POLYMACON HYDROPHILIC

CONTACT LENSES

PRACTITIONER FITTING GUIDE

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IMPORTANT

This fitting guide has been developed to provide practitioners with information covering characteristics of the CooperVision, Inc. polymacon hydrophilic contact lens and to illustrate fitting procedures. Please read carefully and keep this information for future use.

INTRODUCTION:

CooperVision, Inc. contact lenses are for use in one of two lens wear programs, in which practitioners prescribe a Scheduled Replacement Program or a Disposable Wear Program.

In the Scheduled Replacement Program, the lens wearing time is prescribed by the practitioner from 1 to 7 days/6 nights. Each time the lens needs to be removed before the replacement time period has elapsed; the lens must be cleaned and disinfected prior to replacing it back on the eye. The eye care practitioner is encouraged to determine a lens replacement schedule based upon the response of the patient.

In the Disposable Wear Program, the lens wearing time is prescribed by the practitioner from 1 to 7 days/6 nights. Patients are instructed to dispose of the lens at each removal and to use lens care products only on an emergency basis.

The practitioner decides which program is appropriate, recommends a replacement schedule for the patient and provides either the Scheduled Replacement Patient Information Booklet or the Disposable Patient Instruction Booklet.

MATERIAL:

The CooperVision, Inc. polymacon contact lens consists of 2-hydroxyethyl methacrylate cross linked with ethyleneglycol dimethacrylate (62%) and water (38%). The material has a refractive index of 1.43. The CooperVision, Inc. polymacon contact lens has a visible light transmittance of approximately 90% to 98%, depending on tint type.

DESIGN:

All CooperVision polymacon contact lenses are available as spherical lenses. These lenses are hemispherical flexible shells of the following dimensions:

AVAILABLE LENS PARAMETERS

Chord Diameter	12.5 mm to 18.0 mm
Center Thickness	0.03 mm to 1.0 mm depending on power
Inside Spherical Radius	6.5mm to 10.8mm
Sphere Powers	+20.00 D to -20.00 D (daily wear) Plano to -10.00 D (extended wear)
Refractive Index:	1.43
Surface Character:	Hydrophilic
Water Content	38%
Oxygen Permeability (Dk)*:	8.4×10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg) at 35°C
Light Transmittance:	90% to 98% depending on tint type

*Method for determination is the Fatt Method.

INDICATIONS:

Daily Wear: CooperVision, Inc. polymacon contact lenses are indicated for the correction of visual acuity in non-aphakic persons with nondiseased eyes that are myopic or hyperopic and may exhibit astigmatism of 1.50 diopters or less that does not interfere with visual acuity.

Extended Wear: CooperVision, Inc. polymacon contact lenses are indicated for the correction of visual acuity in non-aphakic persons with nondiseased eyes that are myopic or hyperopic and may exhibit astigmatism of 1.50 diopters or less that does not interfere with visual acuity.

The lenses may be prescribed for either daily wear or extended wear from 1 to 7 days between removals for disposal in the Disposable Lens Program or cleaning and disinfection in the Schedule Replacement Program, as recommended by the eye care practitioner (See the WARNNINGS section of the Package Insert which is found at the end of this Fitting Guide with reference to the relationship between the lens wearing schedule and corneal complications.)

PATIENT SELECTION:

Persons who require only vision correction and who would not or could not adhere to a recommended regimen or are unable to place and remove the lenses should not be provided with them. Failure to follow handing and wearing instructions could lead to serious eye infections which might result in corneal ulcers.

Patient communication is vital because it relates not only to patient selection but also to ensuring patient compliance. It is also necessary to discuss the information contained in the Patient Information booklet with the patient at the time of the initial examination and to provide a copy of the Patient Information Booklet to patients.

Patients selected to wear CooperVision, Inc. contact lenses should be chosen for their motivation to wear contact lenses, general health and cooperation. The eye care practitioner must take care in selecting, examining and instructing contact lens patients. Patient hygiene and willingness to follow practitioner instructions are essential to their success.

A detail history is crucial to determining patient needs and expectations. Your patient should be questioned regarding vocation, desired lens wearing time (full or part-time), and desired lens usage (reading, recreation or hobbies).

Initial evaluation of the trial lens should be preceded by a complete eye examination, including visual acuity with and without correction at both distance and near, keratometry and slip lamp examination.

See Contraindications, Warnings and Precaution sections of the Package Insert for additional information on patient selection.

FITTING PROCEDURE:

Perform a preliminary evaluation to determine distance refraction as well as to rule out contraindications to contact lens wear as described in the Package Insert.

Lens power is determined from the patient's spherical equivalent prescription corrected to the corneal plane.

Place the lens on the eye. Allow the lens to remain on the eye long enough to achieve a state of equilibrium. Small variation in the tonicity, pH of the lens solutions and individual tear composition may cause slight changes in fitting characteristics.

The lens should cover the patient's cornea fully, provide discernible movement (0.10mm to 0.30mm) after blink, be comfortable for the patient and provide satisfactory visual performance.

Full coverage of the cornea is defined as the lens edge extending beyond the limbus area in all directions. Initial lens evaluation must be done after at least 10 minutes of lens wear to allow the lens to stabilize and any tearing to subside.

Evaluate Lens Fit:

Criteria	Optimal	Tight	Loose
Centration	Limbus to limbus coverage	Limbus to limbus coverage bubbles beneath center	Limbal exposure
Movement (in primary gaze)	0.5 to 1.5mm	Non	2.0 mm or greater
Lens Edge	Conforms to shape of eye	Indents conjunctiva	Edge standoff or buckle at or near lid
Keratometer Mires	Clear, stable	Unstable, clears after blink	Unstable, changes shape after blink
Comfort	Good	Good initially	Poor
Visual Acuity	Good, stable	Clears after blink	Unstable, poor

Refract Over the Lens:

Determine optimal power and record best visual acuity. Procedures:

With lens in place:

a. Record any patient symptoms related to contact lens wear.
b. Examine lids and conjunctiva
c. Check visual acuity and refract over the lens. Acuity and over-refractions should be checked on two different days before making a power change.
d. With the slit lamp:
    1. Evaluate the lens to insure it continues to satisfy the criteria of a well-fitted lens.
    2. Examine the lens closely for surface deposition and/or damage.

With lens removed:

a. Conduct a thorough slit lamp examination of the cornea with and without sodium fluorescein.
b. Perform Keratometry and compare original values and mire quality.

Vertex Distance Chart

Vertex Distance allowance for lens powers above 5 diopters (calculated for average 12mm dist.) For minus read left to right – for plus read right to left.

- +	- +	- +	- +	- +	- +	- +
5.00 – 4.75	6.37 – 5.87	7.62 – 7.00	9.25 – 8.37	11.50 – 10.00	14.25 – 12.25	17.62 – 14.37
5.12 – 4.87	6.50 – 6.00	7.75 – 7.12	9.50 – 8.62	11.75 – 10.25	14.75 – 12.50	18.00 – 14.50
5.37 – 5.00	6.62 – 6.12	7.87 – 7.25	9.75 – 8.75	12.00 – 10.37	15.00 – 12.75	18.12 – 14.75
5.50 – 5.12	6.75 – 6.25	8.00 – 7.37	10.00 – 9.00	12.50 – 10.75	15.50 – 13.00	18.50 – 15.00
5.62 – 5.25	6.87 – 6.37	8.12 – 7.50	10..25 – 9.12	12.75 – 11.00	15.75 – 13.25	18.75 – 15.25
5.75 – 5.37	7.00 – 6.50	8.25 – 7.62	10.50 – 9.25	13.00 – 11.25	16.25 – 13.50	19.00 – 15.50
5.87 – 5.50	7.12 – 6.62	8.50 – 7.75	10.75 – 9.37	13.50 – 11.50	16.75 – 13.75	
6.00 – 5.62	7.37 – 6.75	8.75 – 8.00	11.00 – 9.62	13.75 – 11.75	17.00 – 14.00	
6.12 – 5.75	7.50 – 6.87	9.00 – 8.25	11.25 – 9.75	14.00 – 12.00	17.25 – 14.25	

K-reading conversion Chart

Diopters - radius	Diopters - radius	Diopters - radius	Diopters - radius	Diopters - radius	Diopters - radius	Diopters - radius
37.25 – 9.06	39.75 – 8.49	42.00 – 8.04	44.25 – 7.63	46.50 – 7.26	48.75 – 6.92	51.00 – 6.62
37.50 – 9.00	40.00 – 8.44	42.25 – 7.99	44.50 – 7.58	46.75 – 7.22	49.00 – 6.89	51.25 – 6.59
37.75 – 8.94	40.25 – 8.39	42.50 – 7.94	44.75 – 7.54	47.00 – 7.18	49.25 – 6.85	51.50 – 6.55
38.00 – 8.88	40.50 – 8.33	42.75 – 7.90	45.00 – 7.50	47.25 – 7.14	49.50 – 6.82	51.75 – 6.52
38.25 – 8.82	40.75 – 8.28	43.00 – 7.85	45.25 – 7.46	47.50 – 7.11	49.75 – 6.78	52.00 – 6.49
38.50 – 8.77	41.00 – 8.23	43.25 – 7.80	45.50 – 7.42	47.75 – 7.07	50.00 – 6.75	52.25 – 6.46
38.75 – 8.71	41.25 – 8.18	43.50 – 7.76	45.75 – 7.38	48.00 – 7.03	50.25 – 6.72	52.50 – 6.43
39.00 – 8.65	41.50 – 8.13	43.75 – 7.71	46.00 – 7.34	48.25 – 6.99	50.50 – 6.68	52.75 – 6.40
39.25 – 8.60	41.75 – 8.08	44.00 – 7.67	46.25 – 7.30	48.50 – 6.96	50.75 – 6.65	53.00 – 6.37
39.50 – 8.54						

When lenses are dispended for vision correction, the wearer must be supplied with an appropriate wearing regimen and must fully understand all lens handling and emergency lens care instructions to prevent lens damage as described in the Package Insert and the Patient Information Booklet.

FITTING SUMMARY:

Fitting performance and visual response should be confirmed with the prescription lenses prior to dispensing, and the management of certain adaptive symptoms should be discussed with the patient prior to dispensing.

It is normal for the patient to experience mild symptoms such as lens awareness, variable vision, occasional tearing (watery eyes) and slightly eye redness during the adaptation period. Although the adaptation varies for each individual, generally within one week these mild symptoms will disappear. If these symptoms persist, the patient should be instructed to contact their eye care practitioner.

During the first few weeks of extended wear, patient may report a small amount of secretions on their eyelids, hazy vision on awakening and occasional dryness of the eyes during the day. These symptoms are minor and may be alleviated by using lubricating/rewetting solution.

WEARING SCHEDULE:

The wearing schedule and replacement schedule should be determined by the prescribing eye care practitioner for each individual patient, based upon a full examination and patient history as well as the practitioner's experience and professional judgment. CooperVision, Inc. recommends beginning extended wear patients with an initial daily wear schedule recommended by the eye care practitioner, followed by a period of daily wear, and gradual introduction of extended wear one night at a time, unless individual considerations indicate otherwise. Patients should be given a wearing schedule and carefully instructed on the handling and care of their lenses, as discussed in the package insert. Also, be sure to complete the Replacement Schedule Record in the Patient Information Booklet. The lens must be removed, cleaned and disinfected or disposed of and replaced with a new lens, as determined by the prescribing eye care practitioner. (See the factors discussed in the WARNINGS section). Once removed, a lens should remain out of the eye for a period of rest for overnight or longer, as determined by the prescribing eye care practitioner.

FOLLOW-UP EXAMINATION:

As with any contact lens, regular recall visits are necessary to monitor corneal health and wearer compliance with instructions. (See Package Insert). Be sure to complete the Check-up Visit Schedule in the Patient Information Booklet for your patient when dispensing lenses.

Follow-up examinations are necessary to ascertain the effects of the lenses on the eyes. The following schedule is a suggested guideline:

- 24 hours post-dispensing
- 7 days
- 1 month
- 3 months
- Every six months thereafter

At the initial follow-up evaluations the eye care practitioner should again reassure the patient that any of the previously described adaptive symptoms are normal, and that the adaptation period should be relatively brief.

During extend wear; there are diurnal changes in the appearance of contact lens fit and the eye response. Therefore, it is advisable that the follow-up visit schedule for extended wear patients Include some morning appointments, as well as some afternoon appointments, in order to better monitor the range of lens and eye responses.

The follow-up examination should include the practitioner's usual soft contact lens evaluation procedures:

- Measure visual acuity at distance and near, binocularly and monocularly.
- Assess lens fit (as described in Fitting Procedure) and lens surface quality.
- Following lens removal, conduct a biomicroscopy evaluation or of the cornea and conjunctiva.
- Keratometry and spectacle refraction should be performed at follow-up visits after approximately 1 month of lens wear. Any deviations from baseline (prefit) measurements should be noted.

ADVERSE REACTION REPORTING:

If your patients experience any adverse effects or complications with the lens, please be sure to notify CooperVision, Inc. toll free at 1-800-628-5367.

CLEANING AND DISINFECTION OF LENSES:

A. PRACTITIONER DISINFECTION OF OPEN LENSES

All lenses that have been opened must be discarded.

B. PATIENT LENS CARE

See the accompanying Package Insert and the Patient Information Booklet for information pertaining to lens care and handling instructions.

LENS ORDERING:

To order the prescription lenses specify power. To order lenses, call us toll free at 1-800-628-5367.

It is essential that you review the Package Insert for a complete discussion of CooperVision polymacon hydrophilic contact lenses Including the Warnings, Precautions, and Adverse Effects sections of the Insert.

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PACKAGE INSERT:

Please refer to the polymacon Package Insert on the CooperVision website (www.coopervision.com).