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Results of childhood glaucoma surgery over a long-term period

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ABSTRACT.
Purpose: **To evaluate long-term results of glaucoma surgery in newborn and infants with glaucoma.**
Methods: **Seventy-nine eyes of 52 children (age: 3 weeks–15.3 years) with primary congenital or secondary glaucoma treated between 2015 and 2017 were included. The median follow-up time was 3.9 years. Conventional probe trabeculotomy, 360° catheter-assisted trabeculotomy, filtering and cyclodestructive surgery were compared. Strict criteria for surgical success were applied: Complete surgical success (IOP below target IOP, no further surgery) and incomplete surgical success (additional surgery allowed) were analyzed, and IOP at baseline and last follow-up was compared.**
Results: **Intraocular pressure (IOP) was significantly reduced in primary congenital (preoperative IOP: 27.8 ± 7.5 mmHg vs. postoperative IOP: 14.2 ± 4.5 mmHg) and secondary glaucoma (preoperative IOP: 29.2 ± 9.1 mmHg vs. postoperative IOP: 16.6 ± 4.7 mmHg). 90% of all eyes reached target IOP with or without medication allowing for additional surgeries. As first surgery, 360° catheter-assisted trabeculotomy had a tendency to higher surgical success than other surgical approaches, while cyclodestructive procedures had lowest.**
Conclusions: **We found very promising surgical results in our childhood glaucoma patient group. Surgical success in both congenital and secondary glaucoma was high.**

Key words: congenital glaucoma – new surgical techniques – 360 degree trabeculotomy

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Introduction

Although glaucoma in newborn and children is rare, there is an unmet need for an early diagnosis and appropriate treatment (Ho & Walton 2004). Only few centers in Europe and in the world focus on the management of childhood glaucoma. Early diagnosed, surgical success rates vary between 70% and 80% for primary congenital glaucoma (Alsheikheh et al. 2007; Papadopoulos et al. 2007; Girkin et al., 2012a, 2012b; Khitri et al. 2012), even though no guidelines are available for the successful treatment of the different forms of the disease. Surgery is challenging and follow-up over lifetime is demanding, including amblyopia prevention, regular measurement of intraocular pressure (IOP), and examinations under general anesthesia in babies. The treatment is highly interdisciplinary involving glaucoma specialists, orthoptists, anesthetists specialized in treating newborns and children, nurses, and human geneticists. Therefore, treatment is reserved to specialized glaucoma centers where expertise is clustered among the different faculties.

Goniotomy has been used with similar success rates to conventional trabeculotomy but can only be performed safely in clear cornea situation (Girkin et al., 2012a, 2012b). Presently, conventional trabeculotomy is still the most common form of treatment for primary congenital glaucoma, but now competes with 360° catheter-assisted trabeculotomy as primary intervention (El Sayed & Gawdat 2018). In the recent years, circumferential trabeculotomy with an illuminated microcatheter or blunted suture has been introduced as a new group of surgeries allowing a treatment of the full Schlemm's canal (Toshev et al. 2018). The canal can be found by either cutting down (deep radial cuts) into the sclera or by the double scleral flap approach (performed in this study) as in canaloplasty of the adult. The advantage of goniotomy is, however, that anteriorly located iris insertion can be freed with the goniotomy knife and no conjunctival opening is needed. On the other hand, trabeculotomy is the more universal procedure as it is suited for all stages of corneal opacities (Grajewski 2018).

We have evaluated long-term results of glaucoma surgery in primary and secondary glaucoma in newborn and children. Moreover, we followed axial length development in both treated and untreated eyes over time.

Material

This study was a retrospective cohort evaluation. Available data on 79 eyes of 52 patients with primary or secondary glaucoma were analyzed. Patients were included if they had received first-time glaucoma surgery in our hospital between 2015 and 2017, were aged 18 years or below at the time of surgery, and had a follow-up of at least 1 year. If these criteria were fulfilled, the patient's whole course of treatment was reviewed. If patients consulted local ophthalmologists for primary care, current data were obtained either from the physician's office or the patients.

Informed consent was obtained from all patients. IRB (ethics committee Rheinland-Pfalz, Mainz, Germany) waived the need for IRB approval. The study and data accumulation were in conformity with all country, federal, and state laws. The study was in adherence to the tenets of the Declaration of Helsinki.

Medical history data as well as data from medical examinations were collected anonymously by reviewing medical charts. General data included age, sex, diagnosis, age at time of diagnosis, and previous eye surgeries performed in domo or in other hospitals. Patients were divided into two subgroups: primary glaucoma and secondary glaucoma (aphakia, Sturge-Weber syndrome, Peters-anomaly, aniridia, Axenfeld-Rieger anomaly).

The number and type of surgical procedures were documented. Surgical procedures included rigid probe trabeculotomy, 360° catheter-assisted trabeculotomy, combined trabeculotomy/trabeculectomy, cyclodestructive treatment (controlled cyclophotocoagulation and cyclocryocoagulation) Ahmed valve implantation, combined trabeculotomy/trabeculectomy and trabeculectomy.

Examination under general anaesthesia

The induction and maintenance of general anaesthesia was performed by an anaesthesiologist, specifically experienced in newborn and childhood anaesthesia (NP). Intraocular pressure was obtained individually propofol-triggered allowing a more comparable measurement to the alert child.

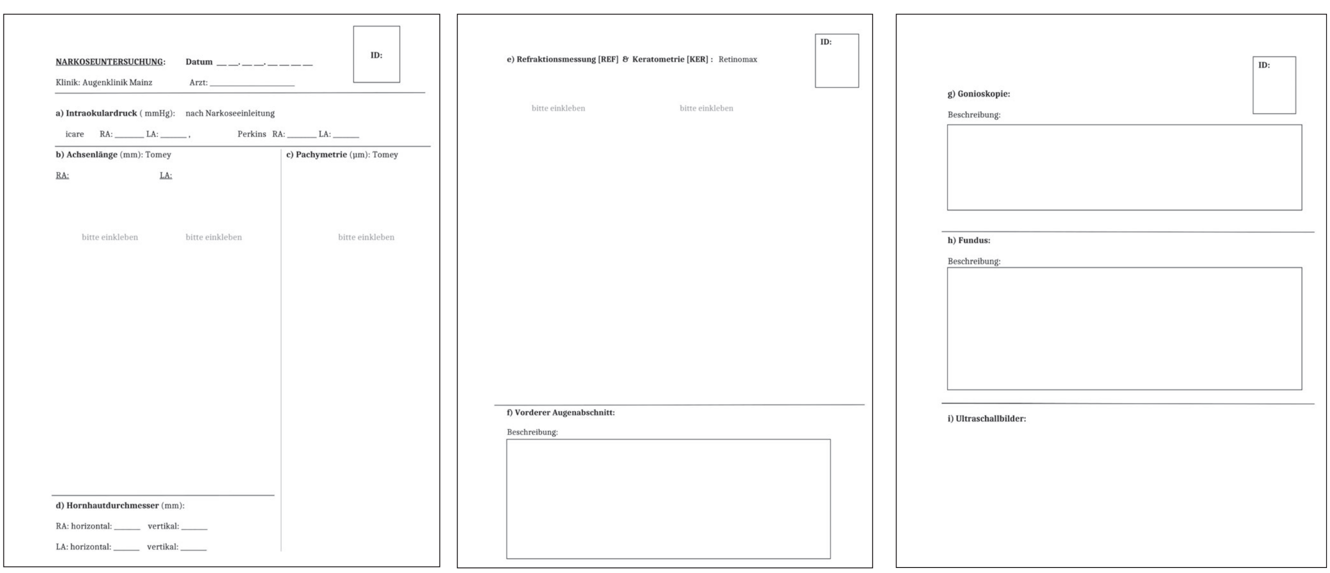
Intraocular pressure (IOP) was measured by hand-held Perkins applanation (model Mk2, Haag-Streit Holding, Köniz, Switzerland) and ICare-tonometer (Icare PRO tonometer, Icare Finland Oy, Vantaa, Finland) after a break of 60 seconds between the two instruments. Both eyes were measured. Axial length was measured by ultrasonography with Tomey-AL-2000 (model AL-2000, Tomey, Nürnberg, Germany), and the corneal diameter of the eye was measured by a caliper. Both parameters were compared to the standard values at the respective age. Anterior segment (cornea, Haab striae, anterior chamber depth, iris configuration, pupil size and configuration, and chamber angle) and posterior part (optic nerve head, macula, and retina) of the eye were examined under the microscope.

Figure 1 presents the examination sheet used in the childhood glaucoma center for all patients undergoing examination in general anaesthesia and/or glaucoma surgery.

Surgery

Probe trabeculotomy

Corneal traction sutures at the limbus with 7.0 silk was performed at the beginning of each surgery. Both Fornix-based or limbus-based conjunctival flaps were performed at the discretion of the surgeon. If the size of the buphthalmic eye was very unfavorable, meaning extreme thinning of the sclera and the cornea, two transconjunctival rectus muscle traction sutures were needed to expose one of the superior quadrants for surgery. A rectangular scleral flap of ½ to 2/3 scleral thickness and 4x4 mm size followed. A second smaller (i.e. 2 mm wide) flap was


NARKOSEUNTERSUCHUNG: Datum __ __. __ __. __ __ __ __
Klinik: Augenklinik Mainz Arzt: ______________
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a) Intraokulardruck (mmHg): nach Narkoseeinleitung
icare RA: ______ LA: ______, Perkins RA: ______ LA: ______
b) Achsenlänge (mm): Tomey
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bitte einkleben bitte einkleben
c) Pachymetrie (µm): Tomey
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d) Hornhautdurchmesser (mm):
RA: horizontal: ______ vertikal: ______
LA: horizontal: ______ vertikal: ______

ID:
e) Refraktionsmessung [REF] & Keratometrie [KER] : Retinomax
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h) Fundus:
Beschreibung:
i) Ultraschallbilder:

Fig. 1. Examination sheet for children undergoing examination in general anaesthesia and/or glaucoma surgery

dissected down to a plane just above the ciliary muscle. By advancing this second flap anteriorly, Schlemm's canal is reached, easily opened, and deroofed. The ostia of Schlemm's canal to both sides can be verified easily. The metal probes (Harms trabeculotome, Geuder AG, Heidelberg, Germany) were then introduced into the canal and rotated into the anterior chamber on both sides avoiding perforating the trabecular-descemet bridge at the site of the deep flap. During this maneuver, the limbus was stabilized at the area of the probe tip from outside with a Kolibri forceps because the plane of rotation is then better defined.

After the trabeculotomy was completed, the second flap was sutured or not at the discretion of the surgeon (EMH, FG). If partial filtration was considered, resection of the second flap was performed. The superficial flap was sutured with four 10/0 nylon sutures. The conjunctiva was closed with a meander-like running suture ("Mainz suture") with 10/0 nylon at the limbus or with 8/0 or 10/0 Vicryl running suture, generally separate for tenon and conjunctiva, depending on the surgeon's preference.

360° catheter-assisted trabeculotomy

Same technique as above was performed until the ostia of the Schlemm's canal were opened. Then, the ostia were tested by BSS instillation. The illuminated catheter (iTrack™ surgical System by Ellex Medical Laser, Australia) was prepared and filled with viscoelastics. Using two forceps, the catheter was advanced over 360°, and when the tip entered the other side of the ostium, the catheter was grasped and gently pulled until it tears through the trabecular meshwork and produced the trabeculotomy. Prior this maneuver, a small paracenthesis was made to inject acetylcholine in case of dilated pupil. Then, the anterior chamber was filled with viscoelastics to protect cornea and lens. Closure of wound was performed the same way as described above.

Orthoptic examination prior to examination under general anaesthesia

All patients underwent orthoptic examination prior examination and surgery. Depending on age, visual acuity was measured by Teller-acuity-test, Cardiff-acuity-test, Lea-Hyvärinen test, and by using standardized optotypes. Visual acuity results were also compared to the standard values at the respective age and evaluated by using LogMar-values.

Definition of surgical success

Complete surgical success was defined by an IOP of 5–17 mmHg after a minimum of 12 months after surgery. Topical medication was allowed but no further surgical intervention.

Incomplete surgical success was defined by an IOP of 5–17 mmHg after a minimum of 12 months after surgery including further surgery.

Statistical analysis

Descriptive statistics was performed for the study population and the two subgroups primary and secondary childhood glaucoma. For continuous variables, mean, standard deviation, and range were calculated for approximately normally distributed data, otherwise median and range were computed. For categorical data, absolute and relative frequencies were computed.

Main outcome measure was surgical success. Secondary outcomes were the development of intraocular pressure over time, visual acuity, refraction, corneal diameter, and axial length development in both eyes. Statistical analysis for these outcomes included *t*-test and non-parametric tests (Wilcoxon test, Mann-Whitney-*U* test).

Kaplan-Meier curves were computed for different surgical procedures. Patients were grouped depending on their first pressure-lowering surgery into probe trabeculotomy, 360° catheter-assisted trabeculotomy, cyclodestructive procedures (controlled photocoagulation and cyclocryocoagulation), and filtering surgery (Ahmed-valve implantation, trabeculectomy, and combined trabeculectomy/trabeculotomy), and the time interval from initial surgery to second surgery or to an elevated IOP over the above defined thresholds (topical medication was allowed) was computed. Due to variable follow up time, the data were right-censored after 3 years. Proportional hazard assumption was checked, and due to not fulfilling them, no Cox regression analysis was conducted. A sensitivity analysis was carried out separating primary and secondary childhood glaucoma cases.

The software R (R Core Team (2020). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL https://www.R-project.org/) was used for the statistical analysis, as was the r-package "survival" (Therneau T (2020). A Package for Survival Analysis in R. R package version 3.2-7).

Results

Seventy-nine eyes of 52 patients (28 female and 24 male patients) were included. Median age at study entry was 35 months (range: 3 weeks to 15.3 years). The range of observation varied due to the retrospective nature of the study (median follow-up time: 3.9 years, IQR 3.2–4.9 years). Seventy percent of all included patients had bilateral glaucoma, 30% presented with unilateral glaucoma. Both, primary and secondary glaucoma, were distributed similarly (52% and 48%, respectively). Haab striae were found in 24% of all eyes.

Table 1 shows the characteristics of the study population.

Surgery

The most common initial surgical technique used in the analyzed collective of children was probe trabeculoctomy (50 eyes), followed by 360° catheter-assisted trabeculotomy (17 eyes), cyclodestructive procedures (controlled cyclophotocoagulation in 7 eyes,

Table 1. Demographic characteristics of the study population

Type of congenital glaucoma	
Primary	27 (52%)
Secondary	25 (48%)
Glaucoma diagnosis	
Unilateral	15 (29%)
Bilateral	37 (71%)
Surgery on one or both eyes	
One eye	25 (48%)
Both eyes	27 (52%)
Age	
Median	35 months
Sex	
Female	28 (54%)
Male	24 (46%)
Type of secondary glaucoma	
Aphakic glaucoma	7 (14%)
Axenfeld-Rieger syndrome	6 (11%)
Sturge-Weber syndrome	2 (4%)
Peters anomaly	1 (2%)
Other	9 (17%)

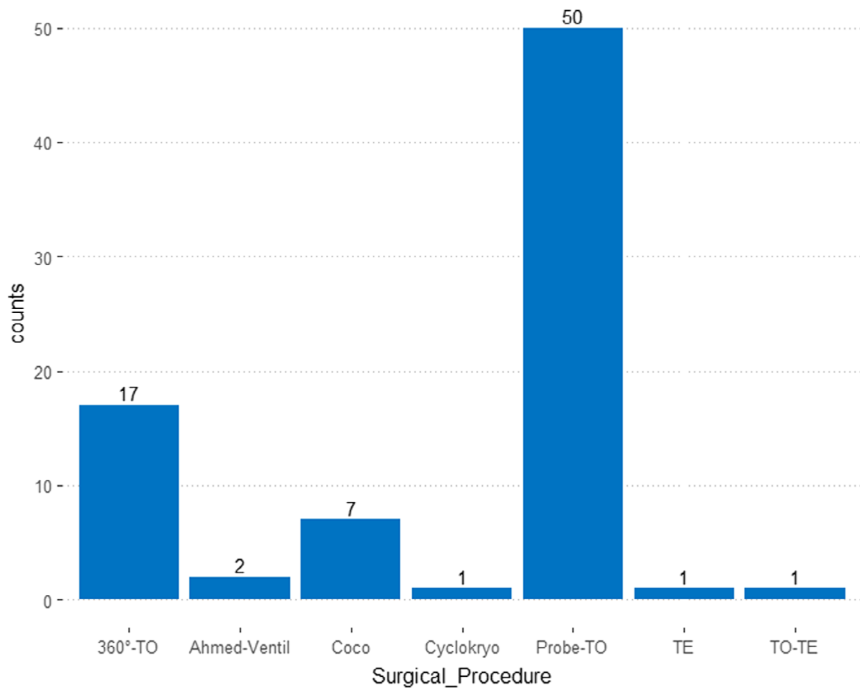

Fig. 2. Distribution of performed surgeries in the whole study population

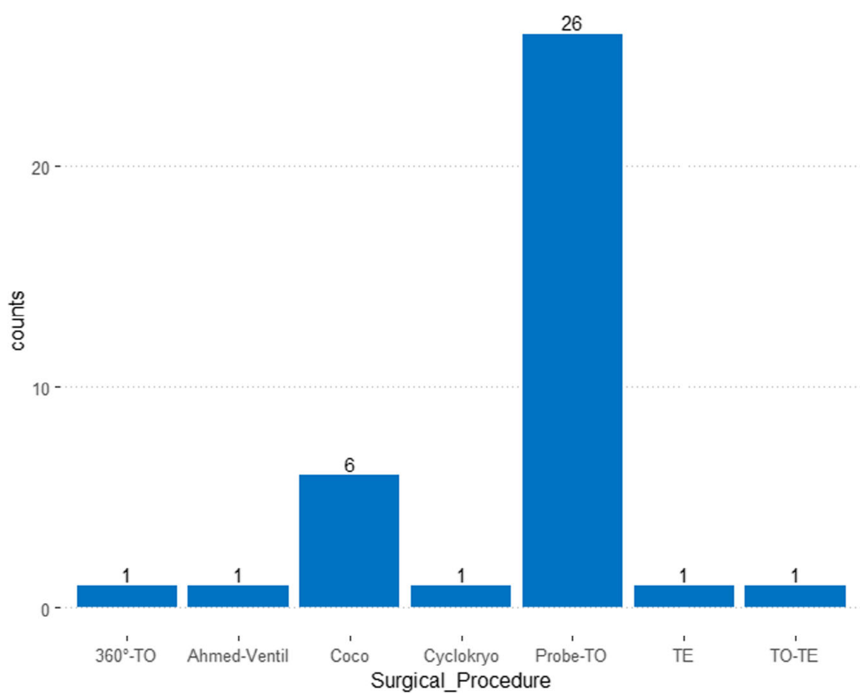

Fig. 3. Distribution of performed surgeries in secondary glaucoma patients

cyclocryocoagualation in 1 eye), and filtering surgery (Ahmed-valve Implantation in 2 eyes, trabeculectomy in 1 eye, and combined trabeculectomy/trabeculotomy in 1 eye). The distribution of performed surgeries in the whole study population is shown in Fig. 2.

Patients with secondary glaucoma received mostly probe trabeculotomy as seen in Fig. 3.

Intraocular pressure (IOP)

Mean preoperative IOP was 28.4 ± 8.3 mmHg among all included eyes (n = 79). At the last follow-up, the IOP was significantly reduced to 15.4 ± 4.7 mmHg ($p < 0.001$). (See Fig. 4).

Intraocular pressure (IOP) was significantly reduced in primary congenital glaucoma eyes (preoperative IOP: 27.8 ± 7.5 mmHg vs. postoperative IOP: 14.2 ± 4.5 mmHg) and secondary glaucoma (preoperative IOP: 29.2 ± 9.1 mmHg vs. postoperative IOP: 16.6 ± 4.7 mmHg).

At the end of follow-up, no statistically significant difference was found between the groups (IOP decrease from preoperative value in primary congenital glaucoma: 14.2 ± 8.1 mmHg; IOP decrease from preoperative value in secondary congenital glaucoma: 13.1 ± 8.9 mmHg, $p < 0.56$).

Overall, thirty-nine eyes (54.2%) achieved an IOP of 17 mmHg or below with or without medication with no further surgical intervention at last follow-up. A total of 67 eyes (90.5%) achieved an IOP of 17 or below including those with topical therapy and further surgery (incomplete surgical success).

In 15 patients with unilateral glaucoma, healthy fellow eyes were also examined. Intraocular pressure (IOP) in fellow healthy eyes was stable over time (preoperative IOP:12.53 mmHg ± 4.17 mmHg, last IOP: 15.79 ± 2.53 mmHg, change: +2.20 ± 5.76 mmHg, $p = 0.63$).

Intraocular pressure (IOP) in glaucoma eyes, which received surgical intervention, IOP decreased by 14.07 ± 7.95 mmHg to 15.67 ± 3.02 mmHg. No significant difference in IOP was found between diseased and healthy eyes at the end of study.

Surgical success of first surgery

The surgical success of first glaucoma surgery is presented in the Kaplan-Meier curve of Fig. 5. Patients with 360° catheter-assisted trabeculotomy showed best success rates, followed by probe trabeculotomy, filtering surgery (Ahmed-valve implantation, trabeculectomy, and combined trabeculectomy/trabeculotomy), while cyclodestructive procedures (controlled photocoagulation and cyclocryocoagualation) showed lowest success rates. Sensitivity analysis including only primary congenital glaucoma cases showed a descriptively slightly better performance of 360° catheter-assisted trabeculotomy than probe trabeculotomy, (Fig. 6), while the treatment frequency of the other procedures was low.

In secondary childhood glaucoma, cyclodestructive treatments showed lower success rates than probe

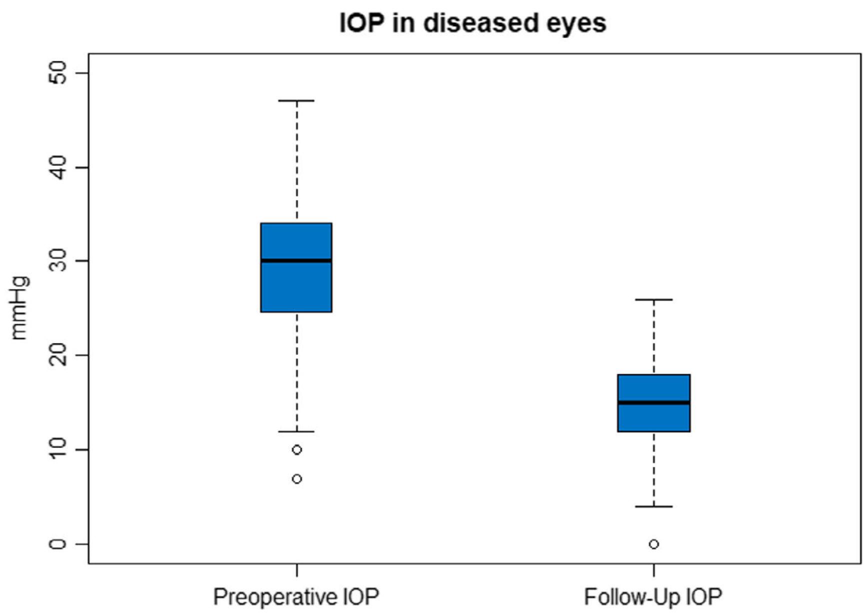

Fig. 4. Change of intraocular pressure (IOP) in all glaucoma eyes after surgery

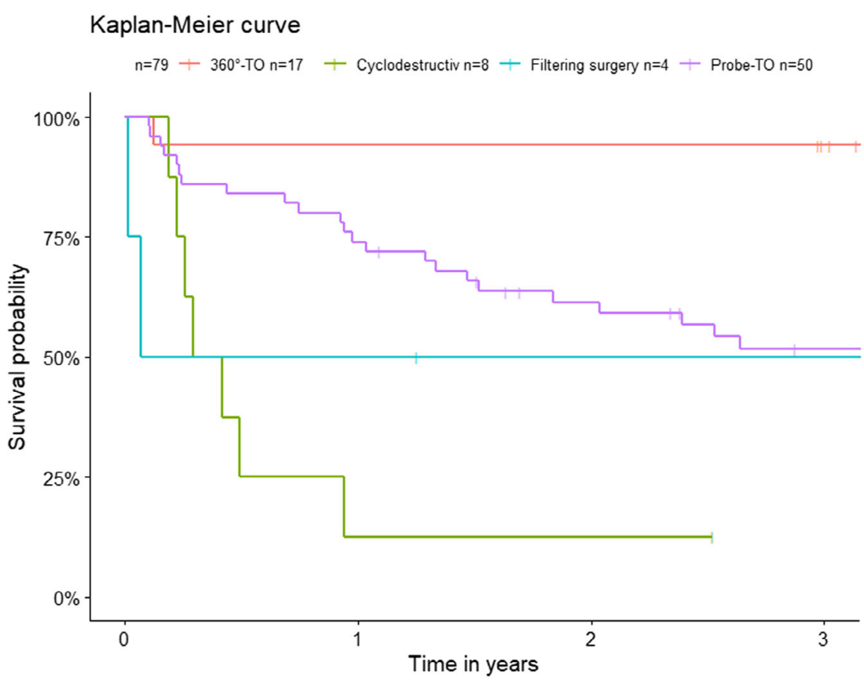

Fig. 5. Kaplan Meier curves representing the success rates of the respective first surgery over the first 3 years

trabeculotomy, while the frequency of the other procedures was low.

Axial length development

Axial length difference to age-matched normative values was +3.91 ± 2.65 mm at baseline (preoperatively) and +3.42 ± 2.31 mm at the end of follow-up. Deviation from normal was significant for both baseline and follow-up axial length ($p < 0.001$). Deviation from normal axial length was smaller at the last follow-up than for the baseline, but the difference was not statistically significant ($p = 0.092$). See Table 2 for comparison with other studies.

Corneal diameter

Corneal diameter (CD) differed to age-matched normal eyes (+3.15 ± 2.11 mm, $p < 0.001$) at baseline (preoperatively) and at the end of follow-up (+2.84 ± 2.16 mm, $p < 0.001$).

Deviation from normal CD was smaller at the last follow-up than for the baseline, but the difference was statistically significant ($p = 0.036$).

Visual acuity

Analysis of visual acuity (VA) was only available in 37% of all eyes. At baseline, mean visual acuity was −0.71 ± 0.86 LogMAR (=0.19 VA in decimals). At last follow up, VA increased slightly to mean −0.67 ± 0.7 LogMAR (=0.2 VA in decimals).

Discussion

We have analyzed long-term data of newborns and children with glaucoma that underwent glaucoma surgery between 2015 and 2017. In a Kaplan-Meier survival-curve describing surgical success over 3 years, 360° trabeculotomy seems to have a higher surgical success compared to other surgical approaches. Cyclodestructive procedures showed low surgical success; thus, they should not be considered as favorable option for surgical first-line treatment.

Compared to other studies, our patient cohort was moderately older than the reported cohorts (Yassin & Al-Tamimi 2016; El Sayed & Gawdat 2017). This might be at least in part explained by the heterogeneous patient cohort including 48% of secondary glaucoma, of whom 14% had aphakic glaucoma. The Infant Aphakia Treatment Study (IATS (Freedman et al. 2015)) investigators found that the risk of developing glaucoma after 5 years was 17% (32% including glaucoma suspects). They furthermore reported that time to development of aphakic glaucoma after lensectomy varies and is described between 1 and 5 years after primary cataract surgery. Therefore, children with secondary (aphakic glaucoma) often are diagnosed and also treated at older age.

Mean intraocular pressure prior surgery was 28.4 ± 8.3 mmHg (mean IOP at the end of observation time was 15.4 ± 4.7 mmHg). Surgery is the only proven therapy in childhood glaucoma and its success is well documented (Elder 1994; Meyer et al. 2000; Filous & Brunova 2002; Mandal et al. 2003; Cai et al. 2004; Mandal et al. 2004; Mandal et al. 2007; Aponte et al. 2011; Lim et al. 2015; Hsu et al. 2018). Comparable results regarding the high IOP at

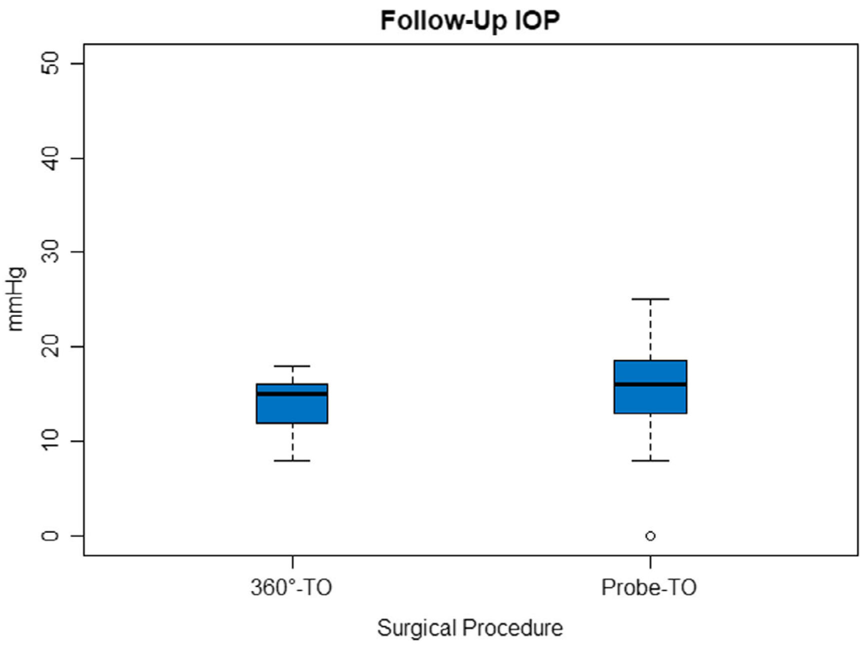

Fig. 6. Box plots comparing long term intraocular pressure (IOP) results in probe versus 360° trabeculotomy (only congenital glaucoma eyes included)

Table 2. Comparison of AL change over time in different study populations

	N	AL – Baseline	AL – End of study period	Age [m]	Follow-up [m]
Own data	**48**	**23.0 ± 2.5**	**23.7 ± 2.3**	**24**	**12**
Cronemberger et al. [2014]	20	24.6 ± 2.7	25.4 ± 2.7	12.1	32.4
Dietlein et al. [1998]	36	21.7 ± 2.5	22.4 ± 1.6	4.4	7.2
Kiefer et al. [2001]	37	22.3 ± 2.6	24.2 ± 2.4	10.3	27.3
Hsu et al. [2018]	56	21.0 ± 2.0	23.3 ± 2.7	8.8	85.1
Alsheikheh et al. [2007]	68	22.6 ± 1.8	24.4 ± 2.0	5.9	57.3
Girkin et al. [2012]	10	23.4 ± 2.7	22.3 ± 2.8	12.5	11
Yalvac et al. [2007]	36	20.4 ± 2.0	22.9 ± 2.2	2.2	38.4
Ikeda et al. [2004]	30	21.9 ± 1.9	25.0 ± 2.7	27.6	114

baseline are well described in literature (varying IOP values between 28 and 35 mmHg) (Meyer et al. 2000; Cai et al. 2004; Zetterberg et al. 2015; Hsu et al. 2018). One study by El-Sayed et al. (2017) even reported preoperative IOP values above 50 mmHg and explained them by the rural poor setting and the inferior health care services.

Interestingly, IOP lowering in both groups, primary and secondary congenital glaucoma, was not different from each other. However, secondary glaucoma patients underwent more glaucoma surgeries, and revisions (and are prone to more complicated development of the disease Aponte et al. 2011; Moschos et al. 2018).

The most frequent initial surgery in our patient cohort was probe trabeculotomy (63.3%) followed by 360° trabeculotomy (21.5%) and cyclodestructive treatment (10.1%). It must be noted that 360° trabeculotomy could not be performed successfully in all cases (3 eyes).

Cyclodestructive treatment in our cohort was mainly cyclophotocoagulation rather than cyclocryocoagulation. Reason for this is that a “controlled” cyclophotocoagulation (CoCo) has been used over the last three decades in our population. This treatment, which was developed in Mainz, has the advantage of avoiding so called pop-effects during the laser application. Therefore, unwanted damage and complications of CoCo are very unlikely, particularly because of the high selectivity of photoabsorption (Preussner 2018). Especially in children with glaucoma, this safe surgery is often used with success in our clinic.

In three cases, the surgical approach was changed intraoperatively from 360° trabeculotomy to probe trabeculotomy due to anterior chamber dysgenesis.

Our study has several limitations. First, data were collected retrospectively. This implicates that follow-up data for some patients could not be collected for all patients. However, some patients visited their local ophthalmologist, and this data was acquired and implemented in the analysis. Second, follow-up time was restricted to available data. However, the median follow-up of 3.9 years is reasonable and adequate time frame for reporting surgical success.

We did not have baseline and follow-up axial length data (48 of 79 eyes) from all patients due to the “real life conditions” of our study. Therefore, clinical assumptions should be considered with caution. However, we found a statistically significant deviation from normal age-matched AL data for baseline measurements. This difference declined to smaller values at study end but did not reach statistical significance, but only a tendency ($p = 0.09$). We used the normative data for axial length measures from Buschmann and colleagues (Buschmann & Bluth 1974) in this study who developed a normative database for axial length values according to age. Axial length degression is described as success (and a decision) parameter when treating childhood glaucoma patients. As shown in part of our study patients, AL relatively decreased over study period in most eyes but absolutely increased over time relative to age. Cronemberger et al. (2014) also recorded longer axial length in eyes with childhood glaucoma at the end of the study and concluded, among others, that normalization of values is not to be expected, but a normalization of the rate of growth might be achieved. Thus, reduction of axial length growth over time is a parameter for reduction of intraocular pressure and successful surgery. This has been reported in other studies, too (Dietlein et al. 1998; Kiefer et al. 2001; Alsheikheh et al. 2007; Girkin et al., 2012a, 2012b; Hsu et al. 2018).

To distinguish between congenital glaucoma and progressive myopia, corneal diameter measurement may be a helpful parameter. Therefore, we have included this parameter in our investigation. Intraocular pressure (IOP) raise (or uncontrolled congenital glaucoma) causes dilatation of the whole eyeball, especially at the vulnerable limbus, leading to an increase of corneal diameter. Myopic eyes show increased axial length but roughly normal corneal diameters and do not exhibit limbal stretching (Kiefer et al. 2001). Furthermore, eyes with congenital glaucoma often have a less myopic refraction than would be expected from their AL. Buphthalmic eyes have flattening cornea, flattening axial lens diameter and deeper anterior chamber. These factors are known to be responsible for less myopia than axial length would predict (Sampaolesi 1983; Sampaolesi 1987; Sampaolesi 1988; Sampaolesi 1988). Regarding corneal diameter evaluation, we could only include 32 eyes, hampering interpreting our data. We found relatively decreasing CD values compared to normative CD data in the study period. The difference in CD measures from normal population values at study end was significantly smaller compared to baseline examination CD values.

In conclusion, we found very promising surgical results in our childhood glaucoma patient group. Although our study includes heterogeneous data on primary and secondary childhood glaucoma, we believe this reflects the reality of a large childhood glaucoma center. In this study, probe trabeculotomy was most often used for surgical treatment. Surgical success seems to be higher for 360° trabeculotomy compared to other surgical approaches. Meanwhile, 360° trabeculotomy has become our preferred surgical treatment option and further evaluation of this surgical approach will give more insight into success rates compared to probe trabeculotomy.

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