	1	9.45
	90	60	5-FU	24.36±5.8	15.6±3.48	75.7	46.9	0	11.1

IOP < 21 mmHg off all glaucoma medications. Complications: athalamia, CD = Collagen device, inflammation hypotony; non bleb-related complications: flat anterior chamber, choroidal detachment, inflammation, hypotony
5-FU = 5-fluoruracil solution; IOP = Intraocular pressure; NA = Not applicable; SK gel = Implant for non penetrating surgery

only by understanding the importance of dealing with the inner wall of Schlemm's canal and with the juxtacanalicular trabecular meshwork. The reason that the newer versions of the NPDS are so promising is that they treat this diseased site, either directly or indirectly (5, 6, 7, 9). In the collagen implantation method, the juxtacanalicular and corneoscleral meshwork is removed physically with forceps. Although exposure of Descemet membrane is performed during the collagen implantation technique as well, it is used for a different reason: to facilitate a larger opening of Descemet's membrane by an Nd:YAG laser. The collagen implant permits this second step procedure by maintaining a translucent space behind Descemet's membrane. Because only recently have the inner wall and trabecular meshwork been physically removed as a modification of the collagen implantation technique, it is unknown whether this will affect the need for future Nd:YAG treatments (6).

Another reason early NPDS attempts without collagen implants failed was the inability to maintain patency of the sclerectomy due to fibrosis (6, 10, 11). The collagen implant clearly was an advance that helped to maintain patency, but the effect was not evident until after the first year, when the procedures without the device begin to fail. This outcome suggests that the collagen implant prevents late fibrosis through a space-occupying mechanism and, after its dissolution at 6 to 9 months, aqueous humor continues to drain through the region previously occupied by the implant (10, 11).

Table V summarizes results with NPDS. The results of glaucoma filtration surgery are not easy to compare for several reasons: the criteria for successful control or probability of success, the length of follow-up, surgical techniques, and the patient composition differed between studies. IOP control seems better when a device is used in comparison to nothing but the use of a 5-FU sponge during the surgery seems to offer a comparable IOP control to that of a device despite the fact that the mechanism of action of these two methods is different. Sanchez et al showed similar postoperative IOP after deep sclerectomy with or without a collagen implant, although the need for postoperative medications was significantly lower when the collagen implant was used (12).

The key to success with these nonperforating techniques is a meticulous dissection of the deep scleral flap including removal of the outer and inner wall of Schlemm's canal without violating the fragile and loose anterior trabecular meshwork (5, 7, 9-11). This requires excellent knowledge of topographic variabilities and skill in lamellar microdissecting. In white populations, the histology of the trabeculectomy specimens from the upper circumference of the eye revealed little or no pigmentation in nearly 70% of the eyes operated (9). Thus, surgical dissection of the deep scleral flap in white people seems to be even more demanding, because in these patients an important intraoperative topographic landmark is missing. Another problem hindering intraoperative identification of Schlemm's canal can be the presence of bridge-like drainage channels running tangentially to Schlemm's canal, which have been described by Rohen (13). When dissecting the deep scleral flap and entering a bridge-like channel, misidentification of Schlemm's canal can lead the surgeon to dissect the deep scleral flap too superficially (6, 7, 9). The risk of inadvertent perforation of the trabeculo-descemetic membrane seems to be somewhat lower in young glaucoma patients, confirming the clinical experience of Sanchez et al, who in a series of 234 deep sclerectomies found a higher incidence of intraoperative perforation in the older patients (12). Dietlein et al found that the uveal meshwork was covered by an endothelial layer not only in secondary and infantile glaucomas, but also in a considerable number of patients with open-angle glaucoma and a history of ALT (7). Nonperforating surgery, such as NPDS, does not dissolve *ab interno* sealing of the meshwork and may therefore be unsuccessful in glaucoma patients following ALT and in patients with secondary glaucoma (7, 9, 14).

The surgical technique has certain intraoperative risks. The most frequently cited intraoperative complication is perforation of the trabeculo-descemetic membrane with an incidence of 3.1 to 26% (Tab. V). There are implications that a microperforation may be beneficial.

In our study of 179 patients (258 eyes) who had NPDS, 27 (10.5%) had a microperforation of Descemet window at the time of surgery without conversion to trabeculectomy. Of these cases, 2 (0.8%) had flat or shallow anterior chamber and hyphema. One patient (0.4%) had dellen.

The number of postoperative complications was significantly lower following NPDS compared to trabeculectomy (8, 15, 16). In a prospective randomized study, postoperative laser flare photometry showed significantly less flare for up to 1 month compared with standard trabeculectomy (16). In our study, there were no complications traditionally associated with a trabeculectomy, including Tyndall, formations of the posterior synechiae, or choroidal detachment. The absence of opening the anterior chamber reduces the risk of long standing hypotony, and no maculopathies have been observed.

The most frequent complication was rise in IOP caused by one or both of the following factors: 1) an internal obstruction (10), due to insufficient filtration through the trabeculo-descemetic plane, or iris prolapse against the filtration site. This was treated as quickly as possible by laser. Nd:YAG laser treatment is recommended for the opening of Descemet membrane, and Argon laser iridoplasty for goniosynechiae or iris prolapse after Nd:YAG laser goniopuncture. This phenomenon occurs when filtration is active and the iridocorneal angle is narrow. This is why closed-angle glaucoma, goniosynechiae, and, in general, narrow angles are contraindications to the method; or 2) an external obstruction at the filtration bleb due to conjunctival fibrosis, which can be treated with injections of 5-FU into the bleb.

Nd:YAG laser goniopuncture was required in 47.3% of cases at 12.19±13.3 months (range 1 to 59) of follow-up. Among these 128 eyes, goniopuncture was used in 32 eyes (12.4%) in the early postoperative period, and in 96 eyes (37.2%) in the late postoperative period.

Argon laser iridoplasty was used in 25 eyes (9.7%): in 20 eyes, for treating goniosynechiae after NPDS, and in 5 eyes, for treating iris prolapse after or goniopuncture (Tab. IV). All patients had factors predisposing to iris prolapse after goniopuncture: trauma, ocular massage, or goniopuncture less than 3 weeks after surgery.

The most common cause of failure of glaucoma surgery is the formation of excessive scar tissue beneath the conjunctiva, which occurs as a natural healing response to surgical trauma (17). Late bleb failure increased with longer follow-up. Therapeutic options included resuming antiglaucoma medication, surgical revision of the original site, trabeculectomy at a virgin site, seton implantation, or a cyclodestructive procedure. Transconjunctival needle revision of the failed bleb was also an alternative (18-20). In our study bleb encapsulation was noted in 18 eyes (7.0%). In all cases additional subconjunctival 5-FU injections into the bleb were given. This procedure significantly increased the surgical success in our study. One patient, at the 1-month mark after NPDS, required further surgery (revision and trabeculectomy) to lower IOP.

The average time that medications were restarted was 20.2 months after NPDS. Among these 129 eyes that received additional medical treatment, 60 eyes (48%) required more than one antiglaucoma medication. NPDS decreased the number of medications (±SD) needed from 2.01 (±0.58) before surgery to 0.84 (±0.9) at last follow-up. In comparison with the results after trabeculectomy presented by Chen et al (18), the average time that medications were restarted was 3.4 years after initial trabeculectomy. Trabeculectomy also decreased the number of medications needed from 2.9 before surgery to 1.5 at last follow-up.

Which technique is the most effective in lowering IOP in patients with primary OAG remains unresolved. In our study the probability success rate, defined by the Kaplan-Meier method as an IOP lower than 21 mm Hg, was 75.74% at 53 months without treatment, and 83.36% with medical or new surgical treatment. The probability success rate with the actuarial method was 66.28% at 60 months without treatment and 77.56% with medical or new surgical treatment (Figs. 1 and 2).

A review of literature of IOP control after trabeculectomies without antimetabolites shows many studies with an average follow-up of fewer than 10 years or with a maximum follow-up of fewer than 12 years. Sources of incongruence may be found in the inclusion criteria for success, the duration of postoperative follow-up, and preoperative and postoperative therapy. Of these studies (21-27) that investigated IOP control, successful IOP control at last follow-up ranged from 95% to 60% and was shown to decrease over time. The longest follow-up study was done by Watson et al (27), who analyzed patients with a follow-up range of 4 to 240 months. At last follow-up, 90% of patients had an IOP of less than 20 mm Hg. The authors therefore suggested that long-term follow-up over 20 years shows no tendency for trabeculectomy to fail once drainage is established. Our results suggest that the probability of success decreases over time (Tabs. II and III). In a nonrandomized comparative trial, Mermoud et al found an IOP of less than 21 mm Hg without medication in 69% after NPDS with CD and in 57% after trabeculectomy without antifibrosis drugs at 24 months postoperatively (15).

NPDS lowers IOP by reducing resistance to aqueous outflow. The exact mechanism for the reduction of IOP following these procedures is, however, not known. Although the majority of resistance to aqueous outflow can be attributed to the trabecular meshwork and the inner wall of Schlemm's canal (5, 7, 9, 13, 28), approximately one-third of resistance to outflow in the human eye lies distal to the inner wall of Schlemm's canal in the enucleated perfused eye (13). Other possible mechanisms for the reduction of IOP following these procedures include transscleral flow, unrecognized microperforation into the anterior chamber, opening of previously nonfunctional areas of Schlemm's canal, and uveo-scleral outflow (6, 8, 10, 15, 28, 29). A combined (subconjunctival and suprachoroidal) outflow pathway might offer a better IOP reduction compared with standard trabeculectomy (8, 15, 30).

In conclusion, 84.9% of the patients in our study did not experience progressive glaucomatous damage 5 years after a first NPDS. NPDS with or without a collagen implant is a filtering technique that is subject to the same risk of fibroblast infiltration. It has the enormous advantage of giving rise to very few complications. The long-term tonometric results are the same as those of trabeculectomy. NPDS is technically difficult to perform and requires an open iridocorneal angle.

Reprint requests to:
Yves Lachkar, MD
Institut du Glaucome
Fondation Hôpital Saint Joseph, Paris
3 ter rue Pierre Larousse
75014 Paris, France

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