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Effectiveness and Safety of XEN45 in Eyes With High Myopia and Open Angle Glaucoma

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Abstract

Précis:

XEN45 implant was an effective and safe procedure in primary open angle glaucoma (OAG) eyes with high myopia. Although the hypotony incidence rate was relatively high, it resolved with medical therapy and was of short duration.

Purpose:

The purpose of this study is to evaluate the effectiveness and safety of the XEN45 stent in eyes with OAG and high myopia.

Design:

Retrospective and multicenter study.

Methods:

Consecutive OAG patients who underwent a XEN45, either alone or in combination with cataract surgery, and had a refractive error higher than −6 D and an axial length ≥26 mm. The primary endpoint was the mean intraocular pressure (IOP) lowering at the last follow-up visit.

Results:

Thirty-one eyes were included (96.8% with a primary OAG diagnosis). The mean refraction was −13.2±5.6 (range: −6.75 to−23.0) D. In the overall study sample, preoperative mean IOP (95% CI) was significantly lowered from 23.5 (20.5–26.4) mm Hg to 13.0 (12.2–13.8) mm Hg at the last follow-up visit, P<0.0001. At the last follow-up visit, 16 (57.1%) eyes achieved an IOP ≤14 mm Hg, 11 (68.9%) of them without treatment. The number of ocular hypotensive medications was significantly reduced from 3.0±1.1 drugs at preoperatively to 0.6±1.0 drugs at the last follow-up visit, P<0.0001. Median (95% CI) follow-up was 24.0 (12.0–24.0) months. Linear regression analysis showed a significant correlation between the preoperative refraction and the IOP lowering (r=0.43, P=0.0155). Needling procedure was performed in 11 eyes (39.3%) and hypotony (defined as an IOP <6 mm Hg) was observed in 8 eyes (28.6%) during the first postoperative day and remained for a week.

Conclusion:

Although the Xen implant effectively lowered IOP in highly myopic eyes with glaucoma, the incidence of hypotony was high, and in most cases, resolved within the first month with medical management and monitoring.

Myopia is the most prevalent refractive defect worldwide, and its incidence is increasing and accelerating exponentially.1,2 In fact, it has been estimated that its prevalence will reach 5 billion people by 2050.2,3

Glaucoma is currently considered as one of the leading causes of irreversible blindness worldwide.4,5 There seems to be a relationship between myopia and glaucoma. In fact, currently available evidence suggests that myopia, particularly high myopia (refractive error ≥6 D), is a risk factor for glaucoma onset; with a 2- to 3-fold increased risk of glaucoma compared with that of nonmyopic subjects.6–12

Moreover, such association becomes stronger as myopia increases,7,11–13 with an increased risk of ~20% for each diopter of myopia.13

Traditional filtering glaucoma surgery may be challenging in patients with high myopia.14,15 High myopia has been associated with an increased risk of hypotony maculopathy in patients who underwent trabeculectomy16,17 and change with its onset is usually limited to the postoperative period but can occur even year later.18

Minimally invasive glaucoma surgery devices have emerged as a safer and less traumatic alternative to the traditional filtering surgery.19

Different papers have evaluated the effectiveness and safety of XEN45 in open angle glaucoma (OAG) patients.20–25 However, the evidence about the use of XEN45 in myopic OAG patients is limited.26,27 A recommendation was made to avoid the use of the XEN implant in patients with myopia, although it was based on the experience of an isolated clinical case.26 Laborda-Guirao et al27 did not find significant differences between OAG eyes with or without high myopia in intraocular pressure (IOP) lowering, success rate, reduction in the number of ocular hypotensive medications (NOHM), or postoperative complications, which clearly suggested that XEN45 may be safely and effectively used in glaucomatous eyes with high myopia. However, that paper was not designed to specifically investigate the results in a high myopic population, furthermore the sample size was limited to 18 eyes.

The incidence rate of postoperative transient hypotony with XEN implant is relatively low and in the majority of cases do not require additional surgical intervention and is usually solved within 1 month.28

This study aimed to evaluate the effectiveness and safety of XEN45 device in patients with OAG and high myopia.

METHODS

Design

Retrospective, multicenter, and open-label clinical study conducted in 5 Italian centers.

The study protocol was approved by the Ethic Committee of the University of Torino (CP-20-001), which waived the need for written informed consent. This study complied with the guidelines of Good Clinical Practice and adhered to the tenets of the Declaration of Helsinki.

Participants

The study was conducted on consecutive OAG patients who underwent a XEN45 implant from January 2019, either alone or in combination with cataract surgery, and had a refractive error higher than −6 D and an axial length ≥26 mm.

Patients with any form of glaucoma other than OAG; progressive retinal or optic nerve disease of any cause; history of major ocular surgery within the previous 6 months; and/or severe conjunctival scars were excluded from the study. Patients with a follow-up <6 months were also excluded.

Minimally Invasive Glaucoma Surgery Device

XEN45 (Allergan, Irvine, CA) was used. The device is composed of cross-linked porcine gelatin, and its measurements are 6 mm length, 150 μm of outer diameter, and 45 μm of inner diameter.

Surgical Technique

All the surgical procedures were performed, under local anesthesia, with mitomycin-C (MMC) (0.1 mL of MMC 0.02%), which was injected in the superior nasal quadrant before to start the surgery.

The device was placed, ab interno, in the superior nasal quadrant. After local anesthesia and skin disinfection, superior nasal conjunctiva was marked 3 mm from the limbus and a highly cohesive viscoelastic was injected into the anterior chamber. The device was injected, through a 1.8-mm corneal paracentesis, at the inferotemporal quadrant. The device was placed immediately superior to the trabecular meshwork and its position was determined intraoperatively by gonioscopy. The viscoelastic material was removed and formation of a bleb was assessed by constant irrigation, into the anterior chamber, of balanced salt solution. Finally, after administration of intracameral cefuroxime, the clear corneal incisions were hydrated with balanced salt solution.

We have published details of the technique elsewhere.24

In those patients who underwent combined surgery, a standard phacoemulsification technique first and XEN implantation followed as previously indicated.

Perioperative care included antibiotic therapy 4 times a day during 1 week and anti-inflammatory therapy with steroids 6 times daily, which was slowly tapered over 3 months.

Follow-up visits included dilated fundus examination, paying special attention in choroidal detachment and hypotony maculopathy.

Patients with bleb fibrosis, flat bleb, and/or elevated IOP underwent needling with MMC (0.1 mg/mL), which was performed in the theater.

Definitions

Complete success was defined as an IOP ≤18 mm Hg and an IOP reduction ≥20%, without any ocular hypotensive medication at the month 12 visit.

Qualified success was defined as an IOP ≤18 mm Hg and an IOP reduction ≥20%, with topical ocular hypotensive medication at the month 12 visit.

Outcomes

The primary endpoint was the mean IOP lowering at the last follow-up visit.

Secondary endpoints included reduction in the NOHMs; proportion of eyes achieving a final IOP ≤12 mm Hg; ≤14 mm Hg; ≤16 mm Hg; or ≤18 mm Hg with or without medications; and incidence of adverse events.

Statistical Analysis

A statistical analysis was performed using MedCalc Statistical Software version 20.015 (MedCalc Software bv; https://www.medcalc.org; 2021).

Data are expressed as number (percentage); mean [standard deviation (SD)]; mean (95% CI); median (95% CI); or percentages as appropriate.

We examined the distribution of continuous variables with a D'Agostino-Pearson test.

A repeated measures ANOVA or a Friedman 2-way analysis test, as appropriate, were used to assess the changes in IOP and in number of antiglaucoma medications.

Linear regression analysis was used to assess the association between refraction and IOP lowering.

The last observation carried forward method was used to input missing data.

Categorical variables were compared with a Fisher exact test or $\chi 2$ test as appropriate.

RESULTS

Among the 40 screened eyes, 31 eyes (31 subjects) met all the inclusion/exclusion criteria and were included in the study.

Overall Study Population

The mean age was 62.1±11.3 years and 20 (64.5%) patients were women. Thirty eyes (96.8%) had a clinical diagnosis of primary OAG, whereas 1 (3.2%) eye had pseudoexfoliative glaucoma.

The mean refraction was −13.2±5.6 D, with a median (interquartile range, IqR) of 11.5 (−18.8 to −8.1) D.

Table 1 shows the main preoperative characteristics of the study sample.

In the overall study sample, preoperative mean (95% CI) IOP was significantly lowered from 23.5 (20.5–26.4) mm Hg to 7.56 (6.5–8.8) mm Hg; 8.8 (7.7–9.9) mm Hg; 11.3 (10.2–12.5) mm Hg; 13.6 (12.4–14.8) mm Hg; 13.2 (12.7–14.2) mm Hg; 12.6 (11.9–13.3); and 13.0 (12.2–13.8) mm Hg at day 1, week 1, months 1, 3, 6, and 12, and last follow-up visit, respectively, $P<0.0001$ each, respectively (Fig. 1).

As compared with baseline, the mean IOP was significantly lowered at all the different time point measured (Table 2). At the last follow-up visit, mean IOP lowering was 39.3±20.5%.

XEN was positioned in the subconjunctival space in 28 (90.3%) eyes, whereas it was positioned in the subtenon space in 3 (9.7%).

The median (95% CI) follow-up was 24.0 (12.0–24.0) months and 18 (58.1%) eyes had a 24-month follow-up period (mean follow-up: 18.5±7.5 mo).

At month 12, the proportion of complete success was 89.3%. Table 3 summarizes the achieved different IOP targets and with an IOP reduction ≥20%.

The NOHM was significantly reduced from 3.0±1.1 drugs at preoperatory to 0.6±1.0 drugs at the last follow-up visit, P<0.0001 (Fig. 2).

Linear regression analysis showed a significant correlation between the preoperative refraction and the IOP lowering (r=0.43, P=0.0155) with the slope of the regression line at −0.62 mm Hg/D, where 95% CI ranged from −1.12 to −0.13 mm Hg/D (Fig. 3).

In the overall study population, best-corrected visual acuity (BCVA) did not significantly change from preoperative values (0.39±0.27) to month 12 (0.40±0.24), P=0.8780. Similarly, in the eyes who underwent XEN solo, there were no significant changes in BCVA between preoperative (0.39±0.27) and month 12 (0.38±0.24), P=0.9187. Nevertheless, in the 3 eyes who underwent combined surgery (XEN + Phacoemulsification), BCVA improved from 0.57±0.09 to 0.75±0.35, although such improvement was not significant (Hodges-Lehmann median difference, P=0.4370).

Regarding bleb morphology, it was classified as flat in 2 (6.5%) eyes; as cystic in 5 (16.1%) eyes; and as diffuse in 24 (77.4%). Eight (25.8%) eyes had avascular bleb, 15 (48.4%) had normal vascularity, and 8 (25.8%) eyes had hyperemic bleb.

Eyes With Previous Refractive Surgery

Four (12.9%) eyes had undergone previous corneal refractive surgery. As expected, pachymetry was significantly lower in those eyes who underwent refractive surgery before XEN implantation than in those who did not (P<0.0001) (Table 1).

As compared with preoperative values, the IOP was significantly lowered at all the different time point measured in both, the eyes who underwent previous surgery and those who did not, without significant differences between them (Fig. 4).

Regarding the NOHM reduction, there was not significant differences between eyes who underwent previous surgery (median: 3.0; IqR: 2.0–4.0) and those who did not (median: 2.0; IqR: 1.0–3.0) (Hodges-Lehmann median difference: 1.0; 95% CI: −1.0 to 2.0), P=0.2965).

Safety

Regarding surgical complications, hypotony (defined as an IOP <6 mm Hg) was observed in 8 (26.6%) eyes during the first postoperative day and remained for a week. Only 1 eye had hypotony at month 1. Figure 5 and Table 4 show the evolution of IOP in those patients who had postoperative hypotonia.

Eight (28.6%) eyes had choroidal detachment, which were successfully solved with medical therapy. One (3.6%) eye had a massive postoperative hyphema and developed a cataract with a reduction of 7 lines in BCVA. One (3.6%) eye had an intraoperative hyphema that was successfully resolved and 1 (3.6%) eye had a subconjunctival hemorrhage.

One (3.6%) eye developed a myopic maculopathy, which resulted in a decrease of 2 lines in BCVA. Finally, mild ptosis was reported in 1 (3.6%) eye.

Table 5 summarizes the postoperative adverse events.

Needling

Needling procedure was performed in 11 (39.3%) eyes, with 3 (10.7%) eyes undergoing an additional needling procedure, and 2 (7.1%) eyes underwent an MMC subconjunctival injection without needling. One (3.6%) eye, who underwent a trabeculectomy before XEN63 implant, required an ex-press implant.

DISCUSSION

The results of our study suggested that XEN45 implant significantly lowered the IOP and reduced the NOHM in a cohort of patients with OAG and high myopia.

In addition, we did not find any differences, in terms of IOP lowering or NOHM reduction, between the eyes who had undergone previous refractive surgery and those who did not.

As far as we know, this is the first study designed specifically for assessing the effectiveness and safety of XEN45 stent in OAG patients with high myopia.

High myopia represents a challenging scenario in glaucoma patients who need surgical treatment. High myopia has been identified as a risk factor for hypotony maculopathy after filtration surgery,16,17,29 and such a risk seems to be long lived.18,30 Moreover, thin sclera may predispose high myopic eyes to have potentially higher complication risk.14,15,31,32

Therefore, some authors have suggested to use deep sclerectomy to overcome the risks of early hypotony in myopic patients.33

The use of XEN device in eyes with high myopia was put into question as a result of the publication of a clinical case that described the clinical outcomes of XEN45 stent in a high myopic and vitrectomized eye of a glaucoma patient.26 Nevertheless, the post hoc analysis of a retrospective study suggested that XEN45 might be safely and effectively used in glaucomatous eyes with high myopia.27

The mean IOP at month 12 and month 24 in the current study seems to be lower than that reported in the literature (Table 6).

In fact, at month 12, 16 (57.1%) eyes had an IOP ≤14 mm Hg, 11 of them without treatment.

In light of these results, it seems that XEN45 effectiveness, in terms of IOP lowering, is greater in the myopic eyes than in emmetropic eyes.20–25,31–37

In addition, this study found a significant relationship between the preoperative refraction and the IOP lowering, suggesting that the greater the myopia the greater the IOP lowering.

It may be hypothesized that either a lower intrascleral resistance,38 or a thinner tenon's capsule,39 or the combination of both may help to achieve low IOP. In favor of this hypothesis is the fact that a longer axial length might be a success factor for trabeculectomy with MMC.40 However, up to now, the role of myopia in IOP changes after glaucoma surgery has not been elucidated. Moreover, there may be a complex relationship between glaucoma and myopia, since a chronic increase in IOP causes remodeling of the collagen structure of the sclera and these changes may be influenced by the baseline structure and mechanical properties of the eye.41

Regarding safety, according to the results of the current study, during the first postoperative day 8 (28.6%) eyes had hypotony. These data seem to be in line with those reported by Laborda-Guirao et al27 in high myopic eyes who underwent a XEN45 device.

According to the results of a systematic review and meta-analysis, the incident rate of transient hypotonia after XEN implantation was around 9.6%.28 These figures seem to be lower than those observed in the present study, although it should be noted that these data correspond to nonmyopic eyes.

Moreover, it should be highlighted that in our study, hypotony was time limited. In fact, in 7 of the 8 eyes the hypotonia was successfully resolved, with medical therapy, within the first week and in the remaining eye, it was resolved within the first month after surgery. This fact may have been because of the intrinsic flow-limiting design of the device, which is based on the Hagen-Poiseuille equation (the outflow resistance depends on the tube length and internal lumen diameter).

The proportion of needling was similar to that reported in previous XEN45 papers.31,33,35

In addition, the incidence of choroidal detachment was 28.6% (8/31), which was slightly higher than that reported previously.20–24,27,31–37 Nevertheless, the higher incidence of choroidal detachment observed in the current study may be either because these patients are at increased risk or because we performed dilated postoperative examinations in all the cases, which, compared with previous studies, meant giving greater attention to this issue. High myopia has been identified as a significant risk factor for postoperative hypotony in other glaucoma surgical procedures. Hamel et al42 reported 38.1% of transient hypotony in patients with glaucoma and high myopia.

This study has several limitations that need to be taken into consideration when interpreting its results. The main limitation of the current study is its retrospective design. Selection bias, observational bias, and confounding are all inherent limitations of retrospective studies. Nevertheless, strict inclusion/exclusion criteria were selected for minimizing this issue. Another limitation is the fact that the post hoc analysis comparing eyes with previous refractive surgery versus eyes without it may be underpowered for detecting difference. According to the results of this study, the power for detecting mean IOP reduction differences at the last follow-up visit between eyes with or without previous refractive surgery was 22%. In addition, we have evaluated a heterogeneous population, which included different types of glaucoma and patients who have previously undergo refractive and glaucoma procedures. Besides its limited sample size, its multicenter design (low number of patients per center), should be considered as study limitations. Nevertheless, it should be taken into consideration the difficulty of recruiting patients with such high myopia. In addition, in a subanalysis of a previous paper conducted on a larger number of patients, 3 authors had similar results both in terms of efficacy and in terms of complications.24 Another issue to consider is that the study was conducted in a Caucasian population. So, appropriate caution is therefore

recommended when extending the results to other populations. Finally, the follow-up period of our study is relatively short. Because glaucoma is a long-life chronic disease, a mean follow-up of 18 months may represent a relatively short period in a lifetime of the disease.

CONCLUSIONS

Although the Xen implant effectively lowered IOP in highly myopic eyes with glaucoma, the incidence of hypotony was high, and in most cases, resolved within the first month with medical management and monitoring. Finally, the proportion of needling procedures was in line with that reported in previous XEN45 papers. The relationship between myopia degree and IOP lowering, although interesting, needs to be further investigated.

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TABLE 1. Main Demographic and Clinical Characteristics of the Study Population

Variable	Overall study sample (n = 31 eyes)	Previous refractive surgery		
		Yes (n = 4)	No (n = 27)	P*
Age, years				
Mean ± SD	62.1 ± 11.3	62.8 ± 10.4	62.0 ± 11.6	0.9144
Sex, n (%)				
Women	20 (64.5)	5 (100.0)	15 (57.7)	0.1328†
Men	11 (35.5)	0 (0.0)	11 (42.3)	—
Eye, n (%)				
Right	13 (41.9)	1 (20.0)	12 (46.2)	0.3679†
Left	18 (58.1)	4 (80.0)	14 (53.8)	—
Lens status, n (%)				
Phakic	18 (58.1)	0	15	0.1012†
Pseudophakic	13 (41.9)	4	12	—
Refraction	−13.2 ± 5.6	−9.1 ± 1.5	−14.0 ± 5.8	0.1321
Axial length	30.3 ± 2.5	30.7 ± 1.2	30.2 ± 2.9	0.7389
PLT, n (%)				
No laser	22 (71)	1 (20.0)	21 (80.8)	0.0171
vSLT	9 (29)	4 (80.0)	5 (19.2)	—
Previous surgery, n (%)				
No	22 (71)	0	23	—
Trabeculectomy	3 (9.7)	1	2	—
Deep sclerectomy	1 (3.2)	0	1	0.0001‡
Laser refractive surgery	4 (12.9)	4	0	—
VTC (macular hole)	1 (3.2)	0	1	—
SCAI, n (%)				
Yes	9 (29.0)	0	9 (34.6)	0.2862
No	22 (71.0)	5 (100.0)	17 (65.4)	—
Preoperative IOP, mm Hg				
Mean ± SD	23.5 ± 7.9	19.8 ± 3.7	24.2 ± 8.4	0.2570
Preoperative medications				
Mean ± SD	3.0 ± 1.1	3.2 ± 1.1	3.0 ± 1.1	0.6153
Central corneal thickness, µm				
Mean ± SD	527 ± 77.8	442.0 ± 81.8	561.7 ± 45.4	< 0.0001
Visual field, dB				
Mean defect				
Mean ± SD	−11.8 ± 6.7	−12.11 ± 3.75	−10.72 ± 5.85	0.6506
BCDVA				
Mean ± SD	0.39 ± 0.3	0.41 ± 0.23	0.41 ± 0.26	0.8320

*Mann-Whitney test.
†Fisher exact test.
‡χ^2 for trend test.
BCDVA indicates best-corrected distance visual acuity; IOP, intraocular pressure; PLT, previous laser treatment; SCAI, systemic carbonic anhydrase inhibitor; SLT, selective trabeculoplasty; VTC, vision-threatening complication.

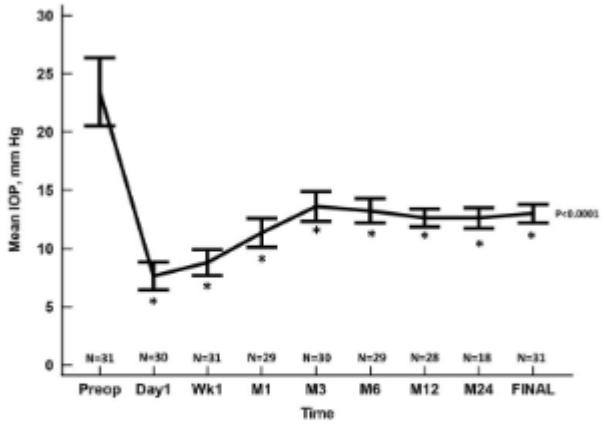

FIGURE 1. Mean IOP in the overall study sample. Vertical bars represent 95% confidence Interval. *$P < 0.0001$ as compared to baseline (repeated measures ANOVA and the Greenhouse-Geisser correction). The last-observation-carried-forward method was used to input missing data for calculating the FINAL IOP. IOP indicates intraocular pressure; Wk: week; M: month

TABLE 2. Adjusted Mean Intraocular Pressure (IOP) Lowering in the Overall Study Sample Throughout the Study

Time	n	Mean (SD) lowering from baseline	*P*
Day 1	30	−15.3 (7.1)	<0.0001
Week 1	31	−14.7 (8.6)	<0.0001
Month 1	29	−12.7 (6.8)	<0.0001
Month 3	30	−10.0 (7.6)	<0.0001
Month 6	29	−10.3 (7.4)	<0.0001
Month 12	28	−11.0 (8.4)	<0.0001
Month 24	18	−9.7 (9.0)	<0.0001
Final	31	−10.5 (8.1)	<0.0001

IOP lowering has been adjusted by preoperative IOP and refractive error.

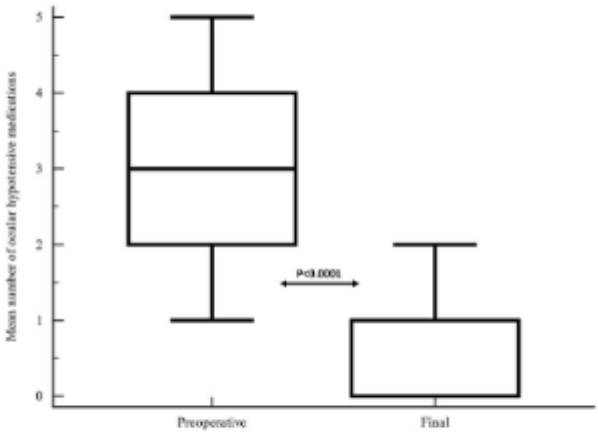

FIGURE 2. Box and whisker plot of the number of ocular hypotensive medication at baseline and at the last follow-up visit. Statistical significance was calculated with Wilcoxon test.

TABLE 3. Proportion of Eyes Who Achieved Different Intraocular Pressure (IOP) Targets and an IOP Reduction ≥20%, With and Without Treatment, at Month 12

	Month 12 (n = 28)	
	Qualified success	Complete success
IOP	N (%)	N (%)
≤12	5 (17.9)	3 (10.7)
≤14	16 (57.1)	11 (39.3)
≤16	21 (75.0)	13 (46.4)
≤18	25 (89.3)	1 (89.3)

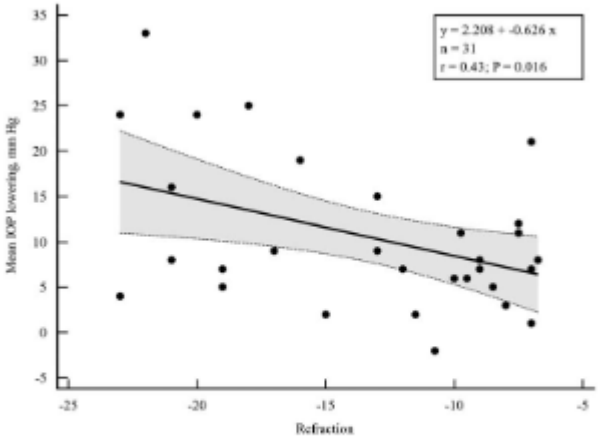

FIGURE 3. Linear regression analysis between intraocular pressure lowering (*y* axis) and preoperative refraction (*x* axis) in the overall study sample.

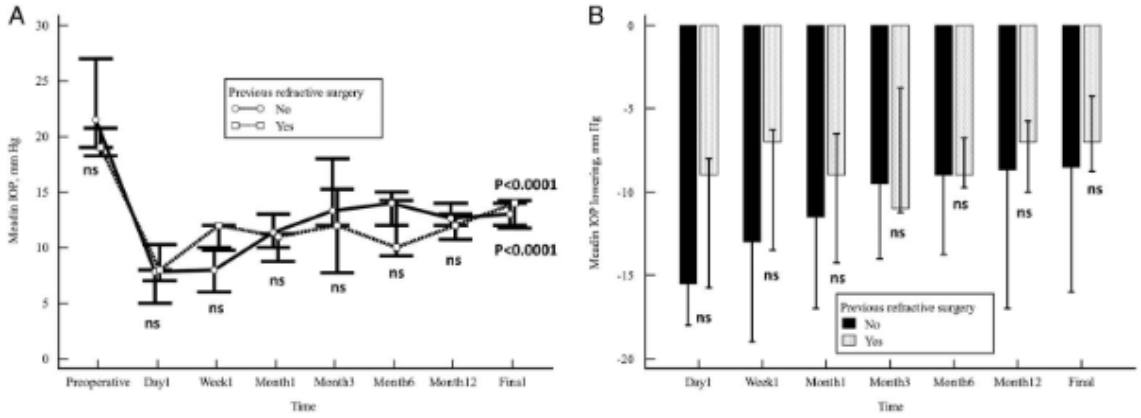

FIGURE 4. A comparison between eyes who underwent previous refractive surgery and those who did not. A, An overview of the median IOP throughout the study. Vertical bars represent interquartile range. As compared with baseline, the mean IOP was significantly reduced, at every time point measured, $P < 0.0001$ (Friedman test). Statistical significance between groups, at the different time point measurements, was determined using the Mann-Whitney *U* test. B, An overview of the median IOP lowering throughout the study. Vertical bars represent interquartile range. As compared with baseline, the mean IOP was significantly reduced, at every time point measured, $P < 0.0001$ (Friedman test). IOP indicates intraocular pressure; IqR, interquartile range.

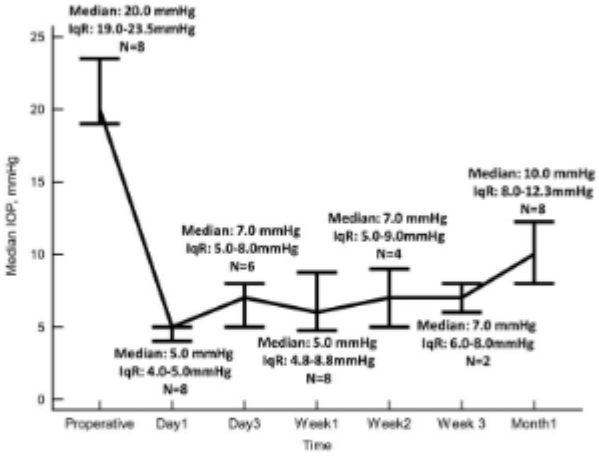

FIGURE 5. Overview of the median intraocular pressure among the 8 eyes with postoperative hypotony. Vertical bars represent interquartile range. IOP indicates intraocular pressure; IqR, interquartile range; N, number of eyes.

TABLE 4. Overview of the Main Demographic and Clinical Characteristics of the Eyes Who Had Hypotony

									IOP								
N	Age	Sex	Eye	Dx	Refrac.	Surgery	PreopBCVA	PreopNOHM	Preop	D1	D3	W1	W2	W3	M1	Needling	PostBCVA
1	61	F	L	PEXG	−7.00	Solo	0.7	3	31	5	5	5	8	NA	13	Y	0.7
2	50	M	R	POAG	−19.00	Solo	0.1	3	21	4	4	4	4	6	7	N	0.1
3	60	F	R	POAG	−8.00	Solo	0.4	3	19	5	8	11	NA	NA	11	N	NA
4	67	F	L	POAG	−7.00	Solo	CF	5	21	5	8	8	NA	NA	8	N	NA
5	54	M	R	POAG	−12.00	Solo	0.7	4	20	3	10	12	NA	NA	12	N	NA
6	44	F	L	POAG	−18.00	Solo	0.4	4	38	NA	NA	4	6	8	8	N	0.2
7	69	F	R	POAG	−9.00	Solo	0,32	2	19	4	6	6	10	NA	10	Y	0.5
8	51	M	L	POAG	−7.00	Comb	0,63	3	13	5	NA	5	NA	NA	13	Y	1
9	79	F	L	POAG	−6,75	Solo	0,5	2	19	5	NA	6	NA	NA	10	N	0.63

BCVA indicates best-corrected visual acuity; Comb, combined procedure; D, day; Dx, diagnosis; F, female; IOP, intraocular pressure; M, male; M, month; N, case number; NOHM, number of ocular hypotensive medications; PEXG, pseudoexfoliative glaucoma; POAG, primary open angle glaucoma; Post, postoperative; Preop, preoperative; Refrac, refraction; W, week.

TABLE 5. Overview of the Intraoperative and Postoperative Adverse Events

Complication, n (%)	Total population (n = 154)
Needling	11 (39.3)
Surgical revision	2 (7.1)
Additional surgery*	1 (3.6)
Hypotony	8 (28.6)
Choroidal detachment	8 (28.6)
Hyphema†	1 (3.6)
Intraoperative hyphema	1 (3.6)
Conjunctival hemorrhage	1 (3.6)
Myopic maculopathy	1 (3.6)
Ptosis	1 (3.6)

*Ex-press implant.

†This eye developed a cataract with a reduction of 7 lines in best-corrected visual acuity.

TABLE 6. A Comparison of the Clinical Outcomes Between the Current Study and the Available Evidence

Study	Preop IOP, mm Hg	M12 IOP, mm Hg	M12 IOP lowering	M 24 IOP, mm Hg	M 24 IOP lowering, mm Hg	Mean preoperative NOHM	Mean NOHM, last visit	Needling rates at last follow-up visit, n (%)
Reitsamer et al[21]	21.4 (3.6)§	14.9 ± 4.5§	−6.5 ± 5.3§	15.2 ± 4.2§	−6.2 ± 4.9§	2.7 ± 0.9§	1.1 ± 1.2§	83 (41.1)
Marcos Parra et al[23]	19.1 (5.4)§	N.A.	−6.7 (−12.9 to −0.5)‖	NA	NA	2.5 (0.8)	0.2 ± 0.6§	13 (20.0)
Fea et al[24]	23.9 (7.6)§	15.5 ± 3.9§	−7.4 ± 7.9	NA	NA	3.0 (1.0)	0.5 ± 1.0§	79 (46.2)
Laborda-Guirao et al[27]*	21.0 (5.2)§	14.7 (13.9 to 15.4)‖	−6.3 (−8.8 to −4.4)‖	NA	NA	2.8 (2.7 to 3.0)‖	1.1 (0.8 to 1.3)‖	7 (8.8)
Gabbay et al [31]	22.1 ± 6.5§	15.4 ± 5.9§	−6.7 ± 6.2§	14.5 ± 3.3§	−7.6 ± 5.2	2.77 ± 1.1§	0.5 ± 1.0§	57 (37.7)
Mansouri et al [32]	20.0 ± 7.5§	NA	NA	14.1 ± 3.7§	−6.4 ± 5.9§	2.0 ± 1.3§	0.6 ± 0.9§	58 (45)
Grover et al[33]	25.1 (3.7)§	15.9 ± 5.2§	−9.1 (−10.7 to 7.5)‖	NA	NA	3.5 (1.0)	1.7‡	21 (32.3)
Ibáñez-Muñoz et al [34] †	22.3 (21.0–23.5)‖	15.3 (14.3–16.3)‖	−7.3 (−9.7 to −5.0)‖	NA	NA	3.0 ± 1.0	1.2 ± 1.2	19 (26.0)
Theilig et al[35]	24.5 ± 6.7§	16.6 ± 4.8§	NA	NA	NA	3.0 ± 1.1§	1.4 ± 1.5§	42 (42.0)
Hengerer et al [36]	32.2 (9.1)§	14.2 ± 4.0	32.2#,‡	N.A.	N.A.	3.1 ± 1.0§	0.3 ± 0.7§	67 (27.7)¶
Wanichwecharungruang and Ratprasatporn[37]	21.6 ± 4.0	15‡	30.6#,‡	14.6 ± 3.5§	32.4#,‡	2.1 ± 1.4	0.5 ± 0.7§	10 (17.5)
Current study	23.5 ± 7.9§	13.0 ± 2.2§	−10.5 (−13.4 to −7.5)‖	12.6 ± 1.7§	−9.7 (−14.1 to −5.2)‖	3.0 ± 1.1§	0.6 ± 1.0§	11 (39.3)

*Overall study sample.
†Mean IOP lowering was −7.3 (−9.7 to −5.0) mm Hg in the primary open angle glaucoma patients and −6.6 (−8.4 to −4.8) mm Hg in the secondary open angle glaucoma eyes.
‡Data about standard deviation was not provided.
§Mean (SD).
‖Mean (95% CI).
¶All the needling procedures were done between week 1 and month 3.
#Percentage.
IOP indicates intraocular pressure; NOHM, number of ocular hypotensive medications.