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Intraocular Pressure Fluctuations Recorded by a Telemetric Sensor after Nonpenetrating Glaucoma Surgery in Primary Open-Angle Glaucoma

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Objective: To investigate short- and long-term intraocular pressure (IOP) fluctuations in patients with primary open-angle glaucoma (POAG) after successful nonpenetrating glaucoma surgery (NPGS, canaloplasty or deep sclerectomy).

Design: A prospective, open-label, multicenter interventional study.

Subjects: A total of 20 patients with POAG who underwent NPGS combined with permanent implantation of a suprachoroidal telemetric IOP sensor (EyeMate-SC, Implandata Ophthalmic Products GmbH). The mean age of the cohort was 66.9 ± 10.6 years. Half were female, and half were male.

Methods: Telemetric IOP measurements were obtained over a 3-year period, excluding the first 180 postoperative days and those during which ocular glaucoma medications were applied. One day was divided into 8 time-of-day (TOD) periods. The median absolute difference (MAD) in IOP between day χ and day $\chi + 7$, 30, 90, 180, and 360 was calculated for each TOD and each eye, in which sequential IOP measurements were accordingly available.

Main Outcome Measures: Intraocular pressure fluctuations.

Results: The mean follow-up duration was 952.8 ± 276.6 days. For analysis, a total of 139 512 mean IOP values were paired. Overall, diurnal IOP decreased by 20.7%, from 11.1 ± 5.0 mmHg in the "early morning" to 8.8 ± 3.2 mmHg in the "late evening," followed by a nocturnal IOP increase of 13.6% to 10.0 ± 3.8 mmHg in the "late night." Independently of the TOD, fluctuations were smallest during the 7-day interval and largest during the 360-day interval. The awake period, lasting from early morning to early evening, displayed increasing MADs with growing time intervals, resulting in moderate IOP fluctuations in the short term (1.5 mmHg < MAD < 2.0 mmHg) and large fluctuations in the long term (MAD > 2.0 mmHg). The late-night TOD displayed the lowest fluctuation amplitude.

Conclusions: Nychthemeral IOP fluctuations persist in eyes with an average IOP of 10 mmHg after successful NPGS. Short-term IOP fluctuations were moderate, whereas long-term fluctuations were large. Irregular IOP measurements are insufficient to assess IOP fluctuation and thus to determine optimal glaucoma management. The implementation of safe and accurate telemetric sensors has the potential to enhance glaucoma management.

Financial Disclosure(s): Proprietary or commercial disclosure may be found in the Footnotes and Disclosures at the end of this article. *Ophthalmology Glaucoma 2026;9:26-36 © 2025 by the American Academy of Ophthalmology. This is an open access article under the CC BY license (http://creativecommons.org/licenses/by/4.0/).*

Supplemental material available at www.ophthalmologyglaucoma.org.

Glaucoma is one of the main causes of irreversible blindness worldwide.[1] Its progression is characterized by progressive retinal ganglion cell degeneration and is associated with increased intraocular pressure (IOP), which has been demonstrated to be the single targetable glaucoma risk factor.[2] However, the concept of IOP fluctuation as a potential glaucoma progression risk factor is becoming increasingly popular.[3,4] With this paradigm shift in glaucoma management, from merely IOP reduction to IOP modulation and stabilization, understanding and controlling IOP fluctuations appears to be more and more important for developing enhanced glaucoma treatment strategies.[3]

A variety of IOP fluctuation entities have been described, including instantaneous, nychthemeral, short-, and long-term fluctuations.[3] Most studies investigating IOP fluctuations or their impact on glaucoma progression rely on infrequent IOP measurements, obtained by Goldmann applanation tonometry (GAT).[5,6]

Nychthemeral fluctuations are assessed by repeatedly measuring the IOP using GAT, which is the current standard

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https://doi.org/10.1016/j.ogla.2025.07.007
ISSN 2589-4196/25

method, although it is susceptible to bias by patient and operator factors.[7–9] This approach has several other drawbacks, beginning with the limited number of measurements.

During the night, patients need to be awakened and are often required to sit. This practice may alter their sleep architecture. It can also affect the true nocturnal IOP profile.[7] In clinical practice, IOP recording sessions conducted over 24 hours are rare and seldom performed more than once owing to limited practicability and availability.[8] As a result, long-term fluctuations are usually overlooked. Consequently, the generalizability of the IOP profile is either missing or falsely assumed. Overall, optimizing IOP monitoring is essential: first, to better understand the impact of IOP fluctuations on glaucoma progression, and second, to promote fast, precise, and adaptive therapeutic decision-making in glaucoma management. Mansouri et al used a ciliary sulcus-based intraocular sensor to monitor IOP fluctuations in a cataract-operated patient collective with primary open-angle glaucoma (POAG) and IOP averages situated at the upper border of the physiological range (i.e., 19 mmHg).[8] However, data on IOP fluctuations in POAG eyes with a well-adjusted average IOP of roughly 10 mmHg after nonpenetrating glaucoma surgery (NPGS) are sparse. Since fluctuations are relatively more pronounced in eyes with low averages of IOP in comparison to those with high averages, such information is critical. In agreement with this, glaucoma progression has been precisely associated with fluctuations in eyes with low IOP averages.[5]

In the ARGOS-SC01 and ARGOS-SC01_FU trials, a glaucoma patient collective received combined NPGS and implantation of a miniaturized telemetric IOP sensor in the suprachoroidal space.[10,11] A close 3-year follow-up provides an excellent platform to study long-term IOP fluctuations in such a patient collective with well-adjusted average IOPs.

Therefore, the objective of this study was to investigate short- and long-term IOP fluctuations in successfully NPGS-operated eyes free of ocular glaucoma medication.

Methods

Design

This follow-up study included measurement data from the prospective, open-label, multicenter interventional ARGOS-SC01 trial and its follow-up ARGOS-SC01_FU trial. The aim was to investigate the safety and efficacy of the suprachoroidal EyeMate-SC implant in glaucoma patients who received NPGS. This study was conducted up to 3 years after EyeMate-SC implantation and followed the tenets of the Declaration of Helsinki. Informed consent was received from each participant, and institutional review board approval was granted (Ethikkommission bei der Ärztekammer des Saarlandes, CIV-18-07-025065, Approval Number: 141/18; Date: 2018.10.30).

Patients

A total of 20 patients with POAG with NPGS indication were prospectively enrolled. Patients were strictly eligible for unilateral sensor implantation, and female patients were required to provide a negative pregnancy test within 24 hours of surgery. Exclusion criteria were neovascular and angle-closure glaucoma; high axial myopia of greater than −6 diopters; hyperopia of greater than +4 diopters; axial length of less than 22 or greater than 26 mm; other known ocular diseases; preceding glaucoma surgery, excluding laser interventions such as trabeculoplasty; nonglaucoma ocular surgery within the 6 months (cataract surgery within 3 months) before EyeMate-SC implantation; other active medical head/neck implants; and serious generalized conditions.

Device

The EyeMate-SC is a microelectromechanical IOP-sensing device designed for permanent suprachoroidal implantation (Implandata Ophthalmic Products GmbH; Fig 1). A lenticular-shaped outer surface with dimensions of 7.5 × 3.5 mm and a centrifugally decreasing thickness from 1.3 mm in the middle to 0.9 mm in the periphery provides excellent adaptation to the curved scleral shape. Astigmatism neutrality has been demonstrated.[12] The application-specific integrated circuit which comprises pressure and temperature sensors, identification and analog-to-digital encoders, as well as a telemetry unit, is bonded to a wire-wound gold microcoil and embedded in medical-grade silicone material. The aluminum- and gold-based device is nonmagnetic, electromagnetically safe, and CE (Conformité Européenne)-certified according to the European medical device law. Calibration is performed before sterilization and packaging, and IOP measurements are performed and checked for plausibility before implantation.

Using a battery-driven external handheld reader device (mesograph), the otherwise passive sensor is powered via electromagnetic coupling, and data retrieval is performed, where up to 3000 reads can be stored. For high precision, each read was calculated as the average of 10 consecutive measurements. Data were wire-transferred or wirelessly transferred using a global system for mobile communications module.

Surgery

Nonpenetrating glaucoma surgery and implantation of the telemetric device into the suprachoroidal space have been previously described in detail.[10] Briefly, after conjunctival opening, a 5 × 5 mm superficial scleral flap was prepared. Below, a deep scleral flap (4 × 4 mm) was created depending on the surgeon's

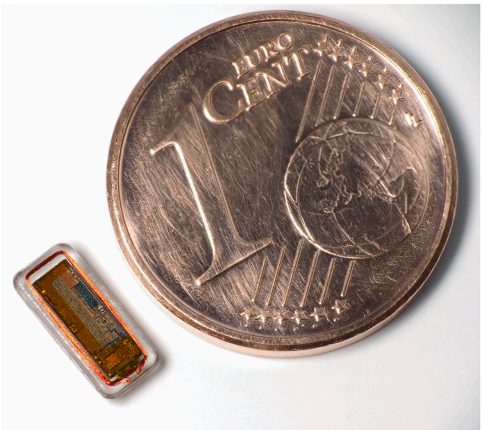

Figure 1. EyeMate-SC shown next to a 1-cent coin for scale.

preference. Either full dissection until choroid exposure (100% thickness technique) was performed or a basal thin scleral flap of 10 to 50 μm was left (90% thickness technique). In either case, the deep scleral flap incision was extended over the scleral spur to open Schlemm canal, and then a trabecular Descemet window was created. Here, deep scleral flap excision and juxtacanalicular trabecular meshwork peeling were performed. At this stage, the canaloplasty procedure included Schlemm canal probing with a microcatheter and tightening using a 10-0 Prolene suture. After suprachoroidal hyaluronic acid application, the EyeMate-SC device was softly inserted into the scleral window between the choroid and sclera using padded forceps to protect the sensor's sensitive composites. Afterward, the superficial scleral flap and conjunctiva were sutured.

Measurements

Patients were instructed to measure IOP at least 4 times daily. For measurement, the handheld reader device needed to be actively positioned near the eye. After data transfer, all reads were recorded in a web database.

Analysis

Days on which ocular glaucoma medications were prescribed were excluded. Additionally, all measurements recorded within the first 180 postoperative days were omitted owing to early IOP fluctuations after NPGS that could potentially bias the results.

To eliminate the impact of diurnal IOP variations, each day was divided into 8 time-of-day (TOD) periods: "early night" from midnight to 2:59 AM, "late night" from 3:00 AM to 5:59 AM, "early morning" from 6:00 AM to 8:59 AM, "late morning" from 9:00 AM to 11:59 AM, "early afternoon" from noon to 2:59 PM, "late afternoon" from 3:00 PM to 5:59 PM, "early evening" from 6:00 PM to 8:59 PM, and "late evening" from 9:00 PM to 11:59 PM. Within each of these TODs, sequential average measurement pairs were created for each eye, for which at least 1 measurement was performed on day χ and at least 1 other measurement was performed in the same TOD on day $\chi + 7$, 30, 90, 180, and/or 360. Cumulation of the measurement pairs for 7-, 30-, 90-, 180-, and 360-day intervals for each TOD creates a large amount of data and enables simple, reliable statistical analysis.

The median absolute difference (MAD) in IOP between day χ and day $\chi + 7$, 30, 90, 180, and 360 was calculated for each TOD and for all eyes in which sequential IOP measurements were accordingly available. These data are described using the median ± interquartile range (IQR). Intraocular pressure fluctuations are labeled as small when MAD < 1.5, moderate when 1.5 < MAD < 2.0, and large when MAD > 2.0 mmHg.

Unpaired *t* tests were used for comparing interval- or TOD-specific sequential measurements among each other and for each TOD (e.g., early afternoon: 7 vs. 360 [interval in days]) or for each time interval (e.g., 7-day interval: late night vs. early afternoon), respectively (Tables S1 and S2). Short-term IOP fluctuations were assessed based on intervals of 7, 30, and 90 days, and long-term fluctuations were based on intervals of 180 and 360 days.

The Kolmogorov−Smirnov test was used for normality testing. Depending on normality assumption, the Mann-Whitney *U* or the *t* test was used to compare two unpaired groups. In addition, the Kruskal−Wallis test and Levene test were used to compare the central tendency and variability, respectively, throughout several unpaired groups that did not yield a normal distribution.

All tests were two-sided and considered statistically significant when $P < 0.001$. Bonferroni correction was conducted to correct for α errors. Analysis was performed using Python (version 3.8.18) and SciPy (version 1.14.1, https://scipy.org/citing-scipy/) software programs.

Results

Half of the enrolled patient collectives were female, and the other half were male. The mean age was 66.9 ± 10.6 years at the surgery timepoint. Nine eyes were right, and 11 were left. A total of 11 eyes were phakic, 7 were pseudophakic, and 2 additional phakic eyes underwent both phacoemulsification and canaloplasty; 11 eyes were treated with canaloplasty and 9 with deep sclerectomy. The median preoperative IOP was 17.0 ± 4.2 mmHg, with a range of 13−36.3 mmHg. At baseline, 19 of the 20 patients were receiving ocular glaucoma medication. The mean number of medications was 2.7 ± 1.0 (range: 0−4), and the baseline IOP values were recorded under this treatment.

Of the 20 patients, 18 were of European descent, 1 was of African descent, and 1 was of Asian descent.

At 360 days, 19 patients completed the visit, followed by 17 at 540 and 16 at 720, 900, and 1080 days. The mean follow-up duration was 952.8 ± 276.6 days. A total of 94 319 measurements were available: 71 897 of these were recorded after the first 180 postoperative days, and among these measurements, 18 712 were excluded owing to ongoing ocular glaucoma medication application, leaving a total of 53 185 measurements for analysis.

The average number of IOP measurements per patient was 3324 ± 2357. Disregarding measurement-free days, the average number of daily IOP reads per patient was 5.53 ± 3.68. This gave an average of 64.1% of days on which more than 4 measurements were collected.

The number of data-contributing eyes varied slightly depending on the time interval and TOD, with the following means ± standard deviation (range): 7 days, 14.9 ± 1.9 (11−16); 30 days, 14.4 ± 2.1 (10−16); 90 days, 12.7 ± 1.4 (10−14); 180 days, 12.4 ± 2.1 (8−14); and 360 days, 11.0 ± 2.2 (7−13).

The median diurnal IOP was 12.3 ± 8.6 mmHg during the first 30 postoperative days, 11.4 ± 5.9 mmHg between postoperative

Table 1. Distribution of the Amount of Sequential Intraocular Pressure Measurement Pairings throughout the Time-of-Day Periods (e.g., Early Morning) and among the Time Intervals (e.g., 90-Day Interval: "90")

Time Intervals	Early Night	Late Night	Early Morning	Late Morning	Early Afternoon	Late Afternoon	Early Evening	Late Evening	Total
7	3	2061	4578	2895	2354	2816	2839	898	18 444
30	4	1429	4039	2631	2135	2614	2576	805	16 233
90	1	1475	3715	2333	1883	2332	2271	678	14 688
180	1	1009	3099	2013	1518	1996	1847	531	12 014
360	0	719	2219	1379	1067	1463	1233	297	8377
Total	9	6693	17 650	11 251	8957	11 221	10 766	3209	69 756

days 30 and 180, and 10.4 ± 4.8 mmHg from day 180 through the end of the 3-year study period.

Among the 53 185 measurements, 29 818 mean values were calculated for all TODs included. For analysis, a total of 139 512 IOP mean values were paired, as the same measurement can be used for several interval pairings. Table 1 displays the distribution of the sequential IOP mean value pairings throughout the TODs and among the time intervals. Owing to a restricted number of pairings (n $<$ 10), data from early night should not be interpreted and are thus not included in the following comparative analysis.

Overall, there was no significant time course in central tendency or variability of the diurnal IOP of the 30 days preceding each included visit (day 180: 10.3 ± 4.8 mmHg; day 360: 9.9 ± 2.6 mmHg; day 720: 10.3 ± 4.2 mmHg; day 1080: 10.5 ± 2.5 mmHg; $P = 0.502$, Kruskal−Wallis test; $P = 0.649$, Levene test). Subgroup analysis yielded consistent results for both canaloplasty ($P = 0.700$, Kruskal−Wallis test; $P = 0.244$, Levene test) and deep sclerectomy cohorts ($P = 0.538$, Kruskal−Wallis test; $P = 0.471$, Levene test).

Figure 2 shows descriptive statistics of the IOP data in relation to the TOD throughout the observation period, overall (Fig 2A), and for the canaloplasty (Fig 2B) and deep sclerectomy (Fig 2C) subcohorts. Overall, diurnal IOP decreased by 20.7%, from 11.1 ± 5.0 mmHg in the early morning to 8.8 ± 3.2 mmHg in the late evening, and the nocturnal IOP increased by 13.6% to 10.0 ± 3.8 mmHg at late night. Comparing both subcohorts, diurnal fluctuation was less after canaloplasty than after deep sclerectomy.

Figure 3 presents boxplots of the early and late IOP values that contributed to sequential pairings for the previously defined intervals. The plots reveal that measurements taken at the later time points of a pairing are often superior to the earlier ones, particularly with increasing time interval. Figure 4 shows the MADs for each TOD and time interval. Figures 5 and 6 show the respective data for the canaloplasty and deep sclerectomy subcohorts.

Overall, independently of the TOD, fluctuations were smallest during the 7-day interval and largest during the 360-day interval. During the awake period, spanning early morning to early evening, the MAD increased with growing time intervals, resulting in moderate IOP fluctuations in the short term (1.5 $<$ MAD $<$ 2.0) and large fluctuations in the long term (MAD $>$ 2.0 mmHg) (Fig 4B−F).

Except for the 7-day interval, MADs increased more with growing time interval in the early morning and early evening than in the TODs between (Fig 4B−F). Thus, during the awake period, the smallest IOP fluctuations occurred in the late morning (Fig 4C), early afternoon (Fig 4D), and late afternoon (Figure 4E). The late-evening TOD is the only TOD that displays reduced IOP fluctuations when switching from a 180-day to a 360-day interval (Fig 4G) and less than 4 significant interinterval differences in MAD (Table S1, available at www.ophthalmologyglaucoma.org). However, this result should be cautiously interpreted because only a small number of pairings (n = 297) was included in the 360-day interval during the late-evening TOD (Table 1).

Table S1 displays P values comparing the MADs among time intervals for each TOD. These data indicate that IOP agreements were best between the intervals of 7 and 30 days, 30 and 90 days, and 180 and 360 days, respectively, which is congruent with the observed interval-dependent MAD patterns (Table S1).

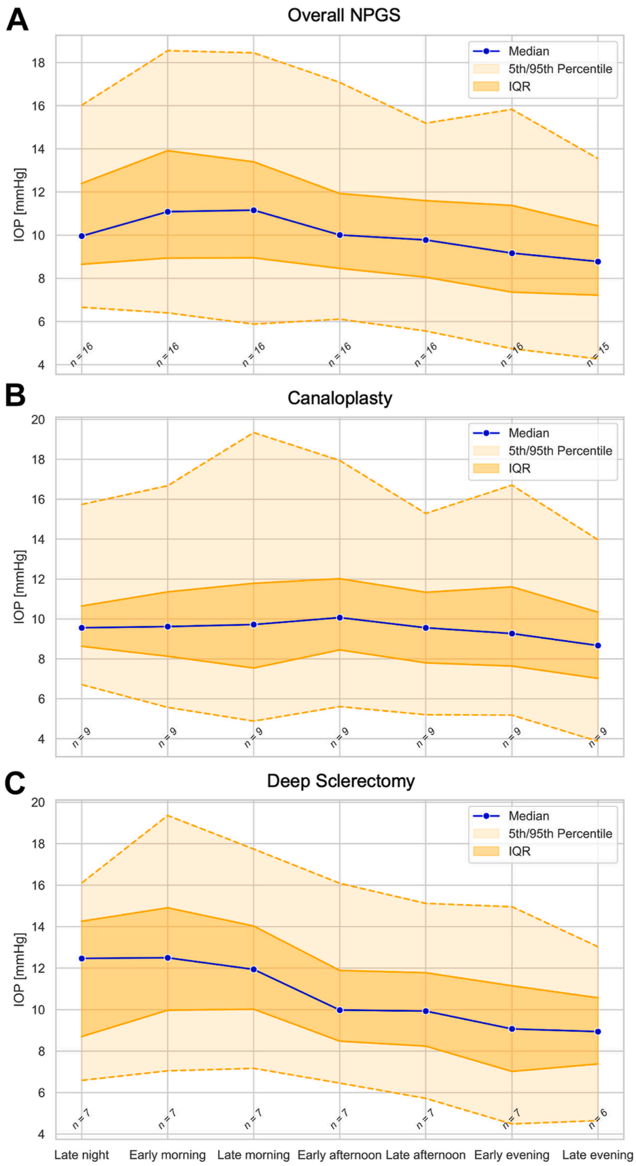

Figure 2. Overall diurnal IOP profile after nonpenetrating glaucoma surgery **(A)**, canaloplasty **(B)**, and deep sclerectomy **(C)**. Median and IQR of IOP (mmHg) measurements relative to time-of-day periods throughout the study's time frame. Q1 and Q3 indicate the lower and upper borders of the IQR, respectively. IOP = intraocular pressure; IQR = interquartile range; "n" indicates the number of data-contributing eyes.

As a matter of fact, the late-night TOD displayed the lowest fluctuation amplitude, with small fluctuations at intervals of 7 (1.0 ± 1.4 mmHg [median ± IQR]), 30 (1.2 ± 1.6), 90 (1.3 ± 1.6), and 180 (1.5 ± 2.0) days, and moderate fluctuations at the 360-day interval (1.9 ± 2.9) (Fig 4A).

Table S2 (available at www.ophthalmologyglaucoma.org) displays the P values comparing the MADs among the TODs for each time interval. Disregarding the late-night period, the MADs were least dependent on the TOD for the 7-day interval (Table S2).

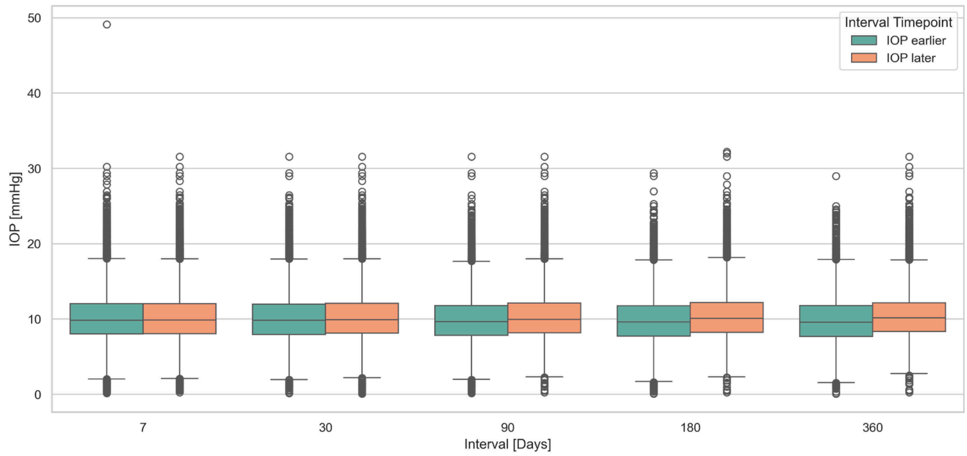

Figure 3. Differences between early and late IOP values, paired to calculate an interval-dependent median absolute difference across a large sample. Boxplots display the median, interquartile range, and 5th and 95th percentiles; outliers are shown as individual symbols. The green boxplots on the left represent earlier time points of measurement of a sequential pairing, while the orange boxplots on the right represent later time points. IOP = intraocular pressure.

Comparing the canaloplasty and deep sclerectomy subcohorts yielded an overall significant difference, with MADs of 1.86 ± 2.49 mmHg in the canaloplasty subcohort and 1.60 ± 2.14 mmHg in the deep sclerectomy subcohort ($P < 0.0001$, Mann−Whitney U test, Table S3, available at www.ophthalmologyglaucoma.org).

Discussion

This study's aim was to investigate short- and long-term IOP fluctuations in successfully NPGS-operated POAG patients with well-controlled IOP averages through continuous implant-based monitoring. We found moderate short-term fluctuations reaching up to 15% and large, long-term fluctuations reaching up to 20%.

Investigating short-term IOP fluctuations is not new. Realini et al observed poor reproducibility of 2-hourly diurnal GAT measurements in treated POAG patients.[13] Contact lens sensor-based 24-hour monitoring showed fair to good reproducibility,[14] while Mansouri et al reported moderate short-term IOP reproducibility using a telemetric sensor.[8] Similar to Mansouri et al, we analyzed a substantial number of measurements, increasing IOP variability pattern estimation precision and outlier effect reduction. Our results align with those of Mansouri et al, showing moderate short-term fluctuations.[8]

Long-term fluctuations, however, are more difficult to assess. Zimmerman et al found moderate to good repeatability over 1 year,[15] while Aptel et al reported poor reproducibility across 6-month intervals.[16] Mansouri et al[8] confirmed poor long-term IOP reproducibility with continuous monitoring.[8] In our NPGS-operated cohort, we observed large long-term IOP fluctuations (up to 20%). Although our data do not reflect typical circadian IOP dynamics, they show persistent diurnal fluctuations after NPGS (Fig 2). This might partly stem from fewer late-evening and early-night data. Nevertheless, IOP would have been expected to be higher in the late night than in the early afternoon.[17] While combined cataract surgery with high-frequency deep sclerotomy did not affect the circadian rhythm,[18] canaloplasty and nonpenetrating deep sclerectomy have not been studied for this, to our knowledge.

In contrast to trabeculectomy, which leaves no true diurnal IOP patterns,[19,20] we show for the first time that despite average IOP normalization, NPGS leaves residual diurnal fluctuations, meaning clinicians should still consider additional IOP measurements at varying times of day, even with well-adjusted averages.

Our atypical diurnal IOP profile might have been influenced by the small sample size, restricted preoperative monitoring, and a study design unfocused on circadian rhythms. Of note, late-night fluctuations were smaller, possibly resulting from a reduced and homogenous nocturnal physical activity, which is known to affect IOP.[21] The late-evening period did not yield such findings, as this data relies on fewer measurements and presumably a more heterogeneous physical activity background.

Canaloplasty showed higher IOP fluctuations than deep sclerectomy but a lesser diurnal fluctuation. However, owing to the small, uncontrolled, heterogeneous sample, these findings are preliminary and require confirmation in larger, prospective studies.

Despite robust data, our study has limitations: a small sample size with a potential bias from eyes exhibiting low fluctuation profiles, data dropout owing to exclusion of the first 180 days, patient number reduction at the 1-year mark, fewer nocturnal readings, no control data to investigate how fluctuation data compare after surgery vs. no surgery, patient-centered measurement timing, and potential confounding from intrinsic and extrinsic factor changes, such as lifestyle or hormonal status[22,23] and seasonal IOP variations.[24] The first 180 days were excluded because of

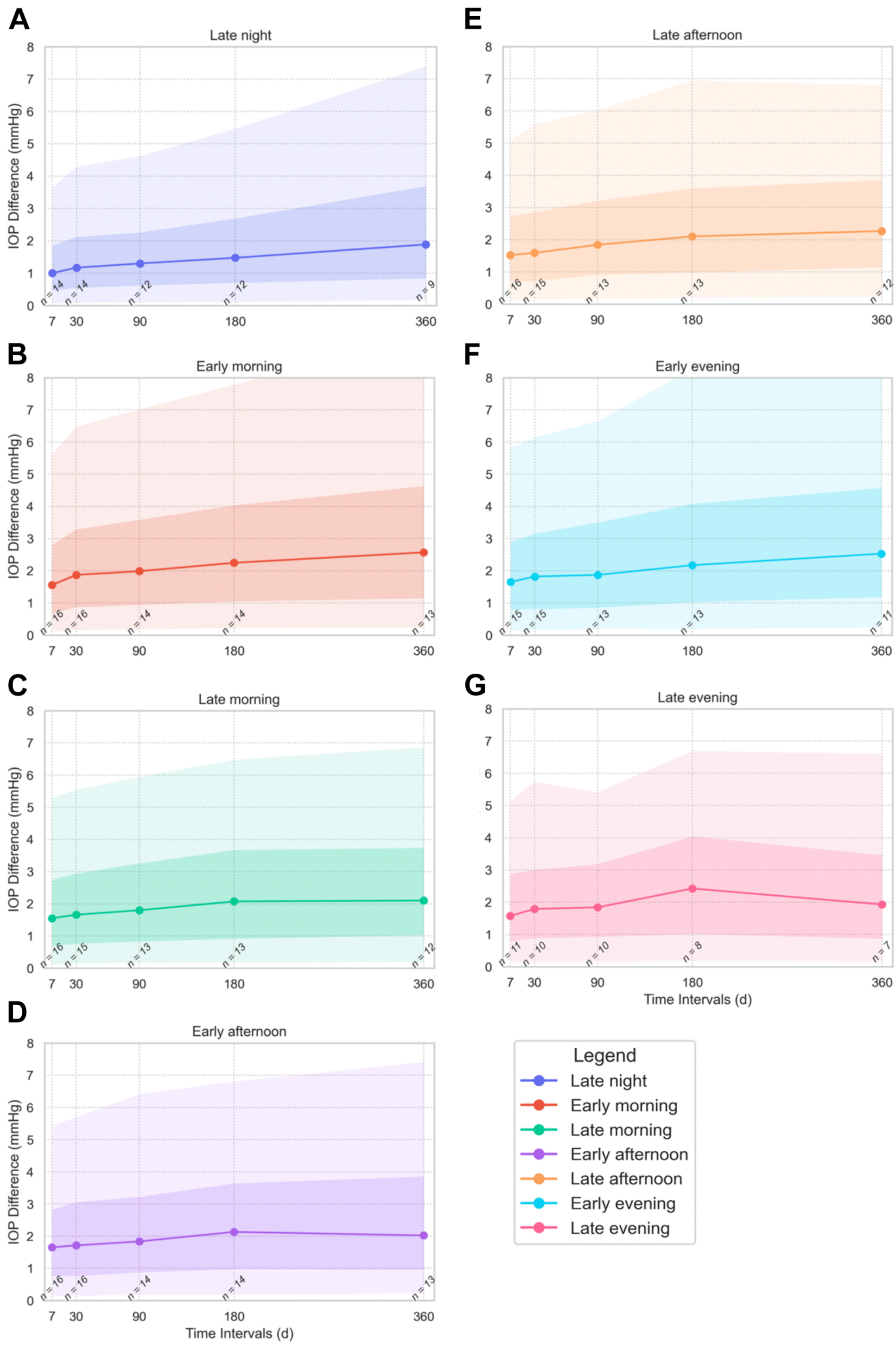

Figure 4. Short- and long-term IOP fluctuations after nonpenetrating glaucoma surgery. Median absolute differences (mmHg) of IOP with interquartile ranges (dark shade) and the fifth—95th percentile range (light shade) at time intervals of 7, 30, 90, 180, and 360 days for each time-of-day, except early night. **A,** Late night, **(B)** early morning, **(C)** late morning, **(D)** early afternoon, **(E)** late afternoon, **(F)** early evening, and **(G)** late evening. IOP = intraocular pressure; "n" indicates the number of data-contributing eyes.

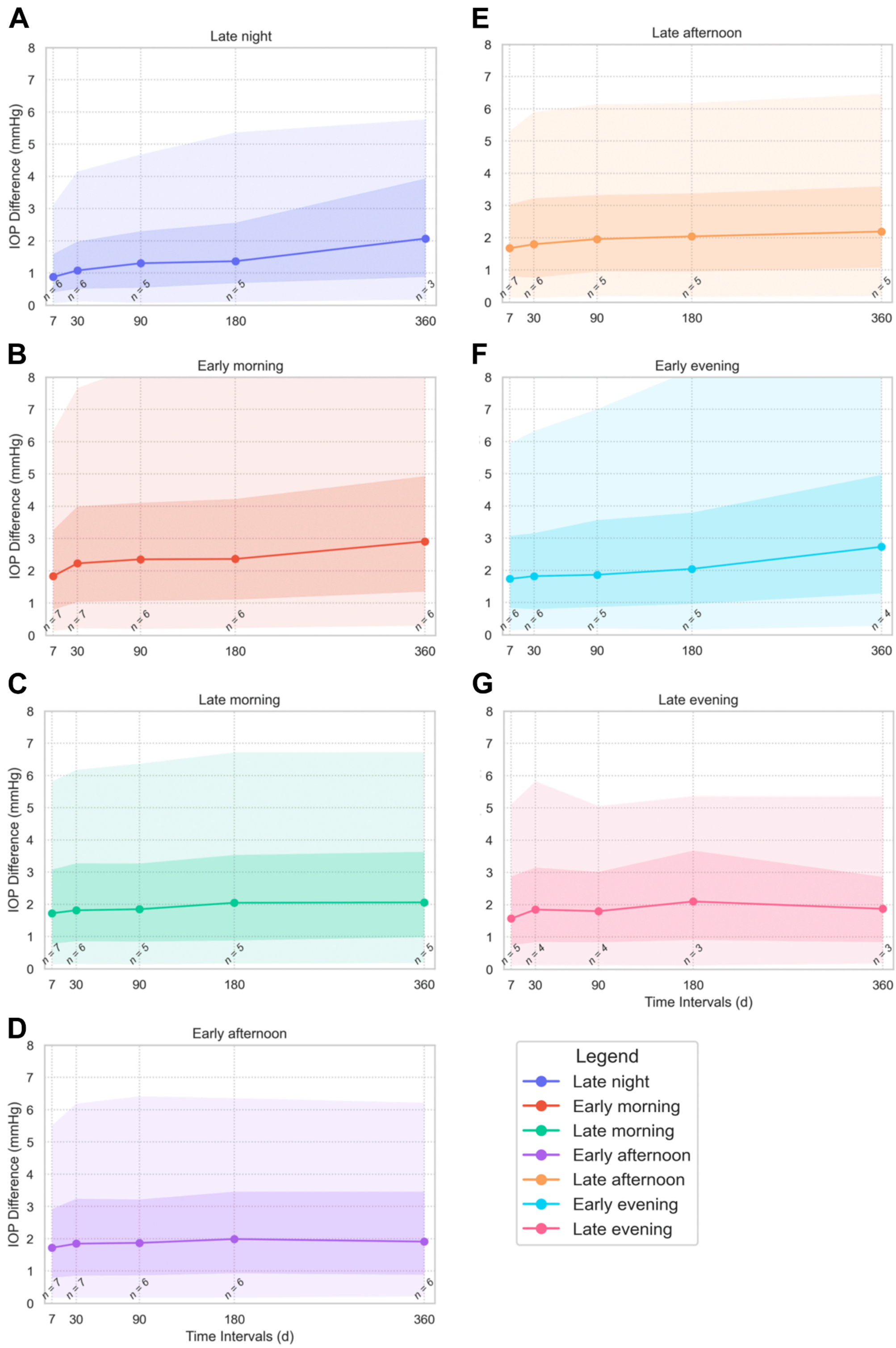

Figure 5. Short- and long-term IOP fluctuations after canaloplasty. Median absolute differences (mmHg) of IOP with interquartile ranges (dark shade) and the fifth—95th percentile range (light shade) at time intervals of 7, 30, 90, 180, and 360 days for each time-of-day, except early night. **A,** Late night, **(B)** early morning, **(C)** late morning, **(D)** early afternoon, **(E)** late afternoon, **(F)** early evening, and **(G)** late evening. IOP = intraocular pressure; "n" indicates the number of data-contributing eyes.

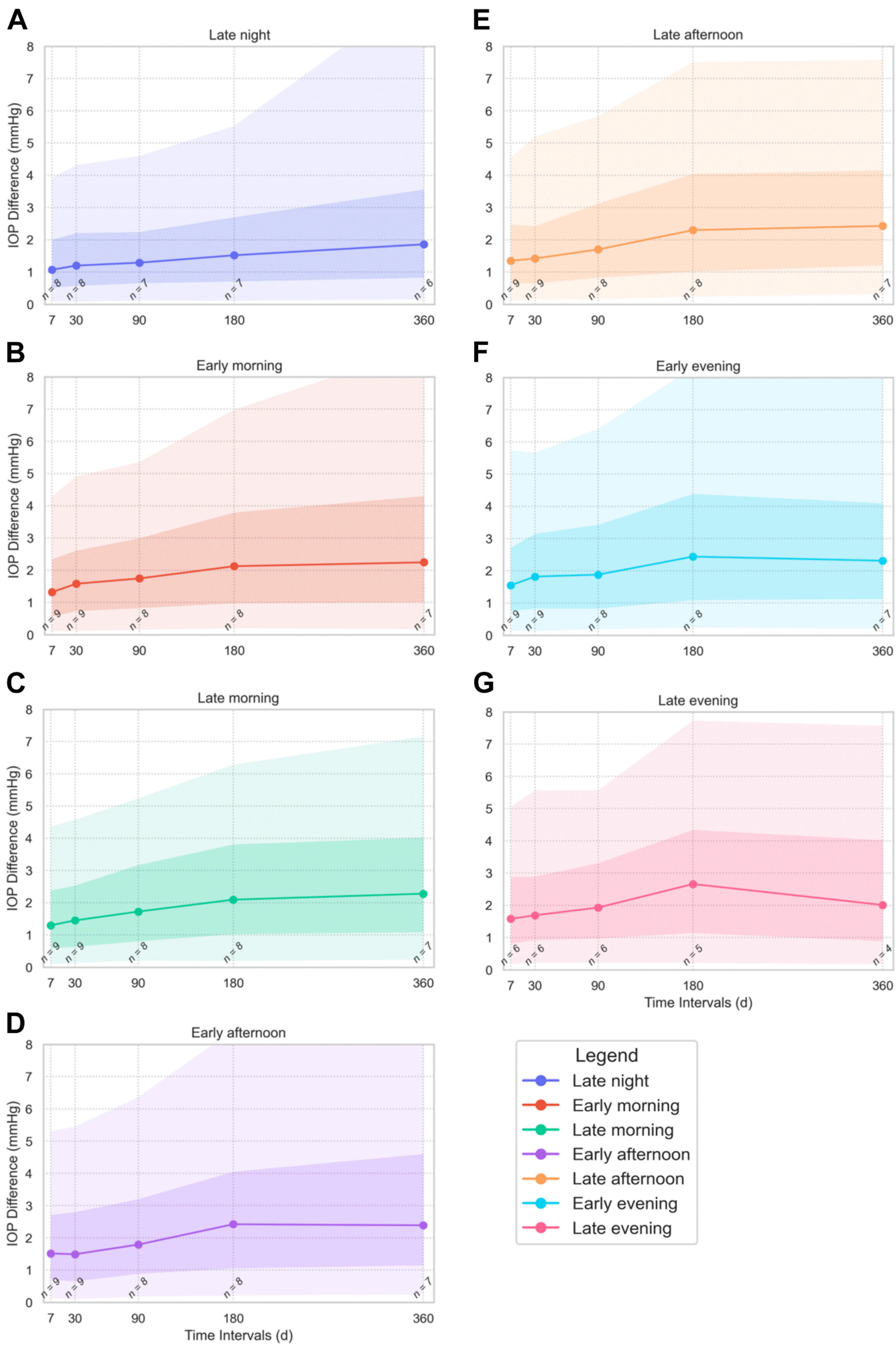

Figure 6. Short- and long-term IOP fluctuations after deep sclerectomy. Median absolute differences (mmHg) of IOP with interquartile ranges (dark shade) and the fifth–95th percentile range (light shade) at time intervals of 7, 30, 90, 180, and 360 days for each time-of-day, except early night. **A,** Late night, **(B)** early morning, **(C)** late morning, **(D)** early afternoon, **(E)** late afternoon, **(F)** early evening, and **(G)** late evening. IOP = intraocular pressure; "n" indicates the number of data-contributing eyes.

higher IOP variability, especially within the first 30 days and up to 180 days, and moderate agreement between telemetric and GAT measurements during this early postoperative period, as previously discussed.[25]

Past this period, the high precision of EyeMate-SC measurements has been demonstrated in previous studies.[10,11,25] In 3 cases, minor adjustments were made to the measured values in reference to GAT. However, these data had already been excluded from the analysis, so the adjustments had no impact herein.

Along with the study by Mansouri et al, our study provides large, continuous long-term IOP data in POAG.[8] Assuming 13 visits per patient in 3 years, in-office GAT would yield 260 IOP measurements, which is 200-fold less than our dataset. Moreover, in-office GAT is more susceptible to external biases than daily routine-based telemetric monitoring.[26]

Our study differs from that of Mansouri et al[8] in a few key aspects: our study duration was almost twice as long (∼31 vs. 19 months) and investigated NPGS-operated eyes averaging 10 mmHg that were untreated with ocular glaucoma medication. By contrast, Mansouri et al focused on cataract-operated eyes averaging 19 mmHg and treated with a variety of ocular glaucoma medications, requiring categorization in 76 cohorts.[8] Thus, the homogenous patient cohort of our study is a strength.

Of note, IOP fluctuations were smaller in our study than in the study by Mansouri et al,[8] which might stem from the surgery type (NPGS vs. cataract surgery), absence of ocular glaucoma medication effects, and overall lower IOP averages.

In any case, the surgical intervention itself inherently limits the generalizability to untreated POAG eyes, as both procedures can lead to sustained IOP reductions.[27] Nonpenetrating glaucoma surgery enhances aqueous outflow through the trabecular or uveoscleral pathways, while cataract surgery, which has been shown to reduce short-term IOP fluctuations in glaucomatous eyes with normative IOP,[28] may achieve this effect through biomechanical, molecular, or physiological mechanisms.[29] Thus, neither study reflects native POAG or healthy eye IOP fluctuations.

The increasing variance with longer time intervals likely reflects intrinsic IOP fluctuations rather than diminished surgical efficacy, as mean IOP remained stable. Although reduced sample size at later time points or longer time intervals may contribute, the large overall data pool clearly supports the interpretation of this pattern as a genuine characteristic of long-term IOP behavior.

Thus, our results have an important clinical implication: even in well-controlled NPGS-operated eyes, single or repeated IOP measurements may fail to capture fluctuation patterns, particularly in the long term. Thus, future studies should implement intensive IOP monitoring to better understand IOP fluctuation patterns in high- and low-IOP average POAG eyes.

In conclusion, nychthemeral IOP fluctuations persist after NPGS. Short- and long-term IOP fluctuations are moderate and large, respectively, underscoring that irregular measurements are insufficient for optimal glaucoma management. Continuous monitoring with safe and precise devices, such as the EyeMate-SC sensor, could enhance glaucoma care by improving the quality and speed of decision-making and thus disease outcomes.

Acknowledgments

The authors wish to thank Stefan Meyer for excellent statistical support and Jenna Flogeras for professional language editing.

Footnotes and Disclosures

Originally received: April 1, 2025.
Final revision: July 14, 2025.
Accepted: July 17, 2025.
Available online: July 24, 2025. Manuscript no. OGLA-D-25-00159.

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Disclosures:

All authors have completed and submitted the ICMJE disclosures form.

The authors made the following disclosures:

P.S.: Patents − pending international patent for the EyeMate-SC system (PCT/EP2015/062 976).

E.M.H.: Grants − Allergan, Novartis, Heidelberg Engineering, Santen, Thea outside the submitted work.

K.M. Grants − Implandata; Nonrelated financial disclosures − Santen, AbbVie, New World Medical, and iStar Medical.

M.J.M. Grants − Implandata; Nonrelated financial disclosures − Acufocus, Allergan, Bausch and Lomb, Bayer, DORC, Heidelberg Engineering, Iridex, Novartis, Oculus, Optos, Roche, Santen, Topcon, and Zeiss.

This study received support from Implandata Ophthalmic Products GmbH, Hannover, Germany, which produced and provided the medical devices under investigation. The Article Publishing Charge (APC) for this article was organized by Projekt DEAL.

HUMAN SUBJECTS: Human subjects were included in this study. This study was conducted up to 3 years after EyeMate-SC implantation and followed the tenets of the Declaration of Helsinki. Informed consent was received from each participant, and institutional review board approval was granted (Ethikkommission bei der Ärztekammer des Saarlandes, CIV-18-07-025065.

No animal subjects were used in this study.

Author Contributions:

Conception and design: Englisch, Szurman

Data collection: Englisch, Mansouri, Dick, Hoffmann, Mackert, Szurman

Analysis and interpretation: Englisch, Trouvain, Wakili, Mansouri, Dick, Hoffmann, Mackert, Langenbucher, Boden, Szurman

Obtained funding: N/A

Overall responsibility: Englisch, Trouvain, Wakili, Mansouri, Dick, Hoffmann, Mackert, Langenbucher, Boden, Szurman

Abbreviations and Acronyms:
GAT = Goldmann applanation tonometry; **IOP** = intraocular pressure; **IQR** = interquartile range; **MAD** = median absolute difference; **NPGS** = nonpenetrating glaucoma surgery; **POAG** = primary open-angle glaucoma; **TOD** = time-of-day.

Keywords:
Intraocular Pressure, Fluctuation, Diurnal, Short term, Long term, EyeMate.

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