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Journal

British Journal of Ophthalmology, 108(11)

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Publication Date

2024-10-22

DOI

10.1136/bjo-2022-323080

Peer reviewed

OPEN ACCESS

Clinical science

Reproducibility of consecutive automated telemetric noctodiurnal IOP profiles as determined by an intraocular implant

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► Additional supplemental material is published online only. To view, please visit the journal online (https://doi.org/10.1136/bjo-2022-323080).

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Received 10 January 2023
Accepted 27 January 2024

To cite: van den Bosch JJON, Pennisi V, Rao HL, *et al*. *Br J Ophthalmol* Epub ahead of print: [*please include* Day Month Year]. doi:10.1136/bjo-2022-323080

ABSTRACT

Background Intraocular pressure (IOP) monitoring in glaucoma management is evolving with novel devices. We investigated the reproducibility of 24 hour profiles on two consecutive days and after 30 days of self-measurements via telemetric IOP monitoring.

Methods Seven primary patients with open-angle glaucoma previously implanted with a telemetric IOP sensor in one eye underwent automatic measurements throughout 24 hours on two consecutive days ('day 1' and 'day 2'). Patients wore an antenna adjacent to the study eye connected to a reader device to record IOP every 5 min. Also, self-measurements in six of seven patients were collected for a period of 30 days. Analysis included calculation of hourly averages to correlate time-pairs of day 1 versus day 2 and the self-measurements vers day 2.

Results The number of IOP measurements per patient ranged between 151 and 268 on day 1, 175 and 268 on day 2 and 19 and 1236 during 30 days of self-measurements. IOP time-pairs of automatic measurements on day 1 and day 2 were significantly correlated at the group level (R=0.83, p<0.001) and in four individual patients (1, 2, 6 and 7). IOP time-pairs of self-measurements and day 2 were significantly correlated at the group level (R=0.4, p<0.001) and in four individual patients (2, 5, 6 and 7).

Conclusions Twenty-four hour automatic measurements of IOP are correlated on consecutive days and, though to a lesser degree, with self-measurements. Therefore a virtual 24-hour IOP curve might be constructed from self-measurements. Both options provide an alternative to frequent in-office IOP measurements.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Peaks in intraocular pressure ('IOP') can occur outside in-office measurements and may contribute to glaucoma progression. Clinically, 24 hour measurements are mainly restricted to hospitalised patients and can be cumbersome for both patient and healthcare personnel.

WHAT THIS STUDY ADDS

⇒ In seven patients with glaucoma who were implanted with an intraocular microsensor, 24-hour automatic telemetric IOP readings were strongly correlated on consecutive days (R=0.83, p<0.001). Self-measurements collected over a 30-day period in six patients were also correlated to 24-hour automatic measurements (R=0.4, p<0.001).

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Both telemetric automatic 24-hour measurements and self-measurements collected over a longer time period can serve as an alternative to frequent in-office or in-hospital IOP measurements to study IOP variations and glaucoma pathophysiology.

INTRODUCTION

Elevated intraocular pressure (IOP) is a major contributing factor for the onset and progression of glaucoma. Current therapeutic options aim at lowering IOP.[1 2] There is mounting evidence that IOP is a highly dynamic parameter, but it is currently not fully understood to which degree the range and timing of IOP fluctuation influence the course of glaucoma progression.[3 4] The major limiting factor in addressing this question has been the inability to capture short-term IOP fluctuations with reasonably high temporal resolution by standard office tonometry.

IOP measurements obtained over 24 hours have shown a greater fluctuation compared with single IOP measurements during office hours, leading in two studies to a therapy change in a considerable number of patients with glaucoma.[5 6] Such IOP measurements are labour-intensive and typically considered only for a subset of patients who appear to progress despite normal in-office IOP. In addition, clinical IOP profiles may not be fully representative of normal IOP fluctuations in a home environment with uninterrupted sleep. Furthermore, some studies have reported that IOP measurements are not conserved on different days when obtained at the same time and have emphasised the importance of obtaining 24-hour measurements on individual days.[7–10]

An alternative approach to measuring IOP throughout a single day is based on constructing a 'virtual diurnal IOP profile' through frequent self-measurement with a home tonometer over the course of one to several weeks.[11 12] However, it is unclear whether such a virtual diurnal curve could be an acceptable alternative to 24-hour measurements of IOP throughout a single day.

Recent advancements in telemetric IOP measurement have overcome some of the limitations of conventional tonometry and allowed for more detailed 24-hour monitoring.[13–18] They can be employed outside the clinic, measure IOP automatically and at much higher measurement rates, while they leave the patients' sleep undisturbed.[14–17] One such study reported IOP patterns in patients with glaucoma using a contact lens sensor and observed moderate to good reproducibility for two visits 1-week apart.[15]

Patients with glaucoma fitted with the Eyemate-IO pressure sensor can measure IOP manually as self-measurements or can be monitored automatically with good accuracy.[18] A previous study investigated the reproducibility of IOP self-measurements in these patients and observed a moderate reproducibility within a 3 months period and a poor reproducibility in a period of a year or longer.[17]

We hypothesise that IOP reproducibility is good on consecutive days, but becomes less reproducible as the time in between measurement sessions increases. In addition, the conscious act of self-measuring IOP might affect the IOP level as compared with unencumbered automated IOP monitoring in individual patients. In the present study, we used both manual and automated measurements with the Eyemate-IO pressure sensor to investigate whether (1) automated noctodiurnal IOP profiles are reproducible on consecutive days, (2) whether these noctodiurnal curves correlate with virtual diurnal profiles after 30 days of IOP self-measurements and (3) whether there are marked differences in IOP level in individual cases between the two measuring modes.

METHODS

The present study is a follow-up study to the ARGOS-02 study, which assessed the safety and performance of a novel, telemetric IOP sensor (Eyemate-IO, Implandata Ophthalmic Products GmbH, Hannover, Germany) that was implanted in the ciliary sulcus at the time of cataract surgery in patients with primary open angle glaucoma (POAG). A detailed description of the study and validation of IOP readings are given elsewhere.[18] In brief, good agreement between Goldmann applanation tonometry (GAT) and the Eyemate self-measurements was previously observed with an intraclass correlation coefficient (ICC(3,k)) of 0.783 (95% CI: 0.743 to 0.817). The Eyemate measurements were on average 3.2 mm Hg higher compared with GAT measurements (95% CI: 2.8 to 3.5 mm Hg). The long-term drift was approximately 1 mm Hg per year. The sensor was recalibrated successfully to be within 2 mm Hg of GAT in patients who showed greater differences between GAT and the Eyemate, though this occurred in only a few cases after the study and continued to be monitored after the study had ended as part of long-term follow-up. In line, the Eyemate sensors were within 3 mm Hg of GAT at the start of the present study.

The Eyemate-IO system comprises a pressure sensor and a handheld reader device. Patients perform a self-measurement after a button press on the handheld reader device while holding it in front of the study eye. The IOP readings are saved on the reader device and can be uploaded by the patient to a secure online database. In the present study, automatic communication between the sensor and reader device was established via an external antenna attached to the reader and placed around the patient's sensor eye as detailed elsewhere.[19] This study configuration allowed data acquisition for at least 24 hours in 5 min intervals.

The present study was part of a wider range of observational experiments divided over 5 days.[19–21] Patients underwent a comprehensive ophthalmological examination prior to study procedures, including best-corrected visual acuity by ETDRS letter charts, visual fields (Humphrey Field Analyzer III), corneal pachymetry, slit-lamp biomicroscopy and funduscopy. Glaucoma was staged according to the Hodapp classification.[22]

In the present study, patients underwent overnight automatic IOP measurements for 2 day–night periods, noted as 'day 1' and 'day 2'. The start of the automatic measurements on day 1 depended on the study protocol and varied from morning to afternoon. Patients came in the next morning for read-out of the IOP data and checking of device settings, after which the recording was repeated until the next morning. Patients wrote down their activities, including wake-up time and approximate sleep time, in a diary during both measurement days. Patients were also asked to perform self-measurements after the study visit for a month and to upload them to the online database to use for study purposes.

The current study was conducted at the Department of Ophthalmology of Magdeburg University Hospital. The study protocol adhered to the tenets of Helsinki and was conducted with local ethics committee approval. Patients provided written informed consent after a detailed explanation of the study prior to participation.

Eleven patients previously implanted with the Eyemate, who were diagnosed with POAG for up to 34 years, took part in the follow-up study. One patient was not willing to take part in the automatic IOP measurements. Three patients were willing to undergo automatic measurements during 1 day–night period. Seven patients were willing to take part in the automatic measurements on two consecutive days and were selected for further analysis. Six of seven patients performed self-measurements in the period of 30 days after the study visit. Data on demographics and other patient details are given in online supplemental table 1. Information on glaucoma medication and timing during the automatic measurements according to the patient's diary are given in online supplemental table 2.

Baseline patient characteristics are presented as mean±SD in case of normal distributed data, non-normal distributed data are presented as median (IQR). Mean IOP was normally distributed among groups and tested for significant differences using double-sided paired t-tests. IOP data obtained via automatic measurements were binned in hourly intervals for day 1 and day 2 separately and statistically compared via correlation of the time-pairs. IOP self-measurements in a period of 30 days after the study visit were obtained from the online database and also binned into hourly intervals. Next, the hourly time-pairs of IOP self-measurements and the automatic measurements on day 2 were correlated. Statistical analysis was performed using R Statistical Software (V.4.0.2; R Foundation for Statistical Computing, Vienna, Austria).

RESULTS

The full resolution of data on two consecutive days of automatic IOP measurements is depicted in seven individual patients in online supplemental file 1. It reveals similar IOP trends between the 2 days, with generally a drop in IOP during the first half of the night period. There also appears a peak in the early morning

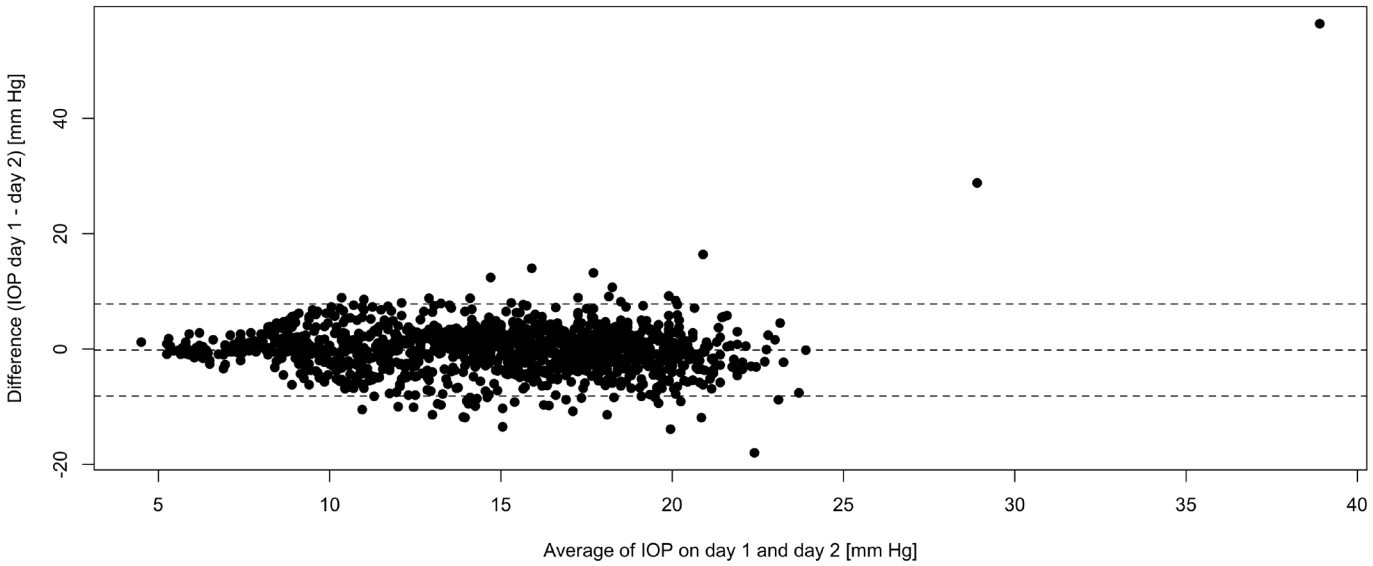

Figure 1 Bland-Altman plot on IOP time-pairs of automatic measurements on day 1 and day 2. Each data point represents a value based on the automatic IOP measurement on day 1 and day 2 at the same time of day. The X-axis depicts the average of each time-pair. The Y-axis depicts the difference of each time-pair. On average, IOP measurements on day 1 were slightly lower than for day 2 with a mean difference of 0.17 mm Hg (based on 1311 measurements, 95% CI: −0.39 to 0.048 mm, p=0.13). The 95% limits of agreement were −8.2 to 7.8 mm Hg. IOP, intraocular pressure.

around the time that patients awakened. The total number of automated measurements during overlapping hours ranged between 151 and 268 measurements, and differed between day 1 and day 2 by up to 24 measurements (online supplemental table 4). There were minimal differences in mean IOP between day 1 and day 2 among patients (online supplemental table 3), that did not reach significance at the group level (n=7). On average, time-pairs of IOP measurements on day 1 were slightly lower than on day 2 with a mean difference of 0.17 mm Hg (95% CI: −0.39 to 0.048 mm Hg, p=0.13, figure 1). The 95% limits of agreement were −8.2 to 7.8 mm Hg. SD and minimum IOP were also comparable on both days. In patients 2 and 5, a difference in maximum IOP of more than 10 mm Hg was observed between day 1 and day 2. Both peaks occurred during the night while patients reported to have been asleep. We observed the hourly IOP time-pairs on day 1 and day 2 to be significantly correlated at the group level (n=7; R=0.83, p<0.001) and at the individual level for four patients (1, 2, 6 and 7). A trend was observed in patients 4 and 5. No significant correlation was observed in patient 3 (figure 2, online supplemental table 4).

Patient 4 appeared to have higher IOP during the night on day 2 compared with day 1. The diary noted a later bedtime and a few more awakenings during the night on day 2. Patient 5 appeared to have higher IOP values on day 1 compared with day 2, mainly in the evening and early night period. There were no clear differences in the evening routine based on the diary notes. Patient 3 did not fill in the diary, hence we cannot extract differences in activities on day 1 and day 2.

Six patients performed and uploaded self-measurements after the study visit (all except patient 3). The total number of self-measurements during the 30 days ranged widely between individual patients (online supplemental table 5). Patient 5 collected 1236 self-measurements in the selected 30-day period, including the night period. In contrast, patient 7 only collected 19 self-measurements and tended to measure around two time points per day (08:00 and 20:00).

Parametrics including mean IOP over the 30 days of self-measurements are shown in online supplemental table 3. While most patients measured higher mean IOP during self-measurements, patient 1 self-measured 1 mm Hg lower mean IOP compared with the mean IOP during the automated measurements. The minimum and maximum IOP values during the self-measurements were also lower compared with the automated measurements in patient 1.

Mean IOP of the self-measurements was not significantly different from mean IOP on day 2 of automated measurements at the group level (n=6). When looking at hourly time-pairs, IOP measurements during self-measurements were significantly higher compared with day 2 of automatic measurements with a mean difference of 2.4 mm Hg (95% CI: 1.6 to 3.2 mm Hg, p<0.001, see figure 3). The 95% limits of agreement were −6.2 to 11.0 mm Hg. Correlations between the self-measurements and the automated measurements on day 2 were weaker than the correlations between automated measurements of day 1 and day 2. Self-measurements and automatic measurements on day 2 still were significantly correlated at the group level (n=6, R=0.4, p<0.001) and at the individual level for four individual patients (2, 5, 6 and 7). A trend was observed in patient 1, while no significant correlation was observed in patient 4 (figure 4, online supplemental table 5). In three out of four patients (patients 2, 6 and 7), both the individual correlations between the automated measurements on day 1 and day 2 and those between self-measurements and day 2 reached significance.

For the automated measurements, night-time IOP was significantly lower than daytime IOP on day 1 and reached borderline significance on day 2 (Δ IOP=2.9 mm Hg, p=0.01 and Δ IOP=2.9 mm Hg, p=0.06, respectively). For the self-measurements, limited night-time IOP measurements were obtained and no diary was available to mark the night period for specific measurements. A preliminary analysis revealed a trend for IOP to be lower between 24:00 and 06:00 than from 06:00 to 24:00 during the self-measurements (patients 1, 2, 4, 5 and 6, see online supplemental file 2, Δ IOP=1.8 mm Hg, p=0.07).

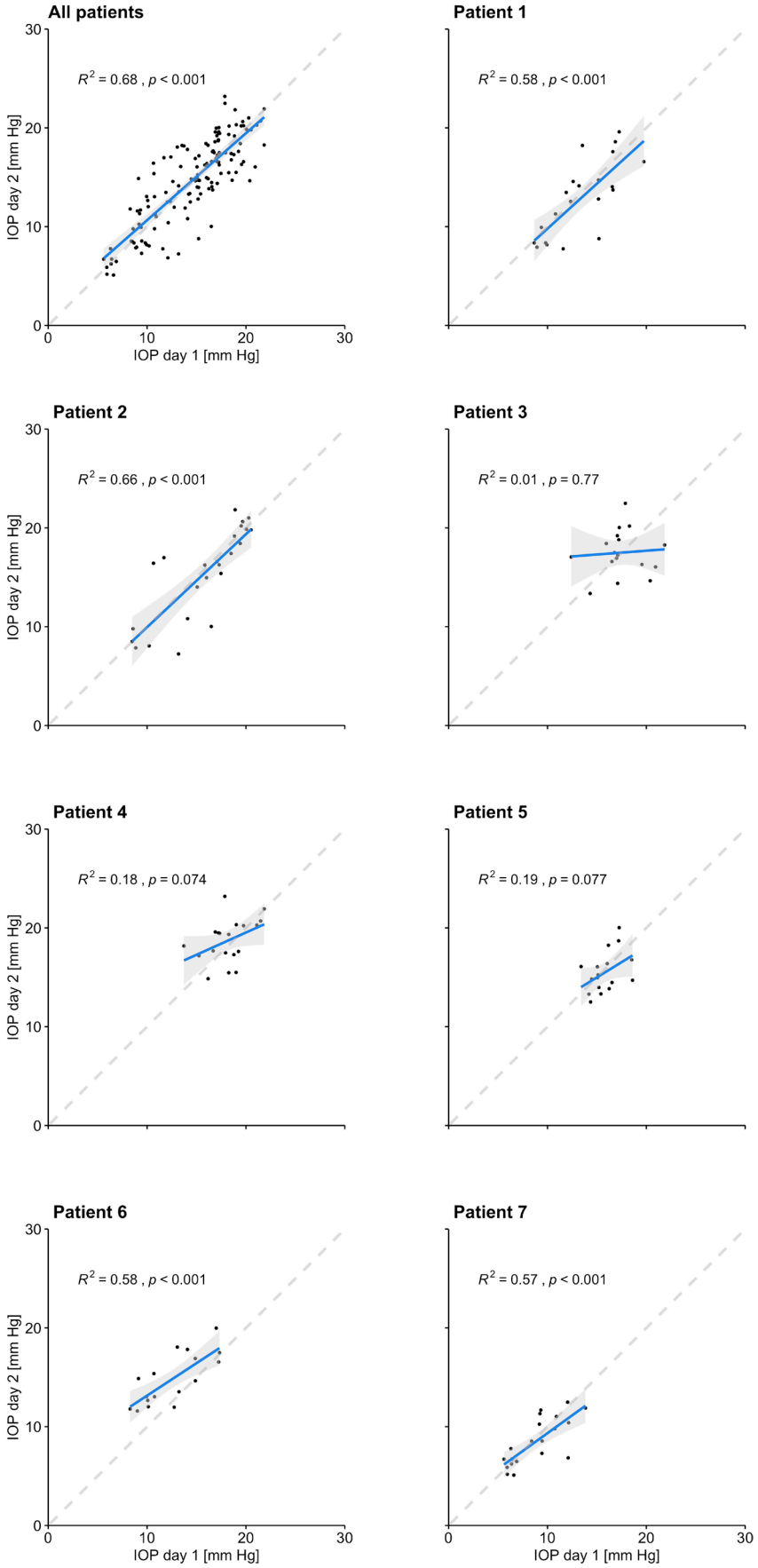

Figure 2 Correlation plots of hourly binned automatic IOP measurements on day 1 and day 2 on a group level (n=7) in the top left panel and for individual patients in the other panels. Line of identity depicted as an interrupted grey line, regression line depicted as a continuous blue line and 95% CI depicted in a light grey area. IOP, intraocular pressure.

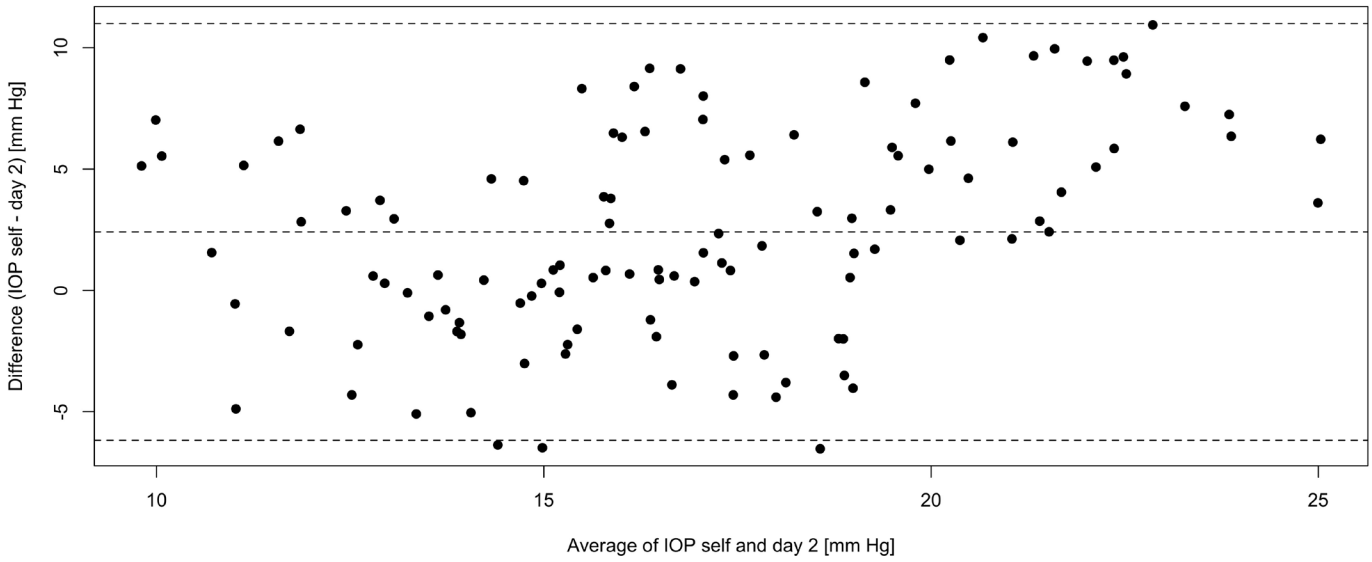

Figure 3 Bland-Altman plot on IOP time-pairs of self-measurements and automatic measurements on day 2. Each data point represents a value derived from the average IOP self-measurement for a specific hour during a 24-hour period and the corresponding average automatic IOP measurement on day 2 for the same hour. The X-axis depicts the average of each time-pair. The y-axis depicts the difference of each time-pair. IOP measurements during self-measurements based on 117 measurements were on average higher than on day 2 of automatic measurements with a mean difference of 2.4 mm Hg (based on 117 measurements, 95% CI: 1.6 to 3.2 mm Hg, p<0.001). The 95% limits of agreement were −6.2 to 11.0 mm Hg. IOP, intraocular pressure.

DISCUSSION

We observed reproducible 24-hour IOP measurements on consecutive days of automated measurements at the group level and at the individual level in four patients with glaucoma. Various differences between previous studies, such as in tonometry methods, measurement timing and frequency and patient group, limit direct comparison with the present study. In general, however, IOP has been reported to be reasonably reproducible in patients with glaucoma in the short term despite considerable variability during the day.[7 9 10 15 17 23] Data on consecutive days are very limited.[9 10 24]

Compared with studies using GAT, the data in the present study are less prone to user error or biomechanical aspects of the anterior segment, considering that measurements have been obtained automatically by an intraocular sensor and without manipulating the eye.[25] In addition, the automated data captured did not restrict movement of the patients, and did not affect their sleep; thus, it is likely to have provided a more accurate assessment of 24-hour IOP variability. In line, we observed that agreement in the present study between two measuring modes of the Eyemate is better compared with previous work that compared Eyemate readings to GAT and assume that it is in part due to less IOP variability occurring during telemetric measurements.[18] Interestingly, Koutsonas *et al*, who used an earlier version of the intraocular sensor in a single patient over three consecutive days, observed good short-term reproducibility of IOP.[26] Previous data on telemetric IOP monitoring are scarce and did not compare IOP on consecutive days, however. Downs[13] investigated 24-hour IOP in non-human primates in sessions that were several days apart using an intraocular device and observed no reproducible pattern. The authors noted that the noctodiurnal rhythm of monkeys might be different from humans. Mansouri *et al*[15] observed a reproducible pattern between two sessions of 24-hour IOP measurements that were obtained 1-week apart in 40 participants (19 patients with glaucoma and 21 glaucoma suspects) using a contact lens sensor. As the method used did not provide values in mm Hg and is highly dependent on biomechanical parameters of the measured eye, comparison with the intraocular sensor used in the present study is limited.

In the present study, five patients exhibited higher mean IOP values, while one patient showed decreased IOP levels during self-measurement compared with the automated measurements on day 2. On average, when evaluating hourly time pairs at a group level, IOP self-measurements were also higher compared with automatic measurements on day 2. Notably, self-measurements tended to overestimate values at elevated IOPs while marginally underestimating them at normal to lower IOPs. We hypothesise that the conscious act of self-measuring could contribute to this difference, possibly due to the stress induced, given that anxiety or emotional stress has been documented to elevate IOP.[27–29] On the other hand, the act of self-measurement would mean stopping other activities and thus cessation of influencing factor and possibly leading to decreased IOP levels in some cases. Regression analyses revealed significant correlations between self-measurements and automated measurements on day 2, although weaker than the correlations between the automated measurements of day 1 and day 2. Besides the previously mentioned factors of inactivity or stress during a self-measurement, variations in self-measurement frequency and the timing of measurements around specific time points may contribute to increased IOP variability. In addition, we assume that the weaker correlations of self-measurements are partly due to longer follow-up periods, which likely increase IOP variability. In line is the study by Mansouri *et al*,[17] who investigated the self-measurements of 22 patients with POAG with the Eyemate sensor over a longer time period retrospectively (the present study investigated a subset of seven patients of this study population prospectively). IOP variability was more reproducible within 3 months (ICCs: 0.52–0.66) compared with longer time periods (ICCs: 0.29–0.51). Interestingly, it is known that IOP has seasonal variability, and this has also been observed in the same patient group in another study, suggesting that there is some stability in long-term IOP variability of self-measurements.[17 30 31] Long-term IOP variability is beyond the scope of the present study. We speculate that

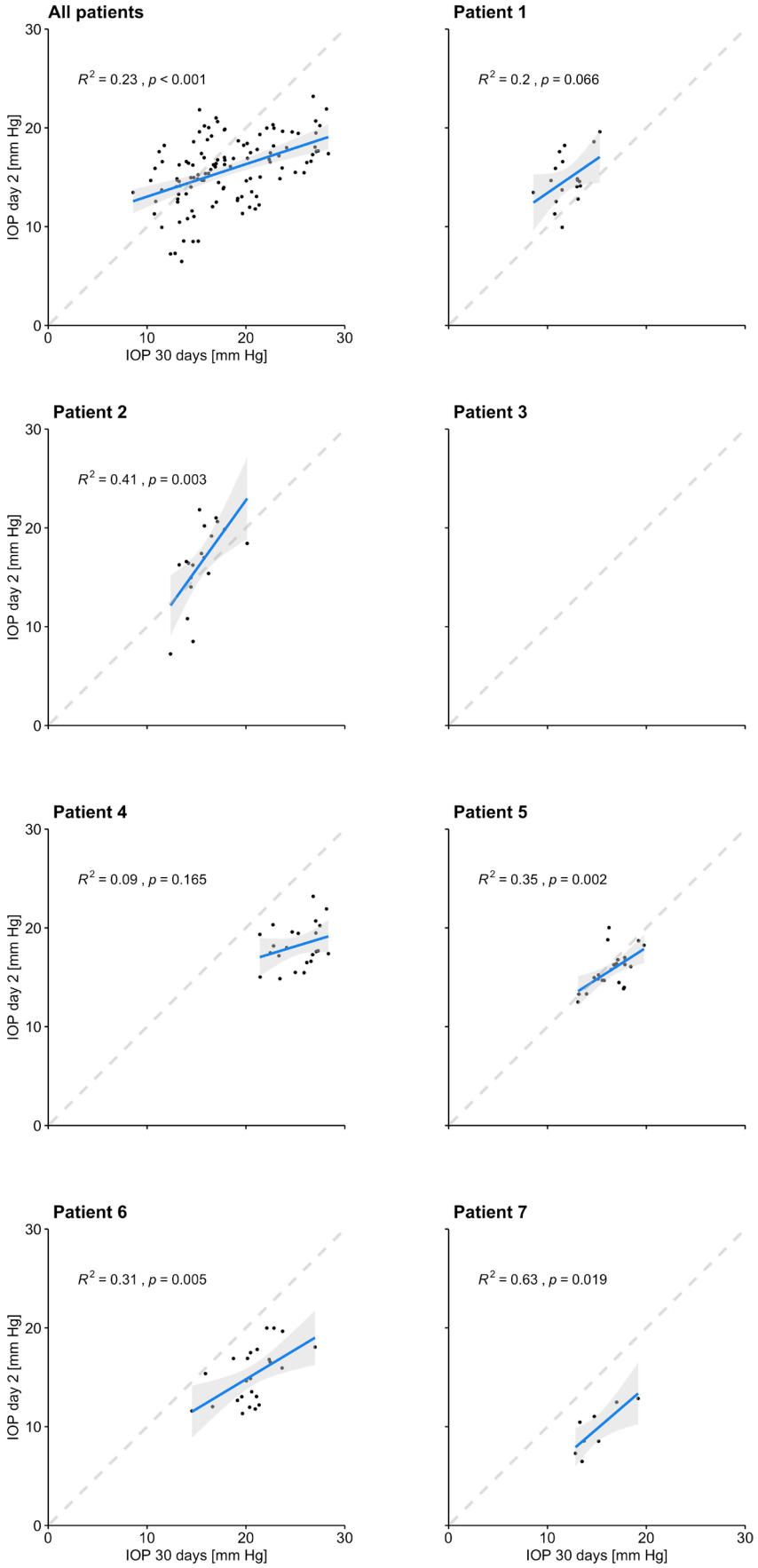

Figure 4 Correlation plots of hourly binned IOP self-measurements over a 30-day epoch and automatic measurements day 2 on a group level (n=7) in the top left panel and for individual patients. Line of identity depicted as an interrupted grey line, regression line depicted as a continuous blue line and 95% CI depicted in a light grey area. IOP, intraocular pressure.

IOP variability in the long-term may be in part related to disease progression.

In the present study, individual analyses revealed significant correlations between self-measurements and automated measurements in four out of six individual patients. Hence, in a subset of patients self-measurement might be sufficient to accurately represent 24-hour IOP variability. Based on our data, however, it cannot currently be predicted which patients might show good correlations between both measuring modes. Moreover, nighttime self-measurements would still require the patients to be awake.

Previous data on self-measurements are limited, with the Icare Home being the main product on the market to the best of our knowledge. Self-tonometry performed with Icare Home is not as accurate as GAT or intraocular measurements and can be difficult to use, though recent literature is more promising.[11] The Icare Home has been used in a subset of patients with glaucoma and allowed the detection of a reproducible IOP peak outside office hours.[12] There are no published data on the IOP diurnal profile reproducibility between particular time points, however.

In the present study, IOP was generally lower during the night with a peak that seemed to coincide with the self-reported wake-up time. In accordance, a number of previous studies reported IOPs to be lower during the night followed by a peak in the morning, including patients with glaucoma with or without pressure lowering medication.[9 11 12 32–34 34–36] Others reported IOP to be higher during the night.[15 16 23 37–40] It could be argued that increased night-time IOP in those studies might be artefacts of eliciting a systemic 'excitation' as seen when patients wake naturally, thus masking lower IOPs during proper sleep. On the whole, literature remains inconsistent with regards to night-time IOP, in part due to differences in methods and glaucoma status, and data may also be influenced by age,[41] the type of antiglaucoma medication[24] and by whether IOP is measured in the supine position or not.[23 37 39 40 42]

An important limitation is that we were restricted to a small and heterogeneous group of seven patients with POAG. Patients were on different glaucoma treatment regimes, which may have altered the IOP rhythm differently.[24] Three patients had controlled IOP without glaucoma medication in the present study. We observed in follow-up data of the ARGOS-02 study that IOP lowered several months after cataract surgery (data not shown). It is known that cataract surgery can lower IOP.[43] However, we could not extract meaningful differences in IOP reproducibility or in the timing of the acrophase of IOP based on the type or timing of glaucoma medication due to the limited number of patients. Future studies should include larger, more homogenous patient groups and include different types of glaucoma as well as patients without glaucoma to justify more extensive statistical analysis.

For the automatic measurements, one limitation is that no overlapping IOP measurements could be obtained in the morning up to early afternoon period in most patients due to logistic constraints on measurement day 1. In addition, we did not adjust the patient's activities or monitor them strictly to control for confounding factors (apart from a patient diary), possibly biasing or affecting the accuracy of the results. On the other hand, adjustment is likely to reduce IOP variability and therefore may strengthen the present correlations. However, due to the small and heterogeneous study group, we were limited in the present study to extract and describe factors that could have affected IOP.

For the self-measurements, interesting differences in measurement behaviour can be observed. Yet results might have been more homogenous if patients had been instructed to measure systematically at particular time points. In addition, we did not register in the present study whether patients were sitting upright or remained supine during the night-time self-measurements, which may have affected the obtained IOP values.

Lastly, it is currently not known how stable diurnal IOP patterns are over additional days and longer time periods, and when they should usefully be repeated. Further studies using the current intraocular sensor should elucidate the reproducibility of both measuring modes at different temporal ranges and also whether glaucoma progression can be determined from changes in IOP profiles. Ideally, automated measurements and self-measurements would assist in glaucoma follow-up, including estimation of the best time for application of antiglaucoma medication. It still needs to be investigated, how many measurements could be useful to support in glaucoma follow-up and whether the optimal timescale of data acquisition can be extrapolated to conventional methods.

To conclude, we present accurate high-resolution IOP data in a small set of patients with POAG with an IOP sensor implant during daily activities and normal sleep. We observed similar 24-hour IOP traces in four out of seven patients with glaucoma on consecutive days of automated measurements. A virtual diurnal curve reconstructed from self-measurements obtained during 30 days in the home setting was, though to a lesser extent, also correlated to the 24 hours IOP trace obtained by automated measurements in four out of six patients. Both measuring modes could therefore be useful in glaucoma follow-up.

Acknowledgements We would like to thank all contributing ARGOS-02 study sites and Angela Ehmer for contacting the patients to take part in the present follow-up study.

Contributors LC and MBH obtained funding and supervised the study. LC, MBH and JJONvdB contributed to the study concept and design. JJONvdB and VP collected the data. JJONvdB analysed the data. LC, MBH and JJONvdB drafted the manuscript. All authors critically discussed the results, commented on and revised the manuscript. LC is the overall guarantor of the study and accepts full responsibility for the work and conduct of the study, had access to the data and controlled the decision to publish.

Funding The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests The present study has been supported by the European Union's Horizon 2020 research and innovation programme under the Marie Sklodowska-Curie Grant Agreement No. 675033 (EGRET plus) and No. 661883 (EGRET cofund). JJONvdB has been funded via Implandata as a beneficiary of the aforementioned EGRET plus international training program. KM and RW are consultants of Implandata.

Patient consent for publication Not applicable.

Ethics approval The name of the Ethics committee is as follows: 'Ethik-Kommission der Otto-von-Guericke-Universität in Magdeburg'. The ID number is '209/17'.The ethics committee approval is uploaded as PDF supplement for editors only.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request.

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