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A novel technique of ab interno glaucoma surgery: follow-up results after 24 months

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Abstract *Purpose:* It was the aim of this study to investigate the efficacy, longevity, and safety of a new ab interno intervention for the treatment of primary open-angle glaucoma (POAG). *Methods:* The previously described method of radiofrequency-mediated "sclerothalamotomy ab interno" was applied in 53 eyes of consecutive patients with POAG between April 2002 and July 2002. Average preoperative intraocular pressure (IOP) was 25.6±2.3 mmHg (range 18–48 mmHg). Sclerothalamotomies were carried out with a custom-made high-frequency dissection 19 G probe (tip 0.3×1 mm) applying bipolar current with a frequency of 500 kHz (tip temperature 130°C). *Results:* After a follow-up period of 24 months, the average IOP was 15.0±1.6 mmHg (range 11–20 mmHg) (p<0.005). The average number of topical agents was 2.6±1.0 (range 1–5) preoperatively. Twenty-four months after surgery such agents were used in only five (9.6%) eyes and the average was 0.21±0.53 (range 0–2). Transient IOP elevation was observed in 12 of 53 eyes (22.6%) postoperatively. In all cases elevated IOP could efficiently be controlled with topical medication. In general, IOP dropped continuously over the course of the 6 months following surgery and then remained constant. *Conclusions:* This study indicates that sclerothalamotomy ab interno is a safe and efficient surgical method for the treatment of POAG. Long-term results clearly demonstrate the longevity of IOP reduction.

Keywords Novel technique · Glaucoma surgery · Long-term follow-up

Introduction

The ongoing attention to innovations in glaucoma surgery reflects the lack of an ideal solution that would promise long-term IOP reduction and eliminate the necessity of supplementary pressure-reducing medication at low complication rates. Trabeculectomy, first described in the 1960s [3, 9, 29], is probably the most widespread approach in glaucoma surgery presently. The intention of trabeculectomy is to bypass the resistance of the trabecular meshwork by channelling aqueous humour directly to Schlemm's canal. In the literature the success rate of trabeculectomy ranges between 32 and 96% [1, 4, 9, 12, 14, 16–18, 20–22, 29, 31–34]. On the other hand, postoperative complications like hypotony and choroidal detachment are reported in up to 24% of cases [6]. Variation in success rates may be explained by different surgical indications, selection of cases, various diagnoses, varying degrees of surgical experience and variations in postoperative medical treatment. Failure of pressure regulation is associated with the absence of a filtering bleb and depends on the duration of follow-up involved. It has become evident that successful reduction in IOP following trabeculectomy is clearly related to the presence of a filtering bleb [25].

The more recent method of non-penetrating deep sclerectomy was first described by Fjodorov in the 1980s [8].

This technique sets out to achieve an improved uveoscleral outflow and therefore is not dependent on the presence of a filtering bleb. Koslov et al. [13] expanded this method by introducing a collagen implant. Literature on non-penetrating deep sclerectomy indicates a success rate of 58–74% without a collagen implant and 74–90% with collagen implantation [5, 23].

In 1976, Benedikt and Hiti [2] described that exposure of the ciliary body (i.e. a form of penetrating sclerectomy) had led to successful long-term IOP regulation in 27 of 38 cases of haemorrhagic, aphakic and irreversible angle-closure glaucoma after failure of filtering surgery. This technique was the basis for the later development of perforating deep sclerectomy, a method which has been used since 1985 and was previously [19] termed "sclerothalamectomy". Bypassing of the trabecular meshwork is an alternative for aqueous humour outflow from the anterior chamber to the Schlemm canal. It is the principal mechanism for non-penetrating glaucoma surgery, in particular for deep sclerectomy and viscocanalostomy. These surgical procedures provide effective IOP reduction as well as the elimination of typical filtration bleb complications [7, 15, 30]. Clinical application of these procedures has been limited by technical difficulties in performing this kind of surgery and the poor predictability of pressure reduction.

The concept of trabecular meshwork bypass as a surgical principle for glaucoma treatment evolved from the discovery that pathologic outflow resistance is caused primarily by the juxtacanicular conjunctive tissue of the trabecular meshwork and, in particular, by the inner wall of the Schlemm canal [10, 11]. A further publication in this area indicates that 35% of the outflow resistance arises distally to the inner wall of the Schlemm canal [24].

Spiegel et al. [28] have described a new surgical technique involving the use of an implanted tube, the so-called trabecular meshwork bypass tube shunt, which should provide a direct connection between the Schlemm canal and the anterior chamber. This surgical technique avoids the technical difficulties of non-penetrating deep sclerectomy, especially the delicate microperforation of the trabecular meshwork in order to ensure the permeability of the Descemet membrane. Furthermore, these techniques avoid the disadvantages of filtration blebs.

All surgical procedures for glaucoma involving the creation of external access may be complicated by the risk of fibroblast proliferation and failure of filtration. The novel procedure published here offers a chance to avoid some of the above-mentioned disadvantages. We refer to this technique as sclerothalamotomy (STT) ab interno.

Patients and methods

Before the clinical study phase, the tips used for the STT ab interno procedure were developed using a large number of pigs' eyes. The high-frequency diathermic technique was already very well known in the application for capsulorrhexis in cataract surgery. It was important to create a design for optimal application of the STT probe in the iridocorneal angle and to evaluate the characteristics of the achieved deep sclerotomy.

Fifty-three STT ab interno procedures were carried out in 53 patients with primary open-angle glaucoma (POAG) between 1 April 2002 and 31 July 2002. The maincriterion for inclusion in this study was an insufficient response to medical treatment of IOP. Data were documented according to a prospective study protocol. The patients' mean age was 71.8±12 years (range 10–92 years). Seventeen patients (32%) were female, 36 patients (68%) male. In 25 cases (47.4%) the right eye, in 28 cases (52.6%) the left eye was treated. No patient received bilateral surgery. Snellen visual acuity was 0.7±0.3 (range 0.1–1.0) preoperatively. In five cases a moderate cataract was observed that had no influence on the visual acuity.

A complete ophthalmologic status check was carried out in each patient prior to surgery, including uncorrected and best-corrected visual acuity, IOP by applanation tonometry, biomicroscopy of anterior segment, funduscopy (in particular, stereoscopic evaluation of the optic nerve head) and computerized visual field testing (Octopus 101, program G2).

Complete ophthalmologic follow-up examinations were carried out postoperatively at days 1, 2, 3 and 4 and after 1, 2 and 4 weeks and 2, 3, 6, 12, 15, 18, 21 and 24 months.

Surgical procedure

A clear corneal incision (1.2 mm wide) was placed in the temporal upper quadrant using a diamond knife. A second corneal incision was performed 120° from the first followed by injection of Healon GV. The high-frequency diathermic probe (Oertli) was inserted through the temporal corneal insertion. Visual inspection of the target zone (opposite the iridocorneal angle) was achieved using a four-mirror gonioscopic lens. The high-frequency tip penetrates up to 1 mm nasal into the sclera through the trabecular meshwork and the Schlemm canal, forming a deep sclerotomy (i.e. "thalami") of 0.3 mm height and 0.6 mm width. This procedure was repeated four times within one quadrant. Healon GV was evacuated from the anterior chamber by means of bimanual irrigation/aspiration. Tobramycin/dexamethasone eye drops were then applied three times daily for 1 month and pilocarpine 2% eye drops three times daily for 10 days.

High-frequency diathermic probe

The high-frequency diathermic probe features an inner platinum electrode which is isolated from the outer coaxial electrode. The platinum probe tip is 1 mm in length,

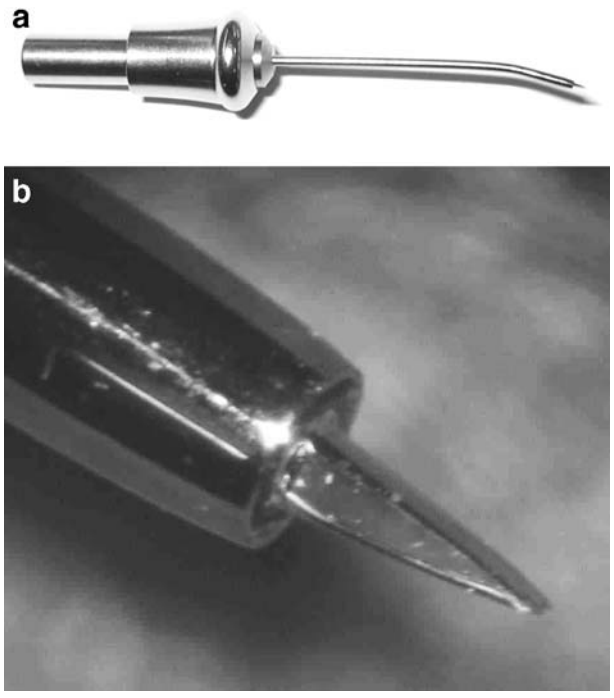

Fig. 1 **a**, **b** STT glaucoma tip (Oertli reference VE 201750)

0.3 mm high and 0.6 mm wide and is bent posteriorly at an angle of 15° (Fig. 1). The external diameter of the probe is 0.9 mm. Modulated 500-kHz current generates a temperature of approximate 130°C at the tip of the probe. The setup provides high-frequency power dissipation in close vicinity to the tip. As a result, heating of tissue is locally very limited and is applied as a rotated ellipsoid.

Evaluation

Statistical evaluation of results was calculated with SPSS Program Version 10. Two-tailed Student t-test was used for statistical evaluation of parametric data. The unit of significance was set at a critical p value of <0.05, including Bonferroni correlation for repetitive use of data sets.

Results

Mean preoperative IOP in the study population of 53 patients with POAG was 25.6±2.3 mmHg (range 18–48 mmHg). Average IOP was 17.6±2.7 mmHg (range 2–36 mmHg) after a follow-up period of 1 day, 14.9±2.4 mmHg (range 2–30 mmHg) after 2 days, 15.7±2.4 mmHg (range 4–28 mmHg) after 3 days, 16.0±2.6 mmHg (range 4–36 mmHg) after 4 days, 19.0±2.6 mmHg (range 12–39 mmHg) after 7 days, 16.9±2.5 mmHg (range 9–44 mmHg) after 1 month, 15.1±1.8 mmHg (range 11–20 mmHg) after 3 months, 14.7±1.7 mmHg (range 11–20 mmHg) after 6 months, 14.8±1.7 mmHg (range 10–20 mmHg) after 9 months, 14.7±1.7 mmHg (range 10 to 20 mmHg) after 12 months, 15.5±1.7 mmHg (range 11 to 20 mmHg) after 15 months, 14.1±1.6 mmHg (range 11–20 mmHg) after 18 months, 16.5±1.7 mmHg (range 12–22 mmHg) after 21 months and 15.0±1.6 mmHg (range 11–20 mmHg) after 24 months, a result which is statistically highly significant ($p<0.005$; Fig. 2). Pressure reduction at any time of standardized follow-up was statistically significant compared to preoperative data at a level of $\alpha<0.03$ (Bonferroni corrected). For all patients the follow-up was 24 months.

At month 24, 45.3% of patients had an IOP <15 mmHg, 77% had an IOP <18 mmHg and 90.6% had an IOP <21 mmHg. After 24 months, 88.7% had achieved >20% reduction in IOP and 79% of treated patients had achieved >30% reduction in IOP. The rate of complete success, defined as an IOP lower than 21 mmHg without medication, was 90.6% at 24 months. THe qualified success rate, defined as an IOP lower than 21 mmHg with or without medication, was 100% at 24 months (Fig. 3).

The average number of pressure-reducing eye agents administered preoperatively was 2.6±1.0. Following surgery, this value was decreased to 0.45±0.72 after 1 month, 0.38±0.60 after 3 months, 0.38±0.69 after 6 months, 0.19±0.52 after 12 months and 0.21±0.53 after 24 months. After 24 months, it was necessary to administer IOP-reducing medication in only five eyes, i.e. 9.6% of all cases.

Average visual acuity after treatment was 0.69±0.31 (range 0.05–1.0). In six eyes (11.3%) moderate cataract developed after surgery but had no influence on visual acuity. Another three eyes (5.7%) developed cataract with a visual acuity decrease of 1 Snellen line.

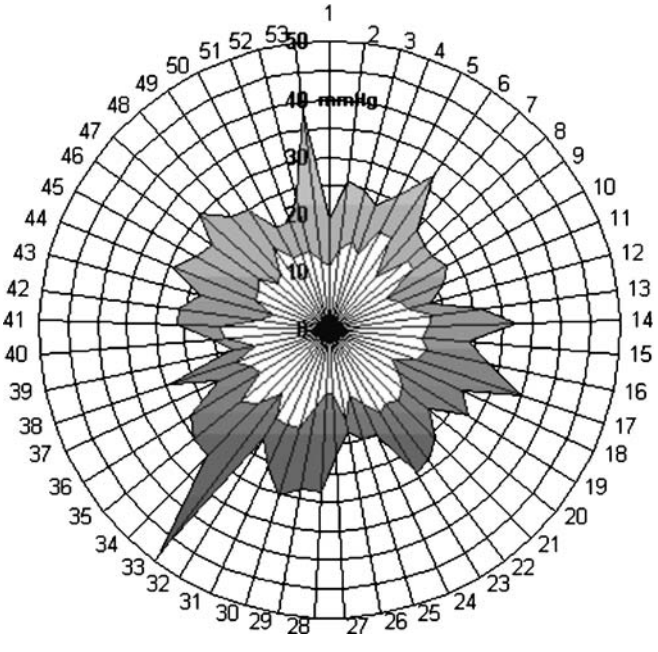

Fig. 2 Average IOP after STT ab interno surgery for all 53 cases at the scheduled examination times

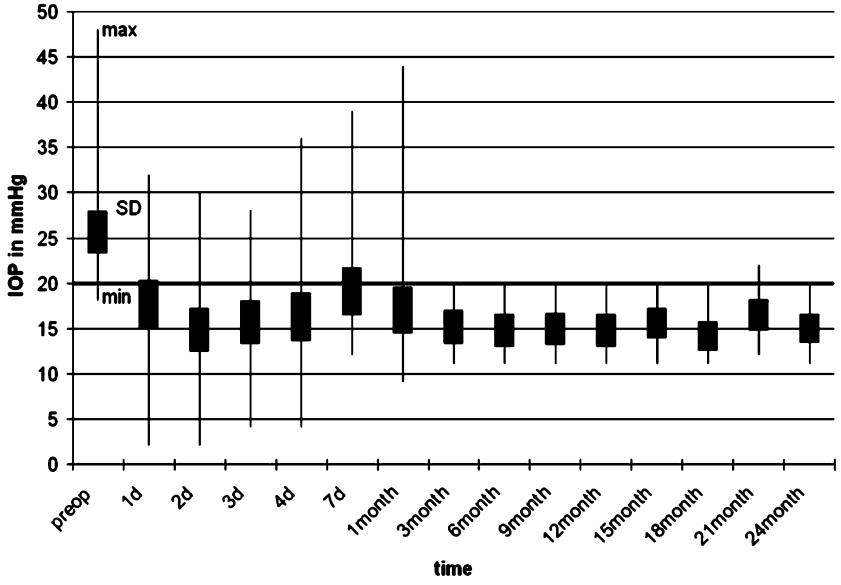

Fig. 3 IOP before and 24 months after surgery

Table 1 Complications after STT ab interno surgery

Complication	Number	Frequency (%)
Temporary IOP elevation	12	22.6
Temporary hypotension	1	1.9
Hyphaema	6	11.4
Temporary fibrin formation	1	1.9

There was no significant difference in the cup/disc ratio between baseline (0.65±0.18) and 24 months after surgery (0.66±0.19; p=0.11).

There were no significant changes in the visual field between baseline, with mean defect (MD) 9.45±2.32 and loss variance (LV) 30.0±5.11, and 24 months after surgery, with MD 8.89±2.59 (p=0.42), LV 34.6±5.84 (p=0.29).

Temporary IOP elevation to a level higher than 21 mmHg was observed in 12 of 53 eyes (22.6%). These patients responded well to pressure-reducing treatment with one agent, and medication could gradually be withdrawn in all of them. A single case of hypotension (1.9%) that lasted for 3 days after surgery was observed. Hyphaema was present in 6 eyes (11.4%); in all cases it disappeared within the first 2 weeks after surgery. One eye (1.9%) exhibited transient fibrin formation at pupillary level. Fibrin was cleared within 1 day after frequent application of topical dDexamethasone (Table 1).

Discussion

This study reports long-term results of a new surgical technique for treating open-angle glaucoma. The STT ab interno method sets out to create a direct channel between the anterior chamber and the Schlemm canal. Persistence of the sclerotomy can be investigated with a three-mirror lens (Goldmann 903). The STT ab interno tip creates a deep sclerotomy with subsequent access of aqueous humour to the scleral layer. Both aspects may facilitate a bypass effect of aqueous outflow. In light of the fact that about 85% of the aqueous humour drains (in physiological terms) trans-trabecularly, we suspect an additional route for aqueous humour absorption in the case of elevated IOP. There is evidence in the literature that such bypass effects may be present after surgical intervention which do not lead to the formation of filtering blebs. In a previous study [19], it was ascertained that eyes without filtering bleb exhibited very stable long-term IOP regulation postoperatively. In addition to the bypassing of trabecular outflow resistance caused by STT ab interno, outflow resistance may be further reduced by scleral thinning at the base of the thalamus. In addition, aqueous humour could perhaps be absorbed by the ciliary body [19, 26]. After early postoperative reduction, the average IOP continued to decline gradually over a period of 6 months before reaching a relatively constant level. It can be speculated that newly formed blood vessel and lymph vessels close to the surgical site may contribute to the decrease in IOP during follow-up [2].

In the literature the success rate for trabeculectomy ranges between 57% and 96% [1, 4, 9, 12, 14–18, 20–22, 29, 31–34], for deep sclerectomy without collagen device between 57% and 74%, and for deep sclerectomy with collagen device between 58% and 90% [1, 5, 15, 23]. The STT ab interno technique, with a complete success rate of 90.6%, is comparable with other published methods of surgery.

Advantages of the STT ab interno method, compared with trabeculectomy and perforating and non-perforating deep sclerectomy, seem to be a lower rate of postoperative complications and a constant level of reduced IOP. Hypo-

tension, a frequent finding in trabeculectomy, perforating deep sclerectomy and non-perforating deep sclerectomy, is a relatively rare postoperative complication of STT ab interno. The most frequent early complications in trabeculectomy are hyphaema (24.6%), shallow anterior chamber (23.9%), hypotony (24.3%), wound leak (17.8%) and choroidal detachment (14.1%). The most frequent late complications are cataract (20.2%), visual loss (18.8%), iris incarceration (5.1%) and encapsulated bleb (3.4%). After STT ab interno cataract development was seen in 17% of cases, with only 5.7% loss of 1 line of visual acuity after 24 months. Compared with other surgical techniques STT ab interno seems relatively safe [1, 5–7, 15, 16].

Transient IOP elevation after STT ab interno may occur in the first 6 weeks and can be effectively brought under control with the use of a topical medication. In most cases, IOP-reducing therapy could be gradually withdrawn 3 weeks after surgery. It was necessary to continue pressure-reducing therapy in 5 of 53 eyes; in all these cases medication was effective in controlling IOP.

Problems of scarring to the Tenon capsule, fibroblast proliferation and secondary occlusion associated with trabeculectomy which are induced by the surgical procedure itself may be the reason for the administration of antimetabolites (mitomycin C at concentration of 0.2–0.4 mg/ml for 1–5 min). Although this practice was conceived to modulate wound healing and thus to counteract scar formation, it often resulted in serious complications, such as scleral necrosis and increased incidence of avascular filter bleb and their late sequelae [27]. The surgical procedure applied in this study avoids stimulation of episcleral and conjunctival proliferations and may therefore be asociated with less secondary cell invasion at the filtering bypass.

Preliminary histological investigations of postmortem human eyes following STT ab interno have not found signs of indirect necrosis in cell layers adjacent to the thalamus formed by high-frequency diathermy. It is yet unknown whether the inner surface of the thalamus will be covered by endothelial cells of corneal or trabecular origin, and whether the thalamus and its function will remain intact on a much longer time scale.

Advantages of STT ab interno include the comparative simplicity and quickness of the surgical procedure itself.

This study points out, that the creation of four thalami has so far proved sufficient, corresponding to a resorption surface area of 2.4 mm^2. This number of thalami was determined empirically. In light of the results of this study the creation of four thalami seems to provide a sufficient long-term decrease in IOP with a low rate of postoperative complications.

A randomized multicentre study will be conducted to compare STT ab interno, trabeculectomy and deep sclerectomy for the surgical treatment of POAG.

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