

## PHACOCANALOPLASTY: 2-YEARS CLINICAL RESULTS

G.D. CĂILEANU<sup>1,2,3</sup> A. STĂNILĂ<sup>4</sup>

**Abstract:** Among the combined procedures that can be performed in patients with concomitant cataract and glaucoma, phacocanaloplasty distinguishes itself by its ability to give a sustained lowered IOP (intraocular pressure) with minimal complications and rapid visual recovery. I designed a prospective study to evaluate 2-years postsurgical safety and efficacy of phacocanaloplasty. End-point results were IOP, number of glaucoma medication still needed, intra- and postoperative complications. IOP was significantly reduced compared with baseline at each time point during the follow-up period, and also the number of medications was lowered. No significant intra- or postoperative complication were reported.

**Key words:** intraocular pressure, Schlemm's canal, microcatheter, phacoemulsification.

### 1. Introduction

Cataract and glaucoma often coexist in elderly patient population. It has been estimated that 20% of cataract procedures are performed in USA in patients with glaucoma and ocular hypertension [2]. Phacoemulsification combined with trabeculectomy (a penetrating antiglaucomatous procedure) has been the preferred surgical approach for managing concomitant cataract and glaucoma. The growing concern about intra- and postoperative complications associated with trabeculectomy determined many surgeons to look for alternative procedures. Several new procedures have been introduced in clinical practice in

conjunction with cataract surgery. These include ab-interno trabeculectomy (Trabectome), trabecular micro-bypass stent (iStent), endoscopic cyclophotocoagulation (ECP), and canaloplasty. Combined with phacoemulsification canaloplasty makes possible a quicker visual recovery compared with trabeculectomy. It is an ab-externo procedure in which Schlemm's canal is canulated with a fibre optic probe that helps in placing and dilating Schlemm's canal with a tensioning suture. The suture exerts adequate stretch on trabecular meshwork to improve aqueous humor outflow. Ideally high-resolution ultrasound is used to confirm the distention of tissues of interest. The procedure is

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<sup>1</sup> Department of Ophthalmology, County Hospital Piatra Neamţ, Romania.

<sup>2</sup> "Lucian Blaga" University of Sibiu, Romania.

<sup>3</sup> Fellow of the European Board of Ophthalmology.

<sup>4</sup> Head of Ophthalmology Department of "Victor Papilian" Faculty of Medicine, "Lucian Blaga" University of Sibiu, Romania.

technically more difficult and has a long learning curve. Combined canaloplasty with phacoemulsification has been shown to lower IOP by approximately 40% in two studies [1], [9]. The purpose of present study is to assess surgical safety and ability of this procedure to lower IOP during the entire follow-up period of 24 months.

## 2. Objectives

Primary end points were IOP values at different time points, number of antiglaucomatous medications still needed, intra- and postoperative complications, hence ascertaining the safety and efficacy of this procedure. Secondly we appreciated visual acuity(VA) recovery.

## 3. Material and Methods

*Patient demographic data* Table 1

Patients/Eyes	[n]	13/15
Age	[years]	
Mean $\pm$ SD		80.15 $\pm$ 5.09
Range		72-86
Sex	n [%]	
Female		5[38.46]
Male		8[61.53]
Residence	n [%]	
Urban		7[53.85]
Rural		6[46.15]
Glaucoma Diagnosis	n [%]	
POAG		11[84.62]
PEXG		2 [15.38]
Type of cataract	n [%]	
Nuclear sclerosis		10[76.92]
Cortical cataract		3[23.07]
No. of preop. meds	n.	
Mean $\pm$ SD		3.13 $\pm$ 0.35
Range		3-4

The study comprised 15 eyes of 13 patients with primitive open-angle(POAG) or exfoliative glaucoma(PEXG) who underwent phacocanaloplasty in Ophthalmology Department of the County

Hospital Piatra Neamţ, between March 2014 and May 2015. All surgeries have been done by the same surgeon (G.D.C). All the patients were able to understand and provided an informed consent about the procedure. Patient demographic data are shown in Table 1.

Two patients were operated on both eyes. 10 patients had nuclear sclerosis and 3 patients had cortical cataract. Inclusion criteria were open angle glaucoma, primitive or secondary and visually disturbing cataract. Exclusion criteria were any form of angle closure glaucoma and congenital glaucoma. A complete ophthalmologic examination was performed preoperatively including IOP measurement by applanation tonometry, visual acuity, gonioscopy, anterior and posterior slit lamp biomicroscopy and visual field examination whenever visual acuity was adequate for this procedure.

### 3.1. Surgical Technique

Phacocanaloplasty has been performed as a one-site procedure, starting with several surgical steps from canaloplasty, then performing phacoemulsification and ending with dilation and tensioning of Schlemm's canal. The canaloplasty part of the procedure was done according to the technique described by Scharioth, using the microcatheter Glaucolight from D.O.R.C. [8] After superior limbal peritomy, a superficial scleral flap of 5x5 mm, 1/3 of scleral thickness is dissected up to clear cornea. There is no bipolar cautery use in order to maintain the integrity of collector system and to avoid scleral collagen shrinkage that might make more difficult the final suture of the flap. A deep scleral flap is then fashioned, 0,5 mm inside the first, of adequate thickness and keeping constant the level of dissection (Fig. 1). Soon after Schlemm's canal is opened the cataract part of the procedure is started by performing phaco incision under

the superficial scleral flap. Two paracentesis are then performed, 120° apart. Anterior chamber is filled with viscoelastic material and continuous circular capsulorhexis is performed with a bent needle. After adequate hydro dissection and hydro delineation, the lens is removed using ultrasound probe (Fig. 2).



Fig. 1. Dissection of the deep scleral flap

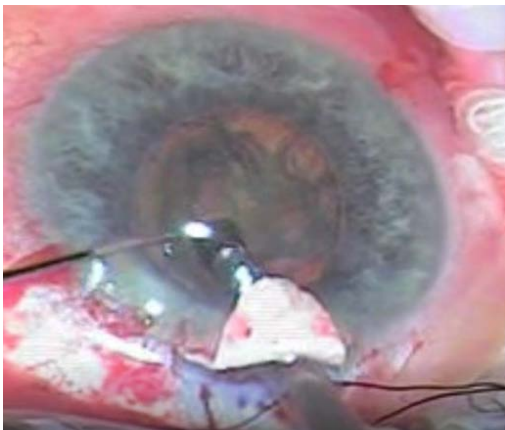


Fig. 2. Lens removal

Capsular bag is then thoroughly cleaned by bimanual irrigation-aspiration and filled with viscoelastic. A foldable one-piece hydrophobic intraocular lens is placed in the capsular bag. The deroofing and preparing of Descemet window continues on the deep

scleral plane. After identifying the two ostia of Schlemm's canal and obtaining an adequate width of the window, the deep scleral flap is excised. The microcatheter Glaucolight from DORC was introduced into the Schlemm's canal, the entire 360° circumference (Fig. 3).

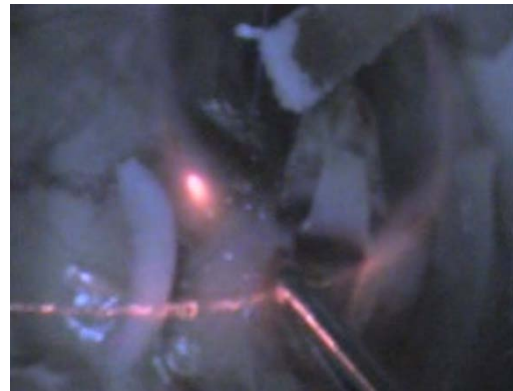


Fig. 3. Illuminated microcatheter through the Schlemm's canal

A 9:0 polypropylene suture was tied at the exteriorized end of the catheter and introduced in the canal during the catheter withdrawal. The suture was tied under tension in the canal using a slip knot. After placement of high viscosity sodium hyaluronate in the scleral lake, the superficial scleral flap was sutured with 5 absorbable sutures (Vicryl 8:0). Anterior chamber was refilled with BSS and conjunctiva repositioned and sutured with 2 absorbable sutures.

### 3.2. Postoperative Management

Immediately after surgery 40mg gentamicin and 2mg dexamethasone were injected subconjunctival in all patients. Postoperatively the patients received a combination of antibiotic and steroid, eye drops during the day and ointment at night, which was tapered according to the degree of intraocular inflammation. Antiglaucomatous medication was

discontinued after the procedure and recommenced according to IOP measurements if necessary.

Postoperatively patients were examined at day 1 and then at 1, 3, 6, 12, 18 and 24 months. At each visit a full ocular examination was performed including best corrected visual acuity assessment, Goldmann applanation tonometry, slit lamp biomicroscopy, gonioscopy and mydriatic funduscopy.

### 3.3. Statistical Methods

Student's t tests were used to compare IOP results at different time points with preoperative IOP. Results with  $p < 0.05$  were considered significant.

## 4. Results

The study group included patients who met the inclusion and exclusion criteria and provided consent for long term follow up. In the study group 11(84.61%) patients had primitive open angle glaucoma and 2

(15.38%) pseudoexfoliative glaucoma (PEXG). The outcomes of the study are presented in Table 2. Only 14 eyes have been evaluated at Month 12 and 10 eyes at months 18 and 24. Efficacy is shown in Figure 4. There was a statistically significant IOP reduction at all time points compared with baseline. Mean number of postoperative meds was  $0.06 \pm 0.25$ , compared with  $3.13 \pm 0.35$  preoperatively. Three eyes had microhyphema at day 1, which cleared spontaneously. No intraoperative or long-term postoperative complications have been encountered. All the patients reported a rapid visual recovery by Month 1.

## 5. Discussion

Cataract and glaucoma are common conditions occurring many times, in the same patient, especially concomitant cataract and glaucoma means answering at least two questions: Does the patient really need both surgeries? If yes, does it make sense to perform them at the same time?

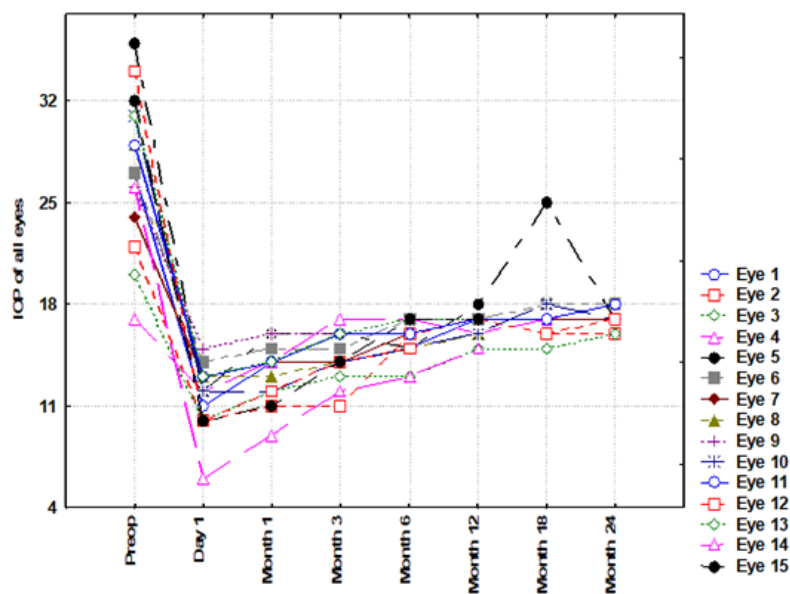


Fig. 4. IOP variation

Outcomes after 24 months

Table 2

Exam	No of eyes	Mean IOP (mmHg) $\pm$ SD	Mean meds(n) $\pm$ SD	t value	df	p value
Preoperative	15	27.400 $\pm$ 5.193	3.133 $\pm$ 0.351			
Day 1	15	11.600 $\pm$ 2.197	0	10.851	28	0.000
Month 1	15	13.133 $\pm$ 1.959	0	9.955	28	0.000
Month 3	15	14.400 $\pm$ 1.639	0	9.245	28	0.000
Month 6	15	15.600 $\pm$ 1.352	0	8.516	28	0.000
Month 12	14	16.571 $\pm$ 0.852	0	7.696	27	0.000
Month 18	10	17.600 $\pm$ 2.757	0	5.451	23	0.000
Month 24	10	17.100 $\pm$ 0.738	0.060 $\pm$ 0.258	6.187	23	0.000

The most important aspect is what's driving the surgery: if the cataract is disturbing and the patient is doing well on one glaucoma medication, a risk/benefit decision is not to perform glaucoma surgery at all. The best choice is then performing only cataract surgery alone, knowing that it lowers long-term IOP by 2-4 mmHg, according to Jampel et al [5]. If the patient has visually significant cataract and is on maximum antiglaucoma medication, the best choice is a combined procedure. This obviates the need for a future cataract operation, given the increased cataract progression after glaucoma surgery, and is associated with a reduced surgical trauma. There is also good evidence that long term IOP is lowered more by combined glaucoma and cataract procedures than by cataract surgery alone. If glaucoma is driving the surgery (the eye has markedly elevated IOP and important nerve damage) a staged approach is better, with glaucoma surgery performed first. Cataract extraction alone is recommended when glaucomatous damage is minimal and IOP is controlled with a low dose, well tolerated medical regimen. When glaucoma is uncontrolled on maximum tolerable medical therapy and induces an immediate threat to vision a two-stage procedure of antiglaucomatous surgery with subsequent cataract extraction is preferred. Between these two extremes

of glaucoma control are those cases for which a combined procedure is felt to be indicated, especially when cataract surgery is planned in an eye with borderline glaucoma control and/or moderate to advanced glaucomatous damage. There are several gaps in our knowledge concerning the optical surgical management of coexisting cataract and glaucoma. The lack of information concerning functional outcomes such as visual field and visual acuity is important because these represent actual disease of glaucoma and IOP is simply a risk factor for the development and progression of the disease. The absence of any quality-of-life measures is another deficiency, particularly regarding the question of staged versus combined procedures. A staged procedure involves two anesthesia, two surgeries and a prolonged period with a significant cataract still present, which is likely to adversely affect quality of life. Traditional filtering and tube surgery can be combined with cataract surgery. Trabeculectomy (the still gold standard of glaucoma surgery) can be performed in the same surgical session with cataract surgery but, as with tube surgery; important issues are prolonged visual recovery and immediate and long-term complications. Being penetrating procedures they involve creation of a fistula in the anterior

chamber, allowing aqueous humour to drain through the subconjunctival route.

Penetration of intraocular space is associated with well-known intermediate and long-term complications, including intra- and postoperative bleeding, shallow anterior chamber, hypotony, choroidal detachment, suprachoroidal haemorrhage, and bleb-related endophthalmitis. [6,7] Another option is ALCON's Ex-PRESS Mini Glaucoma Shunt, that standardizes the ostium for filtering surgery, being placed under a partial thickness scleral flap. It shortens the surgical time and obviates the need for an iridotomy, facilitating visual recovery. Despite its advantages, it had not gained popularity as a valuable alternative, unless the patient has fairly severe glaucoma.

There have been attempts to combine minimally invasive procedures with cataract surgery, and these are important in the light of shifting expectations of cataract surgery patients. Cataract surgery produces increasingly accurate refractive outcomes in record time, but when trabeculectomy is associated with cataract surgery the patient will take several weeks or months to recover vision. Helping these patients by lowering their IOP in long-term without jeopardizing the quick visual recovery they expect may be done with some of the minimally invasive glaucoma procedures. These are: trabectome, endoscopic cyclophotocoagulation, iStent. They still didn't gain widespread acceptance among surgeons performing combined procedures, due to possible trauma to the eye, learning curve and procedure time and cost. A more invasive procedure that can be associated with cataract surgery is canaloplasty with ab-externo approach, performed with cataract removal by phaco through the same incision or on a separate one (phacocanaloplasty). There are three pathological processes in open angle glaucoma: reduced outflow into

Schlemm's canal, collapse of the canal and closure of the collector channels [3]. Schlemm's canal surgery with canal dilation and tensioning is the only glaucoma procedure that corrects all three. The canaloplasty procedure was designed to enhance the outflow of aqueous humor by dilating Schlemm's canal, establishing circumferential flow, and stretching out the TM [4]. It is the first procedure designed to treat the entire Schlemm's canal. A comparison between phacocanaloplasty and phacotrabeulectomy (combination between phacoemulsification cataract surgery and trabeculectomy) has been done in a longitudinal cohort study with 12 months' follow-up by Schoenberg et al [10]. No significant difference in mean IOP at 12 months was found, with a mean of  $14.1 \pm 4.4$  mmHg in the phacocanaloplasty group and  $11.8 \pm 5.4$  mmHg in the phacotrabeulectomy group. Both procedures achieved significant reduction in IOP and improvement in VA at 12 months, with comparable success rates. In a retrospective subset analysis of a prospective, multicentre study, Tetz et al. evaluated 133 eyes of 133 adults with open angle-glaucoma to assess safety and efficacy of canaloplasty to treat open-angle glaucoma when combined with cataract surgery at 3-years follow-up. Eighty-two phakic eyes that received canaloplasty alone were compared with 51 eyes that underwent cataract surgery before or during canaloplasty [11]. Phakic eyes that received phacocanaloplasty had a mean baseline IOP of  $23.9 \pm 5.2$  mmHg and a mean of  $1.5 \pm 1$  glaucoma medications, decreasing to  $13.6 \pm 3.6$  mmHg on  $0.3 \pm 0.5$  mmHg at 3 years postoperatively. Pseudophakic eyes undergoing canaloplasty had a mean baseline IOP of  $23.9 \pm 5.2$  on a mean of  $1.8 \pm 0.8$  glaucoma medications, decreasing at  $15.6 \pm 3.5$  mmHg on  $1.1 \pm 0.8$  medications at 3 years. IOP reductions were significantly greater

and less postoperative medications were needed to control IOP in eyes undergoing phacocanaloplasty compared to eyes which had canaloplasty alone.

In this study 15 eyes of 13 patients with open-angle glaucoma (of primitive or secondary pseudo exfoliative type) underwent phacocanaloplasty, the one-site variant of the procedure, with cataract incision performed under the superficial scleral flap. The difficult parts of the procedure were working in the anterior chamber and capsular bag with instruments held under the superficial scleral flap and fashioning the trabeculo-descemet window under a continuous egress of viscoelastic material from anterior chamber. Adequate ocular tonus requested for preparing the thin trabeculo-descemet membrane is given by the maintenance of viscoelastic material in the anterior chamber and capsular bag after the placement of the intraocular lens. The patients have been followed for 2 years in terms of IOP level and number of medications needed for IOP control. Mean preoperative IOP was  $27.4 \pm 5.1$  mmHg. At day 1 mean IOP was  $11.6 \pm 2.1$  mmHg,  $13.1 \pm 1.9$  mmHg at month 1,  $14.4 \pm 1.6$  mmHg at month 3,  $15.6 \pm 1.3$  mmHg at month 6,  $16.5 \pm 0.8$  mmHg at month 12,  $17.6 \pm 2.7$  mmHg at month 18,  $17.1 \pm 0.7$  mmHg at month 24. There is a statistically significant reduction of IOP at all follow-up moments compared with baseline. Complete surgical success (IOP less than 21 mmHg without medication) was achieved in 9 of 10 eyes at 24 months (90 %) and qualified success (IOP below 21 mmHg with or without medication) was achieved in 10 of 10 eyes (100%). There were no intraoperative complications. The only complication encountered was postoperative microhyphema, at day 1 in 3 eyes, which cleared spontaneously. This is not uncommon after canaloplasty, due to IOP decrease to less than episcleral venous

pressure. The low incidence of postoperative complications is related to the nonpenetrating character of the procedure, the thin trabeculo-descemet membrane acting like a barrier between intraocular space and extraocular medium, allowing only the egress of aqueous humor from anterior chamber.

## 6. Conclusions

Phacocanaloplasty (the one-site procedure) seems to be a good option for long term lowering of IOP in patients with cataract and glaucoma. Although canaloplasty is the least surgeon and patient friendly procedure to be combined with phacoemulsification, it gives the opportunity to a rapid visual and ocular recovery. It is a procedure that treats the entire length of Schlemm's canal, being close to the ocular physiology. Last but not the least, there were no major intra- or postoperative complications. There are several limitations of this study: it is not randomised and it involves a small number of patients. For more consistent conclusions additional studies with an increased number of patients are necessary.

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