New Minimally Invasive, Deep Sclerotomy ab interno Surgical Procedure for Glaucoma, Six Years of Follow-up

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Purpose: The goal of this study is to show the efficacy and safety of an innovative surgical procedure regarding the treatment of open-angle and juvenile glaucoma known as sclerothalamotomy ab interno (STT ab interno).

Patients and Methods: Between February and July 2002 surgery was performed in 58 eyes of 58 consecutive patients, of which 53 were diagnosed with open-angle and 5 with juvenile glaucoma. The procedure was performed with the assistance of a custom-made high-frequency dissection probe (19 gauge with a tip of 0.3×1 mm), which applies a bipolar current of 500 kHz frequency. The probe penetrates approximately 1 mm into the nasal sclera (ab interno) and through the trabecular meshwork and Schlemm's canal, thus forming a deep sclerotomy or ''thalami'' of 0.3 mm height and 0.6 mm width.

Results: The average baseline intraocular pressure (IOP) was 25.6 ± 2.3 mm Hg (range: 18–48 mm Hg) for the open-angle glaucoma group and 39.6 ± 2.3 mm Hg (range: 34–46 mm Hg) for the juvenile glaucoma group. All patients had a minimum follow-up of 72 months. The mean IOP for the stated period was 14.7 ± 1.8 mm Hg for the open-angle glaucoma group and 13.2 ± 1.3 mm Hg for the juvenile group. The IOP after surgery was statistically significantly lower than the baseline IOP at all measured intervals ($P < 0.001$). After 72 months only 11 eyes accounted for a 20.8% continuous antiglaucoma therapy. With regard to the procedure no serious complication was documented.

Conclusions: Sclerothalamotomy ab interno is a minimally invasive, safe, and efficient surgical technique for lowering the IOP in open-angle and juvenile glaucoma.

Key Words: novel technique, glaucoma surgery, long-term follow-up

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Trabeculectomy, first described in the 1960s,[1–3] is most likely the surgical procedure of choice for treating glaucoma. The original intention of trabeculectomy was to bypass the resistance of the trabecular meshwork by channeling the aqueous humor directly into the Schlemm canal. It soon became evident that successful reduction of the intraocular pressure (IOP) after trabeculectomy was clearly related to the presence of the subconjunctival filtering bleb.[4] Despite the initial success, a progressive failure rate regarding this treatment derived in most cases by a subconjunctival fibrosis in the filtering bleb was found later. Later on trabeculectomy was found to be associated with serious vision-threatening complications such as post-operative choroidal effusions and hemorrhage, delayed bleb leaks, and bleb-related infections including endophthalmitis as well. These complications are seen more frequently if antimetabolite agents such as 5-fluorouracil and mitomycin C are used.

Initially, the concept of the trabecular meshwork bypass as a surgical principle for the treatment of glaucoma evolved through the innovation that the pathologic outflow resistance is caused primarily by the juxtacanicular trabecular meshwork and, in particular, by the inner wall of the Schlemm canal.[5,6] Further studies indicated that 35% of the outflow resistance arises distally from the inner wall of the Schlemm canal.[7]

The more recent methods of nonpenetrating deep sclerctomy and viscocanalostomy, first described by Fjodorov et al[8] and Stegmann et al,[9] respectively, attempted to improve the uveoscleral outflow and were therefore not considered dependent on the presence of a filtering bleb. In 1976, Benedikt and Hiti[10] first described a surgical technique for glaucoma in which the ciliary body was exposed (ie, a form of penetrating sclerectomy) in which he reported a successfully long-term IOP regulation in 27 of 38 cases (63.2%) involving hemorrhagic, aphakic, and irreversible angle-closure glaucoma after initially failed filtering surgery. This technique was the cornerstone for the later development of the perforating deep sclerectomy as described in that study and since 1985 is termed as ''sclerothalamectomy.''[11] Later, Spiegel et al[12] described a new surgical technique involving the use of an implanted tube, the trabecular meshwork bypass shunt, which should provide a direct connection between the Schlemm canal and the anterior chamber. This surgical technique avoids any known surgical difficulties of the nonpenetrating procedures.

In conclusion, the sclerothalamotomy ab interno procedure whose initial results are already published in an earlier study, evolved from the later sclerothalmectomy. The results of a 24-month follow-up since the creation of deep sclerotomy ab interno show sufficient decrease of IOP with complete success rate of 90.6% and a low rate of post-operative complications.[13] The aim of this study is to present the 6-year outcomes of this innovative trabecular surgery.

MATERIALS AND METHODS

The main inclusion criterion for this study was an insufficient response to the medical treatment of IOP. Data were documented according to a prospective study protocol. Fifty-three sclerothalamotomies ab interno in 53 patients with open-angle glaucoma and 5 with juvenile

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glaucoma were carried out between February 1, 2002 and July 31, 2002.

A complete ophthalmologic examination was carried out in each patient before surgery including uncorrected and best corrected visual acuity (VA), IOP applanation tonometry, biomicroscopy of anterior segment, fundoscopy or examination of the fundus (in particular, stereoscopic evaluation of the optic nerve head), and computerized visual field testing (Octopus 101, program G2). For example, hyphema, hypotony, IOP elevation, inflammation, corneal changes, and cataract development were examined for early and late side effects.

A complete ophthalmologic follow-up examination was carried out postoperatively every day (first to the fourth day), at the end of the first, second, and fourth week, and at a regular examination at the end of every month, and every 3 months after the first trimester (1st, 2nd, 3rd, 6th until the 72nd month).

High-frequency Diathermic Probe

The high-frequency diathermic probe (Oertli, Switzerland) consists of an inner platinum electrode, which is isolated from the outer coaxial electrode. The platinum probe tip is 1 mm in length, 0.3 mm high, and 0.6 mm in width and is bent posteriorly at an angle of 15 degrees (Figs. 1A, B). The external diameter of the probe measures 0.9 mm. The modulated 500 kHz current generates a temperature of approximately 130°C at the tip of the probe. The setup provides high-frequency power dissipation in close vicinity of the tip. As a result, collateral or local heating of the tissue is very limited as it is applied as a rotational ellipsoid.

Surgical Procedure

A clear cornea incision (1.2-mm wide) was made in the temporal upper quadrant using a diamond knife. A second corneal incision was made 120 degrees apart from the first followed by injection of Healon GV. The high-frequency diathermic probe was inserted through the temporal corneal insertion. Visual inspection of the target zone (opposite iridocorneal angle) was done by a 4-mirror gonioscopic lens. The high-frequency tip penetrated up to 1 mm nasally into the sclera through the trabecular meshwork and Schlemm canal, forming a deep sclerotomy (ie, "thalami") of 0.3 mm height and 0.6 mm width (Figs. 2, 3). This procedure was repeated 4 times within 1 quadrant. Healon GV was evacuated from the anterior chamber with bimanual irrigation/aspiration. Tobramycin/dexamethasone eye drops were then applied 3 times daily for 1 month and pilocarpin 2% eye drops 3 times daily for 10 days.

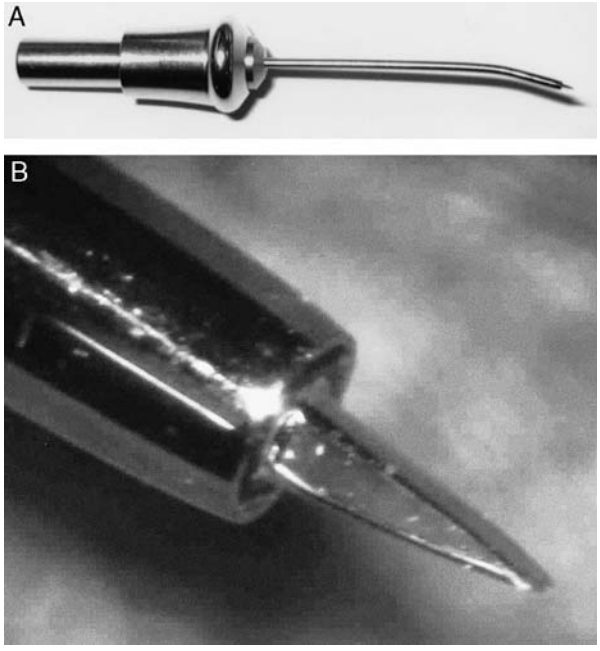

FIGURE 1. A and B, STT Glaucoma Tip (Oertli Reference VE 201750). STT indicates sclerothalamotomy.

Evaluation of the Results

Statistical evaluation of the results was done with the SPSS Program Version 14. Two-tailed Student's t test was used for the statistical evaluation of the 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

The mean age of patients with open-angle glaucoma was 72.3 ± 12.3 years (range: 15-92 y). Seventeen patients (32%) were female, whereas the rest (68%) were male. The mean age of patients with juvenile glaucoma was 9 ± 1.4 years (range: 7-11 y). Four patients (80%) were male and 1 patient (20%) was a female. In 25 cases (47.4%), the right eye was treated and in 28 cases (52.6%) the left eye was treated. With regard to the open-angle glaucoma group, while in the juvenile group was treated in 3 cases (60%) in the right eye, in 2 cases (40%) the left eye was treated.

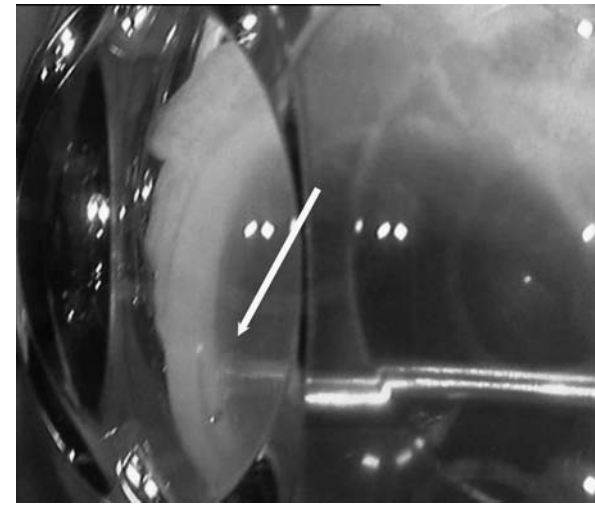

FIGURE 2. Photograph of the tip of a high-frequency diathermic probe introduced in the anterior chamber of a left eye and viewed through a 4-mirror gonioscopic lens (T, N, I: temporal, nasal, and inferior mirrors, respectively). The probe was introduced through a corneal incision at the limbus temporally and pushed forward into the anterior chamber until the tip of the probe (white arrow) reached the nasal iridiocorneal angle on the opposite side of the anterior chamber. The exact position of the tip at the level of the nasal iridiocorneal angle could be visualized through the temporal mirror (T) of the gonioscopic lens.

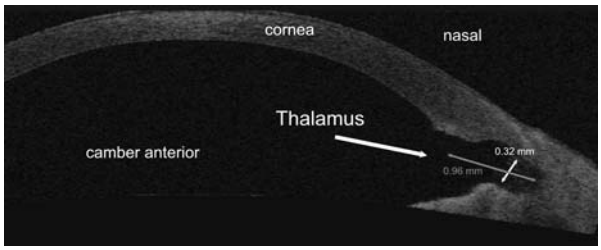

FIGURE 3. OCT imaging (Visante, Model 1000) of the nasal anterior chamber angle of a right eye, 6 weeks after a deep sclerotomy ab interno. A cavity (thalami) of 0.32 mm high and 0.96 mm deep going through the trabeculum meshwork and Schlemm canal into the sclera can be seen at the iridiocorneal angle. OCT indicates optical coherence tomography.

Decimal (Snellen) VA was the baseline for open-angle glaucoma at 0.7 ± 0.3 (range: 0.1-1.0) and for juvenile glaucoma, it was 0.58 ± 0.3 (range: 0.1-0.8). In 9 cases, a moderate cataract was observed in the group of open-angle glaucoma. In 6 cases, VA was not significantly influenced. No damage to the cornea was recognized as a complication of the procedure during or after surgery. All patients attended the scheduled follow-up at 72 months.

The mean baseline IOP for the open-angle glaucoma group of 53 patients was 25.6 ± 2.3 mm Hg (range: 18-48 mm Hg) and for the adjacent group of 5 patients with juvenile glaucoma, it was 39.6 ± 2.3 mm Hg (range: 34-46 mm Hg). The mean IOP after 72 months was 14.7 ± 1.8 mm Hg (range: 10-21 mm Hg) and 13.2 ± 1.3 mm Hg (range: 12-15 mm Hg), respectively. This difference for both the groups was highly significant statistically ($P < 0.001$) in all the postoperative intervals accounted (Figs. 4, 5). The IOP reduction at any time of standardized follow-up was statistically significant compared with the preoperative data at a level of $\alpha < 0.03$ (Bonferroni corrected). However, because of only a few cases in the juvenile glaucoma group conclusive statistics were not available, although the results showed the decreasing tendency of IOP.

At the 72nd month, 52.8% of patients with open-angle glaucoma showed an IOP less than 15 mm Hg, 76% showed an IOP less than 18 mm Hg, and 79.2% showed an IOP less than 21 mm Hg (Fig. 6). Eighty percent of the patients with juvenile glaucoma showed an IOP less than 15 mm Hg, whereas 100% of the patients in this group showed an IOP

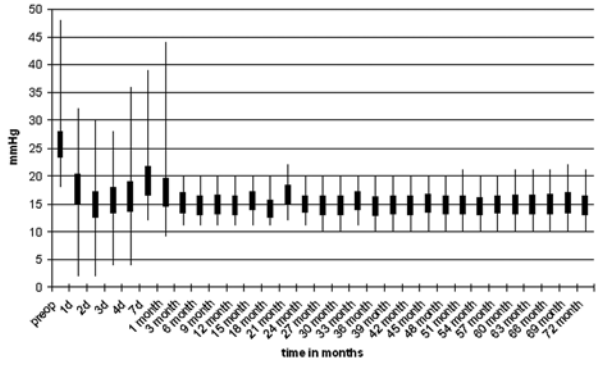

FIGURE 4. Average level of intraocular pressure (IOP) after sclerothalamotomy (STT) ab interno surgery for all 53 cases with open-angle glaucoma at the time of scheduled examination.

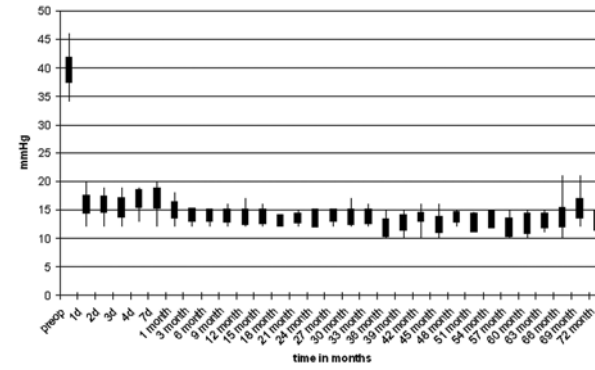

FIGURE 5. Average level of intraocular pressure (IOP) after sclerothalamotomy (STT) ab interno surgery for all 5 cases with juvenile glaucoma at the time of scheduled examination.

less than 18 mm Hg. In the open-angle glaucoma group after 72 months, 84.9% of the patients that were treated achieved more than 20% reduction of IOP whereas a decrease of more than 30% was achieved in 77% of the patients. In the juvenile glaucoma group, a more than 30% decrease of IOP was achieved from all patients.

The IOP values for each of the 53 individual open-angle glaucoma patients before and after 72 months of surgery are shown in Figure 7. The complete success rate, defined as an IOP lower than 21 mm Hg without medication at 72 months, was achieved in 42 patients (79.2%) of the open-angle glaucoma group (Fig. 7) and in 4 patients (80%) of the juvenile glaucoma group. Qualified success rate, defined as an IOP lower than 21 mm Hg, was achieved in all the remaining patients.

All patients were preoperatively under ocular hypotensive agents. The mean number of preoperative ocular hypotensive agents administered per patient was 2.6 ± 1.0 for the open-angle glaucoma group and 3.0 ± 0.0 for the juvenile glaucoma group. After surgery, this value 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, 0.21 ± 0.53 after 24 months, 0.50 ± 0.90 after 36 months, 0.49 ± 0.96 after 48 months, 0.49 ± 0.93 after 60 months, and 0.51 ± 0.97 after 72 months for the open-angle glaucoma group (Fig. 8). The values with regard to

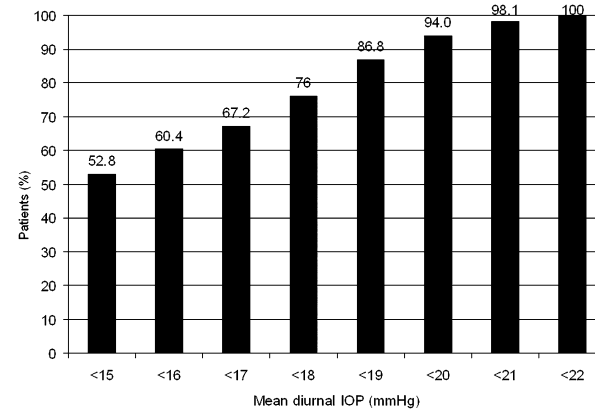

FIGURE 6. Percentages of eyes reaching specified intraocular pressure (IOP) levels in the group of open-angle glaucoma.

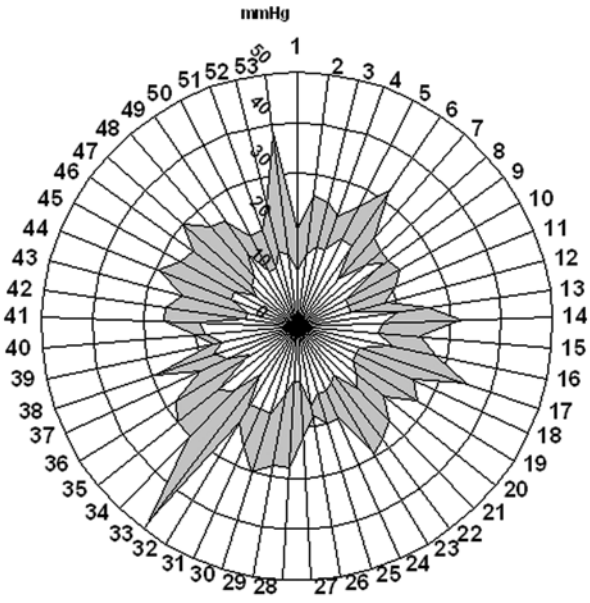

FIGURE 7. Values of IOP before and 72 months after surgery for each individual open-angle glaucoma patients. Complete success (IOP <21 mm Hg without medication) was achieved in 42 patients (79.2%) and qualified success (IOP <21 mm Hg with medication) was observed in 11 patients (20.8%). IOP indicates intraocular pressure.

the juvenile glaucoma group decreased to 0 after 1 month and remained stable till 12 months. At the 12th month, there was an increase of up to 0.2 ± 0.44 and remained unchanged until the 72nd month. After the completion of all follow-ups, it was necessary to administer IOP-reducing agents in only 11 eyes (20.8%) for open-angle glaucoma group and in 1 eye (20%) for the juvenile glaucoma group.

The average VA after treatment was 0.69 ± 0.31 (range: 0.05-1.0) in the open-angle glaucoma group and 0.56 ± 0.36 (range: 0.1-0.8) in the juvenile glaucoma group. In 6 eyes (11.3%) from the open glaucoma group, a moderate cataract development made no change regarding VA. Only in 3 eyes (5.7%) from this group developed

TABLE 1. Early and Late Postoperative Side Effects After Surgery in the Group of 53 Patients With Open-angle Glaucoma

	No. Patients	Percentage
Early postoperative side effects	6	11.4
Hyphema		
Transient fibrin formation	1	1.9
Ocular hypotension	1	1.9
Temporary IOP elevation	12	22.6
Late postoperative side effects		
Cataract with no change visual acuity	3	5.7
Cataract with decreased visual acuity	6	11.4

cataract with decreased VA of 1 Snellen line. There was no significant difference found regarding the cup/disc ratio baseline (0.65 ± 0.18) and after 72 months (0.66 ± 0.18) for the open-angle glaucoma group ($P = 0.11$) and for the juvenile glaucoma group, respectively ($P = 0.37$, 0.60 ± 0.21 at baseline and 0.61 ± 0.19 after 72 months).

There were no significant changes comparing the visual field at baseline with mean defect (MD) 8.38 ± 2.44, loss of variance (LV) 27.7 ± 5.11 and after 72 months with MD 9.03 ± 2.45, LV 28.2 ± 5.66 ($P = 0.29$ for MD, $P = 0.37$ for LV) for the open-angle glaucoma and the juvenile groups, respectively (baseline with MD 8.73 ± 3.12, LV 28.2 ± 29.45, and at 72 months with MD 9.9 ± 1.97, LV 21.3 ± 14.15, $P = 0.56$ for MD, $P = 0.72$ for LV). No side effects or complications were noted in the juvenile glaucoma group.

Some early and late postoperative complications were noted in the larger group who underwent this procedure (Table 1). A hyphema that spontaneously resolved within 2 weeks was observed in 6 eyes (11.4%). Within the first postoperative 24 hours, 1 eye had some anterior chamber fibrin that was treated with topical dexamethasone. One eye (1.9%) had transient ocular hypotension that lasted 3 days. Temporary postoperative ocular hypertension was observed in 12 eyes (22.6%). IOP increase always occurred within the first 6 weeks after the procedure and responded well to less than a 3-week-long ocular hypotensive treatment. Late postoperative complications observed were

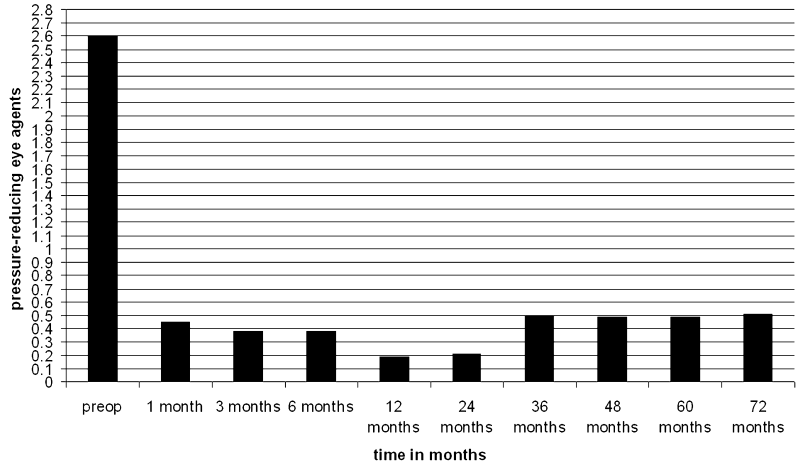

FIGURE 8. Mean number of ocular hypotensive agents administered per patient before surgery and during the postoperative follow-up period of 72 months.

the development of a cataract with a decrease of 1 Snellen line in VA in 3 (5.7%) eyes and with no decrease in VA in 6 (11.3%) others. Although the authors never experienced such intraoperative complications, sclera perforation from the iridocorneal angle into the subconjunctival space, and direct injury to the lens, iris, or cornea by the diathermic probe could potentially occur.

DISCUSSION

This study reports the long-term results of a new surgical technique for treating open-angle glaucoma and juvenile glaucoma. The STT ab interno method intends the creation of a direct channel between the anterior chamber and the Schlemm canal. Persistence of the sclerotomy can be investigated with a 3-mirror goniolens that typically shows a small cavity in the sclera at the level of the trabecular meshwork, a cavity that tends to remain open over time (Fig. 9). The STT ab interno tip creates a deep sclerotomy with subsequent access of the aqueous to the scleral layer. Both aspects may facilitate a bypass effect of aqueous outflow. Despite the fact that approximately 85% of the aqueous humor drains (in physiologic terms) trans-trabecularly, we artificially created an additional route for the aqueous humor drainage 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 an earlier study,[11] it was ascertained that eyes without filter bleb exhibited very stable long-term IOP regulation postoperatively. In addition to the bypassing of trabecular outflow resistance caused by STT ab interno treatment, outflow resistance may be further reduced by scleral thinning at the base of the thalamus. In addition to that, aqueous humor could perhaps be drained to the ciliary body.[11,14] After early postoperative reduction, the average IOP continued to decrease gradually over a period of 6 months. The IOP remains relatively stable after 6 months postoperatively. It can be speculated that the newly formed blood vessel and lymph vessel close to the surgical site may contribute to the decrease in the IOP level during follow-up.[10]

As stated in the literature the success rate for trabeculectomy ranges between 57% and 96%;[2,15–28] for deep sclerectomy without collagen device, between 57% and 74%; and for deep sclerectomy with collagen device, between 58% and 90%.[15,29,30,31] The STT ab interno technique ranges with complete success rate of 90.6% after 24 months of follow-up,[13] 83% after 48 months, and 79.2% after 72 months for open-angle glaucoma and is by far comparable with other filtering surgery methods. The complete success rate for juvenile glaucoma after 48 months of follow-up is 80%. In this small group of 5 patients, which we cannot use for conclusive statistical interpretation, the results show a tendency to decrease with regard to IOP.

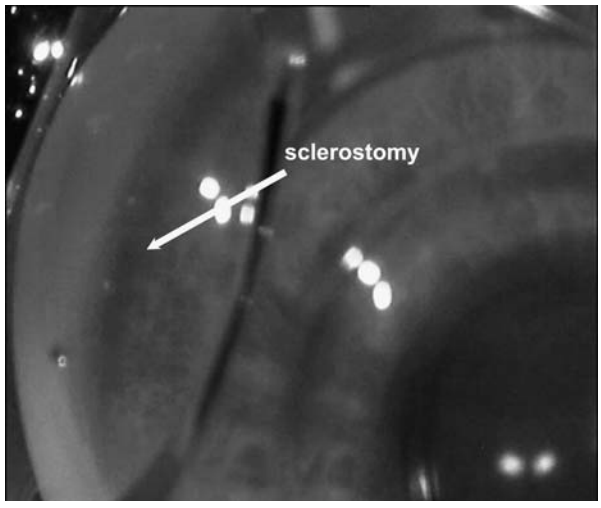

FIGURE 9. View of the sclerostomy by gonioscopy, which remains open over time.

The advantages of the STT ab interno method, compared with trabeculectomy, perforating and nonperforating deep sclerectomy, seem to be the low rate of postoperative complications and a constant level of reduced IOP. Hypotony, a frequent finding in trabeculectomy, perforating deep sclerectomy, and nonperforating deep sclerectomy, is a relatively rare postoperative complication. The most frequent early complications accounted in trabeculectomy are hyphema (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 among patients with open-angle glaucoma, cataract development was seen just in 9 eyes (17.1%) with only 3 eyes (5.7%) sustaining a loss of 1 line of VA after 72 months of follow-up (Table 1). When we compare STT ab interno with other techniques, it seems to be a relatively safe surgical technique.[15,19,29,31–33]

Comparing the results we find a complete success rate, defined as an IOP lower than 21 mm Hg without medication, the decrease from 90.6% at the 24th month to 79.2% after the 72nd month in the group of open-angle glaucoma. We regard as qualified success the decrease in IOP less than 21 mm Hg with agent administration but with a 100% stability of the IOP target (< 21 mm Hg) for the time interval between the 24th month and until the 72nd month or better.

Preliminary histologic investigations of 2 postmortem human eyes after STT ab interno did not indicate signs of indirect necrosis, as, for example, protein denaturation, enlarged or condensed cells, 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. In addition, in vitro experiments performed in porcine enucleated eyes suggested that the aqueous outflow facility increases with the increasing number of deep sclerectomies ab interno (thalamis). Further experiments conducted after perfusing the anterior chamber in enucleated porcine eyes with a drill blue suggests an increase in the uveoscleral outflow pathway after deep sclerectomies ab interno.[34]

Some qualities of this method are the comparative simplicity and quickness of the surgical procedure. In addition, the procedure avoids stimulation of episcleral and conjunctival tissues as in trabeculectomy and conventional nonpenetrating surgery.

In this study, diathermy was used to create 4 thalami and this corresponds to a drainage surface area of 2.4 mm^2. The number of thalami chosen was arbitrary and seems to provide a sufficient long-term decrease in IOP as a low rate of postoperative complications. There is a potential for a

further IOP decrease if 6 applications are made and we are currently investigating that. We are also planning a randomized multicenter study to compare STT ab interno, trabeculectomy, and deep sclerectomy for the surgical treatment of open-angle glaucoma.

With regard to the treatment of these 5 cases diagnosed with juvenile glaucoma, the results are encouraging. Sadly, this number of cases is not enough to get conclusive statistics and the results show only a promising tendency. More studies with a higher number of cases are necessary to indicate a significant result interpretation for juvenile glaucoma.

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SYNOPSIS

Novel minimally invasive, deep sclerotomie ab interno surgical technique is simply to use, safe and efficacious for lowering IOP in open-angle glaucoma and juvenile glaucoma.

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