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Influence of deep scleral flap size on intraocular pressure after deep sclerectomy

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PURPOSE. *To study the effect of several morphometric characteristics of the deep scleral flap on intraocular pressure (IOP) control after deep sclerectomy.*
METHODS. *The authors conducted a nonrandomized prospective study of 56 eyes of 51 patients who underwent deep sclerectomy alone or combined with phacoemulsification. A reticulated hyaluronic acid implant was used in all cases. The surface, volume, and weight of the dissected deep scleral flap were measured and recorded. The correlation between these parameters and the postoperative IOP was evaluated at 6 and 12 months postoperatively.*
RESULTS. *Forty-nine eyes (87.50%) achieved an IOP of 21 mmHg or less without treatment, and the need for medication was decreased significantly ($p<0.001$) at 12 months postoperatively. The authors found a significant inverse correlation between the mean postoperative IOP at 6 months and the surface, volume, and weight of the deep scleral flap, but not at 12 months postoperatively.*
CONCLUSIONS. *Greater weight, surface area, and volume of the deep scleral flap dissected during deep sclerectomy achieve significantly lower postoperative IOPs in the early postoperative period. (Eur J Ophthalmol 2007; 17: 350-6)*

KEY WORDS. *Deep sclerectomy, Deep scleral flap, Glaucoma surgery, Volume and size*

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INTRODUCTION

Deep sclerectomy is a nonpenetrating filtering procedure that provides intraocular pressure (IOP) control comparable to trabeculectomy with fewer complications (1-5).
Several variables, such as performing an ab externo trabeculectomy, placing an implant in the scleral bed, and giving intraoperative antimetabolite supplementation, substantially reduce the postoperative IOP and increase the success rate of the procedure and the probability of achieving lower target IOPs after deep sclerectomy (6-15).
Although some studies have been performed to determine the histologic features of the deep scleral flap (16-19), to our knowledge no study has focused on the effect of the size of the scleral flap, including the surface, volume, and weight, on IOP control. We conducted a prospective clinical study to evaluate whether the size and/or shape of the deep scleral flap performed during deep sclerectomy affect postoperative IOP control.

METHODS

Case selection

This prospective study included patients who underwent uneventful deep sclerectomy with a reticulated hyaluronic acid implant with or without phacoemulsification between February 2004 and May 2005.
Eligible patients had substantial glaucomatous damage and insufficient control of IOP as a result of medication allergies, side effects, poor compliance, or the need for a number of antiglaucomatous medications. Indications for combined surgery included a best-corrected visual acuity (BCVA) of 20/50 or worse with a clinically relevant cataract.
Patients were excluded if they had angle-closure, neovascular, traumatic, uveitic, or phacomorphic glaucoma or were unwilling to participate. All patients provided written informed consent; the study was approved by the hospi-

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tal's Institutional Review Board. All patients had at least 12 months of follow-up after surgery. Patients who had an intraoperative macroperforation of the trabeculo-Descemet's membrane were also excluded.

Before surgery, patients underwent measurement of the BCVA, biomicroscopy, gonioscopy, Goldmann applanation tonometry, 24-2 visual field testing (24-2 Humphrey field analyzer 750, Zeiss/Humphrey Systems, Dublin, CA, USA), and fundus biomicroscopy.

The data prospectively recorded were the age at the time of deep sclerectomy, sex, eye, IOP (measured by Goldmann tonometry), the number of glaucoma medications used, and the preoperative BCVA. The shape of the scleral flap and intraoperative complications were also recorded.

The excised deep scleral flap was preserved immediately in a 0.9% saline solution. The surface, height, and volume were measured with an optical microscope (Nikon Optiphot 2, Nikon GmbH, Düsseldorf, Germany), and the flap was weighed using a precision balance (ScaleMarket AND GR-202, Miami, FL, USA).

Patients were examined 1 day, 1 week, and 1, 3, 6, and 12 months after surgery (and more often when necessary). The VA, biomicroscopic examination, IOP, postoperative complications, and the number of glaucoma medications were recorded at each follow-up visit.

The use of glaucoma medication was reported as the number of drugs taken, with no differentiation as to the type or the frequency of medication use. Fixed combinations of two drugs were considered to be two drugs.

Surgical procedure

All surgical procedures were performed by two of the authors (G.R. or F.J.M.-N.) using a standardized technique. Most surgeries were performed using retrobulbar anesthesia, i.e., 2 to 4 mL of a 1:1 mixture of mepivacaine 2% and bupivacaine 0.75%. First, a fornix-based conjunctival flap was made, the sclera was exposed, and hemostasis performed by wet-field cautery. A one-third scleral thickness superficial parabolic flap (5.0 mm x 5.0 mm) was dissected in the superior quadrant. A second triangle or rectangle of deep sclera was dissected, Schlemm's canal was deroofed, and the trabeculo-Descemet window created. A deep scleral flap was excised and immediately preserved in a 0.9% saline solution. An ab externo trabeculectomy was performed in all eyes and a reticulated hyaluronic acid implant (SKGel®, Corneal Laboratoires, Paris, France) was placed in the scleral bed. The superficial scleral flap was sutured with three to four interrupted nylon 10/0 sutures.

In the combined surgery, phacoemulsification was performed through a temporal or nasal clear corneal incision (in the right and left eyes, respectively) before opening Schlemm's canal. An intraocular lens (AcrySof MA 60 BM, Fort Worth, TX, USA) was used in all cases.

Postoperative follow-up

The usual postoperative treatment included a combination of dexamethasone and tobramycin six times daily for 2 weeks; the dosage was tapered by one drop weekly until the drug was discontinued after 8 weeks. When the vessel density increased or bleb flattening occurred, more intense postoperative antiinflammatory treatment was used, in which prednisolone acetate was administered every 1 to 2 hours during waking hours.

Goniopuncture with a neodymium (Nd):YAG laser was performed when the target IOP range for each patient was not achieved because of insufficient filtration through the trabeculo-Descemet membrane.

Statistical analysis

All statistical analyses were performed using SPSS 12.0 software (SPSS, Chicago, IL, USA). $p<0.05$ Was considered statistically significant.

After showing a normal distribution of the variable IOPs 12 months after surgery, a mean comparison was performed using the Student *t*-test. The number of glaucoma medications was compared using the Wilcoxon signed-rank test.

We used Pearson's correlation coefficient for continuous variables and linear regression to detect confounding variables.

RESULTS

Fifty-six eyes of 51 patients (21 men, 30 women) participated in this study. Table I shows the demographic data. The patient ages ranged from 31 to 87 years. The most frequent preoperative diagnosis was primary open-angle glaucoma. Twenty-one eyes (37.5%) underwent deep sclerectomy and 35 (62.5%) deep sclerectomy combined with phacoemulsification.

The mean preoperative IOP was significantly higher in

TABLE I - DEMOGRAPHIC DATA AND CHARACTERISTICS OF THE STUDY POPULATION

Characteristics	N (%) or mean ± SD (range)
Sex	
Male	21 (41.18)
Female	30 (58.82)
Eye	
Right	27 (48.21)
Left	29 (51.79)
Glaucoma type	
Primary open angle	45 (80.36)
Pseudoexfoliative	7 (12.50)
Pigmentary	4 (7.14)
Phacoemulsification	
Yes	35 (62.50)
No	21 (37.50)
Flap shape	
Rectangular	10 (17.86)
Triangular	46 (82.14)
Age, y	71.84±10.62 (31–87)
Preoperative IOP, mm Hg	22.43±8.51 (12–61)
Preoperative medications	1.93±0.76 (1–4)
Preoperative VA	0.60±0.27 (0.1–1.2)

IOP = Intraocular pressure; VA = Visual acuity

TABLE II - MEAN IOP 12 MONTHS POSTOPERATIVELY ASSOCIATED WITH SEVERAL PARAMETERS

Parameter	No.	Mean (SD)	p value (two-tailed)
Sex			
Male		14.09 (3.77)	0.41
Female		14.94 (3.73)	
Eye			
Right	27	15.56 (3.34)	0.07
Left	29	13.72 (3.92)	
Glaucoma type			
Primary open angle	45	14.44 (3.61)	0.76
Pseudoexfoliative	7	15.23 (2.92)	
Pigmentary	4	14.81 (3.49)	
Flap shape			
Rectangular	10	16.80 (4.20)	0.055
Triangular	46	14.37 (3.44)	
Surgery			
Deep sclerectomy	21	14.43 (3.61)	0.781
Combined surgery	35	14.71 (3.85)	

IOP = Intraocular pressure

eyes that underwent deep sclerectomy alone (p=0.022). Overall, the mean preoperative IOP was 22.43±8.51 (mean ± SD). At 12 months, the mean IOP decreased to 14.61±3.74 mmHg (p < 0.001), 92.86% of eyes achieved an IOP of 21 mmHg or less without treatment, and the mean postoperative number of medications used decreased significantly from 1.93±0.76 to 0.25±0.68 (p<0.001).

Most eyes had a triangular deep scleral flap dissection (82.14%). The mean weight, height, surface, and volume were 8.40±2.31 mg, 0.21±0.01 mm, 12.27±3.75 mm^2, and 2.48±0.74 mm^3, respectively.

We did not find significant differences in the postoperative mean IOPs between the groups at 12 months based on sex, side of operated eye, glaucoma type, or shape of the deep scleral flap. The values for each group and the level of significance are shown in Table II.

No statistically significant differences in IOP control were observed between patients who underwent deep sclerectomy alone and deep sclerectomy combined with phacoemulsification at 6 and 12 months postoperatively (p=0.426 and p=0.781, respectively).

Grouping by surgeon, there was no significant difference between the mean postoperative IOP achieved at 6 and 12 months after surgery (p=0.112 and p=0.77, respectively) or between the mean postoperative decrease of IOP at 6 and 12 months (p=0.486 and p=0.497, respectively).

There was a significant inverse correlation between the mean IOP at 6 months and the surface, volume, and weight of the deep scleral flap, but not at 12 months postoperatively (Tab. III, Figs. 1 and 2). A similar correlation pattern, except for the variable volume at 6 months, was found for the IOP relative decrease (Tab. IV).

Eighteen of the 56 total eyes underwent a goniopuncture during this follow-up period. In 16 of the patients (88.9%) goniopuncture was performed after 6 months of follow-up, and in 2 patients it was performed at 4 months after surgery.

Mean IOP before goniopuncture was 20.83±3.85 mmHg and it descended significantly to a mean IOP after goniopuncture of 13.56±3.82 mmHg (p<0.001). The mean IOP decrease in the group that followed goniopuncture was 7.28±4.11 mmHg.

The mean values of weight, volume, and surface were lower in the group of patients that underwent goniopuncture (7.77 vs 8.69 mg; 2.23 vs 2.59 mm^3; 10.93 vs 12.87 mm^2), but these differences were not significant (p=0.70, 0.89, and 0.89, respectively).

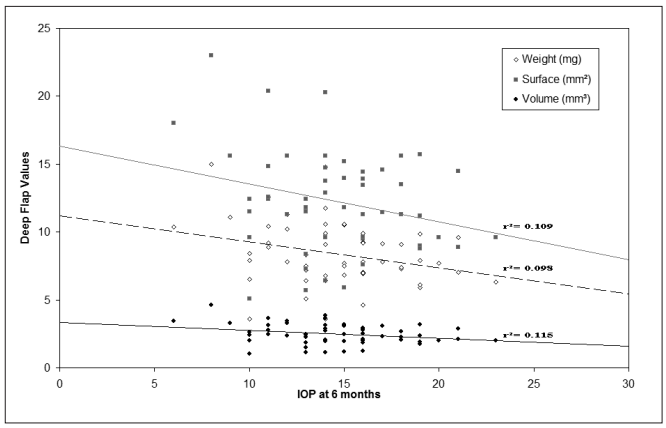

Fig. 1 - *Correlation between intraocular pressure at 6 months and morphologic variables of the deep scleral flap.*

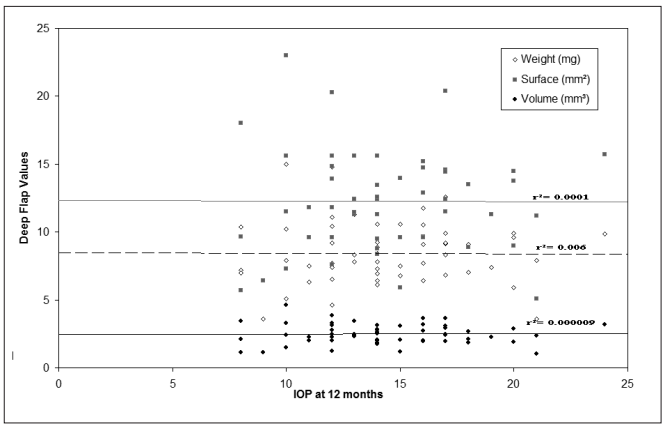

Fig. 2 - *Correlation between intraocular pressure at 12 months and morphologic variables of the deep scleral flap.*

TABLE III - CORRELATION BETWEEN MEAN IOP 6 AND 12 MONTHS POSTOPERATIVELY AND MORPHOLOGIC VARIABLES OF DEEP SCLERAL FLAP

IOP	Weight (mg)		Surface (mm²)		Volume (mm³)	
	6 mo	12 mo	6 mo	12 mo	6 mo	12 mo
Pearson CC	0.313*	–0.08	0.331*	–	0.339*	–0.003
p Value (two-tailed)	0.021	0.955	0.018	0.012	0.012	0.984

*Correlation is significant at the 0.05 level (two-tailed); IOP = Intraocular pressure; CC = Correlation coefficient

TABLE IV - CORRELATION BETWEEN MEAN IOP RELATIVE DECREASE 6 AND 12 MONTHS POSTOPERATIVELY AND MORPHOLOGIC VARIABLES OF DEEP SCLERAL FLAP

IOP decrease	Weight (mg)		Surface (mm²)		Volume (mm³)	
	6 mo	12 mo	6 mo	12 mo	6 mo	12 mo
Pearson CC	0.305*	–	0.301*	–	0.112	–0.083
p Value (two-tailed)	0.036	0.007	0.048	0.028	0.174	0.548
		0.959		0.846		

*Correlation is significant at the 0.05 level (two-tailed); IOP = Intraocular pressure; CC = Correlation coefficient

Using the median value of the weight of the flaps we grouped the patients between thin (weight of flap minor or equal to 7.90 mg) and thick flap patients (weight of flap greater than 7.90 mg). In the first group, 10 out of 30 patients (33.3%) had a goniopuncture. In the thick flap group 8 out of 26 patients (30.7%) underwent a goniopuncture (Tab. V). However, the difference in the percentage of patients who had a goniopuncture in both groups was not statistically significant (p=0.83).

TABLE V - GONIOPUNCTURE RATE AT 12 MONTHS POSTOPERATIVELY

Flap categorization	Number of patients	Goniopuncture (rate %)
Overall	56 1	8 (47.4)
Flap weight, mg		
>7.90	30	10 (33.3)
≤7.90	26	8 (30.7)

DISCUSSION

Nonpenetrating deep sclerectomy has become a widely accepted procedure for surgical glaucoma treatment. Numerous articles have reported successful postoperative IOP control during the short, intermediate, and long term with a low rate of complications (1-4, 20).

Since the introduction of sinusotomy by Krasnov (21), nonpenetrating trabeculectomy by Zimmerman et al (5), and deep sclerectomy by Fyodorov et al (22), numerous variations in the surgical technique for nonpenetrating deep sclerectomy have been described (6-15).

The efficacy of the procedure lies in the creation of a trabeculo-Descemet's membrane to bypass the juxtacanalicular trabeculum and the inner wall of Schlemm's canal which conventional wisdom considers to be the site of highest aqueous outflow resistance (23-25).

Therefore, observation of the anatomic landmarks, a regular and adequately deep plane dissection, and proper deroofing of Schlemm's canal are essential surgical steps. However, the importance of other factors such as the size and morphology of the deep scleral flap are poorly understood. Our primary objective in this study was to gain a better understanding of the importance of deep flap morphology and its effect on IOP control after deep sclerectomy.

In the current study, we recorded and compared the postoperative IOP values after deep sclerectomy with either triangular or rectangular flap resection, after having measured the removed flap weight, surface, volume, and height. Most authors remove a deep scleral triangular or rectangular flap measuring 3 x 3 or 4 x 4 mm. We have found a significant inverse correlation between the mean IOP at 6 months and the weight, surface, and volume of the deep scleral flap (Tab. III). Thus, the larger these parameters are, the lower the postoperative IOP values. Since the flap characteristics are related to each other, we consistently found a similar level of correlation for all three. We also found a significant inverse correlation between the mean relative IOP decrease at 6 months and the weight and surface of the deep scleral flap.

A plausible explanation for this finding is that removing a larger deep scleral flap could result in a wider intrascleral lake. The intrascleral space may serve as a reservoir for aqueous flow into Schlemm's canal and to the subconjunctival space. No relation has been identified between the size of the scleral flap and the reduction in IOP (24); however, an increase in the size of the deep scleral flap resected could maintain the intrascleral lake. Whether a larger deep scleral flap is accompanied by a larger intrascleral lake must be determined using imaging methods such as ultrasound biomicroscopy.

Another possible explanation for this inverse correlation at 6 months could be that a larger deep scleral flap facilitates uveoscleral outflow through a very thin scleral bed after flap resection. This also must be confirmed by imaging studies.

The lack of correlation between the size of the scleral flap and the reduction in IOP at 12 months could be influenced by the fact that 88.9% of the goniopunctures were performed after the first 6 months postoperatively and that goniopuncture was more frequently performed in the group of patients with a thinner deep scleral flap, contributing to equalize IOP in patients with and without goniopuncture. However, the differences in the goniopuncture rate between thin and thick deep scleral flap groups were not statistically significant.

No statistically significant differences on IOP control were observed between patients who underwent deep sclerectomy alone and deep sclerectomy combined with phacoemulsification at 6 and 12 months postoperatively (p=0.426 and p=0.781, respectively). The higher preoperative mean IOP observed in eyes that underwent deep sclerectomy alone compared with those that underwent the combination procedure might be explained by the differences in surgical indication and the stage of glaucoma. Moreover, the need for cataract extraction in patients with glaucoma could also hasten the surgeon's decision to perform a deep sclerectomy at the time of the cataract surgery.

We found no significant difference between the values of postoperative IOP at 6 and 12 months for both surgeons. Since both had the same training and similar experience with deep sclerectomy this result supports the fact that there is a strong correlation between surgical success and surgical experience of the surgeon.

A comparison of mean IOPs at 12 months between eyes with a rectangular and a triangular scleral flap found no significant differences (p=0.055, Tab. II). However, the small number of eyes with a rectangular scleral flap might limit the weight of this finding.

This pilot study is limited by a small number of cases. However, it seems that the scleral size only significantly influences IOP control during the early postoperative period. Park et al have suggested that the progressive decrease of the postoperative IOP reduction may be related

to the decreased size of the subscleral lake (26). This finding has been reported with both hyaluronic acid and collagen implant (27, 28). The scarring process and filtration organization could play a role in the reduction of the subscleral lake. Taking into account these data and regarding the direction of the correlation lines of Figure 2 we would not expect that longer follow-up would show a new change in correlation or a recorrelation of the variables studied.

Considering these limitations, our results allow us to conclude tentatively that a larger deep scleral flap (more weight, surface, and volume) might obtain lower postoperative IOP levels after deep sclerectomy in the first 6 months postoperatively.

In addition, 1 year postoperatively, the goniopuncture rate was lower in patients with larger scleral flap, although differences were not statistically significant.

We could not demonstrate that the shape of the flap (rectangular versus triangular) affects tensional results.

None of the authors has a financial or proprietary interest in any material or method mentioned.

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