Three-Year Efficacy and Safety of the PAUL Glaucoma Implant

Eficácia e Segurança a 3 Anos do Dispositivo de Drenagem Posterior PAUL

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ABSTRACT

INTRODUCTION: PAUL glaucoma implant is a non-valved posterior drainage device with a smaller lumen tube compared with classical alternatives. This study aimed to determine the 3-year efficacy and safety of the PAUL glaucoma implant.

METHODS: Retrospective cohort study. Consecutive patients implanted with a PAUL Glaucoma Implant between December 2018 and August 2020, with a minimum follow-up period of 36 months, were included. The clinical data were acquired from the patients' records. The primary outcome was the reduction in intraocular pressure (IOP) at 36 months, with surgical success defined as ≤18 mmHg and >5 mmHg plus ≥30% drop in IOP from baseline. Failure was defined as not reaching the criteria for success for two consecutive observations after 3 months of follow-up, need for surgical intervention, or significant vision loss. Safety outcomes were also analyzed. A standardized surgical protocol was followed in all cases, which included augmentation with mitomycin C (0.4 mg/mL) and tube ligation with a polyglactin suture.

RESULTS: A total of 27 eyes from 23 patients met the inclusion criteria. Both adult and pediatric forms of glaucoma were included. The mean age at the time of surgery was 36.1±27.5 (5 months - 76 years) years. Two-thirds (n=18) had a history of previous glaucoma surgery. IOP showed a statistically significant reduction at month 36 compared to baseline IOP [preoperative IOP: 30.4±10.5 *vs* postoperative M36 IOP: 13.7±4.7 mmHg; $p<0.001$]. Surgical success was achieved in 66.6% of cases at 36 months. There was also a statistically significant reduction in preoperative medications from 2.8±1.4 to 1.0±0.9 ($p<0.001$). During the follow-up period, persistent hypotony requiring surgical intervention was observed in 1 patient. Revision surgery was necessary in 5 patients (18.5%).

CONCLUSION: The PAUL glaucoma implant is a novel posterior drainage device that shows efficacy and acceptable safety in the long-term treatment of refractory glaucoma.

KEYWORDS: Filtering Surgery; Glaucoma Drainage Implants; Glaucoma/surgery; Intraocular Pressure.

RESUMO

INTRODUÇÃO: O implante de glaucoma PAUL é um dispositivo de drenagem posterior não valvulado com um tubo de menor diâmetro que os tubos de outros dispositivos semelhantes. O objetivo deste estudo foi determinar a eficácia e segurança do implante de glaucoma PAUL a 3 anos.

MÉTODOS: Estudo coorte retrospetivo. Foram incluídos doentes operados entre Dezembro de 2018 e Agosto de 2020, com um *follow-up* mínimo de 36 meses. Os dados clínicos foram retirados dos processos dos doentes. O *outcome* primário consistiu na redução da pressão intraocular (PIO) aos 36 meses, com sucesso cirúrgico definido como PIO ≤18 mmHg e >5 mmHg, e redução de ≥30%. Falência definiu-se como não atingimento dos critérios de sucesso em duas observações consecutivas após 3 meses da cirurgia, necessidade de nova intervenção cirúrgica, ou perda de visão significativa. Foram também analisados *outcomes* de segurança. Foi seguido um protocolo cirúrgico padronizado que incluiu o uso de mitomicina C (0,4 mg/mL) e uma sutura de restrição de poliglactina em redor do tubo.

RESULTADOS: Um total de 27 olhos de 23 doentes cumpriram os critérios de inclusão. Foram incluídas formas adultas e pediátricas de glaucoma. A média de idade na altura da cirurgia foi de 36,1±27,5 (5 meses - 76 anos) anos. Dois terços (n=18) tinham antecedentes de cirurgia de glaucoma. A PIO teve uma redução estatisticamente significativa ao mês 36 comparado com a PIO *baseline* [PIO pré-operatória: 30,4±10,5 *vs* PIO pós-operatória M36: 13,7,0±4,7 mmHg; p<0,001]. Atingiu-se o sucesso cirúrgico em 66,6% dos casos aos 36 meses. Houve também uma redução estatisticamente significativa na medicação hipotensora de 2,8±1,4 para 1,0±0,9 (p<0,001). Durante o período de *follow-up*, um doente apresentou hipotonia persistente com necessidade de intervenção cirúrgica. Em 5 doentes (18,5%) foi necessária cirurgia de revisão.

CONCLUSÃO: O implante de glaucoma PAUL é um dispositivo de drenagem posterior recente que aparenta ser eficaz e com perfil de segurança aceitável para o tratamento a longo prazo de glaucoma refractário.

PALAVRAS-CHAVE: Cirurgia Filtrante; Glaucoma/cirurgia; Implantes para Drenagem de Glaucoma; Pressão Intraocular.

INTRODUCTION

Glaucoma is one of the leading causes of irreversible blindness worldwide and its global prevalence is expected to increase significantly due to the rising life expectancy and an aging population.[1] The most well-known and treatable risk factor is the intraocular pressure (IOP). In the last years, there has been a substantial rise in the utilization of glaucoma drainage devices (GDDs) for managing medically and/or surgically uncontrolled glaucoma.[2–5] GDDs share a common design consisting of a tube that is inserted into the anterior chamber through a scleral fistula, which shunts aqueous humor to a fenestrated end plate in subconjunctival space. These implants vary in terms of the end plate and lumen size and material composition, along with whether or not they incorporate a valve to limit the flow of aqueous humor. The two implants most commonly used and studied are the Ahmed glaucoma valve® (AGV) (New World Medical, Rancho Cucamonga, CA) and the Baerveldt glaucoma implant® (BGI) (Johnson & Johnson, Santa Ana, CA).[6–10] Recently, the spectrum of surgical options widened with the new PAUL® glaucoma implant (Advanced Ophthalmic Innovations, Singapore, Republic of Singapore). The PAUL® glaucoma implant (PGI) is a non-valved posterior drainage device with a smaller lumen tube compared with classical alternatives (127 μm; a third of the BGI's lumen), in an effort to improve safety. Until now, there have been some relatively short follow-up studies that yielded positive results.[11–16] To our knowledge, this is the first study at 3 years. This study also extends the findings of the prior research, which assessed the outcomes of PGI after one year (Patrícia José, *et al*, 2022).[12]

The aim of this study was to determine the 3-year efficacy and safety of the PAUL glaucoma implant using a uniform, standardized surgical procedure.

METHODS

Retrospective cohort study. Consecutive patients from 2 surgical centers - Hospital de Santa Maria (HSM) and Hospital Lusíadas de Lisboa (HLL) - implanted with a PGI between December 2018 and August 2020 with a minimum follow-up period of 36 months were included. Exclusion criteria for analysis were: pregnancy or breastfeeding, com-

bination with cataract surgery and lost to follow-up within 36 months. All surgeries were performed by the same glaucoma surgeons (L.A.P. and A.D.B.), using a standardized surgical protocol in both settings.

This study adhered to the tenets of the Declaration of Helsinki and all patients provided written informed consent for data retrieval as per the General Data Protection Regulation.

Demographic and ocular data were retrieved from the patient's clinical records. Baseline data included glaucoma type, previous ophthalmologic surgeries, best-corrected visual acuity (BCVA) in the logarithm of minimum angle of resolution (LogMAR), intraocular pressure (IOP) measured by Goldmann applanation tonometry and the number of preoperative hypotensive medications. IOP and the number of medications were noted on days 1 and 7; at months 1, 3, 6, 9, 12, 18, 24, and 36 after surgery. Safety parameters included intraoperative and postoperative complications. When required, visual acuity was converted between Snellen and logMAR using standardized conversion tables.

STUDY DEVICE

The PAUL® glaucoma implant (Advanced Ophthalmic Innovations, Singapore, Republic of Singapore) is a non-valved silicone GDD. Its endplate is 0.4 mm thick, has a length of 16.1mm, a width of 21.9 mm and an area of 342 mm^2. Its tube has an inner diameter of 127 µm and an outer diameter of 467 µm.

SURGICAL TECHNIQUE

Surgeries were conducted using sub-Tenon, retrobulbar, or general anesthesia, depending on the individual patient's health status. The same surgical protocol was applied consistently across all cases in both surgical centers, carried out by the same surgical team. A 7-0 silk corneal traction suture was placed at the corneal superotemporal quadrant 1 mm from the limbus. A fornix-based conjunctival flap was created, the sub-Tenon's space was dissected and wet-field cautery of the scleral bed was performed as needed. The PGI endplate was implanted 8 to 10 mm posterior to the limbus, with the lateral wings tucked under the superior and lateral rectus muscles, and sutured to the sclera using two separate 8-0 nylon sutures. Sponges soaked in MMC (0.4 mg/mL) were applied within the sub-Tenon's space over the PGI plate for 90 seconds, followed by thorough saline rinsing. A corneal paracentesis was made using a 15-degree blade, and an ocular viscoelastic device (1% sodium hyaluronate) was used to deepen the anterior chamber (AC). A 25-gauge needle was used to create a scleral tunnel starting 2 mm from the limbus, allowing entry into the AC parallel to the iris plane. The tube was trimmed to an appropriate length and inserted into the AC with the bevel facing upward. A single 7-0 vicryl ligature suture was tied around the tube to achieve complete collapse and prevent postoperative hypotony. Vicryl loses its tensile strength over time, and the duration of its effect was expected to be approximately 1 month until the bleb begins to mature.[17] No ripcord was used. A patch of bovine pericardium (Tutopatch, Tutogen Medical, Bavaria, Germany) or a donor corneal graft (if available) was used to cover the exposed tube. The conjunctiva and Tenon's were sutured at the limbus using two 7-0 vicryl sutures. The AC was rinsed to remove the ocular viscoelastic device and replaced with a balanced salt solution. All patients were instructed to suspend hypotensive medication postoperatively and were started on antibiotic and steroid drops (Tobradex, Novartis, Basel, Switzerland) 4 times a day with gradual tapering over 4 to 6 weeks.

OUTCOMES

Primary outcome was to analyze the absolute and qualified surgical success rate of the PGI at 36 months. Secondary outcomes included safety parameters (intraoperative and postoperative complications).

Surgical success was defined as ≤18 mmHg and >5 mmHg plus ≥30% drop in IOP from baseline, following the recommendations outlined in the World Glaucoma Association's (WGA) Guidelines on Design and Reporting of Surgical Trials.[18] Absolute success if target IOP without hypotensive therapy. Qualified success was achieved when the target IOP was achieved with the use of adjunctive medication. Failure was defined as not reaching the criteria for success for two consecutive observations after 3 months of follow-up, need for further surgical intervention, or significant vision loss (2 or more Snellen chart lines or loss of light perception). Subconjunctival needling was not a criterion for surgical failure.

Postoperative complications evaluated included hypotony requiring intervention, choroidal detachment, hyphema, tube occlusion, tube extrusion, strabismus, cataract, and endophthalmitis.

STATISTICAL ANALYSIS

Demographics and clinical characteristics were presented using the mean (standard deviation) or median (interquartile range: 25th percentile-75th percentile) for quantitative variables and frequencies (percentages) for categorical variables. To compare IOP values between the baseline and 36-month visits, the Wilcoxon matched-pairs signed rank test was used. Kaplan-Meier survival analysis was employed to evaluate the probability of survival. A significance level of p=0.05 was considered. The data analysis was carried out using GraphPad version 10.0 (Dotmatics).

RESULTS

A total of 31 eyes from 27 patients achieved a minimum of 36 months since surgery. Of these, follow-up was lost in 4 cases (1 due to death and 3 due to abandonment), resulting in the inclusion of 27 eyes from 23 patients in the statistical analysis. Demographic data and overall baseline characteristics are listed in Table 1. In our study, both adult

Table 1. Baseline Characteristics of Participating Eyes.

Demographic and Ocular Characteristics	Data (n=27)
Male sex, n (%)	12 (52.2)
Age, mean (SD) Min – Max	36.1 (27.5) 5 months – 76 years
Right Eye, n (%)	12 (44.4)
IOP, mean (SD), mmHg	30.4 (10.5)
Visual acuity, median (P25-P75), logMar	0.69 (0.26-1.00)
Visual field MD, mean (SD), dBa	20.2 (6.3)
No. of preoperative topical medication, mean (SD)	2.8 (1.4)
Oral acetazolamide, n (%)	9 (33.3)
Previous surgeries, n (%) Cataract Vitrectomy Phakic intraocular lens explantation	 14 (51.8) 1 (3.8) 3 (11.1)
Diagnosis, n (%) Primary open-angle glaucoma Congenital/juvenile glaucoma Aphakic glaucoma Neovascular glaucoma Secondary open-angle glaucoma Uveitic glaucoma Pseudoexfoliation syndrome Due to ocular surgery FAP glaucoma	 2 (7.4) 10 (37.0) 2 (7.4) 3 (11.1) 10 (37.0) 4 (40.0) 2 (20.0) 3 (30.0) 1 (10.0)
Previous glaucoma procedures, n (%) Trabeculotomy Glaucoma drainage device Ahmed glaucoma valve Baerveldt glaucoma implant Trabeculectomy Preserflo Microshunt	18 (66.6) 7 (38.8) 4 (22.2) 3 (16.6) 1 (5.5) 6 (33.3) 1 (5.5)

a - Adults, MD

FAP - familial amyloid polyneuropathy; IOP - intraocular pressure; MD - mean deviation; P25 - 25th percentile; P75 - 75th percentile.

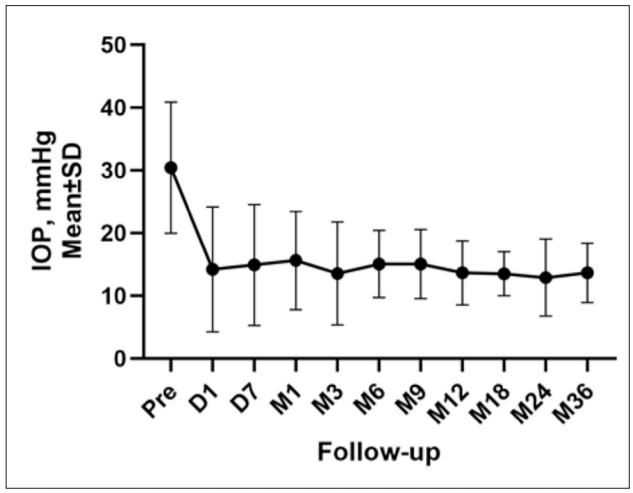
and pediatric forms of glaucoma were included (5 months - 76 years). Two-thirds of eyes (n=18, 66.7%) had a history of previous glaucoma surgery. The study population consisted of individuals with moderate to severe glaucoma, as evidenced by the mean visual field MD (n=14, 20.2±6.3 dB)

OUTCOMES

IOP showed a statistically significant reduction at month 36 compared to baseline [preoperative IOP: 30.4±10.5 *vs* postoperative M36: 13.7.0±4.7 mmHg; $p<0.001$]. Surgical success was achieved in 18 eyes (66.6%) at 36 months. Among these eyes, 7 (25.9%) met the absolute success criteria and 11 (40.7%) met the qualified success criteria. Failure criteria were observed in 9 eyes (33.3%). The causes of failure were: Surgical intervention (n=5), IOP above target (n=3), and loss of light perception (n=1). The number of hypotensive medications showed a statistically significant reduction compared with the preoperative status [preoperative mean 2.8±1.4 *vs* postoperative 1.0±0.9 ($p<0.001$)].

Fig. 1 summarizes IOP and the number of topical medications during follow-up.

Eleven (40.7%) eyes experienced a hypertensive phase (IOP>21 mmHg during the first 3 months) and required topical hypotensive treatment. Most of these eyes (n=7, 63.6%) ultimately achieved qualified success, as it was not possible to reduce their medication. Medication was able to be discontinued in two eyes (Absolute success) and the other two ended up failing (Surgical revision).



	Pré n=27	D1 n=25	D7 n=24	M1 n=25	M3 n=26	M6 n=25	M9 n=22	M12 n=27	M18 n=22	M24 n=22	M36 n=22
PIO, mean (SD), mmHg	30.4 (10.5)	14.2 (9.9)	14.9 (9.6)	15.6 (7.8)	13.6 (8.2)	15.1 (5.3)	15.1 (5.5)	13.7 (5.1)	13.5 (3.5)	12.9 (6.1)	13.7 (4.7)
Med, mean (DP)	2.8 (1.4)	0.0 (0.0)	0.1 (0.5)	0.8 (0.9)	1.0 (1.0)	0.8 (1.0)	1.0 (1.1)	1.2 (1.0)	1.3 (0.9)	1.1 (0.9)	1.0 (0.9)

IOP - Intraocular pressure; Med - number of topical medication.

Figure 1. Intraocular pressure and IOP-lowering medication throughout follow-up.

On further analysis, the type of glaucoma and previous glaucoma surgery were not associated with failure criteria ($p>0.999$).

Fig. 2 depicts the Kaplan-Meier cohort survival curves throughout the 36-month period.

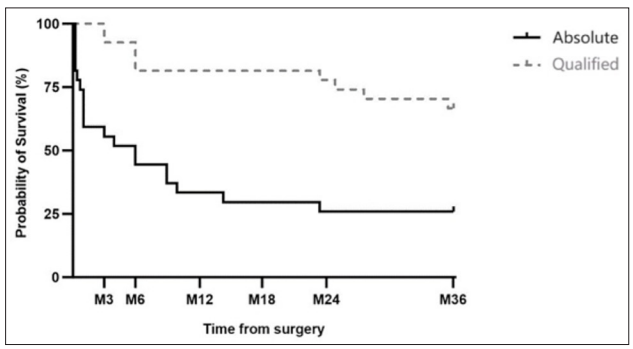


Figure 2. Kaplan-Meier survival curves estimates - qualified and absolute success.

SURGICAL COMPLICATIONS

In terms of intraoperative complications, we recorded a single case of hyphema with spontaneous resolution in the following weeks. The most common postoperative complication was tube occlusion (n=3, 11.1%) caused by tube synechiae in two patients and fibrous tissue ingrowth in

one patient. Milder complications included temporary strabismus (n=1, 3.7%) and hyphema (n=1, 3.7%). Two cases of choroidal detachments were observed, one self-resolving and one where persistent hypotony needed surgical intervention. No cases of early postoperative hypotony requiring intervention were observed. In phakic patients, cataract requiring surgical intervention was observed in 3 patients (23.1%). Table 2 shows intraoperative and postoperative complications.

Table 2. Intraoperative and Postoperative Complications During Follow-up (36M).

	Data (n=27)
Intraoperative, n (%)	
Anesthetic/systemic complications	0
Hyphema	1 (3.7)
Postoperative, n (%)	
Choroidal detachment	2 (7.4)
Hypotony requiring intervention	1 (3.7)
Hyphema	1 (3.7)
Temporary Strabismus	1 (3.7)
Iris synechiae around the tube	2 (7.4)
Fibrous tissue ingrowth	1 (3.7)
Tube extrusion	1 (3.7)
Endophthalmitis	0
Cataract requiring surgery/phakic eyes	3/13 (23.1)
Loss of light perception	1 (3.7)

In 5 patients (n=18.5%) revision surgery was necessary. The reasons for revision were tube occlusion (n=2), tube repositioning (n=1), tube extrusion (n=1), and inability to achieve medical control of ocular hypertension (n=1). Tube repositioning was needed because of subluxation of endplate. Table 3 depicts postoperative interventions.

Table 3. Postoperative interventions.

	Data (n=27)
Surgical intervention, n (%)	
Needling	1 (3.7)
Revision	4 (14.8)
PGI explantation	1 (3.7)
Additional glaucoma surgery	1 (3.7)
Vitrectomy because of choroidal detachment	1 (3.7)
Penetrating keratoplasty	1 (3.7)
Cataract Ssurgery (in phakic eyes)	3 (23.1)

DISCUSSION

In this study, we evaluated the efficacy and safety profile of PGI over a 3-year period in patients with moderate to severe glaucoma. To date, only a limited number of studies have been published regarding the results of PGI. To our knowledge, our study is the first one to report on 3-year outcomes.

In this study involving 27 eyes with PGI, 9 eyes (33.3%) fulfilled the failure criteria, 7 eyes (25.9%) fulfilled the absolute success criteria and 11 eyes (40.7%) fulfilled the qualified success criteria. The closest follow-up study published is at the 2 years mark and only included adults.[13] They described a lower failure rate (17.8%) and higher absolute success (71.1%). Our study showed worse results, but it is common to all studies of GDDs that, over time a reduced success is seen, and the need for adjunctive medication increases.[19,20] Furthermore, it's important to note that in that study, a significant (64.0%) proportion of patients had a preoperative IOP <21 mmHg and there were fewer previous glaucoma surgeries (24.4%). Compared with our study, where only 2 patients (7.4%) had IOP values below that threshold and the majority (66.7%) had a history of prior glaucoma surgery.

The causes of failure were the need for surgical revision (18.5%) and IOP above target (11.1%). Only one patient experienced loss of light perception. This case was an aggressive neovascular glaucoma with a baseline visual acuity of "hand motion". At 1 year after PGI implantation, there was persistent hypotony with choroidal detachment that required a pars plana vitrectomy and resulted in loss of light perception.

The mean IOP at 3 years was 13.7±4.7 mmHg, a statistically significant reduction compared to the baseline IOP of 30.4±10.5 mmHg. Likewise, there was a significant reduction in the mean number of IOP-lowering drugs from 2.8±1.4 to 1.0±0.9 at 3 years. Compared with the aforementioned study, the IOP values are similar (13.9±3.7 mmHg at 2 years), indicating a probable similarity in the overall efficacy profile. The mean number of medications is higher in our study (1.0±0.9 *vs* 0.3±0.7), which is reasonable because of the different follow-up periods.

Noteworthy complications that happened in our study were tube occlusion in 3 patients (11.1%) due to synechiae or fibrous tissue ingrowth, persistent hypotony that required pars plana vitrectomy (1 patient, 3.7%), and tube extrusion that required explantation of the PGI (1 patient, 3.7%). In this patient, the PGI was removed and a Preserflo microshunt was implanted in the superior-nasal quadrant. Out of the three patients with tube occlusion, two patients required surgical revision due to lumen blockage caused by fibrous tissue. The other case resolved spontaneously. In comparison with Tan MC *et al*,[13] we recorded fewer hypotony-related complications (3.7% *vs* 8.9%) and had higher tube rate occlusion events (11% *vs* 8.9%).

In our study, we employed a standardized surgical approach to minimize the variability of results caused by different techniques. Our protocol included augmentation with MMC (0.4 mg/mL) and tube ligation using a 7-0 vicryl ligature suture halfway around the tube as an added flow-restrictive measure. MMC is used to inhibit fibroblast proliferation and minimize fibrovascular scarring. Although its application on GDD surgery lacks comprehensive evidence-based support,[21,22] we used it in all cases due to the fact that these GDD candidates face a heightened risk of surgical failure and have a lower IOP target. Even more in pediatric eyes, where aggressive healing response is believed to be a contributing factor to the lower success rates compared to adults.

An important concern of GDDs is endothelial damage and corneal decompensation. The PGI, due to its smaller external tube diameter, occupies less space in the anterior chamber angle, enhancing the likelihood of a correct positioning away from the endothelium. This concern is imperative in the pediatric population, where the safety of GDDs is of utmost importance due to longer life expectancy. Recent studies have shown good results in the pediatric pop-

ulation.[15] In our study, one patient required a penetrating keratoplasty, albeit due to previous corneal pathology and probably not directly related to endothelial loss from PGI.

While this was not a comparative study, it holds clinical significance to recognize the present benchmark when evaluating our data. At the same follow-up time (36 months), comparing PGI with AGV FP7 and BGI 350 in the ABC study,[7] the mean IOP and glaucoma medications (meds) were 14.4 ± 4.7 mmHg with 2.0 ± 1.4 meds (AGV) and 13.1 ± 4.5 mmHg with 1.5 ± 1.4 meds (BGI). Therefore, PGI achieved a mean IOP between AGV and BGI with fewer IOP-lowering drugs required. Comparing the long-term success and failure rate of PGI at 3 years with AGV FP7 and BGI 350 at 5 years, the failure rate was 44.7% (AGV) and 39.4% (BGI); the qualified success was 38% for both AGV and BGI and absolute success was 8% (AGV) and 14% (BGI). Taking into account the disparities in follow-up time and differences in study methodology, data suggest PGI may be able to deliver similar long-term outcomes. Supporting this hypothesis is the fact that in our study, we followed more strict failure criteria, complying with the WGA guidelines,[18] compared with the ABC study. Regarding safety profile, we recorded a similar rate of serious complications (reoperation and/or vision loss) compared to the ABC study (PGI 22.2%; AGV 15.9%; BGI 24.7%).[8]

This study has several limitations. First, our findings rely on retrospective data. Second, it consists of a relatively small sample, where outliers can significantly influence the results and could have impacted our ability to detect significant factors associated with failure. Thirdly, we included both adult and pediatric forms of glaucoma. Although we have confidence that it represents real-world data and clinical practice, there are differences in glaucoma behavior and it increases the heterogeneity of PGI results.

Furthermore, even though we did not record any case of corneal decompensation, there was no data available on preoperative endothelial cell count. The loss of endothelial cells is crucial in assessing long-term complications of GDD surgery, and clinical studies of this nature recommend preoperative cell count measurements. Additional research with a long-term prospective and randomized design is required to thoroughly compare the PGI with other GDDs.

CONCLUSION

The PAUL implant is a novel posterior drainage device that shows efficacy and acceptable safety in the long-term treatment of refractory glaucoma.

CONTRIBUTORSHIP STATEMENT / DECLARAÇÃO DE CONTRIBUIÇÃO

BGD: Conceptualization, methodology, data collection, analysis and interpretation, original draft preparation, editing.

PJ, DBM: Conceptualization, methodology, data collection, critical review of the contente.

RCB: Conceptualization, methodology, data analysis, critical review of the content, editing, project supervision.

LAP: Conceptualization, critical review of the content, editing, project supervision

ADB: Conceptualization, critical review of the content, editing, project supervision, project administration.

All authors approved the final version to be published.

BGD: Conceitualização, metodologia, recolha de dados, análise e interpretação, preparação do rascunho original, edição.

PJ, DBM: Conceitualização, metodologia, recolha de dados, revisão crítica do conteúdo.

RCB: Conceitualização, metodologia, análise de dados, revisão crítica do conteúdo, edição, supervisão do projeto.

LAP: Conceitualização, revisão crítica do conteúdo, edição, supervisão do projeto.

ADB: Conceitualização, revisão crítica do conteúdo, edição, supervisão do projeto, administração do projeto.

Todos os autores aprovaram a versão final a ser publicada.

RESPONSABILIDADES ÉTICAS

Conflitos de Interesse: Os autores declaram a inexistência de conflitos de interesse na realização do presente trabalho.

Fontes de Financiamento: Não existiram fontes externas de financiamento para a realização deste artigo.

Confidencialidade dos Dados: Os autores declaram ter seguido os protocolos da sua instituição acerca da publicação dos dados de doentes.

Proteção de Pessoas e Animais: Os autores declaram que os procedimentos seguidos estavam de acordo com os regulamentos estabelecidos pela Comissão de Ética responsável e de acordo com a Declaração de Helsínquia revista em 2024 e da Associação Médica Mundial.

Proveniência e Revisão por Pares: Não comissionado; revisão externa por pares.

ETHICAL DISCLOSURES

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Protection of Human and Animal Subjects: The authors declare that the procedures followed were in accordance with the regulations of the relevant clinical research ethics committee and those of the Code of Ethics of the World Medical Association (Declaration of Helsinki as revised in 2024).

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REFERENCES

1. Tham YC, Li X, Wong TY, Quigley HA, Aung T, Cheng CY. Global Prevalence of Glaucoma and Projections of Glaucoma Burden through 2040: a systematic review and meta-analysis. Ophthalmology. 2014;121:2081-90. doi:10.1016/j.ophtha.2014.05.013
2. Desai MA, Gedde SJ, Feuer WJ, Shi W, Chen PP, Parrish RK. Practice Preferences for Glaucoma Surgery: A Survey of the American Glaucoma Society in 2008. Ophthalmic Surgery, Lasers, and Imaging. 2011;42:202-8. doi:10.3928/15428877-20110224-04
3. Rathi S, Andrews CA, Greenfield DS, Stein JD. Trends in Glaucoma Surgeries Performed by Glaucoma Subspecialists versus Nonsubspecialists on Medicare Beneficiaries from 2008 through 2016. Ophthalmology. 2021;128:30-8. doi:10.1016/j.ophtha.2020.06.051
4. Vinod K, Gedde SJ, Feuer WJ, Panarelli JF, Chang TC, Chen PP, et al. Practice Preferences for Glaucoma Surgery: A Survey of the American Glaucoma Society. J Glaucoma. 2017;26:687-93. doi:10.1097/IJG.0000000000000720
5. Yang SA, Mitchell W, Hall N, Elze T, Lorch AC, Miller JW, et al. Trends and Usage Patterns of Minimally Invasive Glaucoma Surgery in the United States. Ophthalmol Glaucoma. 2021;4:558-68. doi:10.1016/j.ogla.2021.03.012
6. Barton K, Gedde SJ, Budenz DL, Feuer WJ, Schiffman J. The Ahmed Baerveldt Comparison Study. Ophthalmology. 2011;118:435-42. doi:10.1016/j.ophtha.2010.07.015
7. Budenz DL, Barton K, Gedde SJ, Feuer WJ, Schiffman J, Costa VP, et al. Five-Year Treatment Outcomes in the Ahmed Baerveldt Comparison Study. Ophthalmology. 2015;122:308-16. doi:10.1016/j.ophtha.2014.08.043
8. Budenz DL, Feuer WJ, Barton K, Schiffman J, Costa VP, Godfrey DG, et al. Postoperative complications in the Ahmed Baerveldt comparison study during five years of follow-up. Am J Ophthalmol. 2016;163:75-82.e3. doi:10.1016/j.ajo.2015.11.023
9. Christakis PG, Kalenak JW, Tsai JC, Zurakowski D, Kammer JA, Harasymowycz PJ, et al. The Ahmed Versus Baerveldt Study: Five-Year Treatment Outcomes. Ophthalmology. 2016;123:2093-102. doi: 10.1016/j.ophtha.2016.06.035.
10. Christakis PG, Zhang D, Budenz DL, Barton K, Tsai JC, Ahmed IIK. Five-Year Pooled Data Analysis of the Ahmed Baerveldt Comparison Study and the Ahmed Versus Baerveldt Study. Am J Ophthalmol. 2017;176:118-26. doi:10.1016/j.ajo.2017.01.003
11. Koh V, Chew P, Triolo G, Lim KS, Barton K; PAUL Glaucoma Implant Study Group. Treatment outcomes using the PAUL glaucoma implant to control intraocular pressure in eyes with refractory glaucoma. Ophthalmol Glaucoma. 2020;3:350-9. doi:10.1016/j.ogla.2020.05.001
12. José P, Barão RC, Teixeira FJ, Marques RE, Peschiera R, Barata A,et al. One-Year Efficacy and Safety of the PAUL Glaucoma Implant Using a Standardized Surgical Protocol. J Glaucoma. 2022;31:201-5. doi:10.1097/IJG.0000000000001969
13. Tan MC, Choy HY, Koh Teck Chang V, Aquino MC, Sng CC, Lim DK, et al. Two-year outcomes of the Paul glaucoma implant for treatment of glaucoma. J Glaucoma. 2022;31:449-55. doi:10.1097/IJG.0000000000001998
14. Vallabh NA, Mason F, Yu JT, Yau K, Fenerty CH, Mercieca K, et al. Surgical technique, perioperative management and early outcome data of the PAUL® glaucoma drainage device. Eye. 2022;36:1905-10. doi:10.1038/s41433-021-01737-1
15. Vallabh NA, Mohindra R, Drysdale E, Mason F, Fenerty CH, Yau K. The PAUL® glaucoma implant: 1-year results of a novel glaucoma drainage device in a paediatric cohort. Graefe's Arch Clin Exp Ophthalmol. 2023;261:2351-8. doi:10.1007/s00417-023-06000-9
16. Weber C, Hundertmark S, Liegl R, Jauch AS, Stasik I, Holz FG, et al. Clinical outcomes of the PAUL® glaucoma implant: One-year results. Clin Exp Ophthalmol. 2023;51:566-76. doi:10.1111/ceo.14235
17. Lloyd MA, Baerveldt G, Nguyen QH, Minckler DS. Long-term histologic studies of the Baerveldt implant in a rabbit model. J Glaucoma. 1996;5:334-9.
18. Shaarawy TM, Sherwood MB, Grehn F. Guidelines on Design and Reporting of Surgical Trials—World Glaucoma Association. Amsterdam: Kugler Publications; 2009.
19. Gedde SJ, Feuer WJ, Lim KS, Barton K, Goyal S, Ahmed II, et al. Treatment Outcomes in the Primary Tube Versus Trabeculectomy Study after 5 Years of Follow-up. Ophthalmology. 2022;129:1344-56. doi:10.1016/j.ophtha.2022.07.003
20. Berteloot S, Correia Barão R, Abegão Pinto L, Vandewalle E, Stalmans I, Lemmens S. Treatment Outcomes Comparing the Paul and Baerveldt Glaucoma Implants After One Year of Follow-Up. J Glaucoma. 2024;33:594-600. d doi:10.1097/IJG.0000000000002366
21. Yoon PS, Singh K. Update on antifibrotic use in glaucoma surgery, including use in trabeculectomy and glaucoma drainage implants and combined cataract and glaucoma surgery. Curr Opin Ophthalmol. 2004;15:141-6. doi:10.1097/00055735-200404000-00015
22. Foo VHX, Htoon HM, Welsbie DS, Perera SA. Aqueous shunts with mitomycin C versus aqueous shunts alone for glaucoma. Cochrane Database of Systematic Reviews. 2019;2019. doi:10.1002/14651858.CD011875.pub2

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