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Measurement accuracy of a stressed contact lens during its relaxation period

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ABSTRACT

We examine the dioptric power and transmitted wavefront of a contact lens as it releases its handling stresses. Handling stresses are introduced as part of the contact lens loading process and are common across all contact lens measurement procedures and systems.

The latest advances in vision correction require tighter quality control during the manufacturing of the contact lenses. The optical power of contact lenses is one of the critical characteristics for users. Power measurements are conducted in the hydrated state, where the lens is resting inside a solution-filled glass cuvette. In a typical approach, the contact lens must be subject to long settling times prior to any measurements. Alternatively, multiple measurements must be averaged. Apart from potential operator dependency of such approach, it is extremely time-consuming, and therefore it precludes higher rates of testing.

Comprehensive knowledge about the settling process can be obtained by monitoring multiple parameters of the lens simultaneously. We have developed a system that combines co-aligned a Shack-Hartmann transmitted wavefront sensor and a time-domain low coherence interferometer to measure several optical and physical parameters (power, cylinder power, aberrations, center thickness, sagittal depth, and diameter) simultaneously. We monitor these parameters during the stress relaxation period and show correlations that can be used by manufacturers to devise methods for improved quality control procedures.

1. Introduction

A soft contact lens is a highly flexible object that can deform under minuscule forces.[1,2] When placed into a test chamber (a cuvette), a soft contact lens undergoes continuous changes as it comes to an equilibrium. These changes result in noticeable differences in the optical properties, such as optical power, cylinder and other aberrations. The incorrect assessment of contact lenses during their production due to these induced stresses may result in significant product release issues. Many of the stresses induced onto a contact lens when worn on the eye correlate to the effects present in the off-eye measurement proces.[3,4,5]

Source of stresses can be divided into stresses due to handling, and stresses due to the changing environment. Handling stresses include:

- Removal of the contact lens from its package, and its transport through the air using a cotton swab or fingers,
- Cleaning the lens, e.g. by rubbing the lens into the palm of a hand with a finger,
- Placing the contact lens into the measurement cuvette.

Inside the test chamber, the contact lens rests on the bottom surface, resembling an inverted bowl. Environmental stresses include:

- Thermal shock when the temperature of the test chamber is different from that of the package,
- Salinity shock, if the solution used in the test chamber is different from the packing solution,
- Gravitational force acting on the resting lens,
- Frictional force between the lens and the bottom glass surface, and
- Suction force between the bottom glass surface and the lens.

All of the listed sources of stress were induced or present throughout the testing processes in the data gathering phase of this paper. For some of the tests, certain stresses were minimized, such as salinity changes, and for other tests certain stresses were emphasized, such as the stress induced by the cleaning process.

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2. Methods

2.1 Testing and equipment

We have selected Nine soft contact lenses for three different manufacturers, Johnson & Johnson, Alcon, and Bausch + Lomb (Figure 1). In the rest of the article, lenses will only be identified by the numbers #1 through #9, assigned in a random fashion.

Figure 1: Test lenses

The test system consists of three coaxially aligned measurement modalities (Figure 2): a Shack-Hartmann wavefront sensor (SHWS), a vision camera, and a low coherence interferometer (LCI)[6]. This combined system employs two commercially available instruments, ClearWave and OptiGauge II, both manufactured by Lumetrics Inc. The integrated system has been assigned a working name of ClearWave Plus, and is used to measure the following parameters:

1. Optical power
2. Cylinder power
3. Spherical aberration
4. Other aberrations (e.g. coma, longitudinal spherical aberration)
5. Diameter
6. Center thickness
7. Sagittal height
8. Base curve (a calculation using diameter and sagittal height)[7]

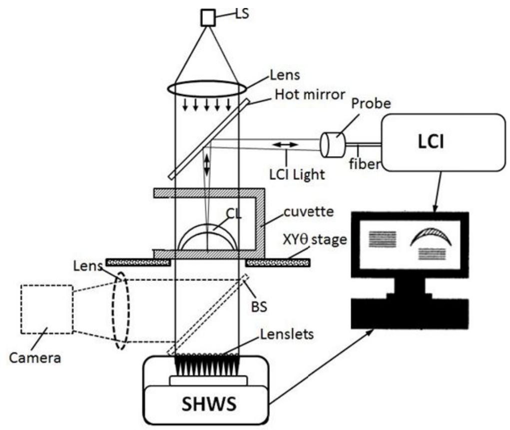


Figure 2: Measurement system layout

For each measurement, a contact lens is loaded into the test cuvette. The cuvette is then positioned into the test chamber. The alignment of the lens typically requires 10 to 20 seconds. If the alignment process takes longer than 90 seconds, the measurement is aborted and the lens is reloaded. Such a limitation is adopted to establish the same starting conditions for different lenses and measurements. After the alignment is completed, the measurements are conducted continuously every 1 minute for approximately 30 minutes.

2.2 Modeling

Modeling is used to determine whether changes in the physical lens parameters of the lens can explain changes in the measured optical properties of the soft contact lens. An idealized soft contact lens model was formed in Zemax modeling software, using spherical anterior and posterior surfaces. The refractive index of the contact lens is assumed to be homogeneous throughout the volume of the soft contact lens. Using the thick lens formula[8], the total lens power (P) is

$$P = \frac{n_l - n_m}{R_a} + \frac{n_m - n_l}{R_p} - t\frac{1}{n_l}\frac{n_l - n_m}{R_a}\frac{n_m - n_l}{R_p},$$

where R_a is the radius of curvature of the anterior surface, R_p is the radius of curvature of the posterior curvature, n_l is the refractive index of the lens material, n_m is the refractive index of the solution, and t is center thickness.

2.4 Monitoring threshold

In accordance with the standard quality control practice for clearing the contact lens for release, a stress level can be considered negligible if the corresponding changes in the optical and mechanical parameters are less than 1/10 of their respective tolerances[9].

3. Results

3.1 Measurement errors

To estimate the noise levels of the measurement system, a rigid contact lens was tested inside a dry cuvette. A rigid contact lens was significantly more stable and resistant to stresses than the soft contact lens, and therefore any errors due to the residual stresses in such a lens can be considered insignificant. In-air measurements also eliminate any uncertainties associated with the presence of solution and hydration. The measurement repeatability of the system is calculated as a standard deviation of 12 consecutive measurements. The lens remains stationary (unperturbed) between the measurements. Table 1 lists the averages and the corresponding repeatabilities for the measured parameters.

Table 1: Measurement system repeatability obtained by measuring rigid contact lens.

Parameter	Units	Average	St. dev. of 12 measurements
Sphere	Diopters	-2.199	0.0003
Cylinder	Diopters	-0.120	0.0003
Spherical aberration	µm	-0.176	9.9E-05
Center thickness	µm	399	0.061
Sagittal height	µm	3276	0.017
Diameter	mm	9.744	0.006

A second experiment is performed to show system noise for a soft contact lens in solution. Lens #9 was measured 12 times in quick succession and the standard deviation results are listed in Table 2. This type of test is called "push button repeatability", where quick consecutive measurements minimize contributions from any changes that may be occuring within the lens.

Table 2: "Push-button" repeatability of 12 measurements of Lens #9 in solution.

Parameter	Units	St. dev. of 12 measurements
Sphere	Diopters	0.005
Cylinder	Diopters	0.007
Spherical aberration	µm	0.010
Center thickness	µm	0.2
Sagittal height	µm	0.001
Diameter	mm	0.038
Base curve	mm	0.039

3.2 Cleaning stress variability

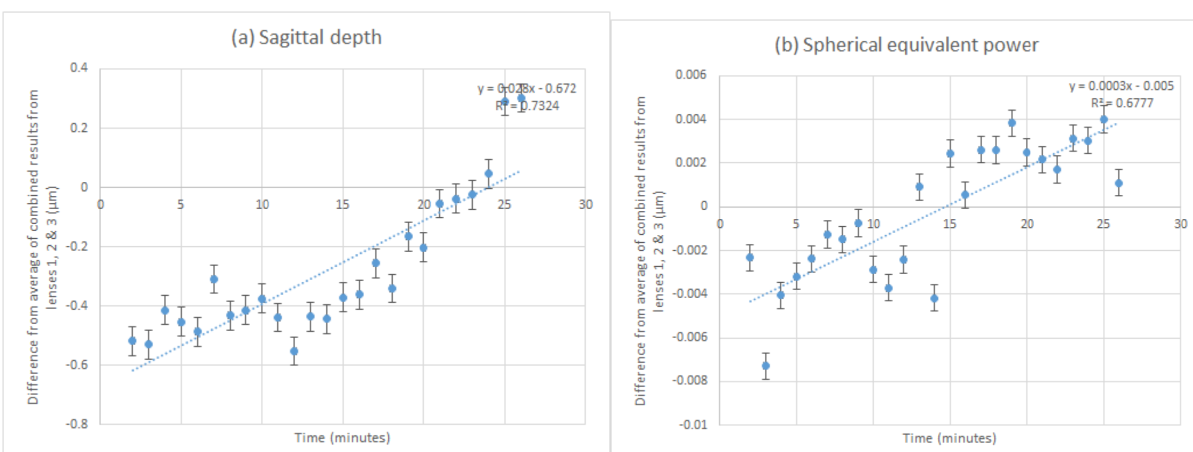
The test lenses were removed from their blister pack packaging and placed into capped glass vials. The capped glass vials were filled with Eye-Lotion buffered saline solution (BSS), part # CMH00074, lot RM15023. The same solution is used to fill the test cuvette during measurements. The lenses were soaked a minimum of 2 hours in the BSS prior to any testing. Each lens was hand cleaned by rubbing it between the operator's index finger and palm, rinsed, and placed into the measurement glass vial for each measurement. Table 3 lists the “remove and re-load” standard deviations for each of the measurement parameters for all the lenses.

Tabel 3: Standard deviations for key lens parameters, using 12 consecutive measurement cycles.

Lens	Sphere (Diopters)	Cylinder (Diopters)	Center thickness (mm)	Diameter (mm)	Sagittal height (µm)	Base curve (mm)
#1	0.045	0.031	0.0002	0.169	0.009	0.157
#2	0.063	0.047	0.0002	0.342	0.017	0.314
#3	0.110	0.062	0.0003	0.428	0.025	0.392
#4	0.057	0.034	0.0002	0.071	0.013	0.058
#5	0.059	0.052	0.0002	0.049	0.019	0.047
#6	0.054	0.039	0.0001	0.085	0.008	0.071
#7	0.032	0.024	0.0001	0.184	0.003	0.181
#8	0.014	0.028	0.0002	0.048	0.006	0.054
#9	0.018	0.021	0.0001	0.061	0.004	0.062

3.3 Stress release dynamics for soft contact lenses

For each measurement, a lens was cleaned using a jet of saline spray, then placed directly into the measurement cuvette. An automated reading was taken each minute for 25 to 35 minutes. The lens remained unperturbed during that time period. The readings from three lenses of the same model were averaged. The averaged plots are presented in Figures 3, 4, 5, & 6.



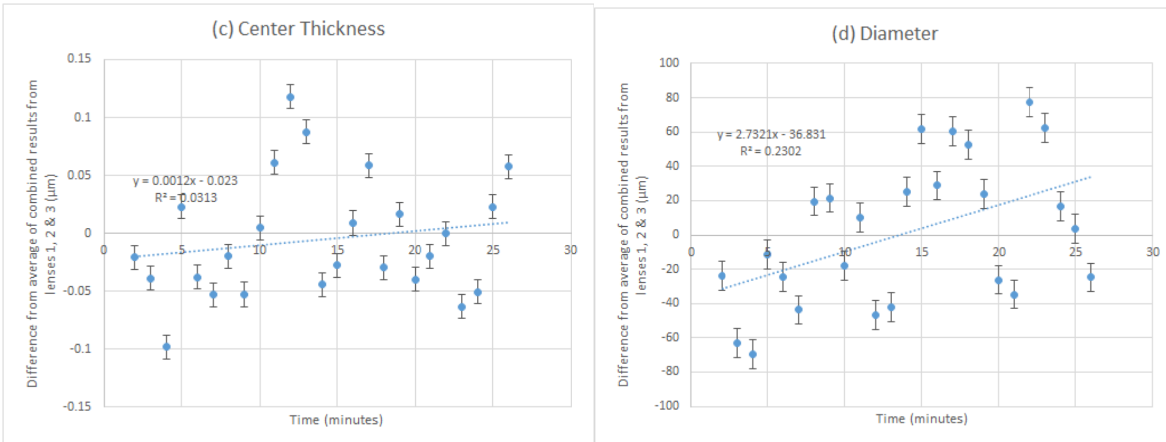


Figure 3: Plots of deviations from the average (a) sagittal depth, (b) SEQ, (c) CT , and (d) diameter for lenses #1 - #3 from the same manufacturer. Each plot shows the average of the measurements for the three lenses.

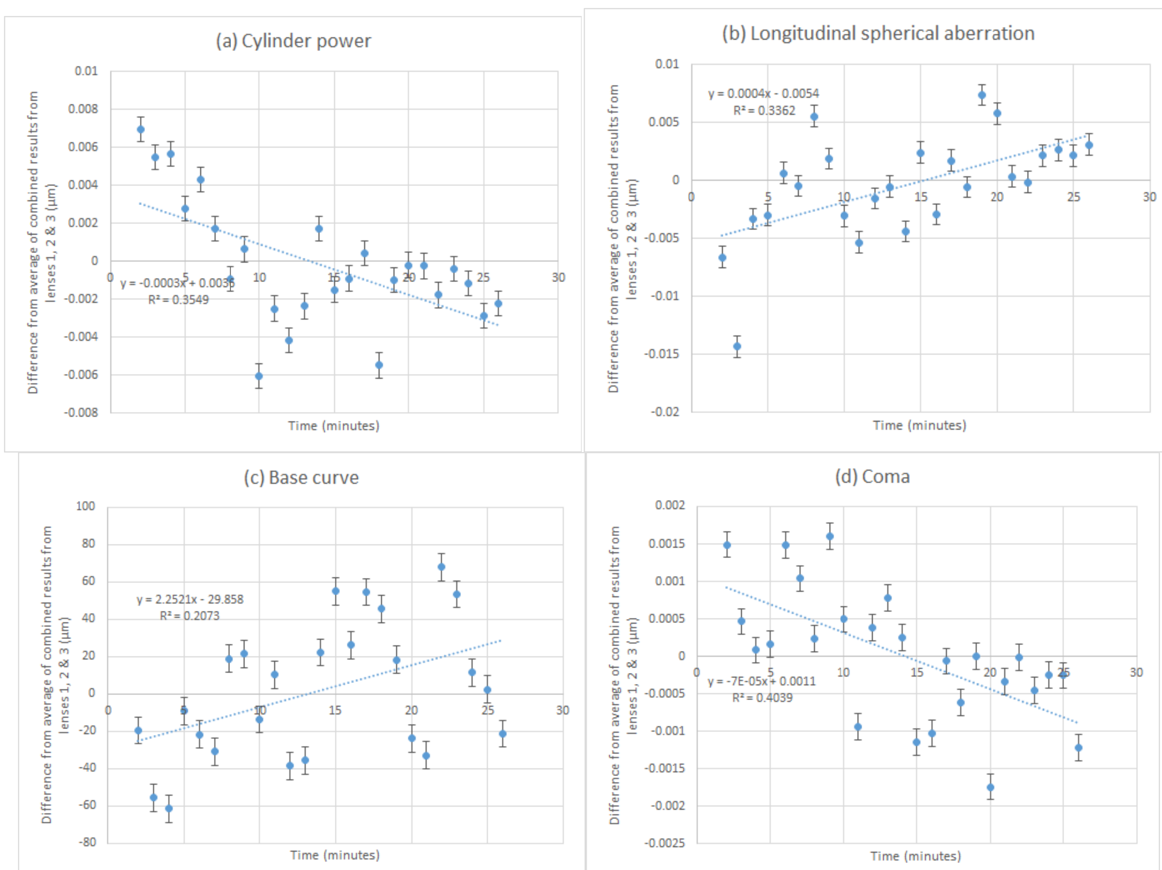


Figure 4: Plots of deviations from the average (a) cylinder power, (b) longitudinal spherical aberration, (c) base curve, and (d) coma for lenses #1 - #3 from the same manufacturer. Each plot shows the average of the measurements for the three lenses.

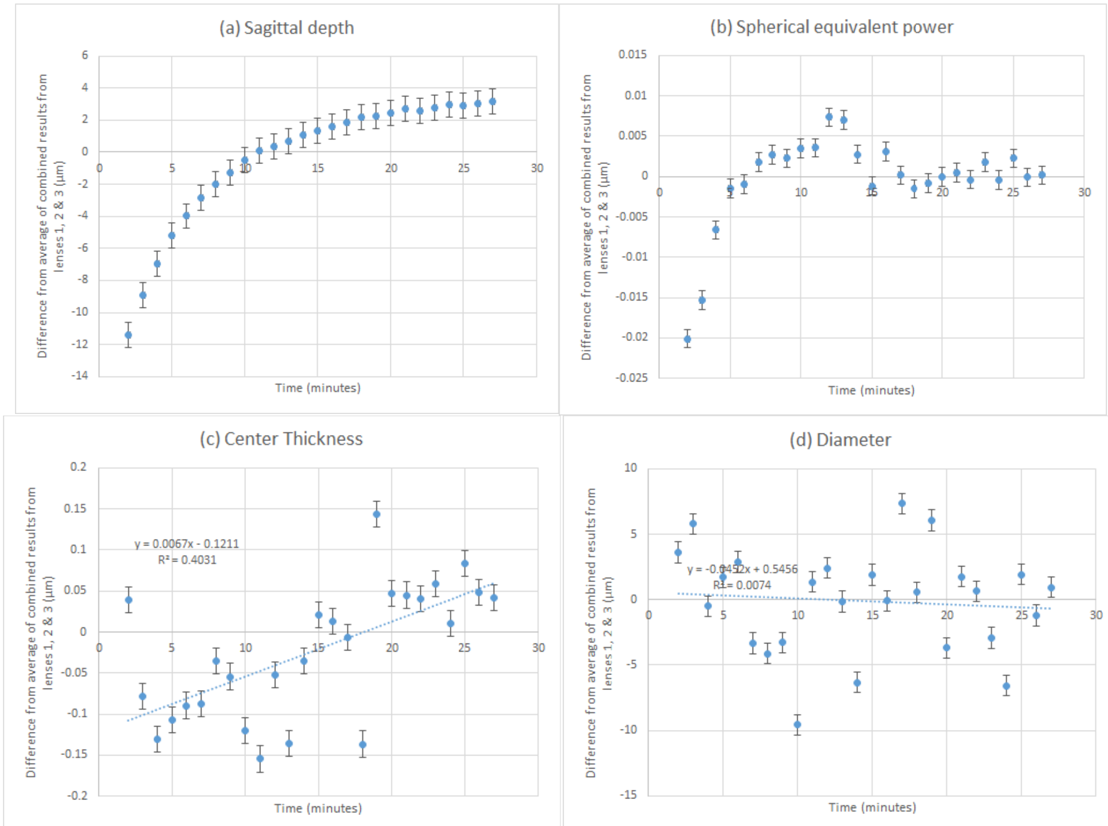


Figure 5: Plots of the deviations from average (a) sagittal depth, (b) SEQ, (c) CT, and (d) diameter for lenses #4 - #6 from the same manufacturer. Each plot shows the average of the measurements for the three lenses.

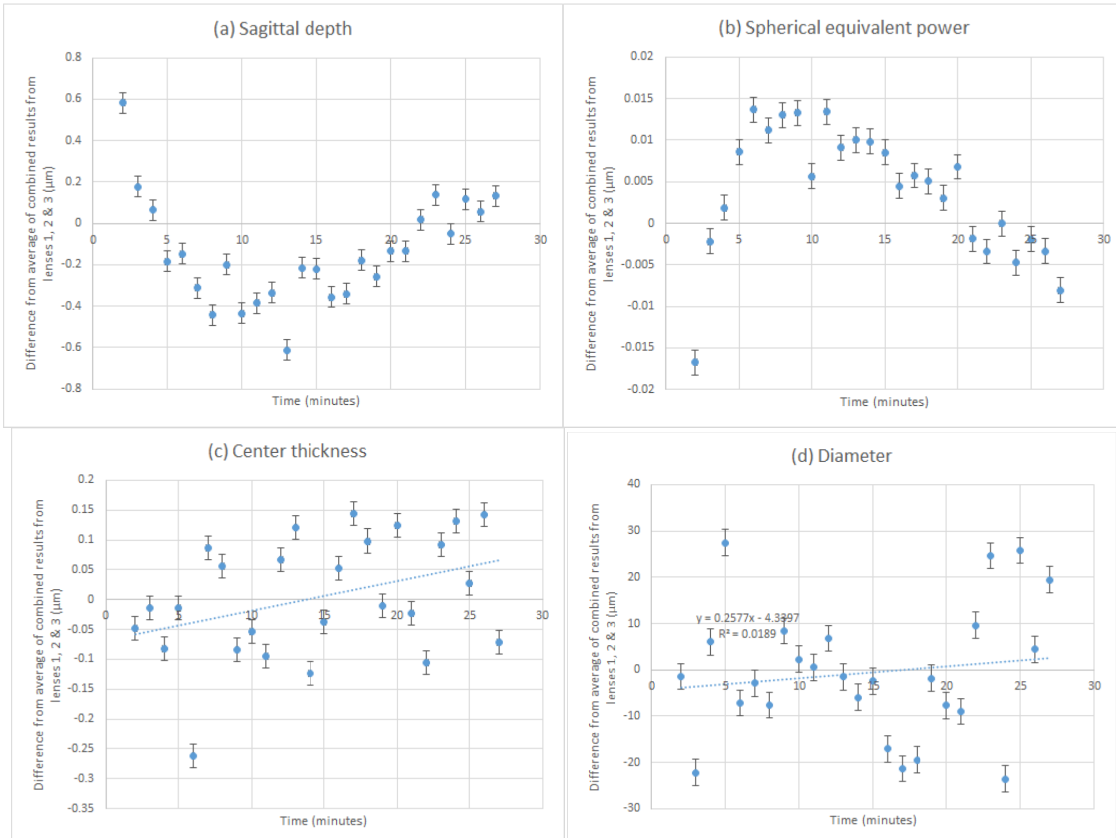


Figure 6: Plots of the deviations from the average (a) sagittal depth, (b) SEQ, (c) CT, and (d) diameter for lenses #7 - #9 from the same manufacturer. Each plot shows the average of the measurements for the three lenses.

Cylinder power, longitudinal spherical aberration, base curve, and coma are shown for lenses #1 - #3 only (Figure 4), but not for the remaining lenses, as the corresponding plots for the rest of the lenses were similar to the plots displayed in Figure 4.

3.4 Saline shock

One lens from each set was subjected to saline shock. We define saline shock as placing the lens into a measurement cuvette filled with DI water, after it has been stored in saline solution for more than 2 hours. The lens is then monitored (measured) over the time period of 25 - 35 minutes. This test is intended to subject these lenses to extreme environments in an effort to understand the effect of environmental stresses.

Figure 7 shows the change in lens #2's parameter as the lens acclimates to the DI water solution. Figure 8 shows the change in lens #8 as it acclimates to the DI water solution.

None of the lenses #4 - #6 could be measured in DI water because the saline shock resulted in a dramatic change to these lenses, where the lenses swelled in height to fill the measurement cuvette and their edges became jagged. Note, however, that contact lens behavior in DI water is not in any way an indication of its safety or efficacy. It is reasonable to conclude that lenses #4 - #6 are the most sensitive to saline changes, and therefore extra care should be taken when moving these lenses between different solutions.

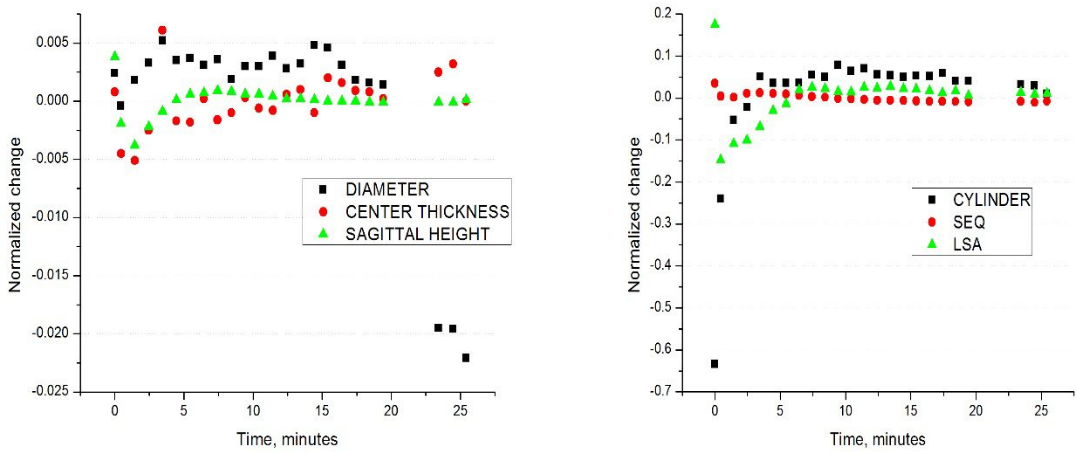


Figure 7: Lens #2 saline shock response

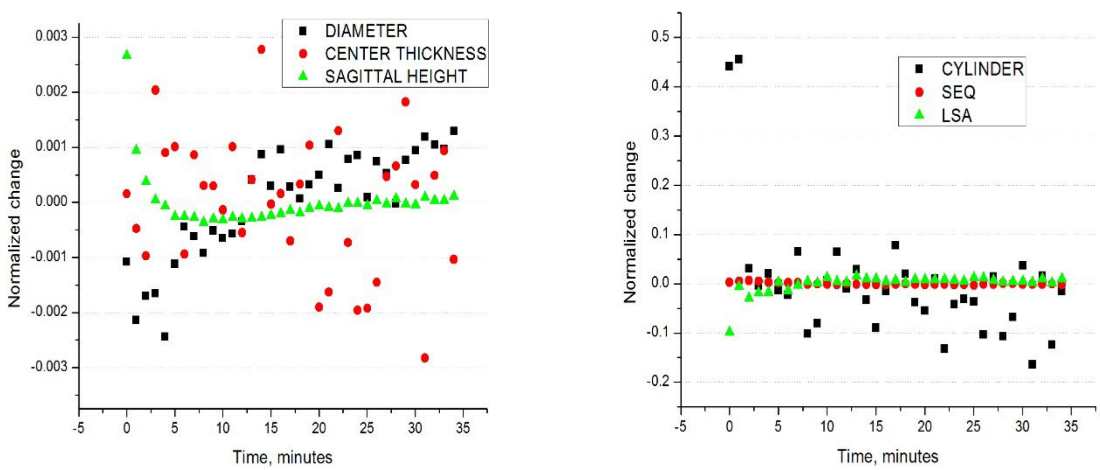


Figure 8: Lens #8 saline shock response

3.5 Thermal shock

Thermal shock is induced by soaking a lens in 35.5° ±1° C saline bath for a minimum of 1 minute and then placing it into the test cuvette held at a room temperature, 21° ±3° C. Figures 9, 10 and 11 show measured parameters for lenses #3, #5 and #7 respectively, after these lenses were subject to the thermal shock.

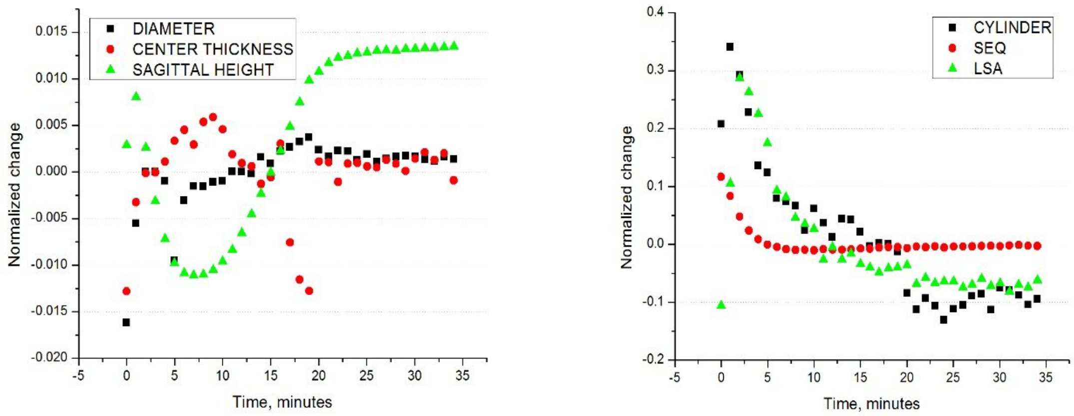


Figure 9: Lens #3's thermal shock response

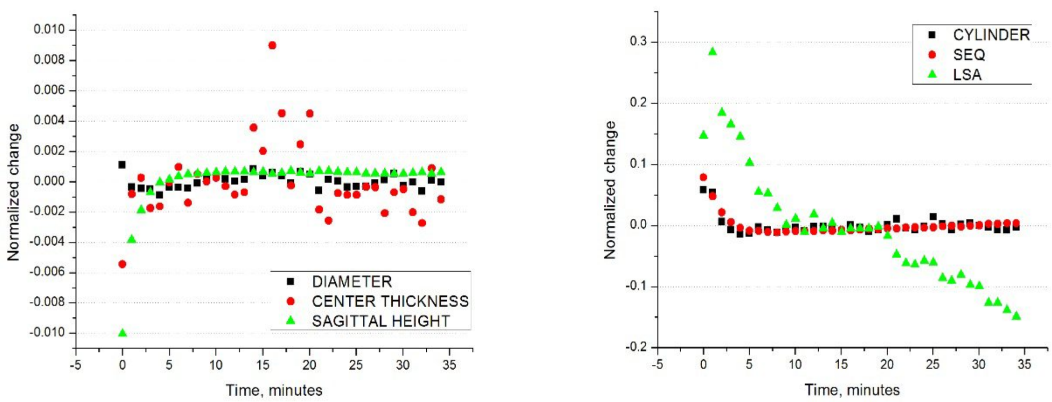


Figure 10: Lens #5's thermal shock response

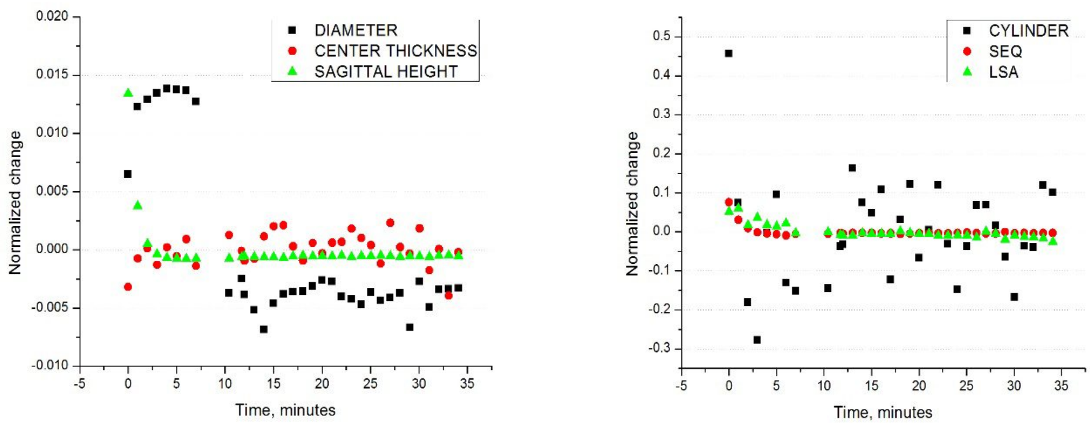


Figure 11: Lens #7's thermal shock response

4. Discussion

The first two graphs in Figures 3, 5 and 6 show the presence of a correlation between sagittal depth and spherical equivalent power for all three contact lenses. For lenses #1 - #6 the increase in the sagittal depth corresponds to the decrease in lens power (the lens has a negative power, therefore the positive change value corresponds to the weaker refractive power). For lenses #7 - #9 the increase in the sagittal depth corresponds to the increase in the lens' negative power. Lenses #1-#3 exhibit stress release dynamics linear with time. It also appears that the equilibrium for these lenses is not reached after 30 minutes. We have monitored and observed continuous changes in these lenses for longer periods of time (overnight). We believe that the changing environment (temperature, humidity, solution evaporation) resulted in the detectable continuous changes for this lens material.

The relaxation dynamics for lenses #4 - #9 is non-linear, showing different behavior at different periods of time, with changes slowing down toward the end of the measurement process.

In the case where the negative power of the lenses increases with the increasing sagittal depth, one can argue that the shape of the lens becomes steeper thus increasing its refractive power. This hypothesis can be quickly checked using the Zemax meniscus lens model. The model shows that 0.6% reduction in both the anterior and posterior radii of curvatures corresponds to the maximum observed change (0.025 diopters) in the refractive power of the soft contact lens. For 7.8 mm radius of curvature such reduction corresponds to 47 microns (7.8 vs 7.753 mm). This estimate is confirmed by observing similar changes in the base curve estimates (see Figure 4c).

However, the refractive power of the lens is primarily dependent on the thickness distribution along the meridian of the contact lens. If the thickness of the lens is also affected by the stresses, where, for example, the lens swells on the periphery slower than in the center, the refractive power of the lens may decrease even if the sagittal depth increases. Future work will involve measuring thickness profile along the lens meridian and therefore obtaining more accurate estimates of the power change due to the changing physical parameters of the lens.

It is also possible to argue that the measured power change is a measurement artifact due the shift of the apex of the lens away from the Shack-Hartmann sensor. However, the corresponding change in power would then be of the opposite direction than what's shown in Figure 5b, for example. In addition, Zemax analysis of the expected power change caused by such positional shift is nearly 100 times smaller than the corresponding spherical equivalent power change seen in Figure 5b.

Saline shock reveals the largest differences between the three manufacturers. For example, lenses #4 - #6 changed so dramatically when placed into DI water, that it became impossible to measure these lenses. Lenses #1 - #3 did not stabilize even 20 minutes after subject to the saline shock. Only lenses from one manufacturer (lenses #7 - #9) handles the saline shock relatively well, and stabilized around the 12 minute mark.

Thermal shock acts similar on all lenses from different manufacturers. No significant trends noted in the relaxation dynamics, and all lenses stabilized after 20 minutes. The only notable variation was in lens #7, where diameter change required the lens be recentered, resulting in the data acquisition gap; after recentering lens #7 was stable.

5. Conclusion

Obtained relaxation data demonstrates relationships between the measured parameters. These relationships may be used to formulate quantitative predictions about the lenses over time. Predictive relationships can be critical in the manufacturing process when developing statistical process controls. Using predictive relationship formulas could potentially reduce the time and expenses associated with the quality control procedures. Each manufacturer's materials have unique properties and respond very differently to the same stress stimulus. An individual approach is therefore required when developing such protocols.

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