Internal sclerostomy using laser ablation of dyed sclera in glaucoma patients: a pilot study

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Abstract

Twelve eyes of 12 patients with refractory glaucoma were treated with internal sclerostomy using laser ablation of dyed sclera. The technique involves iontophoretic impregnation of the sclera at the limbal region with 1% methylene blue and subsequent delivery of a pulsed dye laser beam to the stained area through a gonioscope. The red wavelength of 664 nm generated by the laser is maximally absorbed by the stained sclera and creates a through and through sclerostomy. Successful complete sclerostomy was achieved in seven eyes (58.3%) but there was some reduction of intraocular pressure (IOP) in all cases. Mean pre-laser IOP (of all 12 eyes) was 36.6 mm Hg and 1 hour after therapy it was reduced to 20.0 mm Hg. At the end of the follow-up period (mean 16 months) the mean IOP was 23.7 mm Hg; five eyes (41%) maintained their IOP below 22 mm Hg, and the average number of medications per eye came down from 3.25 to 2.25 per eye. Transient corneal burns with Descemet's membrane folds adjacent to the laser impact zone were detected in eight eyes (67%). No major complications like IOP spike, hyphema, iridodialysis, or retinal detachment have been detected. Clear cornea and dark blue scleral staining are essential for the mechanical success of this procedure. Gonioscopic laser internal sclerostomy of methylene blue dyed sclera is technically feasible and the preliminary results of IOP control in refractory glaucoma are promising. Modifications of the iontophoresis process and laser parameters are currently under investigation in order to improve these results.

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Conjunctival injury following surgical manipulation is believed to be the main reason for subconjunctival fibrosis and subsequent bleb failure in filtering surgery.¹ Complications of filtering surgery such as shallowing of the anterior chamber, hypotony, bleb leak and infection may also be related to conjunctival dissection and ocular penetration. In an attempt to avoid subconjunctival scarring, 5-fluorouracil² or drainage setons³ have been used in refractory glaucoma. However, despite their relatively high success, both still involve invasive intraocular surgery.

Internal, minimally invasive sclerostomy with no conjunctival dissection would appear to offer advantages. Scheie was the first to describe the procedure termed goniotomy, using a sharp blade to make a passage from the anterior chamber to the subconjunctival space.⁴ Success-

ful sclerostomies have already been reported using a mechanical drill,⁵ a laser beam delivered intracamerally through a fibreoptic probe,⁶⁻¹¹ and Nd-YAG laser beam delivery through a gonioscope.¹²⁻¹⁴ However, as the sclera has low optical absorption in the visible and near infrared portions of the spectrum, its ablation by lasers emitting in this region requires extremely high energy with subsequent damage to surrounding tissues. In an attempt to minimise energy levels, Latina *et al*¹⁵ developed the 'dye-enhanced sclerostomy' and successfully performed through and through sclerostomies in animals.^{15,16} The technique involves iontophoresis of the anterior sclera with methylene blue followed by its ablation using the flashlight pumped pulsed dye laser. The laser beam has a wavelength of 664 nm which is at the peak of the absorption curve of the stained sclera. Thus, the laser energy is maximally absorbed at the sclera, causing minimal damage to neighbouring tissues. Other methods of enhancement of scleral light absorption with fluorescein¹⁷ and silver oxide¹⁸ were reported.

In the study presented here, gonioscopic laser internal sclerostomy of dye-enhanced sclera is described in 12 patients with refractory glaucoma.

Materials and methods

SELECTION OF PATIENTS

The criteria for inclusion of patients in the study were as follows:

- (1) Age over 20 years.
- (2) Visual acuity of counting fingers from 1 foot or less in the operated eye.
- (3) Intraocular pressure (IOP) more than 26 mm Hg in two consecutive measurements, despite maximally tolerated medical treatment.
- (4) Patient's willingness to participate in the study and adherence to the follow-up schedule.
- (5) Patient's signature on an informed consent after the potential risks and benefits of the procedure have been fully explained.

Patients with active neovascular glaucoma or corneal opacity preventing visualisation of the angle were not included in the study. However, patients with corneal oedema or bullous keratopathy were topical application of glycerin improved the view of the anterior chamber, as well as one patient with mild rubeosis of the iris but no detectable neovascularisation of the angle, were included.

Before laser treatment and at all intervals postoperatively all patients had a full ophthalmic examination which included: best corrected visual acuity, IOP measurement by applanation

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tonometry, slit-lamp examination, and ophthalmoscopy.

Figures 1–3 Schematic illustration of the three steps of gonioscopic laser internal sclerostomy.

Figure 1 Iontophoresis of sclera with 1% solution of methylene blue through the conjunctiva.

Figure 2 Elevation of conjunctiva from sclera using subconjunctival injection of balanced salt solution or sodium hyaluronate at the treatment site.

OPERATIVE TECHNIQUE

The site to be operated on was selected, the existence of a patent iridectomy and good conjunctival mobility being thought favourable.

Following retrobulbar anaesthesia, while the patient was in the supine position, topical drops of proparacaine hydrochloride 0.5% were instilled. A lid speculum was then inserted and an alligator clip connected to the negative pole of the iontophoresis power supply was attached to it. The positive pole was connected to a wire running through a glass pipette, previously filled with sterile 1% methylene blue solution in distilled water. The pipettes were prepared with tip openings of 100–150 μm , to minimise leakage and excessive corneal staining.

The duration of each iontophoresis staining was 5–7 minutes, using a current of 0.2–0.4 mA. At the selected operation site, the sclera was focally dyed at the limbus and then 2–3 mm posterior to limbus by iontophoretically applying methylene blue through the conjunctiva, to

Figure 3 Delivery of laser beam (664 nm) through the gonioscopic lens to the methylene blue stained sclera.

Table 1 Internal laser sclerostomy – patients' data

Patient no	Age (years)	Sex	Diagnosis	Preceding operations	Visual acuity	Intraocular pressure (mm Hg)	Medical Rx
1	80	M	Primary open angle glaucoma, corneal oedema	–	No light perception	47	Timolol, pilocarpine, 2% propine, diamox
2	77	M	Traumatic glaucoma, mature cataract	1 filter	No light perception	50	Timolol, pilocarpine 2%, diamox
3	55	M	Primary open angle glaucoma, old retinal detachment	–	No light perception	36	Timolol, propine, diamox
4	65	F	Chronic closure angle glaucoma, central retinal vein occlusion, bullous keratotomy	–	No light perception	52	Pilocarpine 2%, diamox
5	38	M	Pigmentary glaucoma	–	Hand movements	27	Timolol, propine, diamox
6	75	M	Chronic angle closure glaucoma, corneal oedema	Extracapsular cataract extraction + intraocular lens implantation	No light perception	27	Timolol, propine, pilocarpine 2%, diamox
7	80	F	Chronic angle closure glaucoma, aphakia	1 filter intracapsular cataract extraction	No light perception	38	Timolol, propine, neptazane
8	72	M	Chronic angle closure glaucoma, central retinal vein occlusion	Laser iridotomy extracapsular cataract extraction + intraocular lens implantation	Hand movements	36	Timolol, pilocarpine 2%, diamox
9	70	M	Primary open angle glaucoma	Filter $\times 2$	Hand movements	28	Timolol, pilocarpine, 2% propine, diamox
10	69	M	Traumatic glaucoma	–	No light perception	30	Timolol, pilocarpine 2%, diamox
11	75	F	Chronic angle closure glaucoma, retinitis pigmentosa, corneal oedema	Laser trabeculoplasty extracapsular cataract extraction + intraocular lens implantation	Hand movements	32	Timolol, pilocarpine 2%, diamox
12	65	M	Primary open angle glaucoma	–	No light perception	36	Timolol, pilocarpine 2%, propine, neptazane

ensure good dye absorption of the sclera along the anticipated oblique route of the laser sclerostomy, thus staining both the internal and the external portions of the expected sclerostomy route.

A single mirror gonioscopic lens, the CGF lens,¹⁴ was used to confirm the presence of dye in the angle, anterior to Schwalbe's line.

In order to prevent inadvertent perforation of the conjunctiva, the stained conjunctiva was elevated with an injection of balanced salt solution using a 30 gauge needle inserted at a site adjacent to the planned filtration bleb. In two patients, subconjunctival injection of sodium hyaluronate was performed.

The laser used was the flashlight pumped pulsed dye laser (Candela Laser Corporation, Wayland, MA). This laser delivers pulses of high energy (100–400 mJ per pulse) with pulse duration of 10 μ s and spot size of 200 μ m. The laser emits red light (664 nm wavelength) which is maximally absorbed by the methylene blue. The laser light was coupled to the slit-lamp delivery system using a 200 μ m fibre. The beam was directed into the angle through the CGF gonio-lens.¹⁹

The basic steps of the procedure are schematically illustrated in Figures 1–3.

POSTOPERATIVE FOLLOW UP

Patients were prescribed prednisolone acetate 1% drops four times daily initially; tapering off to nil after 1 month. In addition, all antiglaucoma medications were discontinued immediately after treatment. The decision to restart treatment was based on postoperative IOP measurements.

Starting 1 hour after treatment, IOP measurement and slit-lamp examinations were performed hourly for 3 hours. The following day, 1 week, 1 month, 3, and 6 months after treatment, visual acuity and IOP were measured, and slit-lamp examination and ophthalmoscopy were performed. All major as well as minor complications of the procedure were documented and, when required, treated medically.

The study was conducted under an Investigational Device Exemption of the Food and Drug Administration (IDE number G880001) and approved by the Israeli Ministry of Health and the institutional human use review board (Helsinki Committee).

Results

Twelve eyes of 12 patients were treated in this

Figure 4 Response of mean intraocular pressure to gonioscopic laser internal sclerostomy.

Figures 5–7 A representative case of successful gonioscopic laser internal sclerostomy.

Figure 5 Immediately following iontophoresis of 1% methylene blue – conjunctival staining.

study. There were nine men and three women with a mean age of 68.4 years (ranging from 38 to 80 years). Mean follow-up time was 16 months (ranging from 13 to 20 months). All patients had end-stage glaucoma as a result of various conditions: primary open angle glaucoma (four eyes), chronic angle closure glaucoma (five eyes), post traumatic glaucoma (two eyes) and pigmentary glaucoma (one eye). Associated ocular diagnoses included: corneal oedema or bullous keratopathy (four eyes), central retinal vein occlusion (two eyes), old retinal detachment (one eye), and retinitis pigmentosa (one eye). Six eyes had at least one previous intraocular operation. Three eyes had at least one filtering surgery and four eyes had previous cataract surgery (three with and one without intraocular lens implantation). The average number of antiglaucoma medications per eye was 3.25 (Table 1).

The end-point of the procedure was very hard to evaluate. The main indication for a successful sclerostomy was the immediate, sharp reduction of IOP. In several eyes, accompanying signs of a through and through opening were evident, such as subconjunctival gas bubbles, subconjunctival haemorrhage, turbulence of debris in the anterior chamber, and diffuse elevation of a conjunctival bleb.

The mean preoperative IOP was 36.6 mm Hg

Figure 6 Immediately following iontophoresis of 1% methylene blue. A gonioscopic view of the treatment site showing dense blue (+++) scleral staining anterior to Schwalbe's line.

Figure 7 Successful sclerostomy 5 months following gonioscopic view of lased site displays blanching and elevation of Descemet's membrane. Note retrodisplacement of the iris posterior to sclerostomy site. Intraocular pressure = 11 mm Hg.

(range: 27 to 52 mm Hg). The mean IOP 1 hour after laser treatment was 20.0 mm Hg (range: 2 to 44 mm Hg). At the end of the follow-up period, mean IOP was 24.5 mm Hg (ranging from 11 to 38 mm Hg). Figure 4 depicts the response of mean IOP of the operated eyes over time.

In seven eyes (58.3%) a patent through and through sclerostomy was evident immediately post laser treatment. This was associated with marked reduction of IOP in all cases. In two eyes, gas bubbles were detected under the conjunctiva above the operated site. These bubbles were first detected immediately after the laser application, remained visible for 3–4 hours afterwards and disappeared within 24 hours. The average laser energy required to complete a sclerostomy was 3.575 J (13 shots of 275 mJ each). Subconjunctival haemorrhage after laser treatment occurred in four eyes, and it usually resolved within 2 weeks. Evaluated 1 week after treatment only one eye displayed a high filtration bleb while in four eyes the filtration bleb was very low and diffuse and in two eyes the bleb could not be demonstrated at all despite substantial reduction of IOP. There was shallowing of the anterior chamber in one eye only, the same eye that had a very high filtration bleb (patient no 11). Long term, none of these seven eyes had a detectable filtration bleb.

Gonioscopically, blanching of the stained sclera was noted in all cases. The Descemet's membrane was successfully perforated in 11 of 12 eyes (91.6%). In most cases, the Descemet's

membrane was found to be elevated and open with cracks and tears of variable sizes and shapes. In some cases, a large flap of Descemet's membrane was formed, with its free edge elevated and exposing the internal sclerostomy. Retrodisplacement of the iris was detected in two eyes (16.6%).

Three degrees of methylene blue staining were achieved: +, ++, +++. Dark blue stain (+++) was observed in five eyes and in all of them the sclerostomy was associated with marked reduction of IOP. Conversely, all three eyes with light blue staining of the sclera (defined as (+) only) had partial sclerostomies. In four eyes with moderate stain (++), only two had reduced IOP. In two eyes, both with scarred and congested conjunctiva, quick turnover of the methylene blue within 30 minutes required repeated iontophoresis before laser treatment.

Figures 5, 6, and 7 display a representative successful internal laser sclerostomy of dye enhanced sclera.

COMPLICATIONS

Flare and cells could be detected in all eyes immediately after the procedure. It resolved within 1 week.

Localised corneal oedema with Descemet's membrane folds were detected in eight eyes (67%). These findings usually resolved within 1–7 days. In one eye, localised Descemet's membrane tear was noted in the corneal periphery adjacent to the sclerostomy site, and was present for 3 months.

One eye that had bullous keratopathy before laser treatment developed persistent corneal erosion and subsequent inflammatory infiltrate that cleared after antibiotic therapy.

Only one eye displayed minimal bleeding in the angle at the treatment site immediately after laser treatment (patient no 1). There was no frank hyphaema and no immediate IOP elevation, retinal detachment, or choroidal effusion after treatment in any eye.

All data regarding treatment parameters, immediate and long term response are summarised in Tables 2 and 3. The response of IOP in all 12 patients is graphically displayed in Figure 8.

Discussion

Our preliminary results with gonioscopic laser

Table 2 Internal laser sclerostomy – treatment parameters and immediate response

Patient no	Intraocular pressure (prelaser)	Methylene blue staining	Laser energy (mJ per pulse × no of pulses)	Sclerostomy	Intraocular pressure (postlaser)	Presence of bleb*	Remarks
1	47	++	250×11	Partial	44	–	Poor view, corneal oedema blood in Rx site, Descemet's folds
2	50	+	220×16	Partial	34	–	Poor view, Descemet's folds
3	36	++	250×12	Complete	12	+	Gas bubbles under bleb corneal burn
4	52	+	250×5	Partial	36	–	Poor view, bullous keratopathy
5	27	+++	250×17	Complete	14	+	Subconjunctival haemorrhage
6	27	++	310×30	Partial	18	–	Poor view, corneal oedema
7	38	+++	300×12	Complete	18	–	Descemet's tear
8	36	+++	280×10	Complete	18	+	Corneal burn subconjunctival haemorrhage
9	28	+++	250×7	Complete	12	–	Subconjunctival haemorrhage corneal burn
10	30	+	310×12	Partial	22	–	Descemet's folds
11	32	++	330×10	Complete	2	++	Gas bubbles, high bleb, shallow anterior chamber Descemet folds
12	36	+++	300×16	Complete	18	++	Subconjunctival haemorrhage

*Bleb was evaluated 1 week after laser internal sclerostomy.

Table 3 Internal laser sclerostomy – long term results

Patient no	Follow-up time (months)	Intraocular pressure	Medical Rx	Sclerostomy	Remarks
1	20	38	Timolol, pilocarpine 2%, propine, diamox	Closed	–
2	20	29	Timolol, pilocarpine 2%, neptazane	Closed	–
3	18	11	Diamox	Open	–
4	16	34	Timolol, diamox	Closed	Corneal abscess resolved with medical Rx
5	16	13	–	Closed	–
6	16	25	Timolol, pilocarpine 2%, propine, diamox	Closed	–
7	16	19	Timolol, propine, neptazane	Open, but tissue fills in	Descemet's roll
8	16	22	–	Open	–
9	16	24	Timolol, pilocarpine 2%	Closed	–
10	13	21	Timolol, propine, pilocarpine 2%, diamox	Open	–
11	13	26	Timolol, diamox	Closed	–
12	13	33	Timolol, neptazane	Closed	–

internal sclerostomy of methylene blue dyed sclera in glaucoma patients are very promising as it appears that a functional, patent sclerostomy is technically feasible using this method.

In our investigation 7 months after gonioscopic laser internal sclerostomy, four of the 12 treated eyes maintained their IOP at 21 mm Hg or under (33%), while five eyes had IOP of less than 22 mm Hg (41%).

Dense scleral staining with methylene blue is one of the most important factors affecting the result of the procedure. Intense dark blue staining results in better absorption of the laser beam with more effective tissue ablation. Factors affecting the quality of the iontophoresis process (like conjunctival scarring and electrical current parameters) will affect the success rate of the laser sclerostomy. Modifications of iontophoresis parameters are currently under way in an attempt to improve scleral conductivity and staining by the methylene blue.

For achieving a through and through sclerostomy, an average laser energy of 3575 mJ had to be delivered. Puncturing of the Descemet membrane was usually the first step in the procedure. Blanching of the stained sclera usually resulted after the first laser shots, which seemed to adversely affect the efficacy of subsequent shots. Consequently, drilling through the external portion of the sclera was always more difficult and required more energy.

Factors associated with the clinical status of the treated eye were also found to play an

important role in the success of the laser sclerostomy.

Clear cornea is essential for proper visualisation of the angle through the gonioscope and efficient laser delivery to the sclera. All four eyes that had pre-existing corneal oedema had only partial sclerostomy. Treatment in all eyes was more difficult owing to the relatively poor view, despite application of topical glycerin for 1 minute.

As expected, long term success rate of laser sclerostomy was affected by the extent of previous surgical manipulation. Four of the six eyes that did not have any surgical intervention before laser sclerostomy were successfully treated, maintaining low IOP with open sclerostomy several months after therapy. This is not surprising, as eyes with previous intraocular surgery usually do poorly after surgical filtering as well.²⁰

Scarred conjunctiva apparently reduces conductivity of methylene blue and is less compliant to the subconjunctival injection. This may affect both the feasibility of sclerostomy formation and long term control of IOP.

One of the main problems remaining is the definition of the end point of the procedure. During treatment, only one eye demonstrated some turbulence of debris that could indicate perforation. In all other eyes, no obvious signs of through and through scleral opening (like anterior chamber shallowing) could be noted during laser treatment. However, as there were no major complications associated with additional laser shots, we believe that overtreatment may not present a special hazard to the eye. Treatment should be allowed to continue until subsequent shots no longer create scleral ablation (usually no more than 20 shots are sufficient).

Signs of successful sclerostomy were evaluated immediately post laser treatment and included: (1) a marked reduction in IOP, (2) detection of gas bubbles under the conjunctiva, suggesting direct communication between the anterior chamber and the subconjunctival space, (3) subconjunctival haemorrhage occurring after laser treatment, suggesting rupture of blood vessels either at the episcleral or conjunctival level. The occurrence of a conjunctival bleb was considered non-contributory at this stage, as most of the conjunctival elevation should be related to the preceding injection.

After sclerostomy, only one eye had a high filtration bleb with shallowing of the anterior chamber, while all other eyes had very diffuse and shallow bleb or no detectable bleb at all. Previously reported diameters of contact laser sclerostomies were in the range of 200–300 μm .^{9,15} We believe the relatively small diameter of the laser sclerostomy compared with surgical sclerectomy may explain the different bleb appearance seen in our patients. Such sclerostomy may result in very slow percolation of aqueous out of the anterior chamber, with relatively low pressure head forming at the episclera and less conjunctival distension. Furthermore, during surgery, the subconjunctival space is swept mechanically with a blunt instrument, separating the conjunctiva from sclera and allowing more efficient bleb formation. We also

Figure 8 Intraocular pressure response to laser sclerostomy in 12 patients.

presume that obliquity of the sclerostomy along with its uneven internal surfaces may add a valve-like mechanism which will control aqueous flow through. Also, as no iris incarceration was noted at the sclerostomy site, peripheral iridectomy may not be needed in this procedure.

As described for another laser treatment to the angle, the Nd-YAG laser trabeculopuncture,^{21 22} in some patients IOP was well controlled despite the absence of a detectable patent trabeculotomy.

Even when there was good long term control of IOP, no eye had a visible bleb. Possibly, one or more of several other mechanisms may be involved: (1) complete narrow sclerostomy allowing percolation of aqueous out but no conjunctival elevation; (2) partial sclerostomy communicating with collector channels or allowing direct diffusion of aqueous through a very thin layer of remnant tissue; (3) cyclodialysis effect with increased uveoscleral outflow; (4) reduced aqueous formation either through direct laser impact or subsequent uveitis; (5) a different conjunctival reaction from that seen in conventional fistulising surgery because the conjunctiva was not surgically dissected.

Despite delivery of very high laser energy, no major damage to adjacent tissues was noted. Eight eyes (67%) displayed corneal oedema adjacent to laser impact zone, with some Descemet folds radiating from that region. This complication was transient and usually resolved within 1–2 weeks. There were no major complications such as increased IOP, hyphaema, retinal detachment, and corneal or conjunctival perforation.

In conclusion, gonioscopic laser internal sclerostomy of dye enhanced sclera is technically feasible. Even in end stage glaucoma patients, some eyes kept their IOP well controlled for several months. Modifications of the iontophoresis process and laser parameters are currently under investigation in an attempt to improve these preliminary results.

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