FIVE-YEAR EXPERIENCE WITH NON PENETRATING DEEP SCLERECTOMY

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ABSTRACT

Purpose: To assess the long-term safety and effectiveness of non penetrating deep sclerectomy (DS) and to compare the incidence and the severity of postoperative complications and the IOP results according to surgical adjuvants (implant device, antimetabolite or both) were used or not.
Material-Methods: Retrospective non randomised study including 171 eyes (136 patients), mean age: 63.9 years) with medically uncontrolled open-angle glaucoma and without previous filtering surgery. 81 eyes (48.2%) had severe glaucomatous damage. All procedures were performed according to the Kozlov's and Memoud's technique. Except for 8 eyes, they were associated with the placement of an implant device (SKGEL® or T-FUX®) and/or intra-operative application of low dose antimetabolite (5-FU in 58 eyes and mitomycine C in 53 eyes).
Results: Mean follow-up was 39.6±18.3 months. According to surgery, DS were categorized in 4 groups: Group 1: DS with Healon GV (n= 8)(4.7%); Group 2: DS with antimetabolite application (n=26) (15.2%); Group 3: DS with placement of an implant (n= 53)(31%). Group 4: intraoperative antimetabolite +implant device (n= 84 eyes)(49.1%). Peroperative microperforations without iris hernia occurred in 35 eyes (21%). 1st month postoperative complications were observed in 90 eyes (52.6%) with mild to moderate hyperfiltration in 27 eyes, excessive scarring of filtration bleb in 38 eyes, and iris incarceration in 10 eyes. 5-FU injections were given in 58 eyes (34%). YAG gonioperforation was needed in 107/171 eyes (63%) and was complicated by iris incarceration in 9 eyes. Early and late spontaneous iris incarceration was observed in 10 eyes. A second filtering procedure was needed in 10 eyes. Mean BCVA decreased from 0.71 preoperatively to 0.65 at the last visit ($p<0.05$). For the 171 eyes, mean IOP decreased from 27.4±8.5 mmHg preoperatively to 15.3±5.3 mmHg (44% reduction)($p<0.05$). Mean number of topical medications was reduced from 2.1 preoperatively to 1.2 ($p<0.05$). Complete (individual target IOP reached without medication) and qualified (individual target IOP reached with and without medications) final success rates were respectively 39% and 76%. 93 eyes (54%) reached a final IOP ⩽15mmHg. Complete probability success rate was 93% at 1 year, 85.6% at 2 years, 69.8% at 3 years, 62.7% at 40 months and 52% at 4 years. Probability success rates increased to 96.5% at 1 year, 92.1% at 2 years, 86.8% at 3 years, 84% at 40 months and 80% at 4 years with adjunctive medical treatment. Mean IOP decrease, complete, qualified success rates and postoperative complications were comparable between the 4 intraoperative groups. The group with implant + antimetabolite had lower complete and qualified probability success rates compared to the other 3 groups ($p<0.05$).
Conclusion: Considering the limitations of this study, deep sclerectomy appears to be a relatively safe and effective procedure. Yag goniopuncture and /or adjunctive medications are frequently needed. Low dose intraoperative antimetabolites and placement of implant do not seem to improve success rates. Patients have to be periodically monitored for iris incarceration.

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RÉSUMÉ

Objectif: Le but de cette étude est d'apprécier l'innocuité et l'efficacité à long terme de la sclérectomie profonde non perforante (SP) et de comparer l'incidence et la sévérité des complications post-opératoires et les résultats tensionnels observés selon que des moyens adjuvants (implant, antimétabolite ou les deux associés) ont été employés ou non en peropératoire.
Matériel-Méthodes: Etude rétrospective non randomisée incluant 171 SP réalisées chez 136 patients (âge moyen: 63.9 ans) porteurs d'un glaucome à

angle ouvert non contrôlé par le traitement médical et indemnes de tout antécédent de chirurgie filtrante. 81 yeux (48.2%) ont des déficits glaucomateux sévères. Toutes les interventions ont été réalisées selon la technique classique de Kozlov et de Mermoud. A l'exception de 8 yeux, elles ont été associées à la mise en place d'un implant (SKGEL® or T-FUX®) et/ou à une application peropératoire d'un antimétabolite à faible dose (5-FU dans 58 cas et Mitomycine C dans 53 cas).

Résultats: Le recul moyen actuel est de 39.6±18.3 mois. En fonction du protocole opératoire, les SP peuvent être scindées en 4 groupes: groupe 1: SP + Healon GV (n=8)(4.7%) ;groupe 2: SP + antimétabolite (n=26)(15.2%); groupe 3: SP+ implant (n=53)(31%); groupe 4: SP + antimétabolite + implant (n=84)(49.1%) dont un implant SKGEL dans 81 cas. Les interventions ont été compliquées d'une microperforation de la membrane trabéculo-Descemétique sans hernie de l'iris dans 35 cas (21%). 90 yeux (52.6%) ont développé des complications au cours du 1er mois postop dont des problèmes d'hyperfiltration légère à modérée dans 27 cas, de fibrose conjonctivo-ténonienne excessive dans 38 cas et 10 enclavements de l'iris. Des injections sous-conjonctivales de 5-FU ont été réalisées dans 58 cas (34%). Des gonioperforations au laser YAG ont été réalisées dans 63% des cas (107/171 yeux) et ont été compliquées par un enclavement de l'iris dans 9 cas. 10 enclavements spontanés précoces ou retardés de l'iris ont été observés. Une 2ème intervention filtrante a été nécessaire dans 10 cas. L'acuité visuelle moyenne est passée de 0.71 en préopératoire à 0.63 au dernier contrôle ($p<0.05$). Pour l'ensemble des SP, la PIO moyenne est passée de 27.4±8.5 mmHg en préopératoire à 15.3±5.3 au dernier contrôle (réduction de 44%)($p<0.05$).Le nombre moyen des médications locales a été réduit de 2.1 en préopératoire à 1.2 au dernier contrôle ($p<0.05$). Les taux de succès complet (PIO cible individuelle atteinte sans médications) et relatif (PIO cible individuelle atteinte avec et sans médications) sont respectivement de 39% et de 76% au dernier contrôle. 93 yeux (54%) ont une PIO finale ⩽ 15 mmHg. La probabilité de taux de succès complet est de 93% à 1 an, 85.6% à 2 ans, 69.8% à 3 ans, 62.7% à 40 mois et de 52% à 4 ans. Elle augmente à 96.5% à 1 an, 92.1% à 2 ans, 86.8% à 3 ans, 84% à 40 mois, et 80% à 4 ans avec traitement médical d'appoint. La diminution de PIO obtenue, les taux de succès complet et relatif et les complications postopératoires sont comparables dans les 4 groupes chirurgicaux. Seul le groupe 4 où ont été employés simultanément un implant et une application d'antimétabolite a une probabilité de succès complet et relatif plus faible que les 3 autres groupes ($p<0.05$).

Conclusion : Compte tenu des limites de notre étude, la sclérectomie profonde nous est apparue être une technique relativement sûre et efficace. Des goniopunctures au laser et/ou un traitement médical d'appoint sont fréquemment nécessaires. Les taux de succès ne semblent pas améliorés par la mise en place d'un implant et/ou une application peropératoire minimale d'un antimétabolite. Un enclavement de l'iris doit être périodiquement recherché.

KEY WORDS

Glaucoma, non penetrating glaucoma surgery, deep sclerectomy, antimetabolite.

MOTS-CLÉS

Glaucome, chirurgie non perforante du trabéculum, sclérectomie profonde, antimétabolite.

The improvement of the safety profile and the efficacy of glaucoma filtering surgery has been a major concern for glaucoma surgeons since many years (20). By allowing to significantly reduce the incidence of the early postoperative complications compared to standard Cairn's trabeculectomy, non penetrating glaucoma drainage surgery has been shown to provide a valuable alternative surgical approach to trabeculectomy for moderate lowering of intraocular pressure (IOP) in patients with open-angle glaucomas (5).
Low IOP and decrease of IOP diurnal fluctuations have been shown to be associated with reduced progression of visual field defects in patients with advanced glaucoma (1). When a filtering surgery is necessary in glaucomatous patients with far advanced glaucomatous damage, intraoperative application of antimetabolites has been recommended to reach target IOP in the low teens (1). With this goal of a safer filtering surgery and faced with a high proportion of patients suffering from severe glaucomatous neuropathy in our clinical practice, we have started by the end of 1998 to perform non-penetrating deep sclerectomy routinely. Surgery was combined with with low dose intraoperative antimetabolite application whenever a low target IOP was needed and/or higher risk for surgery failure was present (4,11).
The purpose of this study was firstly to assess our long-term experience of this technique, with respect to its safety and effectiveness and secondly to compare the incidence and the severity of postoperative complications and IOP results according to surgical adjuvants (implant device, intraoperative antimetabolite or both) were used or not.

MATERIAL-METHODS

1. Patients

Our overall experience had concerned a total of 234 deep sclerectomies (DS) performed by the same surgeon (M.D) between December '98 and June '04. Sixty three procedures were excluded from the analysis owing to incomplete data, too short follow-up and/or an history of previous glaucoma surgery. Therefore, this was a retrospective non randomized interventional case study including 171 consecutive procedures performed in 136 patients (73 women, 63 men) with medically open-angle uncontrolled glaucoma. The mean age of patients was 63.9 + 16.1 years (range: 0.7 to 91 years). African ethnicity concerned 1 patient (1 eye).

2. Surgical procedure

All the procedures were performed according to the Kozlov's and Mermoud's technique as following (18).
After placement of a superior peripheral corneal traction and dissection of a limbus-based conjunctival flap, a one third scleral thickness limbus-based scleral flap measuring 5 mm by 5 mm was dissected and continued into clear cornea on about 1.5 mm.
A second deep scleral flap was then dissected leaving a very thin layer of deep sclera over the choroid. Anteriorly, the dissection was carried out to unroof and remove the external wall of Schlemm's canal. More anteriorly, the excision of the corneal stroma was carried out to the Descemet's membrane. Whenever feasible, a gentle peeling of the internal endothelium of Schlemm's canal and juxtacanalicular trabeculum was done with forceps. At this stage, aqueous humor was seen to percolate through the thin remaining trabecular-Descemet's membrane.
After excision of the deep scleral flap, an implant device was placed in the centre of the deep sclerectomy dissection to maintain the scleral lake open, including either a reticulated hyaluronic implant device (SKGEL® CORNEAL, France, 3.5 x 3.5 mm long, 450 μm thick) or a T-FLUX® implant (4 mm arm length, 2.75 mm body height, 0.1-0.3 mm thick) (Ioltech Lab). Owing to their cost and their current absence of reimbursement by insurance in Belgium, Healon GV (AMO) alone was injected in the center of the deep sclerectomy dissection whenever the patient was reluctant to the placement of an implant device.
Then the superficial scleral flap was repositioned over the implant device and loosely sutured with two 10/0 nylon stitches at the angles. Finally the conjunctiva and Tenon capsule were carefully sutured with a running 10-0 Biosorb® suture (Alcon®).

Most procedures were performed under topical anaesthesia.

3. Intraoperative antimetabolite application

When needed, 2 to 3 small sponges soaked with antimetabolites were applied beneath the conjunctival flap, before the dissection of the superficial scleral flap.
Antimetabolites were applied in 111 out of the 171 eyes (64.9%): 5-fluorouracil (5-FU) (50 mg/ml) was used in 58 eyes (52.3%) whereas Mitomycin C (MMC) was applied (0.2 mg/ml) in 53 eyes (47.7%). The mean duration of application of 5-FU (± SD) was 144±48 seconds (range: 45 to 180 seconds). Those of MTM (± SD) was 58±42 seconds (range: 15 to 180 seconds).

4. Postoperative management

1st month postoperative topical treatment consisted in a combination of neomycin, polymixine and dexamethasone, four to three times daily according to the observed intraocular inflammation.
Argon laser suturelysis and 5 mg 5-FU subconjunctival injections (0.1 ml of 50 mg/ml diluted in 0.4 ml of 0.9% saline) were given whenever clinical signs of excessive scarring of the filtration bleb were observed.
Yag laser goniopuncture was performed at the site of surgery through the trabecular-Descemet's membrane when raised IOP was documented.
Miotics were not prescribed during a short period when trabecular microperforation has occurred preoperatively as well as following laser goniopuncture.

5. Pre- and postoperative monitoring.

Complete ocular examination was carried out preoperatively and postoperatively, at day 1, 7, at 1, 2, and 3 months and every 6 months thereafter.

6. Success criteria

Complete success was defined as a clinical target IOP reached without medication at the last examination for each patient.
Qualified success was considered when an individual final target IOP was reached with or without medication.
According to a consensus point in the literature, YAG laser goniopuncture was considered as being an integral part of the procedure (5).
The calculation of target IOP was done using H. Jampel's formula (13).
Target IOP = maximum IOP – maximum IOP% – Z (Z= optic nerve damage severity factor ranging from 0 to 3).
When "maximum" IOP (which was the value at which glaucomatous damage presumably occurred) was unknown, the calculation was based on the severity of optic nerve damage and the associated risk factors for glaucomatous neuropathy (11).

7. Statistical analysis

The statistical analysis was performed using StatView program (Version 4.5 for MacIntosh, Abacus Concepts).
Unpaired sample two-tailed *t*-tests were used to compare the pre- and postoperative IOP measurements. Chi-square analysis for 2 x 2 tables and Anova test were used for comparative analysis of postoperative complications, success rates, IOP results in procedures associated with surgical adjuvants (implant devices and/or antimetabolites) or not. Cumulative success probability rate was defined using Kaplan-Meier life-table analysis. Log-Rank test was used for comparison between the different subgroups.
A *p*-value of less than 0.05 was considered statistically significant.

RESULTS

General characteristics
Primary open angle glaucoma, normal tension glaucoma and high myopic glaucoma concerned 128 out of the 171 eyes (74.8 %). Other diagnoses included pseudoexfoliative glaucoma in 9 eyes (5.3%), pigmentary glaucoma in 5 eyes (2.9%), nonneovascular secondary open-angle glaucoma in 16 eyes (9.4%) and congenital glaucoma in 13 eyes (7.6%). Thirty four eyes (19.8%) and 3 eyes (1.8%) were pseudophakic or aphakic respectively. The mean number of preoperative medications (±SD) was

2.1±0.8 (range: 0 to 5). The mean duration of preoperative medical treatment (±SD) was 90.1±81.7 months. The mean preoperative central visual acuity was 0.71±0.31. Advanced visual field defects (Mean defect MD >−12 dB in SAP Humphrey perimeter) were present in 81 eyes (48.2%). Table 1 summarizes the demographics of patients.

Intraoperative groups.

According to the surgical protocol, DS could be categorized in four different groups:

Group 1: DS with Healon GV in 8 eyes (4.7%).

Group 2: DS with intraoperative antimetabolite application in 26 eyes (15.2%) with 5-FU in 21 eyes and MMC in the other 5 eyes.

Group 3: DS with placement of an implant in 53 eyes (31%): placement of SKGEL® in 44 eyes and T-Flux® in 9 eyes.

Group 4: Combined use of intraoperative antimetabolite and implant device in 84 eyes (49.1%), with a SKGEL® in the majority of the eyes (81 eyes) and a T-Flux® in the other 3 eyes.

Table 1: *General characteristics of patients.*

136 patients (73_ / 63_) - 171 eyes		
Mean age (years ±SD)	63.9 ± 16.1	
(range)	(0.7 to 91)	
Race (patients)		
Caucasian	135	
African	1	
	n eyes	**%**
Diagnosis		
POAG -NTG	107	62.5
POAG-HM	21	12.3
PXG	9	5.3
Pigmentary GI.	5	2.9
Sec GI.	16	9.4
Congenital GI.	13	7.6
Pseudophakic / aphakic	34 eyes (19.8%) / 3 eyes (1.8%)	
Previous laser	59 eyes (34.5%)	
Preop medications (n ± SD)	2.1 ± 0.8 (range 0 to 5)	
Duration medications (months ± SD)	90.1 ± 81.7	
Mean preop VA (SD)	0.71 ± 0.31	
VF defect (HFA-Sita Standard)	n (168 eyes)	%
Mild (MD ⩽ -6dB)	61	36.3
Moderate (-12 dB MD ⩾ - 6dB)	26	15.5
Severe (>-12dB)	**81**	**48.2**

The mean follow-up time (±SD) was 39.6 + 18.3 months (ranging from 3 to 78 months) and revealed to be significantly longer in the group 2 with intraoperative antimetabolite application alone. The table 2 details the mean follow-up (+SD) in the four different peroperative subgroups.

IOP results and success rates

For the whole sample, IOP significantly decreased from a mean (±SD) preoperative value of 27.4±8.5 mmHg (range: 14 to 56 mmHg) to 15.3±5.3 mmHg (range: 4 to 42 mmHg) at the last postoperative visit, corresponding to a IOP reduction of 44% .93 eyes (54.4%) reached a final IOP lower or equal to 15 mmHg. The graph 1 shows the mean (±SD) IOP results, their standard deviation and the sample size at each time interval. The profile of the IOP was relatively stable with time.

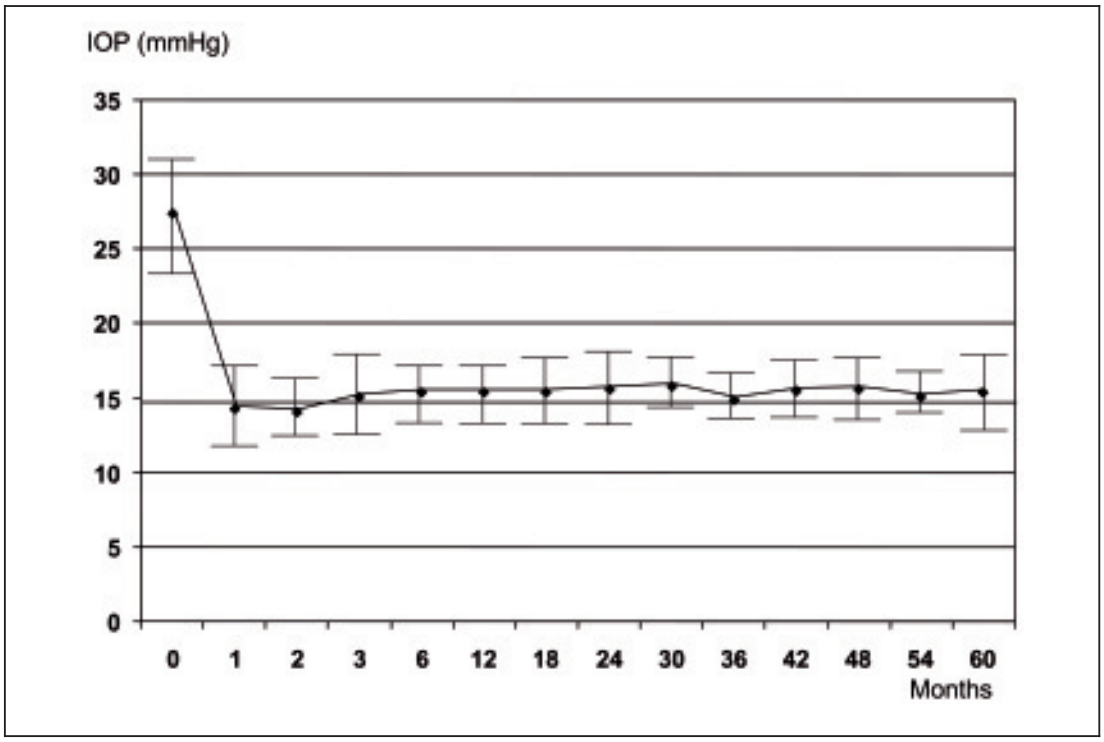
As summarized in table 3, both mean preoperative IOP's and mean IOP reductions were not significantly different in the 4 intraoperative groups at the different visits.

The graph 2 shows the mean IOP evolution in the 4 different subgroups.

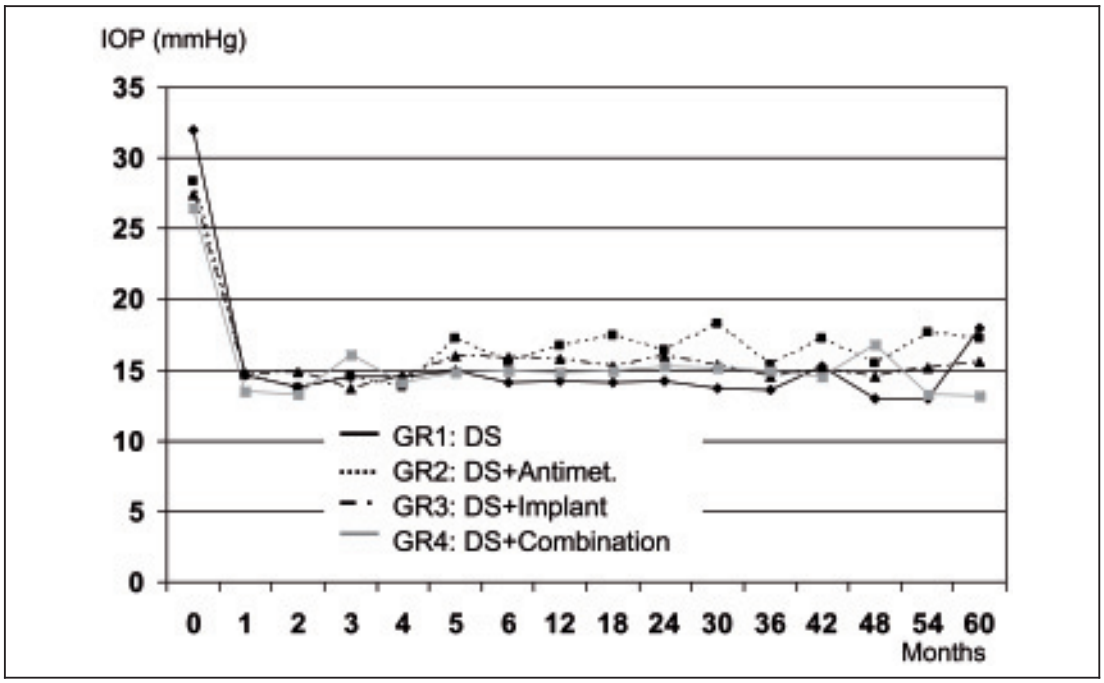
The mean number of medications (±SD) significantly decreased from 2.1 (±0.83) before surgery to 1.2 (±1.2) at the last visit ($p<0.0001$). Among the 103 eyes (60.2%) having needed postoperative medications, only one medication was sufficient in 31 eyes, 2 medications in 48 eyes, 3 medications in 21 eyes and 4 medications in the other 3 eyes. The table 4 shows that both preoperative and final medication mean numbers were not significantly different in the four subgroups.

Table 2: *mean follow-up (FU) (±SD) in the four different intra-operative subgroups.*

	n eyes	**Mean FU ±SD**
Group 1 (Healon GV)	8	39.8±20.8 months
Group 2 (antimetabolite)	**26**	**54.0±19.7 months ($p<0.05$)**
Group 3 (implant)	53	37.7± 15.2 months
Group 4 (implant + antimetabolite)	84	36.4± 17.5 months



Graph 1: mean (±SD) IOP results with their standard deviation and the sample size at each time interval.



Graph 2: Mean IOP evolution in the 4 different subgroups.

Table 3: *mean preoperative IOP's and mean final IOP's in the 4 intraoperative groups.*

	Mean preop. IOP	*Mean final IOP*	*p-value*
	(±SD)	(±SD)	
Group 1 (Healon GV) (n=8)	32.0±11.4	15.2±2.8	>**0.05**
Group 2 (antimetabolite) (n=26)	28.5±9.4	14.9±3.2	
Group 3 (implant) (n=52)	27.5±7.2	15.7±3.6	
Group 4 (implant + antimetabolite) (n=84)	26.5±8.7	15.3±6.7	

Table 4: *summary of the mean preoperative and final medication mean number.*

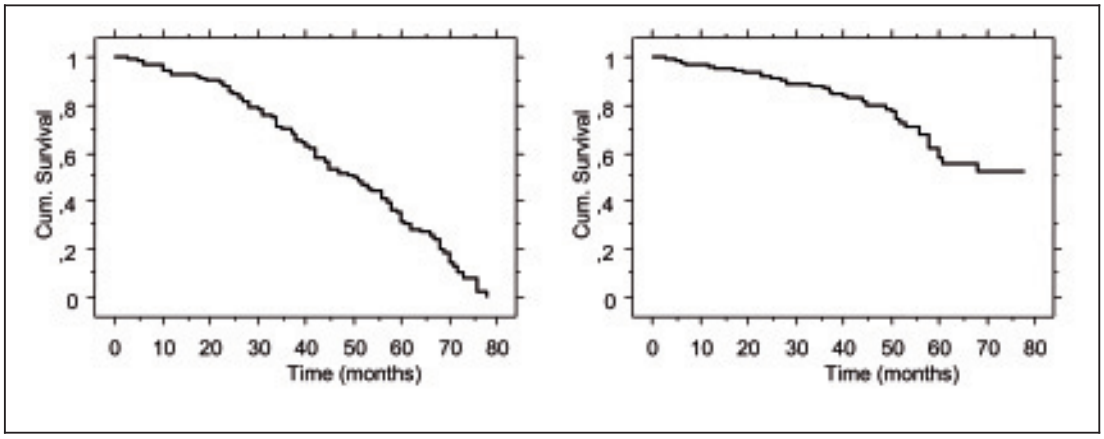
	Preop medi-cations	*Final medi-cations*	p-value
	(n ± SD)	(n ± SD)	
171 eyes	2.1±0.8	1.3±1.2	<0.05
Group 1 (Healon GV) (n=8)	1.8±1.4	0.6±0.9	
Group 2 (Antimetabolite) (n=26)	2.1±0.4	1.3±1.1	
Group 3 (Implant) (n=53)	1.9±0.8	1.1±1.1	
Group 4 (implant + antimetabolite) (n=84)	2.2±0.8	1.3±1.2	>0,05

Table 5: *Frequency of distribution of success rates in the four intraoperative groups.*

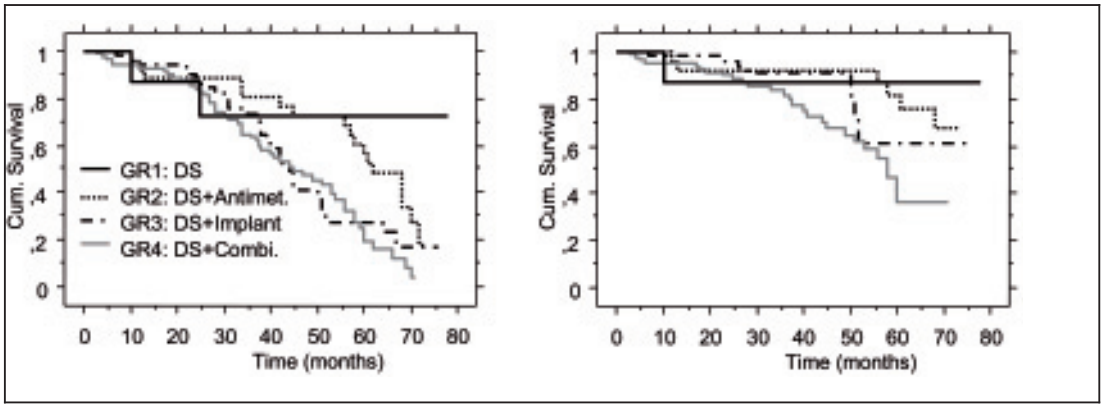
	Complete succes rate	*Qualified succes rate*	*p-value*
n=71 eyes	**66 eyes (39 %)**	**130 eyes (76 %)**	
Group 1 (Healon GN) (n=8)	5 eyes (62.5%)	7 eyes (87.5 %)	X^2>0.05
Group 2 (antimetabolite) (n = 26)	7 eyes (26.9%)	20 eyes (76.9%)	
Group 3 (implant) (n=53)	23 eyes (43.4%)	46 eyes (86.8%)	
Group 4 (implant + antimetabolite) (n=83)	31 eyes (36.9%)	57 eyes (67.8%)	

According to the predefined success criteria, 66 out of the 171 eyes (39%) presented with complete success at the last visit. Qualified success concerned 130 eyes (76%). As illustrated in the table 5, the frequency of distribution of successes was not significantly different between the 4 groups, although the percentages of success were slightly higher in the subgroups 1 (Healon GV alone) and 3 (implant alone).
As shown on graph 3, the overall probability success rate, defined with the Kaplan-Meier method was 93% at 1 year, 85.6% at 2 years, 69.8% at 3 years, 62.7% at 40 months (mean actual follow-up) and 52% at 4 years without medications. The probability success rates increased to 96.5% at 1 year, 92.1% at 2 years, 86.8% at 3 years, 84% at 40 months and 80% at 4 years with medical treatment for the whole sample (171 eyes).
The analysis of the probability success rates observed in the four different operative subgroups showed a tendency for the subgroup 4 with implant device and antimetabolite combination to have lower complete and qualified probability success rates at 40 months (graph 4). At 40 months, the probability complete success rates were 72.9% in the subgroup 1, 76.7% in the subgroup 2, 59.3% in the subgroup 3 and 56.5% in the subgroup 4 (Logrank (Mantel-Cox) p= 0.0095). Concomitantly, the probability qualified success rates were 87.5%, 92%, 91.5% and 75.1% respectively in the subgroups 1 to 4 (Logrank p=0.0239).

Mean final visual acuity
The mean best corrected final visual acuity was slightly but significantly decreased to 0.65±0.33 (p < 0.0001) compared with its preoperative level which was 0.71 + 0.31 range: 0.01 to



Graph 3: Overall complete (on the left side) and qualified (on the right side) probability success rate, defined with the Kaplan-Meier method in the 171 eyes.



Graph 4: Complete (on the left side) and qualified (on the right side) probability success rate, defined with the Kaplan-Meier method in the four different intraoperative subgroups (logrank test $p<0.05$).

1.2). In all cases, progression of lens opacity was responsible for this reduction. As summarized in table 6, the mean final visual acuity was not significantly different between the 4 subgroups.

COMPLICATIONS

1. Peroperative complications

Surgery itself was uneventful in 136 eyes (79.7%). Iatrogenic microperforations of the trabecular-Descemet's membrane occurred in 35 eyes (20.5%). These were associated with a small iris prolapse in 12 eyes (7%) which could be resumed by needle punction (30 gauge needle) in all cases. Associated shallowing of the anterior chamber was not observed in any case.

2. 1st month postoperative complications (table 7)

First month postoperative course was uncomplicated in 81 eyes (47.4%). Mild hyperfiltration associated with transient shallowing of the anterior chamber with or without localized choroidal effusion, was observed in 27 eyes (15.8%). Transient wound leaks which have been successfully managed by conjunctival suture and/or megasoft contact lens placement

Table 6: *Mean best corrected preoperative and final visual acuities with their standard deviation in the four operative subgroups.*

	Preop VA	*final VA*	*p-value*
	(mean ±SD)	(mean ±SD)	
n 171 eyes	0.71±0.31	0.65±0.33	<0.05
Group 1 (Healon GV) (n=8)	0.6+0.4	0.5±0.3	
Group 2 (Antimetabolite) (n=26)	0.6±0.3	0.5±0.3	
Group 3 (implant) (n=53)	0.8±0.3	0.7±0.3	
Group 4 (implant + antimetabolite) (n=84)	0.7±0.3	0.7±0.3	>0.05

were noticed in 8 eyes (4.7%). Excessive scarring of the filtration bleb was observed in 38 eyes (22.2%). 5-FU subconjunctival injections were performed in 58 eyes (34%). The mean number (±SD) of 5-FU injections was 6±3. No significant difference could be noticed in the 4 subgroups with respect with 5-FU postoperative adjuvant therapy.

Iris incarceration associated with increased IOP concerned 10 eyes (5.8%). Peroperative inadvertent microperforation of the trabecular-Descemet's membrane had occurred in four out of them. The 3 others occurred after early YAG goniopuncture. Laser iridoplasties allowed to successfully resolve this complication in 8 eyes. Surgical iris repositioning was needed in 1 eye. Surgical revision of the dissection site was successfully done in one eye.

YAG laser goniopuncture was needed in 107 out of the 171 eyes (62.6%). Goniopuncture was performed slightly more frequently in the subgroup 3 with the implant alone compared to the 3 other subgroups: 69.8% in this group versus 50%, 53.8% and 61.9% respectively in group 1 (Healon GV alone), group 2 (intraoperative antimetabolite application) and group 4 (combination of implant and antimetabolite) (chi-square $p > 0.05$) (table 8). 67% of YAG laser goniopunctures were performed beyond the 6th postoperative month. The mean interval between surgery and laser goniopuncture (±SD) was 14.2±12.4 months (range: 0.5 to 58 months). The mean final IOP (±SD) was not significantly different according goniopuncture was used before 6 months (16.1±4.2 mmHg) or after 6 months (15.2±5.3 mmHg).

Table 7: *summary of the 1st month postoperative complications.*

None	81 eyes (47.4%)
Bleb fibrosis	28 eyes (22.2%)
Hyperfiltration with AC shallowing	27 eyes (15.8%)
Transient wound leaks	8 eyes (4.7%)
Iris prolapse	10 eyes (5.8%)
Others	7 eyes (4.1%)
- *micro-hyphema*	*5 eyes (posttraumatic in 1 eye)*
- *Oedematous corneal decompensation*	*1 eye*
- *endothelial dissection with Tenon's capsule cyst*	*1 eye*
5-FU injections	**58 eyes (34%)**

Table 8: *Frequency of YAG laser goniopunctures in the whole sample and in the 4 intraoperative subgroups.*

n 171 eyes	*107 eyes (62.6%)*	
Group 1 (Healon) (n=8)	4 eyes (50%)	$X^2 p > 0.05$
Group 2 (Antimetabolite) n=26)	14 eyes (53.8%)	
Group 3 (implant) (n=53)	37 eyes (69.8%)	
Group 4 (implant + antimetabolite) (n=84)	52 eyes (61.9%)	

3. Late postoperative complications

Table 9 summarizes the different complications observed beyond the first postoperative month. Among them, blebitis occurred in two eyes (1.2%). Iris prolapse was observed in nine eyes (5.3%). Three of them occurred spontaneously, the six others following YAG laser goniopuncture. Five out of them required a surgical desincarceration.

Table 9: *Complications observed beyond the 1st postoperative month.*

	n eyes	%
None	152	88.9
Blebitis	2	1.2
with perop. antimetabolite	1	
without perop. antimetabolite	1	
Iris prolapse	3	1.8
spontaneous		
post-YAG goniopuncture	6	3.5
Others	8	4.7
Uveitis with choroidal effusion	1	
Macular pucker	2	
Chronic corneal edema	1	
Leaking bleb	2	
Astigmatism	2	

The frequency of distribution of both early and late complications was not significantly different between the different subgroups.
Overall reinterventions are developed in table 10. A second filtering procedure was needed in 10 eyes (5.8%).

Table 10: First-month and late surgical reinterventions (n=19/171 eyes)(11.1%)

Iris desincarceration	6 eyes (3.5%)
Trabeculectomy	6 eyes (3.5%)
Second deep sclerectomy	4 eyes (2.3%)
Excision of Tenon cyst	1 eye (0.6%)
Repeated in situ dissection	2 eyes (1.2%)

DISCUSSION

Previous studies dealing with non-penetrating deep sclerectomy are difficult to compare because criteria for success differ, length of follow-up varies, surgical techniques are different and patient composition differs greatly between published papers (2,3,5-9,12,14-19,21-25). This procedure has been proven to lower IOP usually to the mid-high teens. Based on a final IOP lower than 21 mmHg, reported success rates ranged from 34% to 81% in retrospective studies with a mean final IOP ranging between 11 to 17.8 mmHg (3, 7, 8, 12, 14, 17, 18, 19, 21, 23-25). On the other hand, success rates of less numerous prospective studies that compared deep sclerectomy with trabeculectomy ranged from 40% to 93.20% with mean final IOP ranging from 11 mmHg to 18.75 mmHg (2,6,9,15,18). While IOP control may be better when a device is implanted compared with no device, it has been also suggested that intraoperative 5-FU achieves a similar IOP level (8,16,23).

With a mean follow-up of three years and half, the results of our study can be analyzed at two different levels.
For the whole sample, we confirmed that deep sclerectomy has a relatively safe profile and could be an effective procedure. We found in fact a mean IOP decrease of 44% with a mean final IOP of 15.3 mmHg. 54% of the eyes had final IOP $\leqslant$15 mmHg. Based on a individual target IOP as criterium for success and not on a target IOP $\leqslant$21 mmHg as usually referred, we observed a 39% complete final success rate but a 76% qualified final success rate. These results confirm that adjunctive medications are needed in a high percentage of cases after deep sclerectomy. In agreement with most previous studies, we also found that the probability of success decreases over time: from 93% and 96.5% respectively at twelve months, the complete and qualified success probability decreased to 62.7% and 84% at 40 months. The most important complication we had to manage was iris incarceration which occurred, all in all, in 19 eyes (11%). Ten occurred spontaneously, 9 after Yag laser goniopuncture. Because most of these iris incarcerations were asymptomatic and, as a consequence, were often diagnosed too late and even fortuitously, 6 of them had needed a surgical approach to be treated. In agreement with some previous papers that showed that their rate increases with longer follow-up, YAG goniopunctures were performed in about 63% of the eyes in our experience (16). Importantly, they had been by themselves complicated by iris incarceration in nine eyes, which occurred at different interval times whereas the iridocorneal angle was open in all cases. Early transient administration of miotics following YAG laser goniopuncture would have probably been associated with a reduced incidence of this potentially vision threatening complication (18).

The second part of our study concerns the analysis of the results observed in the four different intraoperative groups: DS alone, DS with intraoperative antimetabolite, DS with implant and DS with combined antimetabolite and implant. Clearly our results must be interpreted very carefully because of the heterogeneous sample size of the different subgroups and the retrospective non randomized nature of this study. However, we found that the mean IOP decrease, the frequency of distribution of complete, qualified success rates and the postoperative complications were comparable between the four subgroups. Interestingly only the group with a combination of implant and peroperative antimetabolite exhibited significantly lower complete and qualified probability success rates compared to the three other groups. The explanations for this higher failure rate in this group are still unclear. Unlike to a previous study that found a significant increase in IOP reduction and complete success rate with adjunctive intraoperative MMC, we found a similar success rate whenever intraoperative antimetabolites were used or not (15). However, our results must be analysed very carefully because they could have been biased by the fact that we used intraoperative antimetabolites, specially 5-FU, at lower application duration than usually recommended to minimize complications related to their use (10). In any case, potential long-term complications associated with the intraoperative use of mitomycin should warn of the potential dangers of the routinely use of antimetabolites during surgery (10,23,24).

CONCLUSION

Considering the limitations of our study, we can conclude that non penetrating deep sclerectomy is a relatively safe and effective procedure. Yag goniopuncture and /or adjunctive medications are frequently needed. Low dose intraoperative antimetabolites and placement of implant do not seem to improve success rates. Patients must be periodically monitored for iris incarceration. Except for high myopic eyes, early short-term pilocarpine will be systematically administered after Yag laser goniopuncture to prevent iris incarceration. In any case, a meticulous skilled surgical technique is crucial to make easier Yag laser goniopuncture, reduce the incidence of inadvertent and/or undiagnosed microperforations of the trabecular-Descemet's membrane, and the associated risk for spontaneous iris incarceration.

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