CLINICAL STUDY

Non-penetrating deep sclerectomy versus trabeculectomy in primary open-angle glaucoma surgery

DORIN CHISELITA

Abstract

Purpose **To compare the intraocular pressure lowering effect and the frequency of post-operative complications in two of the most used filtration surgery techniques: trabeculectomy and non-penetrating deep sclerectomy (NPDS) without collagen implants.**

Methods **Thirty-four eyes of 17 patients with medically uncontrolled symmetrical primary open-angle glaucoma were included in the study. One randomly selected eye per patient had either trabeculectomy or NPDS without collagen implants as the first surgical procedure. The other eye underwent the second filtration surgery technique less than 6 weeks later. Post-operatively, the intraocular pressure (IOP) diurnal curves were determined at 1, 2, 3, 6, 12 and 18 months. The intergroup differences in IOP lowering effect were determined in an analysis of covariance (ANCOVA), with pre-operative IOP as a changing covariate. Kaplan–Meier survival curves were drawn for IOP, and intercurve analysis was performed. Comparisons of the number of post-operative antiglaucomatous medications, as well as of the complication rate, were done by 2 × 2 frequency tables. A p value of less than 0.05 was considered statistically significant.**

Results **There were statistically significant differences in post-operative IOP level between the two groups at 1, 2, 3, 6, 12 and 18 months, with a lower level in the trabeculectomy group. Using the Kaplan Meier cumulative survival curve, the trabeculectomy patients had a better complete success rate than the NPDS patients at 18 months post-operatively. There were statistically significantly fewer complications in the NPDS group.**

Conclusion **Trabeculectomy lowers the IOP more than the NPDS technique. However, the complication rate seems to be lower in NPDS.**

Key words Glaucoma surgery, Non-penetrating deep sclerectomy, Trabeculectomy

Trabeculectomy has become the most commonly performed approach for surgical reduction of intraocular pressure, since its introduction by Cairns.[1–3] Since then technical modifications have been developed, such as a modified trabeculectomy where releasable sutures are used or a scleral tunnel technique similar to that used in phacoemulsification.

One of the most recently used antiglaucomatous filtration surgery techniques is non-penetrating deep sclerectomy (NPDS).[4–6] This technique aims to eliminate or minimise the complications of the classical trabeculectomy. However, Demailly *et al.*[7] found that although NPDS carries fewer complications than trabeculectomy, its medium-term tonometric results remain slightly inferior to those of trabeculectomy.

The purpose of this study was to compare prospectively the tonometric results and post-operative complications in two of the most used glaucoma surgery techniques: trabeculectomy and NPDS without collagen implants.

Patients and methods

Thirty-four eyes of 17 patients (9 men, 8 women) with medically uncontrolled symmetrical primary open-angle glaucoma (POAG) were included in this prospective study. The patients underwent bilateral filtering surgery between January 1998 and August 1999 at the University Eye Clinic Iasi, Romania. The average age of the patients was 60.17 ± 7.30 years (range 48–74 years). Informed consent was obtained from all patients after explaining the risks and benefits of the glaucoma surgery.

Inclusion criteria for the study were a diagnosis of POAG with uncontrolled intraocular pressure (IOP) while under maximal tolerated medical therapy, in both eyes (IOP higher than 23 mmHg on at least two antiglaucomatous drugs). Exclusion criteria were: asymmetrical POAG, secondary open-angle glaucoma or any type of angle-closure glaucoma, previous eye surgery, previous argon laser surgery within 30 days of enrolment in the study, or patients younger than 40 years.

Prof. Dr Dorin Chiselita, MD ✉
University Eye Clinic
St Spiridon Hospital
Independentei Blvd. No. 1
6600 Iasi, Romania
Tel: +40/32/217986
e-mail: dchiselita@yahoo.com

Received: 1 February 2000
Accepted in revised form:
27 September 2000

Table 1. *Definition of post-operative complications*

Complication	Definition
Bleb leakage	Presence of a positive Seidel test (visible aqueous flow with the tear film stained with fluorescein)
Hyphaema	Erythrocytes in the anterior chamber
Flat anterior chamber	Iridocorneal touch in the periphery seen on biomicroscopy
Inflammation in the anterior chamber	Flare seen by biomicroscopy
Bleb encapsulation	An elevated, thick, vascular and tense bleb
Cataract-related surgery	Observed as a direct consequence of filtering surgery; rapid decrease (1 month) in visual acuity, primarily cortical opacity

Pre-operative data included age, sex and ocular history. Also before surgery, all patients had the following examinations: best corrected visual acuity, biomicroscopy, gonioscopy, applanation tonometry with the Goldmann tonometer, visual field testing using the Humphrey visual field analyser (program 30-2; Humphrey Instruments, San Leandro, CA) using the appropriate refraction, fundus examination, and cup–disc (C/D) ratio measurements (Kowa camera).

One randomly selected eye per patient had either trabeculectomy or NPDS without collagen implants as the first procedure. Neither the IOP level nor the visual field defects were criteria for inclusion or exclusion for the first applied surgical technique, and the surgeon was masked to the pre-operative values of these parameters; the surgeon was not included in the team who collected the pre-operative data.

For the first intervention, the patients were randomised in the operating theatre; neither eye had one particular type of surgery first. After the first procedure had been performed the second eye underwent surgery (trabeculectomy or NPDS) less than 6 weeks later.

All surgery was performed by the same surgeon, who had long experience in both techniques, using peribulbar anaesthesia consisting of 4–6 ml lidocaine hydrochloride 4% (Xylocaine).

Non-penetrating deep sclerectomy

A superior rectus muscle suture was placed. The conjunctiva and Tenon's capsule were opened in the upper fornix and the sclera exposed; careful haemostasis was performed. A superficial scleral flap, one-third thickness, 5.0 × 5.0 mm, was dissected 1.0 mm into clear cornea. A triangle of deep sclera was then removed, leaving a thin layer of deep sclera over the choroid posteriorly. Anteriorly, the dissection was made to Schlemm's canal, opening its external wall, leaving in front of it only the Descemet plane, taking care not to perforate it. At this stage, the aqueous humour must rise from the anterior chamber, along the whole trabeculo-Descemet surface. The superficial scleral flap was repositioned and secured in place with two loose 10-0 nylon sutures; the knots were buried. The conjunctiva and Tenon's capsule were carefully closed with interrupted 8-0 silk sutures.

Trabeculectomy

Trabeculectomy was performed using a technique similar to that described by Cairns.[1] A superior rectus muscle suture was placed, and the conjunctiva and Tenon's capsule were opened in the upper fornix. The sclera was exposed, and careful haemostasis was performed.

A one-third thickness limbal-based 4.0 × 4.0 mm scleral flap was dissected. The paracentesis was perfomed. The trabeculectomy was followed by a peripheral iridectomy. The superficial scleral flap was sutured in place with two 10-0 nylon sutures with buried knots. The sutures were adjusted to allow a leakage around the edge of the scleral flap after reformation of the anterior chamber with balanced salt solution through paracentesis. The conjunctiva and Tenon's capsule were sutured with interrupted 8-0 silk sutures.

Post-operatively, patients were treated with topical neomycin and polymyxin B sulphate and dexamethasone (Maxitrol) 3 times a day for 2 weeks, and then with topical fluorometholone 3 times a day for 3–6 months.

Post-operative data (including visual acuity, visual field and C/D measurements, repeated every 3 months) were collected at 1 day, 1 week, and 1, 2, 3, 6, 12, 18 and 20 months, but for the purposes of this study only the IOP diurnal curves at 1, 2, 3, 6, 12 and 18 months were included in the statistical analysis. All post-operative IOP measurements were done by the same physician who was masked to the procedure performed in each eye of a specific patient.

Interocular differences in pre-operative visual acuity, C/D ratio and IOP were assessed by means of a paired Student's *t*-test. The intergroup differences in IOP lowering during the follow-up period were determined using an analysis of covariance technique (ANCOVA), with pre-operative IOP value as a changing covariate (correcting for the influence of pre-operative IOP). Survival analysis, using two pressure criteria (21 mmHg and 30% less than pre-operative IOP), was performed to analyse the success rate. Assessing the visual field evolution was not the aim of this study.

Comparisons between the two groups regarding peri- and post-operative complications (Table 1), as well as regarding post-operative antiglaucomatous medication, were performed using 2 × 2 frequency tables. The

Table 2. *Pre-operative intraocular pressure, visual acuity and cup–disc ratio in the study groups*

	Trabeculectomy	NPDS	*p* value[a]
IOP	27.29 ± 2.08	27.70 ± 2.22	0.5153
Visual acuity	0.47 ± 0.26	0.48 ± 0.23	0.7983
Cup-disc ratio	0.75 ± 0.11	0.75 ± 0.12	0.4302

Values are the mean ± SD.
NPDS, non-penetrating deep sclerectomy; IOP, intraocular pressure.
[a]Paired Student's *t* test.

statistical analysis was performed using Statistica for Windows. A p value of less than 0.05 was considered statistically significant.

Results

Thirty-four eyes of the 17 patients (9 men, 8 women) were enrolled in the study. The average age of the patients was 60.17 ± 7.30 years (range 48–74 years). There were no statistically significant differences between eyes operated on by the different techniques as regards pre-operative visual acuity, C/D ratio and IOP ($p < 0.05$) (Table 2). The mean ± SD follow-up period was 15.35 ± 4.7 months in both groups.

The post-operative IOPs in the two groups are shown in Table 3. There was a significant IOP reduction after surgery in both groups throughout the entire follow-up period. However, in the trabeculectomy group there was a statistically significant higher reduction in IOP compared with the NPDS group (Figs. 1, 2). In the trabeculectomy group, the percentage IOP reduction at 18 months was 35.7% compared with 25.1% in the NPDS group ($p = 0.0015$).

Although the number of cases requiring post-operative antiglaucomatous medications was higher in the NPDS group (9 cases compared with 6 in the trabeculectomy group), this difference was not statistically significant ($p > 0.05$). However, the mean number of antiglaucoma medications at the last control was significantly different (0.29 ± 0.59 in the trabeculectomy group compared with 0.88 ± 0.99 in the NPDS group; $p < 0.01$).

Using a Kaplan–Meier cumulative survival curve, with a target pressure of 30% less than pre-operative IOP considered as the survival limit, the cumulative

Table 3. *Post-operative intraocular pressure in the two study groups*

	Trabeculectomy		NPDS		
Months	%[a]	Mean ± SD (mmHg)	%[a]	Mean ± SD (mmHg)	*p*-value[b]
1	52.4	12.93 ± 1.9	45.6	15.05 ± 2.4	0.0152
2	47.6	14.23 ± 1.5	38.8	16.94 ± 2.9	0.0022
3	44.1	15.17 ± 1.4	33.1	18.52 ± 3.5	0.0012
6	39.6	16.41 ± 1.8	30.9	19.17 ± 3.6	0.0087
12	37.7	16.78 ± 1.6	26.4	20.35 ± 4.5	0.0142
18	35.7	17.27 ± 1.2	25.1	20.90 ± 4.0	0.0015

[a]Percentage of IOP lowering.
[b]Analysis of covariance, with pre-operative intraocular pressure as changing covariate (correcting for the influence of pre-operative IOP).

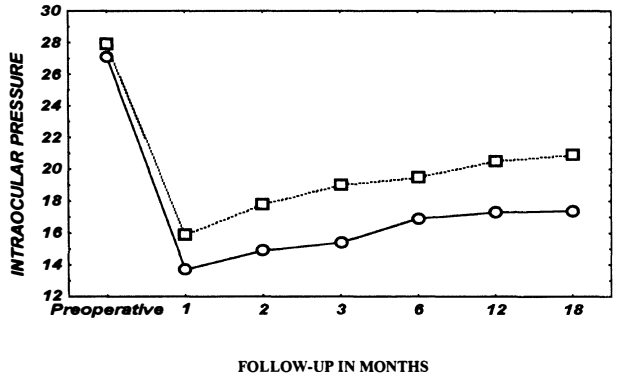

Fig. 1. *Intraocular pressure results in 17 trabeculectomy eyes (continuous line, open circles) and 17 NPDS patients (dotted line, open squares).*

surviving percentage was 85.18% in the trabeculectomy group versus 40.78% in the NPDS group (Cox's F-test: $F = 5.97$, $p = 0.00080$; Fig. 3). When the survival limit was a post-operative IOP of less than 21 mmHg without post-operative medication, the cumulative surviving percentage was 92.59% in the trabeculectomy group versus 44.57% in the NPDS group (Cox's $F = 12.83$, $p = 0.00034$; Fig. 4).

Complications are listed in Table 4. There were statistically significantly fewer complications in the NPDS group. Frank perforation of the trabeculo-Descemet's membrane, which could necessitate conversion to trabeculectomy, was not noted in our series. Microperforation was identified in 3 eyes with no iris prolapse or shallowing of the anterior chamber. The procedures were completed as NPDS that did not require further intervention.

Hyphaema and inflammation were encountered only in the trabeculectomy group. Moreover, it is significant that 5 eyes in the trabeculectomy group needed secondary cataract surgery, compared with none in the NPDS group. However, intraocular hypertension necessitating more hypotensive therapy appeared more frequently in the NPDS group.

Discussion

Trabeculectomy is still one of the most used approaches for surgical reduction of IOP, the many technical changes which have been developed not being able to convince

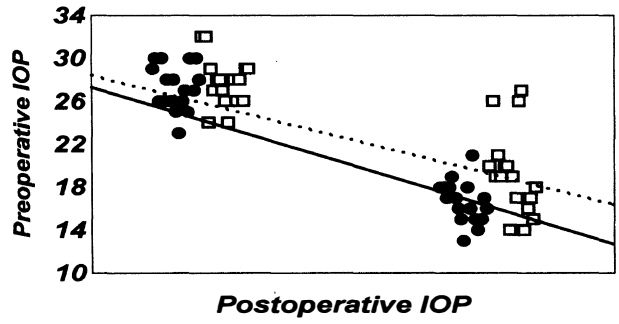

Fig. 2. *Pre-operative intraocular pressure (IOP) versus post-operative IOP in the trabeculectomy group (continuous line, filled circles) and the NPDS group (dotted line, open squares).*

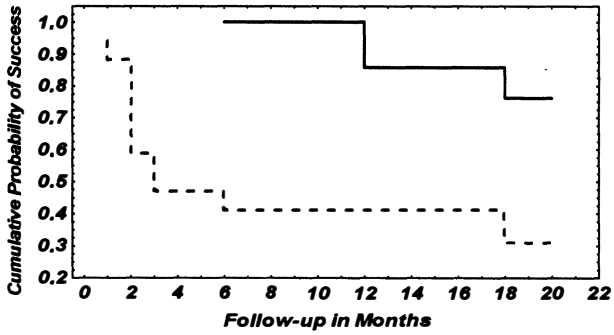

Fig. 3. *Kaplan–Meier cumulative survival curve for a success defined as a post-operative intraocular pressure of 30% less than the pre-operative values: the trabeculectomy eyes (continuous line) had a better long-term success rate than the NPDS patients (dotted line) (Cox's* F-*test:* p = *0.00080).*

glaucoma surgeons to abandon classical trabeculectomy. However, in order to avoid the numerous post-operative complications of trabeculectomy (e.g. hypotony, flat anterior chamber), surgeons have increasingly started to use several techniques of non-perforating filtration surgery (with or without collagen implants), with different rates of success.[4–6,8] Although NPDS carries fewer complications than classical trabeculectomy,[7,9] the tonometric results of this technique remain inferior to those of trabeculectomy.[7]

In our study, both eyes of 17 patients with medically uncontrolled symmetrical POAG were included. One randomly selected eye per patient had either trabeculectomy or NPDS without collagen implants as the first surgical procedure, neither eye having one type of surgery first; the second eye of the same patient underwent the second surgical intervention (trabeculectomy or NPDS) less than 6 weeks later.

Our study compares the two eyes of the same patient with symmetrical POAG, operated on by means of the two different surgical techniques. This design eliminates the bias resulting from the different characteristics of different patients (e.g. other associated pathological conditions, the wound healing rate).

The aim of the study was to follow the IOP lowering results of the two techniques, without the help of collagen implants or antimetabolites.

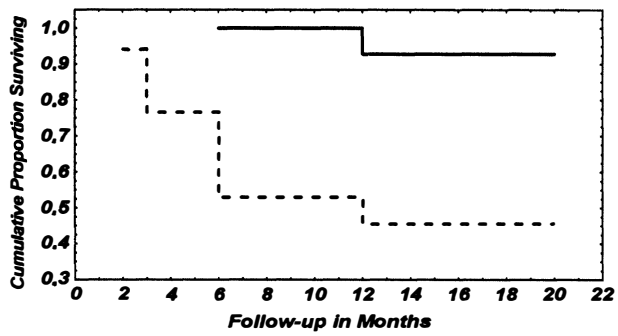

Fig. 4. *Kaplan–Meier cumulative survival curve for a success defined as a post-operative intraocular pressure of less than 21 mmHg without medication. The long-term success rate was better in the trabeculectomy group (continuous line) compared with the NPDS group (dotted line) (Cox's* F-*test;* p = *0.00034).*

Table 4. *Number and percentage of cases with peri- and post-operative complications in the study groups*

	Trabeculectomy	NPDS	*p* value
Seidel positive	2; 12%	2; 12%	> 0.05
Hyphaema	7; 41%	0	0.0030
Flat anterior chamber	3; 18%	0	> 0.05
Inflammation	2; 12%	0	> 0.05
Post-operative ocular hypertension	0	5; 29%	0.0155
Bleb encapsulation	1; 6%	1; 6%	> 0.05
Cataract-related surgery	4; 24%	0	0.0279

The complete success rate of trabeculectomy was far better than that of NPDS when data were analysed using the Kaplan–Meier survival curve for the two IOP limits. Moreover, the number of patients who needed post-operative antiglaucomatous medications was lower in the trabeculectomy group, although the difference between the two groups was statistically not significant. However, complications were more frequently encountered in the trabeculectomy group.

These findings are in contradiction to many studies that have found NPDS has a more satisfactory outcome compared with trabeculectomy.[4,10,11] Our study clearly showed that the IOP lowering rate was higher in the eyes that underwent trabeculectomy than in those that had NPDS.

In one recently published study El Sayyad *et al.*,[12] in 78 eyes of 39 POAG patients, found that NPDS and trabeculectomy offered comparable IOP reduction, success rate and need for post-operative glaucoma medication. However, the post-operative treatment with 5-fluorouracil and goniopuncture with Nd:YAG laser in some of their NPDS cases might have affected the final result of the study.

Although our study included a smaller number of eyes, the different result obtained here could be better understood if one keeps in mind that the two techniques applied by us did not include any help provided by collagen implants or antimetabolites, thus showing clearly the contribution of the technique *per se*. One should remember that the actual mechanism of filtration through the trabeculo-Descemetic plane is still unknown.[7,9] Moreover, the fate of the collagen implants also remains unknown. Demailly *et al.*,[7] in a prospective study comparing NPDS with collagen implants with NPDS without collagen implants, concluded in favour of a technique without implants, as long as a 5-fluorouracil sponge is used.

One of the most important points underlined in our study is that the study was very carefully randomised, and that the two surgical techniques were performed in the two eyes of the same patients with symmetrical disease. Before entering the operating theatre the surgeon did not plan a particular technique for a particular patient based on pre-operative IOP level, visual field or papillary cupping. El-Sayyad *et al.*[12] also used randomisation in their study. However, because they did not provide details of the method used in their study, the differences between their results and ours

could also result from a different technique of randomisation. There are many surgical studies, but some will continue to lack credibility unless assessed by propery randomised trials.[13]

In our study NPDS was a safer procedure, with less important immediate post-operative complications compared with trabeculectomy. This finding is in accordance with other previous studies.[9,14] Inflammation, hyphaema, flat anterior chamber and cataract-related surgery were complications more frequently encountered in the trabeculectomy group, while bleb fibrosis and post-operative ocular hypertension were findings more often occurring in the NPDS group. However, the different types of post-operative complications are related mainly to the differences in the two techniques.

In conclusion, our study suggests that trabeculectomy is a better method for cases in which a larger reduction in IOP is the aim of the treatment, especially in glaucoma patients who progress under a maximal antiglaucomatous medication. However, the use of NPDS could, in less complicated cases, make ambulatory care easier.

References

1. Cairns JE. Trabeculectomy: preliminary report of a new method. Am J Ophthalmol 1968;66:673–81.
2. Drance SM, Vargas E. Trabeculectomy and thermosclerectomy: a comparison of two procedures. Can J Ophthalmol 1973;8:413–5.
3. Watson P. Trabeculectomy: a modified *ab externo* technique. Ann Ophthalmol Glaucoma 1970;2:199–205.
4. Zimmerman TJ, Kooner KS, Ford VJ, Olander KW, Mandlekorn RM, Rawlings EF, *et al*. Trabeculectomy vs nonpenetrating trabeculectomy: a retrospective study of two procedures in phakic patients with glaucoma. Ophthalmic Surg 1984;15:734–40.
5. Zimmerman TJ, Kooner KS, Ford VJ, Olander KW, Mandlekorn RM, Rawlings FE, *et al*. Effectiveness of nonpenetrating trabeculectomy in aphakic patients with glaucoma. Ophthalmic Surg 1984;15:44–50.
6. Fedorov SN, Ioffe DI, Ronkina TE: [Glaucoma surgery: deep sclerectomy]. Vestn Oftalmol 1982;6–10.
7. Demailly P, Lavat P, Kretz G, Jeanteur-Lunel MN. Non-penetrating sclerectomy (NPDS) with or without collagen device (CD) in primary open-angle glaucoma: middle-term retrospective study. Int Ophthalmol 1996–7;20:131–40.
8. Kozlov VI, Bagrov SN, Anisimova SY, *et al*. Non-penetrating deep sclerectomy with collagen. Ophthalmosurgery 1990;3:52–5.
9. Mermoud A, Schnyder CC, Sickenberg M, Chiou AG, Hediguer SE, Faggioni R. Comparison of deep sclerectomy with collagen implant and trabeculectomy in open-angle glaucoma. J Cataract Refract Surg 1999;25:323–31.
10. Gianoli F, Schnyder CC, Bovey E, Mermoud A. Combined surgery for cataract and glaucoma: phacoemulsification and deep sclerectomy compared with phacoemulsification and trabeculectomy. J Catarct Refract Sug 1999;25:340–6.
11. Sanchez E, Schnyder CC, Mermoud A. Comparative results of deep sclerectomy transformed to trabeculectomy and classical trabeculectomy. Klin Monatsbl Augenheilkd 1997;210:261–4.
12. El Sayyad F, Hellal M, El-Kholify H, Khalil M, El-Maghrahy A. Nonpenetrating deep sclerectomy versus trabeculectomy in bilateral primary open-angle glaucoma. Ophthalmology 2000;107:1671–4.
13. Johnson AG. Removing bias in surgical trials. BMJ 1997;314:916.
14. Chiou AG, Mermoud A, Jewelewicz DA. Post-operative inflammation following deep sclerectomy with collagen implant versus standard trabeculectomy. Graefes Arch Clin Exp Ophthalmol 1998;236:593–6.