

ORIGINAL ARTICLE

The Accuracy of Dynamic Contour Tonometry Over Soft Contact Lenses

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ABSTRACT

Purpose. Dynamic contour tonometry (DCT) has been shown to measure the intraocular pressure (IOP) independently of corneal thickness. This study aimed to investigate if DCT remains accurate when the IOP measurement is taken over soft contact lenses (CLs) of different thicknesses and material characteristics.

Methods. This was a prospective clinical study that included 42 patients. Subject age was 22 to 59 years (26.5 ± 6.3 years). Intraocular pressure and ocular pulse amplitude (OPA) measurements were taken under topical anesthesia without CLs and over various daily disposable CLs with -0.50 , $+5.00$, and -5.00 diopters (D) in hydrogel (Nelfilcon A) and in silicone hydrogel (Narafilcon A) materials.

Results. No statistically significant differences were found when comparing the IOP measurements obtained using either of the different CL powers of -0.50 or -5.00 D, irrespective of which CL material was being used. However, the difference of 0.62 mm Hg observed when the Nelfilcon A with a power of $+5.00$ D was used turned out to be highly statistically significant ($p = 0.0002$), whereas the Narafilcon A with the same power of $+5.00$ D, with a small difference of -0.16 mm Hg, was not. Regarding OPA measurements, no significant differences were found between measurements with and without CL neither for different materials nor for change in dioptrical power ($F = 0$, $p = 1.000$).

Conclusions. This study showed good reliability of IOP and OPA measurements over CLs with varying thickness profiles and different soft materials when using the DCT. Only a small but statistically significant difference of 0.62 mm Hg was found for the IOP measurement with the hydrogel CL of $+5.00$ D compared with “no CL.”
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Key Words: dynamic contour tonometer, cornea, intraocular pressure, ocular pulse amplitude, topical anesthesia, hydrogel, silicone hydrogel, contact lens

Goldmann applanation tonometry has long been considered to represent the gold standard for intraocular pressure (IOP) measurement.^{1,2} Its underlying principle is to estimate the necessary force to flatten the central corneal area within a diameter of 3.06 mm. Unfortunately, this makes IOP measurements dependent on corneal properties, such as thickness, rigidity, curvature, and axial length.^{3–6} It is calibrated for a central corneal thickness of 520 μm and hence overestimates the IOP of eyes with thicker corneas and underestimates the IOP of eyes with thinner corneas.⁵ Furthermore, there are practical challenges during IOP measurement when using traditional Goldmann applanation tonometry, such as aligning the two prism mires accurately.

The dynamic contour tonometer ([DCT] Ziemer Ophthalmic Systems, Port, Switzerland) is believed to be largely independent of corneal properties. Boehm et al.⁷ compared DCT readings with intracameral IOP measurements and found the DCT measurements to be accurate.

In certain clinical situations, it may be advantageous or indeed necessary to measure the IOP over a contact lens (CL) *in situ*. Obviously, the use of anesthetic drops can be avoided. It is also helpful in cases where the patient is wearing a bandage CL because lens removal may impair corneal epithelial healing. For eyes with corneal pathology such as bullous keratopathy, abrasions, and ulcers, a lens can serve as a buffer and hence protect the cornea during the IOP measurement. In some countries (such as those of continental Europe), optometrists are not registered to use diagnostic drugs.

Several studies have already shown the IOP measurements to be accurate over soft CLs using various other tonometry methods, and they have been discussed previously.⁸ Using the DCT, IOP measurements have been shown to remain accurate if they were

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carried out over a thin daily disposable hydrogel CL (-0.50 diopters [D]; Filcon IV) on normal corneas with regular topographic maps.⁸ Because the DCT takes a different approach to measure IOP, it was considered interesting to explore the effect of the CL thickness profile and its rigidity on the accuracy of its measurements.

The aim of this study was to determine the reliability of the DCT over soft daily disposable CLs of different dioptric powers and different soft materials (hydrogel and silicone hydrogel).

The Dynamic Contour Tonometer

The underlying principles of the DCT have been previously explained elsewhere.^{8,9} Briefly, the DCT has a specifically designed tip with a concave contact surface that matches the contour of the cornea and hence allows the cornea to assume the shape that it naturally assumes when the IOP is equal to the transverse pressure applied to its anterior surface and its distortion is minimal. A digital pressure sensor integrated in the DCT contoured surface allows a direct IOP measurement across the cornea. Correct positioning of the tip is indicated by an audible signal that changes in pitch with detected variations in pressures. The tip generates an electric signal that is proportional to the IOP level. Rhythmic oscillations corresponding to the pressure signal are detected during 6 to 10 heartbeats. The IOP is calculated automatically and displayed on a digital liquid crystal screen. The quality score of the measurements ranges from excellent (score of 1) to poor (score of 4 or 5) and is simultaneously displayed on the screen.

The main advantage of the DCT is its ability to measure IOP independently of physiologic variables such as corneal thickness, corneal radius, astigmatism, and corneal rigidity. Hence, IOP does not need to be corrected for particularly thin or thick corneas.

The Ocular Pulse Amplitude

The DCT also measures the ocular pulse amplitude (OPA). Its value is expressed in millimeters mercury. The mean value for a normal OPA value is 3 mm Hg, with a mean difference of 0.4 mm Hg between the two eyes. It represents the difference between the mean systolic IOP and mean diastolic IOP.¹⁰ The pulsatile character of the IOP is thought to be caused by the blood volume that is pumped into the eye with each cardiac cycle. In this way, these pulsations might reflect the ocular blood flow.^{11–13} During the past decades, evidence has grown that vascular factors also contribute to the pathogenesis of glaucoma, and hence, the measurement of OPA may help in monitoring the clinical course of glaucoma.^{11,13–18}

METHODS

This was a prospective clinical study, which included 42 white patients (21 right and 21 left eyes), of which 26 were female. The age varied from 22 to 59 years (mean, 26.5 ± 6.3 years).

The inclusion criteria were corneas with a regular topographical shape (i.e., no degeneration or dystrophy affecting corneal thickness or shape) and no presence of ocular pathology (assessed by slit lamp examination). All participants were volunteers from the University of Applied Sciences in Olten. They signed an informed

consent, which also included a comprehensive explanation of possible adverse events of topical anesthesia. Two clinicians were taking measurements (D.S. and F.G.). To exclude any effect of patient anxiety resulting from the first IOP measurement, three additional IOP measurements were carried out with a noncontact tonometer (Nidek NT-530) and two additional DCT measurements were carried out beforehand that were not included for analysis. The following different dioptric powers for the CLs were used: -0.50 , $+5.00$, and -5.00 D. Two different soft materials were used: one hydrogel (Nelfilcon A, CIBA VISION/Alcon) and one silicone hydrogel (Narafilcon A, Johnson, Johnson & Vision Care). One published study showed a small effect of topical anesthesia on IOP.¹⁹ It was therefore decided to cancel out any possible effects this may produce by applying the topical anesthetic oxybuprocaine 0.4% SDU Faure every 15 minutes during the duration of the experiment. This means that if there was a bias caused by anesthesia, it would have been present in all measurements and therefore can be neglected as far as measurements with and without CLs are compared.

In the event of adverse reactions, the trial would have been aborted and the patient would have been sent to the nearby eye hospital. All subjects enrolled for this study completed their study participation and could be included for statistical analysis.

One drop of oxybuprocaine 0.4% SDU Faure was instilled in the examined eye. After the three preliminary noncontact tonometer measurements and the two preliminary DCT measurements, IOP and OPA measurements were carried out with “no CL” and six different CLs as specified above. The order of all measurements, the choice of right or left eye, and the examiner (F.G. or D.S.) were randomized and balanced. Only measurements of high-quality level of 1 or 2 (out of 5 levels) were included for analysis. If an inferior quality appeared, the measurement was repeated until the necessary quality was achieved. This study was conducted in accordance with the ethical commission of Aargau, Switzerland.

During the course of a pilot study in preparation of this clinical study, interobserver reliability between the two examiners F.G. and D.S. was measured. This was done by looking at Bland-Altman plots and estimating the confidence limits of the measurements on 14 eyes. No clinically significant difference, neither for IOP nor for OPA, could be found. The IOP and OPA measurements could hence be considered to be independent of the examiners.

Statistical Analysis

All statistical analysis was carried out using the statistical software R.²⁰ A power calculation was applied to detect a difference of 0.75 mm Hg, with an SD of 1.11, $\alpha = 0.05$ and $1 - \beta = 0.8$, which determined a minimum number of 35 subjects. From the pilot study mentioned before, the SD was estimated with a confidence interval of 1.03 to 1.18 mm Hg and a mean of 1.11 mm Hg. The value 0.75 mm Hg was adopted as a clinically significant difference because this amount represents one-half of the value of the SD of DCT. For these conditions, a sample size of 32, 35, and 40, respectively, was calculated. With respect to this and for a better balanced statistical analysis, it was decided to enroll 42 subjects for this clinical study. A linear mixed-effects model was used, which has been shown to be appropriate for this kind of correlated data.²¹ In the linear mixed-effects models, either IOP or OPA was

TABLE 1.

Means and SDs for IOP and OPA for the overall group without CL

| | Mean value and SD, mm Hg |
|-----|--------------------------|
| IOP | 15.08 ± 2.10 |
| OPA | 2.05 ± 0.69 |

the dependent variable. Candidates for fixed factors in the model-building process were a combination of lens power and lens type called “power lens type” (PLT), a factor with seven levels (i.e., “no CL,” Nelfilcon A, −5.00 D, −0.50 D, and +5.00 D; Narafilcon A, −5.00 D, −0.50 D, and +5.00 D), sex, age, investigator, and test sequence (14 different test sequences had been defined to get a balanced design).

Test subjects were treated as random factors. The model-building process was started by including all measured possible factors. Model reduction was aided by applying StepAIC from package MASS, by which nonsignificant variables could be eliminated one after another.²² Each factor eliminated was further shown to be not significant by an appropriate F test. Diagnostic plots and a Shapiro-Wilk test were applied to examine if the measurement error distribution showed normal distribution.

As a result of this procedure, an ordinary regression table was obtained, showing which factors are statistically significant. The model’s covariance matrix was used to estimate intervals of confidence; where appropriate Bonferroni correction for multiple comparisons was applied.

RESULTS

The results obtained for IOP and OPA were compared in relation to the different dioptric CL powers (−0.50, −5.00, and +5.00 D) and the two soft CL materials (Nelfilcon A and Narafilcon A) used for this study, summarized by the factor PLT. Table 1 shows the mean values and SDs obtained for IOP and OPA for the overall group of subjects, and Table 2 shows the mean values for individual material and power combinations. In this study, all mean OPA values were lower without and with various CL materials and powers tested than the 3 mm Hg one would normally expect.

To keep the presentation of results concise, only one linear fixed model is being discussed in more detail. First, the reduction of nonsignificant factors leads to a model where only one fixed effect term remained, that is, the PLT. The analysis of variance table of

TABLE 2.

Means and SDs for the IOP and OPA for different materials and powers

| CL material | Power, D | Mean IOP and SD, mm Hg | Mean OPA and SD, mm Hg |
|--------------|----------|------------------------|------------------------|
| None | 0.00 | 15.08 ± 2.10 | 2.05 ± 0.69 |
| Nelfilcon A | −5.00 | 14.91 ± 1.77 | 2.05 ± 0.68 |
| | −0.50 | 15.20 ± 2.11 | 1.99 ± 0.77 |
| | +5.00 | 15.71 ± 2.08 | 2.04 ± 0.67 |
| Narafilcon A | −5.00 | 14.95 ± 2.22 | 2.00 ± 0.72 |
| | −0.50 | 14.98 ± 1.92 | 2.01 ± 0.69 |
| | +5.00 | 14.93 ± 2.18 | 2.03 ± 0.69 |

TABLE 3.

Regression table for the linear mixed-effects model

| Term | Value, mm Hg | SE, mm Hg | df | t | p |
|-----------------------|--------------|-----------|-----|-------|--------|
| Intercept | 15.08 | 0.31 | 540 | 48.97 | 0.0000 |
| Nelfilcon A, −0.50 D | 0.11 | 0.17 | 540 | 0.67 | 0.5030 |
| Nelfilcon A, −5.00 D | −0.18 | 0.17 | 540 | −1.06 | 0.2886 |
| Nelfilcon A, +5.00 D | 0.62 | 0.17 | 540 | 3.73 | 0.0002 |
| Narafilcon A, −0.50 D | −0.11 | 0.17 | 540 | −0.63 | 0.5260 |
| Narafilcon A, −5.00 D | −0.14 | 0.17 | 540 | −0.83 | 0.4086 |
| Narafilcon A, +5.00 D | −0.16 | 0.17 | 540 | −0.95 | 0.3434 |

this model shows that besides the constant term, this factor was highly significant ($F_{540} = 6.0$; $p < 0.0001$). From this, it could be concluded that the material and power combination was statistically significant. In the regression table for this model (Table 3), the combination of “Power 0 D” and “no CL” serves as a baseline and is represented in the “Intercept” term. Further differences for other PLTs with respect to this reference value are listed in Table 3, along with SEs, number of degrees of freedom, and p value. As this table contains multiple comparisons, the significance level was corrected by the method of Bonferroni; as there are six comparisons, significance level was lowered to $0.05/6 = 0.00833$ (Table 4).

The Effect of CL Power and Material on IOP

Figs. 1 and 2 show that the IOP values obtained with different lens powers and materials were very similar. Table 3 shows that no statistically significant differences were found when comparing the IOP measurements obtained using either of the different CL powers of −0.50 and −5.00 D, irrespective of which CL material was being used. However, the difference of 0.62 mm Hg observed when the Nelfilcon A with a power of +5.00 D was used turned out to be highly statistically significant ($p = 0.0002$), whereas the Narafilcon A with the same power of +5.00 D with a small difference of −0.16 mm Hg was not.

The Effect of CL Power and Material on OPA

Fig. 3 shows very little difference for any OPA measurements for neither lens power nor CL material. The OPA values were not influenced by any CL power or material used in this study: no

TABLE 4.

Confidence intervals for various lens type and lens power combinations

| Comparison | Lower, mm Hg | Estimate, mm Hg | Upper, mm Hg |
|---------------------------------|--------------|-----------------|--------------|
| No CL vs. Nelfilcon A, −0.50 D | −0.33 | 0.11 | 0.55 |
| No CL vs. Nelfilcon A, −5.00 D | −0.62 | −0.18 | 0.26 |
| No CL vs. Nelfilcon A, +5.00 D | 0.18 | 0.62 | 1.06 |
| No CL vs. Narafilcon A, −0.50 D | −0.55 | −0.11 | 0.33 |
| No CL vs. Narafilcon A, −5.00 D | −0.58 | −0.14 | 0.30 |
| No CL vs. Narafilcon A, +5.00 D | −0.60 | −0.16 | 0.28 |

Confidence levels are 1-0.05/6, accounting for multiple comparisons (Bonferroni).

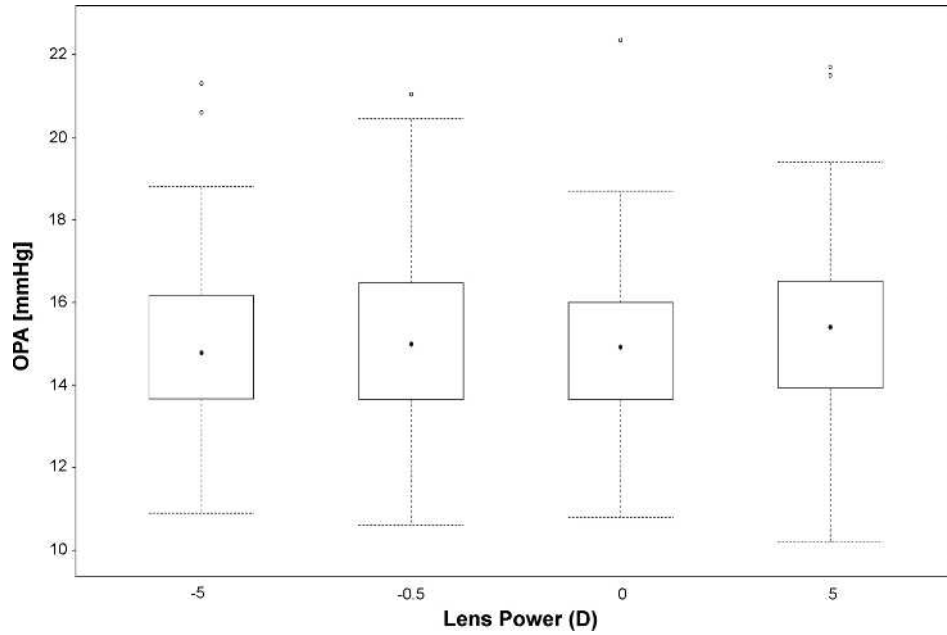


FIGURE 1.
Box plots representing IOP measurements for each lens power.

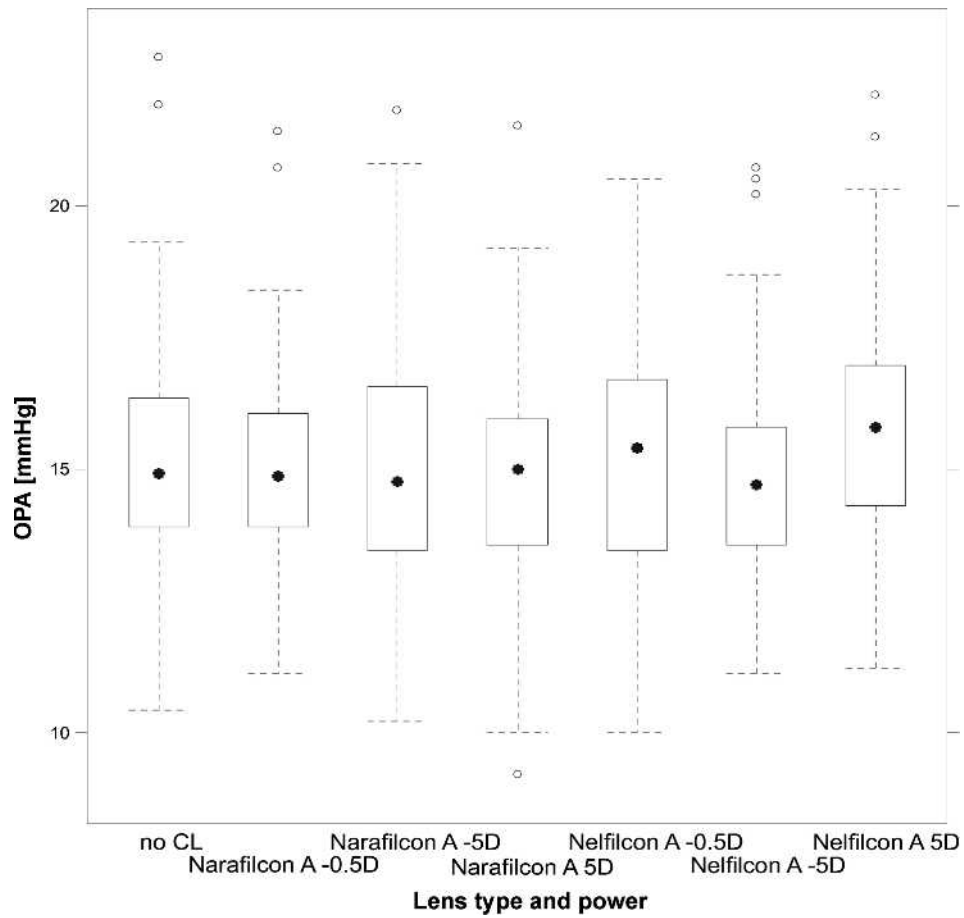


FIGURE 2.
Box plots representing IOP measurements dependent on lens power and CL material.

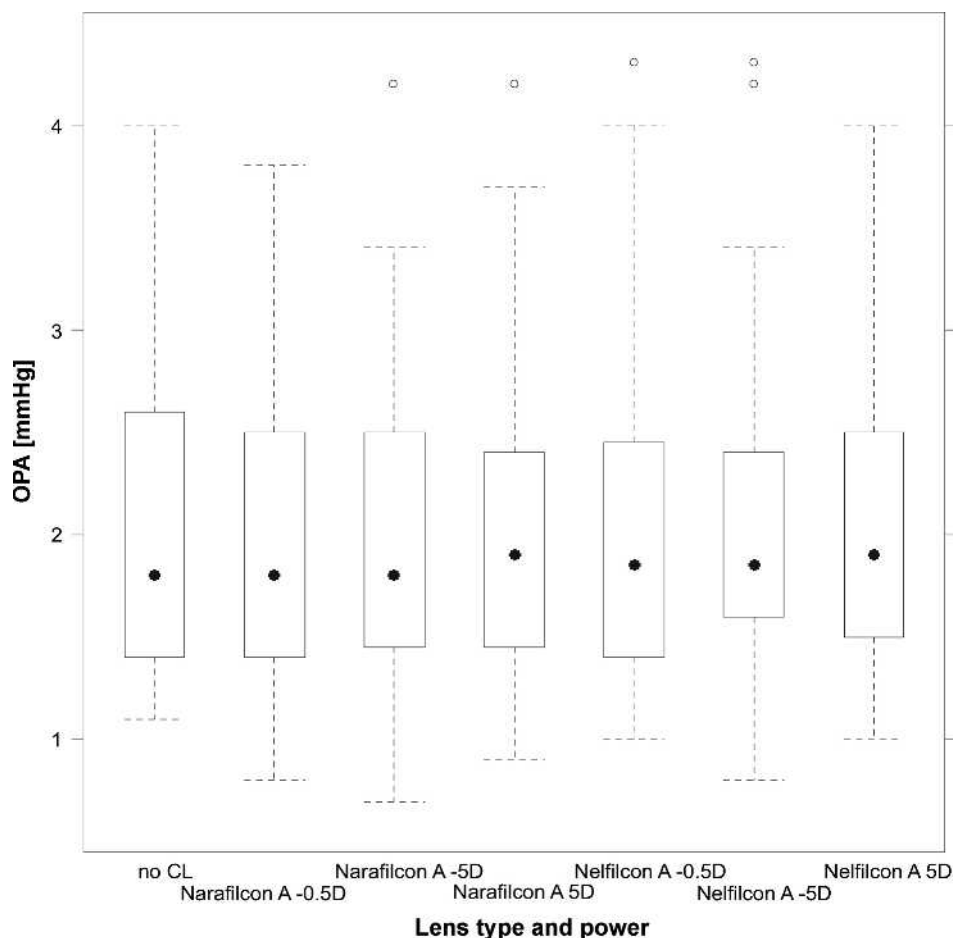


FIGURE 3.

Box plots representing OPA measurements dependent on lens power and CL material.

significant dependency of the OPA from the lens-type power-variable PLT ($F = 0$, $p = 1.000$) was obtained by the linear mixed-effects model.

DISCUSSION

For this study, the reliability of the DCT was evaluated when IOP and OPA measurements were carried out over CLs with various thickness profiles (different dioptric powers) and different soft materials (hydrogel and silicone hydrogel).

Our results showed that the reliability of IOP and OPA measurements over CLs with varying thickness profiles and different soft materials remained good. Only a small but statistically significant difference was found for the IOP measurement with the hydrogel CL of +5.00 D (Nelfilcon A). One possible explanation for this finding could be that the silicone hydrogel material may have provided the DCT sensor tip a more stable surface for its measurement because it has a higher elasticity modulus than the hydrogel material and consequently is stiffer. It is also possible that the hydrogel CL of +5.00 D had in fact a higher center thickness than its silicone hydrogel counterpart, which could have given rise to a higher IOP value in itself. However, this would also mean that the DCT's ability to measure independently of thickness would have to be questioned. Clearly, further studies are required to investigate this issue in more detail.

To cancel out any possible additional effects the topical anesthesia itself could have had on any IOP or OPA results, the instillation of oxybuprocaine was repeated every 15 minutes for the period during which DCT measurements were carried out for the purpose of this study. This means that if there was a bias caused by anesthesia, it would have been present in all measurements and therefore can be neglected as far as measurements with and without CLs are compared.

Interestingly, the mean values for OPA obtained in this study were lower than the expected 3 mm Hg, irrespective of the CL material or power or if a CL was worn at all. There has been some suggestion for a negative correlation between OPA and axial length,^{23–25} but unfortunately, the refractive status was not recorded for the subjects participating in this study. Hence, this finding could unfortunately not be further explored.

CONCLUSIONS

This study showed good reliability of IOP and OPA measurements over CLs with varying thickness profiles and different soft materials when using the DCT. No statistically significant difference was found for the IOP measurement when using daily disposable silicone hydrogel CLs of either power used in this study. A small but statistically significant difference of 0.62 mm Hg ($p = 0.0002$) however was noted when using the daily

disposable hydrogel CL of +5.00 D. Nevertheless, this difference would not be considered to be of clinical relevance. Regarding OPA, no significant difference was found for any power or material of any CL used for this study. In other words, in this study, OPA measurements were not affected by CL power or CL material.

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