CAUTION:
Federal (U.S.A.) law restricts this device to sale by or on the order of a licensed practitioner.
IMPORTANT:
This package insert and fitting guide has been developed to provide practitioners
with information covering characteristics of the BAUSCH & LOMB® PureVision®
(balafilcon A) Visibility Tinted contact lens and to illustrate fitting procedures.
It is effective as of January 2007 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® PureVision® (balafilcon A) Visibility Tinted contact lens is
a soft hydrophilic contact lens which is available as a spherical lens. The lens
material, balafilcon A, is a copolymer of a silicone vinyl carbamate, N-vinyl-
pyrrolidone, a silicone crosslinker and a vinylamine wetting monomer, and is
36% water by weight when immersed in a sterile buffered saline solution.
This lens is tinted blue with up to 300 ppm of Reactive Blue Dye 246.

The physical / optical properties of the lens are:
Specific Gravity: 1.064
Refractive Index: 1.426
Light Transmittance: C.I.E. value—at least 95%
Water Content: 36%
Oxygen Permeability: 91 x 10-11(cm³STP)/cm²/sec x cm Hg @ 35°C Polargraphic Method
@ Boundary and Edge Corrected
1010 x 10-11(cm³STP)/cm²/sec x cm Hg @ 35°C Polargraphic Method
@ Boundary Corrected, Non-Edge Corrected

The PureVision contact lenses, with AerGel™ technology lens material, are
manufactured by the Formcast™ manufacturing process, cast molding process,
and are surface treated by the Performa™ surface treatment process which
transforms hydrophobic silicone to hydrophilic silicone.

The PureVision contact lens may be prescribed for Frequent/Planned
Replacement or Disposable Wear.

LENSES PARAMETERS AVAILABLE:
The BAUSCH & LOMB® PureVision® (balafilcon A) Visibility Tinted contact lens is
a spherical lens shell of the following dimensions:

- Diameter: 14.00 mm
- Center Thickness: 0.05 mm to 0.50 mm
- Base Curve: 8.3 mm and 8.6 mm
- Prowess (Spherical): +6.00 to −12.00*

*+8.3 mm available from −0.25D to −6.00. Additional powers may be introduced
over time, check for product availability.

HOW THE LENS WORKS (ACTIONS):
In its hydrated state, the BAUSCH & LOMB® PureVision® (balafilcon A) Visibility Tinted
contact lens when placed on the cornea acts as a refracting medium to focus
light rays on the retina. When placed on the cornea for therapeutic use, the
PureVision contact lens acts as a bandage to protect the cornea and relieve pain
during treatment of ocular pathologies.

INDICATIONS:
Vision Correction
The BAUSCH & LOMB® PureVision® (balafilcon A) Visibility Tinted contact lens is
indicated for daily wear or extended wear from 1 to 30 days between removals,
for cleaning and disinfection or disposal of the lens, as recommended by the
eye care professional. The lens is indicated for the correction of refractive ametropia
(myopia and hyperopia) in aphakic and/or aphakic persons with
non-diseased eyes, exhibiting astigmatism of 2.00 dipters or less, that does
not interfere with visual acuity. The lens may be prescribed for Frequent/Planned
Replacement Wear or Disposable Wear in spherical powers ranging from +8.00
to −20.00 when prescribed for up to 30 days of extended wear and from
+20.00 to −20.00 for daily wear or extended wear up to 7 days.

Therapeutic Use
The PureVision contact lens is also indicated for therapeutic use. Use as a
bandage contact lens for corneal protection and corneal pain relief during
removal of ocular pathologies as well as post-surgical conditions. Applications
of the PureVision contact lens include but are not limited to conditions such as
the following:
- For corneal protection in conditions such as entropion, trichiasis, tarsal scars,
  recurrent corneal erosion and post surgical pets for corneal protection;
- For corneal pain relief in conditions such as bullous keratopathy, epithelial
  erosion and abrasion, filamentary keratitis, post-keratectomy;
- For use as a bandage during the healing process of conditions such as
  chronic epithelial defects, corneal ulcer, neurotrophic keratitis,
  neurotrophic keratitis, chemical burns, and post surgical epithelial defects.
- For post-surgical conditions that include bandage use such as LASIK,
  PKR, PK, PKT, lamellar grafts, corneal flaps, and additional corneal
  surgical conditions.

PureVision contact lenses for therapeutic use can also provide optical correction
during healing if required.

FREQUENT/PLANNED REPLACEMENT WEAR
When prescribed for Frequent/Planned Replacement Wear, the PureVision
contact lens is to be cleaned, rinsed and disinfected each time it is removed
from the patient’s eye and discarded after the recommended wearing period
prescribed by the eye care professional. The lens may be disinfected using a
chemical disinfection system.

DISPOSABLE WEAR
When prescribed for Disposable Wear, the PureVision contact lens is to be
discarded after each removal.

CONTRAINDICATIONS (REASONS NOT TO USE):
DO NOT USE THE BAUSCH & LOMB® PureVision® (balafilcon A) Visibility Tinted
contact lens when any of the following conditions exist: A
- Acute or 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 hypoplasia (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
- A metallic foreign particle, such as mercury or Thimerosal, in a solution
  which is to be used to care for the PureVision contact lens
- 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 this 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.
- When prescribed for Frequent/Planned Replacement Wear, the need for strict compliance with the care
  regimen including cleaning of the lens case, wearing restrictions, wearing schedule, and follow-up visit
  schedule should be emphasized to the patient.
- Studies have shown that contact lens wearers who are smoke have a higher incidence of adverse reactions
  than non-smokers.

EXTENDED WEAR
- The risk of microbial keratitis has been shown to be greater among users of
  extended wear contact lenses than among users of daily wear contact lenses.
  Some researchers believe that these complications are caused by one or more of the following: a weakening of the cornea's resistance to
  infection, particularly during a closed-eye condition, as a result of hypoxia;
  an eye environment which is somewhat more conducive to the growth of bacteria and other microorganisms, particularly when a regular periodic
  lens removal and disinfecting or disposal schedule has not been adhered to
  by the patient; improper lens disinfection or cleaning by the patient;
  contamination of lens care products; poor lens hygiene by the patient;
  patient unsuitability to the particular lens or lens care schedule;
  accumulation of lens deposits; damage to the lens; improper fitting; length of
  wearing time, and the presence of ocular debris or environmental contamiants.
- While the great majority of patients successfully wear contact lenses,
  extended wear of lenses also is reported to be associated with a higher
  incidence and degree of epithelial microcysts and infiltrates, and endothelial polymegathism, which require consideration of discontinuation or
  restriction of extended wear. The epithelial conditions are reversible upon
  discontinuation of extended wear.
- The long term risk of microbial keratitis has not been determined for this
  lens. Post-marketing studies are in progress. The reversibility of endothelial effects of contact lens wear has not been conclusively established. As a result, practitioners' views of extended

wearing times vary from not prescribing extended wear at all to prescribing flexible wearing times from occasional overnight wear to prescribing extended wearing periods of no lens wear for certain patients, with follow-up visits, and with proper care regimen.

- 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, wettablility, centration and peripheral thickness, and optical zone diameter.
- The oxygen transmission is below the established threshold required to prevent overnight corneal edema for the extremes of the power range, above +3.00 and -5.00. In the U.S. clinical study, the rate of infiltrative keratitis was found to be higher with higher lens powers (see Clinical Studies section of this package insert).
- 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 prescribing eye care professional should carefully monitor the corneal health of the patient and lens performance on eye.
- 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 are fluoresced in use and should become discolored. Whenever fluorescein is used in use, the eyes should be flushed with sterile saline solution that is recommended for use for any use.
- The patient should be instructed to always discard disposable lenses and lenses worn on a frequent/planned replacement schedule after the recommended wear time schedule prescribed by the eye care professional.
- Some patients may not be able to tolerate continuous wear even if able to tolerate the same lenses on a daily wear basis. Some patients who are able to tolerate continuous wear will not be able to wear their lenses continuously for 30 days. Patients should be carefully evaluated for continuous wear before prescription and dispensing, and eye care professionals should contact early and frequent follow-up examination to determine ocular response to continuous wear.
- As with any contact lens wear, follow-up visits are necessary to assure the continuing health of the patient's eyes. The patient should be instructed to return for a follow-up schedule.
- Aphakic patients should be fitted with PureVision contact lenses until the determination is made that the eye has healed completely.

In addition, for THERAPEUTIC USE:
- Close professional supervision is necessary for therapeutic use of PureVision lenses.
- Medications necessary for treatment should be used with caution under close supervision by the eye care professional.
- Consultations in eyes with a history of corneal disease are not recommended.
- Considerations in eyes with a history of corneal disease are not recommended.
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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.
- 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-based cosmetics are less likely to damage lenses than oil-based products.
- Be sure that before leaving the eye care professional’s office, the patient is able to remove lenses promptly if desired or has someone else available to remove them. Be certain that the fingers or hands are free of any material before touching lenses, as microscopic scratches of the lenses may occur, causing distortion vision and/or irritation to the eye.
- Always handle lenses carefully and avoid dropping them.
- Do not touch the lens with fingers.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in the Patient Information Booklet for the PureVision 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.
- For THERAPEUTIC USE, in some circumstances only the eye care professional will insert and remove lenses and if so, patients should be instructed NOT to handle lenses themselves.

Solution Precautions:
- Do not use the Allergen Ultrapure Disinfecting System or any of its components (Ultrapure Disinfecting Solution, Ultrapure Neutralizing Tablets, Lens Plus Daily Cleaner, and Ultrapure enzymatic Cleaner) to clean and disinfect the PureVision contact lens because the lens dimensions will be altered.

Eye injury due to irritation or infection may result from lens contamination. To reduce the risk of contamination, review the appropriate manufacturer’s labeled lens care instructions with the patient.

- Always use fresh unexpired lens care solutions.
- Always follow the manufacturer’s labeling for the use of contact lens solutions.
- Sterile unreserved solutions, when used, should be discarded after the time specified in the labeling directions.
- Always keep the lenses completely immersed in the recommended storage solution when lenses are not being worn (stored). Prolonged periods of drying will damage lenses. Follow the lens care directions for Care for a Dried Out (Dehydrated) Lens in the patient information booklet if lens surface does become dried out.

- Do not use saliva or anything other than the recommended solution for lubricating or wetting lenses.
- Top water, distilled water or homemade saline should not be used as a substitute for any component in the lens care regimens since they have been associated with an Acanthamoeba keratitis infection.
- Never use conventional hard contact lens solutions that are not also recommended for use with prescribed lenses.
- Do not mix or alternate lens care systems or solutions unless indicated in the lens care system labeling.
- Do not heat the chemical disinfection solution or lenses.

Lens Wearing Precautions:
- Never wear lenses beyond the period recommended by the eye care professional.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking Lens. The lens should move freely on the eye for the continued health of the eye. If movement of the lens continues, the patient should be instructed to immediately consult the eye care professional.
- Avoid, if possible, all harmful or irritating vapors and fumes while wearing lenses.
- If sneezes occur products are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.

Lens Case Precautions:
- Contact lens cases can be a source of bacterial growth. To prevent contamination and to help avoid serious eye injury, always empty and rinse the lens case with fresh, sterile rinsing solution and allow to air dry.
- Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or eye care professional.

Topics to Discuss with the Patient:
- As with any contact lens, follow-up visits are necessary to assure the continued health of the patient. 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 your 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:
- Eye 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:

• 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 lens; 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 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.

During THERAPEUTIC USE, an adverse effect may be due to the original disease or injury or may be due to the effects of wearing a contact lens. There is a possibility that the existing disease or condition might become worse when a soft contact lens for therapeutic use is used to treat an already diseased or damaged eye. The patient should be instructed to avoid serious eye damage by contacting the eye care professional IMMEDIATELY if there is any increase in symptoms while wearing the lens.

**CLINICAL STUDIES:**

**EXTENDED WEAR STUDY**

**STUDY DESCRIPTION**

**Study Design**

The objective of this 12-month study was to evaluate the safety and efficacy of the RAUSCH 6 LOMBIO PureVision® (Balafilcon A) Visibility Tinted contact lens worn on a 30-day continuous wear basis, compared to a conventional Control lens worn on a 7-day continuous wear basis. A total of 1640 eyes (820 subjects) were enrolled into this study. Subjects were fitted with a PureVision contact lens on one eye while the contralateral eye was fitted with a Control lens. Subjects were instructed to replace the PureVision contact lens with a new lens every 30 days, and to wear the Control lens overnight for up to six consecutive nights per week. Eyes had one night without lens wear after the scheduled removal. The Control lens was to be replaced with a new lens every 14 days.

Six hundred ten (610) subjects completed the one-year study. Ten subjects discontinued in the daily wear adaptation period, 182 subjects discontinued during the extended wear phase and 18 subjects were not dispensed lenses.

**Patient Assessments**

Subjects were evaluated at follow-up visits scheduled after 24 hours, 10 days, 1 month, 3 months, 6 months, 9 months, and 12 months of lens wear.

**Demographics**

Subject recruitment was open to adapted and unadapted contact lens wearers. There were no restrictions as to the subject’s gender or occupation, but subjects were required to be of legal age (typically 18 or 21) and have the legal capacity to volunteer. The ages of the subjects ranged from 17 to 74 years of age, with a mean age of 33.6, and included 574 females and 226 males, with a ratio of 2.52 females to every male. For the PureVision contact lens the power range used was -0.50D to -9.00D. For the Control lens the power range was -0.50D to -8.50D.

The previous lens wearing experience of the subjects that participated in the study was 5% no lens wear, 43% daily wear, and 51% continuous wear. The refractive errors of the subjects ranged from -0.25D to -11.75D, and included up to -2.00D of astigmatism.

**SUMMARY OF DATA ANALYSES**

**Summary of Data Analyses**

The key endpoints for this study were:
1. Grade 2 and higher slit lamp findings (safety endpoint);
2. Grade 2 and higher corneal infiltrates (efficacy endpoint);
3. Contact lens corrected visual acuity worse than 20/40 (efficacy endpoint).

For each key endpoint, the rates (incidents of endpoint/number of eyes) experienced by eyes in the PureVision contact lens and Control lenses were calculated. The difference in rates between the two lens types was determined and a 95% confidence interval for the difference was calculated. For each key endpoint a “clinically significant difference” in the rates was established before the study started. These “clinically significant differences” were as follows: 10% for total slit lamp findings, 5% for corneal infiltrates, 2% for acuity endpoint. For example, if the true rates of endpoint infiltrates in the subject population were 9.99% in the PureVision contact lens and 5% in the Control lens, these rates would be considered substantially equivalent (difference < 5%).

In order to be successful for a given endpoint, the upper 95% confidence limit for the difference in the study rates had to be less than the pre-established “clinically significant difference.” This means that we are 95% confident that the true difference is within tolerance. The safety and efficacy goals were met for all three key endpoints.

**Results are as follows:**

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>PureVision</th>
<th>Control</th>
<th>Relative Risk PureVision vs Control</th>
<th>Difference %</th>
<th>Upper 95% Confidence Level</th>
<th>Clinically Significant Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scleral Lamellar Incision</td>
<td>Grade 2</td>
<td>138</td>
<td>139</td>
<td>1.0</td>
<td>-0.1%</td>
<td>2.0%</td>
</tr>
<tr>
<td>Corneal Intravascular</td>
<td>Grade 2</td>
<td>23</td>
<td>9</td>
<td>2.6</td>
<td>1.4%</td>
<td>2.0%</td>
</tr>
<tr>
<td>Visual Acuity Worse Than 20/40</td>
<td></td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>-4.3%</td>
<td>8.1%</td>
</tr>
</tbody>
</table>

**Summary of Slit Lamp Findings**

Slit lamp examinations were conducted at every study visit. Each graded slit lamp parameter was scored on a qualitative grade scale ranging from 0 to 4, with Grade 0 representing the absence of findings, and Grades 1 through 4 representing successively worse findings. For each study eye, a determination was made for each parameter as to whether, or not a positive finding was present at any visit. The following table describes slit lamp findings: Grade 2 and ungraded slit lamp findings.

<table>
<thead>
<tr>
<th>Slit Lamp Findings</th>
<th>PureVision</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gradated Slit Lamp Findings (≥ Grade 2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any Finding</td>
<td>17.5%</td>
<td>17.6%</td>
</tr>
<tr>
<td>Corneal Staining</td>
<td>8.2%</td>
<td>8.4%</td>
</tr>
<tr>
<td>Limbal Injection</td>
<td>3.7%</td>
<td>4.3%</td>
</tr>
<tr>
<td>Bulbar injection</td>
<td>5.2%</td>
<td>4.7%</td>
</tr>
<tr>
<td>Tarsal Conjunctival Abnormalities</td>
<td>3.9%</td>
<td>3.9%</td>
</tr>
<tr>
<td>Corneal Infiltrates</td>
<td>2.9%</td>
<td>1.3%</td>
</tr>
<tr>
<td>Epithelial Edema</td>
<td>1.3%</td>
<td>1.8%</td>
</tr>
<tr>
<td>Epithelial Microcysts</td>
<td>0.5%</td>
<td>1.0%</td>
</tr>
<tr>
<td>Corneal Neovascularization</td>
<td>0.0%</td>
<td>1.7%</td>
</tr>
</tbody>
</table>

| Ungraded Slit Lamp Findings |          |
| Other Anterior Segment Abnormalities | 13.2% | 13.8% |
| External Adnexa Abnormalities | 2.7% | 2.7% |
| Conjunctivitis | 2.4% | 2.0% |
| Corneal Stripe | 0.0% | 0.3% |
1. Slit Lamp Finding and Corneal Infiltrates ≥ Grade 2 were the safety endpoints for this study.
2. The total of all Graded slit lamp findings does not equal the category of Any Finding.
3. The more common findings identified as Other Anterior Segment Abnormalities included conjunctival staining; dimples/veils; mucin balls; lipid deposits; and gauze vessels.

It should be noted that the PureVision contact lens and the Control lens were each fit on only the right or left eye for each subject. Rates per subject are expected to be higher when lenses are fit on both eyes.

**Corneal Infiltrates**
The following table describes the rate of corneal infiltrates according to the lens power used.

<table>
<thead>
<tr>
<th>Lens Power</th>
<th>PureVision</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥ Grade 2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Plan to - 3.00</td>
<td>1.7 %</td>
<td>0.9 %</td>
</tr>
<tr>
<td>- 3.25 to - 6.00</td>
<td>3.2 %</td>
<td>1.5 %</td>
</tr>
<tr>
<td>&gt; - 6.00</td>
<td>6.4 %</td>
<td>1.3 %</td>
</tr>
<tr>
<td>Total</td>
<td>2.9 %</td>
<td>1.3 %</td>
</tr>
</tbody>
</table>

**Other Lens-Related Adverse Events**
In addition to the outcomes described above, the following lens related adverse events were noted. This table does not include conjunctivitis or tarsal conjunctival abnormalities, e.g., giant papillary conjunctivitis.

**Other Important Lens-Related Adverse Events**

<table>
<thead>
<tr>
<th></th>
<th>PureVision</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Corneal Scar</td>
<td>14 (1.8 %)</td>
<td>5 (0.6 %)</td>
</tr>
<tr>
<td>Other Ocular Inflammation*</td>
<td>10 (1.3 %)</td>
<td>2 (0.3 %)</td>
</tr>
<tr>
<td>Anterior Chamber Reaction</td>
<td>2 (0.3 %)</td>
<td>1 (0.1 %)</td>
</tr>
<tr>
<td>Permanent Loss of Vision</td>
<td>0 (0.0 %)</td>
<td>0 (0.0 %)</td>
</tr>
</tbody>
</table>

* Other Ocular Inflammation includes episcleritis, scleritis, iritis/uveitis. This condition was reported in association with other conditions such as keratitis, corneal infiltrates, blepharitis, corneal abrasion, and contact lens over wear.

Efficacy Outcomes
The contact lens visual acuity was measured at each scheduled and unscheduled follow-up visit throughout the one-year study. For the 610 subjects that completed the study, visual acuity of 20/20 or better was reported for 87% and 86% of the measurements for the PureVision contact lens and Control lens, respectively. Similarly, visual acuity of 20/25 or better was reported 98% and 97% of the times for the PureVision contact lens and Control lens.

Wearing Time
In this U.S. clinical study subjects were required to maintain a minimum wearing time in order to continue in the study. For the subjects that completed the study, the average continuous wear time for the PureVision contact lens was at least 28.0 days per month, from the 2-month visit through the 12-month visit. At these visits the same subjects reported they were able to wear the PureVision contact lens at least 22 days continuously 94% of the times they were asked.

During the course of the study, 15 subjects were discontinued from the study because they were not able to wear the PureVision contact lens for 30 days. Twenty-one (21) subjects were discontinued from the study because they were not able to wear the Control lens for 7 days.

**OVERNIGHT CORNEAL SWELLING**
Two separate studies assessed the corneal swelling response induced by overnight contact lens wear. In the first study, 30 subjects each wore either a +3.00D, -3.00D, or -9.00D PureVision contact lens and an equivalent power lens made from a conventional hydrogel material (Control lens) on the contralateral eye overnight under closed eye conditions for approximately eight hours. The corneal swelling, measured as the percent increase in the central thickness of the cornea, with the Control lens (9.1%) was significantly greater than that measured in conjunction with the PureVision contact lenses (4.1%).

In the second study, the corneal swelling response was measured under similar conditions. In this study the response to a -3.00D PureVision contact lens (3.0%) was compared to the swelling response to no lens wear (1.9%). The responses were not statistically different (p-value > 0.05).

**THERAPEUTIC USE STUDIES:**
**Introduction:**
Two prospective open-ended non-randomized clinical trials were conducted to evaluate PureVision contact lenses as continuous wear lenses for therapeutic applications. The studies, conducted in Asia, included subjects who presented at the two centers requiring continuous lens wear for relief of corneal pain, a bandage during the healing process of certain corneal conditions and corneal protection.

**STUDY # 1:**
**Study Description**
A total of 54 eyes of 54 patients were reported with a mean wearing time of 1.1 months (range from 1 day to 11 months). Twenty-eight (52%) of the subjects were male and 26 (48%) were female with an average age 50 years (range from 4 to 79 years old).

Thirty-six of the fifty-four subjects (67%) were post surgical cases including post-surgical treatment after refractive laser assisted in-situ keratomileusis (LASIK), photorefractive keratectomy (PRK), phototherapeutic keratoplasty (PTK), and penetrating keratoplasty (PK), corneal grafts, conjunctival flaps, vitrectomy, tumor excision of the conjunctiva, anterior stromal puncture, and phacoemulsiﬁcation leak repair. A total of 7 cases for bullous keratopathy, 3 cases of chemical burn, 3 cases of epithelial abrasion or recurrent erosion, 3 cases of corneal perforation, 1 case neurotrophic ulcer, and 1 case corneal laceration were also treated.
Data Analysis and Results:
Where corneal pain relief was one of the treatment goals, twenty-seven of the 28 (96%) cases were considered successful with complete or considerable pain relief and an additional patient reported partial pain relief (4%). Of the forty cases where the lens was used as a bandage during corneal healing was one of the goals, total success was achieved in 83% (33/40) of the cases and partial success was achieved in 9% (3/40) of the cases. All twenty-one cases (100%) of the subjects needing corneal protection were effective.

STUDY # 2:
Study Description
A total of 30 eyes of 28 subjects were fitted with the PureVision contact lens with a mean wear time of 25.2 days (ranging from 3 days to 3 months). Nineteen (68%) of the subjects were male and 9 (32%) were female with an age range from 9 years to 55 years.

Lenses were categorized included post-surgical bandage use in 27 cases (post-PK, post-deep lamellar keratoplasty, pterygium excision, conjunctival allograft, peripheral ulcerative keratitis, descemetocele, post-chemical burns, and corneal perforation from severe dry eye), mechanical support use for 1 case of bullous keratopathy, symptomatic corneal pain relief for 1 case of filamentary keratitis and healing adjunct in 1 case of a non-healing corneal abrasion.

Data Analysis and Results:
Therapeutic success was reported in 83% of the eyes where the lens was used as a post-surgical bandage, and 100% in each case of mechanical support (1), epithelial abnormalities (1), bullous keratopathy (1), and filamentary keratitis (1). Fifteen of 19 eyes (79%) with post-surgical epithelial defects were successful within 3 days to 3 weeks. All subjects reported symptomatic relief. Complications included infectious keratitis in 2 subjects that were being treated for post-PK persistent epithelial defect and corneal vascularization observed in one case where the cornea was already compromised due to a grade 4 alkali injury. The investigators reported the overall study therapeutic success in 87% (26/30) of the cases.

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 should not be provided with them. 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 PureVision 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

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 corneal measurements for initial contact lens parameter selection, and;
- Collect and record baseline clinical information to which post-fitting examination results can be compared.

A prefitting examination should include sphero-cylindrical refraction and VA, keratometry, and biomicroscopic examination.

2. Initial Lens Power 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 toxicity, 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
- 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. If after the lens has settled on the eye, the patient reports lens sensation, or if the lens is moving or derecteering 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 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:
- Occur, 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 sag 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.
- 4 hours
- 24 hours
- 10 days
- 1 month
- 3 months
- Every 6 months thereafter

At the initial follow-up examinations 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. Depending on the patient's prior experience with contact lenses and/or continuous wear, the eye care professional may consider prescribing a one week period of daily wear adaptation prior to beginning continuous wear.

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. If the patient is wearing the lenses for continuous wear, the follow-up examination should be conducted as early as possible the morning after overnight 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 biomicroscopic examination.

1. The presence of vertical corneal stripe in the posterior central cornea and/or corneal neovascularization may be indicative of excessive corneal edema.

2. The presence of corneal staines 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.
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 ambyloptic 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
      PureVision® (balafilcon A) Visibility Tinted 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 lenses wear may not be optimal for
      such activities as:
      1. Visually demanding situations such as operating potentially dangerous
         machinery or performing 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 not to 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. Examine the patient’s reaction to monovision
   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 newspaper 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 disorientation. 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 accompanied by 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.
- Wearing supplemental spectacles to wear over the monovision contact lenses for specific visual tasks may improve the success of 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 power 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 PureVision contact lens Patient Information Booklet.

HANDLING OF LENSES

Patient Lens Care Directions:
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 and protocols for each individual patient in accordance with the particular lens wearing schedule and care system selected by the professional. The specific instructions for such products and the particular characteristics of the patient.

Frequent/Planned Replacement Wear: For complete information concerning the care, cleaning and disinfection of contact lenses refer to the PureVision® (Baltalicon A) Visibility Tinted contact lens Patient Information Booklet.

Disposable Wear: For complete information concerning emergency lens care, refer to the PureVision contact lens Patient Information Booklet.

Therapeutic Wear: For complete information concerning emergency lens care, refer to the PureVision® (Baltalicon A) Visibility Tinted contact lens Patient Information Booklet or your eye care professional.

CARE FOR A STICKING (NONMOVING) LENS:
If the lens sticks (tends 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.

REPORTING OF ADVERSE REACTIONS:
All serious adverse experiences and adverse reactions observed in patients wearing BAUSCH & LOMB® PureVision® (Baltalicon A) Visibility Tinted 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
1-800-828-9530
In New York State
1-800-462-1720
In Canada
1-866-668-7510

HOW SUPPLIED:
Each sterile lens is supplied in a plastic blister package containing borate buffered saline solution. The container is marked with the manufacturing lot number of the lens, the base curve, sphere, diameter and expiration date.


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