

Optimizing Early Postoperative Outcomes: The Role of Intraluminal PRESERFLO™ Stenting

Otimização do Período Pós-Operatório Precoce: O Papel do *Stent* Intraluminal no PRESERFLO™

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ABSTRACT

INTRODUCTION: The PRESERFLO™ MicroShunt (PMS) is a safe and effective implant for lowering intraocular pressure (IOP) in patients with different types of glaucoma. One of the most common early complications after PMS implantation is hypotony, therefore the use of preventive measures in high-risk patients is advisable.

We aimed to evaluate the efficacy of intraluminal stenting of PMS in preventing hypotony during the early postoperative period.

METHODS: Retrospective comparative cohort study on consecutive patients who underwent PMS implantation with or without intraluminal stenting at Unidade Local de Saúde de Coimbra, between May 2023 and July 2024. The primary outcome was the incidence of hypotony at one week postoperative. Secondary outcomes included overall success and frequency of complications.

RESULTS: Eighty-two eyes (77 patients) with glaucoma underwent PMS implantation. Of these, 21 eyes underwent stenting of the PMS, while 61 eyes were implanted with a non-stented PMS. The stent PMS group was characterized by a higher incidence of high myopia (33.3%) and monocular vision (52.4%) compared to the non-stent group (3.3% and 23.0%, respectively) ($p < 0.001$ and $p = 0.012$). One day after surgery, the mean IOP dropped to 7.8 ± 3.8 mmHg in the non-stent group, and 12.3 ± 5.1 mmHg in the stenting group ($p < 0.001$). After one week of surgery, the mean IOP was 10.4 ± 5.6 mmHg in the non-stent group and 15.1 ± 8.4 mmHg in the stenting PMS group ($p = 0.026$). Hypotony occurred in twenty-eight eyes (45.9%) in the non-stent PMS group and five (23.8%) in the stenting PMS group ($p > 0.05$). A shallow anterior chamber occurred in six eyes in the non-stent PMS group; four of them were associated with choroidal effusion. No cases of shallow anterior chamber or choroidal effusion were observed in the stenting PMS group. Overall surgical success at 3 months follow-up was similar between both groups.

CONCLUSION: In the early follow-up period, intraluminal stenting with 10.0 nylon of the PMS effectively limits the aqueous flow and controls the IOP while reducing postoperative hypotony. Yet, despite stenting, hypotony was still observed in our study, suggesting that aqueous humor leakage alongside the shunt, the extent of PMS occlusion, and population characteristics (age-influencing fibrosis) may contribute to hypotony.

KEYWORDS: Glaucoma Drainage Implants; Glaucoma/surgery; Intraocular Pressure; Ocular Hypotension; Postoperative Care; Stents.

RESUMO

INTRODUÇÃO: O PRESERFLO™ *MicroShunt* (PMS) é um implante seguro e eficaz na redução da pressão intraocular (PIO) em diferentes tipos de glaucoma. A hipotonia é uma das complicações precoces mais comuns, estando recomendado o uso de medidas preventivas em doentes de alto risco.

O nosso objetivo foi analisar a eficácia do *stent* intraluminal no PMS na prevenção da hipotonia no período pós-operatório.

MÉTODOS: Estudo retrospectivo comparativo. Foram incluídos doentes submetidos a implante de PMS com ou sem *stent* intraluminal, na Unidade Local de Saúde de Coimbra, entre Maio de 2023 e Julho de 2024. O *outcome* primário foi a incidência de hipotonia na primeira semana pós-operatória. Os *outcomes* secundários incluíram sucesso cirúrgico e a frequência de complicações.

RESULTADOS: Foram incluídos oitenta e dois olhos (77 doentes). Destes, 21 olhos foram submetidos à colocação de *stent* no PMS e 61 olhos foram submetidos apenas a implante do PMS. O grupo com *stent* apresentou maior incidência de alta miopia (33,3%) e visão monocular (52,4%) em comparação com o grupo sem *stent* (3,3% e 23,0%, respetivamente) ($p<0,001$ e $p=0,012$). No primeiro dia pós-operatório, a PIO média reduziu para $7,8 \pm 3,8$ mmHg no grupo sem *stent* e para $12,3 \pm 5,1$ mmHg no grupo com *stent* ($p<0,001$). Na primeira semana pós-operatória, a PIO média foi de $10,4 \pm 5,6$ mmHg no grupo sem *stent* e $15,1 \pm 8,4$ mmHg no grupo com *stent* ($p=0,026$). Hipotonia ocorreu em vinte e oito olhos (45,9%) no grupo sem *stent* e em cinco (23,8%) no grupo com *stent* ($p>0,05$). Hipotálamia/atalamia ocorreu em seis olhos no grupo sem *stent*; quatro deles com derrame coróideu (DC). Não foram observados casos de hipotálamia/atalamia ou DC no grupo com *stent*. O sucesso cirúrgico aos 3 meses de seguimento foi semelhante entre grupos.

CONCLUSÃO: No período de seguimento precoce, a colocação de *stent* intraluminal com nylon 10.0 é eficaz para limitar o fluxo aquoso e controlar a PIO. Apesar da colocação do *stent*, verificamos casos de hipotonia, sugerindo a influência de outros fatores como a drenagem de humor aquoso ao redor do *shunt*, o grau de oclusão do PMS ou as características da população (idade e fibrose).

PALAVRAS-CHAVE: Cuidados Pós-Operatórios; Glaucoma/cirurgia; Hipotensão Ocular; Implantes para Drenagem de Glaucoma; Pressão Intraocular; Stents.

INTRODUCTION

In recent years, micro-invasive glaucoma surgery (MIGS) and intraocular pressure (IOP) lowering aqueous humor drainage implants have become more popular in treatment algorithms for glaucoma patients. These techniques have been effective in reducing medication burden, particularly in patients at high risk of postoperative complications attributed to conventional glaucoma surgery.^{1,2}

The PRESERFLO™ *MicroShunt* (PMS) is a safe ab-externo subconjunctival device for treating different types of glaucoma. In the longest follow-up study, which spanned five years, an overall success of 82.6% with PMS implantation was achieved without long-term sight-threatening adverse effects.³ Although postoperative complications are less common, transient hypotony was still observed in 11.1% to 39% of cases.³⁻⁷ This complication can be worsened by choroidal detachment in 8.7% to 10.6% of cases, and a shallow anterior chamber in 2% to 13% of cases.³⁻⁷

Preventative measures to address early hypotony in high-risk patients are recommended. Three case series have demonstrated that non-resorbable sutures as intraluminal stents can prevent excessive outflow in the early postopera-

tive period.⁸⁻¹⁰ Given the limited data available, there is still no established consensus or guideline for selecting patients or determining the optimal timing for stent removal.¹¹

This study aims to evaluate the efficacy of intraluminal stenting of PMS in preventing hypotony during the early postoperative period. Furthermore, we aimed to report the characteristics of patients who may require stenting to minimize postoperative events.

METHODS

STUDY DESIGN

The present analysis was a retrospective cohort study of consecutive patients who underwent PMS implantation with or without intraluminal stenting at a tertiary hospital (Unidade Local de Saúde de Coimbra – Hospitais da Universidade de Coimbra, Portugal), between May 2023 and July 2024. Our study adhered to the tenets of the Declaration of Helsinki and was approved by the Ethics Committee.

PARTICIPANTS

The study included adult patients with inadequately

controlled IOP or glaucoma progression, despite maximally tolerated medical therapy. Patients were divided into two groups according to the surgical technique: traditional PMS implantation and PMS implantation with intraluminal stenting. There were no exclusion criteria.

PREOPERATIVE ASSESSMENT

Preoperative baseline characteristics included demographics such as age, sex, and ethnicity. Ocular characteristics comprised: best-corrected visual acuity (BCVA); glaucoma subtype; baseline IOP, and antiglaucoma medications. Additionally, previous laser, cataract, or glaucoma surgery; mean deviation of visual fields; dosage/duration of the mitomycin-C (MMC) application; ocular and systemic comorbidities; anticoagulant or antiaggregant medication; postoperative complications and reinterventions were collected.

SURGICAL PROCEDURES

All surgeries were performed under local or general anesthesia per the previously published recommendation.¹¹ In brief, after a corneal traction suture with 8.0 vicryl, a fornix-based conjunctival flap was created, and minimal cautery was applied to bleeding vessels. MMC was applied (0.2 to 0.4 mg/mL between 2 and 3 minutes) with one saturated corneal sponge or injected subconjunctival and then thoroughly rinsed with based salt solution. A 2 mm scleral tunnel 3 mm posterior to the marked limbus was created with a micro-knife supplied with the MicroShunt, and the anterior chamber was entered using a bent 25-gauge needle parallel to the iris plane. The implant was inserted beveled up through the tunnel and its function was confirmed by observing aqueous outflow from the external end of the shunt. If stenting was done, a 10.0 nylon suture was threaded into the PMS lumen through the external end and advanced until it reached the internal opening. The free end of the suture was then embedded in the corneal tissue to provide easy access for its removal. The Tenon's and conjunctival layers were carefully advanced over the shunt and a limbal 8.0 vicryl suture was done along the limbus. Finally, a subconjunctival injection of dexamethasone was administered.

OUTCOME MEASURES

The primary outcome measure was the incidence of hypotony, defined as an IOP <6 mmHg at one week postoperative. Secondary outcomes included: overall success defined as a decrease of ≥20% of IOP from baseline and an absolute IOP ≤18 mmHg, which was considered qualified or complete based on whether this was reached with or without anti-glaucoma drops; frequency and type of complications; number of glaucoma medications after surgery.

REMOVAL OF INTRALUMINAL STENT

Stent removal was done at the slit lamp under topical anesthesia. It was removed if IOP was ≥18 mmHg in the first two visits or ≥12 mmHg from the third postoperative visit. If the stent was still in place after 1 month of surgery, it was removed based on surgical experience to balance IOP control and hypotony risk.

STATISTICAL ANALYSIS

Snellen BCVA measurements were converted to log-MAR equivalents for data analysis. Clinical and demographic data were expressed in absolute numbers and percentages for categorical variables and as mean plus standard deviation for continuous variables. The Kolmogorov-Smirnov test was used to verify normal distribution. To compare means and proportions among groups, we used independent samples t-tests for normally distributed samples, the Mann-Whitney test for non-normal distribution, and Fisher's exact test for categorical variables. A value of $p < 0.05$ was considered statistically significant. Statistical analysis was performed with SPSS Statistics version 29.0.0 (IBM Corporation, New York).

RESULTS

Eighty-two eyes (77 patients) with glaucoma underwent PMS implantation. Of these, 21 eyes underwent stenting of PMS (sPMS) while the remaining 61 eyes were submitted to a non-stented PMS implantation (nsPMS). The baseline demographic and clinical characteristics are summarized in Table 1 and overall were similar between both groups.

Regarding the types of glaucoma, primary open-angle glaucoma (POAG) was the most common cause ($n=39$, 47.6%) followed by pseudoexfoliative glaucoma (PSX) ($n=20$, 24.4%) and they were equally distributed between groups. Seventeen eyes (20.7%) had undergone prior selective laser trabeculoplasty (SLT). The mean preoperative IOP was 24.7 ± 6.1 mmHg in the nsPMS group, comparable to 26.9 ± 6.0 mmHg in the stented group. Similarly, the average number of topical IOP-lowering compounds was 3.4 ± 0.7 in the nsPMS group and 3.6 ± 0.7 in the sPMS. Most patients were also under oral acetazolamide ($n=47$, 57.3%).

In both groups, one-third of the eyes were pseudophakic ($n=19$, 31.1% in nsPMS vs $n=7$, 33.3% in sPMS), while three eyes in the stented group had prior vitrectomy versus only one eye in the non-stented group (14.3% in sPMS vs 1.6% in nsPMS, $p=0.050$). Additionally, the sPMS group presented a significantly higher incidence of high myopia (33.3%) and monocular vision (52.4%) compared to the non-stent group (3.3% and 23.0%, respectively) ($p < 0.001$ and $p=0.012$).

MMC concentration varied between the groups due to surgeon preference, with the stented group having a mean higher concentration (0.4 mg/mL) than the non-stented (0.3 mg/mL) ($p < 0.001$).

PRIMARY OUTCOME

One day after surgery, the mean IOP dropped to 7.8 ± 3.8 mmHg in the non-stented group, and 12.3 ± 5.1 mmHg in the stented group ($p < 0.001$). After one week of surgery, the mean IOP was 10.4 ± 5.6 mmHg in the nsPMS and 15.1 ± 8.4 mmHg in the sPMS group ($p=0.026$). At one month, the mean IOP increased to 13.5 ± 6.5 mmHg in nsPMS and decreased to 12.8 ± 5.6 mmHg in sPMS ($p=0.677$). At 3-month follow-up, both groups presented with similar IOP levels (Fig. 1). The postoperative outcomes are outlined in Table 3.

On postoperative day one, hypotony was observed in

Table 1. Baseline demographics and clinical characteristics .

	PMS (n=82)	Non-stented PMS (n=61)	Stented PMS (n=21)	p-value
Age (y), mean ± SD	63.3 ± 13.8	63.7 ± 13.9	62.2 ± 13.8	0.660
Sex, n (%)				0.951
Male	59 (72)	44 (72.1)	15 (71.4)	
Female	23 (28)	17 (27.9)	6 (28.6)	
Ethnicity, n (%)				0.755
Caucasian	79 (96.3)	59 (96.7)	20 (95.2)	
African	3 (3.7)	2 (3.3)	1 (4.8)	
District of residence, n (%)				0.628
Coimbra	33 (40.2)	25 (41.0)	8 (38.1)	
Aveiro	23 (28)	16 (26.2)	7 (33.3)	
Leiria	11 (13.4)	8 (13.1)	3 (14.3)	
Castelo Branco	6 (7.3)	5 (8.2)	1 (4.8)	
Viseu	3 (3.7)	3 (4.9)	0	
Guarda	2 (2.4)	2 (3.3)	0	
Santarém	2 (2.4)	1 (1.6)	1 (4.8)	
Lisboa	1 (1.2)	1 (1.6)	0	
Setúbal	1 (1.2)	0	1 (4.8)	
Glaucoma type, n (%)				0.631
Primary open-angle	39 (47.6)	29 (47.5)	10 (47.6)	
Pseudoexfoliative	20 (24.4)	16 (26.2)	4 (19.0)	
Uveitic	6 (7.3)	4 (6.6)	2 (9.5)	
Neovascular	3 (3.7)	2 (3.3)	1 (4.8)	
Steroid-induced	1 (1.2)	1 (1.6)	0	
Traumatic	1 (1.2)	1 (1.6)	0	
Congenital	3 (3.7)	1 (1.6)	1 (4.8)	
Familial amyloid polyneuropathy	5 (6.1)	4 (6.6)	1 (4.8)	
Juvenile open-angle	2 (2.4)	2 (3.3)	0	
Secondary	1 (1.2)	0	1 (4.8)	
Primary angle closure	1 (1.2)	0	1 (4.8)	
Baseline LogMAR BCVA, mean ± SD	0.2 ± 0.2	0.2 ± 0.2	0.3 ± 0.3	0.220
Baseline IOP, mean ± SD	25.2 ± 6.1	24.7 ± 6.1	26.9 ± 6.0	0.075
Baseline number of glaucoma medications, mean ± SD	3.5 ± 0.7	3.4 ± 0.7	3.6 ± 0.6	0.151
Oral acetazolamide, n (%)	47 (57.3)	34 (55.7)	13 (61.9)	0.622
Preoperative MD, mean ± SD	-8.5 ± 7.1	- 8.5 ± 7.0	- 8.9 ± 8.7	0.895
Previous phacoemulsification, n (%)	26 (31.7)	19 (31.1)	7 (33.3)	0.853
Previous laser/surgery for glaucoma, n (%)				0.687
None	62 (75.6)	47 (77.1)	15 (71.4)	
Selective laser trabeculoplasty	17 (20.7)	12 (19.7)	5 (23.8)	
Trabeculectomy	2 (2.4)	2 (3.3)	0	
Express implant	1 (1.2)	0	1 (4.8)	
Previous VR surgery, n (%)	4 (4.9)	1 (1.6)	3 (14.3)	0.050
High Myopia, n (%)	9 (11.0)	2 (3.3)	7 (33.3)	< 0.001
Only eye, n (%)	25 (30.5)	14 (23)	11 (52.4)	0.012
Intraoperative MMC concentration, mean (range)	0.3 (0.2 to 0.4)	0.3 (0.2 to 0.4)	0.4 (0.2 to 0.4)	< 0.001
Intraoperative MMC duration, mean ± SD	2.1 ± 0.4	2.1 ± 0.4	2.1 ± 0.3	0.645

Statistical tests used were Mann-Whitney U Test for continuous variables and Pearson Chi-Square Test for categorical variables. Adjusted Stantardized Residuals IOP – intraocular pressure; MD – mean deviation; MMC – mytomicin-C; PMS – PRESERFLOTM MicroShunt; SD – standard deviation; VR - vitreoretinal.

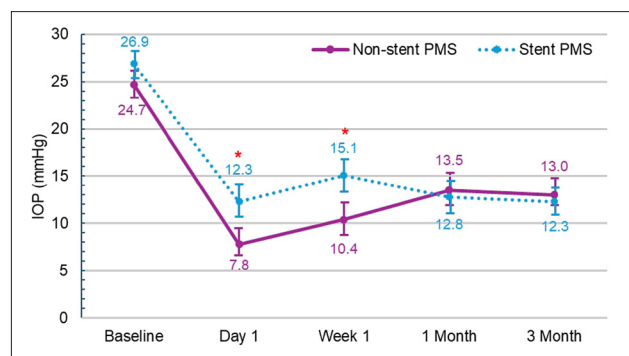


Figure 1. Graph showing baseline (preoperative) and postoperative IOP over 3 months of follow-up.

Mean ± standard deviation. IOP – Intraocular pressure; PMS – PRESERFLO™ MicroShunt * $p < 0.05$.

20 eyes (32.8%) in the non-stent PMS group and in 2 eyes (9.5%) in the stent group ($p = 0.038$). By the end of the first

postoperative week, hypotony persisted in six eyes (9.8%) in the non-stent group and in three eyes (14.3%) in the stent group ($p = 0.591$).

A shallow anterior chamber occurred in six eyes (9.8%) in the non-stent PMS group; four of them were associated with choroidal effusion (6.6%). No cases of shallow anterior chamber or choroidal effusion were observed in the stenting PMS group ($p = 0.135$ and $p = 0.568$, respectively). The postoperative complications are shown in Table 2.

The intraluminal occlusion was removed after 15 ± 12.1 days in sPMS without complications at the slit lamp. The mean IOP before and after removal was 17.9 ± 7.8 mmHg and 12.1 ± 4.1 mmHg, respectively ($p < 0.001$). No patients developed blebitis, endophthalmitis, or adverse hypotony after removal.

SECONDARY OUTCOMES

Overall surgical success at 3 months follow-up was similar between both groups. Fifty-two eyes (85.2%) in the non-

Table 2. Intraoperative and early postoperative complications.

	Non-stented PMS (n=61)	Stented PMS (n=21)	p-value
Intraoperative, n (%)			0.380
Hyphema	3 (4.9)	2 (9.5)	0.631
Postoperative, n (%)			
Hypotony day 1	20 (32.8)	2 (9.5)	0.038
Hypotony week 1	6 (9.8)	3 (14.3)	0.591
Hypotony 1 month	2 (3.3)	0	0.579
Shallow AC	6 (9.8)	0	0.135
Choroidal effusion	4 (6.6)	0	0.568
Bleb leak	4 (6.6)	1 (4.8)	0.620
Avascular conjunctival necrosis	1 (1.6)	0	0.753
Revision, n (%)	4 (6.6)	2 (9.5)	0.643

AC – anterior chamber; PMS – PRESERFLO™ MicroShunt.

Table 3. Treatment outcomes.

	Non-stented PMS (n=61)	Stented PMS (n=21)	p-value
Last follow-up LogMAR BCVA, mean ± SD	0.2 ± 0.2	0.3 ± 0.4	0.112
Postoperative IOP, mean ± SD			
Day 1	7.8 ± 3.8	12.3 ± 5.1	< 0.001
Week 1	10.4 ± 5.6	15.1 ± 8.4	0.026
1 month	13.5 ± 6.5	12.8 ± 5.6	0.677
3 month	13.0 ± 3.5	12.3 ± 4.4	0.524
Overall success at 3 m, n (%)			
Qualified	8 (13.1)	4 (19.0)	0.470
Complete	52 (85.2)	16 (76.2)	0.482
Failure	1 (1.6)	1 (4.8)	-
Postoperative number of glaucoma medication, mean ± SD			
1 month	0.20 ± 0.7	0.19 ± 0.6	0.969
3 month	0.30 ± 0.8	0.48 ± 0.9	0.377

BCVA – best corrected visual acuity; IOP – intraocular pressure; PMS – PRESERFLO™ MicroShunt; SD – standard deviation, m – months.

stented group and sixteen eyes (76.2%) in the stented group achieved complete success ($p=0.482$). Eight eyes (13.1%) in the nsPMS and four eyes (19.0%) in sPMS had an IOP > 18 mmHg and initiated anti-glaucoma medications, thus classified as a qualified success ($p=0.470$). One eye in each group was considered a failure due to an IOP reduction less than 20% compared with baseline. The need for revision surgery was comparable between groups ($n=4$, 6.6% in nsPMS vs $n=2$, 9.5% in sPMS; $p=0.182$).

Within the first month after surgery, the mean number of glaucoma medications was 0.20 ± 0.7 in the nsPMS group and 0.19 ± 0.6 in the sPMS group ($p=0.969$). At 3 months follow-up, the mean number of anti-glaucoma compounds was 0.30 ± 0.8 in the non-stented group and 0.48 ± 0.9 in the stented group ($p=0.377$) (Fig. 2). Oral acetazolamide was not prescribed to any patients during the postoperative period.

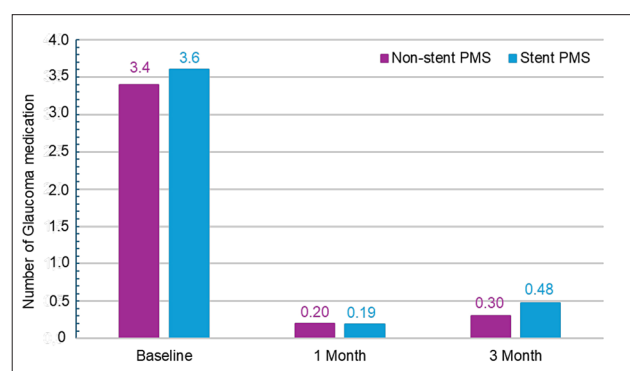


Figure 2. Mean number of glaucoma medications at baseline and follow-up. PMS – PRESERFLO™ MicroShunt

DISCUSSION

This is the first report to investigate the role of intraluminal stenting in patients who underwent PMS implantation in Portugal.

Recent reports have described the use of stenting the PMS for outflow restriction as an option to address early postoperative hypotony,⁸⁻¹⁰ reinforced by the latest modified Delphi panel.¹² In those case-series, hypotony rate varies from absent to 6%, contrasting with the 14.3% incidence observed in our stented cohort during the first postoperative week. All events were transient and self-limiting, with no association with shallow anterior chamber or choroidal effusion, yet they are still undesired due to increased burden for patients (reduced visual acuity and frequent follow-up visits).

We believe that several factors may have contributed to such results: firstly, the baseline characteristics of patients. Our cohort is very heterogeneous compared to the cited studies, especially regarding the different types of glaucoma and the young mean age, which can represent a higher rate of aqueous humor production.¹⁰ Secondly, the degree and extension of PMS partial occlusion. By using a 10.0 monofilament suture with a 20 μ m diameter, we expect to occlude nearly 30% of a standard PMS (70 μ m of tube di-

ameter), which differs from the 8.0 polyamide suture with double the diameter and 60% occlusion used by Luke.⁸ Thirdly, aqueous humor leakage alongside the shunt. In vitro studies showed that hypotony occurred when there was an excessive flow of aqueous humor through the gap between the tube and the sclera, especially if the scleral tunnel width was wide.¹³ Although our procedure used the micro-knife provided by the kit, the possibility of an incorrectly sized scleral tunnel or pocket cannot be dismissed.¹⁰ Lastly, the concentration and method of application of MMC may also be a contributing factor. There is ongoing debate regarding the optimal MMC dosage for patients at risk of hypotony-related complications.^{9,14} While some research has indicated a greater risk associated with higher MMC concentrations after trabeculectomy, these higher concentrations may also boost the success rate of microshunt procedures.^{3,14} We applied 0.04% of MMC in most patients in the stented group compared to nsPMS and the hypotony rate was inferior. We concur with Lupardi's study⁹ that, in PMS implantation, using an intraluminal stent may be preferable to employing a lower MMC concentration to prevent early hypotony. The reasons are twofold: the stent is reversible and using a higher MMC concentration influences long-term surgical failure.

Regarding the timing of stent removal, our time interval was consistent with other studies at approximately two weeks postoperative.⁸⁻¹⁰ The effect on the outflow restriction of the 10.0 monofilament was confirmed by the higher mean IOP observed in the nsPMS group during the first month, along with the significant differences between groups during the first postoperative week and pre- and post-stent removal. In the most recent modified Delphi panel discussion,¹² no consensus was reached regarding the ideal time frame or target IOP for suture removal. Yet, we believe that the decision to remove the stent should be made independently for each patient, not only according to the postoperative IOP but also by observing the filtering bleb. Based on the clinical experience of the glaucoma surgeons, the criteria for stent removal were: IOP ≥ 18 mmHg within the first two weeks and IOP ≥ 12 mmHg starting from the third postoperative visit.

Our 3-month complete success was reached by most of the eyes, 82.9% ($n=68$) in both groups, without a statistical difference. Also, a comparable reduction in anti-glaucoma eye drops use was achieved in both groups (3.5 ± 0.7 to 0.3 ± 0.8). These results are in line with other three- and six-month studies.⁸⁻¹⁰ In the initial three months, patients undergoing stented PMS implantation demonstrated enhanced early IOP control, experienced fewer hypotony complications, and showed no inferiority in surgical success compared to the non-stented group.

Several limitations affect this study, such as its retrospective design and limited duration of follow-up. Only the impact of the 10.0 nylon suture was investigated, and further comparative research is needed to assess the effects of different stent sizes and materials on hypotony rates. Additionally, the decision regarding MMC application was made by glaucoma surgeons and considering that this may

have influenced postoperative outcomes, caution should be considered when interpreting our findings.

CONCLUSION

In conclusion, our study provides real-world data on the hypotony rate of consecutive patients undergoing PMS implantation with and without intraluminal stenting, which is relevant for clinical decision-making in glaucoma surgery. Based on the clinical characteristics of our cohort, we support the hypothesis that placement of an intraluminal suture as a flow restrictor helps stabilize postoperative IOP and minimize the rate of hypotony and associated visual acuity decrease in the early postoperative follow-up period.

CONTRIBUTORSHIP STATEMENT / DECLARAÇÃO DE CONTRIBUIÇÃO

TM: conceptualization, formal analysis, data collection, writing original draft.

JS: Conceptualization, formal analysis, writing - review & editing.

TQ and PF: Formal analysis, writing - review & editing.

JB: Conceptualization, formal analysis, data collection, writing - review & editing.

All authors have read and approved the version to be published.

TM: conceitualização, análise formal, recolha de dados, redação do rascunho original.

JS: Conceitualização, análise formal, redação - revisão e edição.

TQ e PF: Análise formal, redação - revisão e edição.

JB: Conceitualização, análise formal, recolha de dados, redação - revisão e edição.

Todos os autores leram e aprovaram o manuscrito a ser publicado.

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

Conflicts of Interest: The authors have no conflicts of interest to declare.

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Confidentiality of Data: The authors declare that they have followed the protocols of their work center on the publication of patient data.

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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