

Bausch & Lomb PureVision® (balafilcon A)

Visibility Tinted Contact Lenses

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

Bausch & Lomb Incorporated
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SYMBOL REFERENCE GUIDE

For label and cartons:

The following symbol is for the CE Quality Certification			Batch code
	Meets EU Packaging Directive		Authorized representative in the European Community
	Sterilized using steam		Prescription only (USA)
	Caution		Base curve
	Diameter		Temperature limit
	Use-by date		Effective date
	Power		Manufacturer



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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 PureVision® (balafilcon A) Visibility Tinted contact lens and to illustrate fitting procedures. It is effective as of the date on the cover 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 practitioner, but should be made available to patients upon request. The eye care practitioner 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 carbonate, N-vinyl-pyrrolidone, a siloxane crosslinker and a vinyl alanine buffering monomer, and is 36% water by weight when immersed in a sterile borate 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 [cm ³ O ₂ (STP) x cm] / (sec x cm ² x mmHg) @ 35°C Polarographic Method (Boundary and Edge Corrected)
	101 x 10 ⁻¹¹ [cm ³ O ₂ (STP) x cm] / (sec x cm ² x mmHg) @ 35°C Polarographic 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 silicate.

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

LENS PARAMETERS AVAILABLE

The Bausch & Lomb PureVision® (balafilcon A) Visibility Tinted contact lens is a hemispherical shell of the following dimensions:

Diameter:	14.0mm
Center Thickness:	0.05mm to 0.50mm
Base Curve:	8.3mm and 8.6mm
Powers (Spherical):	+6.00D to -12.00D*

* 8.3mm available from -0.25D to -6.00D. 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

Vison 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 practitioner. The lens is indicated for the correction of refractive ametropia (myopia and hyperopia) 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 for Frequent/Planned Replacement Wear or Disposable Wear in spherical powers ranging from +8.00D to -20.00D when prescribed for up to 30 days of extended wear and from +20.00D to -20.00D 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 treatment 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 ptosis for corneal protection;
- For corneal pain relief in conditions such as bullous keratopathy, epithelial erosion and abrasion, filamentary keratitis, post-keratoplasty;
- For use as a bandage during the healing process of conditions such as chronic epithelial defects, corneal ulcer, neurotrophic keratitis, neuroparalytic keratitis, chemical burns, and post-surgical epithelial defects.

- For post-surgical conditions that include bandage use such as LASIK, PRK, PK, PKI, 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 practitioner. 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:

- 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
- Allergy to any ingredient, 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 contact lens wear. **Patients should be advised of the following warnings pertaining to contact lens wear:**

Solution Precautions

Do not use the Ultracare Disinfecting System or any of its components (Ultracare Disinfecting Solution, Ultracare Neutralizing Tablets, Lens Plus Daily Cleaner, and Ultrazyme 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 directions in the package inserts for the use of contact lens solutions.
- Sterile unexpired 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.
- Tap water, distilled water or homemade saline should not be used as a substitute for any component in the lens care regimen 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 practitioner.
- 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 non-movement of the lens continues, the patient should be instructed to immediately consult his or her eye care practitioner.
- Avoid, if possible, all harmful or irritating vapors and fumes while wearing lenses.
- If aerosol products are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.

For each key endpoint, the rates (incidents of endpoint/number of eyes) experienced by eyes in the PureVision® Contact Lenses 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 ≥ Grade 2, 5% for corneal infiltrates ≥ Grade 2, and 5% for the acuity endpoint. For example, if the true rates of endpoint infiltrates in the subject population were 999% 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:

Endpoint	PureVision		Control		Relative Risk/ Pure Vision Control	Difference in %	Upper 95% Confidence Level	Clinically Significant Difference
Slit Lamp Findings ≥ Grade 2	138	175%	139	176%	1.0	-0.1%	2.6%	100%
Corneal Infiltrates ≥ Grade 2	23	29%	10	13%	2.3	16%	29%	5.0%
Visual Acuity Worse than 20/40	0	0.0%	2	0.3%	0.0	-0.3%	0.1%	5.0%

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 presented at any visit. The following table describes slit lamp findings ≥ Grade 2 and ungraded slit lamp findings.

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 practitioner.

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 practitioner 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, the patient should look closely at the lens. If the lens is in any way damaged, **do not** put the lens back on the eye. The patient should place the lens in the storage case and contact the eye care practitioner. 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 practitioner.**

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 practitioner** 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 practitioner IMMEDIATELY if there is any increase in symptoms while wearing the lens.

Corneal Infiltrates

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

PureVision	Lens Power		Corneal Infiltrates (≥ Grade 2)	
	Plano to -3.00		1.7%	
-3.25 to -6.00		3.2%		
> -6.00		6.4%		
Total		2.9%		

Control	Lens Power		Corneal Infiltrates (≥ Grade 2)	
	Plano to -3.00		0.9%	
-3.25 to -6.00		1.5%		
> -6.00		1.3%		
Total		1.3%		

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		PureVision	Control
Corneal Scar		14 (1.8%)	5 (0.6%)
Other Ocular Inflammation*		10 (1.3%)	2 (0.3%)
Anterior Chamber Reaction		2 (0.3%)	1 (0.1%)
Permanent Loss of Vision		0 (0.0%)	0 (0.0%)

* 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 wear.

It should be noted that the PureVision® Contact Lens and control lenses 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.

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 US 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 center thickness of the cornea, with the control lens (91%) was significantly greater than that measured in conjunction with the PureVision® Contact Lenses (41%). 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 (19%). The responses were not statistically different (p-value > .005).

POST-APPROVAL EXTENDED WEAR STUDY

The purpose of this post-approval study was to investigate the occurrence of serious adverse events with the PureVision® Contact Lens when worn on a 30-day continuous wear basis. Serious adverse events were any case of microbial keratitis (infected corneal ulcer) or a loss of more than two lines of best corrected visual acuity.

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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 11 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 keratotomy (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 96% (38/40) 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.

Lens wearing categories included post-surgical bandage use in 27 cases (post-PK, post-deep lamellar keratoplasty, pterygium excision, conjunctival allograft, peripheral ulcerative keratitis, descemetocoele, 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.

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- After the lens removal, instill sodium fluorescein [unless contraindicated] into the eyes and conduct a thorough biomicroscopy examination.
 - The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization may be indicative of excessive corneal edema.
 - 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.
 - 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 a 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 practitioner. Regular checkups, as determined by the eye care practitioner, 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 practitioner. The wearing schedule chosen by the eye care practitioner should be provided to the patient.

Continuous Wear (Greater than 24 hours or While Asleep)

The wearing schedule should be determined by the prescribing eye care practitioner for each individual patient, based upon a full examination and patient history as well as the practitioner's experience and professional judgment. Bausch + Lomb recommends beginning continuous wear periods with the recommended initial daily wear schedule, followed by a year of daily wear, and then gradual introduction of continuous wear one night at a time, unless individual considerations indicate otherwise. The professional should examine the patient in the early stages of continuous wear to determine the corneal response. The lens must be removed, cleaned and disinfected or disposed of and replaced with a new lens, as determined by the prescribing eye care practitioner. (See the factors discussed in the Warnings section.)

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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 practitioner 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.**

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Study Design

The intent of the study was to enroll up to 6,500 subjects who would account for 4,500 to 5,000 subject-years of lens wear enrolled by a minimum of 100 Investigators. Study lenses were dispensed to 6,412 subjects who provided 5,054 patient-years of compliant wear while being followed by 158 Investigators. The age of the eligible subjects dispensed study lenses ranged from 12 to 85, with a mean age of 36 years and a ratio of 174 female subjects for every male. The spherical refractive error of subjects ranged from +10.00D to -15.00D with a mean of -3.4D.

A subject was eligible for entry into the study if the subject:

- was, in the opinion of the Investigator, suitable for continuous soft contact lens wear;
- agreed to wear lenses on a 30-day continuous wear basis; and
- was age 12 or older.

The study protocol did not define exclusion criteria. Subjects that in the opinion of the Investigator were not suitable for continuous wear were excluded from the study. The Investigators were not required to describe preexisting conditions that precluded enrollment.

The study was divided into two phases: Phase 1 lasted for approximately 12 months; Phase 2 was considered optional and consisted of the duration of time a subject was in PureVision® lenses following completion of Phase 1. The maximum length of Phase 2 was 3 years.

In both phases, each subject wore a PureVision® Contact Lens on each eye on a 30-day continuous wear basis. Lenses were worn overnight without removal for 22-29 consecutive nights, and were removed and replaced with new lenses on the morning of the 30th day.

Follow-up visits were scheduled at 6-month intervals following the Enrollment Visit. At the Enrollment Visit and at all scheduled and unscheduled Follow-Up visits, the Investigator evaluated the best corrected spherocylindrical refractive visual acuity and examined the subject for corneal scarring and/or indications of microbial keratitis. The subjects were also questioned regarding their compliance with the lens wear schedule.

The last scheduled follow-up visit during Phase 2 was the 48-Month Visit. If a subject exited the study in Phase 2 before the 48-Month Visit, the subject was considered completed, if he/she completed a 12-Month Visit or later. The duration of the study extended until the time that the last subject enrolled had completed 12 months of contact lens wear in Phase 1.

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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 (3), 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 eyes.

SELECTION OF PATIENTS

The eye care practitioner 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 practitioner must take care in selecting, examining and instructing contact lens patients. Patient hygiene and willingness to follow practitioner instructions are essential to their success.

A 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 practitioner.

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Once removed, a lens should remain out of the eye for a period of rest overnight or longer, as determined by the prescribing eye care practitioner.

Disposable Lens Wear

No lens care is needed. The lenses are discarded every time they are removed from the eye. Lenses should only be cleaned, rinsed and disinfected on an emergency basis when replacement lenses are not available.

Frequent/Planned Replacement

When removed between replacement periods, lenses must be cleaned and disinfected before reinsertion, or be discarded and replaced with a new lens.

Therapeutic Lens Wear

Close professional supervision is necessary and strongly recommended. PureVision® lenses can be worn on a continuous wear basis for up to 30 nights and days or for shorter periods as directed by the eye care practitioner. The eye care practitioner should provide specific instructions regarding lens care, removal, and insertion. In some cases, only the eye care practitioner should handle the lens insertion and 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 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 lens wear may not be optimal for such activities as:

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

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LENS CARE

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 practitioner should recommend appropriate and adequate procedures and products for each individual patient in accordance with the particular lens wearing schedule and care system selected by the practitioner, the specific instructions for such products and the particular characteristics of the patient.

For complete information concerning the care, cleaning and disinfection of contact lenses refer to the Bausch & Lomb PureVision® (balafilcon A) Visibility Tinted Contact Lens Patient Information Booklet.

Soaking and Storing Lenses

Instruction for Use:

Use only fresh contact lens disinfecting solution each time you soak (store) lenses.

WARNING: Do not reuse or "top-off" old solution left in lens case since solution reuse reduces effective lens disinfection and could lead to severe infection, vision loss or blindness. "Topping-off" is the addition of fresh solution to solution that has been sitting in the case.

Rub and Rinse Time

Instruction for Use:

Follow the complete recommended lens rubbing and rinsing times in the labeling of the solution used for cleaning, disinfecting and soaking lenses to adequately disinfect lenses and reduce the risk of contact lens infection.

WARNING: Rub and rinse lenses for the recommended amount of time to help prevent serious eye infections. **Never use water,** saline solution, or rewetting drops to disinfect lenses. These solutions will not disinfect lenses. Not using the recommended disinfectant can lead to severe infection, vision loss or blindness.

Lens Case Care

Instruction for Use:

Clean contact lens cases with digital rubbing with fresh, sterile disinfecting solutions/contact lens cleaner. **Never use water.** Cleaning should be followed by rinsing with fresh, sterile disinfecting solutions (**never use water**) and wiping the lens cases with fresh, clean tissue is recommended. Air-drying or recapping the lens case lids after use without any additional cleaning methods should be avoided. If air-drying, be sure that no residual solution remains in the case before allowing it to air-dry. Replace lens case according to the directions given by your eye care practitioner or the labeling that came with your case. Contact lens cases can be a source of bacterial growth.

All reports of possible microbial keratitis, any report by a clinical investigator of the presence of a new corneal scar or other indication of microbial keratitis, were subjected to a multi-stage evaluation process. A thorough case review for all reports of new corneal scars or other indications of microbial keratitis was completed by a Bausch + Lomb clinician who eliminated cases with clear evidence refuting a microbial keratitis diagnosis. Then a panel of three Bausch + Lomb clinicians reviewed each of the remaining cases, and compared the clinical findings to the study definition of microbial keratitis. The records of the suspect microbial keratitis cases, the opinions and diagnosis of the independent Clinical Investigator and information from any other treating physician were reviewed by the panel and Bausch + Lomb Chief Medical Officer for a final determination.

Results

Of the 6,412 subjects dispensed study lenses, there were 7 cases of microbial keratitis reported for 7 individual subjects. No subject was diagnosed with microbial keratitis in both eyes. The table below presents a summary of the occurrence rates for microbial keratitis, new corneal scars or other indication of microbial keratitis, or permanent decrease in visual acuity of 2 or more lines.

	Cases	Patient-Years	Annual Incidence*	95%CI*
Microbial Keratitis				
All Years	7	5054	139	(3, 25)
First Year	7	3779.5	18.5	(3, 34)
New Corneal Scar or Other Reports Suggestive of Microbial Keratitis				
All Years	35	5154.5	679	(45, 91)
First Year	34	3843	88.5	(58, 119)
Permanent Decrease in Visual Acuity of 2 or More Lines				
All Years	0	5054	0	(0, 098)
First Year	0	3779.5	0	(0, 13)

** / Per 10,000 patient-years*

Patient-years were calculated considering various periods of compliant lens wear. The subjects that wore their lenses, on average, for 3 weeks out of each 4-week period, for all periods of wear contributed 5,054 patient-years of wear. With 7 cases of microbial keratitis for 5,054 patient-years, the incidence of microbial keratitis is 139 cases per 10,000 patient-years of lens wear.

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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

- Lens power is determined from the patient's spherical equivalent prescription corrected to the corneal plane. Select the appropriate lens and place on the eye.

• Allow the lens to remain on the eye long enough (10 to 20 minutes) to achieve a state of equilibrium. Small variations in the tonicity, pH of the lens solutions, and individual tear composition may cause slight changes in fitting characteristics.

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

3. Initial Lens Evaluation

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

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

4. Criteria of 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.

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- 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. Note the distance corrective or correction is in diopters for both eyes. Determine whether the patient functions best with the near add lens over the right or left eye.

- Refractive Error Method
 - For anisometric 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.

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WARNING:

Do not store lenses or rinse lens case with water or any non-sterile solution. Only use fresh solution so you do not contaminate lenses or lens case. Use of non-sterile solution can lead to severe infection, vision loss or blindness.

Water Activity

Instruction for Use:

Do not expose contact lenses to water while wearing them.

WARNING:

Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. If your lenses have been submerged in water when swimming in pools, lakes or oceans, discard them and replace them with a new pair. Ask your eye care practitioner for recommendations about wearing lenses during any activity involving water.

Discard Date on Solution Bottle

Instruction for Use:

Discard any remaining solution after the recommended time period indicated on the bottle of solution used for disinfecting and soaking contact lenses.

WARNING:

Using solution beyond the discard date could result in contamination of the solution and can lead to severe infection, vision loss or blindness.

CARE FOR A STICKING (NON-MOVING) 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 practitioner 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 practitioner.

The total wear time for compliant subjects over the first year of participation in the study contributed 3779.5 patient-years of wear. This results in an incidence of microbial keratitis of 18.5 cases per 10,000 patient-years of lens wear.

There were no confirmed cases of a permanent best corrected visual acuity decrease of more than two lines related to lens wear including the 7 subjects that presented with microbial keratitis. Fifteen subjects were reported to have a best corrected visual acuity decrease of more than two lines during all periods of compliant lens wear that were classified as not lens related. Reasons for these decreases in vision included a retinal hemorrhage, retinal detachments and cataracts.

Conclusions

The incidence of microbial keratitis associated with 30 days of continuous wear of PureVision® Contact Lenses was 139 cases per 10,000 patient-years of lens wear. The 95% confidence interval around this estimate is 3