Clinical Evaluation of Novel Intraocular Pressure Measurement Algorithm Using Back Propagation Neural Network Method for Corvis ST Tonometry

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Purpose: To compare an intraocular pressure estimated Using the Back Propagation Neural Network Method (BPNN-IOP) provided by the dynamic Scheimpflug analyzer (Corvis ST) with biomechanically corrected intraocular pressure (bIOP) algorithm provided by the Corvis ST, IOP obtained from the Goldmann applanation tonometry (GAT-IOP) and the CorVis ST (CVS-IOP) before and after laser refractive surgeries in situ keratomileusis (LASIK) and small-incision lenticule extraction (SMILE).
Methods: 36 Patients scheduled for LASIK and SMILE for myopia or myopic astigmatism were included. Datasets included pre-and post-operative evaluation by Scheimpflug tomography (corneal geometry measurement), IOP obtained from Goldmann applanation tonometry and dynamic Scheimpflug analyzer, and IOP estimated using bIOP algorithm and Back Propagation Neural Network(BPNN) Method.
Results: 14 patients in the LASIK group and 22 patients in the SMILE group were included in the comparative research. All patients were no significant difference in the pre-operative conditions ($p>0.05$). GAT-IOP and CVS-IOP, both values in the pretreatment, showed a significant positive correlation with the central corneal thickness (CCT) (both $P=0.05$ in LASIK and SMILE groups), but no significant correlation between bIOP and CCT, and BPNN-IOP and CCT ($P>0.05$). The IOP values in the pre-operative conditions found significant decreases in GAT (-3.2±3.4 mmHg in the LASIK group and -3.2±2.1 mmHg in the SMILE group; both $p<0.001$) and Corvis ST (-3.2±3.4 mmHg in the LASIK group and -3.2±2.1 mmHg in the SMILE group; both $p<0.001$) compared with pre-operative values, while the CCT reduced -76.4±19.9 µm in the LASIK group and -76.6±19.6 µm in the SMILE group. In contrast with the IOP without biomechanical correction, the difference of bIOP value (-0.1±2.1 mmHg in the LASIK group and -0.8±1.8 mmHg in the SMILE group) and BPNN-IOP value (-0.5±1.1 mmHg in the LASIK group and -0.2±1.2 mmHg in the SMILE group) between pre-and post-treatment did not differ significantly ($p>0.05$).
Conclusions: The IOP estimated readings through the bIOP algorithm and BPNN method before and after LASIK and SMILE had neither significant differences nor correlated with the change of corneal thickness and material properties. By contrast, both IOP reading obtained from the Goldmann applanation tonometry and the Scheimpflug analyzer found a significant effect of thickness and material stiffness pre-and post-operatively.

Key Words: *Intraocular Pressure, Biomechanically Corrected, Biomechanics, Back Propagation Neural Network Method.*

1. INTRODUCTION

Intraocular pressure (IOP) represents a fundamental ocular health and disease summary[1], but the IOP value varies for each person. Usually, the range of IOP value for a healthy eye is between 10 and 20 millimeters of mercury (mmHg), maintaining the ocular geometry to provide a function of refractive optical effect[2]. Once the IOP level is out of the normal range, the risk of vision loss becomes consistently higher[3]. In short, IOP measurement is essential to evaluate ocular health.

Accurate determination of IOP through tonometry is essential for effective eye health management. The clinical reference of the standard tonometer uses to measure IOP by using a contact tonometer, Goldmann applanation tonometer (GAT), which uses the relation between the external force from the contact probe and corneal deformation to assume the pressure inside the eye. This measurement process leads the IOP measurements by GAT (GAT-IOP) to be significantly affected by central corneal thickness (CCT) and corneal material properties, as usually happened under thick CCT[4]. Therefore, high accurate estimation of IOP measurement is related to high accurate estimation of corneal material behavior.

Historically, corneal stiffness measurements were based on ex-vivo tensile testing. The tensile testing of corneal tissue has been accomplished by cutting strips of corneal tissue from a donor's eye and applying a tensile load while measuring the corresponding stretch of the tissue[5-8]. Nevertheless, ex-vivo tensile testing is challenging to apply in clinical practice.

The evaluation of corneal material behavior is much more complex due to its viscoelastic behavior, in which the tangent modulus of the stress-strain relationship is a function of the strain/stress rate, not a constant [3, 9]. While the corneal tangent modulus is the same, three possible situations produce the same IOP value from tonometry [10, 11] as low true IOP (IOPt) with the stiffer corneal tissue, high IOPt with the soft corneal tissue, and intermediate IOPt with the intermediate corneal tissue. In addition, the true IOP is also a factor in the complex assessment of corneal biomechanics since the corneal tangent modulus increases as IOPt increases. As a result, these two factors of IOP and corneal stiffness are difficult to separable[12]. Thus, the challenge faced during the estimation of IOP with unknown corneal material behavior lies in separating or reducing the effects between IOP and corneal material stiffness.

In clinical practice, the corneal thickness change is used to correct refractive errors in myopia or myopic astigmatism by using Laser refractive surgeries such as the Laser-assisted in situ keratomileusis (LASIK) and small-incision lenticule extraction (SMILE)[4, 10]. Several studies mentioned that the IOP measurements using GAT before and after LASIK surgery reduced -3.8±2.2 mmHg in Zadok et al.[13] and -5.4±3.0 mmHg in Siganos et al.[14]. The reduction of GAT-IOP value before and after LASIK surgery has been supposed to result from the corneal geometry changed (as surface topography change, CCT reduction) and corneal material changed associated with the procedure[15, 16]. Moreover, the clinical evaluation in over 8,000 subjects after a myopic refractive procedure mentioned that in addition to the CCT effect, other parameters may still influence IOP measurement error, and alternative tonometric technologies to measure IOP should be applied after a refractive procedure[17]. Overall, the corneal thickness and material properties were changed after refractive surgeries, but the true IOP not[17-20]. Owing to this characteristic of the IOPt, comparing pre-and post-operative IOP measurement helps evaluate the effectiveness of IOP estimation.

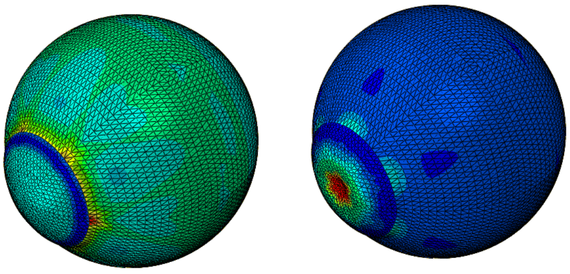
The non-contact tonometer is based on the same principle as the GAT, resulting in a similar effect of the eye geometry parameter and material properties on IOP measurement. Several studies also reported similar average reductions following LASIK in IOP measurements (-6.1±3.4 mmHg with non-contact tonometry, NT-3000, Nidek, in Siganos et al.[14], and -4.6±2.8 mmHg with the Ocular Response Analyzer, ORA, in Pepose et al.[21]).

Corvis ST (Oculus Optikgeräte GmbH, Wetzlar, Germany), a new non-contact tonometer that relies on high-precision, ultra-high-speed, Scheimpflug technology for providing biomechanical response parameters clinically[22], which have the potential to estimate high accurate IOP under the effect of variation in corneal parameter[23]. However, like most other tonometers, the IOP value by CorVis ST(CVS-IOP) was also significantly associated with corneal thickness[22]. In 2018, a biomechanical correction algorithm was developed to compensate for corneal geometry and material stiffness changes. The biomechanical corrected IOP value (bIOP) successfully reduced the effect of corneal thickness and stiffness, even under the change of these parameters during the femtosecond LASIK and ReLEx SMILE surgeries[19].

In this study, numerical analysis based on the finite element method (FEM) simulating the Corvis ST measurement process[19] was conducted to quantify the effects of biomechanical parameters on IOP measurement, and through the Back Propagation Neural Network (BPNN) Method developed a novel intraocular pressure measurement algorithm. The BPNN method allows complex nonlinear relationships between the response variable and its predictors, and it also can regress relationships between them. The characteristic of the neural network method shows that the approach ensures solvability in the estimation of IOP with strange corneal material behavior. In addition, this new IOP value by this algorithm (BPNN-IOP) was validated by using two independent clinical databases involving 20 femtosecond LASIK and 30 ReLEx SMILE patients and compared with GAT-IOP, CVS-IOP, and bIOP to evaluate the effect of biomechanical parameters.

2. METHOD AND PATIENTS

The numerical study relied on finite element models (FEM) that simulate the CorVis ST measurement process (**Fig.1**). The numerical study included 4500 models with variations in CCT (range from 445 to 645 μm, at steps of 0.05 mm), IOPt (ranging from 10 to 30 mmHg, at steps of 5 mmHg), and 300 different material stiffness. Moreover, the range of the ocular geometry parameters covered the typical clinical ranges exported in the literature [24-31], and the range of eye material behavior was setting with the stress-strain curve found by Elsheikh[32]. All biomechanical response parameters were calculated using MATLAB, followed by the same process on the Corvis ST. However, the FE-models used in the remainder of this project employed 65,712 six-noded solid elements (C3D6H), and it has been validated in previous studies[19, 33-35].



(a) (b)

Fig.1 A finite element model of the eye under the measurement process of Corvis ST. (a) prestress at initial geometry before process and (b) Von mises stress distribution at the highest concavity.

The parametric study results showed that the CCT was the principal component affecting biomechanical response parameters (PBR). Once the PBR becomes an input variable through the regression analysis accomplished by the Back Propagation Neural Network (BPNN), the prediction of IOP should still have a corneal thickness effect. Thus, besides biomechanical response parameters, the CCT should consider being one of the input variables for the BPNN training model[19, 33-35].

The BPNN model consisted of four input neurons as CCT, three biomechanical response parameters, and a single output neuron as IOPt. A total of 3150 training datasets and 1350 testing datasets were used. The BPNN training model was shown in **Fig. 2** with two hidden neurons, and the testing results indicated no significant improvement in convergence while the number of hidden neurons increased beyond two. The scatter of the predicted IOP value compared with the IOPt values was assessed using regression analysis and mean squared error (mse) representing R=0.994 and R=0.998 of correlations for the training and testing datasets mse=0.1945 between predicted and actual value. Thus, the results showed that the BPNN model successfully estimated the actual IOP value using biomechanical response parameters.

To evaluate the IOP effectiveness from the BPNN model (BPNN-IOP), 20 femtosecond LASIK and 30 ReLEx SMILE databases, obtained from the Smile Eye Clinic, Munich, Germany[19] and used to evaluate BPNN-IOP before and after treatment. All patients signed written informed consent, and the studies were approved by their local institutional review boards and adhered to the tenets of the Declaration of Helsinki.

The details of pre-and post-operative were shown in **Table 1**. The databases between the LASIK and SMILE groups showed no significant differences in the pre-operative conditions (p>0.05). The relationship of GAT-IOP, CVS-IOP, bIOP and BPNN-IOP with CCT was assessed using Pearson correlation analysis, and analysis of the pre-operative and post-operative IOP values was performed using the paired t-test.

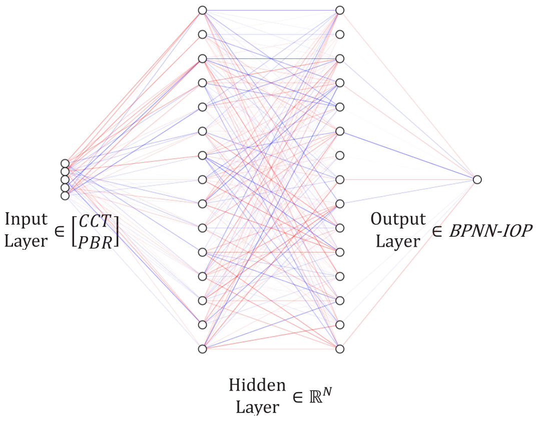


Fig.2 Back Propagation Neural Network architecture.

3. RESULTS

Table 1 showed the pre-and post-operative mean, standard deviation, and range of CCT; age; Spherical Equivalence (SE); and four different IOP measurements with Goldmann applanation tonometry, Corvis ST, biomechanical corrected method, and BPNN model for both the LASIK and SMILE groups, separately.

Table 1 The details of pre-and post-operative data for both LASIK and SMILE groups.

	LASIK Group (n = 20)		SMILE Group (n = 30)	
	Preoperative	Postoperative	Preoperative	Postoperative
CCT (µm)	559.7 ± 31 (505 – 616)	483.3 ± 33.6 (420 – 548)	542.6 ± 30 (499 – 606)	466 ± 33.9 (413 – 558)
Age (years)	36.7 ± 7.4 (27 – 48)	36.7 ± 7.4 (27 – 48)	35.6 ± 7.7 (25 – 51)	36.7 ± 7.4 (27 – 48)
Spherical Equivalence (D)	-3.65 ± 1.12 (-5.38 – -1.25)	-0.13 ± 0.33 (-1.0 – 0.5)	-3.81±0.95 (-5.63 – -2.00)	-0.04 ± 0.26 (-0.75 – 0.75)
GAT-IOP (mmHg)	16.1 ± 1.7 (13 – 20)	12.9 ± 2.5 (10 – 17)	15.6 ± 2.5 (11 – 22)	12.3 ± 2.3 (8 – 18)
CVS-IOP (mmHg)	15.2 ± 2.3 (11.5 – 20.5)	11.6 ± 1.6 (8.5 – 15)	14.4 ± 2.3 (10.5 – 19.5)	11.1 ± 1.9 (6 – 14.5)
bIOP (mmHg)	13.0 ± 1.4 (10.6 – 17.2)	12.8 ± 1.5 (10.3 – 15.6)	13.0 ± 1.9 (10.3 – 17.7)	12.2 ± 1.9 (7.9 – 16.2)
BPNN-IOP (mmHg)	14.0 ± 1.2 (12.5 – 15.2)	13.5 ± 1.2 (9.5 – 15.2)	14.0 ± 1.8 (12.3 – 18.2)	13.8 ± 1.5 (10.3 – 17.2)

Table 2 and **Table 3** showed the Pearson analysis results between the IOP values and CCT in the LASIK group and SMILE group, separately. In all cases, the analysis showed a significant pre-operative correlation between either GAT-IOP or CVS-IOP with CCT, but not between bIOP or BPNN-IOP and CCT; but the linear correlation with CCT in BPNN-IOP was more significant than in bIOP. Hence, the main observation is that the bIOP algorithm was the most successful in reducing correlation with CCT before refractive surgery. However, the BPNN-IOP still has the potential to estimate an accurate IOP to reduce the effect of corneal thickness and material stiffness.

Table 4 showed the paired-samples t-test related to IOP corrections' performance under the corneal geometry change, and material properties change. The results of the paired-samples t-test showed that only the pre-and post-operative bIOP and BPNN-IOP did not differ significantly (P>0.05), but the mean difference between before and after treatment in BPNN-IOP was still more significant than in bIOP. Thus, these results led to the second evidence that the bIOP was the most successful in reducing the CCT and material stiffness on the IOP measurement, and the BPNN-IOP also has the potential to get an accurate IOP reducing the effect of corneal thickness and material stiffness.

Table 2 The result of Pearson's correlation analysis of pre-and post-operative data for LASIK groups.

		LASIK Group (n = 20)	
		R value	P value
Pre-operative	GAT-IOP vs CCT	0.481*	0.032
	CVS-IOP vs CCT	0.480*	0.032
	bIOP vs CCT	0.006	0.980
	BPNN-IOP vs CCT	0.007	0.950
Post-operative	GAT-IOP vs CCT	0.220*	0.047
	CVS-IOP vs CCT	0.362**	0.005
	bIOP vs CCT	0.09	0.705
	BPNN-IOP vs CCT	0.10	0.980

*. Correlation is significant at the 0.05 level (2-tailed).
**. Correlation is significant at the 0.01 level (2-tailed).

Table 3 The result of Pearson's correlation analysis of pre-and post-operative data for SMILE groups.

		SMILE Group (n = 30)	
		R value	P value
Pre-operative	GAT-IOP vs CCT	0.259*	0.045
	CVS-IOP vs CCT	0.329**	0.002
	bIOP vs CCT	0.005	0.978
	BPNN-IOP vs CCT	0.006	0.998
Post-operative	GAT-IOP vs CCT	0.170*	0.037
	CVS-IOP vs CCT	0.354**	0.003
	bIOP vs CCT	0.068	0.706
	BPNN-IOP vs CCT	0.080	0.668

*. Correlation is significant at the 0.05 level (2-tailed).
**. Correlation is significant at the 0.01 level (2-tailed).

Table 4 showed the paired-samples t-test related to IOP corrections' performance under the corneal geometry change, and material properties change. The results of the paired-samples t-test showed that only the pre-and post-operative bIOP and BPNN-IOP did not differ significantly (P>0.05), but the mean

difference between before and after treatment in BPNN-IOP was still more significant than in bIOP. Thus, these results led to the second evidence that the bIOP was the most successful in reducing the CCT and material stiffness on the IOP measurement, and the BPNN-IOP also has the potential to get an accurate IOP reducing the effect of corneal thickness and material stiffness.

Table 4 Differences between post- and pre-operative data for both LASIK and SMILE groups showing the mean, standard deviation, and p-value of differences using the paired t-test results

Post – Pre	LASIK Group (n = 20)		SMILE Group (n = 30)	
	Mean ± SD	p-value	Mean ± SD	P value
CCT (μm)	-76.4 ±19.9	<0.001	-76.6 ±19.6	<0.001
GAT-IOP (mmHg)	-3.2 ±3.4	<0.001	-3.2 ±2.1	<0.001
CVS-IOP (mmHg)	-3.7 ±2.1	<0.001	-3.3 ±2.0	<0.001
bIOP (mmHg)	-0.1 ±2.1	0.795^{**}	-0.8 ±1.8	0.050^{**}
BPNN-IOP (mmHg)	-0.5 ±1.1	0.855^{**}	-0.2 ±1.2	0.105^{**}

*. Mean difference is significant at the 0.05 level (2-tailed).
** Mean difference is significant at the 0.01 level (2-tailed).

4. DISCUSSION

The accuracy of applanation tonometry or dynamic Scheimpflug analyzer is influenced by the ocular biomechanical behavior, as eye geometry and ocular stiffness[4, 13-21, 36-38]. The potential errors of IOP reading lead to a significantly high probability of false positives and false negatives in the diagnosis of ocular disease, as ocular hypertension or glaucoma[21, 39]. Moreover, several attempts in previous studies have been made to quantify the effect of the ocular biomechanical behavior on IOP measurement to reduce its dependence on IOP reading, particularly reducing the influence of corneal geometry and material properties[19, 23, 26, 27, 33-38]. Several correlated IOP algorithms had been developed in these attempts to enable more accurate IOP estimation[36-38]. On the other hand, new techniques such as dynamic contour tonometer (DCT, SMT Swiss Microtechnology AG) and the Ocular Response Analyzer (Reichert Technologies) were also developed to reduce dependence on the ocular biomechanical behavior[15, 37, 40]. Thus, quantifying the ocular biomechanical behavior is necessary for reducing the effect of its on IOP measurement.

Measuring the actual IOP value and tissue material behavior in-vivo is a challenge in quantifying these biomechanical factors[34]. As a result, the IOP estimated algorithm was challenging to be validated its accuracy. According to previous studies, the performance of the IOP estimated algorithm was usually validated by using the laser refractive surgery data, which showed the well-known reduction of IOP reading with applanation tonometry related to corneal thickness and material properties change[15, 37, 40]. In addition, the laser treatment procedures have effects on ocular biomechanical properties in reducing the thickness through ablation and wound-healing process[41-46], but the actual IOP value remains in small change. Therefore, this study compared the effect of laser refractive surgery on different IOP measurement methods to validate our IOP estimated algorithm using the backpropagation neural network method.

In this study, the Pearson correlation analysis demonstrated that the BPNN-IOP correction algorithm could reduce the IOP dependence on CCT and corneal material stiffness before and after LASIK and SMILE performance of BPNN-IOP correction algorithm approached the bIOP algorithm. In previous studies, the bIOP algorithm is more accurate in per- and post-operative conditions and less affects CCT and corneal material properties on IOP reading[15, 37, 40]. Moreover, the Pearson results also demonstrated a significantly strong correlation between GAT-IOP and CVS-IOP with CCT in both per- and post-operative conditions, while the BPNN-IOP and bIOP reading were largely independent on CCT.

The actual IOP value depends on the dynamic balance between the intraocular volume and rate of aqueous humor production and aqueous humor discharge[47]. There is no significant change in these IOP-related factors through laser refractive surgery; even the corneal thickness becomes thin. Therefore, it only slightly influences the actual IOP value, but not a significant difference between pre-and post-operative conditions[48]. According to this assumption, the results of paired t-test in this study demonstrated that the BPNN-IOP (-0.5±1.1mmHg, p>0.05 in LASIK and -0.2±1.2mmHg, p>0.05 in SMILE) and bIOP (-0.1±2.1mmHg, p>0.05 in LASIK and -0.8±1.8 mmHg, p>0.05 in SMILE) remained a slight change after laser operation. Moreover, the results also demonstrated that the reductions of GAT-IOP (3.2±3.4 mmHg, $p<0.01$ in LASIK and 3.2±2.1 mmHg, $p<0.01$ in SMILE) and CVS-IOP (3.7±2.1 mmHg, $p<0.01$ in LASIK and 3.3±2.0 mmHg, $p<0.01$ in SMILE) after laser operation, similarly to the previous studies, GAT-IOP reducing 2.6±2.2 mmHg in Pepose et al.[49], 4.5±3.7mmHg in Qaz et al.[50], 4.9±1.3 mmHg in Dan et al. [37] and CVS-IOP reducing 2.7±1.0mmHg in Dan et al. [37]after laser operation.

The main limitation is that the actual IOP value and the ocular biomechanical behavior are challenging to measure from an in-vivo test. Accordingly, this study used two laser refractive surgery data to prove the influence of ocular biomechanics (including CCT and ocular material properties) on the IOP reading existed. Furthermore, to quantify the influence of ocular biomechanics, the comparative analysis should include the high number of participants with different alternative devices to measure IOP. However, this study only includes the relatively low number of patients with Goldmann applanation tonometer and CorVis ST.

5. CONCLUSIONS

In conclusion, the comparative analysis shows that the IOP value through the biomechanically corrected algorithm and Back Propagation Neural Network method has a high ability to reduce the effect of corneal thickness and tissue's material properties, even under laser refractive surgery. Moreover, both biomechanical methods made IOP value no significant difference between pre-an post-LASIK and SMILE. By contrast, the IOP reading obtained from the applanation tonometry or dynamic Scheimpflug analyzer was not. These results suggest that the IOP measurement should consider the effect of corneal thickness and material properties. Biomechanically corrected algorithm and Back Propagation Neural Network method can reduce the effect of these biomaterial factors and compensate for ocular biomechanics change.

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