

A new bleb-independent surgery namely penetrating canaloplasty for corticosteroid-induced glaucoma: a prospective case series

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Abstract

• **AIM:** To report the outcomes of penetrating canaloplasty for corticosteroid-induced glaucoma in a case series.

• **METHODS:** Penetrating canaloplasty is a bleb-independent filtering surgery unifying canaloplasty and trabeculectomy. In this study, the surgery was performed to restore the natural outflow through surgically expanded Schlemm's canal and generated trabeculum ostium. A total of 10 eyes of 8 patients were treated with penetrating canaloplasty for corticosteroid-induced glaucoma. Intraocular pressure (IOP) and the number of glaucoma medications at postoperative 3, 6, 12, 18, 24, 36, and 48mo were documented as primary endpoint. Complications after the surgery were recorded as secondary endpoint.

• **RESULTS:** Penetrating canaloplasty was accomplished successfully for all 10 eyes, with a mean follow-up of 20.4±13.0mo (range 6-48mo). The mean preoperative IOP and number of anti-glaucoma medications were 45.1±6.5 mm Hg and 3.3±0.5 respectively. The mean post-operative IOP at 3, 6, 12, 18, 24, 36, and 48mo were 15.8±6.0, 14.7±3.3, 15.3±2.0, 15.6±2.6, 17.5±1.8, 16.5±4.9, and 14.0 mm Hg. The number of anti-glaucoma medications at these time points were all 0. This surgery failed to control the IOP in 1 eye at 1mo after surgery. Hyphaema occurred in 3 eyes on the first day after surgery. Postoperative transient IOP increasing was encountered with in two eyes from 1wk to

1mo after surgery. Choroidal detachment developed in one eye but responded well to conservative treatment.

• **CONCLUSION:** Penetrating canaloplasty is effective for corticosteroid-induced glaucoma without serious complications, making it a viable or preferred alternative option.

• **KEYWORDS:** penetrating canaloplasty; corticosteroid-induced glaucoma; intraocular pressure; bleb-independent filtering surgery

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INTRODUCTION

Secondary intraocular pressure (IOP) elevation is common in steroid responders to glucocorticoids^[1-2]. Long-term ocular hypertension may bring with glaucomatous optic nerve damage, that is, corticosteroid-induced glaucoma^[3-5]. The underlying mechanism may involve increased resistance of aqueous humor in flowing through the trabecular meshwork (TM)^[6]. Besides trabeculectomy^[7-8], a standard surgical procedures for glaucoma, corticosteroid-induced high IOP can be managed with trabeculotomy^[9], trabectome^[10], nonpenetrating deep sclerectomy^[11], canaloplasty^[12], viscocanalostomy^[13], gonioscopy-assisted transluminal trabeculotomy (GATT)^[14], Kahook Dual Blade goniotomy^[15], Ahmed glaucoma valve^[16], and XEN Gel Stent^[17]. However, their outcomes have not been assessed with large case-control studies.

Multiple studies have revealed the superiority of canaloplasty to trabeculectomy in treating open angle glaucoma^[18-19]. Matlach *et al*^[20] conducted a prospective randomized clinical trial, showing that canaloplasty and trabeculectomy had comparable IOP-lowering efficacy after 2y for primary open angle glaucoma (POAG), but in the former

antimetabolites use and vision-threatening complications were avoided^[21-22]. Brusini *et al*^[12] reported favorable mid-term outcomes of canaloplasty in patients with corticosteroid-induced glaucoma. Researchers have reported successful viscocanalostomy in three cases with corticosteroid-induced glaucoma^[13].

Considering the outflow resistance mainly increases in TM, tension suture aided canaloplasty can be combined with trabeculectomy to bypass the TM, thus channeling the aqueous humor into the expanded Schlemm's canal. Since trabeculectomy is a penetrating surgery, we coined this combination as "penetrating canaloplasty". This surgery can reflect Cairns's^[23] concept, in which aqueous humor is drained through trabeculectomy-formed fistula into the Schlemm's canal, thus realizing the internal filtration. Our previous study has reported a favorable outcome of penetrating canaloplasty in primary angle-closure glaucoma^[24-25] and traumatic angle recession glaucoma^[26]. Herein we presented the preliminary surgical outcomes of penetrating canaloplasty for corticosteroid-induced glaucoma.

SUBJECTS AND METHODS

Ethical Approval This is a prospective interventional study (No.ChiCTR1900020511). The study complied with the tenets of the Declaration of Helsinki and was approved by the Ethics Committee of the eye hospital of Wenzhou Medical University (YX2018-016). Every subject voluntarily signed the consent form.

Subjects and Preoperative Examinations All patients were diagnosed with corticosteroid-induced glaucoma that was medically uncontrolled (with a definite history of corticosteroid use, IOP still rises to more than 21 mm Hg under maximal tolerable medical treatment, with concomitant glaucomatous optic disc damage and corresponding visual field defects).

Inclusion criteria: 1) corticosteroid induced high IOP; 2) IOP exceeded 30 mm Hg after maximal medical interventions, despite cessation of corticosteroid therapy (if possible) for at least 3mo; 3) fundus and visual field showed concomitant glaucomatous optic disc damage and corresponding visual field defects; 4) gonioscopy demonstrated wide and open angles and an intact Schlemm's canal. Exclusion criteria: 1) other secondary glaucoma, 2) refusal to sign the consent form.

Use of corticosteroid was recorded. All participants received a comprehensive ophthalmic examination within one week before the surgery, which included best-corrected visual acuity (BCVA), slit-lamp biomicroscopy, gonioscopy, IOP measurement with Goldmann applanation tonometer, fundus examination with a 90 D and non-mydratic fundus photography, and Humphrey SITA standard 24-2 perimetry, and retinal nerve fiber layer assessment with spectral-domain optical coherence tomography (OCT).

Surgery This surgery was pioneered by Dr. Liang YB and patented in the United States (<http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO2&Sect2=HITOFF&p=1&u=%2Fnetahml%2FPTO%2Fsearch-bool.html&r=1&f=G&l=50&co1=AND&d=PTXT&s1=15%2F362,478&OS=15/362,478&RS=15/362,478>). All 8 patients (10 eyes) underwent penetrating canaloplasty by an experienced glaucoma surgeon Liang YB. The procedures are listed below.

1) A superior rectus traction suture or a corneal bridle traction suture was placed to expose the surgical field, then a fornix-based conjunctival incision and a 4×4 mm² superficial scleral flap of 1/2 scleral thickness were constructed.

2) Beneath the first flap, a smaller and deeper scleral flap (2×2 mm²) was sculpted. A routine paracentesis incision was made to lower the IOP, so as to obviate the risk of trabeculodesceme membrane detachment. Schlemm's canal was opened and unroofed by the removal of the external wall. The deep scleral flap (2×2 mm²) was then dissected away and both ostia of the canal were repeatedly visco-dilatated with high molecular weight hyaluronic acid (Healon GV), just as procedures in viscocanalostomy.

3) The illuminated microcatheter (iTrack by iScience Interventional, Menlo Park, CA, USA) was then inserted and advanced through the 360° Schlemm's canal, until out of the opposite end.

4) After ligation of a 10-0 polypropylene wire to the distal tip of the microcatheter, the laser microcatheter was retreated. Every two hours, the high polymer sodium hyaluronate (Helon GV, pharmaia company, USA) was injected to expand the Schlemm's canal with the aid of a special screw-driven syringe. After the withdrawal of the microcatheter, the suture was then replaced in the Schlemm's canal. After the Schlemm's canal was fully expanded, the suture was knotted under tension.

5) The trabecular tissue (2×2 mm²) deep at Schlemm's canal was cut off and forwarded. The respective iris root was cut.

6) Finally, the superficial scleral flap was tightly sutured with 10-0 prolene sutures to ensure a watertight closure preventing any bleb formation. The conjunctival flap was then sutured with 10-0 prolene sutures to the peripheral cornea.

Patients were treated with tobramycin and dexamethasone eye drop and ointment, which were tapered in one month after surgery. IOP and anterior segment were measured after surgery.

Follow-up and Outcome Measurements Patients were intensively followed up on the first week after the surgery and the following time points (1, 3, 6, 12, 18, 24, 36, and 48mo). The main observation index included all baseline examinations and IOP, number of glaucoma medications, intra- and postoperative complications, and additional interventions. Morphology of the filtering bleb was assessed using slit-lamp microscope and ultrasound biological microscopy (UBM).

Table 1 Basic characteristics of the patients

Serial No.	Gender	Age (y)	Eye	Cause of corticosteroid-induced glaucoma	Primary disease	Preop. IOP (mm Hg)	NOM	BCVA	Follow-up length (mo)
1.Zhou××	M	24	OD	Methylprednisolone <i>p.o.</i>	SLE	48.3	3	NLP	48
2.Liu××	F	28	OD	Prednisolone acetate eye drops; prednisolone <i>p.o.</i> ; intravitreal injection of triamcinolone acetonide	Panuveitis	55.7	4	0.5	36
3.Chen××	M	25	OD	Dexamethasone eye drops; prednisolone acetate <i>p.o.</i> ; intravitreal injection of triamcinolone acetonide	Behcet's disease	40.9	3	0.3	24
4.Ni××	M	30	OS	Prednisolone acetate eye drops; prednisolone <i>p.o.</i> ; periocular injection of methylprednisolone; retrobulbar injection of triamcinolone acetonide	Panuveitis	38.8	4	0.6	18
5.Jiang××	M	52	OS	Dexamethasone eye drops; posterior sub-Tenon's capsule injection of triamcinolone acetonide	Iridocyclitis; CME	38.3	3	0.1	18
6.Guan××	M	9	OS	Dexamethasone eye drops	Allergic conjunctivitis	47.7	3	0.6	18
7.Guan××	M	9	OD	Dexamethasone eye drops	Allergic conjunctivitis	36.7	3	0.8	18
8.Wang××	M	7	OD	Intravitreal injection of triamcinolone acetonide	Uveitis	43.6	3	0.4	12
9.Mi××	F	20	OD	Prednisolone acetate <i>p.o.</i>	SLE	47.5	3	FC/20 cm	6
10.Chen××	M	26	OS	Dexamethasone eye drops; prednisolone acetate <i>p.o.</i> ; posterior sub-Tenon's capsule injection of triamcinolone acetonide	Behcet's disease	53.5	4	0.7	6
Mean±SD	-	23±13.3	-	-	-	45.1±6.5	3.3±0.5	-	20.4±13.0

Preop. IOP: Preoperative intraocular pressure; NOM: Number of glaucoma medications; BCVA: Best-corrected visual acuity; NLP: No light perception; FC: Fingers counting; SD: Standard deviation; SLE: Systemic lupus erythematosus; CME: Cystoid macular edema.

Surgery was defined as success according to postoperative IOP ≤ 21 mm Hg and IOP reduction by ≥ 20% with (qualified success) or without (complete success) medical treatment. Antiglaucomatous medications were prescribed when IOP was above 21 mm Hg (Figure 1).

Statistical Analysis SPSS Statistics 20.0 (Statistical Product and Service Solutions, IBM, USA) was used for statistical analysis. Student's *t*-test was applied to compare IOP values before and after surgery. Value of *P* < 0.05 was considered statistically significant.

RESULTS

Basic characteristics of the patients are summarized in Table 1. The mean follow-up time was 20.4±13.0mo (range 6-48mo). The mean preoperative IOP and number of anti-glaucoma medications were 45.1±6.5mm Hg and 3.3±0.5, respectively. The mean IOP at 3, 6, 12, 18, 24, 36, and 48mo were 15.8±6.0, 14.7±3.3, 15.3±2.0, 15.6±2.6, 17.5±1.8, 16.5±4.9, and 14.0 mm Hg, respectively. The number of anti-glaucoma medications at these time points were all 0 (Table 2). IOP was well controlled in 9 cases off medication, but not reduced in 1 eye of a patient at 1mo after the surgery. Then this patient received ultrasound cycloplasty, trabeculectomy with mitomycin C (MMC), needling subsequently in the following 7mo, but all failed. A drainage valve was implanted at last. At last follow-up, the IOP in this case dropped to 18.5 mm Hg.

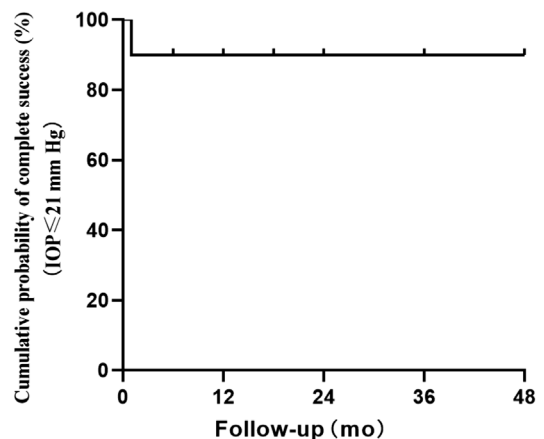


Figure 1 Complete success rate for intraocular pressure ≤ 21 mm Hg (Kaplan-Meier analysis).

Gonioscopy confirmed that prolene sutures were precisely positioned within the Schlemm's canal for the entire follow-up period in all cases. UBM after penetrating canaloplasty shows no subconjunctival filtration bleb (Figure 2). Microhyphaema occurred in 3 eyes, but disappeared within one week through spontaneous absorption. Postoperative transient IOP spike occurred in two eyes which cropped up from one week to one month after surgery. One eye developed choroidal detachment which responded well to conservative treatment. No other complications were observed during or after the surgery. For

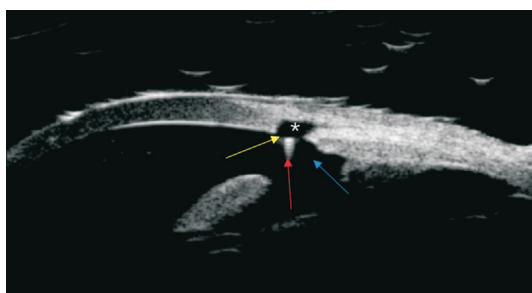


Figure 2 Picture of ultrasound biological microscopy after penetrating canaloplasty Star: Visible deep sclera pool; Yellow arrow: Trabeculectomy-formed fistula; Blue arrow: Peripheral iridotomy; Red arrow: Precisely positioned tension suture within the Schlemm’s canal. No subconjunctival filtration bleb.

Table 2 Pre- and postoperative intraocular pressure

Time points	<i>n</i>	IOP (mm Hg)	NOM	<i>P</i>	IOP reduction (%)
Preop.	10	45.1±6.5	3.3±0.5	-	-
Postop. 3mo	9	15.8±6.0	0	<0.01	65.6
Postop. 6mo	9	14.7±3.3	0	<0.01	68.0
Postop. 12mo	7	15.3±2.0	0	<0.01	65.6
Postop. 18mo	6	15.6±2.6	0	<0.01	65.1
Postop. 24mo	4	17.5±1.8	0	<0.01	61.8
Postop. 36mo	2	16.5±4.9	0	<0.01	68.3
Postop. 48mo	1	14.0	0	<0.01	71.0

The failed surgery is not included in this analysis. *n*: Number of cases at the postop. time point; IOP: Intraocular pressure; NOM: Number of glaucoma medications. The *P*-values for the *t*-test results between preoperative and postoperative data.

uveitic eyes, two eyes had no recurrence of the inflammation postoperatively, four eyes had varying degrees of uveitis reactivation and an addition of corticosteroid.

DISCUSSION

In this case series, penetrating canaloplasty was successfully performed in all the 10 eyes, and the IOP in 9 eyes was decreased without anti-glaucoma medications. Follow-up data proved the encouraging efficacy and safety of this surgery. The average age of 10 cases was 23±13.3y, an age lower than that of POAG cases^[7]. If treated with a routine trabeculectomy, these patients might be plagued with problems related to subconjunctival bleb for a long time. As an internal filtration surgery for restoring the physiological channel, penetrating canaloplasty does not depend on the maintenance of the filtration bleb.

In the development of corticosteroid-induced glaucoma, basement membrane-like materials (positive for type IV collagen) amass in each layer of TM and fine fibrillar materials deposit beneath the inner endothelium of Schlemm’s canal^[27]. We treated corticosteroid-induced glaucoma with penetrating canaloplasty that combines the advantages of canaloplasty

(internal filtration and bleb-free) with trabeculectomy (a patent communication between the anterior chamber and the Schlemm’s canal but with the sclera flap hermetically sutured). In this surgery, the aqueous humor passes through physiological route *via* dual conduits: Schlemm’s canal and the passage between the anterior chamber and Schlemm’s canal. Many patients with corticosteroid-induced glaucoma cannot discontinue glucocorticoids due to their primary diseases. Therefore, this dual-channel surgery can prevent the effect of TM’s further lesions during a long term. In the present study, this surgery achieved an ideal control of IOP off medication, suggesting its high efficacy for these patients.

In the present study, the mean IOP values at postoperative seven time points were favorable for these young patients. Literature shows viscocanalostomy and canaloplasty have the potential to reduce IOP among mid-teens and lower-teens, respectively^[28]. Penetrating canaloplasty is expected to be a promising treatment option for reducing IOP to lower- and mid-teens with corticosteroid-induced glaucoma.

Microhyphaema was the most common surgery-related complication, perhaps due to the blood reflux from the episcleral veins or the collateral damage to iris. Two cases developed postoperative IOP spike between one week and one month after surgery. It may be related to the structural collapse of internal drainage channel caused by long-term high IOP. We hypothesize that there is a time window for the resuscitation of internal drainage channel, so close observation and appropriate intervention should be conducted for these patients. One eye developed choroidal detachment but responded well to conservative treatment. Other reported canaloplasty-related adverse events in POAG include Descemet’s membrane detachment, cataract formation, suture extrusion *etc*^[29-30]. But these events were not observed in this study.

This study lacks of control group. Prospective and randomized studies with better designs and sufficient samples were needed to verify the effectiveness of the surgery.

In conclusion, penetrating canaloplasty is effective for corticosteroid-induced glaucoma without any serious complications, making it a viable or preferred surgical choice.

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Conflicts of Interest: Hu JJ, None; Lin HS, None; Zhang SD, None; Ye WQ, None; Gu J, None; Xie YQ, None; Tang YH, None; Liang YB, None.

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