PACKAGE INSERT / FITTING GUIDE

BAUSCH + LOMB

Biotrue®

ONEday
(nesofilcon A)
Soft (Hydrophilic)
Contact Lenses

BAUSCH + LOMB

Biotrue®

ONEday
for Presbyopia
(nesofilcon A)
Soft (Hydrophilic)
Contact Lenses

℞ ONLY **CAUTION:** Federal law restricts this device to sale by or on the order of a licensed practitioner.

Name and Address of Manufacturer:
Bausch & Lomb Incorporated
Rochester, New York, USA 14609
Printed in the U.S.A.

SL7458
8101901

SYMBOL REFERENCE GUIDE

For labels and cartons:

2	Do Not Reuse
	Temperature Limitation
STERILE	Sterile Using Steam or Dry Heat
	See Instruction Leaflet
CE 0050	Indicates the CE Conformity Marking and the Notified Body Number
EC REP	Authorized Representative in European Community
℞ ONLY	Caution: Federal law restricts this device to sale by or on the order of a licensed practitioner
	Fee Paid for Waste Management
EXP	Use by Date (Expiration Date)
LOT	Batch Code
DIA $Ø_T$	Diameter
PWR (F'_V)	Diopter (Lens Power)
BC	Base Curve

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IMPORTANT

This package insert and fitting guide has been developed to provide practitioners with information covering characteristics of the Bausch + Lomb Biotrue® ONEday (nesofilcon A) Soft (Hydrophilic) Contact Lens and Bausch + Lomb Biotrue ONEday for Presbyopia (nesofilcon A) Soft (Hydrophilic) Contact Lens and to illustrate fitting procedures. It is effective as of January 2014 and supersedes all prior fitting guides for the product described. Please read carefully and keep this information for future use.

This package insert and fitting guide is intended for the eye care professional, but should be made available to patients upon request. The eye care professional should provide the patient with the patient instructions that pertain to the patient's prescribed lens and the recommended wearing schedule

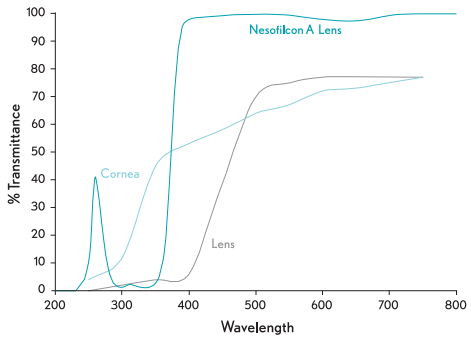
DESCRIPTION

The Bausch + Lomb Biotrue® ONEday (nesofilcon A) Contact Lens and Bausch + Lomb Biotrue ONEday for Presbyopia (nesofilcon A) Contact Lens are soft hydrophilic contact lenses. The lens is made from the nesofilcon A material, a hydrophilic copolymer of 2-hydroxyethyl methacrylate and N-vinyl pyrrolidone, and is 78% water by weight when immersed in a sterile saline solution. A benzotriazole UV-absorbing monomer is incorporated into the manufacturing process to block UV radiation. The transmittance characteristics are less than 5% in the UVB range of 280nm to 315nm and less than 50% in the UVA range of 316nm to 380nm. This lens is tinted blue with Reactive Blue Dye 246.

The physical / optical properties of the lens are:

Specific Gravity:	1.039
Refractive Index:	1.374
Light Transmittance:	C.I.E. Y value - approximately 99%
Water Content:	78%
Oxygen Permeability (Dk):	42×10^{-11} [cm^3O_2(STP) x cm]/(sec x cm^2 x mmHg) @ 35° C (Polarographic Method)

The Bausch + Lomb Biotrue® ONEday (nesofilcon A) Contact Lens and Bausch + Lomb Biotrue ONEday for Presbyopia (nesofilcon A) Contact Lens are to be prescribed for single-use disposable wear.



The typical transmittance profile of nesofilcon A lenses vs a Human Cornea and Human Lens:

Nesofilcon A Lens –Nominal Center Thickness 0.1 mm (-1.25D).

Cornea–Human Cornea from a 24-year-old person as described in Lerman, S., Radiant Energy and the Eye, MacMillan, New York, 1980, p.58, fig. 2-21.

Lens–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, fig. 5.

Warning
UV absorbing contact lenses are NOT substitutes for protective UV absorbing eyewear 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 eyewear as directed.

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 blocking contact lenses help provide protection against harmful UV radiation.

Note
The effectiveness of wearing UV absorbing contact lenses in preventing or reducing the incidence of ocular disorders associated with exposure to UV light has not been established at this time. However, clinical studies have not been done to demonstrate that wearing UV blocking contact lenses reduce the risk of developing cataracts or other eye disorders. Consult your Eye Care Professional for more information.

LENS PARAMETERS AVAILABLE

The Bausch + Lomb Biotrue® ONEday (nesofilcon A) Contact Lens is a hemispherical shell of the following dimensions:

Diameter:	14.2mm
Center Thickness:	0.05mm to 0.75mm (varies with power)
Base Curve:	8.6mm
Powers:	+6.50D to -6.50D in 0.25D steps -7.00D to -9.00D in 0.50D steps

The Bausch + Lomb Biotrue ONEday for Presbyopia (nesofilcon A) Contact Lens is a hemispherical shell of the following dimensions:

Diameter:	14.2mm
Center Thickness:	0.05mm to 0.75mm (varies with power)
Base Curve:	8.6mm
Powers:	+6.50D to -9.00D in 0.25D steps
Add Power:	Low (+0.75D to +1.50D) and High (+1.75D to +2.50D)

Additional parameters may be introduced over time, check for product availability.

HOW THE LENS WORKS (ACTIONS)

In its hydrated state, the Bausch + Lomb Biotrue® ONEday (nesofilcon A) Contact Lens and Bausch + Lomb Biotrue ONEday for Presbyopia (nesofilcon A) Contact Lens when placed on the cornea act as a refracting medium to focus light rays on the retina.

The transmittance characteristics are less than 5% in the UVB range of 280nm to 315nm and less than 50% in the UVA range of 316nm to 380nm.

INDICATIONS

The Bausch + Lomb Biotrue® ONEday (nesofilcon A) Contact Lens is indicated for the daily wear correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and/or non-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity. The lens may be prescribed in spherical powers ranging from +20.00D to -20.00D.

The Bausch + Lomb Biotrue ONEday for Presbyopia (nesofilcon A) Soft (Hydrophilic) Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) and presbyopia in aphakic and/or non-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity. The lens may be prescribed in powers ranging from +20.00D to -20.00D with add power ranging from +0.75D to +5.00D.

The lens is to be prescribed for single-use disposable wear, and is to be discarded after each removal.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the Bausch + Lomb Biotrue® ONEday (nesofilcon A) Contact Lens or Bausch + Lomb Biotrue ONEday for Presbyopia (nesofilcon A) Contact Lens when any of the following conditions exist:

- Acute and subacute inflammation or infection of the anterior chamber of the eye
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids
- Severe insufficiency of lacrimal secretion (dry eyes)
- Corneal hypoesthesia (reduced corneal sensitivity)
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Allergic reactions of ocular surfaces or adnexa (surrounding tissue) that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions
- Any active corneal infection (bacterial, fungal, or viral)
- If eyes become red or irritated

WARNINGS

After a thorough eye examination, including appropriate medical background, patients should be fully apprised by the prescribing professional of all the risks with contact lens wear. **Patients should be advised of the following warnings pertaining to contact lens wear:**

- Problems with contact lenses and lens care products could result in **serious injury** to the eye. It is essential that patients follow their eye care professional's direction and all labeling instructions for proper use of lenses and lens care products, including the lens case. Eye problems, including corneal ulcers, can develop rapidly and lead to **loss of vision.**
- Daily wear lenses are not indicated for overnight wear, and **patients should be instructed not to wear lenses while sleeping.** Clinical studies have shown that the risk of serious adverse reactions is increased when daily wear lenses are worn overnight.
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.
- If a patient experiences eye discomfort, excessive tearing, vision changes, or redness of the eye, the patient should be instructed to **immediately remove lenses** and promptly contact his or her eye care professional.

PRECAUTIONS

Special Precautions for Eye Care Professionals:

- 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 eye care professional 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 eye should be carefully monitored by the prescribing eye care professional.
- Patients who wear aspheric contact lenses, such as the Bausch + Lomb Biotrue® ONEday (nesofilcon A) Contact Lenses or Bausch + Lomb Biotrue ONEday for Presbyopia (nesofilcon A) 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.

- Eye care professionals should instruct the patient to REMOVE A LENS IMMEDIATELY if an eye becomes red or irritated.
- Fluorescein, a yellow dye, should not be used while the lenses are on the eyes. The lenses absorb this dye and become discolored. Whenever fluorescein is used in eyes, the eyes should be flushed with sterile saline solution that is recommended for in-eye use.
- The patient should be instructed to always discard disposable lenses and lenses worn on a frequent/planned replacement schedule after the recommended wearing schedule prescribed by the eye care professional.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.
- Aphakic patients should not be fitted with Bausch + Lomb Biotrue® ONEday (nesofilcon A) Contact Lenses or Bausch + Lomb Biotrue ONEday for Presbyopia (nesofilcon A) Contact Lenses until the determination is made that the eye has healed completely.
- The lenses are prescribed for disposable wear, and are to be disposed of once they are removed from the patient's eye. It is important that patients be instructed to always have available a pair of replacement lenses. In the event that a lens must be removed from the eye because of dust, a foreign body or other contaminant gets on the lens or the lens becomes dehydrated, the lens should be removed and replaced with a replacement lens.
- Eyecare professionals should carefully instruct patients about the following safety precautions. It is strongly recommended that patients be provided with a copy of the Patient Information Booklet for Bausch + Lomb Biotrue ONEday (nesofilcon A) Contact Lens and Bausch + Lomb Biotrue ONEday for Presbyopia (nesofilcon A) Contact Lens, available from Bausch + Lomb, and understand its contents prior to dispensing the lenses.

Handling Precautions:

- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-base cosmetics are less likely to damage lenses than oil-base products.
- Be sure that before leaving the eye care professional's office, the patient is able to remove lenses promptly or have someone else available to remove them.
- Be certain that the fingers or hands are free of foreign materials before touching lenses, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.

- Always handle lenses carefully and avoid dropping them.
- Do not touch the lens with fingernails.
- Carefully follow the handling, insertion, removal, cleaning disinfecting, storing and wearing instructions in the Patient Information Booklet for the Bausch + Lomb Biotrue® ONEday (nesofilcon A) Contact Lenses and Bausch + Lomb Biotrue ONEday for Presbyopia (nesofilcon A) Contact Lenses and those prescribed by the eye care professional.
- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use. Pour the lens into the hand.

Topics to Discuss with the Patient:

- As with any contact lens, follow-up visits are necessary to assure the continuing health of the eyes. The patient should be instructed as to a recommended follow-up schedule.
- Patients should be advised about wearing lenses during sporting and water related activities. Exposure to water while wearing contact lenses in activities such as swimming, water skiing and hot tubs may increase the risk of ocular infection including but not limited to *Acanthamoeba* keratitis.
- Always contact the eye care professional before using any medicine in the eyes.

Who Should Know That the Patient is Wearing Contact Lenses:

- Patients should inform their doctor (health care professional) about being a contact lens wearer.
- Patients should always inform their employer of being a contact lens wearer. Some jobs may require the use of eye protection equipment or may require that you do not wear lenses.

ADVERSE REACTIONS

The patient should be informed that the following problems may occur:

- Eyes stinging, burning, itching (irritation), or other eye pain
- Comfort is less than when lens was first placed on eye
- Abnormal feeling of something in the eye (foreign body, scratched area
- Excessive watering (tearing) of the eyes
- Unusual eye secretions
- Redness of the eyes
- Reduced sharpness of vision (poor visual acuity)
- Blurred vision, rainbows, or halos around objects
- Sensitivity to light (photophobia)
- Dry eyes

If the patient notices any of the above, he or she should be instructed to:

- **Immediately remove the lenses.**
- If the discomfort or problem stops, then look closely at the lens. If the lens is in any way damaged, **do not** put the lens back on the eye. Place the lens in the storage case and contact the eye care professional. If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, the patient should thoroughly clean, rinse, and disinfect the lenses; then reinsert them. After reinsertion, if the problem continues, the patient should **immediately remove the lenses and consult his or her eye care professional**.
- If the above symptoms continue after removal of the lens, or upon reinsertion of a lens, or upon insertion of a new lens, the patient should **immediately remove the lenses and contact his or her eye care professional** or physician, who must determine the need for examination, treatment or referral without delay. (See Important Treatment Information for Adverse Reactions.) A serious condition such as infection, corneal ulcer, corneal vascularization, or iritis may be present, and may progress rapidly. Less serious reactions such as abrasions, epithelial staining or bacterial conjunctivitis must be managed and treated carefully to avoid more serious complications.

Important Treatment Information for Adverse Reactions

Sight-threatening ocular complications associated with contact lens wear can develop rapidly, and therefore early recognition and treatment of problems are critical. Infectious corneal ulceration is one of the most serious potential complications, and may be ambiguous in its early stage. Signs and symptoms of infectious corneal ulceration include discomfort, pain, inflammation, purulent discharge, sensitivity to light, cells and flare, and corneal infiltrates.

Initial symptoms of a minor abrasion and an early infected ulcer are sometimes similar. Accordingly, such epithelial defect, if not treated properly, may develop into an infected ulcer. In order to prevent serious progression of these conditions, a patient presenting symptoms of abrasions or early ulcers should be evaluated as a potential medical emergency, treated accordingly, and be referred to a corneal specialist when appropriate. Standard therapy for corneal abrasions such as eye patching or the use of steroids or steroid/antibiotic combinations may exacerbate the condition. If the patient is wearing a contact lens on the affected eye when examined, the lens should be removed immediately and the lens and lens care products retained for analysis and culturing.

SELECTION OF PATIENTS

The eye care professional should not fit patients who cannot or will not adhere to a recommended care or replacement regimen, or are unable to place and remove the lenses. Failure to follow handling and cleaning 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 ensure 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.

Patients selected to wear Bausch + Lomb Biotrue® ONEday (nesofilcon A) Contact Lenses or Bausch + Lomb Biotrue ONEday for Presbyopia (nesofilcon A) Contact Lenses should be chosen for their motivation to wear contact lenses, general health and cooperation. The eye care professional 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 detailed 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 slit lamp examination.

It is normal for the patient to experience mild symptoms such as lens awareness, variable vision, occasional tearing (watery eyes) and slight redness during the adaptation period. Although the adaptation period varies for each individual, generally within one week these symptoms will disappear.

If these symptoms persist, the patient should be instructed to contact his or her eye care professional.

FITTING PROCEDURE

1. Pre-Fitting Examination

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

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

A pre-fitting examination should include spherocylinder refraction and VA, keratometry, and biomicroscopic examination.

2. Initial Lens Power Selection

SPHERICAL:

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

b. 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.

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

MULTI-FOCAL:

a. Perform a preliminary evaluation to determine distance refraction and near add requirements.

b. Determine patient's spherical equivalent refractive error corrected to the corneal plane.

c. For each eye, select a lens of the power closest to the patient's spherical equivalent distance Rx.

d. Select the appropriate ADD. Use equal adds for both eyes.

- Bausch + Lomb Biotrue ONEday for Presbyopia Low Add +0.75D to +1.50D
- Bausch + Lomb Biotrue ONEday for Presbyopia High Add +1.75D to +2.50D

e. Measure binocular near and distance visual acuity.

f. 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, add plus to the non-dominant eye only. Measure near, then distance VA binocularly then monocularly. To improve distance vision, add minus in -0.25D increments to both eyes. If near vision becomes unacceptable with this change, add minus to the dominant eye only. Measure distance, then near VA, binocularly then monocularly.

g. Make final lens changes and confirm acuity. Attempt to minimize any resultant binocular imbalance.

Demonstrate vision:

a. under normal conditions

b. at near in any position of gaze

c. in decreased illumination

d. at intermediate distances

3. Initial Lens Evaluation

a. 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.

b. 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.

4. Criteria of a Well-Fitted Lens

If the initial lens selection fully covers the cornea, provides discernible movement after a blink, is comfortable for the patient and provides satisfactory visual performance, it is a well fitted lens and can be dispensed.

5. Characteristics of a Tight (Steep) Lens

A lens which is much too steep may subjectively and objectively cause distortion which will vary after a blink. However, if a lens is only marginally steep, the initial subjective and objective vision and comfort findings may be quite good. A marginally steep lens may be differentiated from a properly fitted lens by having the patient gaze upward. A properly fitted lens will tend to slide downward approximately 0.5mm while a steep lens will remain relatively stable in relationship to the cornea, particularly with the blink.

6. Characteristics of a Loose (Flat) Lens

If the lens is too flat, it will:

- Decenter, especially on post-blink.
- Have a tendency to edge lift inferiorly and sit on the lower lid, rather than positioning between the sclera and palpebral conjunctiva.
- Have a tendency to be uncomfortable and irritating with fluctuating vision.
- Have a tendency to drop or lag greater than 2.0mm on upgaze post-blink.

7. Follow-up Care

a. Follow-up examinations are necessary to ensure continued successful contact lens wear. From the day of dispensing, the following schedule is a suggested guideline for follow up.

- 3–4 days post-dispensing
- 10 days
- 1 month
- 3 months
- Every six months thereafter

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

b. Prior to a follow-up examination, the contact lenses should be worn for at least 4 continuous 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, instill sodium fluorescein [unless contraindicated] into the eyes and conduct a thorough biomicroscopy examination.

1. The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization may be 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 fitting lens.
3. 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 re-fitted with a more appropriate lens.

PRACTITIONER FITTING SETS

Lenses must be discarded after single use and must not be used from patient to patient.

WEARING SCHEDULE

The wearing and replacement schedules should be determined by the eye care professional. Regular checkups, as determined by the eye care professional, are extremely important.

Daily Wear

There may be a tendency for the daily wear patient to over-wear the lenses initially. Therefore, the importance of adhering to a proper, initial daily wearing schedule should be stressed to these patients. The wearing schedule should be determined by the eye care professional. The wearing schedule chosen by the eye care professional should be provided to the patient. The lens is to be prescribed for single-use disposable wear, and is to be discarded after each removal.

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 one [1] diopter) in one eye may not be a good candidate for monovision with the Bausch + Lomb Biotrue® ONEday (nesofilcon A) Contact 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 not perform as well for certain tasks with this correction as they have with bifocal reading glasses. Each patient should understand that monovision 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 test for eye dominance can be used.

a. Ocular Preference Determination Methods

- Method 1—Determine which eye is the "sighting dominant 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 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 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.

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 distant 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 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 eye care professional in conjunction with the patient after carefully considering the patient's needs.**
- **All patients should be supplied with a copy of the Bausch + Lomb Biotrue® ONEday (nesofilcon A) Contact Lens Patient Information Booklet.**

MULTI-FOCAL FITTING GUIDELINES

1. Patient Selection

a. 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 one [1] diopter) in one eye may not be a good candidate for the Bausch + Lomb Biotrue ONEday for Presbyopia (nesofilcon A) Soft (Hydrophilic) 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 multi-focal correction. Multi-Focal 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 multi-focal 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 multifocal correction. Patients may not perform as well for certain tasks with this correction as they have with multifocal reading glasses. Each patient should understand that multifocal correction 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 multi-focal contact lenses provide.

2. Lens Selection

a. Select the patient's distance spectacle spherical equivalent (must be in minus cylinder form, ignore the cylinder) and vertex, if necessary.

b. Select the appropriate ADD. Use equal adds for both eyes.

- Bausch + Lomb Biotrue ONEday for Presbyopia Low Add (+0.75D to +1.50D)
- Bausch + Lomb Biotrue ONEday for Presbyopia High Add (+1.75D to +2.50D)

3. Lens Fitting

a. Equilibrate for 10 minutes.

b. Lens should center well with 0.5 – 1.0mm movement in primary gaze, 1.0 – 1.5mm upward gaze.

c. Check distance acuity monocularly in normal room illumination.

d. Over-refract if necessary in 0.25D steps to 20/25.

e. Check distance acuity binocularly. Over-refract if necessary in 0.25D steps to 20/20.

f. Check near acuity binocularly, with distance over-refraction still in place.

4. Symptom Resolution

a. Acuity 0.25D makes a significant difference in acuity, re-check near and distance acuities with over-refraction in place.

b. Distance visual acuity not acceptable –

If patient is wearing two Low ADD lenses:
1. Add –0.25D to the dominant eye.

If patient is wearing two High ADD lenses:
1. Add -0.25D to the dominant eye.
2. Use a Low ADD in the dominant eye and High ADD in the non-dominant eye.

c. Near visual acuity not acceptable –

If patient is wearing two Low ADD lenses:
1. Add +0.25D to the non-dominant eye.
2. Use a Low ADD in the dominant eye and High ADD in non-dominant eye.
3. If near vision is still not acceptable, use High ADD in both eyes.

If patient is wearing two High ADD lenses:
1. Add +0.25D to the non-dominant eye.

5. Trial Lens Fitting

A trial fitting is performed in the office to allow the patient to experience multi-focal correction. Lenses are fit according to the directions in the general fitting guidelines.

Case history and standard clinical evaluation procedure should be used to determine the prognosis. With trial lenses of the proper power in place, observe the reaction to this mode of correction.

6. Other Suggestions

The decision to fit a patient with multi-focal correction is most appropriately left to the eye care professional in conjunction with the patient after carefully considering the patient's needs.

All patients should be supplied with a copy of the Bausch + Lomb Biotrue ONEday for Presbyopia (nesofilcon A) Soft (Hydrophilic) Contact Lens Patient Information Booklet.

HANDLING OF LENSES

Patient Lens Care Direction

When lenses are dispensed, the patient should be provided with appropriate and adequate instructions and warnings for lens care handling. The eye care professional should recommend appropriate and adequate procedures for each individual patient in accordance with the particular lens wearing schedule.

CARE FOR A STICKING (NONMOVING) LENS

If the lens sticks (stops moving), the patient should be instructed to use a lubricating or rewetting solution in their eye. The patient should be instructed to **not** use plain water, or anything other than the recommended solutions. The patient should be instructed to contact the eye care professional if the lens does not begin to move upon blinking after several applications of the solution, and to not attempt to remove the lens except on the advice of the eye care professional.

EMERGENCIES

If chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into your eyes, you should: FLUSH EYES IMMEDIATELY WITH TAP WATER AND THEN REMOVED LENSES PROMPTLY. CONTACT YOUR EYE CARE PROFESSIONAL OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing Bausch + Lomb Biotrue® ONEday (nesofilcon A) Soft (Hydrophilic) Contact Lenses or Bausch + Lomb Biotrue ONEday for Presbyopia (nesofilcon A) Soft (Hydrophilic) Contact Lenses or experienced with the lenses should be reported to:

Bausch & Lomb Incorporated
Rochester, New York 14609
Toll Free Telephone Number
In the Continental U.S., Alaska, Hawaii
1-800-553-5340
In Canada
1-888-459-5000 (Option 1 - English, Option 2 - French)

HOW SUPPLIED

Each sterile lens is supplied in a plastic package containing borate buffered saline solution with poloxamine. Each container is marked with the manufacturing lot number of the lens, diopter power, and expiration date.