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Standardized Rigid Contact Lens Fitting Protocol for Keratoconus

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ABSTRACT

Keratoconus is typically managed by a variety of rigid contact lens fitting techniques and lens designs. The two most fundamental fitting techniques are apical corneal touch (including divided or three-point touch) and apical clearance. In the course of designing a multi-center study of keratoconus patients, a standardized keratoconus fitting protocol was developed. All contact lens parameter options are uniform except for base curve and secondary curve radii, which are determined by interpretation of fluorescein patterns using the CLEK Study trial lens set and protocol. The initial trial lens's base curve is the average keratometric reading; sequentially steeper lenses are applied until definite apical clearance is observed. We have evaluated the feasibility of this standardized fitting protocol on 30 keratoconus patients. Our results suggest that we have developed a standardized contact lens fitting set and fitting protocol to simplify contact lens management in patients with mild to moderate keratoconus.

Key Words: contact lens fitting, cornea, keratoconus, RGP contact lens

Although several rigid contact lens fitting sets for the management of keratoconus have been proposed,[1–4] many practitioners prefer custom designed lenses[4–16] for their keratoconus patients. Custom designs are used because practitioners believe that the unique corneal topography of each keratoconus patient's cornea requires an individually "tailored" lens. Unfortunately, this has resulted in a marked lack of standardization in the contact lens management of keratoconus. Each practitioner believes that his or her fitting method and lens design are the best, and many contact lens fittings are conducted primarily on a "trial-and-error" basis. Little effort has been devoted to the design and implementation of rigid lenses that could be uniformly applied in keratoconus.

In the course of designing a multi-center study of keratoconus, a standardized rigid contact lens fitting set was developed and tested in a number of centers. The fitting set is used to manage mild and moderate keratoconus patients and can be

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readily incorporated into a private practice setting.

Even though most researchers and clinicians reject the theory that rigid contact lenses should be prescribed to retard the progression of keratoconus,[16] patients are generally fitted with rigid gas permeable (RGP) contact lenses in order to provide a regular optical surface to enhance vision. Hydrogel contact lenses[17–21] or spectacles can be prescribed when corneal distortion is minimal and adequate visual acuity is achievable with a subjective refraction. Occasionally, soft toric contact lenses[22] can be prescribed for patients with mild presentations of the disease. Piggyback designs,[23–26] in which a rigid contact lens is fitted over a soft contact lens, are occasionally prescribed when apical corneal erosions develop chronically. Rigid-soft hybrid lenses[27] may be prescribed when there is difficulty in achieving suitable RGP lens positioning or comfort.

The major techniques for fitting rigid lenses in keratoconus, as described by Korb et al.,[1] are: (1) flat,[9] with primary lens support on the apex of the cornea, where the central optic zone of the lens actually touches or "bears on" the central corneal epithelium; (2) divided support, or "three-point touch," with lens support and bearing shared between the corneal apex and the paracentral cornea; and (3) steep,[15] with lens support and bearing directed off the apex and onto the paracentral cornea, with clearance (vaulting) of the apex of the cornea.

Controversy exists as to whether rigid contact lenses have an effect on disease progression and/or severity in keratoconus. Korb et al.[1] reported in 1982 that four of seven eyes wearing large (9.5 mm in diameter) flat rigid contact lenses developed corneal scarring within 1 year, whereas no scarring developed in the seven eyes fitted with the clearance method. Despite these results, the CLEK Screening Study of almost 1600 keratoconus patients found that 75% were fitted with apical touch;[28] i.e., practitioners continue to manage keratoconus patients with flat-fitting rigid lenses. We believe practitioners doubt whether a comfortable apical clearance fit with good vision can be achieved and maintained.

Recently, Caroline[29] has advocated fitting a lid attachment[30] rigid design for keratoconus. Using corneal topography mapping data, the lens is fitted to position superiorly on the flatter "non-affected" portion of the keratoconus cornea. This method has raised concerns regarding the possibility of hastening the progression and complications of the disease by mechanical means.

The purpose of this paper is to present a standardized keratoconus diagnostic lens set and fitting method. An efficient and easy to follow fitting protocol using an inexpensive, yet clinically complete, diagnostic lens set is proposed. The pilot study conducted and reported on in the paper supports this method's clinical usefulness.

METHODS

Thirty keratoconus patients were enrolled into a CLEK pilot study conducted at six clinical sites (Bethesda Eye Institute, St. Louis, MO; University of California, Davis, Department of Ophthalmology, Sacramento, CA; University of Illinois-Chicago, Department of Ophthalmology, Chicago, IL; The Ohio State University, College of Optometry, Columbus, OH; Southern California College of Optometry, Fullerton, CA; and State University of New York, State College of Optometry, New York, NY). Eligibility criteria for an eye's inclusion in the study were: (1) presence of an irregular corneal surface documented by keratometry, retinoscopy, or direct ophthalmoscopy; (2) presence of Vogt's striae or Fleischer's ring in at least one eye; (3) no corneal scar on the eligible eye(s); (4) 20/63 (6/18.9) or better Snellen visual acuity with manifest refraction; and (5) signed informed consent from the patient. Patients were not enrolled if they presented with an ocular disease that would interfere with vision or rigid contact lens wear. Seventeen patients (30 eyes) were randomized into an apical clearance fitting relation (base curve radius 0.2 mm steeper than the first apical clearance diagnostic lens), and 13 (23 eyes) were randomized into apical touch (base curve radius 0.4 mm flatter than the first apical clearance diagnostic lens).

CLEK Diagnostic Lens Design

Parameters for the CLEK diagnostic keratoconus fitting set were determined as follows.

1. Base curve radii were selected to encompass the corneal sagittal heights for mild to moderate keratoconus patients. Increments of 0.05 mm were chosen to increase the fitting sensitivity.

2. Contact lens powers were chosen to provide low minus over-refractions for most of the mild to moderate keratoconus patients.

3. The overall diameter was set at 8.6 mm to provide an interpalpebral fit in which the lens positions over the apex of the conical area of the cornea.

4. The optic zone diameter was standardized at 6.5 mm to minimize areas of tear pooling and debris accumulation under the optic zone of the lens.

5. The secondary curve radius ranged from 8.00 to 8.25 mm in order to obtain average peripheral clearance. Corneal curvatures beyond the cone are similar to corneal curvatures of nonkeratoconus patients.[31] Therefore, secondary curve radii appropriate for nonkeratoconus RGP contact lens fitting are indicated.

6. The peripheral or third curve radius for the tricurve fitting lenses was set at 11.00 mm with a width of 0.2 mm. This curve was selected not only to be a fitting curve, but also to start the posterior edge treatment.

7. Center thicknesses were calculated such that an edge thickness of approximately 0.10 mm was maintained for each trial lens. Center thicknesses are greater than for cosmetic RGP lenses of similar power because of the flatter secondary curve to base curve relation.

8. Diagnostic lenses were fabricated in polymethyl methacrylate (PMMA) material. PMMA was chosen because of its machinability, dimensional stability, durability, and low cost.

However, we actually ordered low Dk fluorosilicone acrylate contact lenses for the patients.

CLEK Study Protocol for Contact Lens Fitting

The contact lens practitioner determined the mean or average keratometry reading, converted it to radius in millimeters, and referred to Table 1 for selection of the initial trial lens from the CLEK Study diagnostic contact lens set.

For example:

Keratometry readings:	48.50/51.50 at 115
Average keratometry value:	50.00 D = 6.75 mm
Select initial trial lens	no. 23

The initial trial lens was applied to the subject's eye and allowed to settle for 10 min before analysis of the fluorescein pattern.

If the initial trial lens was judged to be flat (Fig. 1), the next higher numbered (steeper) trial lens was applied to the eye for fluorescein pattern evaluation. This procedure was repeated until a definite apical clearance pattern (Fig. 2) was achieved. Therefore, the endpoint of the contact lens fitting procedure was the flattest lens in the trial lens set that exhibited a definite apical clearance fluorescein pattern such that the sagittal depth of the base curve chord diameter was greater than the sagittal depth of the cornea for the same chord diameter. The base curve radius of this lens was referred to as the "First Definite Apical Clearance Lens."

If the initial trial lens was judged to be steep centrally, the next lower numbered (flatter) trial lens in Table 1 was applied to the cornea for fluorescein pattern evaluation. This procedure was repeated until a definite apical touch or three-point touch was achieved.

RESULTS

Thirty keratoconus patients provided informed consent and were entered into the CLEK pilot study. The patients were randomized into either an apical clearance or apical touch fit using the standardized lens design. Table 2 shows the flat

TABLE 1. CLEK Study keratoconus diagnostic lens set.[a]

Lens No.	Inside Sagittal Depth Under Optic Zone (mm)	Base Curve Radius in mm (D)	Power (D)	Overall Diameter/Optic Zone Diameter (mm)	Secondary Curve Radius (mm)
1	0.704	7.85 (42.99)	−3.00	8.6/6.5	8.25
2	0.709	7.80 (43.27)	−4.00	8.6/6.5	8.25
3	0.714	7.75 (43.55)	−3.00	8.6/6.5	8.25
4	0.719	7.70 (43.83)	−4.00	8.6/6.5	8.25
5	0.725	7.65 (44.12)	−3.00	8.6/6.5	8.25
6	0.730	7.60 (44.41)	−4.00	8.6/6.5	8.25
7	0.735	7.55 (44.70)	−5.00	8.6/6.5	8.25
8	0.741	7.50 (45.00)	−4.00	8.6/6.5	8.25
9	0.746	7.45 (45.30)	−5.00	8.6/6.5	8.25
10	0.752	7.40 (45.61)	−6.00	8.6/6.5	8.25
11	0.757	7.35 (45.92)	−4.00	8.6/6.5	8.25
12	0.763	7.30 (46.23)	−5.00	8.6/6.5	8.25
13	0.769	7.25 (46.55)	−6.00	8.6/6.5	8.25
14	0.775	7.20 (46.87)	−5.00	8.6/6.5	8.25
15	0.781	7.15 (47.20)	−6.00	8.6/6.5	8.25
16	0.787	7.10 (47.54)	−7.00	8.6/6.5	8.25
17	0.794	7.05 (47.87)	−5.00	8.6/6.5	8.25
18	0.800	7.00 (48.21)	−6.00	8.6/6.5	8.25
19	0.807	6.95 (48.56)	−7.00	8.6/6.5	8.25
20	0.813	6.90 (48.91)	−6.00	8.6/6.5	8.25
21	0.820	6.85 (49.27)	−7.00	8.6/6.5	8.25
22	0.827	6.80 (49.63)	−8.00	8.6/6.5	8.25
23	0.834	6.75 (50.00)	−6.00	8.6/6.5	8.25
24	0.842	6.70 (50.37)	−7.00	8.6/6.5	8.25
25	0.848	6.65 (50.75)	−8.00	8.6/6.5	8.25
26	0.856	6.60 (51.14)	−6.00	8.6/6.5	8.00
27	0.865	6.55 (51.53)	−7.00	8.6/6.5	8.00
28	0.870	6.50 (51.92)	−8.00	8.6/6.5	8.00
29	0.879	6.45 (52.33)	−7.00	8.6/6.5	8.00
30	0.886	6.40 (52.73)	−8.00	8.6/6.5	8.00
31	0.895	6.35 (53.15)	−9.00	8.6/6.5	8.00
32	0.903	6.30 (53.57)	−7.00	8.6/6.5	8.00

[a] All diagnostic contact lenses are PMMA with a third curve radius of 11.00 mm and a third curve width of 0.2 mm. The lenses are lightly blended, and the center thickness is 0.13 mm.

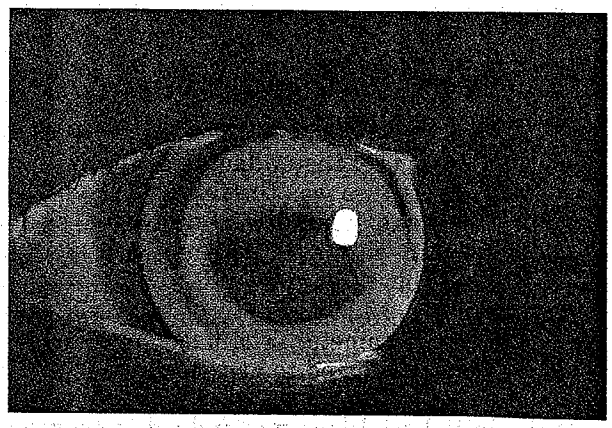

Figure 1. Apical touch fluorescein pattern.

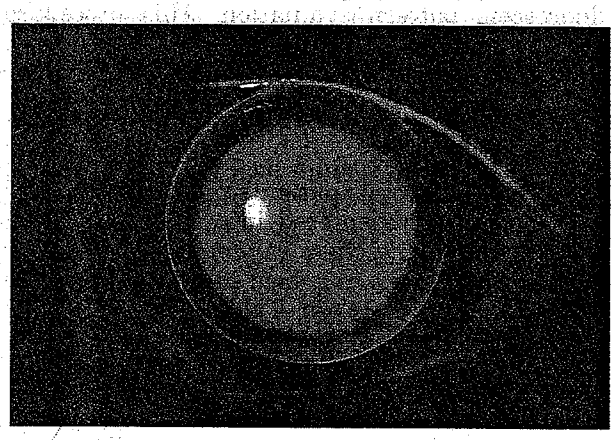

Figure 2. Definite apical clearance fluorescein pattern.

and steep keratometric readings and base curve of the First Definite Apical Clearance Lens for each eye of the enrolled patients. The mean visual acuity for the pilot study subjects randomized into apical clearance fits was equivalent to those of the subjects randomized into the apical touch fits. The mean daily wearing time was 14 h (range 2 to 20 h) for the apical clearance subjects and 13 h (range 4 to 17 h) for the apical touch subjects. Only 3 of the 30 eyes randomized into the apical clearance fit required refitting in order to maintain the apical clearance relation.

Eighteen eyes required refitting during the pilot study period. The most common reasons for this were (four lenses because of each reason): (1) to change the lens power and (2) to steepen the peripheral curves. Three lenses required refitting because of an incorrect initial fit compared to the randomized assignment—the lens being either too steep or too flat originally. In three cases, the lenses were refitted because of the initial lenses becoming too flat. Two of these eyes were randomized to flat fitting, and one eye was randomized to a steep fit. Two lenses were redesigned with larger optic zone diameters as a result of patient-reported symptoms of flare. Finally, two lenses were reordered to solve patient reports of discomfort.

Several contact lenses required modification during the pilot randomization study. The most frequent change (eight lenses) was an adjustment in the secondary or peripheral radii of curvature.

TABLE 2. Keratometric readings and base curve of First Definite Apical Clearance Lens for enrolled subjects.

Subject No.	Eye	Flat/Steep Keratometry Reading	Base Curve of First Definite Apical Clearance Lens in mm (D)
1	OD	45.00/47.50	6.60 (51.14)
	OS	48.50/49.25	6.30 (53.57)
2	OD	41.00/46.50	6.75 (50.00)
	OS	37.50/41.00	8.15 (41.41)
3	OD	42.75/47.50	6.89 (48.98)
	OS	43.75/48.50	6.82 (49.49)
4	OD	43.62/44.25	7.55 (44.70)
	OS	43.25/48.12	7.18 (47.01)
5	OD	46.12/49.00	6.89 (48.98)
	OS	Ineligible eye	
6	OD	Ineligible eye	
	OS	43.37/48.50	5.74 (58.80)
7	OD	46.25/48.12	7.03 (48.01)
	OS	47.25/52.25	6.62 (50.98)
8	OD	Grafted eye	
	OS	50.00/52.50	6.55 (51.53)
9	OD	47.75/48.50	6.82 (49.49)
	OS	49.00/49.25	6.62 (50.98)
10	OD	45.25/46.75	7.26 (46.49)
	OS	45.37/46.25	7.26 (46.49)
11	OD	46.37/50.00	7.05 (47.87)
	OS	47.50/53.25	7.00 (48.21)
12	OD	45.50/52.50	7.20 (46.87)
	OS	41.62/42.37	8.00 (42.19)
13	OD	42.12/51.37	7.00 (48.21)
	OS	43.87/48.37	7.25 (46.55)
14	OD	44.12/46.75	7.00 (48.21)
	OS	44.00/50.00	6.80 (49.63)
15	OD	45.50/48.50	7.35 (45.92)
	OS	43.50/46.75	7.65 (44.12)
16	OD	53.00/57.50	6.51 (51.84)
	OS	51.50/54.00	6.69 (50.45)
17	OD	52.25/59.25	6.51 (51.84)
	OS	47.25/50.50	7.35 (45.92)
18	OD	44.75/49.50	7.04 (47.94)
	OS	Ineligible eye	
19	OD	47.25/50.37	6.75 (50.00)
	OS	45.75/50.25	6.85 (49.27)
20	OD	50.50/52.50	6.70 (50.37)
	OS	48.50/52.00	6.80 (49.63)
21	OD	45.25/46.25	7.25 (46.55)
	OS	45.25/48.25	7.05 (47.87)
22	OD	48.25/52.25	6.55 (51.53)
	OS	43.00/48.00	7.10 (47.54)
23	OD	Ineligible eye	
	OS	43.00/47.00	7.50 (45.00)
24	OD	49.00/50.00	6.62 (50.98)
	OS	44.00/50.25	6.68 (50.52)
25	OD	45.00/45.25	7.03 (48.01)
	OS	47.00/51.25	6.75 (50.00)
26	OD	53.25/63.00	5.81 (58.09)
	OS	44.00/49.75	7.03 (48.01)
27	OD	47.25/47.37	6.75 (50.00)
	OS	46.75/48.12	6.62 (50.98)
28	OD	48.50/52.00	6.63 (50.90)
	OS	47.87/49.62	6.66 (50.68)
29	OD	50.00/57.00	6.30 (53.57)
	OS	Ineligible eye	
30	OD	Grafted eye	
	OS	49.75/51.50	6.65 (50.75)

Four lens edges were modified to improve patient comfort. Heavier blends were applied to three lenses, and three lenses were modified to change the power. Two lenses were made smaller through modification and, in one case, a patient had a spare pair of contact lenses modified.

There were 76 unscheduled visits in addition to the visits for routine follow-up care. This means that on average each enrolled patient presented 2.5 times for unscheduled office visits. Table 3 summarizes the reasons for these unscheduled visits by frequency of occurrence.

The contact lens practitioners at the 6 clinical sites evaluated the acceptability and ease of the fitting protocol using the CLEK Study diagnostic contact lenses and rated the fitting set as an 8 (range 7 to 9) on a scale from 1 to 10 with 10 being excellent. In addition to the 30 pilot subjects, the contact lens practitioners reported at that time that they had fitted a total of 142 eyes of 78 nonstudy patients using the CLEK Study trial contact lens fitting set.

In order to establish a more efficient initial diagnostic lens starting point, base curve radii for minimal apical clearance were compared to measured keratometric readings. The mean flat keratometry reading for the CLEK pilot study subjects was 46.18 D (SD = 3.14 D) and the mean steep keratometry reading was 49.74 D (SD = 3.81 D). The mean base curve radius for minimal apical clearance was 48.94 D (SD = 7.68 D).

DISCUSSION

The purposes of using our keratoconus fitting technique are to: (1) achieve a base curve/cornea relation in which the sagittal depth of the contact lens base curve equals or slightly exceeds the sagittal depth of the cornea under the optic zone area, (2) minimize the area of tear/debris pooling underneath the optic zone area, and (3) allow an adequate exchange of tears.

The keratoconus cornea, like the normal cornea, is aspheric. This might lead one to propose that the first goal could best be achieved by designing a rigid contact lens fitting set with aspheric posterior curves.[11, 32–36] Aspheric base curve lenses were not selected because of the inherent difficulties encountered with their fabrication and analysis.

TABLE 3. CLEK pilot study unscheduled visits.

Reason for Unscheduled Visit	No. of Visits
Blurry vision	23
Lost lens	19
Lens awareness	6
Spectacle blur	4
Lens dispensing	3
Progress check	3
Broken lens	3
Refit	2
Lens warpage	2
Presbyopia	2
Rescheduled appointment	2
Surgery consultation	2
Abrasion	2
Ocular trauma	1
Foreign body removal	1
Iritis	1

Even though the CLEK Study trial lens set simplifies keratoconus contact lens fitting, in-office modifications are still necessary to optimize corneal physiology and patient satisfaction. The most frequent lens modification during the CLEK pilot study was an adjustment of the secondary or peripheral curve radii. A too "tight" peripheral curve system can lead to lens binding and decreased tear exchange. This usually leads to symptoms of reduced wearing time for the keratoconus patient.

Steep or clearance fitting diagnostic keratoconus lenses should be allowed to "settle" on the cornea for 10 to 20 minutes before final assessment of apical fit. It has been observed and reported that a trial lens initially assessed as steep will, after several minutes, appear flat. This is probably the result of the malleability of the keratoconic cornea.

The dispensed lens material should be gas-permeable and durable enough to withstand in-office lens modification. For purposes of the CLEK pilot study we avoided the use of RGP contact lenses with a UV radiation blocker because it may decrease the practitioner's ability to observe and photograph fluorescein patterns.

Recommended Alterations to the CLEK Study Diagnostic Lens Set for Implementation in a Private Practice Setting

Base curve radii could be ordered in approximately 0.10 mm increments for mild keratoconus patients and 0.15 mm increments for moderate keratoconus patients. However, radii should be expanded to include steeper base curves (in approximately 0.20 mm increments) to manage more advanced keratoconus patients.

Larger optic zone diameters, such as 7.0 mm, are recommended for the flatter diagnostic lenses used to manage mild cases of keratoconus. Smaller optic zone diameters, such as 5.5 to 6.0 mm, are recommended for the steeper diagnostic lenses used for advanced cases of keratoconus.

Table 4 is a suggested keratoconus diagnostic lens set for use in a private practice setting, and Table 5 compares this new CLEK Study diagnostic set to existing trial lens fitting sets suitable for keratoconus.

Recommended Alterations to the CLEK Study Fitting Protocol for Implementation in a Private Practice Setting

Larger base curve radii fitting increments (0.10 to 0.20 mm) should be used to obtain the endpoint fit for moderate and advanced keratoconus patients. Bracketing using these larger intervals

TABLE 4. CLEK Study recommended keratoconus diagnostic lens set for use in a private practice setting.

Base Curve in mm (D)	Power (D)	Overall Diameter (mm)/Optic Zone Diameter (mm)	Secondary Curve Radius (mm)	Third Curve Radius (mm)/ Width (mm)	Center Thickness (mm)
7.18 (47.00)	−5.00	8.6/7.0	8.25	11.00/0.20	0.14
7.03 (48.00)	−5.00	8.6/7.0	8.25	11.00/0.20	0.14
6.89 (49.00)	−5.00	8.6/7.0	8.25	11.00/0.20	0.14
6.75 (50.00)	−5.00	8.6/6.5	8.25	11.00/0.20	0.14
6.62 (51.00)	−7.00	8.6/6.5	8.25	11.00/0.20	0.14
6.49 (52.00)	−7.00	8.6/6.5	8.25	11.00/0.20	0.14
6.37 (53.00)	−7.00	8.6/6.5	8.25	11.00/0.20	0.14
6.25 (54.00)	−7.00	8.6/6.5	8.25	11.00/0.20	0.14
6.03 (56.00)	−9.00	8.6/6.0	8.00	11.00/0.20	0.14
5.82 (58.00)	−9.00	8.6/6.0	8.00	11.00/0.20	0.14
5.53 (61.00)	−10.00	8.6/5.5	8.00	11.00/0.20	0.14
5.19 (65.00)	−12.00	8.6/5.5	8.00	11.00/0.20	0.14
4.82 (70.00)	−15.00	8.6/5.5	8.00	11.00/0.20	0.14

TABLE 5. Keratoconus trial set specifications.

Design	Diameter (mm)	Posterior Optic Zone Diameter (mm)	Peripheral Curve Systems for 6.00 mm Base Curve
McGuire	8.6	6.0	53 D/0.30
			47 D/0.30
			39 D/0.30
			29 D/0.40
McGuire	Oval 8.6	6.0	53 D/0.30
	Nipple 8.1	5.5	47 D/0.30
			39 D/0.30
			29 D/0.40
Korb	8.0	5.8	8.3
			9.5/0.50
			10.5/0.20
			(blend with 7.0-mm radius)
Burger	8.0	5.8	8.0/0.60
			10.0/0.40
			(blend with 8.0-mm radius)
CLEK	8.6	6.5	8.25/0.85
			11.0/0.20

will save the practitioner chair time during the fitting process.

CONCLUSIONS

In preparation for a multi-center study of keratoconus patients, a standardized rigid contact lens trial fitting set and fitting protocol were developed and tested. Both steep and flat apical fittings were achieved and maintained with this standardized keratoconus lens design and fitting protocol. Lens design modification may be necessary to fit the wide variety of corneal topographies that are encountered in managing keratoconus patients.

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