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ORIGINAL RESEARCH

Intermediate Outcomes of a Novel Flat Glaucoma Drainage Device in Uncontrolled Primary Open Angle Glaucoma

Ticiana De Francesco[1–4], Mariela Carito Gómez Mejía[5], Iqbal Ike K Ahmed[1,6,7], Mario Eduardo Miranda Velásquez[8]

[1]John A. Moran Eye Center, University of Utah, Salt Lake City, Utah, USA; [2]Department of Ophthalmology and Otorhinolaryngology, University of Campinas, Campinas, Sao Paulo, Brazil; [3]Clinica de Olhos De Francesco, Fortaleza, Ceara, Brazil; [4]Hospital de Olhos Leiria de Andrade, Fortaleza, Ceara, Brazil; [5]Clínica Oftalmológica Mácula D&T, Lima, Peru; [6]Prism Eye Institute, Mississauga, Ontario, Canada; [7]Department of Ophthalmology and Vision Sciences, University of Toronto, Toronto, Ontario, Canada; [8]Clínica de Ojos Futuro Visión, Lima, Peru

Correspondence: Ticiana De Francesco, John A. Moran Eye Center, University of Utah, 65 Mario Capecchi Dr, Salt Lake, UT, 84132, USA, Tel +1 801-581-2352, Email ticianadefrancesco@gmail.com

Video abstract

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Purpose: To evaluate the intraocular pressure (IOP) lowering effect and adverse event profile of the Implante Plano Miranda (IPM), a novel flat glaucoma drainage device.

Methods: Prospective, single-arm, open-label Phase II clinical trial including 24 eyes with uncontrolled primary open-angle glaucoma (POAG) despite maximal tolerated medical therapy, undergoing standalone IPM implantation with adjunctive Mitomycin-C (MMC). Primary outcome was the proportion of eyes achieving surgical success, defined by: ≥ 20% IOP reduction from baseline on same or fewer medications without clinical hypotony or reoperation. Secondary outcomes included changes in IOP, medication burden, endothelial cell density (ECD), and adverse events. Patients were followed for 12 months.

Results: At 12 months, surgical success was achieved in 79.5% of eyes. Median IOP decreased from 24.0 mmHg (IQR 24–26) preoperatively to 14.0 mmHg (IQR 12–17) at one year ($p < 0.0001$), representing a 41.6% reduction. Median glaucoma medications decreased from 4 (IQR 3–4) to 1 (IQR 0–3) ($p < 0.0001$). ECD remained stable (baseline 1,671.98 ± 570.75 vs. 12 months 1,684.37 ± 549.25 cells/mm^2; $p = 0.797$). Minor adverse events occurred in 29.1% of eyes; no serious complications or reoperations were reported.

Conclusion: The IPM was associated with significant IOP reduction and decreased medication use at one year. No serious safety events were observed during the 12-month follow-up. Given the small sample size and single-arm design, larger controlled studies with longer follow-up are necessary to better define the safety and efficacy profile of this device.

Keywords: flat glaucoma drainage device, implante plano miranda, glaucoma surgery, subconjunctival filtering

Introduction

Glaucoma is one of the leading causes of irreversible blindness worldwide, affecting approximately 76 million people in 2020, with projections estimating this number will rise to 112 million by 2040 due to an aging population and longer life expectancy.[1,2] Primary open angle-glaucoma (POAG) is the most prevalent form, with recent estimates indicating that 68.56 million people are affected by this condition globally.[3] This progressive disease is characterized by optic nerve damage, often associated with elevated intraocular pressure (IOP), a key factor in its pathophysiology and the only modifiable risk factor for slowing the progression of visual field loss.[4,5]

Despite significant therapeutic advances, a substantial percentage of OAG patients remain resistant to medical or laser treatments and require escalation to surgical intervention. Trabeculectomy remains one of the most commonly performed incisional procedures for glaucoma. While its efficacy in lowering IOP is well-established, it is still associated with a high rate of complications, particularly hypotony-related ones, and often requires postoperative interventions.[6,7]

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Recently, the surgical management of glaucoma has evolved with the introduction of microinvasive bleb surgery (MIBS) devices, which aim to standardize aqueous outflow through predefined lumen diameters and lengths, thereby reducing hypotony risk and postoperative variability.[8–10] While these devices improve surgical predictability, their flow is largely determined by intrinsic device resistance, and long-term outcomes remain influenced by wound healing and bleb fibrosis.

The Implante Plano Miranda (IPM, MM Instrumentos S.A.C., Lima, Peru) was developed to address some of the limitations associated with both trabeculectomy and fixed-lumen subconjunctival devices. Unlike tubular implants that rely primarily on internal lumen resistance, the IPM is a flat glaucoma drainage device made of non-magnetic surgical steel, a biologically inert material that does not adhere to ocular tissues.[11] The implant is positioned in the anterior chamber under a scleral flap, establishing communication between the anterior chamber and the subconjunctival space. Its flat configuration allows additional modulation of aqueous outflow through scleral flap tension and surrounding tissue dynamics, thereby combining the guarded filtration principle of trabeculectomy with a standardized implantable structure.

In conditions of elevated intraocular pressure, aqueous humor lifts the tissue surrounding the implant, facilitating greater flow into the subconjunctival space and promoting bleb formation. Conversely, at lower IOP levels, tissue apposition limits flow, resulting in slower, more controlled outflow. This proposed pressure-responsive mechanism functions as a physiologic relief valve and may offer a theoretical advantage in adapting to postoperative IOP fluctuations, potentially reducing the risk of hypotony while maintaining effective filtration.

This pilot study aims to evaluate the IOP-lowering effect and adverse event profile of IPM implantation with Mitomycin-C (MMC) in subjects with primary open-angle glaucoma and uncontrolled IOP.

Materials And Methods

This is a Phase II, prospective, single-center, open-label, single-arm clinical trial (registration number EC 041–20) to evaluate the IOP-lowering effect and the adverse event profile of the IPM surgical implant in patients with POAG with an IOP above target or exhibiting visual field progression while on maximal tolerated medical therapy (MTMT) between May 2021 and November 2022. The study was conducted at the research department of the Clínica Mácula D&T in Lima, Peru. The protocol adhered to the tenets of the Declaration of Helsinki and institutional review board approval was obtained from the National Heath Institute of Peru and Via Libre Bioethics committee. Every patient gave informed consent for surgery. Baseline preoperative characteristics recorded include demographics (age, eye, sex, ethnicity, diabetes status) and ocular characteristics (best-corrected visual acuity [BCVA]; IOP at which the decision for surgery was made [baseline IOP]; number of glaucoma medications; cup-to-disc ratio; visual field mean deviation and history of previous ocular surgery).

Inclusion Criteria

The patient inclusion criteria were as follow: subjects $\geq$ 30 years old, diagnosed with primary open-angle glaucoma uncontrolled on MTMT, who had failed traditional glaucoma surgery (trabeculectomy or tubes) or were not considered reasonable candidates for traditional surgery. In the study eye, a BCVA between 20/50 and perception of light, or no perception of light with significant pain was required and a BCVA in the other eye was required to be better than that of the study eye. The subject under study must have been mentally competent and willing to give informed consent.

Exclusion Criteria

Subjects were excluded from the study if within the last three months they have participated, are participating or intend to participate in a study with any investigational agent (drug or device), subjects with serious pulmonary or cardiovascular disorders, cancer at progressive stage, chronic unstable diseases or acute illnesses that may influence the study evaluation, pregnant women, subjects with any type of glaucoma other than primary open-angle glaucoma or with any recent ocular inflammation or infection within the past 30 days, and subjects with any known intolerance or hypersensitivity to topical anesthetics, mydriatics or components of the device.

Study Device

The IPM (Figure 1), invented by Peruvian physician Mario Eduardo Miranda Velásquez, is a flat, non-tubular device made of stainless steel that connects the anterior chamber of the eye to the subconjunctival space. Measuring 4.2 mm × 2 mm × 0.12 mm, the IPM enables the AH to flow through a virtual space formed between the device and the surrounding tissue.[11] This space is created by a pressure gradient between the anterior chamber and the distal end of the implant. When the intraocular pressure reaches a certain threshold, it exerts enough force to lift the surrounding tissue slightly, allowing fluid to pass through the intrascleral space and eventually form a subconjunctival bleb. The flow of AH increases until the system reaches a steady state, at which point the flow entering and exiting the IPM is equal.[11]

The biological risk assessment of the device was performed according to ISO10993-1:2008 parameters. Cytotoxicity, eye irritation, dermal sensitization and endotoxin assays of the IPM were evaluated, complying with the requirements in all tests, proving to be biocompatible.

Surgical Procedure

The procedure for IPM implantation was performed under intravenous sedation and subconjunctival anesthesia with preservative-free Xylocaine 2%. A superior fornix-based conjunctival peritomy over 2 clock hours was created, followed by the application of light cautery to the scleral bed. Two merocele sponges soaked with MMC 0.2 mg/mL were applied to the subtenon space for two minutes, followed by irrigation of the surface of the eye with balanced salt solution. A 4×4 mm scleral flap with 50% scleral thickness was created, and a 15° blade with a width of 1.5 mm was used to enter the anterior chamber, parallel to the iris, followed by implantation of the device into the anterior chamber. Part of the device is positioned under the scleral flap, with 1.5 mm of the device in the anterior chamber. The device is then covered by the scleral flap, which is reapproximated to the scleral bed with two interrupted 10–0 nylon sutures, and the conjunctival flap is closed using an 8–0 Vicryl suture. Subsequently, balanced salt solution was injected into the anterior chamber to ensure the presence of a bleb and confirm that no leaks were present.

Postoperative Management

After the procedure, patients were instructed to stop all glaucoma medications in the operated eye and start topical moxifloxacin drops every 6 hours for two weeks and steroid drops (prednisolone 1%) every 6 hours for 1 to 2 weeks. Patients were seen at postoperative day 1, week 1, and at month 1, 3, 6, 9 and 12. Prior to surgical implantation, IOP was measured through Goldmann applanation tonometry using 2 operator method, best corrected visual acuity (BCVA) through Snellen chart evaluation, visual field, manifest refraction, slit lamp biomicroscopy, anterior and posterior OCT, indirect ophthalmoscopy, gonioscopy and specular microscopy. These tests were repeated at 6 and 12 months post-operatively. Reintroduction of glaucoma medications, needling, digital ocular compression (DOC), anterior chamber (AC) reformation, surgical revisions, and reoperations were performed as per surgeon discretion.

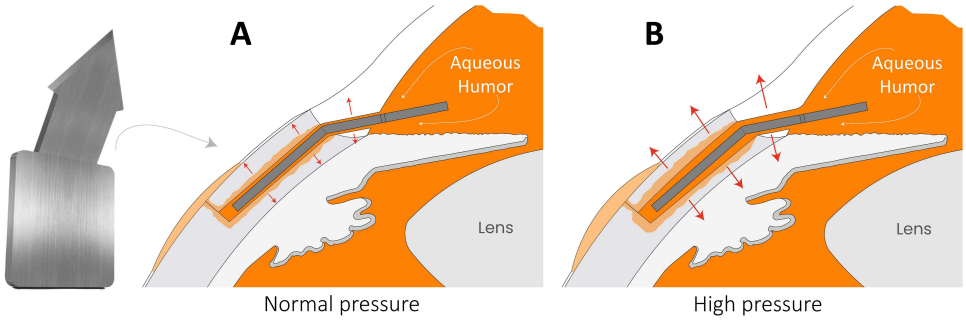

Figure 1 Schematic representation of the proposed mechanism of the IPM. (**A**) Device image and implantation under normal IOP. Limited separation between the implant and sclera may restrict aqueous outflow. Small red arrows indicate low pressure within the scleral tunnel and minimal scleral lifting. (**B**) At elevated IOP, increased pressure may lift the sclera, enlarging the space between the device and sclera and enhancing outflow to the subconjunctival space. Large red arrows indicate greater pressure and increased scleral lifting.

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Primary Outcome

The proportion of eyes achieving surgical success at 12 months was the primary outcome, which was defined by the following criteria: 1) ≥ 20% IOP reduction from the IOP at the time the decision was made to undergo surgical intervention (baseline IOP) on same or fewer glaucoma medications compared to baseline 2) no clinical hypotony (defined as: IOP less than 6 mmHg with a loss of more than 2 lines of vision). Surgical reoperations for glaucoma were defined as immediate failures. Within the first three post-operative months, IOP outside threshold and use of glaucoma medication were not regarded as failures. Instances of in-clinic post-operative interventions, such as needling, AC reformation were not regarded as failures at any point during follow-up if the success criteria were still met. Secondary

Table 1 Baseline Characteristics

Number of patients	24
Number of eyes	24
Age ± SD	67 ± 13.1
Age range	30-90
Ethnicity, no (%)	
Latin	24 (100)
POAG, no (%)	24 (100)
Baseline IOP ± SD	24.2 ± 3.8
IOP range	16-34
Visual field mean deviation, mean ± SD	−23.2 ± 9.8
Glaucoma severity, no. (%)	
Mild	1 (4.2)
Moderate	2 (8.3)
Severe	21 (87.5)
Number of glaucoma medications, no (%)	
0	0
1	0
2	2 (8.3)
3	9 (37.5)
4	13 (54.2)
Previous eye surgeries, no. (%)	
Cataract	13 (50.0)
Trabeculectomy	6 (23.1)
Penetrating keratoplasty	1 (3.8)
Glaucoma implant	2 (7.7)
Glaucoma implant removal	1 (3.8)
Cyclophotocoagulation	3 (11.5)

Abbreviations: IOP, intraocular pressure; POAG, Primary Open Angle Glaucoma; SD, Standard Deviation.

Outcome measures included mean IOP and medication number, postoperative interventions and reoperations. Minor adverse events (including conjunctival leak or dehiscence, hyphema, vitreous haemorrhage, choroidal detachments, macular folds, prolonged inflammation, corneal decompensation, macular edema, diplopia, iris incarceration, or blocked microshunt), serious adverse events (including exposed device, retinal detachment, suprachoroidal haemorrhage, malignant glaucoma, blebitis, endophthalmitis, or loss of light perception), interventions during the postoperative period, and reoperations for glaucoma were recorded and analyzed.

Statistical Analysis

A descriptive analysis of the general characteristics of the participants, including sex and ethnicity, was performed. Surgical success was assessed through survival analysis and displayed using a Kaplan–Meier curve. Continuous outcomes were described as means (standard deviation) or medians (interquartile range [IQR]), depending on the distribution of the data, and compared using repeated-measures ANOVA, with post-hoc Sidak tests for pairwise comparisons between time points. Safety analysis of the IPM was based on the incidence and severity of adverse events reported during the study.

Endothelial cell density (ECD) was evaluated at baseline, 6 months, and 12 months. Analyses were performed using all available observations at each visit. To account for repeated measurements and potential missing observations, a linear mixed-effects regression model with random intercepts for each subject was used to assess changes in ECD over time. Model fit was evaluated using a likelihood ratio test comparing the mixed-effects model to a simple linear model.

Results

Twenty-four eyes from 24 patients were enrolled in the study. The mean age was 67 ± 13.1 years, and 62.5% of the patients were male. All participants were of Latino ethnicity. Most eyes (87.5%) had severe glaucoma, with a mean visual field mean deviation (MD) of –23.26 ± 9.88 dB. Half of the patients were pseudophakic, and nearly half had undergone previous glaucoma surgery. Baseline characteristics are summarized in Table 1.

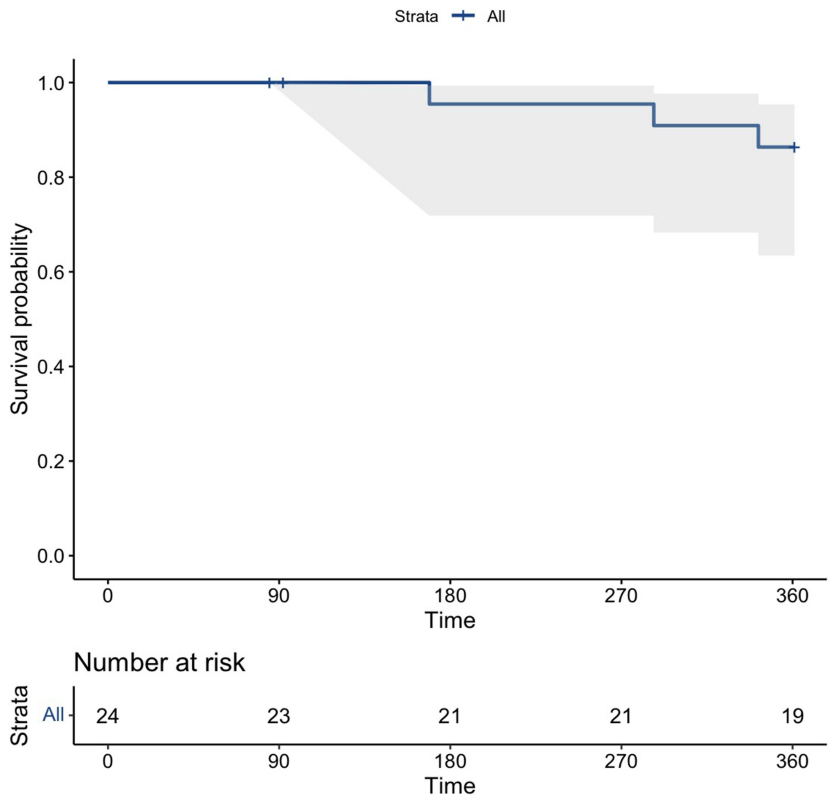

Figure 2 Kaplan-Meier survival curve through 12 months.

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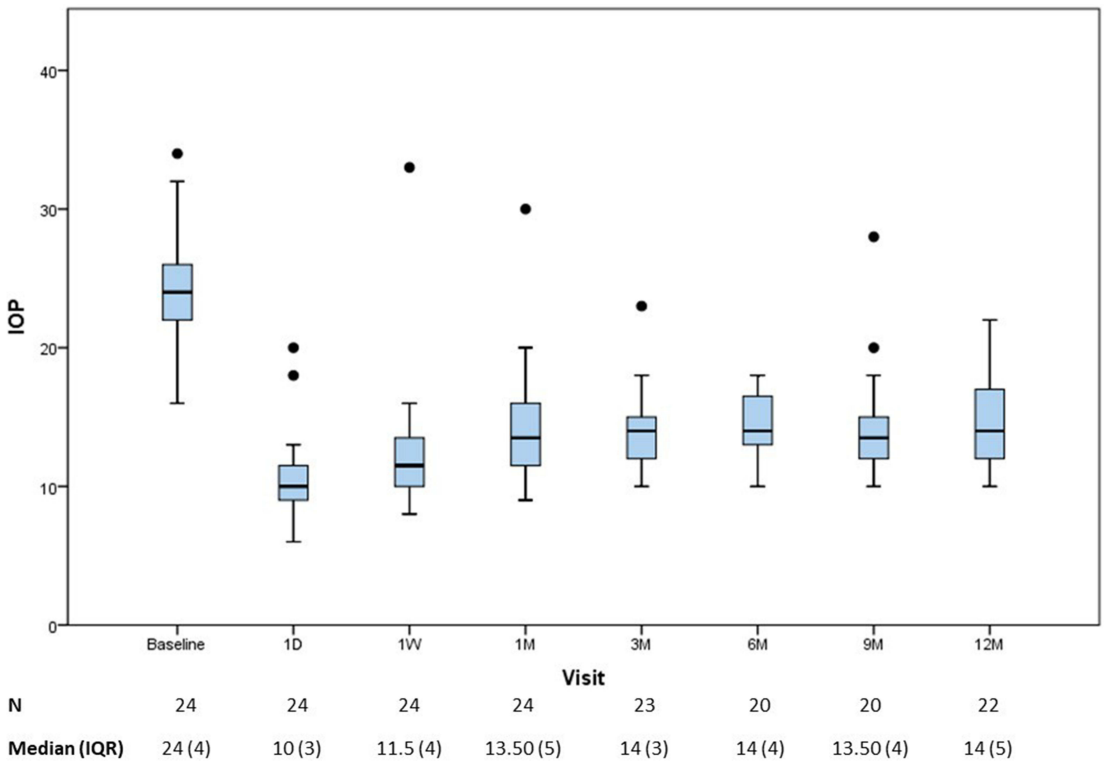

Figure 3 Box and whisker plot of intraocular pressure (IOP) over the course of 12 months of follow-up. The horizontal central lines of each box represent the median, whereas the lower and upper ends of boxes indicate the lower and upper quartiles. The whiskers represent minimum and maximum values. The blackdots represent the outliers. The values below the graph represent the number of eyes remaining in the study in each group after accounting for those lost to follow-up.

Surgical success at 12 months was achieved in 79.5% of the eyes. Kaplan-Meier survival curve is presented in Figure 2. At 1-year, median IOP reduced from 24.0 mmHg (IQR 24–26 mmHg) at baseline to 14.0 mmHg (IQR 12–17 mmHg) ($p<0.0001$; Figure 3), representing an IOP reduction of 41.6%. The median number of glaucoma medications decreased from 4 (IQR 3–4) to 1 (IQR 0–3) at 1 year ($p<0.0001$, Figure 4). Failures were related to insufficient intraocular pressure reduction..

At baseline, BCVA was 0.60 ± 0.43 and 0.76 ± 0.92 at 12 months ($p=0.545$). Endothelial cell density (ECD) at baseline was 1,646.6 cells/mm^2 and 1,641.9 cells/mm^2 at 12 months. There was no statistically significant difference between baseline and 12-month ECD values ($p = 0.92$; Table 2).

Table 3 shows early and late postoperative adverse events over a 1-year period. Minor adverse events were reported on 7 (29.1%) eyes, with no major complications. At the 1-month visit, there was one case of device migration into the subconjunctival space, where the IPM device was not fully covered by the scleral flap. This patient required surgical revision with device repositioning and evolved well with good IOP control. No eyes required secondary glaucoma surgery (reoperations).

Interventions were required in 2 eyes (8.3%), including needling with MMC and laser suture lysis. Postoperative interventions are summarized in Table 4.

Discussion

This phase II, open-label, single-arm clinical trial represents the first clinical evaluation of the Implante Plano Miranda in human eyes, offering important preliminary evidence regarding its IOP-lowering effect and adverse event profile in patients with uncontrolled primary open-angle glaucoma. The IPM is a novel, flat, non-tubular implant designed to regulate aqueous humor outflow through a self-modulating pressure gradient, and its performance in this trial demonstrates promising surgical outcomes.

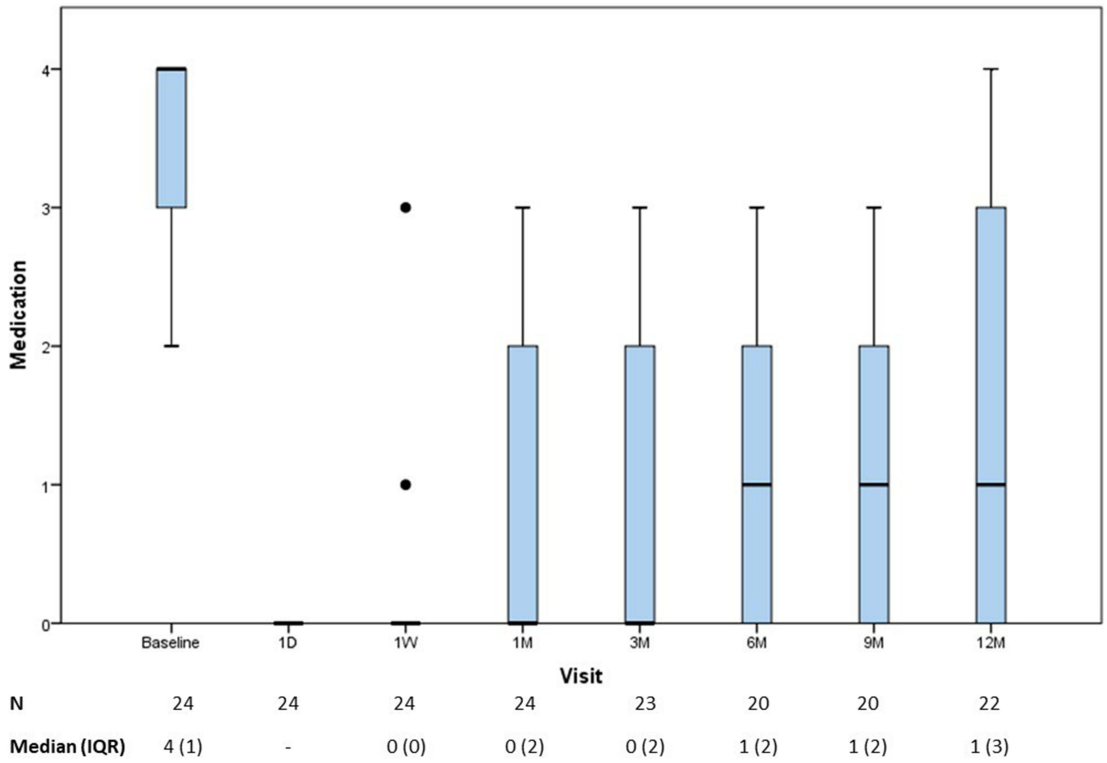

Figure 4 Box and whisker plot of number of glaucoma medications over the course of 12 months of follow-up. The horizontal central lines of each box represent the median, whereas the lower and upper ends of boxes indicate the lower and upper quartiles. The whiskers represent minimum and maximum values. The blackdots represent the outliers. The values below the graph represent the number of eyes remaining in the study in each group after accounting for those lost to follow-up.

At 12 months, 79.5% of eyes achieved surgical success. Mean IOP reduced from 24.0 mmHg (IQR 24–26 mmHg) at baseline to 14.0 mmHg (IQR 12–17 mmHg) at one year, representing a 41.6% IOP reduction. These outcomes are consistent with, and in some respects favorable compared to other glaucoma subconjunctival drainage devices.[11–14] The TVT study reported complete and qualified success rates of 25% vs. 29% and 42% vs. 21% for tube versus trabeculectomy at 5 years, respectively. Additionally, IOP was reduced by 41.4% in the tube group and 49.5% in the trabeculectomy group, consistent with our results.[14] Importantly, the IPM achieves this effect without relying on a lumen or valve, instead utilizing a flat stainless-steel surface to generate a dynamic virtual space through which aqueous humor can exit based on real-time pressure differentials. It is worth noting that most eyes in this study had advanced glaucoma, with a mean visual field mean deviation of -23.26 ± 9.88, and nearly half had undergone previous glaucoma surgery. These are typically refractory cases, in which surgical outcomes tend to be less favorable due to extensive structural damage and conjunctival scarring. It is conceivable that surgical outcomes may be even more favorable in less advanced cases or in patients with virgin eyes who have not undergone previous filtration procedures.

Fibrosis remains a leading cause of failure in glaucoma surgeries such as trabeculectomy and drainage device implantation. Maintaining a functional filtering bleb is essential, but healing responses, particularly fibroblast

Table 2 Endothelial Cell Density Over the Course of 12 Months Follow-Up

Time (months)	No. Eyes	Mean ECD	Lower 95% CI	Upper 95% CI	p-value
Baseline	24	1646.6	1423.9	1869.4	–
6	20	1661.8	1558.5	1765.1	0.77
12	22	1641.9	1542.3	1741.6	0.92

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Table 3 Early and Late Postoperative Adverse Events

	Total	Early (<3 mos)	Late (>3 mos)
Complications, n (%)	7 (29.1)	3 (12.5)	4 (16.6)
Minor, n (%)	7 (29.1)		
Blocked implant	0	–	–
Cataract	1 (4.1)	–	1 (4.1)
Choroidal detachments	0	–	–
Conjuntival leak/Dehiscence	0	–	–
Corneal descompensation	0	–	–
Macular degeneration	1 (4.1)	–	1 (4.1)
Diplopia	0	–	–
Hyphema	0	–	–
Implant migration	1 (4.1)	–	1 (4.1)
Iris incarceration	0	–	–
Macular edema	0	–	–
Macular folds	1 (4.1)	1 (4.1)	–
Papilloedema	1 (4.1)	1 (4.1)	–
Prolonged inflammation	0	–	–
Retinal venous obstruction	1 (4.1)	–	1 (4.1)
Vitreous haemorrhage	1 (4.1)	–	1 (4.1)
Major, n (%)	0		
Blebitis	0	–	–
Endophthalmitis	0	–	–
Exposed implant (implant erosion)	0	–	–
Loss of light perception	0	–	–
Malignant glaucoma	0	–	–
Retinal detachment	0	–	–
Suprachoroidal haemorrhage	0	–	–

proliferation from Tenon's capsule, can result in conjunctival scarring and bleb failure, even with the use of antifibrotic therapies.[15,16] It is important to highlight that the IPM implantation technique involves creating a scleral flap and a puncture at the sclerocorneal limbus, an approach closely resembling traditional trabeculectomy. Because the implant occupies much of the intrascleral space beneath the flap, it may theoretically act as a spacer, limiting tissue apposition and modulating flow through flap margins. In addition, the pressure-responsive separation between the implant and surrounding tissue may contribute to dynamic flow regulation. However, these proposed mechanisms remain hypothetical and were not directly evaluated in this study. Whether this configuration reduces postoperative fibrosis or hypotony requires confirmation through comparative and longer-term investigations.

Table 4 Postoperative Interventions

Intervention, n (%)	**2 (8.3)**
Suturelysis	1 (4.1)
Needling with MMC	1 (4.1)
AC tap	0
5-FU injection	0
Laser to ostomy	0
AC reformation	0
MMC injection	0
Choroidal drainage	0

A notable secondary outcome in our study was the significant reduction in medication burden, from a median of 4 (IQR 3–4) to 1 (IQR 0–3) at 12 months, reducing dependence on topical medications and benefiting patient adherence and quality of life. The IPM also demonstrated an encouraging safety profile. No serious adverse events were observed, and most of the complications were self-limiting or successfully managed in clinic. No cases of clinical hypotony or bleb-related infections were observed during the 12-month follow-up. Endothelial cell density did not show a statistically significant change over this period. However, given the small sample size and limited duration of follow-up, these findings should be interpreted cautiously, and definitive conclusions regarding long-term endothelial safety require longer-term follow-up to adequately characterize the safety profile of this procedure.

This study is limited by its small sample size, single-center setting, and lack of a control group, which restrict generalizability and prevent direct comparisons with other surgical approaches. The 12-month follow-up provides only intermediate outcomes, and longer-term efficacy and safety remain unknown. Importantly, the study population consisted predominantly of eyes with advanced glaucoma, and nearly half had undergone prior glaucoma surgery. These factors are typically associated with more complex surgical courses and may significantly influence outcomes. As such, the results may not be directly generalizable to patients with earlier-stage disease or surgery-naïve eyes, and caution is warranted when extrapolating these findings to broader glaucoma populations. Additionally, the definition of surgical success allowed postoperative interventions without classifying them as failures, consistent with commonly used definitions in glaucoma surgical trials; however, this approach may have influenced the reported success rates.

Conclusions

This pilot study is the first to report clinical outcomes of the Implante Plano Miranda in human eyes with primary open-angle glaucoma. The findings indicate that the IPM is a promising surgical option, achieving significant intraocular pressure reduction and a notable decrease in medication burden at 12 months postoperatively. Notably, most eyes in our study had advanced glaucoma, and nearly half had undergone prior glaucoma surgery, factors typically associated with lower surgical success rates. Despite this, the IPM demonstrated a favorable success profile, highlighting its potential value even in refractory cases. However, given the small sample size, single-arm design, and intermediate follow-up, these findings should be interpreted cautiously. Larger, controlled studies with longer follow-up are necessary to more definitively establish the safety profile, efficacy, and comparative role of the IPM among established glaucoma surgical options.

Data Sharing Statement

The authors do not currently plan to share individual deidentified participant data or additional study documents.

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Disclosure

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Science, Vialase, Visci Ltd, Visus Therapeutics, Vizzario, and Zilia, Inc, outside the submitted work. **Mario E. Miranda Velásquez**: MM instrumentos S.A.C (Lima, Peru): ownership. In addition, Dr Mario Miranda Velasquez reports patents issued US10758412, EU3175820, Brazil 112016030196, India 201747000640, Israel 249688, Japan 6825761, Mexico 392355, China 106687072, China - Hong Kong 1237641, China - Macau 2015-800358813, Korea 102268311, Thailand 96087, Peru 20151266, Colombia 2016005603, Chile 2016003238, Singapore 10201901871; and he worked at the Clínica Mácula D&T between September 2018 and March 2020. The research department of the clinic conducted the clinical trials of the implant, which began in April 2021, more than a year after he stopped working there. During his time at Clínica Mácula D&T, he was never a part of the research department and only worked treating patients as a regular ophthalmologist. The authors report no other conflicts of interest in this work.

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