

**From deep sclerectomy to canaloplasty  
Is it possible to re-establish the natural outflow in patients with chronic  
open-angle glaucoma**

**Ph.D. Thesis (handout)**

**Gabor B. Scharioth M.D.**

**Department of Ophthalmology  
Faculty of Medicine  
University of Szeged  
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## 1. Introduction

Glaucoma is an optic neuropathy in which the optic nerve is damaged with typical loss of nerve fibers and increasing cupping of the optic disc, leading to progressive, irreversible loss of vision. Worldwide, glaucoma is the second leading cause of blindness and affects approximately 66 million people in the world. There are many different sub-types of glaucoma but they can all be considered a type of optic neuropathy.

The major risk factor for most glaucomas and focus of treatment is increased intraocular pressure. Intraocular pressure is a function of production of liquid aqueous humor by the ciliary processes of the eye and its drainage through the trabecular meshwork and/or the Schlemm's canal.

If the condition is detected early enough it is possible to arrest the development or slow the progression by medical and surgical means. There is some evidence that primary surgical treatment is superior to primary medical treatment in patients with open-angle glaucoma. First successful antiglaucomatous surgery was performed by German ophthalmologist Albrecht von Graefe in 1852. Since early 1970s trabeculectomy described by Sugar, Cairns and later Frimopoulos became the standard of care in open-angle glaucoma surgery. This widely used procedure involves a surgically formed pathway for aqueous humor between the anterior chamber and the subconjunctival space to lower intraocular pressure in the treatment of glaucoma. The main goal is the formation of a conjunctival filtering bleb. This is a relatively unphysiological approach and scleral as well as conjunctival scarring led to introduction of antimetabolites as an adjunctive for filtering bleb-dependent glaucoma surgeries. Numerous intraoperative and postoperative complications have been cited. All this led surgeons to search for a more physiological and bleb independent surgical approach in IOP lowering glaucoma surgery. Surgical treatment of the natural aqueous outflow system, including Schlemm's canal, to restore normal function and IOP control without penetration of the intraocular space has long been the interest in the study of open-angle glaucoma as an alternative to penetrating and bleb-dependent methods.

Several techniques of nonpenetrating filtering glaucoma surgery based on Krasnov's sinusotomy have been described. Stegmann et al. described a variant of nonpenetrating glaucoma surgery and termed it viscocanalostomy to emphasize the importance of injecting high-viscosity sodium hyaluronate (Healon GV) into the Schlemm's canal and the surgically created ostia as well as into the sclerectomy site under the superficial scleral flap.

Further development of non-penetrating approaches included the use of implants at the surgical site in the late 1990s and early 2000s.

All previous non-penetrating glaucoma surgeries were able to reach two to three clock hours of Schlemm's canal while a procedure treating the entire canal should be theoretically more effective. We reported on a technique using the 6x0 polypropylene suture for catheterization of the entire Schlemm's canal and while withdrawing the suture a 10x0 polypropylene suture is installed in the canal and finally knotted under tension. This is a very difficult and time consuming technique with a relatively high risk of mispassage of the 6x0 polypropylene suture into the anterior chamber or suprachoroidal space. Recent advances in technology have allowed surgeons to use a flexible microcatheter to access the entire length of Schlemm's canal more atraumatically. This technique is called canaloplasty and seems to be the logical evolution to viscocanalostomy.

## **2. Objectives**

The objectives of the thesis were as follows:

- to perform nonpenetrating glaucoma surgery with two different implants in open-angle glaucoma and analyzing postoperative outcomes
- to develop a new surgical technique for glaucomatous eyes with increased outflow resistance due to peripheral anterior synechiae and analyzing postoperative outcomes
- to perform iTrack-assisted canaloplasty and analyzing the postoperative intraocular pressure lowering effect
- to develop a surgical technique and instrumentation for canaloplasty with placing a 360° tensioning suture into the Schlemm's canal
- to develop an intraoperative non-contact system for visualisation of the anterior chamber angle and the Schlemm's canal during canaloplasty
- to directly demonstrate the way of aqueous outflow after incisional glaucoma surgery and to boost the concept of bleb-independent incisional glaucoma surgery

## **3. Materials and methods**

All patients had open-angle glaucoma and were treated with deep sclerectomy as intraocular pressure lowering approach. The semen analysis and evaluation procedures were performed in accordance with the WHO 1999 standards criteria. Written informed consent was obtained from all patients.

### **Deep sclerectomy with implants**

To avoid secondary collapse of the scleral lake due to adhesion of the superficial scleral flap or contact of descemet window, a space-maintainer implant is placed in the surgically created scleral bed. In deep sclerectomy we have used over the past decade SK-Gel (Corneal, France) and T-Flux (Carl Zeiss Surgical GmbH, Germany).

Initially an interindividual retrospective analysis was carried out to compare the outcome of both implants. For the study we analyzed four groups. First group included 13 patients with deep sclerectomy and implantation of SK-Gel. Second group included 5 patients with combined phacoemulsification, intraocular lens implantation and deep sclerectomy with SK-Gel. In the third group in 31 patients deep sclerectomy with implantation of T-Flux was performed. And finally the fourth group phacoemulsification, intraocular lens implantation and deep sclerectomy with T-Flux was performed in 23 patients.

A second study with intraindividual comparison of both implants in combined phacoemulsification and nonpenetrating glaucoma surgery was performed. From January 2000 to December 2006, 321 eyes of 189 patients were treated with deep sclerectomy and simultaneous phacoemulsification in the Augenzentrum Recklinghausen, Germany. Out of this number, a total of 17 patients with 34 eyes were identified who had received the absorbable device SK-GEL 3.5 in one eye and the nonabsorbable T-Flux device in the contralateral eye. Preoperative and postoperative intraocular pressure and medical therapy were evaluated for these studies.

### **Nonpenetrating glaucoma surgery with goniosynechiolysis ab-interno**

The presence of peripheral anterior synechiae usually prevents sufficient aqueous humor outflow, possibly leading to surgical failure.

We therefore developed a surgical technique for selective treatment of peripheral anterior synechiae during nonpenetrating glaucoma surgery and retrospectively reviewed medical records of patients who had been subject to nonpenetrating glaucoma surgery at our department between January 2000 and December 2006. 20 eyes of 16 patients were identified who had been scheduled for a combined surgery with non-penetrating glaucoma surgery, namely deep sclerectomy with goniosynechiolysis ab interno, introduction of an adjuvant implant phacoemulsification and posterior chamber intraocular lens implantation. In all cases the indication for the surgery was primary open angle glaucoma with goniosynechia at the superior part of the irido-corneal angle and cataract. In none of the eyes the target pressure could be achieved by conservative medical therapy because of insufficient efficacy or drug

intolerance. A minimum follow-up of 12 months was necessary to qualify for inclusion to this study. Following data were collected and analyzed: age, gender, pre- and postoperative intraocular pressure (IOP), pre- and postoperative glaucoma medication, type of glaucoma implant and complications during and after the surgery.

### **iTrack assisted canaloplasty**

To evaluate the effect of canaloplasty pre- and postoperative intraocular pressure and antiglaucomatous medical therapy in 73 consecutive eyes with open-angle glaucoma (including primary open-angle glaucoma, pseudoexfoliation syndrome and pigment dispersion) were analyzed with a minimum follow-up of 12 months.

### **Catheterless canaloplasty**

If an iTrack assisted canaloplasty would reduce the intraocular pressure by using a commercially available, but very expensive catheter, is it possible to bypass the entire Schlemm's canal with a self made catheter? We have used a 6x0 polypropylane suture with self made blunt tip to perform canaloplasty.

### **Intraoperative optical coherence tomography**

To evaluate the use of an intraoperative online anterior segment optical coherence tomography (OCT) imaging system for modern glaucoma surgery we used a specially designed microscope mounted anterior segment optical coherence tomography device (modified Visante, Carl Zeiss Meditech, Germany). This device uses 1300 $\mu$ m wavelength and should be therefore suitable for anterior segment visualization including superficial intrascleral structures like Schlemm's canal. Initial tests with a Visante OCT were performed in patients after deep sclerectomy to visualize the scleral lake and intrascleral implants. Schlemm's canal could not be shown in this setting. Then the modified microscope mounted technology was used for different ophthalmic surgeries but especially for glaucoma surgery to visualize the anterior chamber angle and, if possible, the canal of Schlemm.

### **Flow test after incisional glaucoma surgery**

There is still controversy about the mechanism of aqueous humor outflow / resorption in intraocular pressure lowering glaucoma surgery. Many studies have been conducted to prove postoperative outflow pathway after glaucoma surgery using high resolution ultrasound or

optical coherence tomography. But all these techniques could only interpret indirect postoperative findings like bleb formation, suprachoroidal space formation etc. We have used trypan blue filling of the anterior chamber prior to intended cataract surgery in eyes after incisional glaucoma surgery. Then for about 60 seconds the anterior segment was observed to check for appearance of the dye. All cases were recorded and afterwards analyzed. Between December 2008 and December 2009 twelve eyes with previous incisional glaucoma surgery have been tested in this way.

#### **Development of new surgical device / instrument for canaloplasty procedure**

After intensive experience with different nonpenetrating glaucoma surgery procedures and canaloplasty some changes in the used instruments and devices became obvious to the author. A company (DORC Internation, The Netherlands), experienced in the development of ophthalmic microsurgical devices and instruments, was contacted and asked to help in the development of a new simplified catheter for canaloplasty and for improved instrumentation.

## **4. Results**

### **Interindividual comparison of SK-Gel versus T-Flux in nonpenetrating glaucoma surgery**

Out of the 72 patients included in this study 65 could be followed after 12 months. In the only SK-Gel group 10 patients and in the phaco+SK-Gel group 5 patients could be controlled after 12 months. In the only T-Flux group 28 patients from initially 31 and in the phaco+T-Flux group 22 patients from initially 23 could be controlled at the 12 months visit. All patients not included at 12 months were excluded because of a second incisional glaucoma surgery during the follow-up period.

The mean preoperative intraocular pressure was  $18.4 \pm 5.5$  mmHg and after 12 months  $13.1 \pm 3.8$  mmHg. At no point a significant difference between the subgroups was recognized. Complications were minor and included one eye with postoperative positive Seidel test (SK-Gel group) and one eye with cataract formation requiring surgery at 6 months after the deep sclerectomy with T-Flux. Transient ocular hypotension with intraocular pressure below 7 mmHg were found in 28 eyes (39%). In only one eye a revision with resuturing of the scleral flap was necessary.

### **Intraindividual comparison of SK-Gel versus T-Flux in nonpenetrating glaucoma surgery**

Of the 17 patients eligible for case analysis under the above mentioned criteria, 3 were male and 14 female with a mean age of 77.1 +6.8 years ( $\pm$  standard deviation). The overall mean follow-up period was 26.5 +16.4 months in the SKGEL group and 27.2 +16.0 months in the T-Flux group, with a range from 6 to 48 months in both groups. The mean preoperative IOP was 20.6 +7.3 in the SKGEL group and 19.9 +7.2 mm Hg in the T-Flux group and hence considered comparable ( $p > 0.05$ ).

In both groups the surgical intervention led to a clinically relevant result: In the SKGEL group the mean preoperative IOP decreased to a mean final IOP of 14.8 +5.3 mm Hg (-5.8 mm Hg or -28.1%), and in the T-Flux group to 14.7 +3.3 mm Hg (-5.2 mm Hg or -26.1%). The difference between both groups is statistically not significant ( $p > 0.05$ ). The mean number of antiglaucoma medications before surgery was 2.0 +0.8 substances in both groups, with a minimum of one substance and a maximum of 4 substances. With both implants the need for antiglaucoma treatment decreased after surgery to 0.3 +0.7 medications at the final visit. In other terms, only 3 eyes per group required a permanent treatment after surgery, with a maximum of 2 substances. 2 eyes, one in each group, needed a transitory therapy with betablocker drops for a short time, and no further therapy was necessary in these eyes afterwards.

At the end of the observation period a qualified success (IOP < 21 mm Hg with or without treatment) was found in all 17 eyes with the T-Flux device (100%), and in 16 eyes with a SKGEL implant (94.1%). Complete success (IOP < 21 mm Hg without treatment) was achieved in 14 T-Flux eyes (82.4%) and in 13 SKGEL eyes (76.5%).

### **Deep sclerectomy with goniosynechiolysis ab interno**

With the presented surgical technique, a selective treatment of peripheral anterior synechiae was possible during nonpenetrating glaucoma surgery by direct visual control through a trabeculo-Descemet's window in 19 of 20 eyes (95%).

The mean preoperative IOP was 20.3  $\pm$ 5.2 mmHg on 2.4  $\pm$ 1.0 medication. One year postoperatively the mean IOP was 15.3  $\pm$ 3.3 mmHg on 0.6  $\pm$ 1.0 medication (compared to preoperative IOP:  $p=0.004$ ).

A postoperative IOP of  $\leq 21$  mmHg was achieved in 17/19 eyes (89.5%) 3 months, and in 12/19 eyes (63.2%) 12 months postoperatively without medication. In the remaining 10.5% (month 3) and 36.8% (month 12) an addition of a mean of 0.3 and 0.6 medication respectively achieved an IOP  $\leq 21$  mmHg or the target pressure.

### **iTrack assisted Canaloplasty**

Out of more the 200 successfully performed iTrack assisted canaloplasties since March 2008 seventythree eyes were eligible for case analysis under the above mentioned criteria. The mean preoperative intraocular pressure was  $23.8\pm 5.6$  mmHg. At the 12 months visit the mean intraocular pressure was  $13.8\pm 2.4$  mmHg. Antiglaucomatous medication preoperative was  $2.2\pm 1.0$  drugs and dropped to  $0.23\pm 1.0$  drugs at 12 months. Additional ND-YAG laser goniotomy had to be performed in 4 eyes. In 32 eyes postoperative hyphema of more than 1mm was noted. In the remaining 41 eyes at least some erythrocytes or a minimal hyphema was noted. None of the cases required an anterior chamber lavage. In 19 eyes a circumscribed peripheral descemetoc detachment was noted, sometimes with blood in this cavity. In none of these cases this complication caused a reduced best corrected visual acuity in the postoperative period. Absorption of the OVD and/or blood could take up to several months. Two eyes had transient choroidal detachment. None of these eyes developed a maculopathy. Overall no serious complication was noted. No eye required additional glaucoma surgery during the first 12 months postoperative period.

Qualified success rate after 12 months with regards to a postoperative target pressure of 18mmHg was 90.4%. Complete success rate was 86.3%.

### **Catheterless Canaloplasty**

Since September 2006 we have performed 156 deep sclerectomies with 6x0 polypropylene assisted canaloplasty with successful placing 10x0 tensioning suture. Preparation of a blunt tipped slightly curved 6x0 polypropylene suture was possible. After initial success with relatively easy passage of the suture, encouraging us to continue and improve the technique, most cases did require several attempts to pass the suture 360°. If the suture could not pass in one direction a second attempt was made in the opposite direction. In case of sudden stop, indicating a mispassage into a large collector channel or a fibrosed Schlemm's canal, the 6x0 polypropylene suture was left in place and a second 6x0 polypropylene suture was advanced into the canal. In some cases additional maneuvers like bending the tip of the suture like with iTrack assisted canaloplasty was necessary.

In 15 eyes a misdirection of the suture with perforation into the anterior chamber or the suprachoroidal space was noted. But in all of these eyes finally the 360° cannulation could be completed and a 10x0 polypropylene suture placed.

In another 26 eyes the cannulation of the Schlemm's canal could not be completed. In these cases SK-Gel was implanted in the sclerectomy site. Finally in 3 eyes macro perforation with



conversion to penetrating glaucoma surgery with peripheral iridectomy occurred. In these eyes no implant could be placed under the superficial scleral flap.

In two eyes with aphakia and open angle glaucoma secondary to pseudoexfoliation syndrome we have used catheterless canaloplasty in combination with implantation of a posterior chamber intraocular lens with intrascleral haptic fixation. This technique we have developed for eyes with insufficient or no capsular support. Because this technique does not require anterior chamber angle haptic fixation or iris fixation it is especially useful in glaucomatous eyes.

### **Intraoperative optical coherence tomography**

With permission of the local ethics committee we have performed optical coherence tomography in more than 80 ophthalmic surgeries, including nonpenetrating glaucoma surgery. In all cases we have initially looked for Schlemm's canal. In none of the cases the canal was clearly visible preoperatively. In all 8 cases of canaloplasty with intraoperative use of optical coherence tomography the Schlemm's canal was clearly visible during the cannulation with iTrack catheter. In these cases we have used the iTack catheter to inject ophthalmic viscosurgical device to enlarge the lumen of the Schlemm's canal. This was clearly visible, but in 3 eyes the lumen of the canal did not enlarge less dramatically due to microperforation of the inner wall of Schlemm's canal.

After placing the tensioning suture in all 8 eyes with canaloplasty a distension of the inner wall of Schlemm's canal could be observed, indicating successful distension. Distension was checked next to the sclerectomy site, at 3, 6 and 9 o'clock position. Distension was in all cases highest next to the sclerectomy site, but same at 3, 6 and 9 o'clock position. Distension suture within the lumen of the Schlemm's canal was visible in all cases.

No device related complication occurred. The device was easy to use with the help of a trained assistance.

### **Flow test after incisional glaucoma surgery**

Five eyes after previous trabeculectomy have been operated. While two eyes showed a typical pattern of cystic conjunctival bleb, two eyes showed no sign of external filtration and only one eye did show a formation of a subconjunctival bleb with diffuse subconjunctival filtration. Five eyes after deep sclerectomy did show a diffuse subconjunctival filtration with at least in two eyes signs of mixed resorption with trypan blue filling of episcleral veins.

Two eyes after successful canaloplasty showed no sign of subconjunctival filtration but filling of episcleral veins with trypan blue.

In all eyes with external appearance of trypan blue this occurred in the surgical site or next to the surgical area. No complication related to this flow test occurred.

### **Glaucolight and Scharioth's glaucoma forceps**

After more than 12 months of processing and testing a new catheter for canaloplasty was developed and is now commercially available.

This device is called Glaucolight. It is a specially designed lightfiber with an atraumatic tip design for smooth transfer through the Schlemm's canal. Its outer diameter is only 150µm. This small diameter allows flexible 360° followability of the Schlemm's canal. The material is ductile. Bending the tip reduces the risk for misdirection of the catheter during the passage through Schlemm's canal. It has an integrated battery powered red LED light source. The LED is switched on simply by pressing a contact on the case. The battery lasts for several hours. The illuminated tip indicates the position of the catheter in the Schlemm's canal during the passage. The special suture fixation notch at the distal end of the fiber assures a firm fixation of the stretching-suture in combination with minimizing injury effect of the suture knot to the wall of Schlemm's canal during the withdrawal. The clip attached to the light source is used to fix the catheter to the sterile patients drape next to surgical area during the procedure.

During the testing period 22 eyes have been operated with this new device and in all cases a successful 360° cannulation could be performed. No complication related to the device occurred. The passage through the Schlemm's canal was found smooth and atraumatic.

The forceps developed for modern glaucoma procedures is a modified tying forceps with an enlarged tip with a groove for easier and safer grasping of the catheter during cannulation.

This atraumatic tip could also be used during the procedure for atraumatic but safe manipulation of the scleral flap.

The distal end of the forceps has a special marker for blunt marking of a parabolic 5x5mm superficial scleral flap. The special design of this marker allows observation of the episcleral vessels during marking to select an adequate area for dissection. This reduces the need for diathermy during flap preparation.

## 5. Summary and conclusions

The results of our retrospective analysis confirm the results of other studies, in that in open-angle glaucoma a deep sclerectomy with implantation of a device in combination with phacoemulsification lowers IOP in a clinically relevant way over a long period.

We proved that the effect of deep sclerectomy with implantation of a device is independent from the absorbable or nonabsorbable property of the implant, while the risks of a combined surgery are few when performed by an experienced surgeon.

Peripheral anterior synechiae could cause failure in nonpenetrating glaucoma surgery. We developed a new technique for release of goniosynechiae in the area of the descemet window and could prove that with this new surgical technique deep sclerectomy could be performed successfully in case of peripheral anterior synechiae without the need of conversion to penetrating glaucoma surgery.

Canaloplasty is a new effective bleb-independent intraocular pressure lowering-procedure with a very low complication rate.

As an unreported postoperative finding almost all eyes had some amount of intracameral bleeding.

The commercially available catheters for canaloplasty (Glaucolight, DORC, The Netherlands and iTrack, iScience, USA) reduces surgical time and improves the safety of the procedure. But canaloplasty can be performed even without the need of this expensive device with the help of a self made catheter (blunt tipped polypropylene suture 6x0). As a new finding we could show that the procedure was successful even without injection of ophthalmic viscosurgical device throughout the entire Schlemm's canal.

Our new catheter and forceps simplifies intraoperative manipulations.

Longer follow-up is needed to understand the long term success rate and effects of the tensioning suture on intraocular tissue.

Intraoperative optical coherence tomography is a new technique to visualize intraocular structures with very high resolution. This technology could be helpful in modern glaucoma surgery as well as other ophthalmic surgical techniques (i.e. refractive intraocular implants, corneal surgery, femtosecond-assisted cataract surgery). We could show that this new system is able to image intraoperative the Schlemm's canal and distension of the inner wall of

Schlemm's canal during canaloplasty. Further development of this system with higher resolution and improved recording speed is recommended. Faster computer technology could lead to three dimensional imaging with new options in ophthalmic surgery and diagnostics.

To prove the concept of bleb-independent glaucoma surgery we have developed the intraoperative flow test with trypan blue. With this test the outflow of aqueous humor after incisional glaucoma surgery was directly visualized. At least in some eyes we could prove the bleb independent character of canaloplasty.

Nonpenetrating bleb independent glaucoma surgery is possible, has a very low complication rate and could lead to re-establishing the natural outflow in patients with open-angle glaucoma.

## **Awards**

Video Award at the Video Film Festival during 15<sup>th</sup> Congress of German Ophthalmic Surgeons, 2002, Nuernberg, Germany for "Non-penetrating Glaucoma Surgery in Case of Goniosynachiae"

and

Video Award at the Video Film Festival during XXVIII Congress of the European Society of Cataract and Refractive Surgeons, 2010, Paris, France for "Optical Coherence Tomography Assisted Anterior Segment Surgery"

## **Publications**

### **List of publications directly related to the subjects of the Thesis:**

1. Wiermann A. Zeitz O. Jochim E. Matthiessen L. Wagenfeld P. Galambos G. **Scharioth G.** Mathiessen N. Klemm K. : A comparison between absorbable and non-absorbable scleral implants in deep sclerectomy (T-Flux and SK-Gel). *Ophthalmologie*. 2007;104(5):409-414 **(IF: 0.791)**
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24. **Scharioth G.B.** : Triamcinolon Assisted ILM-Peeling. in *Jaypee's Video Atlas of Ophthalmic Surgery Vol. 2*, Jaypee Brothers Medical Publisher Ltd,
25. **Scharioth G.B.** : Intraocular IOL Refolding for Explantation. in *Jaypee's Video Atlas of Ophthalmic Surgery Vol. 2*, Jaypee Brothers Medical Publisher Ltd,
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