PROFESSIONAL FITTING AND INFORMATION GUIDE

for the 55 Spherical/Aspheric, 55 Spherical/Aspheric Blue, 55 UV Spherical/Aspheric, 55 UV Spherical/Aspheric Blue, 55 UV Spherical/Aspheric Color, 55 Toric, 55 Toric Blue, 55 UV Toric, 55 UV Toric Blue, 55 Multifocal, 55 Multifocal Blue, 55 UV Multifocal and 55 UV Multifocal Blue (methafilcon A) Soft (Hydrophilic) Contact Lens

CAUTION - Federal (USA) law restricts this device to sale by or on the order of a licensed practitioner

INTRODUCTION:

Eye care practitioners may prescribe the 55 Spherical/Aspheric, 55 Spherical/Aspheric Blue, 55 UV Spherical/Aspheric, 55 UV Spherical/Aspheric Blue, 55 UV Spherical/Aspheric Color, 55 Toric, 55 Toric Blue, 55 UV Toric, 55 UV Toric Blue, 55 Multifocal, 55 Multifocal Blue, 55 UV Multifocal and 55 UV Multifocal Blue (methafilcon A) Soft (Hydrophilic) Contact Lens for single use disposable wear or frequent replacement. When prescribed for a Disposable Wearing Schedule, the lenses are not intended to be cleaned or disinfected and should be discarded after a single use. When prescribed for a Frequent Replacement Program, the lenses may be disinfected using chemical or hydrogen peroxide disinfecting systems.

The 55 spherical/aspheric, 55 toric, and 55 multifocal lenses are made from methafilcon A which is a hydrophilic polymer of 2-hydroxyethyl methacrylate and methacrylic acid, crosslinked with ethylene glycol dimethacrylate, and using azobisisobutyronitrile (AIBN) as a initiator. A UV absorbing monomer, 2-[3-(2H-Benzotriazol-2y1)-4-hydroxyphenyl] ethyl methacrylate, may be incorporated into the lens polymer and used to block UV radiation. The graph of spectral absorbance curve is shown in Fig. 1. The UV blocker for 55 UV lenses averages 87.630 % in the UVA range of 316 nm to 380 nm and 98.975 % in the UVB range of 315 nm to 280 nm. The lenses contain 55% water by weight and may be tinted blue using Pigment Blue 15(Copper phthalocyanine) for visibility.

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

PRODUCT DESCRIPTION:

The 55 spherical/aspheric lenses are available in single vision lens designs and spherical lenses. The 55 toric lenses are available in double slab-off back surface designs and as astigmatic lenses. The 55 multifocal lenses are available in aspherical lens designs.

The lens material (methafilcon A) is a hydrophilic polymer of 2-hydroxyethyl methacrylate and methacrylic acid crosslinked with ethylene dimethacrylate, and using azobisisobutyronitrile (AIBN) as an initiator. A UV absorbing compound, 2-[3-(2H-Benzotriazol-2y1)-4-hydroxyphenyl] ethyl methacrylate may be incorporated into the lens polymer. The lenses contain 55% water by weight and each lens is supplied sterile in a blister container in saline solution. The lenses may be tinted blue using Pigment Blue 15(Copper phthalocyanine) for visibility.

The UV blocker for 55 UV lenses averages 87.630 % in the UVA range of 316 nm to 380 nm and 98.975 % in the UVB range of 315 nm to 280 nm.

NOTE: Long term exposure to UV radiation is one of the risk factors associated with cataracts. Exposure is based on a number of factors such as environmental conditions (altitude, geography, cloud cover) and personal factors (extent and nature of outdoor activities). UV-absorbing contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing

UV-absorbing contact lenses reduce the risk of developing cataracts or other eye disorders. Consult your eye-care practitioner for more information.

WARING: UV-absorbing contact lenses are NOT substitutes for protective UV absorbing eye wear such as UV absorbing goggles or sunglasses because they do not completely cover the eye and surrounding area. You should continue to use UV absorbing eye wear as directed.

LENS PARAMETERS AVAILABLE:

The 55 spherical/aspheric, 55 toric, and 55 multifocal lenses are hemispheric flexible shells of the following dimensions:

Diameter:	14.0 mm to 15.0 mm
Center Thickness:	0.06 mm to 0.40 mm
Base Curves:	8.30 mm to 9.30 mm
Powers:	+12.00 Diopters to -20.00 Diopters

For 55 toric lenses:

Cylinder Powers:	- 0.50D to - 2.50D
Axis:	Full circle (in 10°steps)

For 55 multifocal lenses:

Add powers:	Continuous add power to +3.25
Zone Sizes:	1.5, 1.9 mm

The physical/optical properties of the lens are:

Specific Gravity:	1.106
Refractive Index:	1.404 (wet)
Light Transmittance**(**381 nm ~ 780 nm**)**:	96.777 %
UVA Transmittance**(**316 nm ~ 380 nm**)**:	12.370 %
UVB Transmittance**(**280 nm ~ 315 nm**)**:	1.025 %
Oxygen Permeability:	21.4×10^{-11}

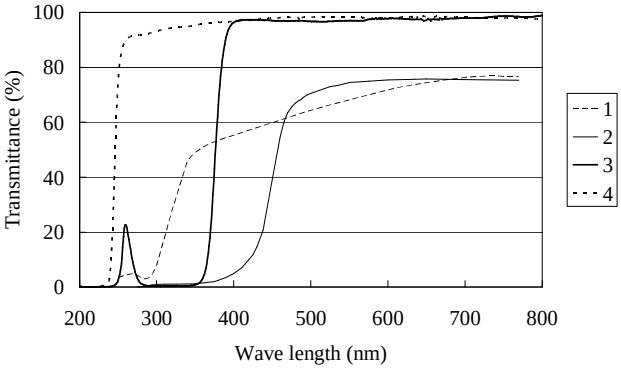

Fig. 2 The graph of spectral transmittance curve

1. Human cornea from a 24 year-old person as described in Lerman, S., Radiant Energy and the Eye, New York, 1980, p. 58, Figure 2-21.
2. Human crystalline lens from a 25 year-old person as described in Waxler, M., Hitchins, V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p. 19, Figure 5.
3. The UV lenses.
4. The lenses without UV absorbing monomer.

* The data was obtained from measurements taken through the central 3-5 mm portion of the thinnest marketed version of the UV lens (-3.00D, 0.070 mm center thickness) and

measured according to ISO 18369-3:2006 – Ophthalmic optical – Contact Lenses – Part 3: Measurement methods.

WARING: UV-absorbing contact lenses are NOT substitutes for protective UV absorbing eye wear such as UV absorbing goggles or sunglasses because they do not completely cover the eye and surrounding area. You should continue to use UV absorbing eye wear as directed.

FITTING PROCEDURE OUTLINE:

1. Pre-fitting examination
2. Initial lens power and base curve selection
3. Initial lens evaluation
4. Follow-up care

FITTING PROCEDURE:

A. Spherical/Aspheric Lenses

1. Pre-Fitting Examination

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.

A prefitting examination should include:

- a full patient history and biomicroscopic examination to ensure that there are no contra-indications to contact lens wear,
- a sphero-cylindrical spectacle refraction.

2. Initial Lens Power and Base Curve Selection

- Lens power is determined from the patient's spherical equivalent prescription corrected to the corneal plane. Select the appropriate lens and place on the eye.
- Allow the lens to remain on the eye long enough (10 to 20 minutes) to achieve a state of equilibrium. Small variations in the tonicity, pH of the lens solutions, and individual tear composition may cause slight changes in fitting characteristics.
- Allow any increase in tear flow to subside before evaluating the lens. The time required will vary with the individual.

3. Initial Lens Evaluation

- To determine proper lens parameters observe the lens relationship to the eye using a slit lamp.
  - Movement: The lens should provide discernible movement with:
    - ✓ Primary gaze blink
    - ✓ Upgaze blink

- ✓ Upgaze lag
- ➢ Centration: The lens should provide full corneal coverage.

- Lens evaluation allows the contact lens fitter to evaluate the lens/cornea relationship in the same manner as would be done with any soft lens. If after the lens has settled on the eye, the patient report lens sensation, or if the lens is moving or decentering excessively, the lens should not be dispensed. Alternatively, if the patient reports variable vision, or if the lens shows insufficient movement, the lens should not be dispensed.

4. Criteria of Optimal fit lens:

In order to allow the lens to stabilize to the eye environment, a minimum of 20 minutes should be allowed before evaluating the lens fitting characteristics

- Optimal fit lens includes the following:
  - Minimal biological response.
  - Good comfort levels.
  - Good center with the eye in primary position.
  - Total corneal coverage should be maintained at all times (including during eye movements).
  - Small lens movement with good recovery on push-up test is the most important indicator of the lens mobility.
  - Clear and stable vision should be achieved with over refraction.
  - The lens's axis mark should stay at horizontal level (180°).

5. Characteristics of a Tight(Steep) Lens

- Tight fit is characterized by:
  - No free lens movement with version or upgaze.
  - Resistance to movement on push-up with sharp return to center.
  - Scleral indentation and conjunctival vessel blanching may be present.
  - Possible variable vision and over refraction with improvement in vision immediately after a blink.

6. Characteristics of a Loose(Flat) Lens

- Loose fit is characterized by:
  - Decentered lens with the eye in primary position.
  - Position only corneal coverage in primary position and with eye movement.
  - Possible edge flexing and stand off.
  - Excessive movement with version and upgaze.
  - Lens easily decentered on push-up.
  - Variable vision and over refraction with worsening of vision immediately after blink.

7. Follow-up Care

- Follow-up examinations, as recommended by the eyecare practitioner, are necessary to ensure continued successful contact lens wear.
- Prior to a follow-up examination, the contact lenses should be worn for at least 2 continuous hours and the patient should be asked to identify any problems which might be occurring related to contact lens wear.
- 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.
- After the lens removal, conduct a thorough biomicroscopy examination.
  - The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization is indicative of excessive corneal edema.
  - The presence of corneal straining and/or limbal-conjunctival hyperemia can be indicative of an unclean lens, a reaction to solution preservatives, excessive lens wear, and/or a poorly fitting lens.
  - Papillary conjunctival changes may be indicative of an unclean and/or damaged 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 fitted with a more appropriate lens.

B. Toric Lenses

1. Pre-Fitting Examination

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.

A prefitting examination should include:

- a full patient history and biomicroscopic examination to ensure that there are no contra-indications to contact lens wear,
- a sphero-cylindrical spectacle refraction.

2. Initial Lens Power and Base Curve Selection

- Select a trial 55 spherical lens with a power most similar to the patients refractive needs, or order a diagnostic lens to the prescription which most closely matches that of the patient.
- Allow the lens to remain on the eye long enough (10 to 20 minutes) to achieve a state of equilibrium. Small variations in the tonicity, pH of the lens solutions, and individual tear composition may cause slight changes in fitting

characteristics.

- Allow any increase in tear flow to subside before evaluating the lens. The time required will vary with the individual.

3. Initial Lens Evaluation

- Determine contact lens power. It is usually preferable to use the spectacle Rx as the only basis for the contact lens power. The sphere and cylinder power of the spectacle Rx becomes the sphere and cylinder power of the contact lens. There are two exceptions:
  - If spectacle cylinder power falls between available contact lens cylinder powers, prescribe the lesser contact lens cylinder power. The sphere power can be increased -0.25D to compensate if desired. This can vary depending on your interpretation of the patient's subjective responses.
  - When the spectacle lens power in any principle meridian is greater than 4.00D, the spectacle refraction should be vertexed to the corneal plane. This can affect both the sphere and cylinder powers ordered.

    Ex. Spectacle Rx -6.00 -2.75×180

    Contact lens power ordered -5.75 -2.50×180
- Determine contact lens axis.
  - Compensation for rotation is limited to 20°.
  - If the marks on the trial lens rotate clockwise (the way you see it), add the amount of rotation to the cylinder axis of the over refraction.
  - If the marks on the trial lens rotate against the clock, subtract the amount of rotation from the cylinder axis of the over refraction.

    Ex. Spectacle Rx -3.50 -1.25×80

    Rotation 20° clockwise

    Final lens prescription: -3.5 -1.25×100
- To determine proper lens parameters observe the lens relationship to the eye using a slit lamp.
  - Movement: The lens should provide discernible movement with:
    - ✓ Primary gaze blink
    - ✓ Upgaze blink
    - ✓ Upgaze lag
  - Centration: The lens should provide full corneal coverage.

4. Criteria of Optimal fit lens:

In order to allow the lens to stabilize to the eye environment, a minimum of 20 minutes should be allowed before evaluating the lens fitting characteristics.

- Optimal fit lens includes the following:
  - Minimal biological response.

- Good comfort levels.
- Good center with the eye in primary position.
- Total corneal coverage should be maintained at all times (including during eye movements).
- Small lens movement with good recovery on push-up test is the most important indicator of the lens mobility.
- Clear and stable vision should be achieved with over refraction.
- The lens's axis mark should stay at horizontal level (180°).

5. Characteristics of a Tight(Steep) Lens

- Tight fit is characterized by:
  - No free lens movement with version or upgaze.
  - Resistance to movement on push-up with sharp return to center.
  - Scleral indentation and conjunctival vessel blanching may be present.
  - Possible variable vision and over refraction with improvement in vision immediately after a blink.

6. Characteristics of a Loose(Flat) Lens

- Loose fit is characterized by:
  - Decentered lens with the eye in primary position.
  - Position only corneal coverage in primary position and with eye movement.
  - Possible edge flexing and stand off.
  - Excessive movement with version and upgaze.
  - Lens easily decentered on push-up.
  - Variable vision and over refraction with worsening of vision immediately after blink.

7. Follow-up Care

- Follow-up examinations, as recommended by the eyecare practitioner, are necessary to ensure continued successful contact lens wear.
- Prior to a follow-up examination, the contact lenses should be worn for at least 2 continuous hours and the patient should be asked to identify any problems which might be occurring related to contact lens wear.
- 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.
- After the lens removal, conduct a thorough biomicroscopy examination.
  - The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization is indicative of excessive corneal edema.
  - The presence of corneal straining and/or limbal-conjunctival hyperemia can be indicative of an unclean lens, a reaction to solution preservatives, excessive lens

wear, and/or a poorly fitting lens.

- Papillary conjunctival changes may be indicative of an unclean and/or damaged 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 fitted with a more appropriate lens.

C. Multifocal Lenses

1. Pre-Fitting Examination

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.

A prefitting examination should include:

- a full patient history and biomicroscopic examination to ensure that there are no contra-indications to contact lens wear,
- a sphero-cylindrical spectacle refraction.

2. Patient selection

There are more factors should be considered when fitting multifocal contact lens, such as objectives, lifestyle, expectations and desired usage. The eye care professional should communicate with patients and explain their options for presbyopia whether they are former contact lens wearers or not. According to different particular needs, they may choose multifocal lenses, monovision lenses or wear their spherical lens with reading spectacles when necessary.

- Strong motivation is the most important factor in success to wear contact lenses. The best candidates are those who are able to tolerate minor visual imperfections and whose occupations do not demand precise vision. The patient must be willing to return and pay for multiple office visits in order to achieve optimal fit, vision, and eye health.
- It is important to consider the ocular manifestations of advancing age. These include reduced tear quantity and quality; smaller pupil size; slower pupillary responsiveness; flaccid eyelids; decreased corneal sensitivity; and decreased best visual acuity due to cataract, macular degeneration, or other age-related changes. Severe dry eye patients, however, are poor candidates for contact lenses.
- Low refractive errors are not ideal for bifocal lens wearers.
- Lower success rates have also been found with higher add powers, high sensitivity to small lens changes during refraction, and cylinder greater than 1.00 D in multifocal contact lens wearers.

3. Initial Lens Power and Base Curve Selection

- Perform a preliminary evaluation to determine distance refraction and near add requirements.
- Determine the lens power from the patient's spherical equivalent prescription

corrected to the corneal plane.

- For each eye select the appropriate lens of the power closest the patient's spherical equivalent distance Rx.
- Select the appropriate ADD.
  - For each lens the near and intermediate powers are concentrated primarily in the contral portion of the optical zone while the distance power is contained in the surrounding portion.
  - Select the near power of the lens based on the patients ADD power.

    The 55 multifocal lenses (Continuous add power to +3.25 in 0.25D increments)

    ADD: The nearest power of the lens based on the patients ADD range.
- Measure binocular near and distance VA.
- Make adjustments in power as necessary. The use of hand held trial lenses will simplify fitting and minimize lens changes.
  - To improve near vision, add plus in +0.25D increments to both eyes. If distance vision becomes unacceptable with this change:

    A. Add plus to the non-dominant eye only. Measure near, then distance VA binocularly then monoculary, or

    B. Change a higher ADD power trial lens to improve near vision directly for each eye.

    Ex. Remove the ADD +2.00D trial lens (-4.00D ADD +2.00D) and wear the ADD +2.25D trail lens (-4.00D ADD +2.25D).
  - To improve distance vision, add minus in -0.25D increments in both eyes. If near vision becomes unacceptable with this change:

    a. Add minus to the dominant eye only. Measure distance, then near VA, binocularly then monocularly or

    b. Change a higher ADD power trial lens to improve distance vision directly for each eye.

    Ex. Remove the ADD +2.00D trial lens (-4.00D ADD+2.00D) and wear the ADD +2.25D trail lens (-4.25D ADD +2.25D).
- Make final lens changes and confirm acuity. Attempt to minimize any resultant binocular imbalance.
  - under normal conditions
  - at near in any position of gaze
  - in decreased illumination
  - at intermediate distances

4. Initial Lens Evaluation

- According to the patient's occupations, hobbies and visual requirements, the eyecare practitioner should assist them properly find out their available options.
- The manufacturers should collected information and data from successful fitting experiences of the multifocal contact lens and their fitting guides are based upon this

knowledge.

- Because many designs depend on pupil size, the eye care professional should understand a patient's most common lighting environments, overrefract and demonstrate the lenses in these illumination conditions.
- To determine proper lens parameters observe the lens relationship to the eye using a slit lamp.
  - Movement: The lens should provide discernible movement with:
    - ✓ Primary gaze blink
    - ✓ Upgaze blink
    - ✓ Upgaze lag
  - Centration: The lens should provide full corneal coverage.
- Lens evaluation allows the contact lens fitter to evaluate the lens/cornea relationship in the same manner as would be done with any soft lens. If after the lens has settled on the eye, the patient report lens sensation, or if the lens is moving or decentering excessively, the lens should not be dispensed. Alternatively, if the patient reports variable vision, or if the lens shows insufficient movement, the lens should not be dispensed.
- Telling the patients that the lenses will "meet most visual needs most of the time" can help them to fit the most appropriate contact lenses. It is important to understand that some patients cannot be fit successfully with presbyopic (multifocal or monovision) contact lenses.

5. Criteria of Optimal fit lens:

In order to allow the lens to stabilize to the eye environment, a minimum of 20 minutes should be allowed before evaluating the lens fitting characteristics.

- Optimal fit lens includes the following:
  - Minimal biological response.
  - Good comfort levels.
  - Good center with the eye in primary position.
  - Total corneal coverage should be maintained at all times (including during eye movements).
  - Small lens movement with good recovery on push-up test is the most important indicator of the lens mobility.
  - Clear and stable vision should be achieved with over refraction.
  - The lens's axis mark should stay at horizontal level (180°).

6. Characteristics of a Tight(Steep) Lens

- Tight fit is characterized by:
  - No free lens movement with version or upgaze.
  - Resistance to movement on push-up with sharp return to center.
  - Scleral indentation and conjunctival vessel blanching may be present.
  - Possible variable vision and over refraction with improvement in vision

immediately after a blink.

7. Characteristics of a Loose(Flat) Lens

- Loose fit is characterized by:
  - Decentered lens with the eye in primary position.
  - Position only corneal coverage in primary position and with eye movement.
  - Possible edge flexing and stand off.
  - Excessive movement with version and upgaze.
  - Lens easily decentered on push-up.
  - Variable vision and over refraction with worsening of vision immediately after blink.

8. Addaption

It may take many weeks adaptation. Because of the longer, more difficult adaptation period, it is important that the patient is motivated.

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 adaptation 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 only drive during optimal driving conditions, After adaptation and success with these activities, the patient should be able to drive under other conditions with caution.

9. Follow-up Care

- A follow-up visit should be scheduled about 1 week after dispensing each refit.
- Follow-up examinations, as recommended by the eyecare practitioner, are necessary to ensure continued successful contact lens wear.
- Prior to a follow-up examination, the contact lenses should be worn for at least 2 continuous hours and the patient should be asked to identify any problems which might be occurring related to contact lens wear.
- 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.
- After the lens removal, conduct a thorough biomicroscopy examination.
  - The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization is indicative of excessive corneal edema.
  - The presence of corneal straining and/or limbal-conjunctival hyperemia can be

indicative of an unclean lens, a reaction to solution preservatives, excessive lens wear, and/or a poorly fitting lens.

- Papillary conjunctival changes may be indicative of an unclean and/or damaged 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 fitted with a more appropriate lens.

10. Patient Education

All patients do not function equally well with 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 multifocal contact lens 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 as well as the advantages of clear near vision in straight ahead and upward haze that the multifocal contact lens provide.

These considerations should be reminded to the patient when fitting the multifocal lenses:

- For presbyopia patients, it may hard to achieve very fine vision at both near and distance conditions. Auxiliary glasses are sometimes needed for extremely small print.
- The lenses will “meet most visual needs most of the time”. It is important to understand that some patients cannot be fit successfully with presbyopic (multifocal or monovision) contact lenses.
- It may take more time to achieve a fit and acceptable vision by exchanging lenses.
- It is more difficult to achieve fine vision when the patient’s cylinder is greater than 1.00D.
- When compared to spectacles, blur vision may happen.
- For some special conditions (distance or light), the vision may not be so clear.
- Presbyopia is a condition where with age, the dry eye feeling may occur more often than before. The patient should take care of their eyes particularly.

IN OFFICE CARE OF TRIAL LENSES:

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

Each contact lens is shipped sterile in a blister container with a saline solution. Hands should be thoroughly washed and rinsed and dried with a lint free towel prior to handling a lens. In order to insure sterility, the blister container should not be opened until immediately prior to use.

Prior to reusing in a diagnostic procedure or before dispensing to a patient, lenses should be surface cleaned and disinfected.

Chemical (Not Heat) Disinfection:

WARNING: Lenses prescribed on the Frequent Replacement Program can be disinfected, but lenses on the Disposable Wearing Schedule cannot.

- Clean the contact lenses with a recommended cleaning solution and thoroughly rinse them with a recommended rinsing solution.
- After cleaning, to disinfect, carefully follow the instructions accompanying the disinfecting solution in the care regimen recommended by the lens manufacturer or the eyecare practitioner.
- When using hydrogen peroxide lens care systems, lenses must be neutralized before wearing. Follow the recommendations on the hydrogen peroxide system labeling.
- Do not heat the disinfection solution and lenses.
- Leave the lenses in the unopened storage case until ready to put on the eyes.
- Caution: Lenses that are chemically disinfected may absorb ingredients from the disinfecting solution, which may be irritating to the eyes. A thorough rinse in fresh sterile saline solution prior to placement on the eye should reduce the potential for irritation.

LENS DEPOSITS AND USE OF ENZYMATIC CLEANING PROCEDURE:

WARNING: Lenses prescribed on the Frequent Replacement Program can be disinfected, but lenses prescribed on the Disposable Wearing Schedule cannot.

Enzyme cleaning may be recommended by the eyecare practitioner. Enzyme cleaning removes protein deposits on the lens. These deposits cannot be removed with regular cleaners, Removing protein deposits is important for the well being of the patient's lenses and eyes. If these deposits are not removed, they can damage the lenses and cause irritation.

Enzyme cleaning does NOT replace routine cleaning and disinfecting. For enzyme cleaning, the patient should carefully follow the instructions in the enzymatic cleaning labeling.

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 the lenses feel.

Daily Wear
Maximum Wearing Time:

Day	Wearing Time (Hours)
1	4
2	5
3	6
4	7
5	8
6	9
7	10
8	11
9	12
10 and after	All waking hours

CLINICAL ASSESSMENT:

Criteria of a Well-Fitted Lens:

- Minimal biological response.
- Good comfort levels.
- Good center with the eye in primary position.
- Total corneal coverage should be maintained at all times (including during eye movements).
- Small lens movement with good recovery on push-up test is the most important indicator of the lens mobility.
- Clear and stable vision should be achieved with over refraction.

Characteristics of a Tight (Steep) Lens:

- No free lens movement with version or upgaze.
- Resistance to movement on push-up with sharp return to center.
- Scleral indentation and conjunctival vessel blanching may be present.
- Possible variable vision and over refraction with improvement in vision immediately after a blink.

Characteristics of a Loose (Flat) Lens:

- Decentered lens with the eye in primary position.
- Position only corneal coverage in primary position and with eye movement.
- Possible edge flexing and stand off.
- Excessive movement with version and upgaze.
- Lens easily decentered on push-up.
- Variable vision and over refraction with worsening of vision immediately after blink.

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 astigmatism (greater than 2.50 diopter) in one eye may not be a good candidate for monovision with the 55 spherical/aspheric, 55 toric, and 55 multifocal lenses.

   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 drivers 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 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, 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 as well as the 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 tests for eye dominance can be used.

A. Ocular Preference 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 correction, 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 emmetropic patient would only require a near lens while a bilateral myope may require only a distance lens

Example:

A presbyopic emmetropic 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 prebyopic 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 news print and finally smaller type sizes.

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

   An initial unfavourable 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 adaptation 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 only drive 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 Patient Instructions for 55 Spherical/Aspheric, 55 Spherical/Aspheric Blue, 55 UV Spherical/Aspheric, 55 UV Spherical/Aspheric Blue, 55 UV Spherical/Aspheric Color, 55 Toric, 55 Toric Blue, 55 UV Toric, 55 UV Toric Blue, 55 Multifocal, 55 Multifocal Blue, 55 UV Multifocal and 55 UV Multifocal Blue (methafilcon A) Soft (Hydrophilic) Contact Lens.

Please refer to the Package Insert for:

Actions
Indications
Contraindications
Warnings
Precautions
Adverse Reactions
Lens Care Directions
Chemical Lens Disinfection
Lens Deposits and Use of Enzymatic Cleaning
Care for a Dehydrated Lens
Care for a Sticking (Nonmoving) Lens
How Supplied
Reporting of Adverse Reactions