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COMPARISON OF THREE METHODS OF TONOMETRY IN PATIENTS WITH INACTIVE THYROID-ASSOCIATED ORBITOPATHY

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SUMMARY

Introduction: Intraocular pressure (IOP) measurement in patients with thyroid-associated orbitopathy (TAO) can be difficult and misleading, particularly in patients with diplopia and eye deviation (esotropia or hypotropia). However, when measuring IOP, it is also necessary to pay sufficient attention to TAO patients without diplopia in primary gaze direction and without motility disorder that might not be readily apparent.
Purpose: The aim of this study was to evaluate the accuracy of measurement of intraocular pressure (IOP) using three different types of tonometers: the rebound tonometer (iCARE), the Goldmann applanation tonometer (GAT) and the non-contact airpuff tonometer (NCT) in patients with inactive TAO.
Materials and Methods: A total of 98 eyes of 49 adult patients with TAO were examined. The study group included 36 females and 13 males, with an age range of 19–70 years and a median age of 55.0. All the patients had evidence of thyroid disease, a history of mild to moderate TAO, no clinical signs or symptoms of active disease, and no diplopia in direct gaze direction. In addition to a comprehensive eye examination, all the patients underwent measurement of intraocular pressure with three tonometers: NCT, iCARE, and GAT. The measurements with these three devices were compared.
Results: The mean IOP was 18.1 ± 2.4 mmHg (range 13–25 mmHg) with GAT, 22.3 ±5.0 mmHg (range 13–35 mmHg) with NCT, and 18.0 ±2.4 mmHg (range 13.3–26 mmHg) with iCARE. The mean difference between the GAT and iCARE measurements (using the Bland-Altman analysis) was -0.1 ±1.16 mmHg (limits of agreement -2.4 to 2.1). The mean difference between the GAT and NCT measurements was 4.2 ±3.6 mmHg (limits of agreement -2.8 to 11.2). The mean difference between the iCARE and NCT measurements was -4.3 ±3.7 mmHg (limits of agreement -11.6 to 2.9). No significant difference was found between GAT and iCARE ($p = 1.000$). However, there was a significant difference between GAT and NCT ($p < 0.0001$), as well as between iCARE and NCT ($p < 0.0001$).
Conclusions: In patients with TAO, NCT significantly overestimates IOP values compared to the GAT and ICare. By contrast, the iCARE rebound tonometer provides IOP measurements comparable to the gold standard GAT in these patients.
Keywords: intraocular pressure, thyroid-associated orbitopathy, Goldmann applanation tonometry, non-contact tonometry, iCARE rebound tonometer

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INTRODUCTION

Thyroid-associated orbitopathy (TAO) is a serious, chronic eye disease associated with autoimmune thyroid gland disorder, most commonly with Graves-Basedow disease. The course of the disease typically has three phases. The first active progressive phase, accompanied by varying degrees of inflammatory symptoms, is followed by a plateau phase in which the condition gradually stabilizes. In the third, final phase, gradual fibrosis of tissues occurs when the disease activity ceases entirely, and cosmetic and functional changes are now permanent.

Increased intraocular pressure (IOP) in patients with TAO was first described more than 100 years ago. Whereas previously published studies did not primarily focus on disease phase and severity (which may have been the reason for the ambiguous to contradictory results), studies published in the last decade have begun to take these factors into account. The prevalence of intraocular hypertension (IH) is undoubtedly higher in patients with TAO than in the general population [1,2] and is also associated with a more severe involvement of the orbital structures, particularly the extraocular muscles [3]. In cases of long-term active TAO, IH is considered a risk factor for the onset of open-angle glaucoma [4]. However, a higher prevalence of open-angle glaucoma has not been unequivocally confirmed in patients with TAO.

In TAO, it is necessary to devote special attention to the technique of measuring IOP, particularly when the extraocular muscles are affected, and the eyeball is deviated in either hypotropia or esotropia. However, based on our practical experience, the type of tonometer used is also essential. Kuebler et al. [5] found that whereas non-contact tonometers (Corvis ST and Ocular Response Analyser; ORA) significantly overestimated IOP in comparison with Goldmann applanation tonometry (GAT), the values obtained using the iCARE rebound tonometer were comparable with those obtained with GAT. However, the study included patients with varying severity of the disease (and therefore varying degrees of involvement of the extraocular muscles) in both the active and inactive phases of TAO.

Our study aimed to compare the concordance of IOP measurement in patients with TAO in the inactive phase using three different types of tonometers: iCARE rebound tonometer, Goldmann applanation tonometer (GAT), and non-contact tonometer (NCT). We only included patients without diplopia in direct forward gaze position, i.e., in other words, those suitable for district eye clinic referral and, therefore, not requiring follow-up in a tertiary center. These were often patients in whom chronic effects of TAO may not be readily apparent.

MATERIAL AND METHOD

Study design and cohort characteristics

A total of 98 eyes of 49 adult patients (36 women, 13 men) aged 19 to 70 years (median 55.0 years) who attended the consulting center for TAO at the Department of Ophthalmology at the Faculty of Medicine and Dentistry of Palacký University and the University Hospital in Olomouc, were included in the study. All the patients had received the diagnosis and treatment of thyroid disease and had a history of mild to moderate TAO (Table 1) which had previously required immunosuppressant therapy (oral prednisone, or IV methylprednisolone). However, the patients had not been receiving systemic therapy for at least one year. TAO was inactive with a Clinical Activity Score (CAS) of 0 (Table 2). We performed a comprehensive eye examination in all the patients (determination of visual acuity, examination of the anterior and posterior eye segments and of the periocular region). We devoted special attention to eyeball motility and the presence of diplopia. All patients in whom diplopia (permanent or intermittent) persisted in direct forward gaze position were excluded, as were patients who already wore prismatic correction. Residual diplopia in maximal gaze directions, which was unnoticed by patients in everyday life, was not among the exclusion criteria. Additional exclusion criteria

Table 1. Classification of severity of thyroid-associated orbitopathy (TAO) according to the European Group on Graves' Orbitopathy (EUGOGO). In our study, only patients with mild to moderate TAO were enrolled

Mild TAO	Patients whose features of GO have only a minor impact on daily life that have insufficient impact to justify immunomodulation or surgical treatment. They usually have one or more of the following: • minor lid retraction (< 2 mm) • mild soft-tissue involvement • exophthalmos < 3 mm above normal for race and gender • no or intermittent diplopia and corneal exposure responsive to lubricants
Moderate-to-severe TAO	Patients without sight-threatening GO whose eye disease has sufficient impact on daily life to justify the risks of immunosuppression (if active) or surgical intervention (if inactive). They usually have two or more of the following: • lid retraction ≥ 2 mm • moderate or severe soft-tissue involvement • exophthalmos ≥ 3 mm above normal for race and gender • inconstant or constant diplopia
Sight-threatening (very severe) TAO	Patients with dysthyroid optic neuropathy and/or corneal breakdown

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Table 2. Assessement of activity by the Clinical Activity Score (CAS) in patients with thyroid-associated orbitopathy (TAO) according to the European Group on Graves' Orbitopathy (EUGOGO). In our study, only inactive patients with CAS = 0 were enrolled

Spontaneous retrobulbar pain
Pain on attempted upward or downward gaze
Redness of eyelids
Redness of conjunctiva
Swelling of conjunctiva (chemosis)
Swelling of eyelids
Swelling of caruncle or plica

were previous eye surgery (anti-glaucomatous, vitreoretinal, refractive), strabismus surgery, condition following decompression of the orbit, any corneal pathology, and astigmatism of more than 2.5 diopters. IOP was measured in all the patients with the aid of three different types of tonometers: Goldmann applanation tonometer (GAT; Köniz, Switzerland); iCARE rebound tonometer (iCARE; Tiolat, Helsinki, Finland); and non-contact tonometer (NCT; Reichert AT 555). All the measurements were performed during the morning hours. We always performed a measurement using NCT first, followed by a measurement with the aid of iCARE and GAT. A pause of at least five minutes was allowed between each measurement, and the measurements were performed by a single examiner (MK).

The Ethics Committee of the University Hospital and the Faculty of Medicine and Dentistry at Palacký University Olomouc approved the study protocol. The study was conducted in accordance with Good Clinical Practice and the Helsinki Declaration.

Statistical analysis

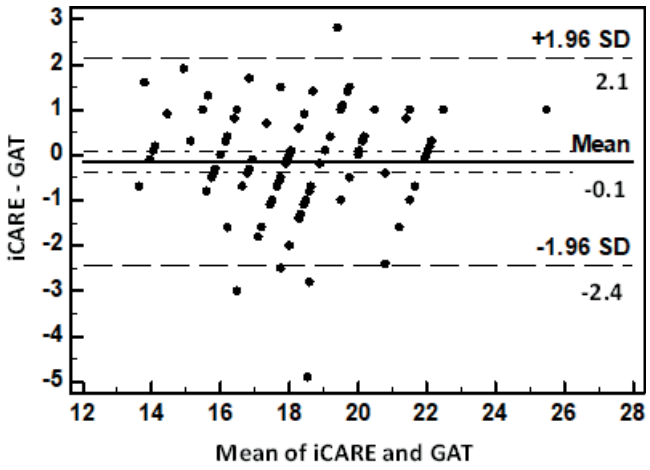
The software SPSS version 15 (SPSS Inc., Chicago, USA) and the software MedCalc version 20.105 (MeCalc Software Ltd, Belgium) were used for the statistical analysis of the data. The results were evaluated by the Wilcoxon paired test and Bonferroni correction. The dependency between the values measured by GAT, NCT, and iCARE was assessed with the Spearman correlation coefficient and further analyzed with the Bland-Altman analysis. The normality of the data was verified using the Shapiro-Wilk test. The tests were conducted at a level of significance of 0.05.

RESULTS

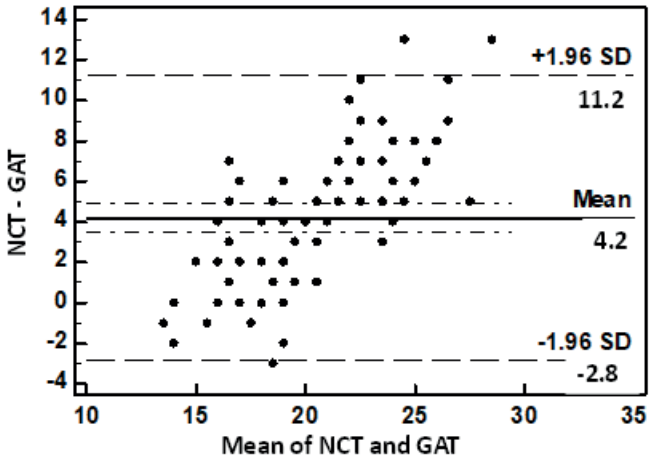
The mean IOP measured using GAT was 18.1 ±2.4 mmHg (13–25 mmHg), using NCT 22.3 ±5.0 mmHg (13–35 mmHg), and using iCARE 18.0 ±2.4 mmHg (13.3–26 mmHg). The values of IOP measured with the aid of NCT were significantly higher ($p < 0.0001$) than those obtained with GAT and iCARE.

Using the Bland-Altman analysis, we found that the mean difference between GAT and iCARE is −0.1 ±1.16 mmHg (limits of agreement −2.4 to 2.1), and there is no statistically significant difference between the methods. It is evident from Graph 1 that there is no systematic difference between the methods (the differences are distributed symmetrically around zero), and there is no perceptible trend in the differences.

The mean difference between GAT and NCT was 4.2 ±3.6 mmHg (limits of agreement −2.8 to 11.2), and between iCARE and NCT, the mean difference was −4.3 ±3.7 mmHg (limits of agreement −11.6 to 2.9). In both cases, the 95% confidence interval of the mean differences does not cover zero, and there is a statistically significant difference between the methods. It is evident from the Bland-Altman analysis in Graphs 2 and 3 that a systematic difference exists between the methods (the differences are not distributed symmetrically around zero). In Graph 2, most of the differences are positive, meaning that higher values were measured with NCT than with GAT. A trend is manifested



Graph 1. Blant-Altman graph of the dependence of pressure difference measured using Goldman applanation tonometry (GAT) and iCARE tonometer. The horizontal solid line represents the average value of the difference, dashed lines represent the 95% Confidence interval

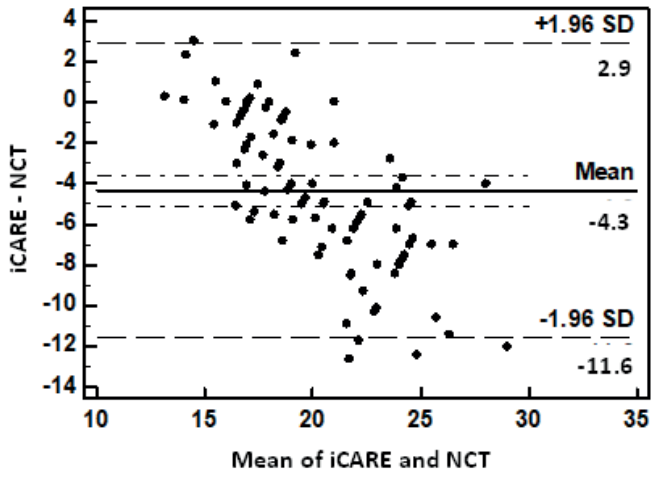


Graph 2. Blant-Altman graph of the dependence of pressure difference measured using non-contact tonometry (NCT) and Goldman applanation tonometry (GAT). The horizontal solid line represents the average value of the difference, dashed lines represent the 95% Confidence interval

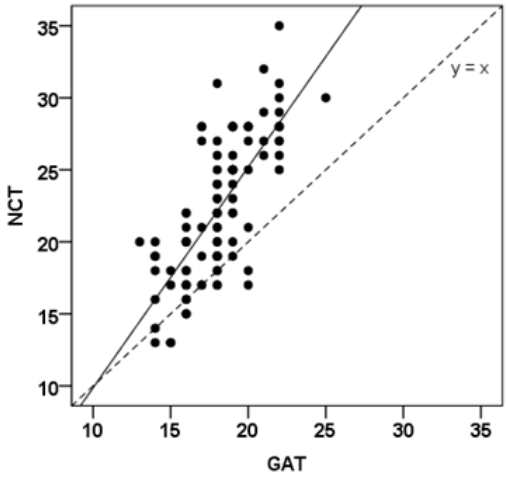
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in the differences; thus, the differences depend upon the mean (the greater the mean, the greater the difference). In Graph 3, a significant trend is also obvious. Almost all the values measured with the iCARE method were lower than those measured using the NCT method.

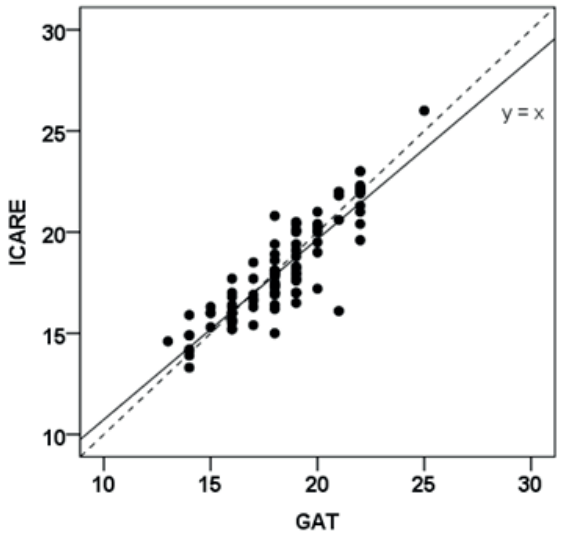
We, therefore, did not determine any statistically signi-



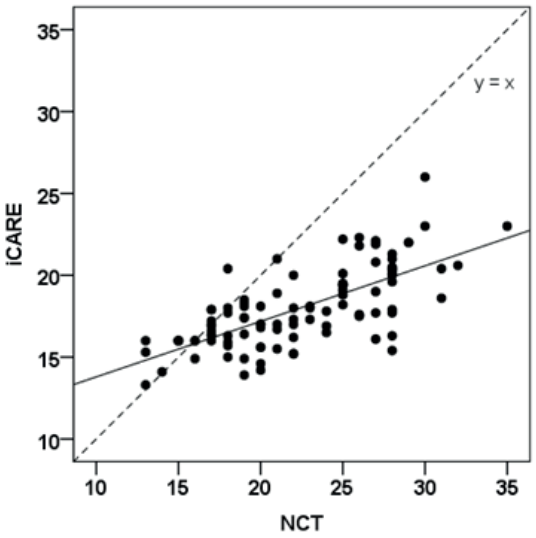
Graph 3. Blant-Altman graph of the dependence of pressure difference measured using iCARE rebound tonometer and non-contact tonometry (NCT). The horizontal solid line represents the average value of the difference, dashed lines represent the 95% Confidence interval



Graph 5. Dot correlation graph between values measured using the Goldman applanation tonometer (GAT) and the non-contact tonometer (NCT)



Graph 4. Dot correlation graph between values measured using iCARE rebound tonometer and Goldman applanation tonometer (GAT)



Graph 6. Dot correlation graph between values measured with iCARE rebound tonometer and using non-contact tonometer (NCT)

Table 3. Spearman correlation coefficient – correlation of measured intraocular pressure for individual methods, the strongest correlation is Goldman applanation tonometry (GAT) with the iCARE

	R	R^2	ICC
GAT & NCT	0.734	0.538	0.575
GAT & iCARE	0.867	0.751	0.883
NCT & iCARE	0.675	0.456	0.549

GAT – Goldmann applanation tonometry, NCT– non-contact tonometry, iCARE – iCARE rebound tonometry, R – Spearman correlation coefficient, ICC – Intraclass correlation coefficient

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ficant difference (p = 1.000) between the GAT and iCARE methods. By contrast, we determined a statistically significant difference between GAT and NCT (p < 0.0001) and between iCARE and NCT (p < 0.0001).

A Spearman correlation analysis confirmed that GAT correlates most strongly with iCARE (Table 3). It is evident in the point correlation graph (Graph 4) that the difference between the GAT and NCT methods increases along with the increase in IOP values. The correlation between the GAT and iCARE methods and iCARE and NCT is illustrated in Graphs 5 and 6.

DISCUSSION

Glaucoma in the setting of TAO is classified among secondary open-angle glaucoma caused by an extrabulbar pathology. The pathogenetic mechanisms, which in some patients with TAO may lead to an increase in IOP, are complex and typically involve a combination of several factors. They always depend mainly on disease duration and phase (active, inactive), as well as the type of predilection for the involvement of the orbital tissue (extraocular muscles, fat tissue), as to which of the factors will contribute most to the increase in IOP in a particular patient. One of the main causal factors is an increase in episcleral venous pressure and constriction of venous outflow from the orbit, which occurs as a consequence of inflammatory infiltration of the retrobulbar orbital tissues and an expansion of the fat and conjunctival tissue (and the extraocular muscles). Among other factors, during the course of TAO, excessive production of glycosaminoglycans also occurs, possibly even in the trabecular meshwork, which may lead to an increase in outflow resistance. The last important known mechanism that may increase IOP is the degree of involvement of the extraocular muscles [6]. In the acute phase of the disease, inflammatory infiltration and edema of the muscles occur.

Consequently, the relaxation capacity of the muscle is impaired, and an insufficiency of a corresponding antagonist causes diplopia. In this phase, we usually find only clinically discrete motility disorders in maximal gaze directions (most often disorders of elevation in abduction). If the disease progresses to the next phase, gradual fibrosis of the muscles occurs, and diplopia may become permanent even in the primary position. The extraocular muscles may progressively transform into rigid fibrous strips without active or passive motility. Because the medial and inferior rectus muscles are the most commonly affected [7], the eyeball is generally deviated downwards or in esotropia in the final phase of the disease.

It is precisely due to the above-described changes (restrictive myopathy) that increased IOP (mostly up to 15 mmHg) in upward gaze is a relatively common finding in patients with TAO. A linear dependency has been demonstrated between the degree of eye deviation (hypotropia) and increased IOP in upward gaze [8,9,10]. This phenomenon occurs as a result of the so-called "pincer mechanism". In an effort to fix upward gaze (in the case of hypotropia of the eye, an effort to fix direct forward gaze), the tension of the superior rectus muscle increases, but the affected inferior rectus muscle does not relax. This results in compression of the eyeball and, subsequently, an increase in episcleral venous pressure and IOP. This theory is in accordance with published studies which have confirmed that a significant reduction in IOP occurs following surgery for restrictive strabismus or following intramuscular administration of botulinum toxin A [11,12].

As a result, measurement of IOP in patients with TAO with eye deviation due to restrictive myopathy (especially hypotropia of the eye) is challenging. Measurement with GAT is considered to be the gold standard. However, it is necessary to be aware that the precision and reliability of measurement are influenced not only by corneal thickness, but also by corneal curvature and other biomechanical properties. We measure with GAT as standard in the center of the cornea at the slit lamp. If there is significnat hypotropia or esotropia of the eye, we have to perform the measurement in the periphery of the cornea, and in extreme cases even partially on the sclera. However, in the periphery, the cornea has different biomechanical properties: it is thicker than in the center and has a flatter curvature, to name only a few. In particular, corneal thickness may, therefore, lead to a potential overestimation of IOP. On the other hand, it has been demonstrated that corneal hysteresis is lower in patients with TAO than in the healthy population [13,14]. However, despite all these circumstances, measurement of IOP with the aid of GAT in the case of TAO remains the best possible option. Based on our experience with patients with TAO, we do not recommend NCT because it often falsely produces very high values, particularly in patients with an involvement of the inferior rectus muscle (if the eye is in the primary position in hypotropia). The patient attempts to fix the affected eye into the device, and the above-described pincer mechanism results in an increase in IOP.

Kuabler et al. [5] compared the results of IOP measurement in 29 patients with TAO using four different tonometers (GAT, iCARE, ORA, Corvis) demonstrating concordance only between GAT and iCARE. In comparison with GAT, ORA and Corvis overestimated IOP. Nevertheless, this study included patients with mild, moderate, and severe forms of TAO in the active and inactive phases. Therefore, the study did not consider whether (and to what extent) motility was impaired. Pérez-López et al. [14] focused on the biomechanical properties of the cornea in 30 patients in the inactive phase of TAO, among other factors, also comparing the values of IOP measured using GAT and ORA, and arrived at the same results. The values of IOP obtained with ORA were significantly higher than those obtained with GAT.

Falsely high values of IOP may be measured using non-contact types of tonometers in eyes with restrictive myopathy (primarily in hypotropia) due to the pincer mechanism, which is well known, and we can confirm this from our own experience. However, our study aimed to determine the concordance between the measured values of IOP with the aid of three types of tonometers in patients without significant motility disorders after suffering from TAO, which required systemic therapy. We only included patients without an apparent eye deviation (i.e., without diplopia in direct forward gaze) in the study, and we excluded all patients

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with prismatic correction. Our results confirmed that, in this group of patients, the IOP values measured using NCT were significantly higher than in the case of GAT or iCARE. This can be explained particularly by the fact that when using a sufficiently sensitive examination method, a certain degree of involvement of the extraocular muscles can be identified in most patients with TAO. In patients who require systemic therapy in the active phase (i.e., moderate and severe forms of TAO; mild form in case it significantly affects the quality of life), the involvement of at least one muscle is virtually inevitable. In the case of sufficiently intensive systemic therapy, we can prevent permanent consequences in terms of diplopia in direct forward gaze; however, we cannot prevent a certain degree of reparative changes in the muscle tissue. The result may be only subjectively non-troublesome diplopia in a certain maximal gaze direction, or mild phoria, which patients with good binocular functions can compensate for without difficulties. Upon measurement of IOP with the aid of NCT, the head position (according to the placement of the forehead) is often inclined slightly forward. Upon fixation on the central point during measurement, an elevation in IOP may occur due to the above-described muscle changes (particularly if the inferior rectus muscle is affected). This hypothesis is supported also by the fact that the increase in IOP in upward gaze is typically more pronounced in patients with TAO than in healthy individuals [9].

By contrast, the measurement results using an iCARE tonometer in our cohort corresponded with the values measured using GAT. The iCARE tonometer is based on the method of "rebound tonometry". This well-tolerated method does not require corneal anesthesia and can be used in immobile patients and in children. In our study, we used the tonometer iCARE PRO (other types are the older TA01, the newer HOME, and the ic100V) [16]. It is the iCARE PRO that is used most frequently in published studies and that demonstrates good concordance with GAT in healthy individuals and in patients with glaucomatous disease [17,18,19]. Experience with the iCARE tonometer in patients with TAO has been published sporadically, nonetheless with good results, as discussed above [5,14].

Our study had relatively strict inclusion criteria; to the best of our knowledge, it is the first with this design. However, its limitations include the fact that measurements were performed by a single examiner who therefore did not perform the applanation measurement blind (this one was the last to be performed). It would therefore be appropriate to verify the results in the future in a further study on which we are currently working.

CONCLUSION

Based on our results and our experience from practice, we recommend measurement of IOP with the aid of GAT or with an iCARE tonometer in all patients with a history of TAO since NCT may overestimate IOP values. We recommend these methods for patients with TAO with no signs of restrictive strabismus and eye deviation apparent in the primary gaze direction. For this reason, it is always necessary to inquire patients about a possible history of TAO in outpatient practice.

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