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Intraocular Pressure Telemetry for Managing Glaucoma during the COVID-19 Pandemic

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Purpose: To evaluate in glaucoma patients the feasibility and use of remote monitoring of intraocular pressure (IOP) with an implanted telemetry sensor during the coronavirus disease 2019 (COVID-19) lockdown.

Design: Cross-sectional study.

Participants: Patients previously implanted with a telemetric IOP sensor (Eyemate; Implantsdata GmbH) were included.

Methods: Intraocular pressure measurements acquired by the patients during the lockdown were collected by physicians who were located remotely. A questionnaire was sent to 10 participating study centers to evaluate the clinical impact of remote monitoring of IOP via the IOP sensor system.

Main Outcome Measures: Number of patients who obtained home IOP measurements.

Results: Data were available from all centers and from 37 eyes of 37 patients (16 patients with a sulcus-based sensor and 21 patients with a suprachoroidal sensor). Thirty-four patients obtained IOP measurements during the lockdown. Mean age of the patients was 69.3 ± 9.6 years, and 48.6% were women. A total of 8415 IOP measurements from 370 measurement days were obtained. Based on remote IOP measurements, treatment was changed in 5 patients. In another 5 patients, treatment change was considered when physicians received the IOP measurements after the lockdown. Nine of the 10 study centers judged remote IOP measurements to have a clinical impact.

Conclusions: These results show the feasibility of patient-acquired measurement of IOP in conjunction with remote IOP monitoring by physicians with an implantable sensor. The data obtained impacted clinical decision making, including adjustment of ocular hypotensive therapy and avoiding unnecessary office visits during the COVID-19 pandemic. *Ophthalmology Glaucoma* 2021;4:447-453 © 2020 by the American Academy of Ophthalmology

In late 2019, an outbreak of a novel coronavirus disease (coronavirus disease 2019 [COVID-19]) emerged in Wuhan, China, and spread quickly throughout the world. Coronavirus disease 2019 is a highly contagious disease capable of progression to acute respiratory distress syndrome and even death. By mid-March 2020, nonurgent ophthalmologic care largely had ceased, and only patients with urgent or emergent problems were examined.^{1,2}

These mitigation measures led to the cancellation of most clinic visits, including those for glaucoma care. Despite glaucoma being an irreversibly blinding disease, ophthalmologists considered most visits and scheduled surgeries for glaucoma to be nonurgent, especially when balanced against the risk of possible COVID-19–related death in elderly patients. For instance, in the United States, a nearly 80% initial decrease in ophthalmology visits occurred,^{1,2} whereas in a single large tertiary ophthalmology department in London, 30 000 glaucoma outpatient visits were canceled during the acute phase of the COVID-19 pandemic.³

To replace the sudden and unexpected cancellation of in-person visits, virtual clinics were opened by many ophthalmologists. Previous studies have shown the usefulness

of telemedicine in ophthalmic conditions ranging from diabetic retinopathy⁴ to follow-up care after cataract surgery.⁵ However, the value of glaucoma virtual clinics has been questioned because of the need for ancillary tests to guide clinical decision making. These include tonometry, visual field examination, and structural evaluation of the optic nerve head using fundus photography and OCT. Recent advances in home monitoring of intraocular pressure (IOP)⁶ and visual fields⁷ have the potential to expand telemedicine in glaucoma. However, to date, these tests have not been tested and validated sufficiently for routine use. The rebound tonometer (Icare HOME), which can be used by patients at home, has been approved by various regulatory agencies. However, it has not been adopted widely for remote monitoring because of difficulties with patient self-monitoring and the acquisition cost of the device.⁸

The Eyemate (Implantdata Ophthalmic Products GmbH) telemetric IOP sensor is a permanent implantable monitoring device for use in patients with open-angle glaucoma that has received regulatory approval for use in Europe. It represents a reliable method of IOP monitoring that does not

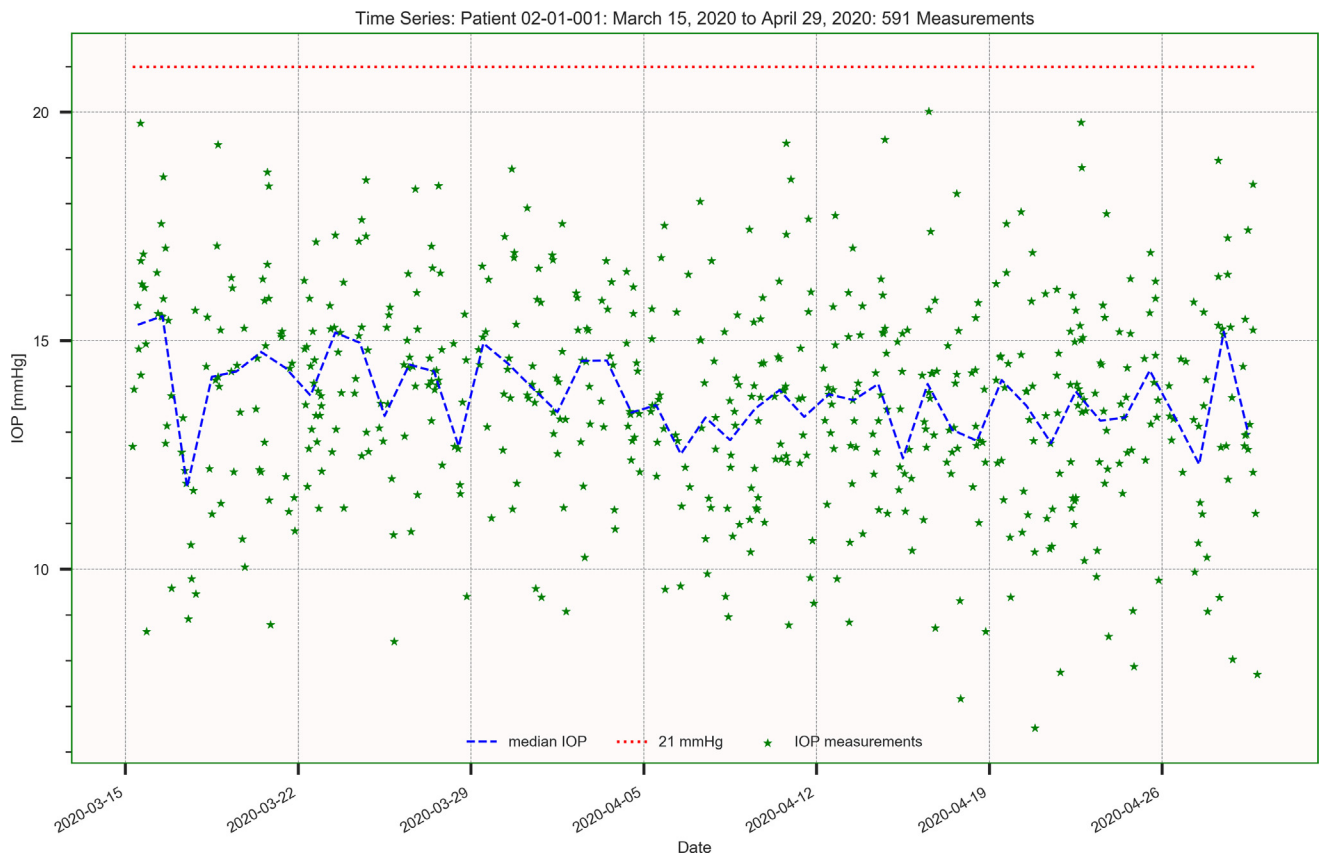


Figure 1. Graph showing wide variability of intraocular pressure (IOP), despite topical treatment with a prostaglandin analog and α agonist. Average IOP values are less than the target of 15 mmHg.

necessitate regular examinations in the office and requires only minimal patient adherence. It has been shown to be safe, well tolerated, and able to provide reliable IOP measurements over more than 1 year of follow-up.⁹ The purpose of the current study was to evaluate the role of telemetry-obtained IOP measurements to guide remote decision making during the COVID-19 pandemic in glaucoma patients previously implanted with the telemetric sensor.

Methods

Study Design

This study included participants from 2 ongoing prospective multicenter clinical trials (ARGOS-03 and ARGOS-SC) and 2 centers (Switzerland and the United Kingdom) that have implanted the Eyemate-IO in regular clinic patients. The ARGOS-03 study investigates the long-term safety and performance of the Eyemate-IO in patients with primary open-angle glaucoma. Details of the ARGOS-02 study have been presented previously.⁹ Patients were followed up for at least 2 years after successful implantation of the sensor system. The ARGOS-SC study investigated the safety and performance of a novel IOP sensor that is placed within the suprachoroidal space during nonpenetrating glaucoma surgery.¹⁰ Both studies adhered to the tenets of the Declaration of Helsinki, received ethics committee or institutional review board approval at each study site, and were registered at [ClinicalTrials.gov](https://www.clinicaltrials.gov)

(Identifiers, NCT03651336 and NCT03756662). All participants provided informed consent.

A questionnaire was developed to evaluate the usefulness of telemetric IOP measurements to guide remote clinical decision making during the COVID-19 lockdown (defined as March 15, 2020–April 29, 2020) in Germany, Switzerland, and the United Kingdom. During this time, nonemergent and nonurgent clinic visits had to be canceled by law in these countries. The questionnaire, along with graphic representation of the Eyemate IOP measurements, was sent to all study centers.

Intraocular Telemetric Intraocular Pressure Sensors

The Eyemate sensor is implanted in the ciliary sulcus during routine cataract surgery, as described previously.¹¹ The rectangular Eyemate-SC sensor is implanted into the suprachoroidal space during nonpenetrating glaucoma surgery and contains the same microelectromechanical system application-specific integrated circuit as the Eyemate-IO device. It also uses the same principle of power supply and data transfer as the Eyemate-IO. The application-specific integrated circuit is bonded to a wire wound gold microcoil and hermetically encapsulated in medical grade silicone rubber material. The dimensions of the implant are 7.5×3.5 mm with a thickness of 1.3 mm at its center and 0.9 mm at the edges.

An external handheld reader device contains a power source and generates the electromagnetic field to power the sensor via electromagnetic coupling, which also acts as an antenna for the transmission of the signals provided by the sensor. The reader can store up to 3000

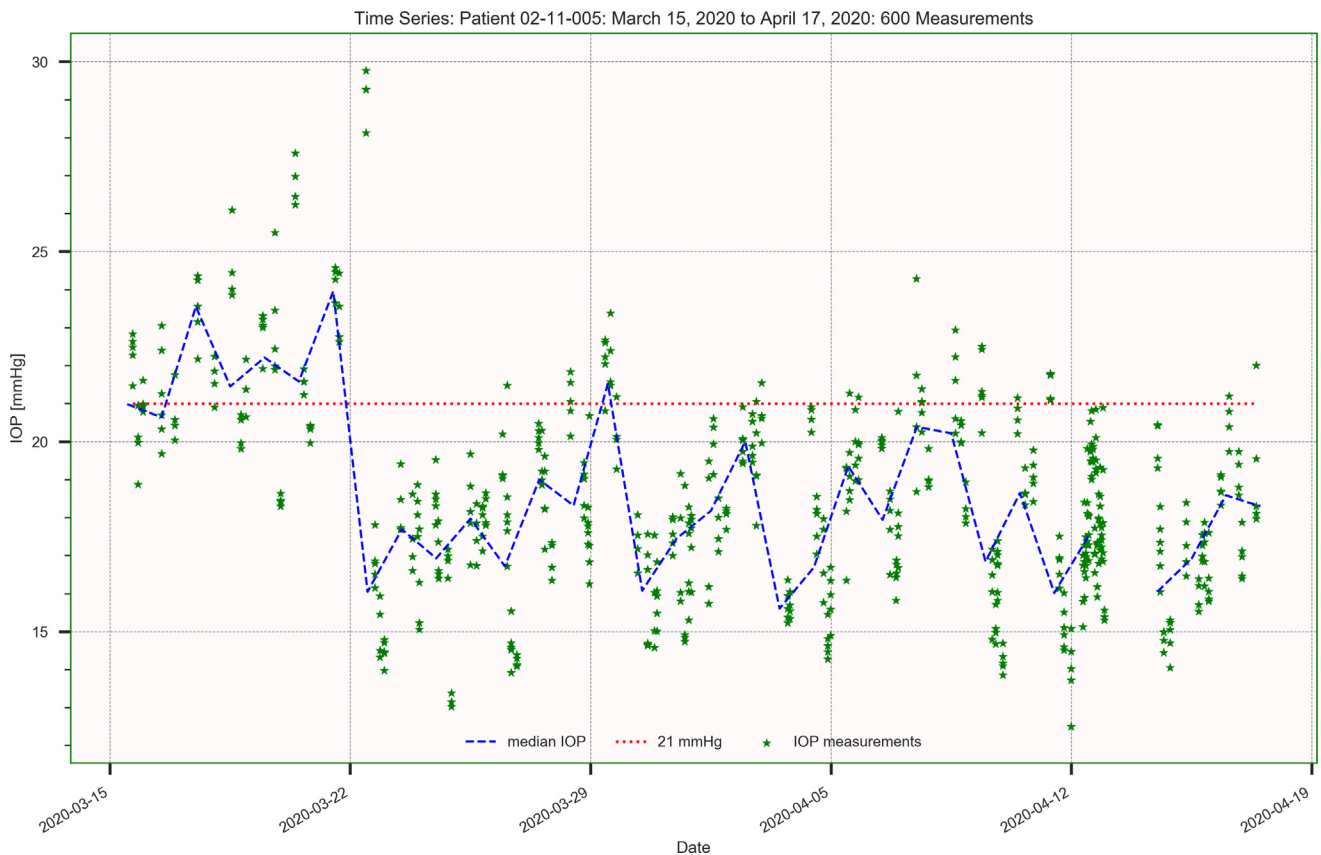


Figure 2. Graph showing that despite evidence of intraocular pressure (IOP) lowering when an additional glaucoma drop was added on March 20, 2020, average IOP seemed to remain at more than the target of 15 mmHg.

individual IOP readings, which can be transferred to a computer via a cable connection or wirelessly into a web-based database. To obtain an IOP measurement, the reader device and the sensor implant need to be brought in close proximity with each other after the patient presses the button on the reader to activate the electromagnetic coupling sequence. Technically, 10 measurements per second are made. Patients were instructed to measure their own IOP with the provided reader unit as often as they wanted, but at least 4 times daily. The measured data, recorded in the external reader device, were transferred into a web-based database. The treating physicians had internet-based access to the database. All the measurements stored in the database were used for analysis.

Statistical Analysis

Descriptive statistics included mean and standard deviation for continuous variables. The tests were 2-tailed and P values of less than 0.05 were considered statistically significant. All calculations were performed with commercially available software (Stata version 14.2; StataCorp).

Results

All 10 contacted centers returned the questionnaires (7 in Germany, 2 in Switzerland, and 1 in the United Kingdom). Data were available from 37 eyes of 37 patients (16 patients with the Eyemate-IO sensor and 21 patients with the Eyemate-SC sensor). The mean age of the 37 study participants was 69.3 ± 9.6 years,

and 48.6% were women. In all, 94.6% were White, 2.7% were Black, and 2.7% were Asian. The educational level of patients was: 13.5% tertiary, 56.7 secondary, and the remainder primary.

During the lockdown period, 16 patients were seen for an office visit. In 13 cases, these were previously scheduled study visits that were judged to be important enough to be maintained despite the lockdown. One visit was scheduled after a cardiovascular adverse event resulting from decompensated heart failure (ramipril 5 mg and torsemide 5 mg), which required changes both in systemic medication and glaucoma eye drops (i.e., timolol-containing eye drops were discontinued), 1 visit was because of a potential device adverse event, and 1 visit because of suspected visual field progression.

In all, 34 patients continued to use the Eyemate system to obtain daily IOP measurements. Three patients stopped using the Eyemate system. Reasons for discontinuation of the Eyemate system were perceived restriction with daily activities, lack of interest, and difficulty with handling the external reader. A total of 8415 IOP measurements from 370 measurement days were obtained during the lockdown period, representing an average of 37 ± 11 measurement days (range, 1–46 measurement days) per patient. On measurement days, an average of 6.1 IOP measurements were obtained.

Based on these measurements, management was changed in 5 patients (14%). In 3 patients, a change occurred in ocular hypotensive medications; in 1 patient, an office visit was performed; and in 1 patient, glaucoma surgery was scheduled. Figures 1, 2, 3, and 4 show selected patients for whom treatment was changed based on remote IOP monitoring.

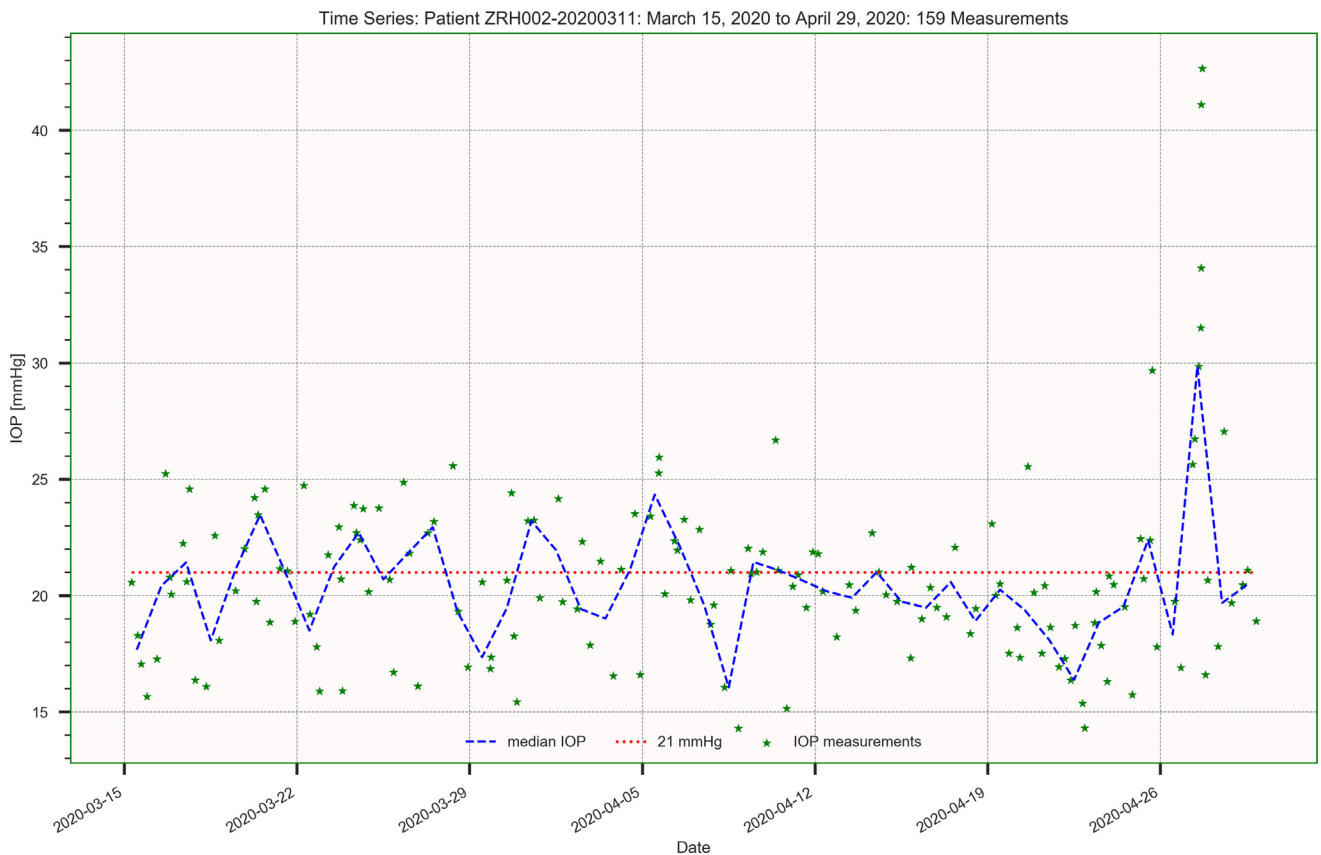


Figure 3. Graph showing intraocular pressure (IOP) measurements that are consistently more than 21 mmHg. The decision was made to change IOP-lowering treatment.

Some treating physicians did not have access to Eyemate system measurements during the lockdown period. These investigators were provided with their patients' Eyemate measurements retrospectively and were asked how these data would have influenced their clinical management if they had real-time access to the information. They responded that having had access to IOP readings would have had a clinical impact on decision making in 5 patients. For 3 patients, it would have led to escalation in ocular hypotensive medications because of large IOP fluctuations and unmet IOP targets. In 2 patients, it would have prompted an additional office visit to verify IOP and discuss suspected adherence issues. In the remaining 24 patients, the status was judged to be well controlled and no office visit was scheduled. When asked whether remote IOP measurements were helpful during the COVID-19 pandemic, 9 of 10 centers were in agreement. [Table 1](#) presents replies by center.

Discussion

In this study, we showed that 92% of patients who previously had been implanted with the IOP telemetric sensor were able to measure their IOP and provide these measurements to their physicians electronically during the COVID-19 lockdown. Patients obtained an average of 6.1 daily IOP measurements, a frequency similar to that observed in a long-term study with the same IOP device (5.8 measurements/day).¹² An important finding was that physicians who had access to these remote IOP measurements adjusted their clinical decision making

in 5 patients (14% of total), in 3 patients leading to a change in treatment, and in 1 patient leading to surgery. In another 5 patients, clinical management also would have been adjusted if the physicians had timely access to the IOP measurements. Taken together, remote IOP monitoring during the approximately 2-month lockdown period would have led to changes in clinical management, mostly in adjustment of ocular hypotensive therapy, in almost one third of patients. This rate of treatment change is relatively high and may be higher than practiced in a normal clinic setting. Whether it is explained by the availability of continual IOP data or because of the lockdown is a matter of future research. Equally important is the fact that the remaining patients were found to have IOP values that were within the target range. Therefore, these patients could be reassured and unnecessary clinic visits could be postponed. The use of remote IOP monitoring reduced patient anxiety after the interruption of in-person care, as confirmed by the study investigators ([Table 1](#)). Two-way synchronous communication is an important feature in a telemedicine model. In this study, when lack of compliance was suspected as a source of uncontrolled IOP, some clinicians contacted patients by phone to inquire about problems with their medications such as difficulties in procuring or applying them.

Intraocular pressure is but 1 important parameter in the management of glaucoma, and implantable IOP sensors are at present out of reach for most glaucoma patients. Ophthalmologists rarely determine glaucoma progression based on

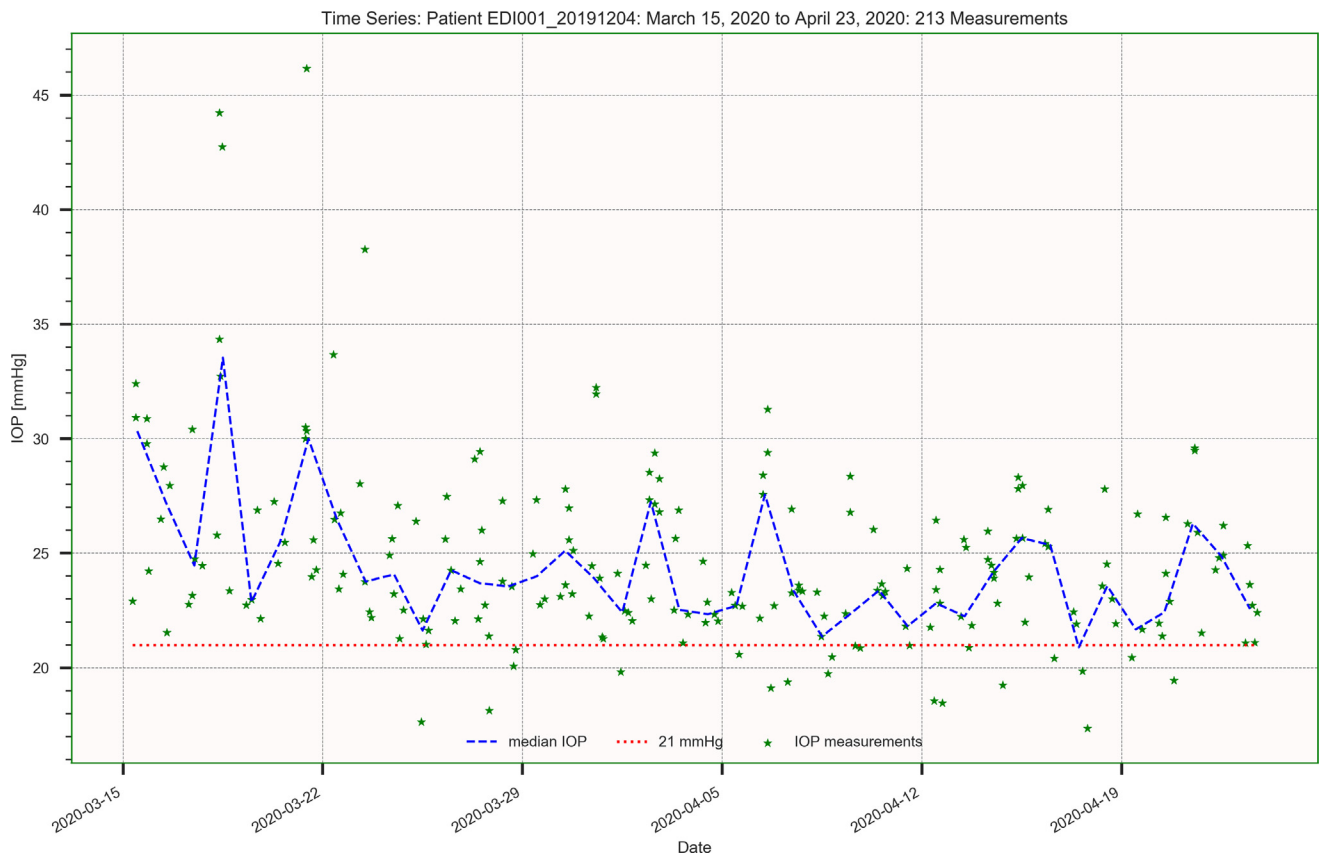


Figure 4. Graph showing that intraocular pressure (IOP) measurements are consistently more than 21 mmHg. The decision was made via a virtual consultation to schedule glaucoma surgery.

IOP in isolation. This decision usually is based on changes in visual fields or structural changes of the optic nerve head. Early progress has been reported in both of these areas. For instance, tablet-based perimetry devices, such as the Melbourne Rapid Fields (Glance Optical) have been developed for remote glaucoma evaluation¹³ and have been shown to be reliable in detecting moderate to advanced glaucoma visual field loss.¹⁴ Smartphone-based optic disc imaging also may have potential for remote glaucoma monitoring, but may need pupil dilation and an assistant to capture high-quality pictures.^{15,16} It is likely that the enduring COVID-19 pandemic will serve as a catalyst for advances in these sectors. The fact that 13 patients required a face-to-face visit emphasizes the fact that the availability of remote IOP data did not obviate the need for other physical clinical examinations.

This was a multicenter study with 10 involved sites, and it does have some limitations. The main limitation is the relatively small sample size and the selective profile of patients who may not be representative of the average glaucoma patient. Some centers had been involved with the IOP sensor technology for several years in more than a dozen of patients, whereas others had only recent experience with few patients. Therefore, it is possible that this discrepancy in experience may have led to differences in interpretation and handling of remote IOP data. Also, given the innovative nature of the device and the need for intraoperative surgery for its implantation, the profile of study patients may differ

from average glaucoma patients, precluding the generalization of these findings. Twenty-one patients in this study had been implanted with the novel suprachoroidal telemetric IOP sensor. This device is implanted into the suprachoroidal space during nonpenetrating glaucoma surgery. These patients currently are within the first year of postoperative follow-up. Most of these patients have well-controlled IOPs without the need for ocular hypotensive medications. Therefore, it is not surprising that a high percentage of patients in this study were found to have IOPs within the target range during the lockdown period. Finally, patients who agree to participate in clinical trials tend to be more motivated and health conscious than the average patient. The fact that 3 of 37 patients did not use their device to obtain IOP measurements because of perceived restrictions of daily activities or device handling difficulties suggests that universal acceptance of an IOP monitoring system may face practical difficulties.

In conclusion, we found that patients previously implanted with the telemetric IOP sensor were able to acquire their own IOP measurements. Moreover, in most cases, treating ophthalmologists had access to their patients' data. During the COVID-19 lockdown period, these data impacted glaucoma management. For virtual glaucoma clinics to be a meaningful substitute for in-person care, future innovations in remote testing of visual fields and optic disc topography are needed to complement remote IOP monitoring.

Table 1. Assessment of Usefulness of Remote Intraocular Pressure Monitoring by Study Center

Center	“Did Remote Eyemate Intraocular Pressure Measurements Have an Impact During the Coronavirus Disease 2019 Lockdown?”
1	No. “IOP variations were already known; no new information to clinic visits.”
2	Yes. “Eyemate IOP [readings] were stable and within range. No need for medications and no AEs.”
3	Yes. “Eyemate-SC readings show a continuous increase in IOP with repeated measurements above 21 mmHg after 05.04.2020 in 1 patient. In light of these readings, we would recommend an unscheduled visit to reassess IOP by Goldmann applanation tonometry and likely start local medication.”
4	Yes. “Monitoring IOP without clinic visits.”
5	Yes. “Very helpful. We were assured that patients were well controlled, and we could therefore safely cancel visits during COVID[-19] lockdown and safely postpone visits to the post-lockdown period. Patients were happy.”
6	Yes. “Eyemate measurements were only evaluated after being notified of unacceptable values, but then given full consideration for treatment adjustment.”
7	Yes. “Due to general health problems, 1 patient would not have been able to come to measure IOP in the clinic with or without the pandemic. So, for this patient it is a very good option to be able to make a few safety IOP measurements comfortably from at home. Otherwise we would have no measurements at all.”
8	Yes. “If we had seen the quantity and quality of IOP fluctuations and peaks over the target goal, I would have modified treatment earlier. Surgery has to be discussed if additional eyedrops have no sufficient effect.”
9	Yes. “Through the continuous measurements of IOP done by the patients at home, abnormalities were easily and quickly noticed and visits at the doctor’s office could be better planned.”
10	Yes. “Very useful as it allowed remote IOP monitoring, reducing the risk of patients attending the hospital.”

AE = adverse event; COVID-19 = coronavirus disease 2019; IOP = intraocular pressure.

Footnotes and Disclosures

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HUMAN SUBJECTS: Human subjects were included in this study. Both studies adhered to the tenets of the Declaration of Helsinki, received EC/IRB approval at each study site and were registered at clinicaltrials.gov (NCT03651336 and NCT03756662). All research adhered to the tenets of the Declaration of Helsinki. All participants provided informed consent.

No animal subjects were included in this study.

Author Contributions:

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Analysis and interpretation: Mansouri, Kersten-Gomez, Hoffmann, Szurman, Choritz, Weinreb

Data collection: Mansouri, Kersten-Gomez, Hoffmann, Szurman, Choritz, Weinreb

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Overall responsibility: Mansouri, Weinreb

Abbreviations and Acronyms:

COVID-19 = coronavirus disease 2019; **IOP** = intraocular pressure.

Keywords:

COVID-19, Glaucoma, Intraocular pressure, IOP, Lockdown, Monitoring, Telemetry.

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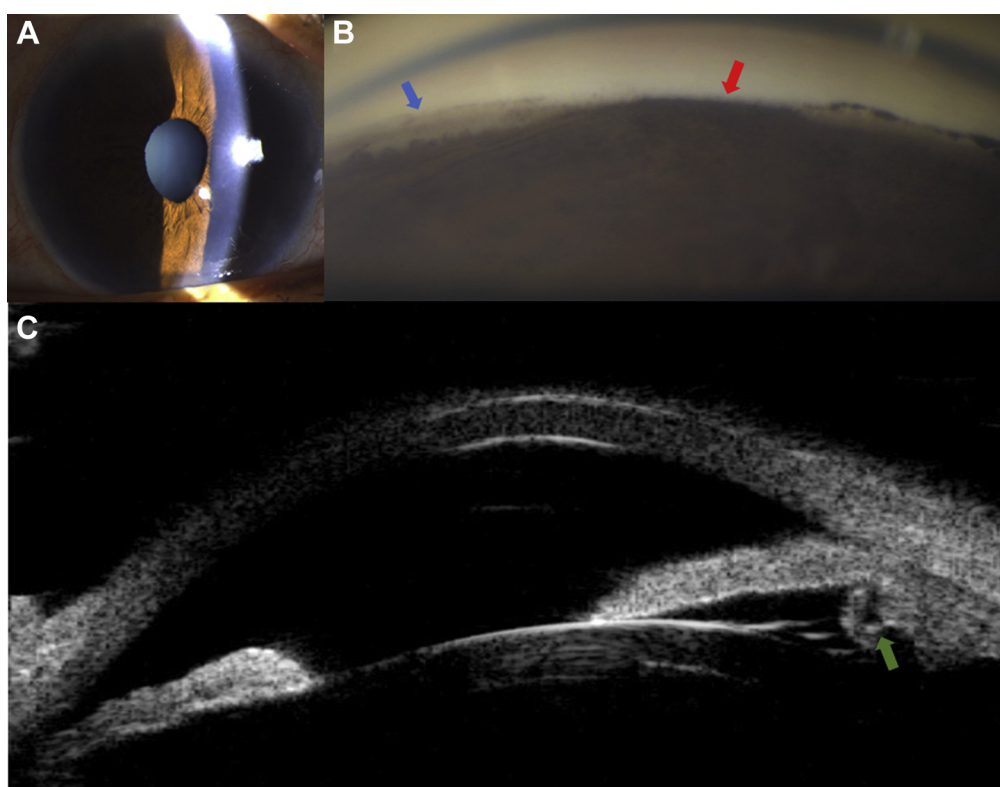
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Pictures & Perspectives



Peaked Pupil and a Bumpy Iris: Don't Stop Looking

A 71-year-old woman had an inferiorly peaked pupil (Fig A). Gonioscopy revealed a small bump in the inferior iris with localized angle closure (Fig B, red arrow), while the rest of the angle was open (Fig B, blue arrow). Ultrasound biomicroscopy showed a small iridociliary cyst (Fig C, green arrow). Primary iridociliary cysts are epithelial-lined spaces arising from the iris and ciliary body's pigmented epithelial layer and are usually benign (Magnified version of Fig A-C is available online at www.ophtalmologyglaucoma.org).

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