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## Analyse UBM du site de filtration après sclérectomie profonde postérieure modifiée utilisant un tube Ex-PRESS™ X-50

Ariane CHAPPAZ

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#### UNIVERSITE DE LAUSANNE - FACULTE DE BIOLOGIE ET DE MEDECINE

#### Hôpital ophtalmique Jules-Gonin

### Analyse UBM du site de filtration après sclérectomie profonde postérieure modifiée utilisant un tube Ex-PRESS<sup>TM</sup> X-50

#### THESE

préparée sous la direction du Docteur Corinne Schnyder, PD, MER

avec la collaboration du Docteur André Mermoud

et présentée à la Faculté de biologie et de médecine de l'Université de Lausanne pour l'obtention du grade de

#### DOCTEUR EN MEDECINE

par

#### Ariane CHAPPAZ

Médecin diplômé de la Confédération Suisse Originaire de Monthey (Valais)

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Co-Directeur de thèse

Expert Monsieur le Professeur Wassim Raffoul

Directrice de l'Ecole Madame le Profess

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Analyse UBM du site de filtration après sclérectomie profonde postérieure modifiée utilisant un tube Ex-PRESS TM X-50

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Madame le Professeur Stephanie Clarke Directrice de l'Ecole doctorale

S Cleaces

# Analyse UBM du site de filtration après sclérectomie profonde postérieure modifiée utilisant un tube Ex-PRESS<sup>TM</sup> X-50

Ce travail de thèse est une analyse par ultrasonographie biomicroscopique (UBM) du site de filtration après sclérectomie profonde postérieure modifiée avec implantation d'un tube Ex-PRESS<sup>TM</sup> X-50.

Vingt six patients atteints d'un glaucome à angle ouvert, ont participé à cette étude prospective et non-comparative. Le critère d'inclusion est un glaucome à angle ouvert non contrôlé malgré un traitement topique maximal.

Différents types de chirurgie filtrante sont effectués dans la chirurgie du glaucome dont la trabéculectomie et la sclérectomie profonde.

L'intervention chirurgicale pratiquée dans cette étude consiste en l'implantation d'un tube Ex-PRESS<sup>TM</sup> X-50 de format défini (3 mm de longueur et 50 µm de diamètre interne) dans la chambre antérieure,au niveau du trabeculum, sous un volet scléral, ce qui permet le drainage de l'humeur aqueuse vers les espaces sous-conjonctivaux, avec diminution de la pression intraoculaire.

Cette technique implique uniquement une dissection d'un volet scléral superficiel, sans volet scléral profond comme d'une sclérectomie profonde classique.

Les modes de fonctionnement de cette sclérectomie profonde modifiée sont explorés par UBM, qui donne des images à haute résolution, semblables à des coupes anatomiques.

Le volume de l'espace intrascléral créé artificiellement peut en effet être mesuré et mis en corrélation avec la pression intraoculaire et donc avec le taux de succès. Les différents types d'échogénécité de la bulle de filtration sous-conjonctivale provoquée par la dérivation de l'humeur aqueuse sont également observés. La présence éventuelle d'une filtration supplémentaire au niveau choroïdien est aussi détectée.

De février 2007 à juin 2008, nous avons suivi chez les vingt six yeux des vingt six patients le volume intrascléral, la filtration sous-conjonctivale et la filtration choroïdienne le cas échéant, de même que l'acuité visuelle, la pression intraoculaire, le nombre de traitement antihypertenseur topique et les complications.

Les résultats démontrent une réduction de 41 % par rapport à la pression intraoculaire préopératoire, ce qui est statistiquement significatif (p<0.0005). En ce qui concerne l'acuité visuelle, les valeurs demeurent stables. Par ailleurs, le nombre de médicaments antiglaucomateux diminue de façon significative de  $2.5 \pm 1.2$  en préopératoire à  $0.7 \pm 1.0$  au dernier examen (p<0.0005). Le volume de l'espace intrascléral, apparaissant toujours en échographie d'aspect fusiforme, n'est pas corrélé de façon significative avec un meilleur succès chirurgical bien que l'on aperçoive une tendance à une corrélation entre un plus grand volume et une pression intraoculaire plus basse.

La classification la bulle de filtration se fait selon les 4 catégories de bulle de filtration décrites dans la littérature. La répartition révèle une majorité de type L soit hypoéchogène:15/26 (58%) et une proportion identique, soit, 4/26 (16%), de bulles hyperéchogènes (type H) et encapsulées (type E); les bulles de filtration plates et hyperéchogènes (type F) sont les moins nombreuses 3/26 (11 %).

La ligne hyporéflective visible dans 19 % des cas entre la sclère et la choroïde représentant potentiellement un drainage suprachoroïdien, n'est pas associée statistiquement à une meilleure filtration et une pression intraoculaire plus basse mais demeure une troisième voie de filtration, en plus de la filtration sous-conjonctivale et intrasclérale.

En conclusion, cette technique différente, offrant une plus grande sécurité et des résultats satisfaisants sur l'abaissement de la pression intraoculaire, peut être, dans certains cas, une alternative à la sclérectomie profonde classique ,dont elle partage les mécanismes de filtration objectivés par ultrasonographie biomicrioscopique.

## UBM analysis of the filtering site after a modified posterior deep sclerectomy using the Ex-PRESS<sup>TM</sup> X-50 tube

<sup>1</sup>Ariane Chappaz\*, <sup>2</sup>Sylvain Roy\*, <sup>1</sup>Elie Pitchon, <sup>1</sup>Evangelia Gkaragkani, <sup>2</sup>Emilie Catherine Ravinet, <sup>2</sup>Corinne Schnyder, <sup>2</sup>André Mermoud

1. Glaucoma Unit, Jules Gonin Eye Hospital, University of Lausanne Lausanne, Switzerland 2. Montchoisi Glaucoma Center, Lausanne, Switzerland

\*These authors have equally contributed to this work

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#### **Address for correspondence:**

Dr. Sylvain ROY
Glaucoma Center
Montchoisi Clinic
Chemin des Allinges, 10
CH - 1005 LAUSANNE (VD)
Phone: +41/21/619 37 42

Fax: +41/21/619 36 28 E-mail: **sylvain.roy@epfl.ch** 

#### ABSTRACT

**Purpose:** 

To study the filtering site using ultrasound biomicroscopy. (UBM) after posterior deep sclerectomy with Ex-PRESS<sup>TM</sup> X-50 implant in patients undergoing filtering surgery.

**Methods:** 

Twenty-six patients that participated in this prospective, non comparative study underwent a posterior deep sclerectomy and an Ex-PRESS<sup>TM</sup> X-50 tube implantation. Clinical outcome factors recorded include: intraocular pressure, number of antiglaucoma medications, best corrected visual acuity (BCVA), frequency and types of Six complications. months postoperatively, ultrasound biomicroscopy examination was performed.

**Results:** 

Mean follow up was 12.0±3.4 months. Mean IOP decreased from 21±5.7 mmHg to 12.4±3 mmHg. At last follow-up examination, 65% of eyes had a complete success and 30% a qualified success. The mean number of antiglaucoma medications decreased from 2.5±1.2 preoperatively to 0.7±1 at the last follow-up postoperatively. BCVA was not changed. 27 complications were observed. On the UBM images, the mean intrascleral space volume was 0.25±0.27 mm3 and no relationship was found between volume and intraocular pressure reduction. We noted in 5/26 (19%) eyes a suprachoroïdal hypoechoic. Low-reflective blebs (L-type) were the most common: 15/26 (58%). No correlation between UBM findings and surgical success was evident.

**Conclusions:** Deep sclerectomy with Ex-PRESS™ X-50 tube implantation seems an efficient glaucoma surgery. It allows satisfactory IOP reduction with a low number of post operative complications. The advantages of deep

sclerectomy with collagen implant are maintained with this modified technique. In both, the same reflective types of filtering blebs are present (high, low, encapsulated and flat). The UBM underlines the three mechanisms of aqueous humor resorption previously identified but no correlation with surgical success can be proved.

**Key words:** 

Open Angle Glaucoma, Filtering surgery; Deep sclerectomy; Ex-PRESS tube.

#### INTRODUCTION

Glaucoma is a multifactor disease caracterized by progressive atrophy of the optic nerve fibers. Primary open-angle glaucoma (POAG) represents the most common form of glaucoma in Europe. It gradually and progressively reduces the visual field and leads to blindness if untreated. It is responsible for 10%-15% of blindness worldwide and it is the second cause of loss of vision in industrialized countries<sup>1</sup>. The main risk factor is an elevated intraocular pressure. Classical trabeculectomy has potentially serious postoperative complications, e.g. overfiltration, which can induce hypotony or ocular hypertension resulting from a flap sutured too tightly without adjustable sutures. The releasable scleral flap sutures technique, which has the same result than the standard trabeculectomy regarding the stabilisation of the intraocular pressure, was developed in order to reduce the incidence of postoperative hypo or hypertony<sup>2-3</sup>.

To decrease the complication rate of trabeculectomy, deep sclerectomy was proposed<sup>4,5</sup> In deep sclerectomy, the aqueous outflow is selectively routed through the trabeculo-Descemet's membrane and the obstacle at the level of the juxta-canalicular trabeculum and the Schlemm's canal is removed without penetrating into the anterior chamber. This non-penetrating surgery may reduce the occurrence of hypotony, hyphaema, choroïdal effusion, shallow anterior chamber, intraocular inflammation and cataract. The aqueous humor resorption or "filtration" occurs essentially at the level of the intrascleral and the subconjunctival filtering bleb as well as in the subchoroidal space. Having then three aqueous humor resorption mechanisms, the size of the subconjunctival bleb is relatively shallow and diffuse<sup>6-7</sup>.

However deep sclerectomy surgical technique presents a significant learning curve for surgeons because the anterior dissection of the trabeculo-Descemet's membrane without perforation is very challenging. In this paper, we described a new surgical technique that has been developed to simplify deep slerectomy. This includes a simplified scleral dissection and avoids the delicate and complex dissection of the classical deep scleral flap, removing the roof of Schlemm's canal. A posterior deep sclerectomy is performed under a superficial scleral flap. An Ex-PRESS<sup>TM</sup> X-50 tube,

3.0 mm in length with an inner diameter of 50 µm is inserted under the superficial scleral flap. With this new procedure the control of the filtration is given by the regular aqueous outflow resistance induced through the 50 µm tube diameter. This technique is a modified deep sclerectomy offering hypothetically the same advantage of low post operative complications. Using ultrasound biomicroscopy we assessed the volume of the intrascleral cavity, the presence of a subconjunctival bleb, as well as the presence of any subchoroïdal filtration

The aim of this study was to study the success and complications of this new minimally penetrating deep sclerectomy using the Ex-PRESS<sup>TM</sup> X-50 tube and to study the relationship between the different outflow route observed using the UBM images and the surgical outcome.

#### MATERIALS AND METHODS

#### Patients:

A prospective non-randomized unmasked single centre trial was performed between February 2007 and June 2008. The patients were enrolled (non consecutives cases) after formal approval by the Ethical Committee of the University of Lausanne. A written informed consent was obtained from all participants before surgery. Patients with primary open-angle glaucoma, pseudo-exfoliative glaucoma and low-tension glaucoma were included. The indication for surgery was uncontrolled glaucoma with progression on visual field defect despite maximally tolerated antiglaucoma treatment. Preoperative assessment included: best corrected visual acuity (BCVA) using the Snellen charts, IOP measurement using the Goldman applanation tonometer (GAT Haag Streit, Bern, Switzerland), performing a comprehensive slit-lamp examination including a gonioscopy, fundus examination, and a visual field evaluation Octopus G2 program, (Haag Streit, Bern, Switzerland). The number and type of antiglaucoma medications used prior the surgery were also recorded. At all postoperative visits, the same examination were performed. Furthermore, the number of postoperative complications as well as postoperative fibrosis modulation treatment (bleb needling with Mitomycin C (MMC) subconjunctival injection) were recorded. Follow up visits were perform at the first and seventh day, then at 1, 2, 3, 6 and 12 months.

#### Surgical Procedure:

All eye were operated by two experienced surgeon (A.M, E.R) using the same surgical procedure and equipment. A retrobulbar anesthesia was performed using 0.75% bupivacaine, 4% lidocaine hydrochloride and 50 IU hyaluronidase solution. The surgical technique was already described in details in a previous paper 9. Briefly, a 5x4 mm limbus based superficial scleral flap, 300 µm thick, was dissected using a crescent ruby knife (Figure 1.A). A 0.2 mg/ml MMC solution was administered under the scleral and the conjunctival flaps for 30–60 seconds in patients at risk for subsequent fibrosis (Figure 1.B). A 3x4 mm deep sclerectomy was performed and leaving a very thin scleral

layer over the choroid and ciliary body (fig X). The Ex-PRESS<sup>TM</sup> X-50 implant was inserted through a 21 G paracenthesis into the anterior chamber just anterior to the deep scleral space at the level of schemm's canal. Thirteen eyes underwent phacoemulsification through a lateral corneal incision at the time of glaucoma surgery. The superficial scleral flap was sutured with two 10.0 nylon sutures and the conjunctiva was closed with two lateral 9.0 Vincryl sutures. Postoperative treatment consisted in topical tobramycin and dexamethasone 5 times a day, that was gradually tapered over one month follow by two months of three in day non steroidal anti-inflammatory drug.

#### Glaucoma Drainage Implant:

The Ex-PRESS<sup>TM</sup> X-50 tube is a miniature stainless steel IRM-compatible biocompatible device with a rounded tip, a disk-like flange and a spur-like projection to prevent extrusion. Description of the structure and design was already published <sup>8,10</sup>.

#### Surgical Success:

A complete success was obtained when the IOP was  $\leq$  18 mmHg and > 6 mmHg without medication. A qualified success used the same criteria with medication. The result was a failure when the IOP was higher than 18 mmHg despite medication or if further glaucoma surgery was required.

#### Ultrasound Biomicroscopy:

The Humphrey UBM model 840 (Humphrey-Zeiss Instruments, Inc, San Leandro, CA) works with a probe which emits a 50 MHz sound wave probe. UBM imaging was performed 6 months after surgery. The same experienced investigator performed the scans in order to avoid interobserver variability in the interpretation of visualized anatomic landmarks (E.P.). Two images were selected one from longitudinal or radial scans and one from the transverse scans in which the maximum extend of the intra-scleral space was visible. For each scan the software programme (ImageJ 1.38x, NIH, Bedestha, USA) converted the maximum height and the maximum anteroposterior length of the intrascleral space in mm, which were then manually delineated. By using

the mathematical formula,  $V=4/3.\pi.\Sigma(Lv.Lh)hv.hh/8$  (where Lv=vertical length, Lh=horizontal length, hv= vertical height, hh= horizontal height) these measurements allowed determination of the intrascleral volume (Figures 1 and 2). The image processing was repeated at least 4 times for each eye in order to minimize bias in the calculation of the volume.

The subconjunctival filtering blebs were also evaluated and classified into four categories according to Yamamoto's method which is based on variable reflectivity<sup>11</sup>. When the internal reflectivity of the bleb was hypoechoic compared with the sclera, the bleb was called type L (low echogenicity). When the internal reflectivity of the bleb was hyper-echoic or iso-echoic compared with the sclera, the bleb was called type H (high echogenicity). When an echoic cavity was present inside the filtering bleb, it was called type E (encapsulated). When the bleb was flat or absent, it was called type F(flat).

The indication for the antifibrinotic bleb treatment were signs of excessive scaring with important conjunctival injection, progressive elevatum of IOP and fibrosis at the level of the bleb.

#### Statistical Analysis:

Results were given as mean  $\pm$ -standard deviation. Statistical analysis was performed using the paired two-tail Student t test. Correlation was determined using the Pearson correlation coefficient. Results were considered significant when p < 0.05. Cumulative success rates were assessed using the Kaplan-Meier survival curves.

#### **Results**

A total of 26 eyes of 26 patients (14 men, 12 women) were enrolled. The mean age was  $74.0 \pm 9.6$  years (mean  $\pm$  standard deviation SD) (range 44 to 89). All patients were Caucasians. Eleven of the 26 (42%) had had previous failed filtering surgery. The mean follow-up was  $12.0 \pm 3.4$  months. The demographic data are presented in Table I.

The mean preoperative IOP dropped from  $21.0 \pm 5.7$  mmHg to  $12.4 \pm 3$ 

mmHg. This reduction in pressure correspond to a 41% IOP reduction and was significant (p<0.0005) (Figure 3 and 4).

The mean number of antiglaucoma medication per patient decreased significantly from  $2.5 \pm 1.2$  preoperatively to  $0.7 \pm 1.0$  at last follow-up (p<0.0005). Nine patients (35%) were still using antiglaucoma medication at last visit. (Figure 5)

The mean visual acuity improved postoperatively compared to its preoperative level (0.7  $\pm$  0.3 vs. 0.5  $\pm$  0.3), but the difference was not statistically significant (p=0.09). (Figure 6)

Based on the Kaplan-Meier cumulative survival curve the complete success was 53.8% and the qualified success was 80.8%. Only one case was considered as a failure (IOP = 19 mmHg) (Figure 7)

Complications are listed in the Table II. In 16 of 22 cases, the complications resolved spontaneously. Finally hypotony was transient and did not result in maculopathy. We did not observe any infections, corneal or conjunctival erosions, or implant extrusions. No significant cataract formation was to be seen.

Postoperative bleb management and fibrosis modulation were performed in 9 eyes (35%). The treatment included needling with or without MMC injections.

#### Ultrasound Biomicroscopy Findings:

Characteristics of the UBM findings including aspect of the subconjunctival bleb, volume of the intrascleral space and presence of the subchoroidal hypoechoic area are shown in Table III.

In all cases, a well-circumscribed, non reflective spindle-shaped into scleral space was present and persisted at the final examination. (Figure 8). The mean intrascleral bleb volume measured was  $0.25 \pm 0.27$  mm3 (range from 0.04 to 1.06).

There was a certain tendency of lower IOP when the intrascleral space was bigger. However there was no statistically significant correlation between the volume measured at the time of the UBM examination and the IOP control level ( $R^2$ = 0.1381). (Figure 9). We find various volumes in the group of surgical success ( $R^2$ = 0.003). In addition, small volumes can not be statistically attributed to surgical failure ( $R^2$ = 0.0062) but we remark an inclination of higher pressure.

The number of needlings or injections of antimetabolites was not dependent to the size of the filtering bleb ( $R^2 = 0.002$ ).

Regarding the subconjunctival filtering bleb, four different types were identified (Figures 10-13). The frequency distribution was the following: 15/26 (58%) of low reflective blebs (L-type), 4/26 (16%) of high reflective blebs (H-type), 4/26 (16%) of encapsulated blebs (E-type) and 3/26 (11%) of flattened blebs (F-type). From these 4 types 6/15 of type L (40%), 1/4 of type H (25%), and 2/3 of type F (67%) required drug therapy. No correlation was found between the types of filtering bleb and surgical success ( $R^2 = 0.005$ ).

It is worth mentioning that the encapsulated blebs presented clinically as a diffuse bleb. The cystic aspect of some blebs detected by the slit lamp was not recognizable by UBM.

A clear suprachoroïdal space under the floor of the scleral chamber was observed in 5 eyes (19%). This appears as a hyporeflexive suprachoroidal line (Figure 12 and 14. A significant association of a low IOP with the presence of a suprachoroidal hypoechoic area was not found ( $R^2 = 0.0003$ ).

#### **DISCUSSION**

There have been many modifications in design, construction, and implantation techniques of intraocular glaucoma devices for over a century. In 1907 Rollet introduced the first concept of aqueous shunts bringing the aqueous humor from the anterior chamber into the subconjunctival space at the limbus<sup>12</sup>. The results was unsatisfactory because of excessive healing. In 1969 Molteno developped a short acrylic tube connected to a thin acrylic plate which was secured onto the episclera, forming a posterior orbital filtering bleb<sup>13</sup>. All of the currently available glaucoma drainage devices are based on this concept.

The Ex-PRESS<sup>TM</sup> microtube was developed to propose a new alternative surgery for glaucoma. Initially the device was inserted at the limbus directly under the conjunctiva. Despite its rapidity and simplicity of realization, this procedure was abandoned in view of a high ratio of conjunctival erosion and fibrosis<sup>14-15</sup>.

Our study confirms the hypothesis that the placement of the tube under the superficial scleral flap avoids conjunctival erosion since we did not have any. More studies supported this observation 16-17.

The Ex-PRESS tube placed under a superficial scleral flap has shown good results and allows the creation of an efficient subconjunctival bleb 18.

To enhance the aqueous humor resorption and lower the size of the subconjunctival filtering bleb we proposed to add a deep sclerectomy under the superficial scleral flap with the aim of provide a intrascleral filtering bleb as well as a subchoroïdal uveo-scleral outflow.

A complete success rate was achieved in 53.8% of our patients. It is very important to note that in our group there is 42% of patients with glaucoma surgical antecedents (one to two operations). Traverso et al. <sup>14</sup> described a complete success rate of 61.5% (Target IOP ≤18 mmHg at 2 years) when the tube (EX-PRESS<sup>TM</sup> R50) was implanted under the conjunctival flap. Coupin et al. <sup>17</sup> had a success rate of 62.6 % with an IOP less than 21 mmHg with the implantation under the scleral flap. Using a similar procedure, Dahan et al. <sup>16</sup> reported that an intraocular pressure drop by 41% at 1 year

and 45% at 2 years. The decrease in intraocular pressure in our study was 41%. In another study, also with R-50, Maris et al. reported a 90% success rate with the following success criteria:  $IOP \ge 5$  mmHg and  $\le 21$  mmHg with or without glaucoma medications <sup>18</sup>.

The combined posterior deep sclerectomy with Ex-PRESS X-50 tube is an easy surgical technique and does not require the difficult Schlem's canal opening and the dissection of the trabeculo-descemet's membrane such as in classic deep sclerectomy. It also does not need to perform an iridectomy such as in trabeculectomy. The post operative follow up shows also few complications. The complications observed were transient and did not lead to failure.

By comparison, the mean visual acuity was slightly better postoperatively although we find no evidence of statistical significance. This might be due to the fact that half of the eyes only underwent concomitant lens extraction. Only one patient experiences a decrease in visual acuity (due to maculopaty).

Zarnowski et al.<sup>19</sup> reported similar rate of post operative complications and IOP reduction's level between an Mini-Ex-Press tube implantation in comparison to deep sclerectomy.

Ultrasounds have been employed in medicine since 1955. The use in ophthalmology dates from the 1990s.<sup>20</sup> Ultrasound biomicroscopy allows precise assessment of the anterior segment structure. It offers a high resolution image and this is an essential help to understand phenomenon and mechanisms in the physiopathology of glaucoma. Furthermore, the technology allows good assessment of the filtration's site after filters surgery<sup>21</sup>

Ultrasound biomicroscopy assess three different outflow pathways such:

- 1. Subconjunctival filtration: in all cases, a persistent diffuse filtering bleb is visible clinically. This bleb appears small and discret. The aspect visualised by UBM(low-reflective, high-reflective, encapsulated and flattened), is not a prognostic factor for the success of the surgery, and consequently the final IOP
- 2. Intrascleral aqueous resorption: the aqueous humor is diverted via a shunt from the anterior chamber to an intrascleral space. A new cavity is then formed with an

aqueous resorption as showed in experimental studies<sup>31</sup>.

3. Uveo-scleral drainage: filtration to the suprachoroidal space is possible because the thin layer of sclera covering the bottom of the intrascleral space allows the aqueous humour to reach the subchoroïdal space.

In our study, the reflectivity inside the conjunctival bleb is divided into 4 categories: the majority being low reflective (15/26) accompanied with an equivalent number of hyperreflective or encapsulated blebs (for every 4/26). It must be kept in mind that after a trabeculectomy with mitomycine C in Yamamoto et al's study<sup>11</sup>, the distribution of filtration blebs (in  $21.4 \pm 12.8$  months) are the following: type L (76%), type H (9.4%), type F (11.1%) and type E (3.4%). These last two are seen much more frequently in eyes needing drug therapy. We can not underline a relation between these distinctions and pressure control ( $R^2 = 0.006$ ) because we have not enough cases in our study to obtain a statistical significance.

All encapsulated cases did not required additional medication. On account of the low number of patient, it is difficult to find a statistically significant correlation.

Previous reports showed that the commonly L-type bleb had a correlation with a positive surgical outcome<sup>22-23</sup>: a UBM study of deep sclerectomy with hyaluronic acid implant speculates that hyporeflectivity of the conjunctival bleb is a sign of filtering<sup>22</sup>. The UBM evaluation of filtering blebs after laser suture lysis trabeculectomy<sup>23</sup> identified a correlation between low reflectivity inside the bleb and good IOP control. Another case of deep sclerectomy<sup>26</sup> detected a majority of the H type, however not associated with the success. Studies on viscocanalostomy have failed to discern an association<sup>24-25</sup>.

Some publications mention that after a deep sclerectomy, a supraciliary hypoechoic area was correlated with lower IOP<sup>22,28-30</sup>. This supraciliary hypoechoic area represents the uveoscleral filtration<sup>22</sup>. It has to be rememberd that a hypoechoic area in the suprachoroidal space may be seen in normal eyes. However, to our experience, this normal anatomic variant is much smaller than what was observed in this study. Otherwise this finding was not considered as definitive as it disappeared after one year of follow-up<sup>26</sup>. In our experience, the number is too low to find a statistical correlation.

Thus the presence of a suprachoroïdal hypoechoic band did not predict a better IOP control. Two hypotheses are proposed for the physiopathology<sup>28-29</sup>. The mechanism may be due to ciliary body detachment by suprachoroidal drainage of aqueous humor. The aqueous humor filtrates through the thin scleral wall forming the floor of the intrascleral lake to the suprachoroidal space. The second assumption for choroidal resorption thanks to the creation of small clefts in the deeper sclera during the deep slcerectomy with subsequent effusion can not be applied in our surgical technique.

The size of the decompression chamber is in our sample did not correlated positively with the efficiency for IOP-reduction, such as confirmed by another study<sup>22</sup>. We find the same observation similary in the study of Kazakova et al.<sup>30</sup>. The size of the intrascleral cavity was independent of the IOP. They measured a mean volume of the cavity of 1.8 mm<sup>3</sup> (range 0.11-6.53). By comparison we obtained 0.25 mm<sup>3</sup> (range 0.04-1.06). An intrascleral space was absent in 4 eyes whereas we have an intrascleral cavity in 100% of cases. An other difference remaind on the suprachoroïdal filtration with them the mean IOP was significantly lower in their study.

#### Conclusion

Deep sclerectomy can be replaced by a less delicate intervention with the implantation of the Ex-PRESS<sup>TM</sup> X-50 tube. The filtration's surgery can be simplified by means of a tube positioned under a superficial scleral flap. That is in this case an Ex-PRESS Mini Glaucoma shunt. This procedure appears easy to repeat and allows good results.

Because of the small number of cases, we however not statistically correlate the success rate and level of postoperative IOP with the sure or the quality of the bleb although we retain an evidence of a better IOP control in relationship with the volume of the intrascleral bleb. We find equally the same types of filtration's blebs described in the deep sclerectomy. Our UBM study objectives the presence of 3 aqueous resorption's mechanisms: subconjonctival, intrascleral, and suprachoroïdal.

Our approach concerning the Ex-PRESS<sup>TM</sup> X-50 miniature glaucoma implantation seem to be safe and efficient but needs to be completed by other UBM studies with a larger number of patients and after a longer follow-up period.

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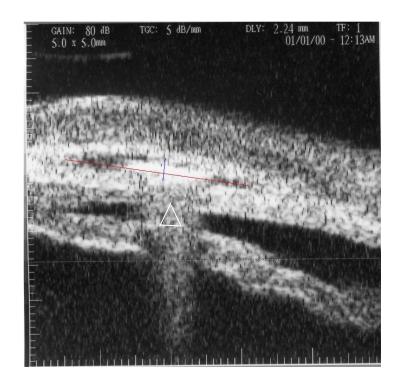
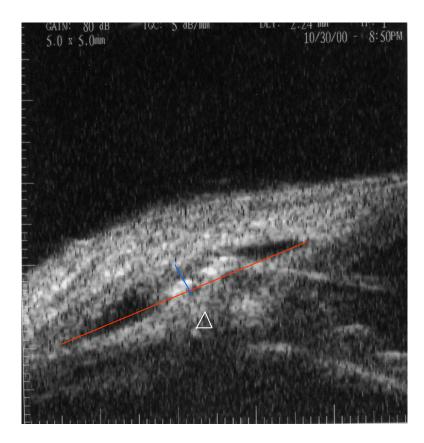


Figure 1: Horizontal scan. Ultrasound biomictroscopy image after posterior deep sclerectomy with Ex-PRESS<sup>TM</sup> X-50 implant. Red line corresponds to the maximum anteroposterior length, blue line the maximum height. Visible shadow of the tube Ex-PRESS (arrowhead)



**Figure 2:** Radial scan. Visible shadow of the tube Ex-PRESS (arrowhead).

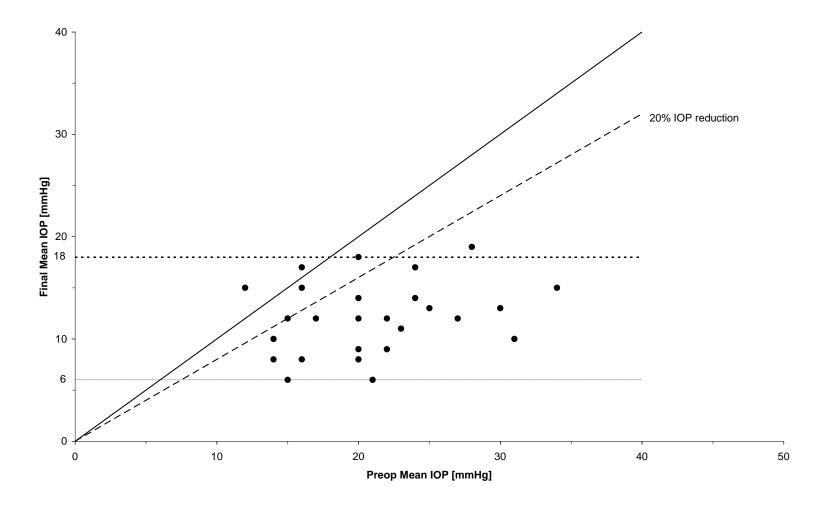
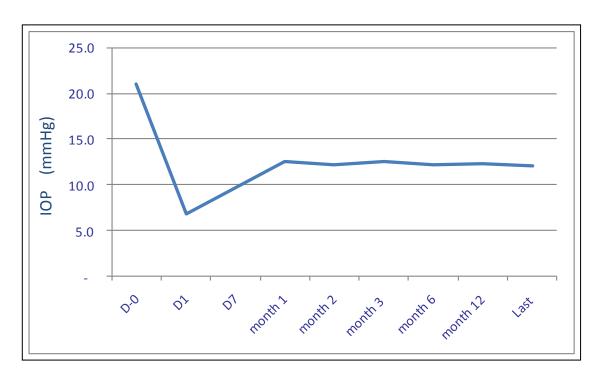
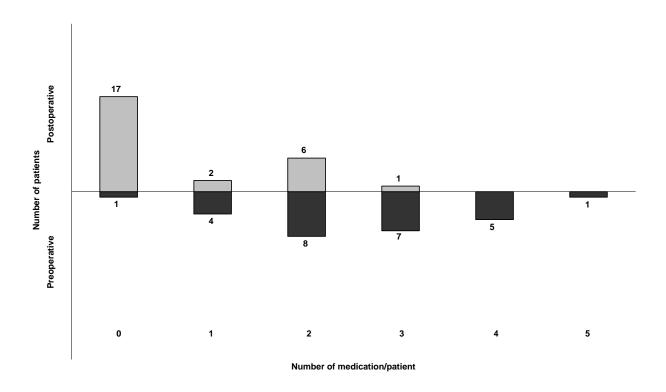


Figure 3: Intraocular pressure (IOP) before and after posterior deep sclerectomy with Ex-PRESS<sup>TM</sup> X-50 implant. Dashed line represents the upper limit for success (IOP  $\leq$  18 mmHg), and continuous line represents the lower limit for success (IOP  $\geq$  6 mmHg), respectively



**Figure 4**: Intraocular pressure profile after posterior deep sclerectomy with Ex-PRESS<sup>TM</sup> X-50 implant.



**Figure 5**: Number of drugs before and after surgery.

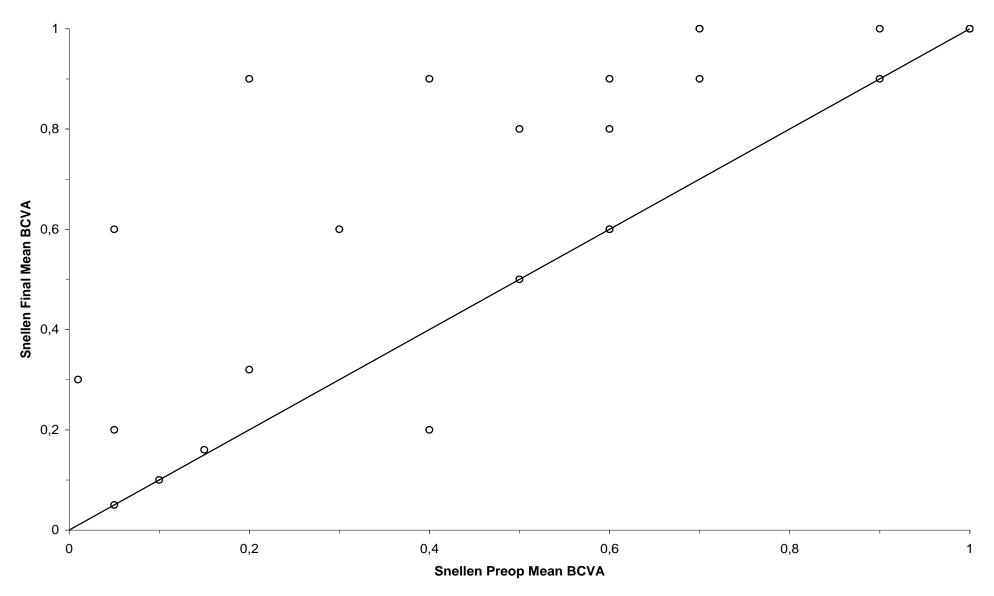


Figure 6: Best corrected visual acuity pre- and postoperative.

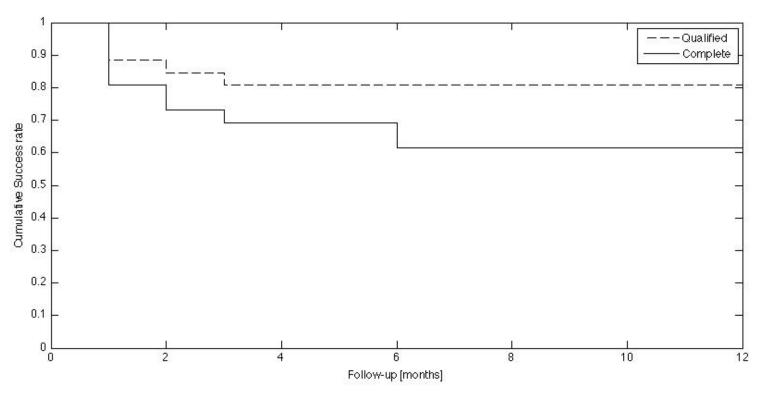


Figure 7: Cumulative success rate according to Kaplan Meier survival curbe.

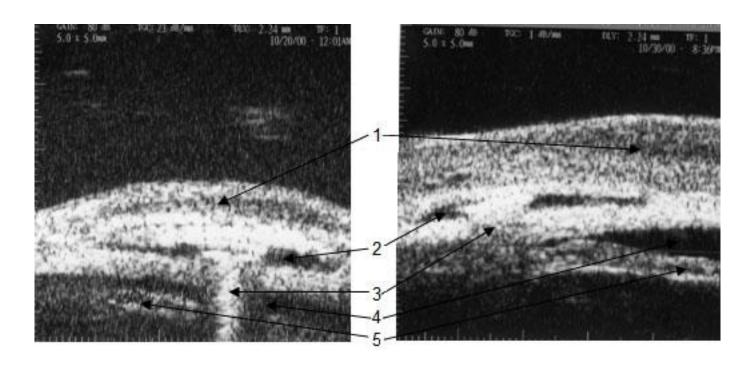
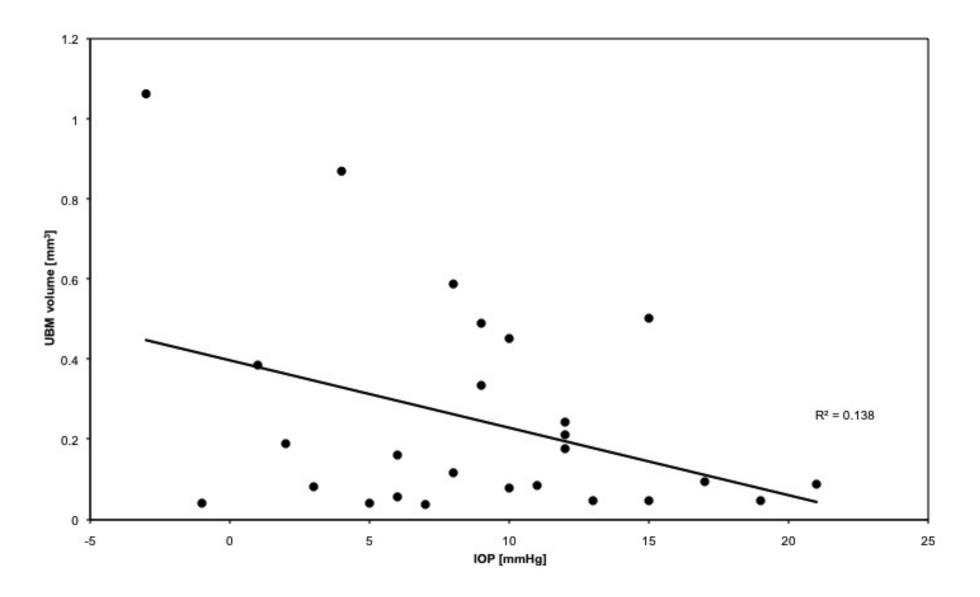


Figure 8: (Horizontal section). UBM of the filtering bleb. (1) subconjunctival bleb (2) intrascleral space (3) acoustic shadowing caused by the tube (4) anterior chamber, (5) iris.



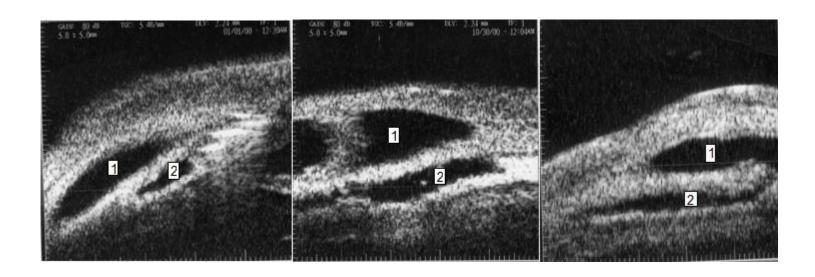
**Figure 9:** Correlation beween the volume of the intrascleral space and the intraocular pressure.



Figure 10: Horizontal scan. L-Type reflectiv Bleb (arrow).



Figure 11: Radial scan. H-type Bleb (arrow).



**Figure 12:** 1 = Encapsulated blebs 2 = Subchoroidal hypoechoic area.



**Figure 13:** F-type bleb (arrow).

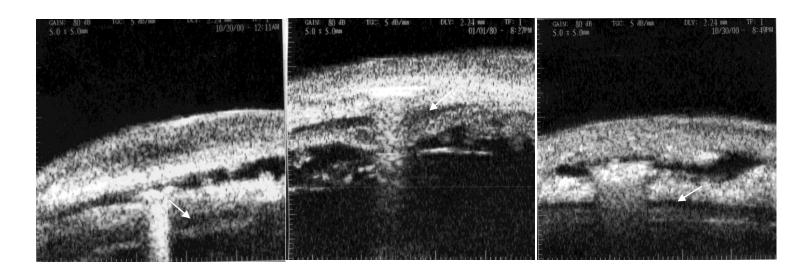


Figure 14: Supraciliary hypoechoic area (arrow).

					Mean follow up		Number previous	Previous interventions for this	
N° Patient	Age	Sex	Eye	Diagnostic	Months	<u>C/D</u>	glaucoma surgeries	glaucoma	Other diagnosis
1	75	Male	OS	PEX	12,6	0,8	1	TRABp	Myopic astigmatism retinal detachment
2	67	Female	OD	POAG	19,0	0,8	1	TRABy	High myopia with myopic chorioretinal atrophy with CNV
3	77	Female	OD	PEX	13,8	Tilted disc	0		High myopia, iridodonesis corneal decompensation
4	80	Male	OS	LTG	13,1	0,7	0		S/p blow out fracture left orbit
5	74	Female	OD	POAG	17,6	0,6	0		
6	67	Male	OD	POAG	14,0	0,6	0		
7	86	Female	OS	POAG	14,3	0,75	0		DMLA
8	73	Female	OS	POAG	10,7	0,3	2	PI, IRE	
9	83	Female	OD	POAG	6,7	0,3	0		
10	69	Male	OD	PEX	14,5	0,85	2	DSCI, PI	Retinitis pigmentosa
11	89	Male	OD	POAG	15,0	0,9	0		Convergent strabismus
12	58	Male	OD	POAG	15,3	0,3	0		
13		Male	OS	POAG	12,0	0,7	4	TRABy,PI, TRABp, CPC	
14		Female	OS	POAG	12,4	0,6	0	110 m j,1 i, 110 m p, e1 e	Keratitis
15		Male	OS	POAG	15,0	0,5	1	PI	110244445
16		Male	OD	POAG	11,6	0,75	0		Amblyopia ex-anisometropia
17		Male	OS	POAG	13,0	0,95	3	DSCI	Diabetic retinopathy
18		Male	OD	POAG	9,3	0,65	0		Amblyopia (severe stabismus and refractive error )
19	79	Female	OS	POAG	9,0	0,8	0		Blepharoptosis
20	77	Female	OD	PEX	9,1	0,7	0		
21	44	Female	OS	POAG	11,3	0,9	2	TRABy(2×)	
22	64	Female	OS	PEX	11,9	0,6	0		
23		Female	OD	POAG	10,8	0,7	0		
24		Male	OS	POAG	7,5	0,6	1	PI, IRE	Temporal superior branch retinal vein occlusion
25	61	Male	OD	POAG	5,8	0,8	3	TRABy, DSCI, IRE	
26	80	Male	OS	POAG	5,6	0,6	3	PI, DSCI, TRABy	Ischemic neuropathy, hypertensive arteriopathy
				Average	12,0				
				SD	3,4				1

**Table I. Patient data (N=26).** POAG = Primary Open-Angle Glaucoma, PEX = Pseudoexfoliation Glaucoma, LTG= Low tension Glaucoma, TRABp = Trabeculoplasty, TRABy = Trabeculectomy, IRE = Iridectomy, PI = peripheral Iridotomy, DSCI = Deep Sclerectomy with Collagen Implant, CPC = Cyclophotocoagulation. SD = Standard Deviation

Postoperative complications	Number of eyes	Percentage (%)
Seidel	6	23
Scider	0	23
Corneal oedema	1	4
Hyphema	1	4
Shallow anterior chamber	2	8
Device rotation or		
malposition	2	8
Choroidal bleeding	1	4
Choroidal detachment	4	15
Endophthalmitis	1	4
Malignant glaucoma	1	4
Conjunctival retraction	1	4
Conjunctival erosion	0	0
Cystoïd macular oedema	1	4
Bleb fibrosis	1	4
Hypotony IOP≤ 6mmHg	2	8
Cataract	0	0

**Table II:** Rate and kind of complications

Patient	FB	Volume	CHOR
1	L	0,18	1
2	L	0,04	0
3	L	0,05	0
4	L	0,87	0
5	L	0,59	1
6	Н	0,50	0
7	F	0,05	0
8	Е	0,09	0
9	L	0,08	0
10	L	0,49	0
11	L	0,11	0
12	Н	0,45	0
13	F	0,08	0
14	L	0,38	0
15	Н	0,04	0
16	Е	0,08	1
17	Е	0,21	1
18	Е	0,16	1
19	L	0,04	0
20	F	0,24	0
21	L	0,04	0
22	L	0,08	0
23	Н	0,04	0
24	L	0,19	0
25	L	1,06	0
26	L	0,33	0

**Table III:** FB= type of reflectivity inside the filtering bleb. H= high reflective, L= low reflective, F= flat, E= encapsulated. Volume in mm³ of the intrascleral cavity.CHOR= presence of suprachoroïdal hypoechoic area.