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ORIGINAL RESEARCH

Performance and Safety of Minimally Invasive Nasal Trabeculostomy (MINT™) in Open-Angle Glaucoma: A 12-month Open-Label Study on Patients with No Other Glaucoma Surgeries

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Purpose: Minimally invasive nasal trabeculostomy (MINT™) is an ab interno, stent-less, trabecular-opening glaucoma procedure designed to reduce intraocular pressure (IOP) in patients with open-angle glaucoma (OAG). This 12-month, prospective, single-arm, open-label study aimed to evaluate the performance and safety of the MINT device in patients with OAG with uncontrolled IOP.

Methods: Eligible patients had uncontrolled OAG (IOP ≥21 mmHg with maximum tolerated glaucoma medications). The primary efficacy endpoint was the proportion of patients achieving ≥20% IOP reduction from baseline on the same or fewer medications at Week 24. Secondary efficacy endpoints were mean change in IOP from baseline at Weeks 24 and 52, and the proportion of patients achieving a ≥20% reduction in IOP from baseline on the same number or fewer medications at Week 52.

Results: The procedures were performed between 11 April 2022 and 24 October 2022 by one surgeon (LV) at the Ophthalmologic Center after S.V. Malayan, Yerevan, Armenia. Sixty-six eyes of 66 patients underwent the procedure; 63 and 56 patients completed the Week 24 and 52 visits, respectively. Fifty-two of 63 (82.5%) patients achieved the primary endpoint. The mean (standard deviation) baseline IOP (22.7 ± 1.4 mmHg) was reduced by 34.2% to 15.0 ± 2.8 mmHg at Week 24, and by 35.3% to 14.7 ± 2.4 mmHg at Week 52. Twenty-two adverse events (AEs) were reported, including 20 postoperative ocular AEs in 15 patients. Ocular AEs were non-serious and mild.

Conclusion: In this patient population, the MINT device achieved an 82.5% success rate as per the FDA-recommended primary endpoint. IOP was lowered from baseline, below the European Glaucoma Society target range for early glaucoma (<20 mmHg) in 98.4% of patients and moderate glaucoma (<17 mmHg) in 68.3% of patients. No intraoperative and minimal postoperative complications were reported.

Clinical Trial Registration: https://clinicaltrials.gov/study/NCT05638906 (NCT05638906).

Keywords: ab interno, glaucoma filtration surgery, IOP-lowering medication, minimally invasive nasal trabeculostomy, open-angle glaucoma

Introduction

The goal of glaucoma therapy is to reduce intraocular pressure (IOP) with medications, laser treatment or surgery.[1–3] Incisional surgery, such as trabeculectomy, has proven effective at lowering IOP; however, the potential severity of intra- and postoperative complications are a serious consideration, meaning these procedures are usually reserved for patients who are unlikely to maintain sight with only pharmacological or laser intervention.[2,4] Newer minimally invasive glaucoma surgery (MIGS) devices are used to reduce IOP by reducing resistance to outflow via the trabecular meshwork (TM) and Schlemm's canal (SC).[5,6] MIGS procedures are increasingly favored over traditional surgeries owing to the

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reduced invasiveness, relatively quick recovery, and improved safety profile.[5,6] As the reduction of IOP with MIGS is lower than with traditional surgical interventions, the suitable patient will usually have mild to moderate glaucoma with target IOP in the mid to high teens with the additional aim of reducing the burden of topical medication.[4,6]

The Minimally Invasive Micro Sclerostomy (MIMS®) device was developed by Sanoculis Ltd to reduce IOP via an ab interno stent-less bleb-forming procedure.[2] The device creates a sclerostomy channel to allow aqueous humor to drain, similar to conventional trabeculectomy.[2] Studies have demonstrated an efficacy and safety profile that is comparable to existing MIGS devices, and the device has received CE-mark approval in Europe.[2]

The Minimally Invasive Nasal Trabeculostomy (MINT™) device, also developed by Sanoculis, uses the same design and components as the MIMS device, except for a minor difference in the trephine movement inside the surgical tool. Instead of a sclerostomy drainage channel, the MINT device can be used to efficiently create several distinct trabeculostomies, each penetrating into the nasal TM tissue to increase drainage of aqueous humor without penetrating through the whole sclera; thus, potentially minimizing the occurrence of intra- and postoperative complications. The main serious adverse events of MIMS are early hypotony when the amount of OVD left in the AC at the end of the procedure is too little, or on the other hand early IOP spikes when too much OVD is left in the AC.(2).

Technically, MIMS and MINT are administered with the same device. However the two procedures aim at different targets in the eye therefore the device is programmed to penetrate into two different depths, 600 microns for MINT and 2000 microns for MIMS.

The main difference between MIMS and MINT is that in MIMS with some similarity to Trabeculectomy a filtration channel is created that combines the anterior chamber to the subconjunctival space where the outflow resistance at an early stage is minimal. As opposed to Trabeculectomy where the scleral flap may be closed tightly, with MIMS OVD must be injected into the AC at the end of the procedure to temporarily increase the resistance to flow of the created channel until healing occurs in the subconjunctival space and outflow resistance increases. With MINT, only the trabecular meshwork is treated, the collector channels and the episcleral veins manage outflow resistance line to provide at least 10 mmHg resistance and keeps the IOP stable In addition no OVD is left in the AC for the MINT procedure, improves the safety of MINT over MIMS by limiting the potential for IOP spikes as no OVD is left in the AC.

This 12-month, prospective, single-arm, open-label study was designed to evaluate the IOP-lowering efficacy and safety of the MINT device in patients with open-angle glaucoma (OAG) with uncontrolled IOP in subjects that had no other glaucoma surgeries.

Methods

Study Design

This is a prospective, single-arm, single-center (Ophthalmologic Center after S.V. Malayan, Yerevan, Armenia), open-label study with intra-patient comparisons (ClinicalTrials.gov Identifier: NCT05638906). The study was approved by the local Independent Ethics Committee of S. Malayan Eye Center, Yerevan, Armenia, and conducted in accordance with the Declaration of Helsinki, Good Clinical Practice, ISO 14155:2020 standard, and the local/national guidelines and regulations of the S. Malayan Eye Center.

Patients were enrolled and the procedures performed between 11 April 2022 and 24 October 2022. All patients were treated by Dr. Voskanyan, using the same configuration of the MINT device (A32-000). Dr. Voskanyan has been an ophthalmic surgeon since 1991 and has performed thousands of surgeries using MIGS devices as part of clinical studies and regular surgical practice.

The MINT device is similar to the MIMS device, which has undergone exhaustive preclinical and clinical testing. The design of this study was based on the prior preclinical and clinical experience with the MIMS device, as well as the published recommendations of the World Glaucoma Association (WGA) guidelines on design and reporting of glaucoma surgical trials, and ANSI Z80.27–2014(R2019) Standard for Implantable Glaucoma Devices.

In this study, patients serve as their own control over time with repeated observation, which controls for interpatient variation. Since spontaneous improvement in IOP was not expected, treatment outcomes from the MINT device were not expected to be affected by natural disease history.

Outcome measures were chosen to demonstrate performance as assessed by well-accepted and characterized efficacy and safety measures in surgical treatments for glaucoma. Endpoints were based on recommendations from WGA, International Council of Ophthalmology Guidelines, and European Glaucoma Society (EGS) guidelines, where the EGS recommends that an IOP of 18–20 mmHg with a reduction of > 20% may be sufficient in early glaucoma phase.[3] The primary endpoint of 20% reduction in IOP is the United States Food and Drug Administration (FDA)-recommended primary effectiveness endpoint for implantable MIGS devices.[7] The primary endpoint follow-up time of 24 weeks is sufficient time for evidence of complications to arise and is aligned to the past assessment of ab-interno MIGS devices, allowing indirect comparison with these devices. Additional post-hoc analyses were performed based on target IOP recommendations from the EGS Guide on Surgical Innovation for Glaucoma.[6]

Patients

Eligible patients were diagnosed with uncontrolled OAG, defined as an IOP >20 mmHg when using maximum tolerated glaucoma medications. Patients were eligible for inclusion with the following criteria: 18–85 years old with IOP ≥21 mmHg at screening; OAG, diagnosed in accordance with EGS criteria;[3] Shaffer grade ≥III in all four angle quadrants in the study eye; treated with 0–5 ocular hypotensive medications in the study eye; and willing and able to attend all scheduled follow-ups, and provide informed consent. Patients were excluded with any of the following criteria: any form of glaucoma other than primary open-angle glaucoma (POAG); any ocular conditions with a poorer prognosis in the fellow eye than in the study eye; history of ocular disease, severe trauma, or previous surgery in the study eye, except for clear corneal cataract surgery; peripheral anterior synechiae, rubeosis or other angle abnormalities in the study eye; penetrating keratoplasty or any ocular pathology that may interfere with IOP measurements; vitreous present in anterior chamber (AC), prior vitrectomy or vitreous hemorrhage in the study eye; clinically significant ocular inflammation or infection within 90 days before screening in either eye; best corrected visual acuity (BCVA) worse than 20/40 (Snellen equivalent) in the fellow eye; inability to discontinue use of blood thinners; uncontrolled systemic disease that in the opinion of the investigator would put the patient's health at risk and/or prevent the patient from completing all study visits; participation in another clinical trial within the last 30 days before the screening visit; pregnant or lactating.

Device

The MINT device was provided by Sanoculis Ltd (A34-000). It comprises a surgical device and an activation device (Figure 1). The surgical device is a sterile, disposable component, intended for a single use, composed of a stainless steel 304 micro-trephine and needle assembled inside a plastic handpiece that transmits the rotating motion from the activation device. The activation device is intended for repeated use and non-electronic parts are reprocessed by autoclave before each use. It comprises a controller that manages the activation pulse duration and rotations per minute, a motor, and a footswitch that allows the user to activate the machine. The MINT device is similar to a marketed Sanoculis device, the MIMS device, except for the length of the trephine penetration into the tissue.[2]

Figure 1 MINT Device.
Notes: (**a**) Activation device, including footswitch, motor, and controller; (**b**) surgical device including micro trephine and needle assembled inside a plastic handpiece.
Abbreviation: MINT, minimally invasive nasal trabeculostomy.

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Surgical Procedure

The patients were prepared for the procedure according to standard of care and local guidance practices, including topical anesthesia (tetracaine 1%). A small clear temporal corneal incision of 1.5 mm was made using an ophthalmic knife through which an ocular viscoelastic device (OVD) (BioLon®, Ferring Pharmaceuticals; or DuoVisc®, Alcon) was injected into the AC to ensure stability of the structure. The MINT device was inserted into the AC through the corneal cut and moved forward until the tip reached the angle as depicted in Figure 2; visualization was aided with the use of a gonioprism. The tip of the device was then placed on the pigmented trabecular band in the nasal quadrant. The MINT device was activated and penetrated through the TM and SC into the outer wall of SC to a depth of 200–300 µm (Figure 3). The trephine rotates at 3000 RPM to create an ~150 µm opening in the TM with minimal damage to surrounding tissues. This procedure was repeated five times to create five openings in the inferonasal TM about 1 clock hour apart. The device was then removed from the eye. The OVD was replaced with balanced salt solution and the corneal cut was sealed by hydration. Topical antibiotics and steroid drops were instilled immediately post-procedure to reduce inflammation and prevent infection, and patients followed a regimen of dexamethasone drops four times a day for at least 4 weeks until the inflammation resolved.

Study Visits and Assessments

The study eyes/patients were evaluated at the following postoperative visits: Day 1, Day 7 (± 2 days), Day 14 (± 3 days), Week 4 (± 7 days), Week 12 (± 14 days), Week 24 (± 14 days). Additional optional follow-up study visits at Week 38 (± 14 days) and Week 52 (± 21 days) were included. All patient data were recorded on a dedicated case report form (CRF) as allocated per each scheduled follow-up visit. If required, additional visits were scheduled according to physician discretion and were reported as such within the CRF (interim visits). Demographics, full medical history (general and glaucoma related), glaucoma type, and number and type of glaucoma medications were recorded at

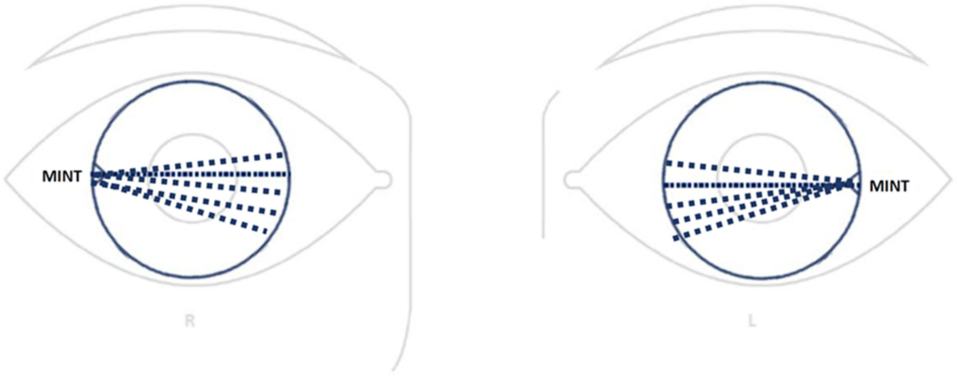

Figure 2 Depiction of the Surgical Device insertion angle towards the nasal trabeculostomy site.
Abbreviation: MINT, minimally invasive nasal trabeculostomy.

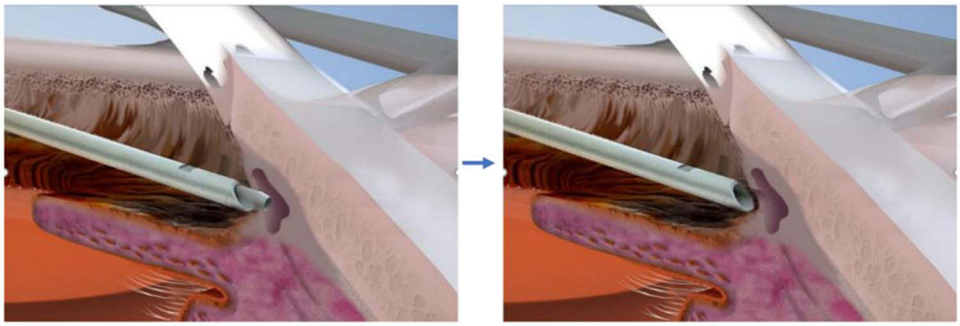

Figure 3 Depiction of Surgical Device at the nasal trabeculostomy site.

screening. Additionally, IOP, glaucoma medications, BCVA, complications/adverse events (AEs) and biomicroscopy were documented at screening/baseline and at all postoperative visits. At each visit, two IOP measurements were taken using a calibrated Goldmann applanation tonometer and the average measurement was recorded. In the case of ≥4 mm difference between the two IOP measurements, a third measurement was taken and the average of the two closest readings was recorded. Intraoperative complications and AEs were recorded during the procedure. All surgeries were recorded via a dedicated surgical microscope camera. Additional ophthalmologic investigations included refraction (BCVA), biometry, and anterior segment optical coherence tomography (OCT) at Visits 3–8, and macular OCT, specular microscopy, fundus examination, and optic disc assessments at Visits 5–8. Automated 360 degrees gonioscopy photographs were also taken at 4 weeks, 24 weeks and 52 weeks, however many photographs had inadequate quality.

Outcome Measures

The primary efficacy endpoint was the proportion of patients achieving a ≥20% reduction in IOP from baseline on the same number or fewer ocular hypotensive medications at Week 24. Requirement for reintroduction of ocular hypotensive medications was as judged by the physician. Secondary efficacy endpoints were as follows: mean change in IOP from baseline at Week 24, proportion of patients achieving a ≥20% reduction in IOP from baseline on the same number or fewer medications at Week 52 (optional visit), and mean change in IOP from baseline at Week 52 (optional visit). Safety endpoints included the incidence of AEs related to the MINT device/procedure, including visual acuity and intra- and postoperative complications throughout the study follow-up. Exploratory endpoints included proportion of patients achieving target IOP 5–≤ 18 mmHg without reoperation for glaucoma with the same or fewer medications, or medication free.

Post-Hoc Analyses

Additional post-hoc analyses included the proportion of patients with IOP 6–15 mmHg, 16–20 mmHg, and >20 mmHg at baseline, Week 24, and Week 52; proportion of patients with 0, 1, 2, or ≥3 medications for glaucoma at baseline, Week 24, and Week 52; proportion of patients <17 mmHg and <20 mmHg without reoperation for glaucoma with the same or fewer medications, or medication free, at Week 24 and Week 52.

Additional success criteria included proportion of patients achieving ≥25% reduction in IOP from baseline on the same number or fewer medications at Week 52, and proportion of patients achieving a mean IOP ≤ 21 mmHg *and* a ≥25% reduction in IOP from baseline on the same number or fewer medications at Week 52. These criteria were included based on the EGS Guide on Surgical Innovation for Glaucoma 2023 target IOP recommendations, including the use of more than one set of criteria in presentation of data.[6]

Statistical Analysis

Based on practical and scientific considerations, it was assumed that analysis of 65 patients would be sufficient to meet the study objectives. Assuming an 8% dropout rate, 71 patients were enrolled into the study.

Data collected at each visit were compared with baseline values. For data analysis, continuous variables were described using means and standard deviations (SDs). Dichotomous variables were presented as percentages. Two-sided 95% Clopper–Pearson confidence intervals (CIs) were calculated for all measured values. Number and percentage of reported AEs were stratified by severity, relationship to device/procedure, and resolution status. Individual patient pre- and postoperative IOP were analyzed in a scatterplot, with indicators of the different prespecified success criteria marked on the plot for visual analysis. Paired *T* test was used to compare the IOP at 24 and 52 week to baseline.

Results

Patient Disposition and Baseline Characteristics

Of 71 patients screened and enrolled, the MINT surgical procedure was performed on 66 eyes of 66 patients. The remaining five recruited patients received an alternative surgical treatment and were excluded from the study (see below). The procedure was performed in 34 right and 32 left eyes. Patient demographics and baseline characteristics are shown in Table 1.

The mean baseline IOP was 22.7 ± 1.4 (95% CI: 22.4–23.0) mmHg. At baseline, patients were treated with an average of 0.88 ± 0.81 (95% CI: 0.7–1.1) ocular hypotensive medications. Of the 66 patients on whom the procedure was performed, 63 (96%) patients completed the Week 24 visit. Of the remaining three patients, two were lost to follow-up. One patient missed the Week 24 visit, but returned for the Week 38 visit. The three patients who missed the Week 24 visit were not included in the performance analysis but were included in the safety analysis. Fifty-four and 56 patients completed the Week 38 and Week 52 optional follow-up visits, respectively.

Effectiveness

There was only one out of 66 MINT procedures where intraoperative device malfunction allowed for only 3 trabecular penetrations instead of 5. The patient however, remained in the study. All other 65 cases underwent a complete decent MINT procedure. In 5 additional cases the MINT procedure was not done due to unavailability of a MINT device due to exploitation of all allocated devices for a specific surgical session. These patients could not be delayed to the next MINT surgery session and were offered and underwent an alternative anti-glaucoma surgical procedure. These cases were of course excluded from the 71 patients who were recruited for the study. The technical function of the device was tested immediately prior to the procedure to verify the integrity of the surgical device; 10 devices were marked under Device Deficiency. In nine devices the surgical tool (trephine) was locked into the surgical device. They were therefore disqualified for use prior to surgery, and the procedures were performed with another tested MINT device. In one device the surgical tool did not return to its sleeve as expected after 3 penetrations, and the surgeon decided to abort creation of two additional channels, as required per protocol, and sealed the paracentesis. As noted above, the patient continued with the follow-ups as per the protocol. For the primary endpoint, at Week 24, 52/63 (82.5% [95% CI: 70.9–90.9]) patients treated with the MINT device achieved ≥20% IOP reduction from baseline on the same or fewer number of medications and did not require any reoperation for glaucoma. At Week 52, 52/56 (92.9% [95% CI: 82.7–98]) patients treated with

Table 1 Patient Demographics and Baseline Characteristics

Demographics/Characteristics	Patients (N=66)
Mean age, y (SD)	63.8 (10.6)
Sex, n (%)	
Female	38 (57.6)
Male	28 (42.4)
Race, Caucasian, n (%)	66 (100)
Prior surgeries or laser treatments for glaucoma, n (%)	0 (0)
Baseline endothelial cell count (cells/mm^2), mean (SD)	2306 (485)
Type of glaucoma: POAG, n (%)	66 (100)
Mean medicated IOP, mmHg (SD)	22.7 (1.4)
Mean number of IOP-lowering medications	0.88 (0.81)
Operative eye, n (%)	
Right	34 (51.5)
Left	32 (48.5)
Phakic	52 (78.8)
Pseudophakic	14 (21.2)

Abbreviations: IOP, intraocular pressure; POAG, primary open-angle glaucoma; SD, standard deviation.

the MINT device achieved ≥20% IOP reduction from baseline on the same or fewer number of medications and did not require any reoperation for glaucoma. A scatterplot of pre- and 52-week postoperative IOP measurements for each patient, including number of medications at Week 52, is shown in Figure 4.

At Week 24 and 52, 48/63 (76.2% [95% CI: 63.7–86.0]) and 44/56 (78.6% [95% CI: 65.6–88.4]) patients, respectively, achieved ≥20% IOP reduction from baseline and were medication free.

At Week 24 and 52, the mean IOP ± SD dropped from baseline of 22.7 ± 1.4 (95% CI: 22.4–23.0) mmHg to 15.0 ± 2.8 (95% CI: 14.3–15.7) mmHg (P<0.01, paired *t* test) and 14.7 ± 2.4 (95% CI: 14.1–15.4) (P<0.01, paired *t* test), respectively, following treatment with the MINT device, resulting in a mean reduction in IOP from baseline of 34.2% and 35.3%, respectively (Figure 5).

At Week 24 and 52, 62/63 (98.4%) and 56/56 (100%) of patients, respectively, had an IOP <20 mmHg, and 43/63 (68.3%) and 43/56 (76.8%), respectively, had an IOP <17 mmHg. The patient distribution of IOP is shown in Figure 6.

The mean number of glaucoma medications was reduced from 0.88 ± 0.81 (95% CI: 0.7–1.1) at baseline to 0.19 ± 0.50 (95% CI: 0.1–0.3) (P<0.01, paired *t* test) and 0.21 ± 0.49 (95% CI: 0.1–0.3) (P<0.01, paired *t* test) at Week 24 and 52, respectively, resulting in a mean reduction of 78.3% and 76.0%, respectively, as shown in Figure 7. Patient distribution of glaucoma medications by timepoint is shown in Figure 8.

At Week 24 and 52, the prespecified success criteria of the proportion of patients achieving target IOP 5–≤18 mmHg from baseline without reoperation for glaucoma was 87.3% (95% CI: 76.5–94.4) and 89.3% (95% CI: 78.1–96.0) with

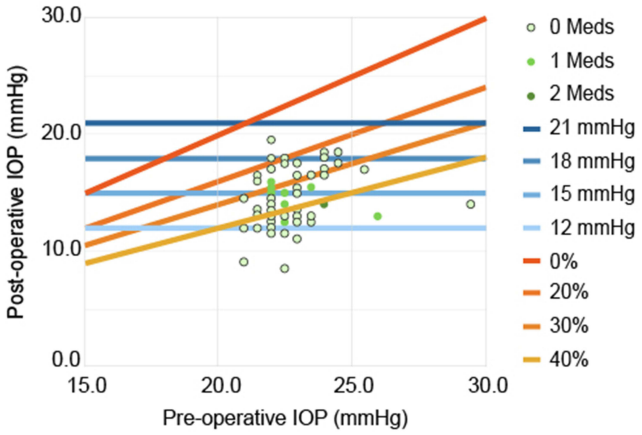

Figure 4 Pre- and 52-week postoperative IOP.
Notes: Individual dots denote each patient, with the color indicating the number of medications at 52 weeks post-procedure. Horizontal lines indicate significant IOP targets, and diagonal lines indicate percentage reduction in IOP from pre- to post-procedure at Week 52, where the solid black line would indicate no change. Dots below the shallower lines indicate a greater percentage reduction in IOP.
Abbreviations: IOP, intraocular pressure; Meds, medications.

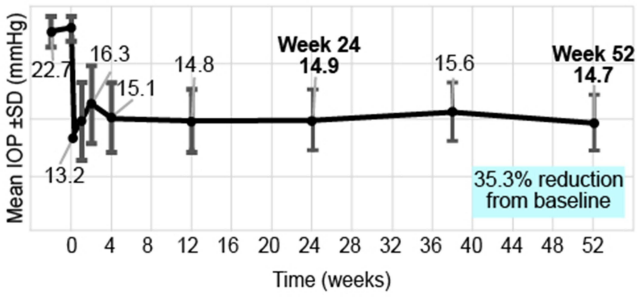

Figure 5 Mean IOP (mmHg) by study visit.
Notes: Values are mean with standard deviation. Bolded Week 24, and Week 52 are the primary endpoint and primary safety follow up.
Abbreviation: IOP, intraocular pressure.

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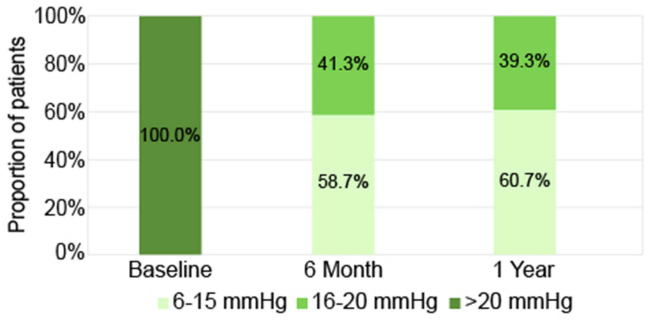

Figure 6 Distribution of IOP at baseline, Week 24, and Week 52.
Abbreviation: IOP, intraocular pressure.

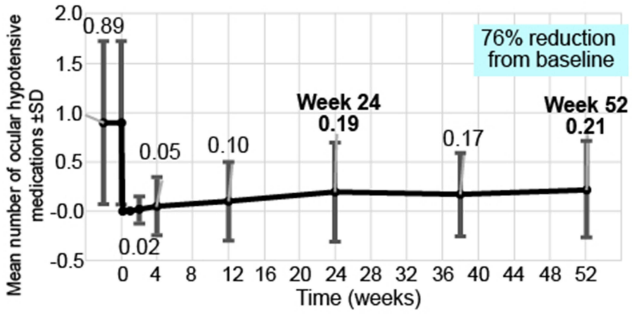

Figure 7 Mean number of ocular hypotensive medications by study visit.
Notes: Values are mean with standard deviation. Bolded Week 24, and Week 52 are the primary endpoint and primary safety follow up.
Abbreviation: SD, standard deviation.

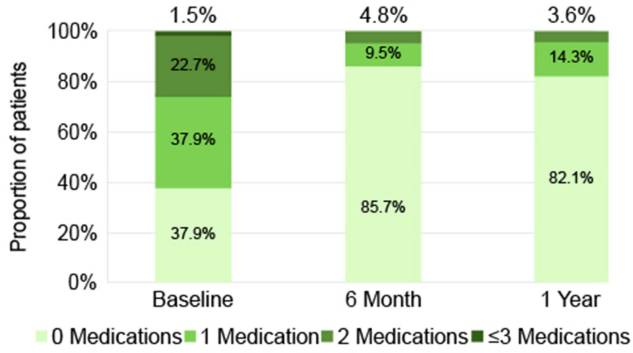

Figure 8 Distribution of number of ocular hypotensive medications for glaucoma at baseline, Week 24, and Week 52.

the same or fewer medications, respectively, and 75.0% (95% CI: 61.6–85.6) and 81.0% (95% CI: 69.1–89.7%) medication free, respectively. Post-hoc analyses of additional success criteria at Week 52 showed 42/56 (75.0% [95% CI: 61.6–85.6]) patients achieved a ≥25% reduction in IOP from baseline on the same number or fewer medications *and* a mean IOP ≤21 mmHg at Week 52.

Of the 56 patients who have completed one year follow-up there were 13 pseudophakic and 43 phakic patients. The results for both groups were similar. IOP decreased from 22.75±1.4 to 14.72±2.37 mmHg in the phakic group and from 22.71±1.27 to 14.65±2.8 mmHg in the pseudophakic group.

Automated 360 degrees gonioscopy images were taken periodically in all patients using a Nidek machine. Despite technical difficulties in obtaining good quality images, in a substantial number of patients trabecular holes were clearly demonstrated as shown in Figure 9.

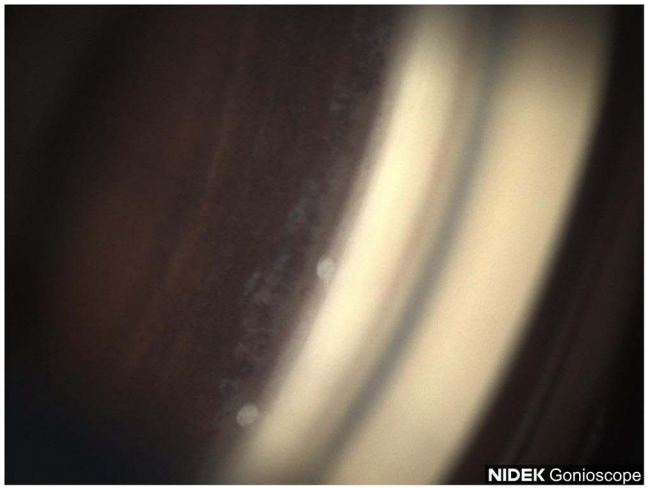

Figure 9 (gonioscopy) Trabecular holes as seen with the automated Nidek gonioscope. Observed holes have remained unchanged throughout the study period.

Safety

A total of 22 AEs were reported over the 52-week follow-up period, including 20 postoperative ocular AEs reported in 15/66 (22.7%) patients. All ocular AEs were non-serious of a mild severity. One death was recorded, but this was deemed unrelated to the intervention. No intraoperative complications were reported. A full summary of AEs is shown in Table 2.

Of 20 ocular AEs, eight events of mild iris/AC bleeding were reported in eight patients on Day 1 and were considered as most probably related to the MINT procedure; The observed cases of hyphema were mainly microscopic only and resulted from blood entering from Schlemm's canal into the anterior chamber through the five trabecular openings. In nearly all cases it was observed in the first postoperative day and none where observed in the 1 week follow-up visit.

Six AEs reported in four patients at Week 52, including two BCVA decrease (≥2 lines) due to cataract formation and maturation, and four cataract formation or acceleration, were defined as mild events possibly related to the procedure. One mild event of BCVA decrease (≥2 lines) in one patient (Week 24), and one cataract formation in the fellow eye (Week 52) were defined as probably not related to the procedure. The patients with postoperative BCVA decrease or cataract formation/acceleration were referred for phacoemulsification surgery. Two additional events of cataract surgery were reported in two patients, who decided to withdraw their consent for participation in the study at the Month 9 visit and underwent phacoemulsification surgery, regardless of the outcomes of the MINT surgery. These patients were excluded from the Week 52 efficacy analysis set but were included in the safety analysis set. These two events were

Table 2 Summary of AEs

AEs, n (%)	Event Occurrence (N=66)
Ocular AEs (not requiring reoperation), n (%)	n=20 (30.3%)
Early events (Week ≤12)	
Iris bleeding/AC bleeding (hyphema)	8 (12.1)
Pain/discomfort	2 (3.0)
Late events (Week >12)	
BCVA decrease (≥2 lines) (Week 24)	3 (4.5)
Cataract formation or progression (Week 52)	5/43 (11.6)
Cataract surgery (following voluntary subject's withdrawal from the study) (Week 24)	2/50 (4.0)
Non-ocular AEs (n=2)	2 (3.0)
Death (due to heart attack) (SAE)	1 (1.5)
Stomach surgery	1 (1.5)

Abbreviations: AC, anterior chamber; AE, adverse event; BCVA, best corrected visual acuity; SAE, serious adverse event.

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defined by the investigator as not related to the study device/procedure at any time point. Two mild events of pain and discomfort in the study eyes of two patients (Day 14) were judged by the investigator as not related to the procedure. No events of postoperative ocular inflammatory reaction or infections were reported in this study. No patients were referred for reoperation for glaucoma following the MINT procedure during the follow-up period. Anterior segment OCT images from the inferonasal and nasal quadrant were obtained in all participants. Apart for showing absence of peripheral anterior synechiae in all cases, it was impossible to demonstrate clearly the trabecular holes created by the trepan.

There were no cases of iris plugging the trabecular holes. Iris plugging occurs when the IOP is very low and the flow-rate is high. With the MINT procedure, due to the remaining collector channels and episcleral veins outflow resistance, IOP is nearly never reduced below 10 mmHg and the flow is relatively slow, so it does not pull the iris into the trabecular openings.

Discussion

In this prospective, single-arm, single-center, open-label study in Caucasian patients with POAG, 82.5% and 92.9% of patients treated with the MINT device achieved ≥20% IOP reduction from baseline on the same or fewer number of medications and did not require any reoperation for glaucoma at Week 24 and Week 52 post-procedure, respectively, in line with the FDA-recommended primary effectiveness endpoint. At Week 24 and 52, the mean IOP was 15.0 mmHg and 14.7 mmHg, following a mean reduction in IOP of 34.2% and 35.3% from baseline, respectively. Importantly, this average reduction was achieved from Day 1 post-procedure, stabilized by Week 4 and maintained through to Week 52 of follow-up (Figure 5). While target IOP is determined by an individual patient's status, this reduction in IOP is clinically relevant and within the target range for early (<20 mmHg) and moderate (<17 mmHg) glaucoma;[3] at Week 52, 100% and 76.8% of patients achieved IOP levels below these targets, respectively. Where percentage reduction in IOP is used as a target, ≥25% reduction could be considered appropriate in patients with mild/early disease,[6] as per the EGS guidelines for surgical innovation. In this study, 75.0% of patients achieved these criteria with the same number or fewer medications. Concurrently, use of glaucoma medications was reduced by 78.3% and 76.1% from baseline to Week 24 and Week 52 of follow-up, respectively. This reduction in glaucoma medication can reduce concomitant issues including ocular surface toxicity, patient adherence for IOP control, and economic burden of medications.[8] All procedures were completed without complications, all postoperative ocular AEs were non-serious, and no patients required reoperation.

A systematic literature review was conducted to review IOP-lowering performance and safety at 24 weeks and 52 weeks of follow-up on similar ab interno devices (eg Trabectome, iStent® and iStent inject®, Hydrus®, iTrack™, Kahook Dual Blade® [KDB], OMNI® Surgical System, and STREAMLINE® Surgical System), and MIMS®. The Week 24 and 52 mean post-operative IOP (~15.0 mmHg) and mean percentage IOP reduction (~35%) with the MINT device was comparable to that of trabecular MIGS (ranging from ~12.2 to 17.7 mmHg[9–28] and 17.2 to 51.8%,[11,14,23–25,27,28] at Week 24 and 52, respectively).

The Week 24 and Week 52 mean percentage reduction in the number of glaucoma medications in MINT-treated eyes of ~77% is similar to the 78.3–87.1%, reported for eyes undergoing trabeculotomy using KDB combined with phacoemulsification[11,27] and the ~79% reported for OMNI Surgical System combined with phacoemulsification.[14] It should be noted that the range of medication reduction for the devices included in the review is wide (26.9–93.8%), possibly due in part to differing approaches to reintroduction of medications in the studies evaluated.[9–11,14,16,17,19,21–25,27]

Surgical success rates for 24 weeks and 52 weeks of follow-up were also assessed, with success definitions adapted to accommodate for variability in reported criteria. Based on the primary success criteria for the MINT procedure (IOP reduction from baseline of ≥20% on the same or fewer number of medications at 24 weeks *and* no reoperation for glaucoma), the success rate was ~86%, which is similar to the reported ~87% with iStent Inject[28] and 89.5% with STREAMLINE Surgical System combined with phacoemulsification.[23] When considering the most strict success criteria of target IOP within 5–18 mmHg and no reoperation for glaucoma, with no medications, the ~78% success rate of the MINT procedure is higher compared with that reported for the Trabectome procedures (9.3–66.0%[28,29]), and comparable to that reported for the OMNI, iStent, and Hydrus procedures when combined with phacoemulsification (71.0–88.0%).[17,30] Overall, across several endpoints, the MINT device performed similarly to equivalent devices at 24 and 52 weeks of follow-up. It is also important to note that while some of the above mentioned data demonstrate outcomes of MIGS combined with phacoemulsification, which has been shown to further reduce IOP,[17,29,31] this study

evaluated the IOP-lowering effect of MINT in isolation of cataract surgery, further demonstrating that the benefit is due solely to the MIGS procedure and not cataract surgery.

With the MINT device demonstrating IOP-lowering efficacy comparable to existing MIGS devices, choice of procedure in patients with mild to moderate POAG will depend on individual patient requirements. The ab interno approach, lack of implanting an intraocular device, reduced penetration depth, and lack of bleb with the MINT procedure will likely reduce the risk of intra- and postoperative complications. Compared with the other studied ab interno devices, in this study, the MINT device was not associated with any intraoperative complications, and was associated with a comparable or lower incidence of postoperative complications.[9–13,15–20,22–30,32–36]

Comparisons in this literature review demonstrate a consistency or improvement upon efficacy and safety of existing ab interno devices; however, comparisons are limited by differences in the study design and patient populations, and further studies would be required to confirm this.

Limitations of this study include a relatively short mandatory follow-up period (24 weeks, and optional visits up to 52 weeks) and small sample size (N=66), which lacked diversity in terms of glaucoma type, limiting the generalizability of the results. The 5 cases in which the procedure was not done due to an administrative problem of MINT device availability and the 3 patients who did not show for the 24 week visit decreased the number of eligible cases to 63. Despite the fact that the required sample size was 65 we assume that this lack of 2 patients from the required N of 65 has not substantially biased the results. In addition, the lengthy travel to Yerevan and the unstable situation in the country due to an on and off military conflict, affected the proportion of subjects who have completed the one year follow-up period. The lack of a control group and the open-label nature of the study, also have the potential to introduce bias. Further data are needed with extended follow-up, and a larger, more diverse patient population including patients of Asian or African American origin. Randomized controlled studies comparing MINT to other MIGS procedures would further validate the efficacy and safety of the MINT procedure. Additionally, as patients with glaucoma also have high concomitant rates of cataract, further investigation is needed to understand the combined effect on IOP and safety outcomes with other common ophthalmologic interventions, such as phacoemulsification. Based on prior studies evaluating both a MIGS procedure and cataract surgery,[17,29,31] there is a need to study the effect of MINT combined with phacoemulsification to explore its potential advantage over each procedure alone.

Most glaucoma surgeons have become quite comfortable with trabecular surgery. Despite this, precise maneuvering in the angle is a demanding task. The main advantage of the MINT over the other ab-interno procedures is its simplicity to use. The automation of the machine moving in and out eliminates the need for manipulating the trabecular tissue, especially repositioning it intraoperatively. Also, there are no stents left inside the eye with MINT, the integrity of the Schlemm's canal remains undisturbed and the trabecular tension is left intact, potentially keeping the outer wall undisturbed, thereby not distorting of the collector channels.

Conclusions

In summary, in this patient population the MINT device effectively lowered IOP from baseline to a comparable level to that of similar MIGS procedures. Safety outcomes were also comparable to existing MIGS procedures, with no intraoperative complications (as noted by this study) and minimal postoperative complications, possibly owing to the less invasive and efficient nature of this procedure. This automatic, easy to perform trabecular trephination procedure, which is stent-less and maintains the Schlemm's canal anatomy, may be considered as an alternative to other more complicated and more invasive MIGS procedures.

Abbreviations

AC, anterior chamber; AE, adverse event; BCVA, best corrected visual acuity; CI, confidence interval; CRF, case report form; EGS, European Glaucoma Society; FDA, United States Food and Drug Administration; IOP, intraocular pressure; KDB, Kahook Dual Blade; MIGS, minimally invasive glaucoma surgery; MIMS, Minimally Invasive Microsclerostomy; MINT, Minimally Invasive Nasal Trabeculostomy; OAG, open-angle glaucoma; OCT, optical coherence tomography; OVD, ophthalmic viscosurgical device; POAG, primary open-angle glaucoma; SC, Schlemm's canal; SD, standard deviation; TM, trabecular meshwork; WGA, World Glaucoma Association.

Data Sharing Statement

The study protocol and study data are available upon request to the corresponding authors.

Ethics and Consent Statements

This study was conducted at the S. Malayan Eye Center, Yerevan, Armenia. The study was approved by the local Independent Ethics Committee of S. Malayan Eye Center, Yerevan, Armenia, and conducted in accordance with the Declaration of Helsinki, Good Clinical Practice, ISO 14155:2020 standard, and the local/national guidelines and regulations of the S. Malayan Eye Center.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

Disclosure

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