POWER PROFILES: A SCLERAL MULTIFOCAL ANALYSIS

by

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ABSTRACT

Background: Scleral contact lenses have gained great popularity in the contact lens community. As more practitioners are using them, their uses are being expanded to include multifocal scleral lenses. Are these lenses reaching the full add power? How quickly from optical center does the power transition from the near to distance optics? What is the maximum positive power and where is this located from optical center? The purpose of this study is to analyze various scleral multifocal contact lens designs in two different distance powers, and to determine what the anterior surface power profiles of the lenses look like. *Methods*: Thirteen (13) different scleral multifocal contact lens designs (26 lenses total) were evaluated. Lens 19 was excluded due to breakage. Power measurements with varying distances from optical center were generated using the NIMO TR1504. Power profiles were obtained for all lenses as well as maximum plus power. *Results*: Due to the small number of lenses, no measurement results were significant. There were trends showing differences in the center to full distance power between myopic and hyperopic lenses. Other notable differences included: difference in zone sizes between lenses, power graduation from near to distance zone, and positioning of near optics. *Conclusion*: Depending on the lens design and distance power ordered, scleral multifocal lenses need to transition from near to distance power quickly enough so that proper optics can be presented in front of the pupil for clear visual acuity. This reinforces the importance of contact lens practitioners working in concert with their manufacturing laboratory to understand the lens design being worked with, as each design is different and may require different adjustments. A larger sample size is needed along with further investigation to ensure the accuracy of this type of analysis.

Acknowledgement Page

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CHAPTER 1

INTRODUCTION OF SCLERAL CONTACT LENSES AND THEIR IMPACT IN THE PRESBYOPIC PATIENT

Scleral contact lenses were the first contact lenses introduced in the late 1800s. ("History | Scleral Lens Education Society", 2017) These lenses were first made from blown glass, which caused corneal oxygen deprivation after short wear times. In the early 1900s, the introduction of moldable polymethylmethacrylate (PMMA) made the manufacturing of lenses less complex, but not easily reproducible. PMMA still lacked adequate levels of oxygen permeability, therefore, the problem of corneal edema persisted. Due to this problem and advancements of other contact lens modalities such as gas permeable corneal lenses and silicone hydrogel soft lenses, scleral lenses were not commonly used for years. The advent of high oxygen transmissible materials, changes in lens shape to vault the cornea instead of touch the surface, and advancements/discoveries for use of lenses to manage anterior segment ocular disorders has made lens mainstream again. Improvements in vision and comfort for keratoconus, severe dry eye, epithelial basement membrane dystrophy, and pellucid marginal dystrophy, when compared to soft or gas permeable lenses, have attributed to the lens's success.

With more research and familiarity of fitting scleral lenses, practitioners have expanded the scope of wear to include patients without surface disease. More recent yet, manufacturers have designed multifocal scleral lenses for the presbyopic patient. Designed with a concentric far-near optical distribution, the lenses are able to provide the presbyopic patient with clear distance and near vision.

It is typical for a scleral contact lens to decenter inferior temporally. (Rosen & Lotoczky, 2016) For the single vision patient, this typically presents little to no optical distortions or miscorrection. But for the presbyopic patient who is looking through a concentric design, this can pose a potential visual distortion or blur. Because the transition zone is decentered, it is likely presbyopic scleral lens wearer's visual complaints of blurred vision and/or distortion are due to the patient viewing at the transition of the lens.

The goal of this study is to analyze the multifocal scleral contact lens power profile. We want to see how quickly the power changes between the near and distance optics, in addition to locating where the maximum add power of the lens is located. Comparing the powers to the decentration of the lens can provide feedback for future multifocal scleral lens designs in hopes of alleviating the blur and distortion symptoms experienced by the presbyopic patient. Determining the maximum add power can provide feedback in determining the various lens power needed.

CHAPTER 2

METHODS

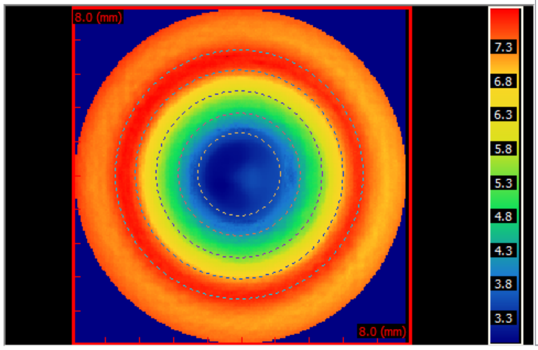
Thirteen (13) different commercially available scleral multifocal contact lens designs (26 lenses total) were evaluated from various manufacturers. Lenses were ordered based on manufacturer's suggested parameters, with the diameter ranging from 14.0mm to 18.0mm (depending on available design parameters). Each design was ordered in a -3.00D and a +3.00D distance power with a +2.00 add. Each manufacturer determined the optimal sagittal depth/base curve based on a 11.80mm horizontal visible iris diameter and keratometric readings of 7.85mm (43.00D) using their fitting guides. All lenses were fabricated in the suggested material for that particular design. Each test lens was then given a randomized number by a third party, so the instrument operators were unaware of the lens design. Lenses were evaluated for any damage, including chips and or breaks. Lens 19 was excluded due to breakage.

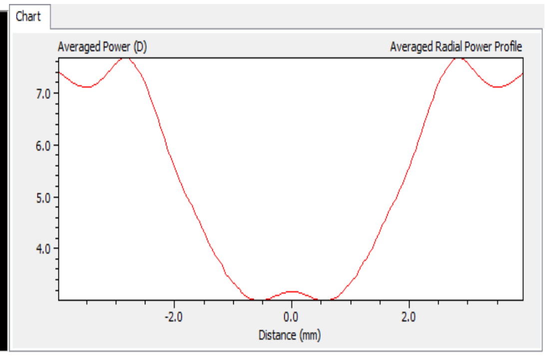
The lenses were cleaned prior to measurements with Boston Simplus® and stored in a dry contact lens case. The lens diameter was confirmed using a 7X contact lens magnifier to the nearest tenth of a millimeter. The base curve was confirmed with the American Optical radiuscope. The radiuscope was properly calibrated according to the manufacture instructions and the base curve measured to the nearest one hundredth of a millimeter. The center thickness was confirmed with a calibrated WO-600 Dial Contact Lens Thickness Gauge to the nearest one hundredth of a millimeter.

The NIMO TR1504 was used to determine the power of the lenses at various locations from the optical center. The NIMO TR1504 was calibrated according to manufacturer instructions. The index of refraction for the lens being measured, along with the center thickness, diameter and base curve were entered into the NIMO TR1504 software.

(Figure 1): NIMO TR1504 Contact Lens Mapper (Joannes, et al., 2015)

The aperture diameter of the lens area to be measured, optical zone diameter, was set at 8.00 mm for all lenses. A power map and a profile map of each lens was imaged.





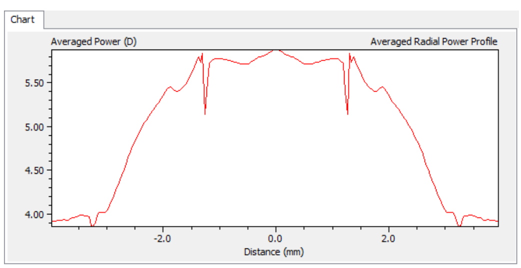
(Figure 2): Power map as captured for Lens 11 (Figure 3): Power profile map for Lens 11

Using the power map, the dioptric powers at optical center in addition to 1.00 mm, 1.50 mm, 2.00 mm, 2.50 mm, 3.00 mm, and 3.50 mm from optical center were recorded.

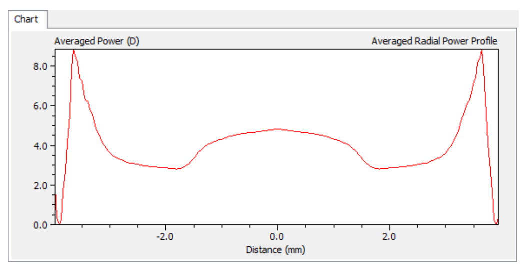
CHAPTER 3

RESULTS

The average power for the center two millimeters, the power at points from optical center, and maximum add powers of each lens are recorded in Table 1 for minus distance power lenses and Table 2 for plus distance power lenses. Results showed that although the ordered distance powers of the lenses were the same, measurements taken varied among the individual lens designs. For example, lens 13 and lens 25 are both center-near plus lenses, but they differ significantly in the location of full add power, as shown in Figures 4 and 5.

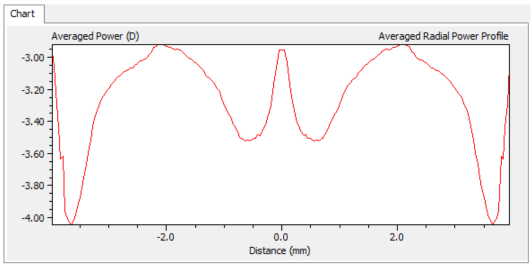


(Figure 4): Lens 13 Power Profile

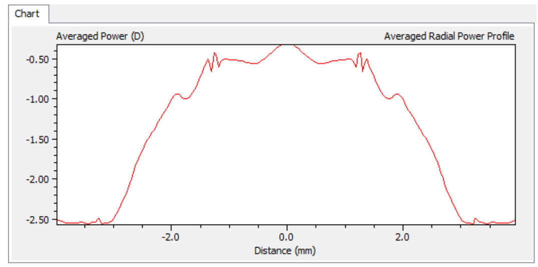


(Figure 5): Lens 25 Power Profile

Lens 13 reaches full distance power near the 2.00 mm from center point, but lens 25 does not reach it within the 8.00 mm measurement zone. Differences were apparent in the design, maximum power reached, and the distance from optical center at which the maximum plus powers were met. For example, lens 1 is center-distant and contains minimal add, while lens 16 is center-near and contains minimal distance power.



(Figure 6): Lens 1 Power Profile



(Figure 7): Lens 16 Power Profile

Sixty-four percent of the lenses studied were measured to be center-near. While most of the hyperopic lenses exceeded the full add power within the 8.00 mm zone, lenses 14 and 25 did not reach full add power. There were also two myopic lenses which did not reach full add power, lenses 1 and 21.

Minus Distance Power Lenses									
Lens	Distance PWR	Central 2.00 mm	1.00 mm	1.50 mm	2.00 mm	2.50 mm	3.00 mm	3.50 mm	Max Plus Power
1	-3.00	-3.43	-2.71	-2.78	-3.17	-3.22	-2.81	-2.68	-2.67
3	-3.00	-2.69	-2.58	-2.56	-1.96	-1.24	-1.17	-1.12	-1.01
5	-3.00	-1.18	-2.43	-3.07	-3.13	-3.20	-3.36	-3.57	-0.52
7	-3.00	-3.12	-2.99	-1.91	-0.94	+0.34	+0.18	-0.82	+0.52
10	-3.00	-2.92	-2.85	-2.51	-2.03	-1.33	-0.70	-0.67	-0.64
12	-3.00	-1.02	-1.41	-2.57	-2.95	-2.99	-3.11	-3.17	-0.50
15	-3.00	-0.83	-1.43	-2.95	-3.01	-3.08	-2.95	-2.90	+0.37
16	-3.00	-0.52	-0.53	-0.66	-0.95	-1.53	-2.49	-2.60	-0.32
18	-3.00	-1.04	-2.12	-2.97	-3.18	-3.31	-3.47	-3.66	-0.52
21	-3.00	-2.81	-2.89	-2.86	-2.48	-2.40	-2.13	-1.85	-1.48
22	-3.00	-0.98	-1.22	-2.23	-3.02	-3.13	-3.18	-3.21	-0.58
23	-3.00	-1.15	-1.11	-2.29	-3.30	-3.51	-3.41	+0.11	+2.41
26	-3.00	-1.31	-1.75	-2.68	-2.58	-2.78	-2.88	-3.19	-0.77

(Table 1): Power Readings at Distance from Optical Center and Maximum Plus Powers for Minus Distance Power Lenses

Plus Distance Power Lenses									
Lens	Distance PWR	Central 2.00 mm	1.00 mm	1.50 mm	2.00 mm	2.50 mm	3.00 mm	3.50 mm	Max Plus Power
2	+3.00	+4.72	+4.43	+2.90	+2.60	+2.66	+2.86	+2.99	+5.12
4	+3.00	+3.27	+3.22	+3.48	+4.41	+4.97	+5.63	+6.63	+7.52
6	+3.00	+4.51	+4.21	+3.34	+2.88	+3.08	+3.53	+4.00	+5.04
8	+3.00	+3.40	+3.49	+3.81	+4.71	+5.88	+6.27	+6.61	+6.61
9	+3.00	+4.74	+4.18	+3.31	+3.28	+3.64	+3.99	+4.19	+5.06
11	+3.00	+3.11	+3.22	+4.27	+5.39	+7.06	+7.57	+7.12	+7.69
13	+3.00	+5.75	+5.76	+5.48	+5.50	+4.90	+4.14	+4.07	+5.92
14	+3.00	+4.26	+4.02	+3.02	+2.80	+3.01	+3.40	+3.85	+4.76
17	+3.00	+4.78	+4.37	+3.44	+3.87	+3.94	+4.28	+4.66	+5.34
19	+3.00	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
20	+3.00	+3.15	+3.50	+3.81	+4.30	+4.92	+5.60	+5.62	+5.73
24	+3.00	+5.11	+4.301	+3.61	+3.78	+3.95	+4.13	+4.56	+5.64
25	+3.00	+4.55	+4.42	+3.26	+2.90	+3.13	+3.84	+1.56	+4.82

(Table 2): Power Readings at Distance from Optical Center and Maximum Plus Powers for Plus Distance Power Lenses

CHAPTER 4

DISCUSSION

Contact lenses have been a pivotal option providing optimal and comfortable vision for patients for many years. The introduction of soft and gas permeable lenses provided a reasonable and affordable visual solution for patients with normal ocular health seeking an alternative to spectacles. Over time, an increase in oxygen permeable materials have decreased corneal neovascularization associated with lens wear, cleaning regimens have reduced the risk of infection for contact lens patients, and lens designs have provided single vision patients with exemplary visual acuity.

The historical role of scleral lenses has been to provide improved vision and comfort for patients with compromised anterior segment structures, including corneal ectasias, and neurotrophic or exposure keratopathies. This is widely supported as Medicare recognizes scleral lenses as the only prosthetic devices approved for ocular surface disease. (Barnett & Messer, 2014) The pool of patients treated with scleral lenses continues to expand. Scleral lenses are now being used for patients with normal corneas, especially those whose refractive parameters are beyond those of traditional contact lens parameters. In addition to high myopia, hyperopia, and astigmatism, presbyopic patients, who are looking to correct their distance and near vision with contacts alone, are now able to benefit from multifocal scleral designs. Studies have shown that presbyopic patients often prefer to wear contact lenses instead of glasses in hopes of maintaining their youthful appearance. (Geerling, 2009)

Although soft contacts can offer a realistic and regularly achievable option for presbyopes, contact lens dropout continues to be a major obstacle to overcome. Dryness and discomfort are the main two reasons for dropout. Dryness occurs in 50-75% of contact lens wearers and leads to dropout in up to 24% of these patients. (Geerling, 2009) Due to the natural aging process, it is common for the spectacle and/or contact lens presbyopic patient to experience dry eye syndrome. In as much as 3.23 million women and 1.68 million men aged more than 50 years have moderate to severe dry eye with women being affected twice as much as men. (Geerling, 2009) The contact lens dropout also increases with age, likely due to the concurrent increase in dry eyes. Contact lens dropout increases around age 40 and significantly increases around age 42. Furthermore, visual satisfaction related to scleral lenses on normal corneas can cause dropout. (Rosen & Lotoczky, 2016) Unlike patients with anterior surface diseases or disorders, patients with normal corneas are accustomed to clear vision. Changes from minor displacement of optics of scleral lenses still improve quality of vision in life for patients with diseases, such as keratoconus. But these minimal changes can be highly noticeable in patients with normal corrective power and corneas, causing blur/strain.

Although improvements are continually being made to soft lenses, dry eye symptoms continue to burden patients and contact lens dropout rates continue to increase with age. In a study examining symptoms associated with severe dry eye and the introduction of Boston scleral lenses, patients reported the highest level of improvement in pain and quality of life with scleral lenses when compared to other lens modalities. Introducing multifocal scleral contact lenses offers a bridge to treat both presbyopia and dry eye simultaneously for the middle aged patient while maintaining their youthful appearance. (Jacobs & Rosenthal, 2007)

Multifocal sclerals have indeed resolved the presbyopic patients' simultaneous dry eye and hope to retain their youthful appearance problems. A new obstacle to overcome with these lenses focuses on the power profile design. Scleral lenses commonly displace inferior temporally. (Rosen & Lotoczky, 2016) With the common concentric distance-near design, the decentration can cause the transition zone from near to distance powers to be aligned with the visual axis. For the patient, this presents as symptoms of blur and distortion. It is understood that the blur is likely induced by the misalignment of the transition zones between near and far when compared to the center of the pupil. But how can the lens design be studied to offer improvements in design, and consequently, decrease in blur/distortion symptoms?

Our study was to analyze the power profiles of multifocal scleral contact lenses produced by various manufacturers. The NIMO TR1504 from Lambda-X provides contact lens manufacturers with an advanced and unique measurement technology that can enable clear understanding of power profiles to determine clinical functionality. (Joannes, et al., 2015) The instrument uses the Schlieren method phase-shifting principle to measure light beam deviation at up to 1000 x 1000 data points available to the camera. Without needing precise positioning of the lens, the NIMO TR1504 offers accuracy and reproducibility for rigid contact lenses with a standard deviation of 0.02D for sphere power and 0.026D for cylinder power, as determined by a ring test. (Joannes, et al., 2015)

The major point of interest for this study was the maximum add power of the lens and how far from optical center that point was reached. Presbyopia begins around 40 years old and continually increasing until stability is reached at approximately 60 years old. Optically, this process of change requires increases in add power as age increases. Typical add powers range from +0.75 diopters to +2.75 diopters. Variations of even +/- 0.25 diopters can cause strain for the patient or demand a different working distance. Therefore, if the maximal add of the lens is not accurate, the patient can experience visual dissatisfaction. As previously stated, patients with normal corneas and historically good vision can be more sensitive to minor and small dioptric differences. (Rosen & Lotoczky, 2016) Table 3 shows the maximal add and the point from optical center this is reached for center-near designs. Table 4 shows the maximal add and the point from optical center this is reached for center-distance designs. Excluding lens 23, due to outlying power readings, the range of maximum add power for the remaining center-near lenses is +1.756 to +3.367 diopters; a difference of +1.611 diopters. The range of dioptric variation for center-distance is +0.333 to +4.687; a difference of +4.354 diopters. For an emerging presbyope requiring a +0.75 diopter add, this widespread variation of +1.611 and +4.354 could significantly impact vision.

Understanding the power profiles of these lenses allows for a better understanding of the appropriate add power to order for the presbyopic patient when fitting with a multifocal scleral lens. On average, the maximum add power was +2.70 diopters for the plus lenses and +2.50 diopters for the minus lenses Taking this into consideration, if near vision is subjectively and/or objectively not to the expected level, practitioners can order an add approximately +0.25-+0.50 diopters weaker.

Lens	Maximum Add Power (diopters)	Distance from Optical Center (mm)
2	+2.12	0.293
5	+2.478	0.403
6	+2.042	0.000
9	+2.060	0.477
12	+2.500	0.110
13	+2.915	1.320
14	+1.756	0.183
15	+3.367	0.073
16	+2.678	0.037
17	+2.343	0.477
18	+2.483	0.403
22	+2.418	0.073
23	+9.214	3.888
24	+2.644	0.370
25	+1.822	0.073
26	+2.236	0.000

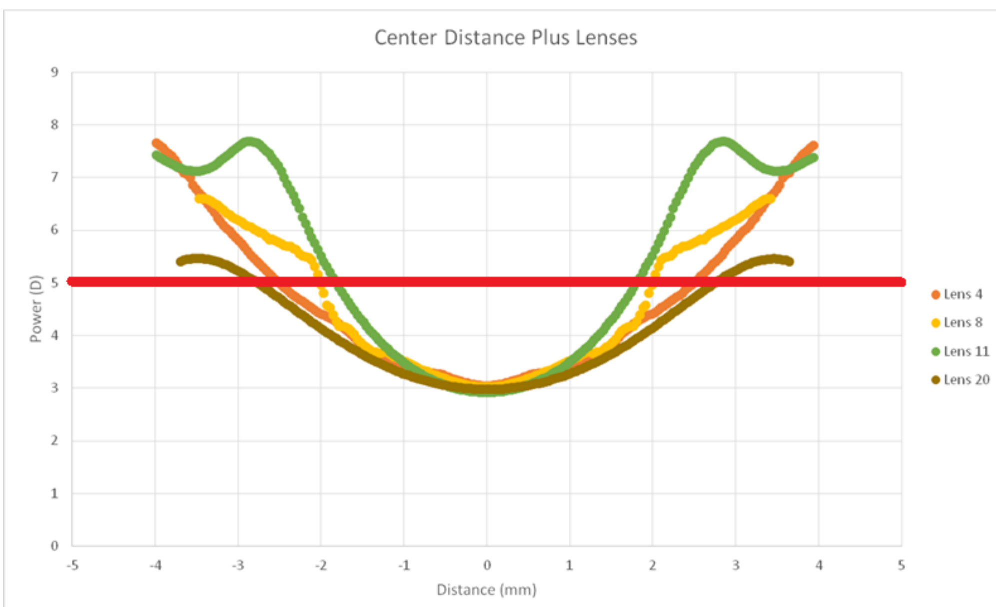
(Table 3): Maximum Add Power and Distance from Optical Center for Center- Near Lenses.

Lens	Maximum Add Power (diopters)	Distance from Optical Center (mm)
1	+0.333	1.650
3	+1.990	3.668
4	+4.190	3.961
7	+3.522	2.788
8	+3.606	3.485
10	+2.362	3.705
11	+4.687	2.898
20	+2.725	3.595
21	+1.518	3.961

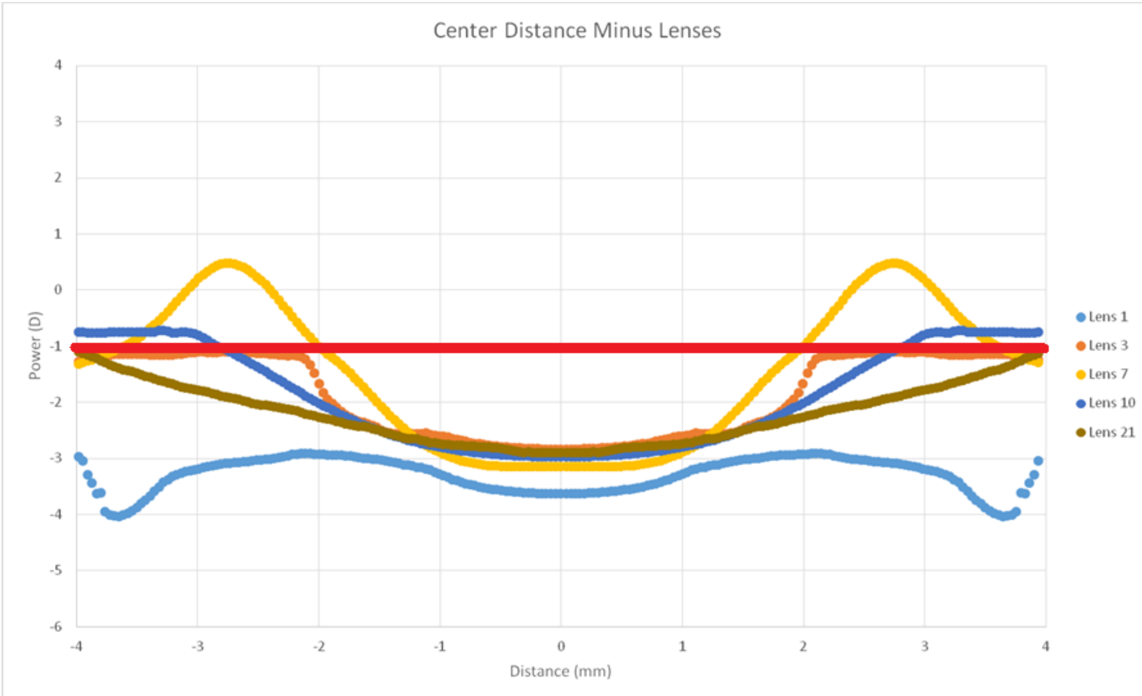
(Table 4): Maximum Add Power and Distance from Optical Center for Center- Distance Lenses.

Differences in power between transition zones can also affect patients' working distances and clarity of near vision. A study conducted by Frank Zheng analyzed soft multifocal contact lenses and the effects on objective and subjective vision. (Zheng, 2015) The focus of this study was to determine if the decentration commonly seen in soft lenses impacted vision. Overall, it was determined that horizontal decentration decreased vision both subjectively and objectively. The study also analyzed how increases in the add power changed vision. It was determined that any increase in add power changed both the subjective and objective vision, with an inconclusive effect on distance vision. This study looked specifically at soft contact lenses, which move on average 0.25-0.50 mm with blinks. (Zheng, 2015) The movement paired with the lens decentration likely contributed to decreases in vision both subjectively and objectively. Scleral lenses do not move on the eye like soft contact lenses, but their displacement can cause visual disturbances similar to conclusions by Zheng. For this reason, the power profiles of multifocal scleral lenses need to be evaluated.

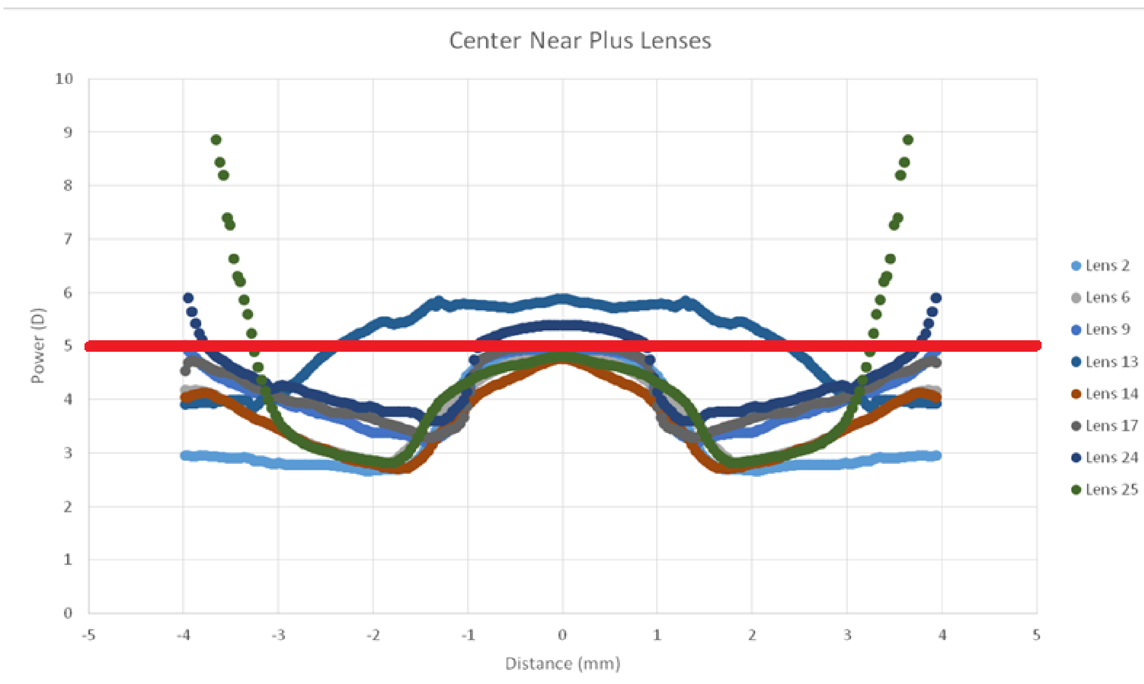
The following graphs demonstrate the power profiles of each lens, with the maximum add power indicated by the horizontal red line. Graphs 1 and 2 show the differences in powers as distance from the optical center increases for center-distance lenses; graphs 3 and 4 show the change in power as distance from the optical center increases for center-near lenses. The slope at which the power changes is variable between lenses, as demonstrated in Graphs 5 and 6, which show power profiles for all plus and minus lenses, respectively. This inconsistency between lenses could cause objective and subjective visual differences between lenses. To improve further, a study of vision objectively and subjectively needs to be performed with multifocal scleral contact lenses.



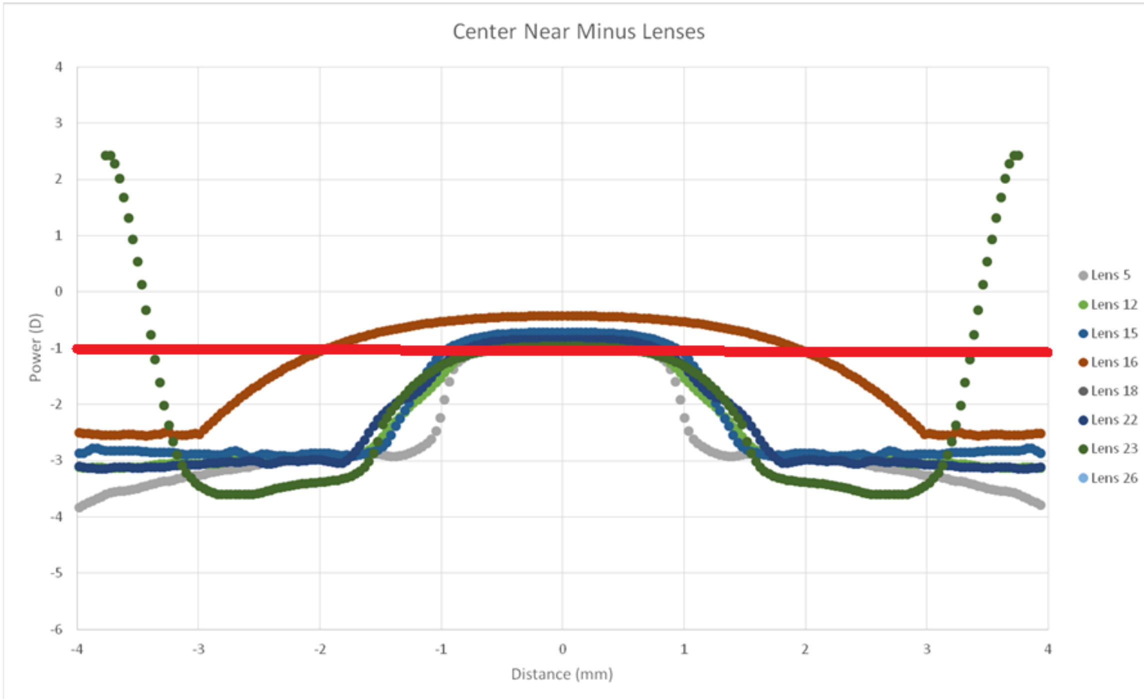
(Graph 1) Changes in Power for Plus Center-Distance Lenses as the Distance from Optical Center Increases



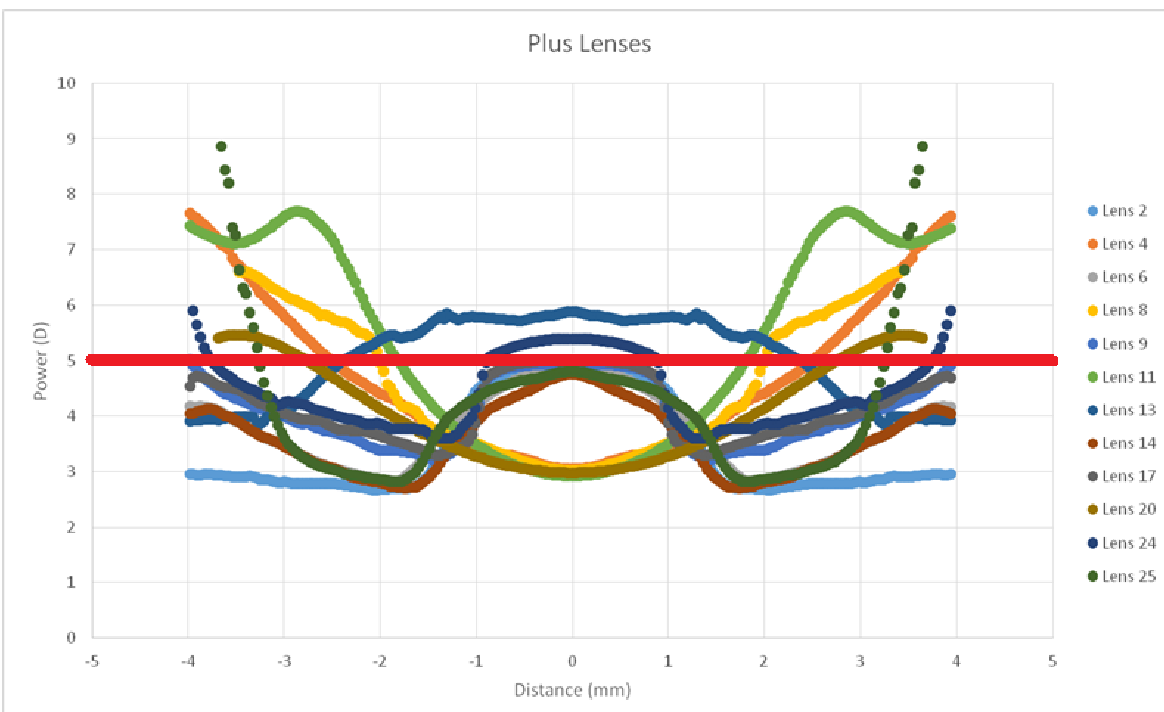
(Graph 2) Changes in Power for Minus Center-Distance Lenses as the Distance from Optical Center Increases.



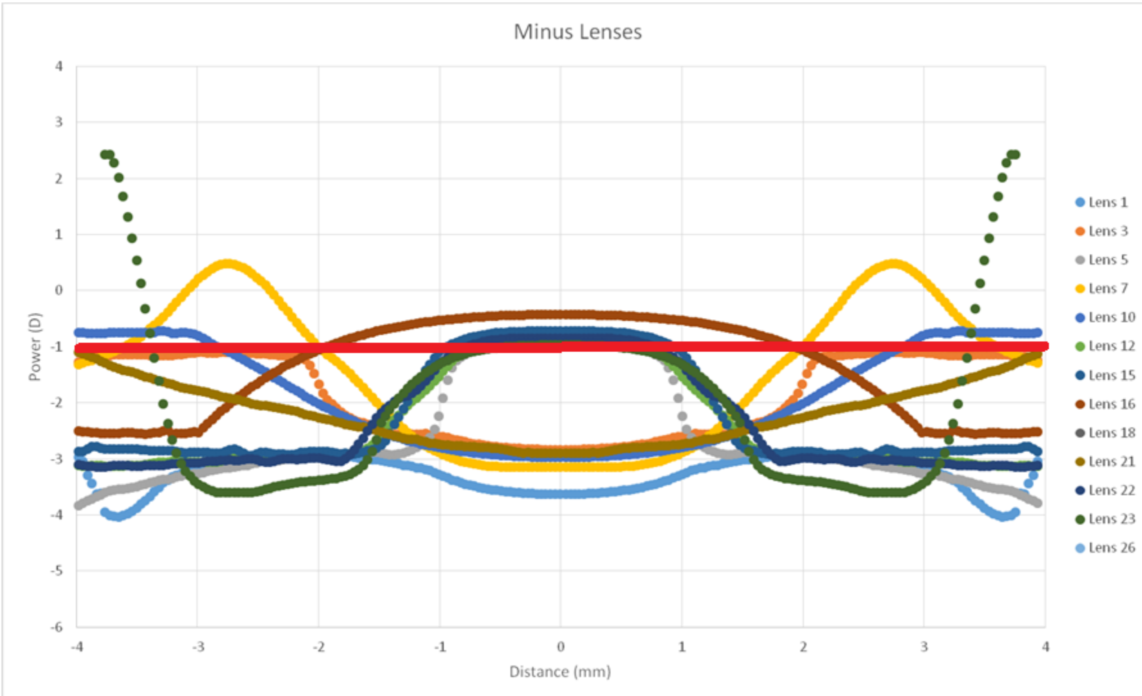
(Graph 3) Changes in Power for Plus Center-Near Lenses as the Distance from Optical Center Increases



(Graph 4) Changes in Power for Minus Center-Near Lenses as the Distance from Optical Center Increases



(Graph 5) Changes of Power for all Plus Lenses as distance from Optical Center Increases



(Graph 6) Changes of Power for all Minus Lenses as distance from Optical Center Increases

In conclusion, understanding the optics and power profiles of different designs of multifocal scleral lens can provide feedback to the manufacturers. Combined with measurements of consistent displacement of the lens on the eye, lens designs can be enhanced. The final goal would be to design a new lens with an accurate maximum add power in a position that coincides with the decentration of the lens to prevent blur and distortion while wearing the multifocal scleral contact lens.

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