Intraocular pressure changes and corneal biomechanics after hyperopic small-incision lenticule extraction

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Research article

Keywords: hyperopia, SMILE, IOP, corneal biomechanics

Posted Date: December 4th, 2019

DOI: https://doi.org/10.21203/rs.2.18089/v1

Abstract

Background: To compare intraocular pressure (IOP) measurements by a dynamic Scheimpflug analyzer (Corvis ST), a non-contact tonometer, and the ocular response analyzer following hyperopic small-incision lenticule extraction (SMILE).

Methods: Thirteen patients underwent hyperopic SMILE in one eye each were prospectively enrolled. IOP and corneal biomechanical parameters were measured preoperatively and 1 week, 1 month, and 3 months after surgery with a non-contact tonometer (IOPNCT), Corvis ST (biomechanical corrected IOP, bIOP), and the ocular response analyzer (Goldmann-correlated intraocular pressure [IOPg], cornea compensated IOP [IOPcc]). A linear mixed model was used to compare IOP and biomechanical values among the methods at each time point.

Results: IOPNCT, IOPg, and IOPcc dropped significantly after surgery, with the amplitude being 3.15±0.48 mmHg, 5.49±0.94 mmHg, and 4.34±0.97 mmHg, respectively, at the last visit. IOPNCT decreased by 0.11±0.06 mmHg per μm of removed central corneal thickness. bIOP did not change significantly after surgery. Before surgery, no difference was found among the measurements (P> 0.05). After surgery, IOPNCT and bIOP were higher than IOPg and IOPcc. bIOP is independent of cornea thickness at the last visit, while correlated significantly with corneal biomechanics as other three IOP values did.

Conclusion: bIOP (biomechanical corrected IOP as measured with the Corvis ST) seems to be an accurate parameter to measure IOP after hyperopic SMILE.

Background

Cornea refractive surgery corrects the refractive error by removing part of the corneal tissue, and accordingly changes both the corneal shape and corneal biomechanics. This causes changes in intraocular pressure (IOP) measurements as shown in previous studies.[1, 2] It is estimated that more than 200,000 eyes may be at risk of a missed glaucoma diagnosis based on a conservative 2% incidence of glaucoma among the nearly 10 million refractive procedures performed.[3] It is generally accepted that IOP measurements falsely decrease after corneal myopic refractive surgery. This is observed in photorefractive keratectomy, laser in situ keratomileusis (LASIK), and myopic small incision lenticule extraction (SMILE).[1, 4]

The principle of hyperopic correction, which differs from that of myopic correction, is to make the central cornea steeper. In SMILE, this is achieved by creating a concave lenticule that is thinnest in the central area. Liu[5] reported that hyperopic SMILE can cause more distortion of collagen fibril formation than myopic SMILE in animal models, and therefore the changes of IOP measurements may be different from myopic SMILE. Schallhorn et al[4] reported that hyperopic ablations (both photorefractive keratectomy (PRK) and LASIK) lower measured IOP, smaller than myopic ablations did, and this decrease in IOP was weakly related with preoperative spherical equation after hyperopic LASIK and not related in hyperopic

PRK. Since absence of flap in SMILE as well as different laser was used, it would be of great interest to explore the IOP changes induced by hyperopic SMILE.

The current study aimed to explore the effect of hyperopic SMILE on IOP assessment using different measurement methods.

Methods

Subjects

Thirteen hyperopic patients (13 eyes) were enrolled prospectively between March 2017 and June 2018 at the Eye and ENT Hospital of Fudan University (*Table 1).*. Approval was obtained from the ethics committee and informed consent was signed by each patient. All procedures adhered to the tenets of the Declaration of Helsinki.

Inclusion criteria were as follows: age ≥ 18 years; sphere +2 to + 6.0 diopters (D), with astigmatism up to 3.0 D.

Patients with abnormal topography, intraocular surgery history, and suspected or diagnosed glaucoma were excluded.

The preoperative examination included slit lamp examination, objective and subjective refraction, uncorrected distance visual acuity (UDVA) measurement, corrected distance visual acuity (CDVA) measurement, corneal tomography with a rotating Scheimpflug camera (Pentacam, Oculus, Wetzlar, Germany), and fundus examination.

IOP Measurement

IOP_{NCT} (non-contact IOP): The non-contact tonometer (TX–20, Canon, Tokyo, Japan) was used. One average value was calculated from 3 measurements automatically. Measurement repeatability was identified in previous study.[6]

bIOP (biomechanical corrected IOP): The Corvis ST (Corneal Visualization Scheimpflug Technology instrument; Oculus, Wetzlar, Germany) is a Scheimpflug-based dynamic corneal tonometer, which incorporates the parameters of corneal biomechanics and IOP. The system uses an algorithm to calculate biomechanically corrected IOP (bIOP), compensating for changes in corneal thickness and stiffness.[7]

IOPg (Goldmann-correlated IOP), IOCcc (cornea compensated IOP), CRF (corneal resistance factor), and CH (corneal hysteresis): These four values were derived from ocular response analyzer (ORA, Reichert Ophthalmic Instruments, Depew, NY, USA). ORA uses an air puff to deform the cornea. Due to its viscoelastic nature, the cornea resists the air puff, resulting in different values for the inward and outward flexing, which was termed corneal hysteresis (CH). The Corneal resistance factor (CRF) represents the

resistance of cornea.[8] Each eye was measured 4 times, and only measurements with a waveform score greater than 5 were used.

Three corneal biomechanical parameters derived from Corvis ST were analyzed: A1 Time (first applanation time), and HC DA (deformation amplitude, the largest anterior- posterior displacement of the cornea apex at the highest concavity phase) were the most repeatable and reproducible parameters.[9] SP- A1 (resultant pressure [adjusted pressure at A1 (adj AP1)—biomechanically compensated IOP (Biop)] divided by deflection amplitude at A1) was a new parameter describing the cornea stiffness, and higher values means stiffer cornea.[2]

All measurements were performed by the same examiner (FD) to decrease inter-observer variability, and taken at approximately the same time of day.

Surgical Techniques

All surgeries were performed by the same surgeon (ZXT). After standard sterile draping, all patients were treated with the VisuMax laser (Carl Zeiss Meditec AG, Jena, Germany, version 3.1) with repetition rate being 500 kHz and the pulse energy being 30 nJ. The following settings were used for hyperopic SMILE: the cap diameter was 8.8 mm and the thickness 120 μm; the optical zones ranged between 5.3 mm and 6.3 mm, with a 2-mm transition zone; and a single 2.0-mm side cut was performed at the 12’o clock position with an angle of 90°.

The specific steps of SMILE were performed as described by Li.[10] Total suction time was approximately 35 seconds. After lenticule scanning, the surgeon used a splitter to separate the upper interface, following the lower lenticule interface separation. The lenticule was then removed through the superior incision. Afterwards, the surgeon examined the cornea with a built-in slit lamp to detect whether parts of the lenticule remained. One drop of prednisolone and levofloxacin was applied at the end.

All surgeries were performed successfully, with no intraoperative or postoperative complications.

After surgery, patients were instructed to use fluorometholone eye drops 8 times a day, and to reduce the usage frequency by 1 every 3 days (totally 24 days). Artificial tears were prescribed for 3 to 4 weeks, to be used if needed.

Follow-up

Patients were examined at 1 week, 1 month, and 3 months after surgery. At each visit, visual acuity, subjective refraction, corneal topography, and IOP measurements using three devices were performed.

Statistical Analysis

All data were recorded and analyzed using SPSS (version 22, IBM Corp,USA). The *Kolmogorov–Smirnov* test was firstly used to check the normality of data. Linear mixed-model analysis of variance with post hoc least significant difference multiple comparisons were used to compare the postoperative IOP measurements between different visits and different methods at the same visit. The *Spearman rank* correlation was used to assess the corneal biomechanical parameters obtained from the Corvis ST and to determine potential postoperative factors affecting the postoperative IOP measurements. $P< 0.05$ was considered statistically significant.

Results

All patients completed 3-months follow-up visit. The safety index (postoperative CDVA/preoperative CDVA) was 0.96 ± 0.12, and the efficacy index (postoperative UDVA/preoperative CDVA) was 0.93 ± 0.14 at the last visit.

IOP measurement changes

The IOP values at different points of time are shown in *Table 2.* Before surgery, no difference was found among the measurements. At 1 week postoperatively, the IOP_{NCT} was 2.52 ± 1.11 mmHg higher than IOPg ($P = 0.04$); bIOP was 2.32 ± 0.85 mmHg higher than IOPg($P = 0.02$); and IOP_{NCT} was no different with bIOP. One month after surgery, bIOP was 3.60 ± 0.89 mmHg higher than IOPg ($P = 0.004$) and 3.32 ± 0.86 higher than IOPcc ($P = 0.005$), and IOP_{NCT} was 2.56 ± 0.50 mmHg higher than IOPg ($P = 0.001$). No difference was found between IOP_{NCT} and bIOP. At 3 months postoperatively, bIOPwas the highest IOP value (IOP_{CC}: $\Delta = 3.29 \pm 0.63$ mmHg, $P = 0.001$; IOPg: $\Delta = 3.68 \pm 0.91$ mmHg, $P = 0.003$; IOP_{NCT}: $\Delta = 2.13 \pm 0.70$ mmHg, $P = 0.01$). No difference was found between IOPg and IOPcc during all visits.

Except for bIOP, the other three measurements were lower after surgery than preoperatively. IOP_{NCT} remained stable from preoperative to 1 month after surgery (post–1 month vs post–3 months, $\Delta = 1.85 \pm 0.82$ mmHg, $P = 0.04$), and decreased 3.15 ± 0.48 mmHg at post–3 months compared with preoperative values ($P< 0.001$), with 0.11 ± 0.06 mmHg reduction per micro removed cornea tissue (ΔIOP_{NCT}/lenticule thickness).

Compared with preoperative values, IOPcc started to decrease at 1 week ($\Delta = 2.71 \pm 1.04$ mmHg, $P = 0.03$), and went on till 1 month ($\Delta = 4.94 \pm 1.25$ mmHg, $P = 0.006$). IOPg decreased by 4.30 ± 1.13 mmHg ($P = 0.007$) at 1 week after surgery and was stable afterwards. IOPg showed the greatest difference between pre- and postoperative values ($\Delta = 5.49 \pm 0.94$ mmHg, $P = 0.001$) of all 4 measurements at 3 months postoperatively. (*Figure* 1)

Cornea biomechanical changes and Correlation Analysis

The biomechanical parameters from ORA and Corvis ST were shown in *Table 3.* CRF and SP-A1 dropped significantly after surgery (P < 0.05). No significant difference was found among follow up visits in terms of CH, A1 Time and HC DA.

Using Spearman analysis, at 3 months visit, HC DA was negatively related with all IOPs (r ranges from –0.82 to –0.74, P< 0.05). IOPg and IOPcc were correlated with CRF (r = 0.68~ 0.91, P < 0.05) and postoperative CCT (r = 0.83 ~ 0.95, P < 0.01). bIOP was independent of preoperative CCT as well as postoperative CCT and correlated with A1 Time (r = 0.87, P = 0.001) and HC DA (r = –0.74, P = 0.01) at the last visit. IOP_{NCT} at the last visit was correlated with homologous CRF, A1 Time and HC DA as well as preoperative IOP_{NCT} (r = 0.86, P = 0.001). (*Table 4)*

Discussion

Accurate IOP measurement is extremely important for ophthalmologists, because falsely low IOP readings may delay the diagnosis of ocular hypertension or glaucoma.[11] In this study, we evaluated the effect of hyperopic SMILE on different IOP measurement techniques. It is the first report of this kind to the best of our knowledge.

In this study, the average decrease of IOP measurements from pre- to postoperatively ranges from 0.42 to 5.48 mmHg among the different measurement techniques used. Lee[12] reported IOP_{NCT} decreased by 2.04 ± 1.44 mm Hg after myopic transepithelial PRK and by 2.63 ± 1.60 mmHg after myopic Femtosecond-LASIK 6 months postoperatively. Li[13] also demonstrated that ΔIOP_{NCT} per micrometer of ablated tissue after 6 months was 0.05 ± 0.02 mmHg in a myopic SMILE group, and 0.05 ± 0.03 mmHg in a myopic Femtosecond-LASIK group, which seems smaller than the 0.11 ± 0.06 mmHg in present study. Reinstein et al[14] found that postoperative tensile strength was greatest after SMILE, followed by PRK, and was lowest after LASIK. Thus, different corneal stiffness impairments may partially account for the different IOP reduction among surgeries. Besides, epithelium preservation and flap-free procedures may result in difference in pressure resistance. Moreover, the hyperopic lenticule, different from myopic ones, is thinnest at the center, which causes less thinning of the central cornea. It may lead to different wound healing processes, though the direct relationship between would healing and IOP measurement remains to be quantified.[15]

The present study used four IOP measurement methods, three of them trying to correct for the biomechanical changes of the cornea caused by corneal refractive surgery. We found that bIOP (biomechanical corrected IOP, measured with the Corvis ST) was the one most closely approximating the preoperative IOP values, and other three ones did lower estimate IOP after hyperopic SMILE. Similar results were observed in myopic LASIK and myopic SMILE.[16, 17] Lee[12] also reported unchanged bIOP after myopic LASIK and PRK. Previous studies have demonstrated that central corneal thickness (CCT) can influence IOP measurement. Liu et al[18] reported that IOP readings may have a 2.87-mmHg range due to the variation in CCT, but have a much larger range of 17.26-mmHg range due to changes of corneal biomechanical properties alone. Biomechanical properties therefore seem to have a much greater

effect on IOP than CCT. In this study, we found both cornea biomechanics and CCT were related with the IOP values. But for bIOP, no correlation with preoperative as well as postoperative CCT was found, as pre- and postoperative values were similar after hyperopic SMILE just as they were after myopic SMILE, indicating it is a reliable assessment method after surgery.

In this study, IOPg and IOPcc were constant during all visits, and were both related with CCT as well as cornea biomechanics. This is in accordance with results from Mollan,[19] but in contrast with Sullivan-Mee[20], who found IOPcc was higher than IOPg. Different types of disease studied may be responsible for this discrepancy. Sullivan-Mee measured IOPgand IOPcc in patients with potential or diagnosed glaucoma, while Mollan chose keratoconus patients and a control group. IOPg, an average value of inward pressure and outward pressure, is considered identical with Goldmann applanation tonometry.[21] IOPcc is affected to a less degree by corneal thickness and corneal biomechanical properties. The present results indicated that IOPg and IOPcc showed no difference when assessing hyperopic SMILE related IOP changes.

IOP_{NCT} was most commonly used clinically. In this study, IOP_{NCT} decreased 3.15 ± 0.48 mmHg after hyperopic SMILE, greater than bIOP, but less than IOPg and IOPcc did. Although Wolfs et al. reported that IOP was positively correlated with CCT,[22] we did not find a significant correlation between preoperative CCT and IOP_{NCT} values in this study. In addition, the IOP_{NCT} at the last visit was correlated with preoperative IOP_{NCT} and some corneal biomechanical properties, suggesting that cornea biomechanical instead of CCT may be of greater importance when predicting IOP_{NCT} after hyperopic SMILE. Additional studies are warranted to further confirm this concept.

There are several limitations in this study. The study lacks corresponding measurements with Goldmann applanation tonometer, which is considered the gold standard of IOP measurements. In addition, the sample size in the current study is small, and a larger sample size and longer study duration are needed.

Conclusion

In conclusion, IOP_{NCT} decreased after hyperopic SMILE, and its value is correlated with preoperative IOP_{NCT} as well as corneal biomechanical properties. bIOP seems to be an accurate parameter to assess postoperative IOP.

Declarations

Ethics approval and consent to participate:

Approval was obtained from the ethics committee of Eye and ENT Hospital of Fudan University, and informed consent was signed by each patient.

Consent for publication: Not applicable.

Availability of data and material:

The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests:

The authors have no financial or proprietary interest in the materials and products presented herein.

Funding:

National Natural Science Foundation of China for Young Scholars (Grant No. 81500753),

The receiver is LMY, one of the first author in present study, contributing to interpreting the patient data.

Natural Science Foundation of China (Grant No. 81570879) & (Grant No. 81770955),

Project of Shanghai Science and Technology (Grant No.17140902900)，Grant No.17411950200，

Both two funding above are received by ZXT, who is corresponding author in this study, contributing to study design and major correction of whole study.

Authors' contributions:

LMY and WSS analyzed and interpreted the patient data regarding the hematological disease and the transplant. SJM and FD performed the histological examination of the kidney, and was a major contributor in writing the manuscript. KM and ZXT contributed to major revise and study design. All authors read and approved the final manuscript

Acknowledgements: Not applicable.

Abbreviations

IOP: intraocular pressure

SMILE: small-incision lenticule extraction

IOP_{NCT}: non-contact tonometer

bIOP: biomechanical corrected IOP

ORA: the ocular response analyzer

IOPg: Goldmann-correlated intraocular pressure

IOPcc: cornea compensated IOP

LASIK: laser in situ keratomileusis

PRK: photorefractive keratectomy

UDVA: uncorrected distance visual acuity

CDVA: corrected distance visual acuity

CH: corneal hysteresis

CRF: cornea resistant factor

A1 Time: first applanation time,

HC DA: deformation amplitude, the largest anterior- posterior displacement of the cornea apex at the highest concavity phase

SP- A1: resultant pressure [adjusted pressure at A1 (adj AP1) – biomechanically compensated IOP (Biop)] divided by deflection amplitude at A1

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Tables

Table 1 Baseline information of enrolled patients.

	Hyperopia group	(range)
Age (y)	32.8 ± 9.0	(18-45)
Male (%)	3/13	/
Spherical diopter (D)	4.17 ± 1.55	(2.00-6.00)
Cylinder (D)	-0.90 ± 0.75	(-2.25-0.00)
CCT (μm)	546.7 ± 25.3	(507.0-601.0)
Km (D)	42.26 ± 1.12	(40.60-44.70)
Lenticule thickness	89.0 ± 24.0	(46.0-132.0)

CCT = central corneal thickness; Km = mean keratometry

Table 2 IOP values of the four methods at each time point.

	pre	Post-1w	Post-1m	Post-3 ms	P
IOP_{NCT}	15.40 ± 3.20	14.73 ± 3.74	13.87 ± 3.96	12.08 ± 2.83	0.006
bIOP	15.77 ± 4.18	14.21 ± 1.87	14.30 ± 1.76	14.13 ± 1.61	0.878
IOPg	15.23 ± 4.84	11.75 ± 3.56	10.36 ± 3.19	10.51 ± 3.83	< 0.001
IOP_{CC}	14.62 ± 3.94	11.54 ± 1.07	10.46 ± 2.83	10.90 ± 2.80	< 0.001
P	0.928	0.045	< 0.001	<0.001	

IOP_{NCT} = non-contact intraocular pressure; biop = biomechanical corrected intraocular pressure; IOPg = Goldmann-correlated intraocular pressure; IOPcc = cornea compensated intraocular pressure.

Table 3 Corneal biomechanical parameters measured using the ocular response analyzer and Corvis ST.

	pre	Post-1w	Post-1m	Post-3 ms	P
CH	11.47 ± 1.47	10.88 ± 1.19	11.05 ± 1.95	11.12 ± 1.14	0.13
CRF	11.25 ± 2.22	9.71 ± 1.64	10.15 ± 2.33	9.51 ± 1.87	.001
A1 Time	7.10 ± 0.52	6.87 ± 0.24	6.93 ± 0.57	6.88 ± 0.31	0.23
HC DA	1.03 ± 0.14	1.13 ± 0.14	1.14 ± 0.15	1.11 ± 0.08	0.12
SP -A1	114.87 ± 16.67	93.64 ± 18.00	92.08 ± 20.82	94.03 ± 19.07	0.001

CH = cornea hysterisis CRF = cornea resistance factor; A1 Time = first applanation time; HC DA = deformation amplitude, the largest anterior-posterior displacement of the corneal apex at the highest concavity phase; SP-A1= Resultant pressure [adjusted pressure at A1 (adj AP1) – biomechanically compensated IOP (Biop)] divided by deflection amplitude at A1

Table 4 Correlations between IOPs and corneal biomechanical parameters at 3 months visit (r [P]).

	IOP_{NCT}	bIOP	IOPg	IOPcc
CH	0.48 (0.16)	0.28 (0.44)	0.56 (0.09)	0.22 (0.54)
CRF	**0.75 (0.01)**	0.59 (0.07)	**0.91 (0.001)**	**0.68 (0.03)**
A1 Time	**0.66 (0.03)**	**0.87 (0.001)**	**0.71 (0.03)**	0.64 (0.06)
HC DA	**-0.76 (0.006)**	**-0.74 (0.01)**	**-0.82 (0.007)**	**-0.76 (0.02)**
SP A1	0.49 (0.15)	0.32 (0.37)	**0.72 (0.04)**	0.49 (0.22)
CCT	0.49 (0.11)	0.32 (0.31)	**0.95 (0.001)**	**0.83 (0.003)**
Km	-0.05 (0.89)	0.29 (0.36)	-0.24 (0.51)	-0.36 (0.30)

r = correlation coefficient; CCT= central cornea thickness at 3 month after surgery CH = cornea hysterisis CRF = cornea resistance factor; A1 Time = first applanation time; HC DA = deformation amplitude, the largest anterior-posterior displacement of the corneal apex at the highest concavity phase; SP-A1= Resultant pressure [adjusted pressure at A1 (adj AP1) – biomechanically compensated IOP (Biop)] divided by deflection amplitude at A1; IOPNCT = non-contact intraocular pressure; biop = biomechanical corrected intraocular pressure; IOPg = Goldmann-correlated intraocular pressure; IOPcc = cornea compensated intraocular pressure.

Figures

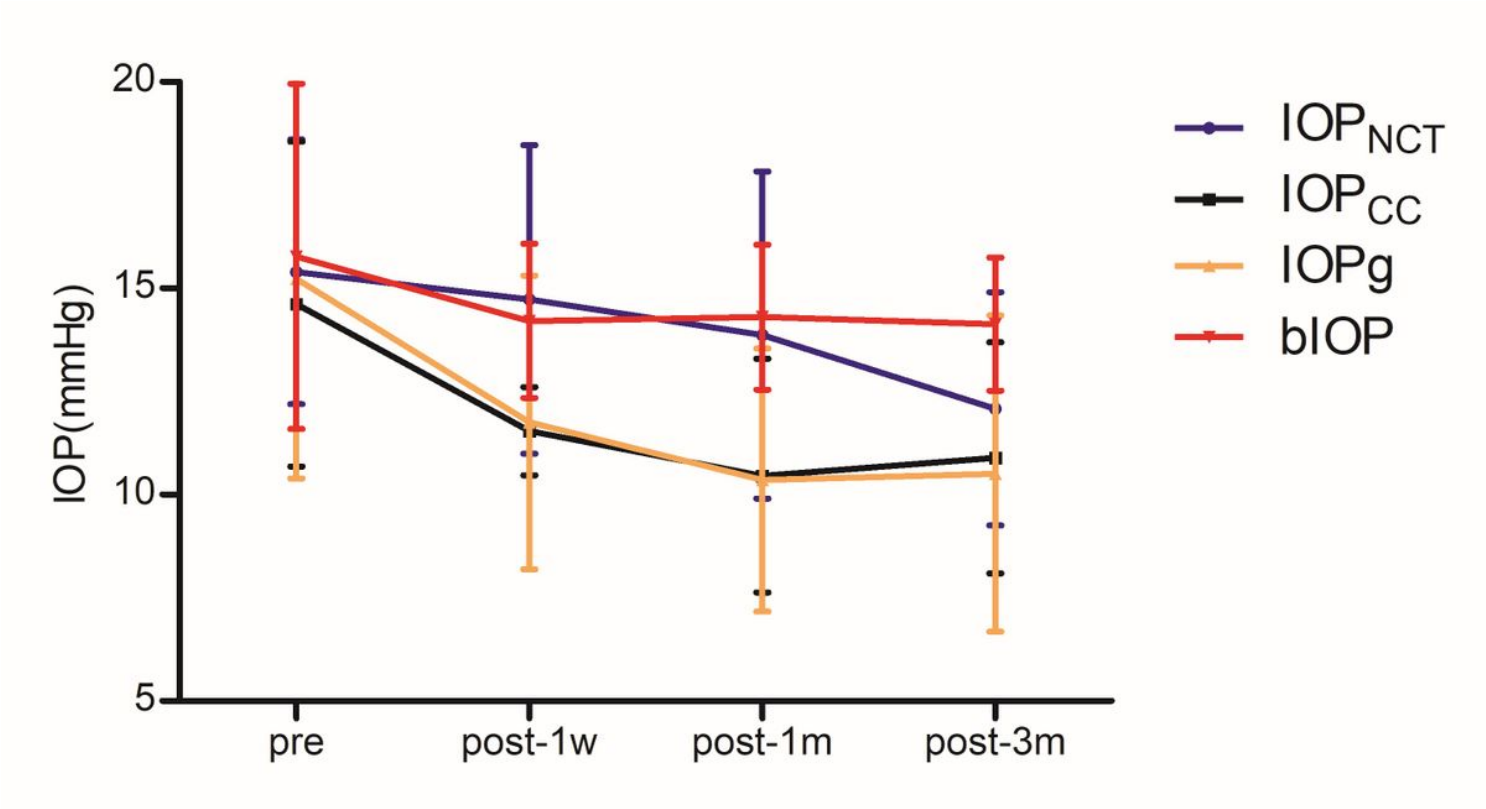

Figure 1

IOP measurement changes during the follow-up.