



PROFESSIONAL FITTING AND INFORMATION GUIDE

FLOSI (wilofacon A)

Rigid Gas Permeable Contact Lenses for Daily Wear

ONSI-56 (onsifocon A)

Rigid Gas Permeable Contact Lenses for Daily Wear

TYRO-97 (hofacon A)

Rigid Gas Permeable Contact Lenses for Daily Wear

FOR SPHERICAL, ASPHERIC, TORIC AND BIFOCAL CONTACT LENS

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a licensed practitioner. See package insert for additional information.



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FLOSI (wilofacon A)

ONSI-56 (onsifocon A)

TYRO-97 (hoyocon A)

Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lenses for Nearsightedness (Myopia), Farsightedness (Hyperopia), Astigmatic (Toric) Lenses to Correct Astigmatism. Bifocal Lenses to Correct Presbyopia

INTRODUCTION:

These Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lenses are made from fluoro silicone acrylate polymers with a water content of less than one percent.

For a complete listing of available lens parameters, please refer to LENS PARAMETERS AVAILABLE.

PRODUCT DESCRIPTIONS:

FLOSI (wilofacon A), ONSI-56 (onsifocon A), TYRO-97 (hoyocon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lenses are available in spherical designs in the clear untinted or blue, green, blue-violet and gray tinted varieties and in blue with UV-blocker. Each is a shell of the following dimensions.

Spherical Contact Lens:

Horizontal Lens Size:	6.5 mm to 11.50mm
Base Curve:	6.50mm to 9.50mm
Distance Powers:	+12.00D to -20.00D
Center Thickness:	
for low minus	0.05mm to 0.30mm
for plus	0.10mm to 0.70mm

Aspheric Lens

Eccentricity	0 to 1.5
Peripheral Curves	0.1 to 1.0mm

Toric Lens

Axis	1 to 180 degrees in 1-degree steps
Cylinder power	0.50 to 4.00D

Translating Bifocal Contact Lens:

Horizontal Lens Size:	8.00mm to 10.50mm
Base Curve:	6.50mm to 8.50mm
Distance Power:	+12.00D to -20.00D
Add Power	1.00 to 4.00D



These rigid gas permeable materials, for making contact lenses are formulations of trifluoroethyl methacrylate polymer with tris (trimethylsiloxy)methacryl oxypropylsilane 3-trimethoxysilylpropylmethacrylate methacrylic acid 1,3-bis(3- methacryloxypropyl)tetrakis (trimethylsiloxy)disiloxane ethylene glycol dimethacrylate 2-hydroxyethyl methacrylate N-vinylpyrrolidone. The blue tinted lenses contain D&C Green No. 6; the green lenses contain D&C Green No 6 and CI Solvent Yellow 18; the gray lenses contain D&C Green No 6, D&C Violet No. 2, and CI Solvent Yellow 18; the blue-UV lenses contain D&C Green No 6 and a UV absorber, 2-(2'-hydroxy-5'-methacryloxyethylphenyl)-2H-benzotriazole. The colorants are used in quantities approved for use in contact lenses and proportions required to obtain the desired color.

ACTION:

SEE PACKAGE INSERT FOR INFORMATION

INDICATIONS (USES):

SEE PACKAGE INSERT FOR INFORMATION

CONTRAINDICATIONS (REASONS NOT TO USE) WARNINGS AND ADVERSE REACTIONS:

SEE PACKAGE INSERT FOR INFORMATION

Caution: FLOSI (wilofoccon A), ONSI-56 (onsifocon A), TYRO-97 (hoyocon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lenses are shipped to the practitioner non- sterile. Clean and condition lenses prior to use.

PRECAUTIONS:

Clinical studies have demonstrated that contact lenses manufactured from the FLOSI (wilofoccon A), ONSI-56 (onsifocon A), TYRO-97 (hoyocon A) Rigid Gas Permeable materials are safe and effective for their intended use. However, due to the small number of patients enrolled in clinical investigation of lenses, all refractive powers, design configurations, or lens parameters available in the lens material are not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the eyecare practitioner should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.

The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing eyecare practitioner.



Patients who wear aspheric contact lenses to correct presbyopia may not achieve the best corrected visual acuity for either far or near vision. Visual requirements vary with the individual and should be considered when selecting the most appropriate type of lens for each patient.

Please refer to the Package Insert for a complete list of **Precautions**

SELECTION OF PATIENTS:

SPHERICAL OR TORIC LENSES

Patients who require a daily wear lens and are not-aphakic and have non-diseased eyes. The patients should have a refractive error which does not exceed 20.00 diopters of myopia or 12.00 diopters of hyperopia. The choice of sphere or toric is dependent on the refractive error to be corrected. Patients with smaller amounts of refractive or corneal astigmatism (less than about 3.00D) can usually be fit in a spherical lens, while patients with higher amounts often require a toric lens to achieve acceptable acuity or fit. Patients with higher amounts of lenticular astigmatism may also require a toric lens to achieve acceptable acuity.

Patients are selected who have a demonstrated need and desire for a refractive correction with rigid gas permeable contact lenses and who do not have any of the contraindications for contact lenses described in the package insert.

ASPHERIC OR BIFOCAL LENSES

Presbyopic patients who desire improved vision at far and near without the use of spectacles are candidates for either:

- the translating bifocal (add to +4.00D) or
- the aspheric lens (add to 1.25) with an eccentricity >0.4

Candidates for an aspheric lens with eccentricity ≤ 0.4 include patients who:

- Do not have presbyopia, and
- Require a lens that conforms more closely to their corneal shape than a spherical lens.



FITTING PROCEDURE RIGID GAS PERMEABLE SPHERICAL CONTACT LENS

FLOSI (wilfocon A), ONSI-56 (onsifocon A), TYRO-97 (hoyocon A) Rigid Gas Permeable Spherical Contact Lenses may be fitted using the standard techniques for rigid gas permeable contact lenses whether the patient is a new fit, former hydrophilic contact lens wearer, or former rigid (or hard PMMA) contact lens wearer. The choice of lens parameters is based solely on the need to provide the best visual acuity consistent with proper physical comfort.

Fitting Criteria:

Conventional rigid lens fitting techniques are used. This guide is only a general recommendation and the specification for an individual patient will depend on the eyecare practitioner's professional judgment.

1. Prefitting Examination:

A completed refraction and visual health examination should be performed.

A pre-fitting patient history and examination are necessary to:

- determine whether a patient is a suitable candidate for daily wear contact lenses (consider patient hygiene and mental and physical state).
- make ocular measurements for initial contact lens parameter selection
- collect and record baseline clinical information to which post- fitting examination results can be compared.

2. Initial Lens Power Selection:

Standard procedures for determining power of rigid gas permeable contact lenses may be used, including compensation for vertex distance.

3. Initial Diameter Selection:

Usually lens diameters between 8.8 mm to 11.5 mm are used to maximize centering to the cornea and to minimize lens movement. Lens diameters outside this range are occasionally used for some eyes. This guide is only a general recommendation and the specification for an individual patient will depend on the eyecare practitioner's professional judgment.

Determining Lens Diameter:

- If K is: 42.00 and flatter..... use 9.8 mm diameter
- 42.25 to 44.0..... use 9.5 mm diameter
- 44.25 and steeper.....use 9.2 mm diameter



Lens diameter is primarily a function of the base curve but may be influenced by power (plus lenses require a larger diameter to compensate for weight) and anatomical considerations (small palpebral opening, excessively large pupil, etc.)

4. Initial Base Curve Selection:

The base curve is generally fitted on the flattest keratometric finding (fitting on "K") but may vary according to the corneal astigmatism or other individual requirements. This guide is only a general recommendation and the specification for an individual patient will depend on the eyecare practitioner's professional judgment.

Determining Lens Base Curve:

The following table can be used to empirically determine the initial lens parameters.

<u>Cylinder</u>	<u>9.2</u>	<u>9.5</u>	<u>9.8</u>
0 to .75	BC = .25 steeper	on K	.25 flatter
1.00 to 1.50	BC = .50 steeper	.25 steeper	on K
> 1.50	BC = .75 steeper	.50 steeper	.25 steeper

As can be seen from the above table, the base curve determination is a function of corneal cylinder and lens diameter. This guide is only a general recommendation and the specification for an individual patient will depend on the eyecare practitioner's professional judgment.

5. Initial Lens Evaluation.

Movement:

Blink induced lens movement should optimally move downward with the lid motion and then upward with the lid motion. During the interblink period the lens should have little or no motion.

Positioning:

The lens should position centrally or slightly superiorly to minimize both lens movement and lid sensation. Diagnostic lenses are essential in fitting patients whose corneal topography has been distorted by previous contact lens wear.



FITTING PROCEDURE FOR RIGID GAS PERMEABLE TORIC CONTACT LENS

The overall and optic zone diameters are chosen using the same criteria as with spherical lens designs. Generally, bitoric lens diameters are about 0.2 mm smaller than spherical lenses designed for intrapalpebral fitting. It is important to avoid lid attachment since lid action may cause the lens to rotate from the intended axis.

There are two opposing considerations when selecting the toric posterior surface of a bitoric contact lens in order to achieve the optimum fit. The toric surface must conform close enough to the corneal contour to minimize rotation of the lens. However, some deviation from perfect lens-to-cornea conformation is needed to create pumping of the tear fluid.

The base curve in the flatter meridian should usually be made 0.25 D flatter than the cornea. The base curve in the steeper meridian should be 0.50 to 1.25 D flatter than the cornea depending on the amount of corneal astigmatism. This additional "fit factor" is summarized in the following table:

Corneal Cyl (D)	FIT FACTOR	
	Flat Meridian	Steep Meridian
2.00	On K	.50 flatter
2.50	.25 flatter	.50 "
3.00	.25 "	.75 "
3.50	.25 "	.75 "
4.00	.25 "	1.00 "
5.00	.25 "	1.25 "

Mandell, R.C., Moore, C.F.: A Bitoric Lens Guide That Really Is Simple. Contact Lens Spectrum, November 1988, 83-85.

The calculations of the toric lens powers are divided for the two principal meridians and treated as though they are two separate lenses.

The Mandell-Moore Bitoric Lens Guide presents the steps to be taken in a bitoric lens calculation and a simple form to be used in following these steps. This method follows exactly the same steps as are used to arrive at a spherical contact lens prescription.

Example

Readings:	OD 44.00 @ 180/47.25 @ 090
	OS 42.00 @ 180/46.50 @ 090
Refraction:	OD -3.50 -3.50 x 180
	OS +12.50 -4.00 x 180



At the top of the form, enter K readings for flat and steep meridians and the spectacle Rx in minus cylinder form.

- Line 1* Enter the flat K reading and the steep K reading where indicated.
- Line 2* Enter the spherical power of the spectacle Rx. Then add the sphere and cylinder power algebraically and record this value in minus cylinder form where indicated.
- Line 3* If either power value is greater than 4.00 D, convert the spectacle Rx to the corneal plane using the Vertex Distance Correction table on the form.
- Line 4* Add the "fit factor." This adjustment promotes an alignment fit. First, enter the fit factor for the flat meridian, which will always be 0.25 D and have a minus sign. Next, enter the same value under sphere power, which will have a plus sign. Repeat the same process by finding the fit factor for the steeper meridian and enter the values.
- Line 5* The base curve Rx is calculated by adding the values in line one and four. The power is determined by adding lines three and four.

As with spherical lenses, center thickness is a function of lens design. With bitoric lenses, the center thickness is based from the least minus or greatest plus power.

Intermediate and peripheral curves can be generated in either a spherical or toric design. Spherical peripheral curves will result in an oval optic zone. Review the spherical lens section for actual parameter determination.



<i>Right Eye</i>				
Keratometry				@
Spectacle Rx (minus cylinder form)			x	
	Flattest K	Sphere Power	Steepest K	Sph+cyl pwr
1. Enter K		XXXXXXXX		XXXXXXXXXX
2. Enter Spectacle Power				
3. Vertex Correction				
4. Fit Factor	(-)	(+)	(-)	(+)
Add Lines	1 & 4	3 & 4	1 & 4	3 & 4
5. Final CL Rx				
	Base Curve	Power	Base Curve	Power

<i>Left Eye</i>				
Keratometry				@
Spectacle Rx (minus cylinder form)			x	
	Flattest K	Sphere Power	Steepest K	Sph+cyl pwr
1. Enter K		XXXXXXXX		XXXXXXXXXX
2. Enter Spectacle Power				
3. Vertex Correction				
4. Fit Factor	(-)	(+)	(-)	(+)
Add Lines	1 & 4	3 & 4	1 & 4	3 & 4
5. Final CL Rx				
	Base Curve	Power	Base Curve	Power

If the spectacle lens power is less than 4.00 diopters, then line 3= line 2. Otherwise: for minus power spectacle lenses, find the power in the left side of the column and convert to the power in the right side of the column, but retain the minus sign. For plus power spectacle lenses, find the power in the right side of the column, and convert to the power in the left side, but retain the plus sign.



VERTEX DISTANCE CORRECTION							
4.00	3.75	8.00	7.25	12.00	10.50	16.00	13.25
4.25	4.00	8.25	7.50	12.25	10.75	16.25	13.50
4.50	4.25	8.50	7.75	12.50	10.75	16.50	13.75
4.75	4.50	8.75	8.00	12.75	11.00	16.75	13.75
5.00	4.75	9.00	8.00	13.00	11.25	17.00	14.00
5.25	5.00	9.25	8.25	13.25	11.25	17.25	14.00
5.50	5.25	9.50	8.50	13.50	11.50	17.50	14.25
5.75	5.50	9.75	8.75	13.75	11.75	17.75	14.50
6.00	5.50	10.00	9.00	14.00	12.00	18.00	14.50
6.25	5.75	10.25	9.00	14.25	12.00	18.25	14.75
6.50	6.00	10.50	9.25	14.50	12.25	18.50	15.00
6.75	6.25	10.75	9.50	14.75	12.50	18.75	15.00
7.00	6.50	11.00	9.75	15.00	12.50	19.00	15.25
7.25	6.75	11.25	10.00	15.25	12.75	19.25	15.50
7.50	7.00	11.50	10.00	15.50	13.00	19.50	15.75
7.75	7.00	11.75	10.25	15.75	13.00	19.75	16.00

If the spectacle lens power is less than 4.00 diopters, then line 3= line 2. Otherwise: for minus power spectacle lenses, find the power in the left side of the column and convert to the power in the right side of the column, but retain the minus sign. For plus power spectacle lenses, find the power in the right side of the column, and convert to the power in the left side, but retain the plus sign.

CORNEAL CYL, D	FIT FACTOR	
	FLAT MERIDIAN	STEEP MERIDIAN
2	ON K	.50 FLATTER
2.5	.25 FLATTER	.50 “
3	.25 “	.50 “
3.5	.25 “	.50 “
4	.25 “	.50 “
5	.25 “	.50 “



FITTING PROCEDURE RIGID GAS PERMEABLE TRANSLATING BIFOCAL CONTACT LENS

- Select a patient with +4.00 add or lower interested in full-time wear.
- Interview patient regarding expected lens use, vocation and hobbies, previous type of lens wear, etc.
- The same pre-fitting criteria apply for both spheric and bifocal RGP fittings. Please refer to the spherical lens fitting guide.

Initial lens diameter selection is based on the same factors as for a spherical lens. Refer to trial lens size chart in the spherical fitting guide.

Using the amount of corneal cylinder, the base curve may be determined by the following table:

<u>Corneal Cylinder, D</u>	<u>Base Curve</u>
0.00	0.25 D flatter to On K
0.25 - 0.75	On K to 0.25 D steeper
1.00 - 1.75	0.25 to 0.75 D steeper
>2.00	0.75 to 1.25 D steeper

- Select the proper trial lens and place it on the patient's cornea. Wait approximately 10 minutes or until tearing subsides and check for lens positioning and movement. Ideally, the lens will ride up with the blink and then quickly drop to a position which is near the center of the cornea. Centering is important when fitting bifocal lenses. If the trial lens does not center, you may find an unanticipated amount of residual astigmatism. To correct this, follow the steps in the problem-solving section.
- Lens powers (far center, add periphery) may be determined by conventional methods.
- Center thickness is a function of lens design. Refer to the spherical fitting guide for further details
- Look for central to superior-central lens position. This provides for adequate distance vision, while reducing edge glare and flare in dim light or at night. ONSI™-56 (onsifocon A) RIGID GAS PERMEABLE TRANSLATING BIFOCAL CONTACT LENSES provide both far and near vision, meaning that the lens must translate easily across the corneal surface as the patient looks from distance to reading tasks. Proper base curve selection will usually ensure that the lens will move easily along the vertical corneal meridian.
- Evaluate fluorescein pattern and lens translation.



Evaluation of Lens Positioning

- Preferred Alignment fit with central to superior/central positioning Fit
- 0.1mm Steeper Increased apical clearance, combined with mid-peripheral bearing Fit
- 0.1mm Flatter Increased central bearing with loss of lens stability Fit

Evaluation of Lens Position and Movement

- Ideally, the lens should position in the central to superior/central position, with the lens optics situated over the pupil.
- Typically, the fluorescein pattern will demonstrate "alignment" along the flattest corneal meridian.
- During downward gaze the lens should easily translate superiorly providing maximum reading vision.
- NOTE: If an alignment fitting relationship combined with acceptable vertical translation cannot be achieved with the initial diagnostic lens, simply choose the next steeper or flatter base curve and evaluate.



FITTING PROCEDURE FOR RIGID GAS PERMEABLE ASPHERIC CONTACT LENS

The same pre-fitting criteria apply for both spheric and aspheric RGP fittings. Please refer to the spherical lens fitting guide.

Initial lens diameter selection is based on the same factors as for a spherical lens. Refer to trial lens size chart in the spherical fitting guide. In addition, owing to the aspheric lens design, the fitter will not need to determine peripheral curves.

Using the amount of corneal cylinder, the base curve may be determined by the following table:

<u>Corneal Cylinder, D</u>	<u>Base Curve</u>
0.00	0.25 D flatter to On K
0.25 - 0.75	On K to 0.25 D steeper
1.00 - 1.75	0.25 to 0.75 D steeper
>2.00	0.75 to 1.25 D steeper

Select the proper trial lens and place it on the patient's cornea. Wait approximately 10 minutes or until tearing subsides and check for lens positioning and movement. Ideally, the lens will ride up with the blink and then quickly drop to a position which is near the center of the cornea. Centering is important when fitting aspheric lenses. If the trial lens does not center, you may find an unanticipated amount of residual astigmatism. To correct this, follow the steps in the problem-solving section.

Lens power is best determined by over-refraction with a trial lens in place. Perform the calculation steps as you would with a spherical lens. Refer to the spherical lens-fitting guide for details.

Center thickness is a function of lens design. Refer to the spherical fitting guide for further details.

Note: A bifocal effect should be expected for eccentricities > 0.4 . When fitting the aspheric lens for presbyopia, practitioners should select only patients who need an add of +1.25 or less.

Patient Education

All patients do not function equally well with aspheric multifocal correction. Patients may not perform as well for certain tasks with this correction as they have with bifocal reading glasses. Each patient should understand that aspheric multifocal lenses, as well as other presbyopic contact lenses, or other alternative, can create a vision compromise that may reduce visual acuity and depth perception for distance and near tasks. During



the fitting process it is necessary for the patient to realize the disadvantages of the lack of clear near vision in straight ahead gaze that aspheric multifocal lenses provide.

Adaptation

Visually demanding situations should be avoided during the initial wearing period. A patient may at first experience some mild blurred vision, dizziness, headaches, and a feeling of slight imbalance. You should explain the adaptational symptoms to the patient. These symptoms may last for a brief minute or for several weeks. The longer these symptoms persist, the poorer the prognosis for successful adaptation.

To help in the adaptation process the patient can be advised to first use the lenses in a comfortable familiar environment such as in the home.

Some patients feel that automobile driving performance may not be optimal during the adaptation process. This is particularly true when driving at night. Before driving a motor vehicle, it may be recommended that the patient be a passenger first to make sure that their vision is satisfactory for operating an automobile. During the first several weeks of wear (when adaptation is occurring), it may be advisable for the patient to drive only during optimal driving conditions. After adaptation and success with these activities, the patient should be able to drive under other conditions with caution.

Other Suggestions

The success of the aspheric multifocal technique may be further improved by having your patient follow the suggestions below.

-Having supplemental spectacles to wear over the aspheric contact lenses for specific visual tasks may improve the success of aspheric correction. This is particularly applicable for those patients who cannot meet state licensing requirements with a aspheric correction.

-Make use of proper illumination when carrying out visual tasks.

Success in fitting aspheric multifocal lenses can be improved by the following suggestions.

-Refine the lens powers if there is trouble with adaptation. Accurate lens power is critical for presbyopic patients.

*** The decision to fit a patient with an aspheric multifocal correction is most appropriately left to the eyecare practitioner in conjunction with the patient after carefully considering the patient's needs.**



* **All patients should be supplied with a copy of the Wearer's Instructions for the FLOSI (wilfocon A), ONSI-56 (onsifocon A), TYRO-97 (hoyocon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lenses**

6. FOLLOW UP CARE:

- a. Follow-up examinations, as recommended by the eyecare practitioner, are necessary to ensure continued successful contact lens wear. Follow-up examinations should include an evaluation of lens movement, centration, comfort and fluorescein pattern. Lens movement will decrease as tear volume is diminishing during adaptation. The patient should also begin to feel more comfortable. An assessment of vision and eye health, including inspection of the cornea for edema and/or staining, should be performed.
- b. Prior to a follow-up examination, the contact lenses should be worn for at least 4 contiguous hours and the patient should be asked to identify any problems which might be occurring related to contact lens wear.
- c. With lenses in place on the eyes, evaluate fitting performance to assure that CRITERIA OF A WELL FITTED LENS continue to be satisfied. Examine the lenses closely for surface deposition and/ or damage.
- d. After the lens removal, conduct a thorough biomicroscopy examination.
 1. The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization is indicative of excessive corneal edema.
 2. The presence of corneal staining and/or limbal-conjunctival hyperemia can be indicative of an unclean lens, a reaction to solution preservatives, excessive lens wear, and/or a poorly fitted lens.

If any of the above observations are judged abnormal, various professional judgments are necessary to alleviate the problem and restore the eye to optimal conditions. If the CRITERIA OF A WELL FITTED LENS are not satisfied during any follow-up examination, the patient should be re-fitted with a more appropriate lens.



MONOVISION FITTING GUIDELINES:

1. Patient Selection

A. Monovision Needs Assessment

For a good prognosis the patient should have adequately corrected distance and near visual acuity in each eye. The amblyopic patient or the patient with significant residual astigmatism (greater than 1.00 diopter) in one eye may not be a good candidate for monovision with the ONSI™-56 (onsifocon A) Rigid Gas Permeable Contact Lens.

Occupational and environmental visual demands should be considered. If the patient requires critical vision (visual acuity and stereopsis) it should be determined by trial whether this patient can function adequately with monovision. Monovision contact lens wear may not be optimal for such activities as:

- (1) visually demanding situations such as operating potentially dangerous machinery or performing other potentially hazardous activities; and
- (2) driving automobiles (e.g., driving at night). Patients who cannot pass their state driver's license requirements with monovision correction should be advised to not drive with this correction, OR may require that additional over-correction be prescribed.

B. Patient Education

All patients do not function equally well with monovision correction. Patients may not perform as well for certain tasks with this correction as they have with bifocal reading glasses. Each patient should understand that monovision, as well as other presbyopic contact lenses, or other alternative, can create a vision compromise that may reduce visual acuity and depth perception for distance and near tasks. During the fitting process it is necessary for the patient to realize the disadvantages and advantages of clear near vision in straight ahead and upward gaze that monovision contact lenses provide.

2. Eye Selection

Generally, the non-dominant eye is corrected for near vision. The following test for eye dominance can be used.

A. Ocular Performance Determination Methods



Method 1 - Determine which eye is the "sight eye." Have the patient point to an object at the far end of the room. Cover one eye. If the patient is still pointing directly at the object, the eye being used is the dominant (sighting) eye.

Method 2 - Determine which eye will accept the added power with the least reduction in vision. Place a trial spectacle near add lens in front of one eye and then the other while the distance refractive error correction is in place for both eyes. Determine whether the patient functions best with the near add lens over the right or left eye.

B. Refractive Error Method

For anisometropic corrections, it is generally best to fit the more hyperopic (less myopic) eye for distance and the more myopic (less hyperopic) eye for near.

C. Visual Demands Method

Consider the patient's occupation during the eye selection process to determine the critical vision requirements. If a patient's gaze for near tasks is usually in one direction, correct the eye on that side for near.

Example:

A secretary who places copy to the left side of the desk will usually function best with the near lens on the left eye.

3. **Special Fitting Considerations**

Unilateral Lens Correction

There are circumstances where only one contact lens is required. As an example, an emmetropia patient would only require a near lens while a bilateral myope may require only a distance lens.

Example:

A presbyopic emmetropia patient who requires a +1.75 diopter add would have a +1.75 lens on the near eye and the other eye left without a lens.



A presbyopic patient requiring a +1.50 diopter add who is -2.50 diopters myopic in the right eye and -1.50 diopters myopic in the left eye may have the right eye corrected for distance and the left uncorrected for near.

4. **Near Add Determination**

Always prescribe the lens power for the near eye that provides optimal near acuity at the midpoint of the patient's habitual reading distance. However, when more than one power provides optimal reading performance, prescribe the least plus (most minus) of the powers.

5. **Trial Lens Fitting**

A trial fitting is performed in the office to allow the patient to experience monovision correction. Lenses are fit according to the directions in the general fitting guidelines and base curve selection described earlier in the guide.

Case history and standard clinical evaluation procedure should be used to determine the prognosis. Determine which eye is to be corrected for distance and which eye is to be corrected for near. Next determine the near add. With trial lenses of the proper power in place observe the reaction to this mode of correction.

Immediately after the correct power lenses are in place, walk across the room and have the patient look at you. Assess the patient's reaction to distance vision under these circumstances. Then have the patient look at familiar near objects such as a watch face or fingernails. Again, assess the reaction. As the patient continues to look around the room at both near and distance objects, observe the reactions. Only after these vision tasks are completed should the patient be asked to read print. Evaluate the patient's reaction to large print (e.g. typewritten copy) at first and then graduate to newsprint and finally smaller type sizes.

After the patient's performance under the above conditions are completed, tests of visual acuity and reading ability under conditions of moderately dim illumination should be attempted.

An initial unfavorable response in the office, while indicative of a guarded prognosis, should not immediately rule out a more extensive trial under the usual conditions in which a patient functions.



6. **Adaptation**

Visually demanding situations should be avoided during the initial wearing period. A patient may at first experience some mild blurred vision, dizziness, headaches, and a feeling of slight imbalance. You should explain the adaptational symptoms to the patient. These symptoms may last for a brief minute or for several weeks. The longer these symptoms persist, the poorer the prognosis for successful adaptation.

To help in the adaptation process the patient can be advised to first use the lenses in a comfortable familiar environment such as in the home.

Some patients feel that automobile driving performance may not be optimal during the adaptation process. This is particularly true when driving at night. Before driving a motor vehicle, it may be recommended that the patient be a passenger first to make sure that their vision is satisfactory for operating an automobile. During the first several weeks of wear (when adaptation is occurring), it may be advisable for the patient to drive only during optimal driving conditions. After adaptation and success with these activities, the patient should be able to drive under other conditions with caution.

7. **Other Suggestions**

The success of the monovision technique may be further improved by having your patient follow the suggestions below.

- Having a third contact lens (distance power) to use when critical distance viewing is needed.

- Having a third contact lens (near power) to use when critical near viewing is needed.

- Having supplemental spectacles to wear over the monovision contact lenses for specific visual tasks may improve the success of monovision correction. This is particularly applicable for those patients who cannot meet state licensing requirements with a monovision correction.

- Make use of proper illumination when carrying out visual tasks.

Success in fitting monovision can be improved by the following suggestions.

- Reverse the distance and near eyes if a patient is having trouble adapting.

- Refine the lens powers if there is trouble with adaptation. Accurate lens power is critical for presbyopic patients.



-Emphasize the benefits of the clear near vision in straight ahead and upward gaze with monovision.

- * **The decision to fit a patient with a monovision correction is most appropriately left to the eyecare practitioner in conjunction with the patient after carefully considering the patient's needs.**

- * **All patients should be supplied with a copy of the Wearer's Instructions for the FLOSI (wilfocon A), ONSI-56 (onsifocon A), TYRO-97 (hoyocon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lenses**

IN OFFICE CARE OF TRIAL LENSES:

Eyecare practitioners should educate contact lens technicians concerning proper care of trial lenses.

RECOMMENDED INITIAL WEARING SCHEDULE

Although many practitioners have developed their own initial wearing schedules, the following sequence is recommended as a guideline. Patients should be cautioned to carefully follow the wearing schedule recommended by the eyecare practitioner regardless of how comfortable the lenses feel.

Daily Wear

Maximum wearing time:

Day	Wearing Time (Hours)
1	5
2	6
3	7
4	8
5	9
6	10
7	15
8 and after	All hours awake



CLINICAL ASSESSMENT:

1. Criteria of a Well-Fitted Lens

The lens should ideally move freely with the blink and drop quickly to a position near the center of the cornea. It is especially favorable if the lens rides slightly under the upper lid since that will reduce lens edge sensation and make the lens more comfortable. The lens should not ride exceptionally high so that excessive lid pressure is exerted on the superior lens margin. Over an extended wearing period, this inevitably leads to structural changes in the superior corneal epithelium. The lens should center well and move adequately following the blink.

2. Characteristics of a Tight (Steep) Lens

A lens that is too tight will show reduced movement upon blinking. The lens will be centered or decentered inferiorly and exhibit little or no movement. Bubbles may be detected behind the lens.

3. Characteristics of a Loose (Flat) Lens

A lens that is too loose will move excessively on the cornea following each blink. The lens may ride in either a position that is too high or too low or in an eccentric position. A loose lens is usually uncomfortable for the patient.

HANDLING OF LENSES:

Standard procedures for rigid gas permeable lenses may be used.

Caution: FLOSI (wifocon A), ONSI-56 (onsifocon A), TYRO-97 (hifocon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lens are shipped to the practitioner non-sterile. Clean and condition lenses prior to use.

PATIENT LENS CARE DIRECTIONS:

Please see package insert.

CARE FOR A STICKING (NON-MOVING) LENS:

Please See Package Insert



VERTEX DISTANCE AND KERATOMETRY CONVERSION CHARTS

Standard charts may be used.

REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing or experienced with the lenses should be reported to:

ACUITY POLYMERS, INC.
1667 Lake Avenue, Bldg. 59, Suite 303
Rochester, NY 14615 USA
+1 (585) 458 8409

HOW SUPPLIED

Each lens is supplied non-sterile in a plastic lens storage case containing one or two lenses. The container is marked with the patient name, base curve, distance power, diameter, center thickness, color, and lot number.