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Combined Ex-PRESS LR-50/IOL implantation in modified deep sclerectomy plus phacoemulsification for glaucoma associated with cataract

THESE

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par

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Combined Ex-PRESS LR-50/IOL implantation in modified deep sclerectomy plus phacoemulsification for glaucoma associated with cataract

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Madame le Professeur Stephanie Clarke
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RAPPORT DE SYNTHESE

BUT

Le but de cette étude est de suivre prospectivement les résultats d'une sclérectomie profonde (SP) modifiée en utilisant le tube Ex-PRESS LR-50, associée à une phacoémulsification avec implantation d'une lentille intraoculaire (LIO), dans la chirurgie combinée du glaucome et de la cataracte.

METHODE

Nous avons inclus dans l'étude 24 yeux de 24 patients présentant un glaucome médicalement non contrôlé et une cataracte justifiant son ablation.
Une phacoémulsification avec implantation d'une LIO est effectuée. Puis le tube Ex-PRESS LR-50 est inséré au niveau du canal de Schlemm, dans la chambre antérieure, sous un volet scléral. Une SP postérieure partielle est ensuite pratiquée afin de créer une bulle de filtration intrasclérale.
Le taux de succès complet a été défini par une pression intraoculaire (PIO) $\leq$ 18 mmHg sans traitement et le taux de succès relatif par une PIO $\leq$ 18 mmHg avec ou sans traitement.
En cas de fibrose ou de kyste de la bulle de filtration, une injection sous-conjonctivale d'une solution de Mitomycin C à 0.02% est réalisée, avec ou sans needling.

RESULTATS

Le suivi moyen était de 40.1±10.8 [moyenne±DS] mois. En préopératoire, la PIO se situait à 18.1±5.3 mmHg; la meilleure acuité visuelle corrigée (MAVC) était mesurée à 0.6±0.3 (échelle de Snellen) et le nombre de médicaments hypotenseurs oculaires était de 2.3±1.1.
La PIO a diminué de 25.4% à 24 mois et de 27.0% à 48 mois. A 24 mois, 19 patients (86.3%) avaient une MAVC supérieure ou égal à 0.5, et à 48 mois la MAVC était mesurée à 0.7±0.3. Lors de la dernière visite, le nombre moyen de médicaments se situait à 0.6±0.8 ($p<0.05$).
Des injections sous conjonctivales d'une solution de Mitomycin C à 0.02% ont été nécessaires dans 5 yeux. Aucune érosion conjonctivale n'a été constatée. Deux complications majeures ont été observées. Une endophtalmie, deux jours après l'intervention chirurgicale avec phtisis secondaire du globe oculaire. Une obstruction du tube Ex-PRESS LR-50 par de la fibrine, ayant justifié son ablation avec SP classique en un autre site.

CONCLUSION

Le tube Ex-PRESS LR-50 inséré dans la chambre antérieure avec une SP modifiée réduit efficacement la PIO dans la chirurgie combinée du glaucome et prévient l'érosion conjonctivale, une complication importante lorsque l'implant n'est pas couvert par un volet scléral.

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ORIGINAL ARTICLE

Combined Ex-PRESS LR-50/IOL implantation in modified deep sclerectomy plus phacoemulsification for glaucoma associated with cataract

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PURPOSE. *This is a prospective study reporting on modified deep sclerectomy (DS) using the Ex-PRESS LR-50 in combined cataract and glaucoma surgery.*

METHODS. *Twenty-four eyes of 24 patients with medically uncontrolled glaucoma underwent modified DS. After phacoemulsification and intraocular lens implantation, the Ex-PRESS LR-50 was inserted into the anterior chamber under a scleral flap. A partial posterior DS was performed to provide an intrascleral bleb. The complete success rate was intraocular pressure (IOP) without medication ≤18 mmHg; the qualified success rate was IOP ≤18 mmHg with or without medication. Postoperative bleb management (subconjunctival mitomycin C injections ± needling) was performed in case of postoperative hypertension or bleb fibrosis.*

RESULTS. *Follow-up was 40.1±10.8 (mean ± SD) months. Preoperatively, IOP was 18.1±5.3 mmHg, best-corrected visual acuity (BCVA) was 0.6±0.3, and number of medications was 2.3±1.1. The IOP decreased by 25.4% at 24 months and by 27.0% at 48 months. At 24 months, 19 patients (86.3%) achieved a BCVA of 0.5 or better, and at 48 months the mean BCVA was 0.7±0.3. At the last visit, the mean number of medications was 0.6±0.8 ($p<0.05$). The complete and qualified success rates were 45.6% and 85.2%. Mitomycin C injections were performed in 5 eyes. No conjunctival erosions over the Ex-PRESS LR-50 were seen.*

CONCLUSIONS. *The Ex-PRESS LR-50 inserted into the anterior chamber after modified DS efficiently lowers IOP in combined surgery, preventing conjunctival erosion, a significant complication when using this device without scleral flap coverage.*

KEY WORDS. *Cataract surgery, Combined cataract and filtering surgery, Drainage device, Glaucoma, Glaucoma surgery, Minimally invasive surgical procedure, Trabeculectomy*

INTRODUCTION

Glaucoma is the second leading cause of blindness worldwide (1). When nonsurgical means of reducing intraocular pressure (IOP) to the target IOP fail, filtering surgery is necessary.

Classic trabeculectomy was developed by Cairns in the late 1960s (2). This penetrating technique, bypassing the trabecular meshwork resistance, has well-documented complications such as hypotony, hyphema, flat anterior chamber (AC), choroidal detachment, choroidal effusion or hemorrhage, endophthalmitis, and surgery-induced cataract (3).

Deep sclerectomy (DS), a nonpenetrating filtering procedure, has been designed in an attempt to avoid the sudden hypotony encountered during and immediately after trabeculectomy. This goal is achieved by dissecting the filtering trabeculo-Descemet membrane (TDM), which will en-

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sure a reproducible postoperative IOP. This procedure also creates new outflow pathways through the thin remaining TDM, the intrascleral filtering space connected to drainage vessels, and the subchoroidal space. These new routes for the aqueous humor (AH) outflow may decrease the size of the subconjunctival and sub-Tenon filtering bleb (4).

Anterior dissection of the TDM during DS requires a high degree of surgical skill to avoid perforation of the TDM. Wide use of such procedure is therefore limited to the learning curve required to minimize the risk of such a complication. To increase the safety of this technique and to lower the time of surgery, new miniature glaucoma devices inserted at the level of Schlemm canal (SC) were developed in the late 1990s. The AH is drained from the AC directly through the tube to the intrascleral space and then forms a subconjunctival bleb. However, recent articles reported high complication rates after implantation of Ex-PRESS R-50 immediately under the conjunctiva (5-8).

The purpose of this article was to prospectively study the success rate and complications of a modified DS using a new model of Ex-PRESS device under a scleral flap. This model was designed to avoid the initial complications reported in early models, such as conjunctival erosion and tube extrusion. The Ex-PRESS LR-50 glaucoma drainage device introduced at the level of SC drains AH from the AC to the intrascleral and the subconjunctival spaces because a scleral flap is being performed under the conjunctiva.

METHODS

This prospective nonrandomized study was performed on 24 eyes of 24 patients with medically uncontrolled glaucoma at the Glaucoma Unit, Jules Gonin Eyes Hospital, Lausanne University, between April 2003 and September 2007. This study was approved by the Ethical Committee of the University of Lausanne. Each patient was informed in detail about the surgery and its complications prior to giving consent. Each intervention was a combined glaucoma surgery with phacoemulsification and intraocular lens (IOL) implantation performed by one experienced surgeon (A.M.) between April 2003 and January 2004.

Preoperative data

A comprehensive examination was performed before surgery and at 1 and 7 days as well as 1, 3, 6, 12, 18, 24, 36, and 48 months after surgery. All examinations included Snellen distance best-corrected visual acuity (BCVA), biomicroscopy, IOP measurement with Goldmann applanation tonometer, and fundus and vertical cup/disk ratio (C/Dv) observation. Ultrasound pachymetry and visual field using the Octopus 1-2-3, dG2 program were performed only once before surgery.

Medically uncontrolled glaucoma was defined based on IOP measurements, C/Dv ratio, and visual field testing. When any one of these parameters showed evidence of progression in glaucoma, filtering surgery was proposed to limit further deterioration and to reduce the need for additional antiglaucoma drugs. In addition, when lens opacities were also viewed using biomicroscopy, with reduction in visual acuity and the patient complaining of glare, cataract extraction was proposed and a combined glaucoma/cataract procedure was performed. Only patients with combined surgery were included in this study. Inclusion criteria were pseudoexfoliative, primary open-angle, angle-closure, and normal-tension glaucomas. Exclusion criteria were traumatic, congenital, or neovascular glaucomas, age younger than 18 years, pregnancy or breast-feeding, and inability to comply with the follow-up program or unwillingness to participate in this study.

Glaucoma drainage implant

The Ex-PRESS version LR-50 (Optonol Ltd.) is a miniature device used to drain the AH from the AC to the intrascleral space. It is a small tube, 2.96 mm long, with an outer diameter of 400 µm and a lumen diameter of 50 µm, made of biocompatible, MRI-compatible stainless steel (9).

Surgical technique

The surgical technique of classic DS has been described previously (10, 11). In this study, all patients underwent phacoemulsification and IOL implantation followed by a slightly modified DS technique (2-site approach). After a fornix-based opening of the conjunctiva and a dissection of a 5 x 5-mm superficial scleral flap, a 4 x 3-mm deep scleral flap was removed just behind the SC. The device was then inserted into the AC at the level of SC and the superficial scleral flap was sutured back in place over the tube. Viscoelastics were left in the AC to prevent collapse and postoperative hypotony. The scleral flap was secured using 2 nylon 10.0 sutures, and conjunctiva closed us-

ing running Vicryl 8.0 suture. Postoperatively, patients were treated with topical tobramycin and dexamethasone tid for 1 month and then with topical diclofenac bid for 2 months.

Postoperative management

When the filtrating bleb at any postoperative visit showed signs of fibrosis leading to an increase in IOP, a subconjunctival injection (0.1 to 0.2 mL) of a 0.02% solution of MMC was administrated. In cases of encysted bleb, a needling procedure was performed at the slit lamp prior to the MMC injection at the same time. Aqueous humor leak through the bleb was made visible using fluorescein dye and was then defined as a Seidel-positive sign. When posterior capsular opacities developed after cataract surgery, neodymium:YAG (Nd:YAG) laser capsulotomy was performed.

Criteria for success

Surgery was considered a success when IOP was measured, without addition of any glaucoma drugs, to be >6 mmHg and either ≤18 mmHg for criterion A or ≤15 mmHg for criterion B. Qualified success used the same criteria, but with medication. Failure occurred when IOP was >18 mmHg despite maximally tolerated medication, and/or further glaucoma surgery was required, when the device had to be removed, or when light perception was lost.

Statistical analysis

Data are expressed as the mean ± SD. Results were analyzed using a 1-way analysis of variance and Student *t*-test for parametric data (IOP), Wilcoxon signed-rank test for nonparametric data (BCVA, number of medications), and Kaplan-Meier survival curves at the end of follow-up. Results were considered significant when $p<0.05$.

RESULTS

The 24 patients included in this study were between 66 and 91 years of age. Demographic data are shown in Table I. The follow-up period was 40.1±10.8 months. Thirteen patients achieved a complete follow-up, 2 subjects discontinued the study (1 after removal of the device and 1 after a second filtering procedure), 6 were lost to follow-up, and 3 died. Four patients had previous Nd:YAG laser iridotomy, 1 patient had peripheric iridectomy, 2 patients had retinal detachment surgery, and 1 patient had vitrectomy for epiretinal membrane peeling. All patients complained of visual disturbance resulting from lens opacities. The most common glaucoma diagnosis was pseudoexfoliative glaucoma (50%). In addition, 10 patients had nonglaucomatous pathology, mainly hypertensive retinopathy and age-related macular degeneration.

The preoperative IOP was 18.1±5.3 mmHg (Tab. II). The IOP decreased by 25.4% at 24 months and by 27.0% at 48 months. The difference between the preoperative and postoperative IOP was significant ($p<0.05$). Figure 1 shows the evolution during all follow-up visits. There was a clear decrease immediately after the surgery, followed by a gradually increased IOP, and stabilization at around 13 mmHg.

The BCVA was 0.6±0.3 preoperatively. At 24 months, 13 patients (59.0%) achieved a BCVA of 0.8 or better, 6 (27.3%) achieved a BCVA between 0.5 and 0.8, and 3 (13.7%) had a BCVA below 0.5 ($p<0.05$). At 48 months, 52.6% of the remaining patients achieved a BCVA of 0.5 or better (mean 0.7±0.3). The BCVA measured at the end of follow-up slightly decreased, but this was due to diseases unrelated to the combined surgery (retinal diseases, e.g.,

TABLE I - DEMOGRAPHICS

Characteristics	No. (%) or mean ± SD
Patients	24
Age, y	77.9±7.1 (range 66-91)
Female/male	18 (75)/6 (25)
White	24 (100)
Follow-up, mo	40.1±10.8
Lost to follow-up	6 (25)
Deceased	3 (12.5)
Previous surgery	7 (29.17)
Glaucoma	5 (20.83)
Nd:YAG laser iridotomy	4
Peripheral iridectomy	1
Retinal*	3 (12.5)
Glaucoma diagnosis	
Pseudoexfoliative	12 (50)
Primary open angle	5 (20.8)
Secondary	3 (12.5)
Angle closure	2 (8.3)
Normal tension	2 (8.3)

*One patient combined with iridectomy procedure.

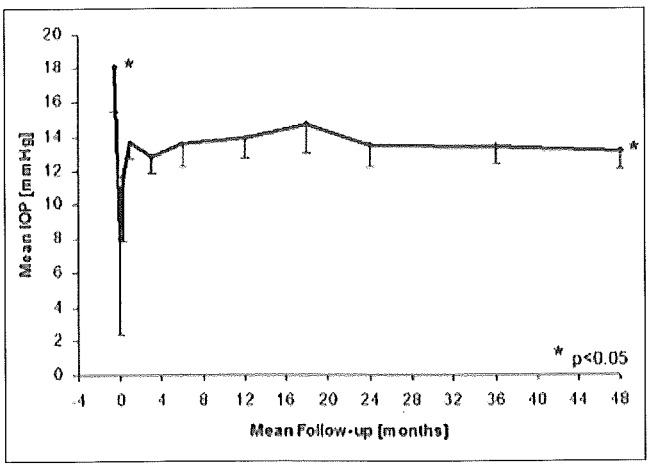


Fig. 1 - *Evolution of the mean intraocular pressure (IOP) over time.*

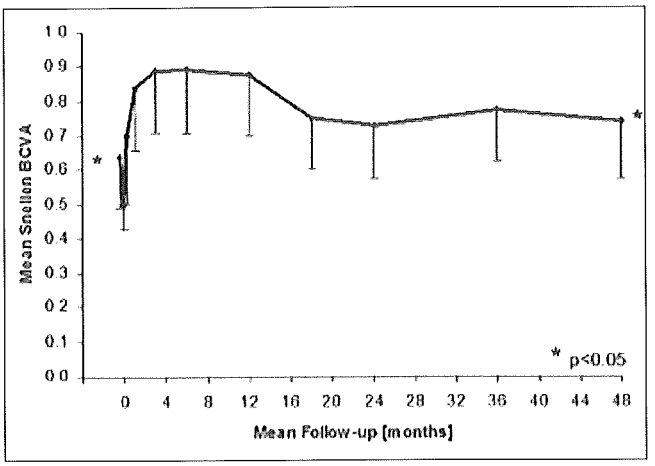


Fig. 2 - *Evolution of the mean best-corrected visual acuity (BCVA) over time.*

TABLE II - PREOPERATIVE AND POSTOPERATIVE DATA AT 24 AND 48 MONTHS

	Preoperative (n=24)	24 months (n=22)	48 months (n=13)
Intraocular pressure, mmHg	18.1±5.3	13.5±2.5	13.2±2.2
Best-corrected visual acuity	0.6±0.3	0.7±0.3	0.7±0.3
No. medications	2.3±1.1	0.6±0.9	0.6±0.8

Values are mean ± SD.

TABLE III - POSTOPERATIVE COMPLICATIONS

Complications	No. (%)
Early minor (first month)	
IOP spikes during the first month*	4 (16.6)
Bleb leak	3 (12.5)
Hyphema	2 (8.3)
Flat anterior chamber	2 (8.3)
Choroidal effusion	2 (8.3)
Contact between device and cornea	1 (4.2)
Retinal branch vein occlusion	1 (4.2)
Cystic bleb/no bleb	5 (20.8)
Late minor	
Posterior capsular opacities	13 (54.2)
Macular edema	1 (4.2)
Early major (first week)	
Endophthalmitis	1 (4.2)
Late major	
Tube clotted	1 (4.2)

IOP spikes = intraocular pressure >21 mmHg.
*Mean intraocular pressure 35 mmHg.

diabetic retinopathy, age-related maculopathy, vascular occlusion) (Fig. 2).

The number of medications significantly dropped after surgery and remained fairly stable thereafter (Fig. 3) ($p<0.05$). Every patient was on IOP-lowering drugs before surgery but only 6 patients needed such drugs 48 months postoperatively.

The preoperative C/Dv was 0.7±0.2, the visual field mean deficit was 5.4±7.3 decibels, and the pachymetry measured 531.4±25.2 µm.

Early minor complications listed in Table III resolved within 1 month and were more frequent in patients diagnosed with pseudoexfoliative glaucoma. During the first week, 4 patients had IOP spikes (IOP >21 mmHg). Two of these patients needed Healon® removal after day 1 and the other 2 were under control after the first week. One of them had hypotonia with micro-Seidel and choroidal effusion, followed by hypertonia, which was treated by subconjunctival 0.02% MMC injection. The second patient, who presented a shallow AC associated with pseudoexfoliative glaucoma, was treated with ar-

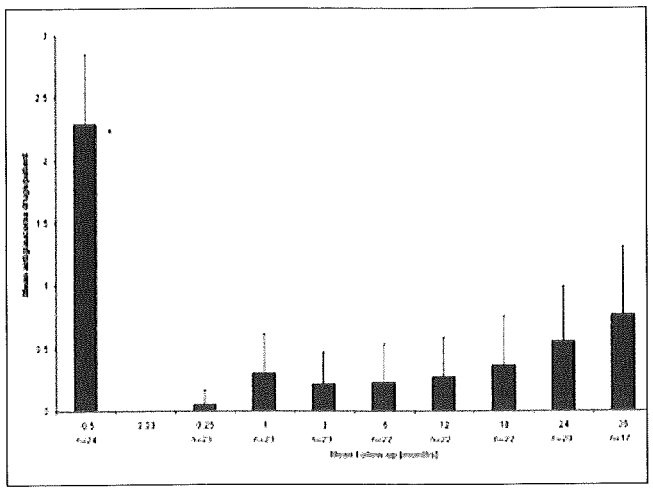
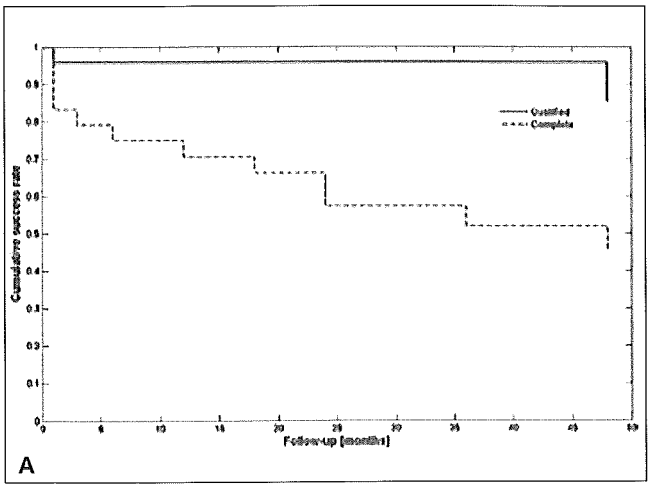


Fig. 3 - *Evolution of the mean number of medications over time.*



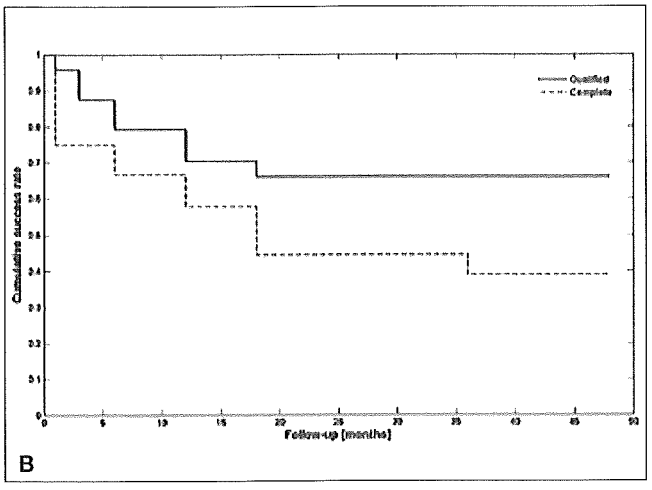


Fig. 4 - *Kaplan-Meier cumulative survival curve. Criterion* **A** *for success = intraocular pressure <18 mmHg. Criterion* **B** *for success = intraocular pressure <15 mmHg.*

gon laser to break the posterior sutures of the scleral flap and benefited from 1 subconjunctival MMC injection. For the remaining 2 patients with positive Seidel, 1 case resolved spontaneously and for the other patient, the conjunctiva needed to be revised after 3 weeks due to wound dehiscence and a flat filtering bleb.

For postoperative management, 8 subconjunctival MMC injections were given for 5 patients (pseudoexfoliative glaucoma). Two cases resulted from IOP spikes, while the other 3 were caused by fibrosis of the filtering bleb, which was the main postoperative complication directly related to this glaucoma surgery. One of these patients required concomitant bleb needling. The mean final IOP after MMC injection was 15.0±2.6 mmHg. Of the 24 patients, 13 developed posterior capsular opacities following lens replacement. These opacities were severe in 6 patients, who required Nd:YAG laser capsulotomy, performed between 6 and 48 months, to restore visual acuity.

Two major complications were reported. Two days after surgery, a blebitis with endophthalmitis developed in a diabetic patient (66 years old), and culture of the smear was positive for *Streptococcus* hemolytic group C. This complication required drainage of the abscess, antibiotics injection, and removal of the device. One week later, the conjunctiva was necrotic, the cornea was melting, and 2 weeks later the eye was hypotonic and ended in phthisis bulbi. The previously described patient (pseudoexfoliative glaucoma) with hypotonia with micro-Seidel and choroidal effusion needed 4 antiglaucoma medications at 36 months to get the IOP to 18 mmHg. At 41 months, the device was clotted with fibrin deposits, which required a classic DS with MMC injection performed in another site, the device remaining untouched. The result was satisfactory, the IOP being around 8 mmHg without any medication 7 months after the second surgery.

Based on Kaplan-Meier cumulative survival curve at 48 months, and referring to criterion A, the complete success rate was 45.6% and the qualified success rate was 85.2%. Using criterion B, the success rates were 38.9% and 66.0%, respectively (Fig. 4).

DISCUSSION

This article reports on the surgical outcome of a prospective study of modified DS and phacoemulsification in combined glaucoma and cataract surgery. Watson et al and Molteno et al reported on the long-term results after trabeculectomy (3, 12). The most common complications that occurred shortly after trabeculectomy alone were hyphemas, shallowing of the AC, and choroidal detachment. Reduction in visual acuity was reported in 30% to 50% of patients (3). The success rate remained at 85% to 90% (3, 4).

Deep sclerectomy was proposed to lower the incidence of potential vision-threatening complications related to sudden hypotony occurring following trabeculectomy (4, 10-15). Karlen et al, Shaarawy et al, and Bissig et al studied long-term results after DS with collagen implant (DSCI) (14, 16, 17). They found a lower number of complications compared to that of trabeculectomy studied by Watson et al (12). Bissig et al mentioned 9% hyphema, no shallow AC, and 8% choroidal detachment after DSCI (17). The success rate was 91% after 8 years and 89% at 10 years follow-up (11, 16, 17). The drawback of this technique lies in the increased risk of perforation of the very thin TDM when performing the anterior dissection of the deep scleral flap into clear cornea. Karlen et al mentioned that the risk may be as high as 30%, at least during the learning phase (14). In this respect, Bylsma suggested that if the safety margin of glaucoma surgery could be increased significantly without sacrificing efficacy, surgical intervention for glaucoma might be considered earlier (13).

In the late 1990s, Optonol Ltd. (Neve Ilan, Israel) developed a new glaucoma drainage device in the form of a miniature glaucoma implant, namely the Ex-PRESS R-50™. The rationale behind proposing such a device for glaucoma surgery was mostly to simplify the surgical technique and to lower the related surgical complications. The early model was designed to be inserted under the conjunctiva, to shunt the trabeculum resistance with a direct connection between the AC and the subconjunctival filtering space. Rivier et al demonstrated that this technique was associated with a relatively high number of complications, despite good IOP control in the uncomplicated cases (8). The success rate was 54% 4 years after surgery. The 2 major complications were tube obstruction and conjunctival erosion. The authors proposed to protect the conjunctiva by shielding the tube under a superficial scleral flap. Steward et al, Garg et al, and Tavolato et al have all reported complications following Ex-PRESS tube implantation (6, 7, 18). Dahan et al presented a modification of the original surgical technique using an Ex-PRESS tube under a scleral flap (19). This technique was found to be safe and effective with few complications when the tube was implanted under a scleral flap. Similarly, Coupin et al obtained good results using such a drainage device under a scleral flap (20). The use of the scleral flap to cover the tube reduced the risk of conjunctival erosion. The success rate reported was 87%. In a study comparing trabeculectomy and the Ex-PRESS miniature glaucoma device implanted under a scleral flap, Maris et al showed that the Ex-PRESS implant had similar IOP-lowering efficacy with a lower rate of early hypotony when compared with trabeculectomy (21). Early postoperative hypotony and choroidal effusion were significantly more frequent after trabeculectomy when compared with the Ex-PRESS implant.

In an attempt to avoid the major complications due to the Ex-PRESS R-50 and to simplify the DS technique, a modified DS with a new glaucoma drainage device, the Ex-PRESS version LR-50, was proposed. This new technique has the advantage of avoiding the difficult dissection of TDM while still getting benefit from the mechanisms of resorption of AH in the scleral space after DS. The AH is directly routed from the AC into the scleral space through a miniature drainage device and subsequently drained in the subconjunctival space and collecting vessels. Contrary to the technique of Dahan et al and Coupin et al, where no removal of the deep scleral flap was performed, the modified DS was helping aqueous to flow into the scleral space instead of being directly drained in such subconjunctival space (19, 20).

In terms of the IOP-lowering effect, implantation of the Ex-PRESS LR-50 resulted in a significant decrease by 25.4% at 24 months and 27.0% at 48 months, with a mean pressure at 13.2±2.2 mmHg on average. Most of these favorable results were in pseudoexfoliative glaucoma (almost 45%). This compares favorably with the report by Coupin et al, with an IOP of 14.0±2.0 mmHg and 14.3±2.3 mmHg at 6 and 12 months, respectively (20). Dahan et al reported 14.5±5.0 mmHg and 14.2±4.2 mmHg IOP at 12 and 24 months after surgery, respectively (19). Maris et al indicated an IOP of 13.7±11.3 mmHg and 11.5±11.1 mmHg at 6 and 15 months after implantation of the Ex-PRESS tube, whereas IOP was 12.8±11.7 mmHg and 8.7±9.9 mmHg for the trabeculectomy group at the same time interval (21).

There was a significant reduction in the number of glaucoma medications after implantation of the drainage device. Starting from a mean number of medications of 2.3±1.1, this number was dramatically lowered to a mean of 0.6±0.8 after surgery. Coupin et al indicated that the number of topical antiglaucoma medications went from a mean of 1.9±1.0 down to 1±1.0 after surgery (20). Dahan et al mentioned that only 2 patients needed antiglaucoma medications after implantation of the Ex-PRESS when preoperatively 14 patients were using such medications for glaucoma (19). Similarly, Maris et al noted an important reduction in the mean number of medications before and after surgery (3.7±0.9 vs 0.7±1.2) (21).

The BCVA improved for most of the patients after cataract extraction. While the mean BCVA before surgery was 0.6, 59% of patients achieved a postoperative BCVA of 0.8 or better. This compares favorably with the work of Rivier et al, reporting an increase to 0.74±0.34 48 months after surgery (8). The role of lens extraction in reducing IOP is controversial. The lensectomy increases the AC depth and widens the iridocorneal angle, promoting easy egress of AH through the trabeculum and the drainage device (22).

The minor postoperative complication rates (shallow AC, transient choroidal effusion, hyphema, bleb leakage) were comparable with those reported in the literature. Maris et al reported 8% choroidal effusion, 2% flat AC, 4% hyphema, and 6% bleb leakage, while Dahan et al reported 8.3%, 4.1%, and 8.3% rate, respectively, for the same complications (19, 21). No bleb leakage was reported in their study. The authors mentioned 3 (12.5%) cases of device-iris contact, with 1 device requiring repositioning (19). Coupin et al described 6 cases of athalamy (6%) 1 day after surgery (20). The only serious major complication we encountered was endophthalmitis, occurring 2 days after surgery, which ended in phthisis bulbi. Maris et al also described a late-onset bleb leak and endophthalmitis in one of their patients (21). It is difficult to say whether this complication resulted directly from the Ex-PRESS LR-50 tube implantation or could have been induced by the combined surgery with phacoemulsification. We had 1 tube obstruction considered as a late major complication 41 months after surgery. This complication was mentioned by Rivier et al in their study, where they found 4 (11.4%) cases of obstruction of the tube at 6 and 18 months after implantation of an Ex-PRESS R-50 under the conjunctiva (8). No eyes in our study developed erosion through the conjunctiva and exposure of the device, as described in previous studies with Ex-PRESS implantation without a scleral flap (5, 6, 8, 23). The implantation of the device under a scleral flap seems to represent a real advantage compared with the previous technique, because no conjunctival erosion was seen and the reported cases of hypotony were significantly decreased.

Some limitations are present in this study. Of the initial number of patients at the start of the study, about half were withdrawn by the end of the follow-up (lost to follow-up, death, or removed from study). The number of patients was relatively small (n=24), although other articles have also reported on a small number of patients (5, 19, 23). The filtering device was not masked to the physician during the slit-lamp examination and this could have led to a bias during the evaluation. The nonrandomized and nonconsecutive selection of patients was also a possible bias. There was no control group (simple DS without filtering device) to compare IOP evaluation. An endothelial cell count would have given some information about the potential effect of a filtering device implanted in the AC. The advantages of our study were the longer follow-up when compared to other articles and having the same surgeon performing the same operative technique for all patients.

In conclusion, the Ex-PRESS LR-50 glaucoma device used in a modified DS, which avoids the difficult dissection of the TDM, has a satisfactory success rate 3.5 years after surgery. The IOP was significantly lowered and remained stable with a considerable reduction in antiglaucoma medications. The visual acuity improved after this filtering surgery, which was combined with phacoemulsification. Overall, the complication rate was low; only 1 case of endophthalmitis with phthisis bulbi and 1 case of tube clotting were reported. The implantation of the device under a scleral flap, which prevents conjunctiva erosion and tube dislocation, represents a potential advantage over the previous subconjunctival technique. Studies including a larger number of patients with long-term follow-up will provide further information on the efficacy and safety of this modified surgical technique.

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