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ORIGINAL RESEARCH

Effect of Trabeculodescemetic Window Perforation in Deep Sclerectomy on Intraocular Pressure in Primary Congenital Glaucoma

Abdulaziz AlQattan · Konrad Schargel · Ibrahim AlJadaan · Nouf AlZendi · Gorka Sesma

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ABSTRACT

Introduction: Primary congenital glaucoma causes vision loss if intraocular pressure is uncontrolled. Nonpenetrating deep sclerectomy is effective in treating primary congenital glaucoma. However, the effects of inadvertent trabeculodescemetic window perforation remain unclear.

Methods: This retrospective cohort study included patients with primary congenital glaucoma who underwent nonpenetrating deep sclerectomy between 2014 and 2021. The perforation group had intraoperative trabeculodescemetic window perforations; the non-perforation group did not. The primary outcome was intraocular pressure between the groups over 15 months. The secondary outcomes included surgical success and complications.

Results: The study included 74 eyes of 44 patients. The cohort comprised 31 perforated and 43 non-perforated eyes. Both groups showed significant intraocular pressure reduction without significant between-group differences in complete (68 vs. 77%), qualified (19 vs. 9%), or failed (13 vs. 14%) treatments. The median intraocular pressure decreased from 39 to 14 mmHg in the perforation group and 35 to 12 mmHg in the non-perforation group. Of the 74 treated eyes, 68 (92%) showed no complications.

Conclusions: An inadvertent trabeculodescemetic window perforation during nonpenetrating deep sclerectomy for primary congenital glaucoma did not significantly affect intraocular pressure outcomes compared to non-perforated cases over 15 months. Nonpenetrating deep sclerectomy reduced intraocular pressure regardless of intraoperative perforation in patients with primary congenital glaucoma. Perforation of the trabeculodescemetic window was associated with a low incidence of postoperative complications.

Keywords: Primary congenital glaucoma; Nonpenetrating deep sclerectomy; Intraocular pressure; Trabeculodescemetic window; Perforation

Abdulaziz AlQattan and Gorka Sesma have contributed equally to the manuscript, warranting their recognition as co-first authors.

A. AlQattan · G. Sesma (✉)
Pediatric Ophthalmology and Strabismus Division, King Khaled Eye Specialist Hospital, Al Urubah Branche Rd., West Building 2nd Floor, 11462 Riyadh, Saudi Arabia
e-mail: gsesma@kkesh.med.sa

K. Schargel · I. AlJadaan · N. AlZendi
Glaucoma Division, King Khaled Eye Specialist Hospital, Riyadh, Saudi Arabia

Key Summary Points

Why carry out this study?

Nonpenetrating deep sclerectomy (NPDS) is an effective surgical technique for reducing intraocular pressure (IOP) in pediatric patients with primary congenital glaucoma (PCG).

The effect of inadvertent intraoperative trabeculodescemetic window (TDW) perforation during NPDS on long-term IOP control in PCG remains unclear.

What was learned from the study?

This retrospective cohort study compared IOP outcomes between patients with PCG and inadvertent TDW perforation and those without perforation during NPDS.

Over 15 months, the perforation and non-perforation groups showed significant IOP reduction from baseline but no significant between-group differences in IOP or surgical success rates.

Inadvertent TDW perforation during NPDS does not significantly affect the long-term IOP outcomes in pediatric patients with PCG.

INTRODUCTION

Primary congenital glaucoma (PCG) is a significant cause of childhood blindness in Saudi Arabia, having an estimated prevalence ten times greater than that in Western countries. The high rate likely relates to consanguinity; increased CYP1B1 mutations predispose individuals to more severe forms of PCG [1–4].

PCG involves increased intraocular pressure (IOP) due to the abnormal development of the eye's drainage system. Obstructed drainage can damage the optic nerve and impair vision if not addressed. Studies have evaluated different surgical procedures, such as trabeculotomy, trabeculectomy, and goniotomy, for treating PCG; these procedures are the most common treatments for this condition [5–7]. Unlike in Western countries, preferred interventions have not demonstrated favorable outcomes in Saudi Arabia, including goniotomy, trabeculotomy, and trabeculectomy [8–11]. Conversely, nonpenetrating deep sclerectomy (NPDS) has demonstrated promising outcomes, improving the safety of conventional filtering procedures [12].

Trabeculectomy and NPDS attempt to bypass outflow resistance by shunting the aqueous humor from the anterior chamber. Trabeculectomy effectively functions as a careful full-thickness removal of the trabecular meshwork (TM), creating a sclerostomy anterior to the TM and Schlemm canal (SC), allowing free flow of fluid into the open lumen of the SC, bypassing trabecular resistance. Creating a fistula between the anterior chamber and subconjunctival space bypasses the conventional and uveoscleral pathways [13]. NPDS involves creating a deep scleral flap to expose the underlying sclera, thereby unroofing the SC, removing its inner wall along the juxtacanalicular meshwork, and eliminating the site of maximum aqueous outflow resistance. This technique aims to preserve the integrity of uveal and corneoscleral tissues to reduce IOP without entering the anterior chamber [14].

Compared with other glaucoma surgeries, NPDS avoids perforation and reduces complications [5, 15]. However, accidental trabeculodescemetic window (TDW) perforations can occur, especially while learning the procedure [14, 16]. In deep sclerectomy, microperforation refers to a controlled, small-scale perforation of the trabeculo-Descemet membrane (TDM) during the surgical procedure. This perforation allows the aqueous humor to gradually egress through the trabeculo-Descemet's window (TDW), helping reduce IOP without causing severe hypotony or hypotony-related complications [14, 17, 18].

Microperforation has been linked to various surgical procedures, including deep sclerectomy, phacoemulsification, and cyclophotocoagulation, and has been found to reduce IOP [19–21]. The mechanisms through which

microperforations reduce IOP include transscleral flow, the opening of nonfunctional areas of the SC, and uveoscleral outflow [19]. The efficacy of microperforations for significantly reducing IOP has been demonstrated [22]. In addition, using microperforations is associated with an effective decrease in IOP in medium-term follow-up, suggesting potential as a long-term solution for managing glaucoma [17].

Inadvertent perforation, also known as macroperforation, during deep sclerectomy, refers to an unintended and larger-scale perforation of the trabeculo-Descemet membrane (TDM) with or without iris prolapse that occurs during the surgical procedure. This perforation can result in uncontrolled aqueous humor outflow, potentially leading to hypotony and other related complications. Studies report a 30% conversion rate to trabeculectomy or unintentional perforations [23]. The documented occurrence of inadvertent perforation during deep sclerectomy emphasizes the need for careful surgical techniques to minimize their risk [24]. Cheng et al. have proposed that inadvertent ruptures in the juxtacanalicular tissue and the inner wall of SC are potential routes for aqueous humor entry following perforations, underscoring the significance of inadvertent perforations on postoperative outcomes [25].

Few studies have compared the effects of macroperforation on IOP after NPDS. The effect of inadvertent intraoperative NPDS perforation on long-term IOP in patients with PCG remains unclear, with conflicting evidence. Lükes et al. found increased IOP after TDW perforation in patients with PCG undergoing NPDS [26]. Conversely, other studies have shown long-term efficacy and safety between penetrating deep sclerectomy and traditional NPDS [27–29].

Despite the promising outcomes of perforation during NPDS, critical knowledge gaps exist for the specific effects of inadvertent TDW perforation on long-IOP reduction in pediatric patients with PCG. Prior analyses have focused on other populations, mentioned this complication only secondarily, or compared different procedures rather than directly investigating the effect of TDW perforation after NPDS, specifically for PCG [30, 31]. This lack of evidence on the effects of accidental perforation during NPDS for PCG highlights this issue, especially given the devastating vision loss that PCG can cause if IOP is not well controlled. Analyzing the effect of inadvertent perforation during NPDS for PCG on postoperative IOP will provide clinically useful data for guiding surgical choices and handling complications during NPDS in these patients. Therefore, we aimed to compare IOP outcomes after NPDS with and without inadvertent perforation in pediatric PCG cases.

METHODS

Study Design

This retrospective observational cohort study was conducted at the King Khaled Eye Specialist Hospital (KKESH) in Riyadh, Saudi Arabia, on children with PCG who initially underwent NPDS. The study comprised two cohorts: patients who developed TDW perforation during surgery (perforation group) and patients who did not experience perforation (nonperforation group). The study period spanned from June 2014 to June 2021. The study's primary outcome was comparing the IOP between the two cohorts at various time points before surgery, during the follow-up period, and 15 months after surgery to determine the effect of perforation on IOP. The procedure's success in achieving the target IOP reduction was determined using three parameters: *absolute success*, defined as IOP readings < 21 mmHg without any antiglaucoma medications or further surgeries; *qualified success*, defined as IOP readings of 6–21 mmHg with antiglaucoma medications; and *failure*, defined as IOP readings > 21 mmHg, even with medications. Survival analysis was conducted to quantify the risk of failure in both groups, with IOP as the secondary outcome.

Ethical Considerations

This study was performed in accordance with the Helsinki Declaration of 1964 and its later

amendments, and was approved by the Institutional Review Board of King Khaled Eye Specialist Hospital (Protocol RP 23032-R). The requirement for informed consent was waived by the institutional review board as this is a retrospective study using de-identified data from existing medical records.

Data Collection

The study conducted a thorough analysis of the electronic medical records to identify patients diagnosed with PCG and to distinguish those who underwent NPDS and subsequently developed perforation from those who did not. Therefore, consecutive patients in each group were carefully selected for further examination. The collected data were recorded in a predesigned coded data sheet and then transferred to Stata version 17 (StataCorp LLC; College Station, TX, USA) statistical software for analysis. The sample size calculation for this study was performed using Epi Info 7.2.2.2 (Centers for Disease Control and Prevention, Atlanta, GA, USA). The study used an unmatched cohort design with a two-sided confidence level of 95%, a ratio of unexposed to exposed individuals of 1.5, a power of 80%, and an estimated baseline incidence of 50%. Based on these parameters, a sample size of 70 eyes was selected: 28 in the perforation group and 42 in the non-perforation group. A post hoc power analysis was conducted based on the IOP values observed in the 31 perforated and 43 non-perforated eyes to determine whether our study was adequately powered to detect potentially subtle differences between the groups. Our study had 80% power to detect a true between-group IOP difference of 2.5 mmHg at 15 months with a two-sided alpha of 0.05. All patients treated at the hospital during the study period who met the inclusion criteria were recruited for this study. The final sample comprised 74 eyes from 44 patients divided into perforation ($n = 31$) and non-perforation ($n = 43$) groups based on exposure status.

Participants

Participants were eligible for the study if they met the following criteria: diagnosis of PCG, NPDS as planned as the first surgical procedure, age 0–15 months, and had at least six follow-up appointments for at least 15 months after surgery. The perforation group included patients who exhibited unmistakable signs of TDW perforation with or without iris prolapse. The exclusion criteria were prior glaucoma surgery, ocular trauma or infection, other significant ocular abnormalities, other forms of glaucoma, other ocular comorbidities affecting IOP, systemic diseases with ocular manifestations, patients outside the specified pediatric range, those with insufficient clinical data in their medical records, and those with < 15 months of postoperative follow-up. Studies have demonstrated that microperforation enhances the success of NPDS [32]; therefore, patients with microperforation were excluded from this study.

The cohorts' baseline demographic and clinical characteristics included age, sex, procedure, family history, consanguinity, and the affected eye. In addition to demographic variables, various clinical characteristics were recorded, including surgery date, baseline IOP, horizontal corneal diameter, central corneal thickness, and transparency at the first follow-up after surgery. The patients underwent a comprehensive ophthalmological examination under anesthesia after admission, which included IOP measurement using an iCare IC200 (iCare Finland Oy, Vantaa, Finland) tonometer, corneal diameter measurements, portable slit-lamp examination of the anterior and posterior segments of the eye, ocular fundus examination, cycloplegic refraction, B-scan ultrasonography, axial length, and ultrabiomicroscopy (UBM). This multimodal approach enabled the complete assessment of ocular conditions. The intervention details were carefully documented, including the date of surgery, patient's age at the time of surgery, surgical technique used, any intraoperative complications beyond perforation, occurrence of hypotony during the procedure, anterior chamber depth, iris prolapse, and whether iridectomy was performed.

Surgical Procedure

Deep sclerectomy was performed by consultants or fellows under the direct supervision of consultants. Corneal traction sutures were placed to expose the superior quadrant, and a limbal conjunctival incision was made. Mitomycin C (0.25 mg/ml) was applied to the subconjunctival space by using collagen sponges for 2 min. A 5 × 4-mm scleral superficial flap and a 4 × 3-mm deep flap were created. The deep flap was carefully dissected until it reached the SC, where spontaneous aqueous percolation was observed. The dissection was continued until a point 1.5 mm from the clear cornea was reached. The deep flap was cut, the superficial flap was loosely closed with two stitches in the corner areas using 10–0 nylon, and the conjunctiva was sutured continuously with 8–0 absorbable sutures. For cases where perforation of the TDW occurred with iris prolapse, iridectomy was performed, and the superficial flap was tightly closed. In cases where there was only mild or partial iris prolapse, with the TDW remaining partially intact, the iris was reduced using a thin spatula through paracentesis, an intracameral acetylcholine chloride intraocular solution (10 mg/ml; Miochol, Bausch & Lomb, Rochester, NY, USA) was injected, and iridectomy was avoided.

After surgery, patients were administered topical 1% prednisolone acetate and moxifloxacin antibiotics for at least 4 weeks. Postoperative check-ups were conducted to monitor patient recovery at 48 h, 1 month, and 3, 6, 9, and 15 months after surgery. During the follow-up period, data on the date of visit, anterior chamber depth, IOP, cycloplegic refraction, presence or absence of choroidal detachment, type and number of antiglaucoma medications used, and postoperative complications were recorded. All patients were evaluated under sedation provided by the dedicated sedation department at the KKESH. This department is staffed by a highly trained team of nurses, anesthesiologists, and pediatricians who follow strict protocols and guidelines for administering and monitoring sedation.

Statistical Analysis

Categorical variables are expressed as numbers and percentages; numerical variables are expressed as medians with their respective interquartile ranges [IQR]. Fisher's exact test was used to analyze qualitative variables, and the Wilcoxon–Mann–Whitney test was used to analyze the differences between groups for continuous and non-normally distributed variables. Univariate and multivariate logistic regression analyses were used to evaluate possible correlations between perforation, iris prolapse, iridectomy, IOP, and other clinical and demographic variables. The results are presented as odds ratios (ORs) accompanied by a confidence interval of 95%. A Kaplan–Meier curve determined each group's failure probability. Cox regression with the Breslow test was used to determine the discrepancies between the two groups regarding IOP during the follow-up period. Statistical significance was set at $P < 0.05$.

RESULTS

The study group comprised 74 eyes of 44 patients who underwent deep sclerectomy; 31 eyes (42%) experienced intraoperative perforation. Bilateral deep sclerectomy was performed in 30 patients; five exhibited perforations in both eyes. The cohort comprised 31 perforated and 43 non-perforated eyes. The median [IQR] age was 19 (6–92) days in the perforation group and 37 (12–61) in the control group ($P = 0.91$). The follow-up period was 26 (19–37) months. Fellows operated on 48 eyes (65%); experienced consultants operated on 26 eyes (35%). Demographic and clinical findings are summarized in Table 1. Comparisons between the groups showed no significant differences in sex, affected eye, family history, consanguinity, mitomycin C use, paracentesis, age, horizontal corneal diameter, central corneal thickness, surgeon level, or axial length. In the perforation group, 18 of the 31 eyes (58%) had iris prolapse (Fig. 1). Iris prolapse occurred in 18 of the 31 perforated eyes (58%). We performed iridectomy in 16 eyes and reduced prolapse through

Table 1 Outcomes of primary congenital glaucoma deep sclerectomy: A comparison of demographic and clinical characteristics in cases with and without intraoperative perforation

	Perforation		Non-perforation		Total	*P* value
	Frequency	%	Frequency	%		
Eyes	31	(100)	43	(100)	74	
Gender						
Male	13	(42)	23	(53)	36	0.36
Female	18	(58)	20	(47)	38	
Affected eye						
OD	17	(55)	21	(49)	38	0.64
OS	14	(45)	22	(51)	36	
Family history						
Yes	9	(29)	12	(28)	21	0.59
No	17	(55)	28	(65)	45	
NR	5	(16)	3	(7)	8	
Consanguinity						
Yes	12	(39)	24	(56)	36	0.36
No	5	(16)	5	(12)	10	
NR	14	(45)	14	(32)	28	
Mitomycin						
Yes	31	(100)	42	(98)	73	0.73
No	0	(0)	1	(2)	1	
Paracentesis						
Yes	11	(35)	9	(21)	20	0.21
No	4	(13)	3	(7)	7	
NR	16	(52)	31	(72)	47	
Anterior chamber depth after surgery						
Shallow	1	(3)	0	(0)	1	0.32
Formed	30	(97)	41	(95)	71	
NR	0	(0)	2	(5)	2	
Level of the surgeon						
Fellow	16	(52)	32	(74)	48	0.06
Consultant	15	(48)	11	(26)	26	

Table 1 continued

	Median	[IQR]	Median	[IQR]	*p*-value
Age (days)	19	[6–92]	37	[12–61]	0.91
Age of surgery (days)	53	[43–71]	73	[48–187]	0.23
Horizontal corneal diameter (mm):	12.1	[12–13]	12.5	[12–13]	0.95
Central corneal thickness (microns)	790	[740–847]	750	[700–860]	0.47
Axial length (mm):	21.3	[20.2–21.9]	21	[19.1–22.5]	0.53

OD right eye, *OS* left eye, *NR* not recorded, *IQR* interquartile range

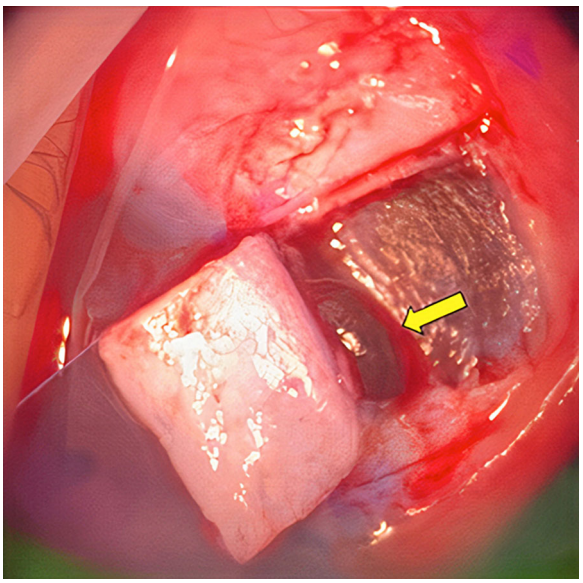

Fig. 1 Iris prolapse through the perforated trabeculodescemetic window during deep sclerectomy. A deep sclerectomy photograph reveals an inadvertent perforation of the trabeculodescemetic window and consequent iris prolapse (indicated by the *yellow arrow*). An irregular iris contour bulging through the perforation indicates the loss of normal anatomy

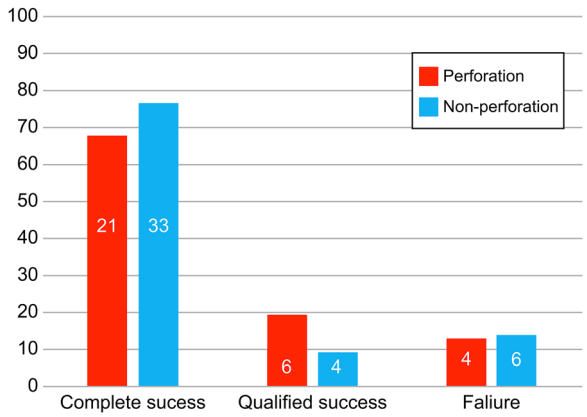

Fig. 2 Outcomes of deep sclerectomy with and without intraoperative perforation. This bar graph shows the percentage of eyes with complete success, qualified success, and failure after deep sclerectomy with and without intraoperative perforation

paracentesis in two eyes. In the perforating group, 68% achieved complete success; 77% achieved the same success rate in the non-perforating group ($P = 0.21$). The qualified success rate was 19% in the perforating group and 9% in the non-perforating group ($P = 0.18$). The failure rate was 13% in the perforating group and 14% in the non-perforating group ($P = 0.53$); no significant differences were observed between the two groups for rates of complete success, qualified success, or failure (Fig. 2).

IOP was measured before and after treatment for the perforating and non-perforating procedures. The baseline IOP in the failure group had the widest distribution. After treatment, the IOP

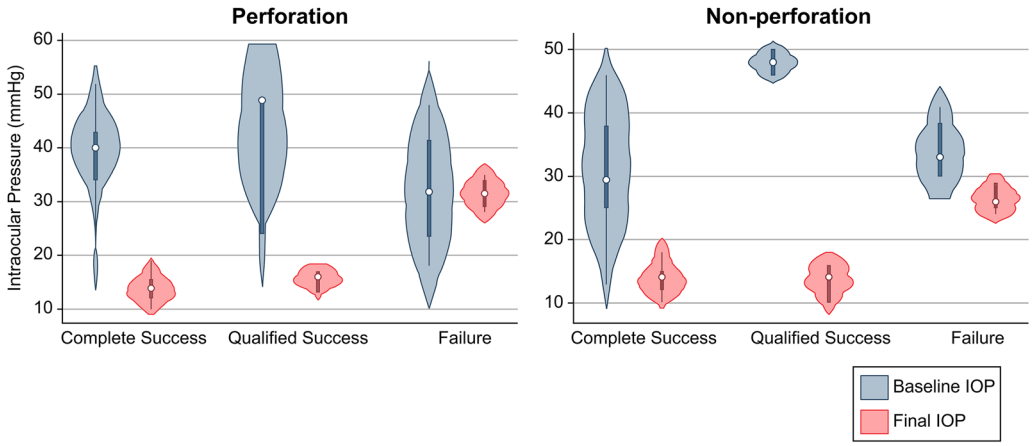

Fig. 3 Effect of perforation on intraocular pressure reduction after deep sclerectomy. This violin plot shows the distribution of baseline and final intraocular pressure (IOP) in eyes undergoing deep sclerectomy with (n = 31) and without (n = 43) intraoperative perforations. The *white dot* represents the median, and the *black bars* indicate the interquartile range

results were more consistent, as depicted by the narrow violin plot. Significant reductions in IOP after surgery were observed in both cohorts in the complete and qualified success groups ($P < 0.001$). Non-perforating procedures reduced IOP more than perforating procedures in the complete success group; these differences were not statistically significant ($P = 0.68$). Both cohorts showed no statistical differences in the baseline and final IOP, except for the baseline IOP in the perforation complete success group, which was greater than that in the non-perforation complete success group ($P = 0.006$). The lowest final IOP was observed with non-perforating procedures for complete success. Perforating and non-perforating IOP changes were comparable in cases of failure. Figure 3 shows the greater IOP reduction for complete and qualified success, with narrower violins showing treatment-normalizing IOP.

IOP measurements and reductions are shown as medians and interquartile ranges for the perforating (n = 31) and non-perforating (n = 43) procedures (Table 2). Non-perforating deep sclerectomy led to greater significant IOP reductions at all visits, with 54–74% lowering versus 46–68% with perforating surgery. The differences between the techniques were significant at the second follow-up ($P = 0.03$) but not others. In both groups, IOP decreased substantially from baseline after treatment ($P < 0.001$) and remained low throughout the follow-up visits. Although an IOP reduction of 2.7 mmHg greater was observed in the non-perforated group compared with the perforated group at 15 months, it was not statistically significant in the primary analysis ($P = 0.12$). Based on post hoc power analysis, our study was likely underpowered to conclude that the observed difference was statistically significant.

No significant association was found between the baseline IOP and the risk of intraoperative perforation (OR 0.95, 95% CI 0.89–1.01, $P = 0.06$). Intraoperative perforation was not significantly associated with IOP levels at the final follow-up visit (adjusted OR 0.95 per mmHg, 95% CI 0.89–1.05, $P = 0.41$). In unadjusted models, no significant link was found between IOP before or after surgery and the chances of perforation, iris prolapse, or the need for iridectomy. The unadjusted model found no evidence that preoperative or postoperative IOP affects the risk of these complications in pediatric glaucoma surgery. None of the p values for IOP were statistically significant (Table 3). For the IOP outcomes in the adjusted models, intraoperative TDW perforation was associated with a greater IOP at the final follow-up (OR 1.29 per mmHg increase, 95% CI 1.01–1.65; P = 0.04). Intraoperative perforation may lead

Table 2 Intraocular pressure changes from baseline at different follow-up times in patients with primary congenital glaucoma who underwent deep sclerectomy

	Perforation (n = 31)				Nonperforation (n = 43)				
IOP (mmHg)	**Median [IQR]**	**Median [IQR] IOP reduction from baseline**	**IOP reduction (%)**	***p* value for changes in IOP after surgery**	**Median [IQR]**	**Median [IQR] IOP reduction from baseline**	**IOP reduction (%)**	***p* value for changes in IOP after surgery**	***p* value for IOP differences between groups**
IOP baseline:	40 [33–45]				35 [25–40]				0.047
IOP 1st follow-up:	12 [8–13]	27 [15–33]	68	< 0.001	12 [10–14]	26 [17–33]	74	< 0.001	0.75
IOP 2nd follow-up:	15 [11–18]	23 [11–32]	58		17 [15–22]	16 [10–21]	46		0.03
up:									
IOP 3rd follow-up:	15 [13–20]	23 [12–29]	58		16 [13–19]	19 [13–24]	54		0.82
IOP 4th follow-up:	15 [13–19]	24 [19–28]	60		14 [12–17]	19 [11–25]	54		0.63
IOP 5th follow-up:	14 [11–17]	27 [15–33]	68		14 [12–18]	17 [9–25]	49		0.45
IOP 6th follow-up:	14 (13–17)	23 [15–29]	58		14 [12–17]	18 [11–25]	51		0.67

IOP intraocular pressure (mmHg), *IQR* interquartile range

Table 3 Intraoperative perforation, iris prolapse, and iridectomy during deep sclerectomy for primary congenital glaucoma: Logistic regression analysis for clinical and demographic factors

IOP baseline	Unadjusted						Adjusted					
	Perforation		Iris prolapse		Iridectomy		Perforation		Iris prolapse		Iridectomy	
	OR (95% CI) 0.95 (0.89–1.01)	***p* value 0.06**	**OR (95% CI) 1.05 (0.97–1.15)**	***p* value 0.22**	**OR (95% CI) 1.07 (0.98–1–17)**	***p* value 0.11**	**OR (95% CI) 0.96 (0.90–1.02)**	***p* value 0.09**	**OR (95% CI) 1.16 (0.95–1.41)**	***p* value 0.14**	**OR (95% CI) 1.29 (1.00–1.67)**	***p* value 0.05**
IOP last follow-up	0.95 (0.89–1.05)	0.41	1.12 (0.97–1.29)	0.11	1.12 (0.97–1.29)	0.11	0.97 (0.87–1.08)	0.49	1.43 (0.95–2.15)	0.09	1.70 (1.04–2.77)	0.06
Region procedence	1.01 (0.87–1.15)	0.97	0.89 (0.68–1.17)	0.40	0.97 (0.75–1.24)	0.80	0.92 (0.77–1.10)	0.47	0.85 (0.50–1.44)	0.53	0.54 (0.25–1.16)	0.11
Age (days)	0.99 (0.99–1.01)	0.23	1.00 (0.99–1–00)	0.81	1.00 (0.99–1.01)	0.88	0.99 (0.99–1.01)	0.27	0.99 (0.99–1.1)	0.31	0.99 (0.98–1.01)	0.10
Sex	0.63 (0.24–1.59)	0.33	3.00 (0.59–15.36)	0.19	1.60 (0.35–7.30)	0.54	0.59 (0.17–2.08)	0.49	2.44 (0.22–27.75)	0.47	1.76 (0.16–19.83)	0.65
Family history	0.76 (0.36–1.57)	0.46	1.25 (0.46–3.38)	0.67	1.05 (0.40–2.79)	0.92	0.78 (0.26–2.34)	0.18	0.87 (0.12–6.33)	0.89	0.47 (0.05–3.96)	0.48
Consanguinity	0.70 (0.42–1.17)	0.18	1.59 (0.68–3.74)	0.28	1.11 (0.50–2.47)	0.81	0.81 (0.40–1.65)	0.57	2.91 (0.33–25.38)	0.33	3.15 (0.34–29.39)	0.31

OR (95%CI) odds ratio with 95% confidence interval, *IOP* intraocular pressure

to greater resistance to aqueous outflow over time, resulting in greater IOP at the final postoperative visit.

The last follow-up showed no significant connection between patients who had undergone iridectomy and those with greater IOP (OR 1.70, $P = 0.06$). No other baseline factors were significantly associated with surgical complications. Overall, the results suggest that greater pre- and postoperative IOP may increase the chances of requiring iridectomy when performing glaucoma surgery in pediatric patients.

In the Kaplan–Meier survival analysis (Fig. 4), non-perforating surgery showed a slightly greater probability of achieving a low IOP than perforating surgery at all time points. However, the difference between the survival curves was not statistically significant based on the Cox regression Breslow test ($P = 0.67$). Sixty-eight eyes (92%) showed no complications. During the procedure, four eyes (5%) had corneal perforation during traction suture placement. In addition, we noted one TDW was perforated with a cautery tip and one superficial flap buttonhole. In the immediate postoperative period, one eye (1%) in the perforation group presented with a shallow anterior chamber.

DISCUSSION

Inadvertent macroperforation of the TDW during deep sclerectomy did not significantly affect IOP outcomes compared to non-perforated procedures. Both perforated and non-perforated deep sclerectomies were effective in reducing IOP.

Consistent with the findings of AlDarrab et al. and Elhofi et al., we found the IOP decreased after perforation. Notably, no significant differences were observed in IOP values between the perforation and non-perforation cohorts during NPDS [32, 33]. Kalala et al. reported that the perforating deep sclerectomy technique yielded results similar to those of traditional NPDS regarding efficacy and safety [27].

Our study found similar IOP values between the perforated and non-perforated groups. The discrepancy in baseline IOP between the perforation and non-perforation complete success groups was minimal, possibly attributed to the sample size or selection. The mechanisms involved in deep sclerectomy are intricate and exceed the scope of TDW. After the aqueous humor flows through the TDW, it collects in a scleral lake under the superficial scleral flap at the sclerectomy site. This scleral reservoir, which is an artificial space, may function as the first intrascleral filtration bleb [27]. ElSayyad et al. reported that some aqueous humor enters the suprachoroidal space, passes through the subconjunctival pathway, and reaches the filtration bleb [34]. A scleral flap can help regulate the aqueous outflow by providing resistance [35]. Episcleral venous drainage, conjunctival bleb, scleral channels, and suprachoroidal filtration are potential mechanisms for lowering IOP.

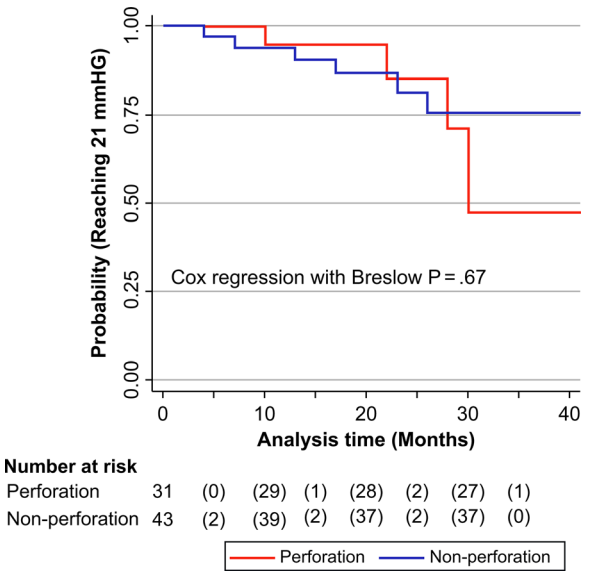

Fig. 4 Effect of perforation on time to reach target IOP after deep sclerectomy. The Kaplan–Meier survival curve in this study compared the time required to reach a target IOP of ≤ 21 mmHg between patients who underwent deep sclerectomy with intraoperative perforation ($n = 31$) and those who did not ($n = 43$). The number of patients at risk in each group at various time points is shown below the x-axis, and the probability of reaching the target IOP over time is plotted for each group

Over time, internal drainage pathways, including the intrascleral, TM, and suprachoroidal pathways, significantly reduce IOP. These pathways help regulate aqueous outflow resistance [36]. Deep sclerectomy reduces IOP by opening multiple channels for aqueous outflow. Even with a full-thickness opening of the TDW, the layered architecture of deep sclerectomy allows outflow through alternative routes. This architecture may explain why IOP reduction was similar between the perforated and non-perforated groups, even when the scleral flap was closed after perforation. The blended approach of macroperforation with iridectomy and tight flap closure preserves the architecture of deep sclerectomy, which may help avoid complications such as hypotony that can occur with trabeculectomy. This combined procedure may optimize safety and IOP reduction when managing intraoperative perforations. However, further research is needed to determine the ideal balance of techniques to maximize efficacy while minimizing adverse events.

The surgery outcome did not demonstrate any statistically significant difference regarding perforation ($P = 0.06$), regardless of whether it was performed by a fellow or expert; most procedures were conducted by fellows under close supervision. This finding is consistent with previous research, suggesting that surgeon experience is not associated with the outcomes of this procedure and may challenge the commonly held belief that difficulties are inevitable while learning NPDS with appropriate supervision [16].

Unlike adult procedures, our pediatric deep sclerectomy study did not involve intentional SC peeling. The nearly full-thickness dissection of the deep scleral flap may bypass the need to expose the SC separately. In children, the extreme thinness of the ocular tissues could allow deep flap creation alone to open the canal, precluding further manual peeling. We did not visualize an intact canal roof during surgery. The substantial flap dissection depth in pediatric eyes may eliminate the requirement for manual canal deroofing, which is typical in adults. Further research should investigate whether pediatric deep sclerectomy requires less canal manipulation because of deep flap formation and tissue thinness.

The most frequent complication during the surgery was corneal perforation at the time of traction suture placement. Viscoelastic use in the anterior chamber did not affect the final IOP in either group. This avoidable complication is common in surgeons with less experience with learning curves. Careful observation of the needle during the corneal passage, good magnification, and practice in wet-lab sessions can be beneficial to circumvent this unnecessary complication. No complications typically associated with trabeculectomy were observed during the procedure, including hyphema, choroidal, or retinal detachment.

One patient had a shallow anterior chamber in the immediate postoperative period. Despite TDW perforation, the safety profile of NPDS, as established in this study, is at least comparable to and likely superior to trabeculectomy. Our results indicate that deep sclerectomy is effective for reducing IOP in children with PCG, even if it results in intraoperative TDW macroperforation. Surgeons can proceed with deep sclerectomy as planned, even if inadvertent perforation occurs. The low complication rate after perforated deep sclerectomy suggests that it may be safer than trabeculectomy when managing intraoperative TDW macroperforations during pediatric glaucoma surgery. Therefore, deep sclerectomy can be considered a viable alternative to trabeculectomy. In summary, this study suggests that deep sclerectomy is effective and safe for reducing IOP in patients with PCG, even if it results in perforation.

Limitations

This study had a small sample size, but power analysis showed the ability to detect significant differences. The sample size was one of the largest for this rare population, given the scarcity of PCG and perforation after NPDS. This study provides valuable insights into the outcomes of this rare population, for which large, controlled, multicenter trials are unlikely. Standardized data collection was implemented to minimize potential biases, and systematic inclusion/

exclusion criteria were applied to improve comparability. The study was from a single center, and multiple surgeons performed the procedure, limiting the generalizability of the results. Causality cannot be determined from association-based retrospective analyses, and these biases and limitations were considered when interpreting the results.

CONCLUSIONS

This investigation highlights that NPDS effectively decreases IOP in perforation and non-perforation groups of patients with PCG. Although differences in baseline IOP existed between the two groups, the variations in IOP and percentage reductions from baseline were comparable across the multiple follow-up periods. This finding supports that NPDS is a plausible and safe treatment option for reducing IOP in patients with PCG, regardless of whether perforation occurs.

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Data Availability. The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Conflict of Interest. Abdulaziz AlQattan, Konrad Schargel, Ibrahim AlJadaan, Nouf AlZendi, and Gorka Sesma declare that they have no competing interests.

Ethics Approval. This study was performed in accordance with the Helsinki Declaration of 1964 and its later amendments, and was approved by the Institutional Review Board of King Khaled Eye Specialist Hospital (Protocol RP 23032-R). The requirement for informed consent was waived by the institutional review board as this is a retrospective study using de-identified data from existing medical records.

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