# Self-Monitoring of Intraocular Pressure Outside of Normal Office Hours Using Rebound Tonometry: Initial Clinical Experience in Patients With Normal Tension Glaucoma

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**Purpose:** To determine the value and accuracy of 24-hour intraocular pressure (IOP) phasing using Icare ONE rebound tonometry (RTONE), in subjects with normal tension glaucoma (NTG).

**Methods:** Eighteen consecutive patients with treated NTG were studied, all subjects had undergone 24-hour IOP phasing during a 1-year period. Each patient had daytime (08:00 to 16:00) IOP phasing with Goldmann applanation tonometer at 2-hourly intervals; at these same time points an IOP reading was also obtained by the patient using RTONE. Self-measured IOPs were then recorded at home using RTONE between 18:00 and 06:00 (at 2-hourly intervals). The frequency with which the phasing results altered clinical management was evaluated.

**Results:** The mean peak IOP was significantly higher during nighttime phasing (15.78 ± 4.8 mm Hg) compared with daytime phasing (12.83 ± 2.7 mm Hg, $P = 0.0018$) and clinic IOP measurements (11.8 ± 1.6 mm Hg, $P < 0.0001$). Following IOP phasing a change in management occurred in 10 of 18 patients (56%). In the majority of these patients, a peak IOP was identified during nighttime phasing compared with daytime phasing, this difference was significant ($P = 0.0090$). There were strong correlations between the IOP measurements obtained with Goldmann applanation tonometer and RTONE (Spearman $r$ values $>0.60$, $P < 0.001$).

**Conclusions:** This study suggests that in patients with NTG with progression that is disproportionate to their clinic IOP measurements, 24-hour phasing can reveal higher IOP spikes than those identified during typical office hours. RTONE is a safe, easy to use, and accurate device for self-monitoring of IOP.

**Key Words:** Icare ONE rebound tonometry, self-tonometry, intraocular pressure, normal tension glaucoma, 24-hour IOP phasing

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The pathogenesis of disease development and progression in normal tension glaucoma (NTG) remains unknown. NTG is considered a multifactorial disorder and disease development is associated with intraocular pressure (IOP)[1,2] and vascular factors.[3,4] IOP, however, remains the only treatable risk factor.

Similar to other biological parameters, IOP varies throughout the day and night in both normal and glaucomatous subjects.[5,6] Large circadian variations in IOP have been suggested to have a contributory role in glaucoma progression.[7,8] Moreover, short-term IOP fluctuations and intervisit IOP variations have been identified as prognostic factors for glaucoma progression.[9] IOP peaks have been reported to occur in the morning,[8,10] during the nocturnal or early morning period[5,11,12] or even increase gradually through the day. It is therefore unsurprising that previous studies have reported a failure to detect peak IOP measurements during office hours.[13]

In practice, most clinicians rely on sporadic IOP measurements taken during office hours to diagnose and manage glaucoma patients. When glaucomatous optic neuropathy progresses in subjects with apparently normal or controlled IOP measured during office hours, 24-hour IOP phasing can provide integral information that will assist in the management of individual patients. Potential issues in performing 24-hour IOP phasing include impracticality, lack of resources and cost.

The Icare-ONE rebound tonometer (RTONE) (Icare Finland, Oy, Espoo, Finland) measures IOP without the need for topical anesthesia. It was designed for use by both health care professionals and self-monitoring by patients. RTONE is a portable handheld device that measures IOP using the impact/induction principle. In brief, a solenoid magnetized probe in the device is bounced off the cornea, impacts and then rebounds from the cornea. The deceleration of the probe caused by the eye is used to calculate the IOP.[14] Multiple studies have reported good correlation between IOP measurements taken with Goldmann applanation tonometry (GAT) and ICare rebound tonometry.[15–17]

In this study we report on a consecutive series of patients with NTG undergoing 24-hour IOP self-monitoring using the RTONE. Our primary aim was to assess the clinical value of IOP measurements performed outside of office hours and whether these influenced management. Thereafter we sought to assess correlation between IOP measurements taken with GAT and RTONE.

## METHODS

### Patients

A retrospective review of clinical notes was conducted for all patients with diagnosed NTG undergoing 24-hour IOP phasing at Wolverhampton and Midland Counties Eye Infirmary between June 2013 and July 2014. Patients' details were identified from the hospital IOP phasing register. The decision to refer a patient for 24-hour IOP phasing was made by the consultant (U.S.R.). The primary reason for performing 24-hour IOP phasing in the patients was that they all demonstrated progressive glaucomatous

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optic neuropathy (defined as progressive visual field loss on sequential Humphrey 24-2 visual field testing) despite medical therapy and this was not explained by their apparently normal or controlled IOPs measured during office hours. There was no specific criteria set to define "controlled IOP"; however, it was agreed by the physician that the IOPs were significantly lower than the maximum recorded pressures for each individual patient.

A diagnosis of NTG was based on glaucomatous optic nerve appearance, with corresponding visual field loss, open angle on gonioscopic examination, and a maximum untreated IOP < 22 mm Hg with GAT measured during office hours. Patients were excluded if they self-reported failed compliance with glaucoma treatment or if they failed to perform the nighttime IOP measurements.

All patients were assessed by a nurse practitioner, for suitability of 24-hour IOP phasing and self-monitoring of IOP with RTONE, before attending for phasing. These patients then attended a nurse-led IOP phasing clinic between the hours of 8.00 AM and 5.00 PM. The nurse practitioners in these clinics were trained in the use of both GAT and RTONE. During the daytime hours, IOP was measured using both GAT and RTONE, in both eyes every 2 hours with the patient in the sitting position. GAT measurements were performed by the trained ophthalmic nurse. RTONE measurements were obtained by the patient under the supervision of the trained ophthalmic nurse to ensure appropriate technique and accuracy of IOP measurement.

Between the hours of 6.00 PM and 6.00 AM patients self-monitored their IOP at home using the RTONE. IOP measurements were recorded every 2 hours. Patients were advised to wait approximately 5 minutes after waking to allow them to awake sufficiently to perform the measurements. They were also requested to use the RTONE while they were in a seated, upright position, as they had done for the daytime measurements.

There were no strict criteria used to change clinical management after 24-hour IOP phasing. Indeed any change in clinical management was determined after discussion with the individual patient. In general where there was a significant fluctuation in IOP or IOP spike, the aim of changing clinical management was to treat these spikes. Where there was no IOP spike identified, the aim was to further lower target IOP.

## Data and Statistical Analysis

Peak daytime (8.00 AM to 5.00 PM), nighttime (6.00 PM to 6.00 AM) IOP phasing measurements and IOP measurements taken in clinic before phasing were calculated and compared. Additional data collected included patient age, central corneal thickness, Humphrey visual field mean deviation, and number of medical glaucoma treatments at time of IOP phasing; prior neuroimaging and 24-hour blood pressure monitoring; and patients' comments on ease of use of RTONE and clinical outcome post IOP phasing. We define peak clinic IOP as the highest recorded IOP measurement (with GAT) taken before 24-hour IOP phasing during clinic hours (9.00 AM to 5.00 PM), when the patient was on the same glaucoma treatment as when they were listed for phasing.

Categorical variables were tested with Fisher's exact test. Continuous nonparametric variables were tested with the Mann-Whitney test, and parametric variables were tested with the Student *t* test. A *P*-value $< 0.05$ was used to indicate statistical significance. Data analysis was performed using GraphPad prism (version 5.00; California).

In addition, the daytime GAT and RTONE IOP measurements for those patients with complete recorded data (n = 10 patients) in the study, were further analyzed. Wilcoxon sign-rank test and Bland-Altman plots were used to evaluate intermethod (GAT and RTONE) agreement; for Bland-Altman analysis, a range of agreement was defined as mean bias of ± 2 SDs. For these assessments of agreement measurements taken at 4.00 PM were used.

# RESULTS

In total 19 patients, with NTG, were referred for 24-hour IOP phasing between June 2013 and July 2014. One patient reported failure to comply with glaucoma treatment at the time of IOP phasing and was therefore excluded from the study, thus 18 patients were included in this study (9 men, 9 women). The mean age of the patients was 59.9 ± 12.2 years (median, 64 y; range, 39 to 81 y). The mean central corneal thickness was OD 524 ± 58.7 μm (range, 405 to 617 μm), OS 526 ± 47.7 μm (range, 462 to 616 μm). At the time of listing for 24-hour IOP phasing the median Humphrey visual field mean deviation was OD −11.19 (interquartile range, −18.28 to −5.92), OS −10.23 (interquartile range, −14.26 to −2.87). Topical antiglaucoma medications were being used in 35 eyes (18 patients); 3 eyes (2 patients) had previous augmented trabeculectomy. Neuroimaging had been performed in 14 patients, in all cases there was no other identifiable cause for a progressive optic neuropathy. Twenty-four hour blood pressure monitoring was performed in 11 of 18 patients; a single patient was identified as a nocturnal dipper.

## IOP Measurements

Mean peak IOP for the different time periods are summarized in Table 1. The mean peak IOP was higher during daytime phasing compared with prior clinic visits, with a mean of 12.8 ± 2.7 versus 11.8 ± 1.6 mm Hg ($P = 0.0439$). The mean peak IOP was significantly higher during nighttime phasing compared with daytime phasing and clinic, with a mean of 15.78 ± 4.8 versus 12.83 ± 2.7 mm Hg ($P = 0.0018$) versus 11.8 ± 1.6 mm Hg ($P < 0.0001$) (analysis of variance for 3 groups, $P < 0.0001$). The peak IOP was recorded outside of office hours in at least 1 eye in 9 patients (50%).

The magnitude of the IOP peak found during phasing times compared with clinic IOP are shown in Table 2. A significant peak of ≥ 4 mm Hg compared with clinic IOP was found in 5 eyes and 14 eyes during daytime and

**TABLE 1.** Comparison of Peak IOP Measurements Taken During Prior Clinic Visits, Daytime Phasing and Nighttime Phasing

| | Clinic | Daytime Phasing | Nighttime Phasing |
|---|---|---|---|
| Mean peak IOP (mm Hg) | 11.78 | 12.83 | 15.78 |
| Median | 12.00 | 12.00 | 16.00 |
| SD | 1.57 | 2.65 | 4.72 |
| 95% CI | 11.25-12.31 | 11.93-13.73 | 14.17-17.39 |

CI indicates confidence interval; IOP, intraocular pressure.



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**TABLE 2.** Comparison of Magnitude of Intraocular Pressure Peaks Between Clinic Measurements and Phasing Measurements

| Magnitude of IOP Peak (mm Hg) | Between Daytime and Clinic (No. Eyes) | Between Nighttime and Clinic (No. Eyes) |
|---|---|---|
| < 4 | 31 | 22 |
| ≥ 4 | 5 | 14 |

IOP indicates intraocular pressure.

nighttime phasing, respectively; this was statistically significant ($P = 0.0309$, Fisher's exact test).

After the 24-hour IOP phasing, a change in management occurred in 10 patients (56%): 8 patients were listed for an augmented trabeculectomy, 1 patient was given additional antiglaucoma medication, 1 patient was referred to neuroophthalmology for a second opinion due to more rapid visual field loss without evidence of IOP fluctuation during 24-hour phasing. Of the 9 patients receiving additional glaucoma intervention, 6 had their IOP peak occur during nocturnal phasing only. The remaining 3 patients had IOP peaks identified during both daytime and nighttime phasing. This difference was statistically significant ($P = 0.0090$, Fisher's exact)

## Comparison Between IOP Measurement Methods

Using the Wilcoxon sign-ranked text and Spearman rank correlation there were good correlations between the IOP measurements obtained with GAT (obtained by a trained nurse practitioner) and RTONE (obtained by the patient under supervision) for right and left eyes (Spearman rank correlation $r$ values range from 0.61 to 0.86, all $P < 0.001$). The Bland-Altman plot comparing GAT and RTONE tonometry readings (Fig. 1) showed reasonable agreement between the 2 methods for both right and left eyes. The 95% limits of agreement between the 2 methods ranged from −2.3 to 2.9 mm Hg for the right eye and from −3.8 to 4.4 mm Hg for the left eye. The 2 methods seem to consistently provide similar measures because the level of disagreement is unlikely to include clinically important discrepancies (mean difference of 0.3 mm Hg for each eye, Fig. 1).

## DISCUSSION

The present study has 2 main purposes: to assess the value of 24-hour IOP phasing in patients with treated but progressive NTG, and to evaluate the role of self-monitoring of IOP with RTONE.

Firstly, our study identified an increase in the mean peak IOP during both daytime and nighttime phasing compared with prior clinic IOP measurements. Although these differences were statistically significant, the trend and significance was much greater when comparing nighttime IOP phasing to both daytime phasing and clinic IOP measurements. The mean peak IOP was significantly higher during nighttime phasing compared with daytime phasing and clinic, with a mean of 15.78 ± 4.8 versus 12.83 ± 2.7 mm Hg ($P = 0.0018$) versus 11.8 ± 1.6 mm Hg ($P < 0.0001$).

Moreover, 50% of patients had their peak IOP measurement recorded in at least 1 eye outside of office hours (during nighttime phasing), hence it is less likely that this peak reading would have been picked up with daytime phasing alone. Other studies have shown similar results. Barkhana et al[18] found that 47% of eyes undergoing 24-hour IOP phasing had their peak IOP measurement obtained outside of office hours, 14% of these occurred at 6 AM.

When considering the magnitude of the IOP peak, previous studies have shown limited benefit in performing 24-hour phasing compared with daytime phasing alone. Specifically, Moodie et al[19] showed that only 5% patients with an IOP peak of > 3 mm Hg compared with office hours IOP measurements, would have been missed had only daytime phasing been performed. Contrary to this our study shows that a total of 14 of 36 eyes had a peak IOP that was > 3 mm Hg than the peak IOP known from previous clinic visits; in 9 of these eyes the peak would have been missed if only daytime phasing had been performed ($P = 0.0309$). As the study population in Moodie et al[19]

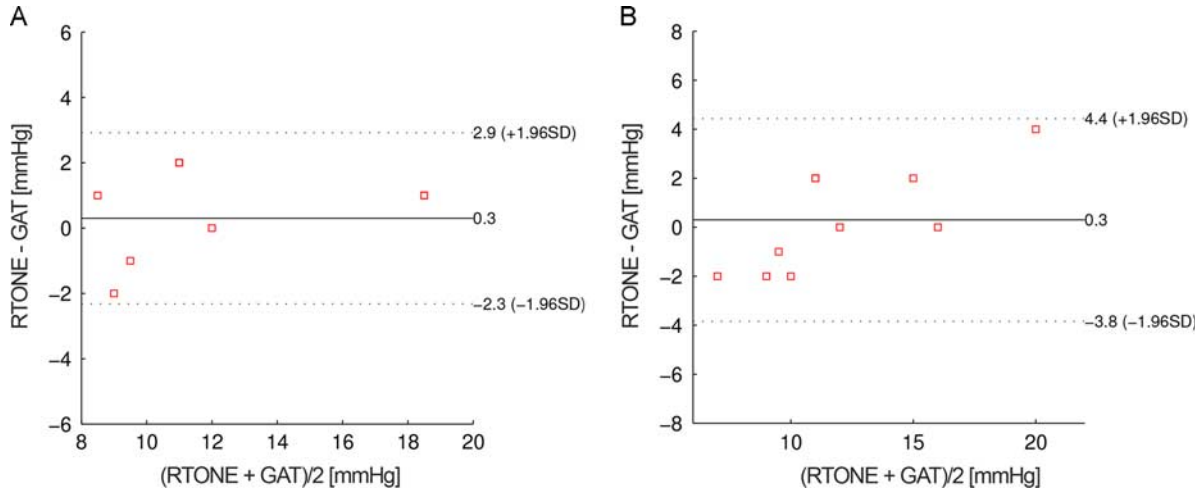


**FIGURE 1.** Bland-Altman plots for right (A) and left (B) eyes for 10 patients tested at 4.00 PM Goldmann applanation tonometer (GAT) corresponds to intraocular pressure (IOP) obtained by a trained nurse practitioner using GAT. Icare ONE rebound tonometry (RTONE) corresponds to IOP obtained by the patient using an Icare rebound tonometer. Solid line bias was 0.3 mm Hg for each eye line. The dotted lines represent 95% limits of agreement.

consisted of a much broader variety of glaucoma etiologies compared with our study, it can be speculated that the difference in our results is a mere reflection of the different study populations.

Similar to other studies[18,19] we had 50% patients (n = 9) in whom a change in their glaucoma management was initiated following 24-hour phasing. Moodie et al[19] found that 56% patients had their management changed as a result of 24-hour phasing compared with 49% patients undergoing daytime phasing. Interestingly they identified that only 15% of these patients had their peak IOP occur during the nighttime. In contrast, we found that the majority of patients (6/9, 67%) in whom glaucoma management was changed following 24-hour phasing had their peak IOP occur during the nighttime phasing period.

Conflicting results have been obtained regarding the 24-hour pattern of IOP in patients with NTG.[10,20,21] These differences may be attributable in part to different IOP measurement techniques, study populations, or body positions. Lee et al[12] assessed the IOP patterns of 177 patients with newly diagnosed untreated NTG and identified 3 major IOP rhythms (diurnal acrophase, nocturnal acrophase, and no acrophase) and a highest mean IOP at night when patients were supine.

Previously 24-hour IOP phasing necessitated inpatient hospital admission, thus placing demands on already limited resources. Self-tonometry or other devices that can be safely used in the outpatient setting are potential solutions. Despite promising initial results, contact lens–embedded sensor for IOP measurements is not currently available in routine clinical practice.[22] RTONE, therefore, offers a plausible alternative and has been shown to be reliable in the hands of patients.[17,23–25] The proposed benefits of RTONE include high patient acceptance, ability to self-monitor IOP and take numerous readings throughout the day and night, no need for eye drops, and outpatient use. Disadvantages include potential trauma to the cornea and imprecise IOP measurements due to a failure to take readings from the center of the cornea and a learning curve to use the device. Halkiadakis et al[23] identified that patients were able to use RTONE accurately after 3 attempts. To eliminate bias from the learning curve with the RTONE, we used the IOP measurements taken at 4.00 PM (fifth measurement taken) for the Bland-Altman plots.

Although good agreement in IOP values between rebound tonomtery, including RTONE, and GAT have been reported,[17,23–25] rebound tonometry may be less accurate in the higher IOP range (> 23 mm Hg)[26] and with increasing CCT.[24] Our results indicate that IOP measurements obtained with RTONE and GAT correlated extremely well (Spearman rank correlation $r$ values range from 0.61 to 0.86, all $P < 0.001$). Bland-Altman analysis showed a mean tendency to overestimate IOP in comparison with GAT reading by 0.3 mm Hg. This excellent correlation may be a reflection of our population of NTG where the IOPs are less likely to be overestimated.

Self-monitoring devices are not new to medicine. Self-monitoring of blood sugars in diabetic patients, for example, has long been accepted and well tolerated by patients. When evaluating a new device that is likely to be used by the patient it is important to assess the patient's perception and ease of use of the specific device. In this study, a few patients independently provided feedback on the use of RTONE; however, this was not formally evaluated with the use of a patient questionnaire. Hence, evaluating the ease of use of RTONE is outside of the scope of this study. To improve future compliance with the use of RTONE and indeed product development, we suggest that studies assessing patient experiences with this device should be considered.

The limitations of our study include all those inherent to a retrospective study with a small sample size and future studies with larger populations are expected to provide important insights. In addition, complete data for comparison of daytime IOP measurements between GAT and RTONE was only available for 10 patients, which may introduce bias to this analysis. A further limitation of this study, which is inherent of any self-monitoring device, is that the data retrieved are dependent on the patients truthfully checking and recording their IOP at 2-hourly intervals. The effect of this was potentially minimized in part by our patients' initial agreement to partake in 24-hour IOP phasing and also their assessment of suitability for phasing. Finally, our findings cannot be generalized for all types of open-angle glaucoma. However, this may also be seen as an advantage. Our study population is homogenous: patients with treated NTG with evidence of progressive visual field loss in the face of controlled IOP during office hours. Hence, our study is determining the role of 24-hour IOP phasing in this select population group.

Measuring IOP during sleep may be influenced by the effect of awakening,[27] and this would therefore introduce a potential bias in the IOP measurements recorded. The ideal device is therefore one that is able to measure IOP in a patient's natural sleeping state, without waking. The contact lens–embedded sensor for IOP measurements,[22] is therefore a potential alternative. However, this device is not routinely available in clinic practice, nor does it measure IOP, it actually records changes in corneal curvature which are then correlated to reference IOP measurements taken. Hence, the RTONE remains a plausible device for the purposes of self-monitoring IOP, until a better alternative is available.

In summary, this study suggests that in patients with NTG with glaucoma progression that is disproportionate to their clinic IOP measurement, 24-hour phasing can reveal higher IOP spikes than those identified during office hours. Therefore, 24-hour IOP phasing is a useful intervention to consider in these cases where evidence of glaucoma progression occurs despite apparent controlled IOP measured during office hours. To facilitate 24-hour IOP phasing with minimum impact on already limited hospital resources we need a device that is portable, easy to use for self-monitoring, and correlates well with GAT IOP measurements. For this purpose we propose RTONE as the best currently available method for self-monitoring of IOP.

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