PROFESSIONAL FITTING GUIDE

Oxfore®100 (hexafocon A)

Rigid Gas Permeable Contact Lenses

CAUTION: Federal (U.S.A) law restricts this device to sale by or on the order of a licensed eye care professional.

CooperVision® Specialty EyeCare Paragon

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INTRODUCTION:

The Oxfore®100 (hexafocon A) Contact Lens is composed of aliphatic siloxanyl fluoromethacrylate copolymer with a UV light absorber. The lens is available in clear, blue, ice blue, violet, red, and green tints. The tinted lenses contain the following color additives:

Color	Color Additive
Blue	D & C Green No. 6
Ice Blue	D & C Green No. 6
Violet	D & C Violet No. 2
Red	D & C Red No. 17
Green	D & C Green No. 6, Perox Yellow No. 9

For a complete list of available lens parameters, please refer below.

DESCRIPTION:

The Oxfore®100 (hexafocon A) Rigid Gas Permeable Contact Lens is available as a spherical, aspheric, toric or multifocal design, for daily wear only. Semi-scleral and scleral lenses are available for daily wear only.

LENS PARAMETERS AVAILABLE:

(Note: not all parameter combinations are available in all designs)

Spherical and Aspheric Lens:

Diameter	7.0 to 21.0mm
Base Curve Range	4.00 to 11.50mm
Power Range	-20.00 to +20.00D (in 0.25D steps)

Toric Lens:

Diameter	7.0 to 21.0mm
Base Curve Range	4.00 to 11.50mm
Power Range	-20.00 to +20.00D (in 0.25D steps)
Toricity	Up to 9.00 Diopters

Multifocal Lens (Centered, Decentered, Crescent):

Diameter	7.0 to 21.0mm
Base Curve Range	4.00 to 11.50mm
Power Range	-20.00 to +20.00D
Add Power	+1.00 to +3.75D
Segment Heights	-2.00mm to +1.00mm
Prism Ballast	0.5 to 3.5 prism diopters

Scleral / Semi-Scleral Lens:

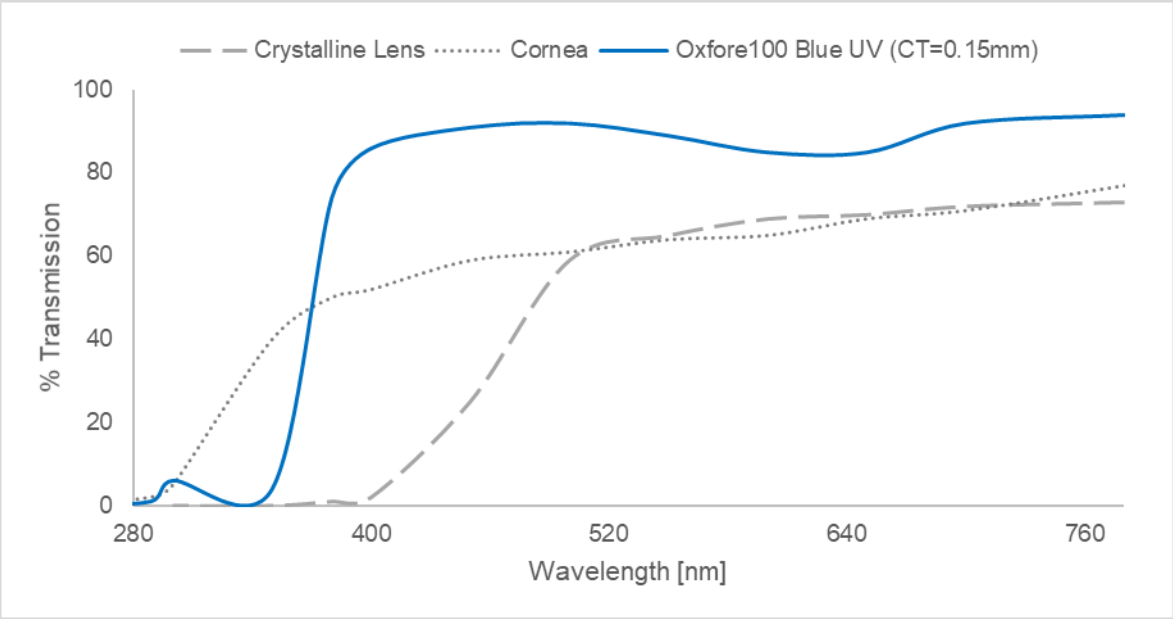
Diameter (D)	12.5 to 21.0mm
Base Curve (OZR)	4.00 to 11.50mm
Powers	-25.00 to +35.00D (in 0.25D steps)

The lenses above can have a center thickness (CT) of 0.07 to 0.65mm, depending on the design, power and diameter of the lens.

The physical/optical properties of the lens are:

Hardness (Shore D)	81
Specific Gravity:	1.27
Refractive Index:	1.415
Surface Character:	Hydrophobic
Wetting Angle (sessile):	≤79 degrees
Light Transmittance:	96% [average %T (380-780nm)]
Water Content:	Less than 1.0% by weight
Oxygen Permeability:	100×10^{-11} $(cm^2/sec)(mL\ O_2/(mL \times mmHg))$ Dk*

*Method for determination of oxygen permeability: ISO/DIS 9913.1 1994. Optics and optical instruments - Contact lenses - Part 1: Determination of oxygen permeability and transmissibility with the Fatt method. (PHEMA Standard)



Oxfore®100 (hexafocon A) Contact Lens - Spectral transmittance curve for Oxfore®100 (hexafocon A) Contact Lens – Ice Blue Tint and UV absorbing agent (sample thickness Oxfore®100 (hexafocon A) lens thickness = 0.12mm.

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

WARNING : UV-absorbing contact lenses are NOT substitutes for protective UV-absorbing eyewear such as UV-absorbing goggles or sunglasses. Persons should continue to use their protective UV-absorbing eyewear as directed."

ACTIONS:

The Oxfore®100 (hexafocon A) Contact Lens, when placed on the cornea, acts as a refracting medium to focus light rays on the retina. The Oxfore®100 semi-scleral and scleral contact lens, when placed on the conjunctiva, vaults over the cornea and acts as a refracting medium to focus light rays on the retina.

The Oxfore®100 (hexafocon A) Contact Lens is a lathe cut firm contact lens with spherical or aspheric back surfaces. The posterior curve is selected to properly fit an individual eye, and the anterior curve is selected to provide the necessary optical power to correct refractive error. A peripheral curve system on the posterior surface allows tear exchange between the lens and the cornea.

The Oxfore®100 (hexafocon A) Toric Contact Lens provides a more even surface over the different curvatures of the astigmatic cornea and thus helps to focus light rays on the retina.

The Oxfore®100 (hexafocon A) Multifocal Contact Lens provides the necessary optical powers to correct different refractive errors for distance and near requirements.

INDICATIONS (USES):

The Oxfore®100 (hexafocon A) Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, astigmatism and presbyopia) in aphakic and non aphakic persons with non-diseased eyes. The lenses may be disinfected using a chemical disinfection system only.

See **WARNINGS** for information about the relationship between wearing schedule and corneal complications.

CONTRAINDICATIONS (REASONS NOT TO USE):

DO NOT USE the Oxfore®100 (hexafocon A) Contact Lens when any of the following conditions exist:

- Acute and subacute inflammation or infection of the anterior segment of the eye

- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids
- Severe insufficiency of lacrimal secretion (dry eyes), except when using a semi-scleral or scleral lens design that maintains a fluid chamber between the cornea/conjunctiva and the contact lens
- Corneal hypoesthesia (reduced corneal sensitivity), except when using a semi-scleral or scleral lens design that maintains a fluid chamber between the cornea/conjunctiva and the contact lens and acts as a protective barrier for the cornea
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Allergic reactions of ocular surfaces or surrounding tissues that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions
- Allergy to any ingredient in a solution which is to be used to care for the Oxfore®100 (hexafocon A) Contact Lens
- Any active corneal infection (bacterial, fungal, or viral)
- If eyes become red or irritated
- Incomplete healing following eye surgery

WARNINGS:

PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE.

It is essential that the patient follows the directions of the eye care practitioner and all labeling instructions for proper use of contact lenses and lens care products, including the lens case.

Patients should be advised of the following instructions for use and warnings pertaining to contact lens wear:

a) Soaking and Storing Your Lenses

Instruction for Use:
Use only fresh multi-purpose (contact lens disinfecting) solution each time you soak (store) your lenses.

WARNING*:*
Do not reuse or "top off" old solution left in your 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 your case.

b) Rub and Rinse Time

Instruction for Use:
- Rub and rinse your lenses according to the recommended lens rubbing and rinsing times in the labeling of your multi-purpose solution to adequately disinfect your lenses.

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

c) Lens Case Care

Instruction for Use:
- Empty and clean contact lens cases with digital rubbing using 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. Never air-dry or recap the lens case lids after use without any additional cleaning methods. If air drying, be sure that no residual solution remains in the case before allowing it to air dry.
- Replace your lens case according to the directions given you by your eye care professional or the labeling that came with your case.
- Contact lens cases can be a source of bacterial growth.

WARNINGS
- Patients should be advised of the following warnings pertaining to contact lens wear:
- Problems with contact lenses and lens care products could result in **serious injury** to the eye. It is essential that patients follow their eye care professional's direction and all labeling instructions for proper use of lenses and lens care products, including the lens case. Eye problems, including corneal ulcers, can develop rapidly and lead to **loss of vision**.

- Daily wear lenses not indicated for overnight wear, and patients should be instructed not to wear lenses while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when daily wear lenses are worn overnight.
- Smoking increases the risk of corneal ulcers for contact lens users, especially when lenses are worn overnight or while sleeping.[1,2]
- 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.
- **UV-absorbing contact lenses are NOT substitutes for protective UV-absorbing eyewear such as UV-absorbing goggles or sunglasses because they do not completely cover the eye and surrounding area. Persons should continue to use their protective UV-absorbing eyewear as directed**.
- Never use tap water.
- Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. If your lenses have been submersed in water such as when swimming in pools, lakes or oceans, you should thoroughly clean and disinfect them before insertion. Ask your eye care professional for recommendations about wearing your lenses during any activity involving water.

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[1]CLAO Journal, January 1996; Volume 22, Number 1, pp. 30-37

[2]New England Journal of Medicine, September 21, 1989; 321 (12), pp. 773-783

PRECAUTIONS:

CAUTION: NON-STERILE. ALWAYS CLEAN AND DISINFECT LENSES PRIOR TO USE.

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 and wear schedule for a patient, the eye care professional should consider all lens characteristics that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.
- The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing eye care professional.
- The following patients may experience a higher rate of adverse effects associated with contact lens wear:
    - Patients with a history of acute inflammatory reactions to contact lens wear.
    - Patients with a history of giant papillary conjunctivitis associated with contact lens wear.
    - Patients with a history of ocular allergies may need to temporarily discontinue lens wear during certain times of the year.
    - Patients with a history of non-compliance with contact lens care and disinfection regimen, wearing restrictions, wearing schedule, or follow-up visit schedule.
    - Patients who are unable or unwilling to understand or comply with any directions, warnings, precautions, or restrictions. Contributing factors may include but are not limited to age, infirmity, other mental or physical conditions, and adverse working or living conditions.
    - Patients who are unwilling or unable to adhere to a recommended care regimen, or who are unable to insert and remove lenses, should not be provided with them.
- Eye care professionals should instruct the patient to remove the lenses immediately if the eye becomes red or irritated.
- The use of fluorescein is contraindicated in those persons who have a known hypersensitivity to any component.
- The presence of the ultraviolet (UV) light absorber in the Oxfore®100 (hexafocon A) Contact Lens material may require equipment enhancement to visualize fluorescein patterns adequately. (Refer to the Fitting Guide for detailed instructions.)
- As with any contact lens, follow-up visits are necessary to assure the continuing health of the patient’s eyes. The patient should be instructed as to a recommended follow-up schedule.
- Aphakic and other post-surgical persons should not be fitted with Oxfore®100 (hexafocon A) Contact Lenses until the determination is made that the eye has healed completely.
- Upon receipt, lenses should be cleaned and conditioned prior to first insertion, following the manufacturer’s instructions on the use of the contact lens solutions.

- Patients who wear aspheric contact lenses to correct presbyopia may not achieve the best-corrected visual acuity for either far or near vision. Visual requirements vary with the individual and should be considered when selecting the most appropriate type of lens for each patient.
- It is advised that wound healing and corneal curvature are stable prior to fitting Oxfore®100 lenses for post-surgical or other compromised corneas.

Eye care professionals should carefully instruct patients about the following care regimen and safety precautions. It is strongly recommended that patients be provided with a copy of the Patient Instructions for the Oxfore®100 (hexafocon A) Rigid Gas Permeable Contact Lens available from Menicon Paragon Vision Sciences, Inc. and understand its contents prior to dispensing the lenses.

Handling Precautions:
- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-based cosmetics are less likely to damage lenses than oil-based products.
- Before leaving the eye care professional's office, the patient should be able to promptly remove lenses or should have someone else available who can remove the lenses for him or her.
- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- Always handle lenses gently and avoid dropping them on hard surfaces.
- Do not touch the lens with fingernails.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in the Patient Instructions for the Oxfore®100 (hexafocon A) Contact Lens 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.

Solution Precautions:
- Always use fresh unexpired lens care solutions.
- Always follow directions in the package inserts for the use of contact lens solutions.
- Sterile unpreserved 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 the lenses are not being worn (stored). Prolonged periods of drying may reduce the ability of the lens surface to return to a wettable state.
- Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.
- Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions.
- Do not heat the cleaning, wetting, and/or soaking solution and lenses. Keep away from extreme heat.
- Use only a chemical (not heat) lens care system. Use of a heat (thermal) care system can damage the Oxfore®100 (hexafocon A) Contact 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 in **Care for a Sticking (Non-Moving) 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 professional.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- If aerosol products such as hair spray 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. Lens cases should be emptied, cleaned, rinsed with the sterile contact lens solution recommended by the lens case manufacturer (never use tap water), and allowed to air dry.
- Lens cases should be replaced at regular intervals as recommended by the lens manufacturer or your eye care professional.

Topics to Discuss with the Patient:
- As with any contact lens, follow-up visits are necessary to assure the continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.
- Patients should be advised about wearing lenses during water activities and other sports. Exposing contact lenses to water during swimming or while in a hot tub may increase the risk of eye infection from microorganisms.
- Always contact the eye care professional before using any medicine in the eyes.
- Certain medications may cause dryness of the eye, increased lens awareness, lens intolerance, blurred vision or visual changes. These include, but are not limited to, antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers, oral contraceptives and motion sickness medications. Caution patients using such medications accordingly and prescribe proper remedial measures.

Who Should Know That the Patient is Wearing Contact Lenses:
- Patients should inform the doctor (health care professional) about being a contact lens wearer.

- Patients should always inform the employer of being a contact lens wearer. Some jobs may require the use of eye protection equipment or may require that the patient not wear contact 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 that something is in the eye such as a foreign body or 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 lenses.**
- If the discomfort or problem stops, then look closely at the lens. If the lens is in any way damaged, do not put the lens back on the eye. Place the lens in the storage case and contact the eye care professional. If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, the patient should thoroughly clean, rinse, and disinfect the lenses; then reinsert them. After reinsertion, if the problem continues, the patient should **immediately remove the lenses and consult the eye care professional**.

If the above symptoms continue after removal of the lens, or upon reinsertion of a lens, or upon insertion of a new lens, the patient **should immediately remove the lenses and contact his or her eye care professional** or physician, who must determine the need for examination, treatment or referral without delay (See Important Treatment Information for Adverse Reactions). A serious condition such as infection, corneal ulcer, corneal vascularization, or iritis may be present and may progress rapidly. Less serious reactions such as abrasions, epithelial staining or bacterial conjunctivitis must be managed and treated carefully to avoid more serious complications.

Important Treatment Information for Adverse Reactions

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

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

SELECTION OF PATIENTS:

The Oxfore®100 (hexafocon A) Rigid Gas Permeable Contact Lens is available as a spherical, aspheric, toric or multifocal design are indicated for daily wear for the correction of refractive error (myopia, hyperopia, presbyopia and/or astigmatism) in aphakic and non-aphakic persons with non-diseased eyes.

Persons who require only vision correction and who would not or could not adhere to a recommended care regimen for the Oxfore®100 (hexafocon A) Contact Lens 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 ensuring patient compliance.

The patient characteristics necessary to achieve success with Oxfore®100 lenses are similar to those for other rigid gas permeable contact lenses. A thorough pre-fitting examination should be conducted to ensure the patient is a suitable candidate for rigid gas permeable contact lens wear. It is necessary to make an assessment of general health, patient hygiene, motivation and the willingness to comply with practitioner instructions.

PREPARING A RGP LENS FOR FITTING:

Oxfore®100 (hexafocon A) Contact Lenses should be thoroughly cleaned with the recommended cleaning solution and disinfected/hydrated in the recommended soaking/conditioning solution according to the labeled directions for use prior to placement on the eye to insure maximum surface wettability.

PRE-FITTING EXAMINATION:

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

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

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 of the cornea, bulbar conjunctiva, and limbus, anterior chamber and tarsal abnormalities.

The following evaluations apply to all Corneal lens designs:

1. Characteristics of a Well-Fit Lens

A good fit positions appropriately following the blink with minimal lag and the optical portion of the lens does not deviate from the pupil when the lens is drawn upwards. Ideally, the lens will ride up with the blink and then quickly return to a position of rest.

2. Characteristics of a Steep Lens

A steep lens usually shows restricted movement. The fluorescein pattern will show central pooling, excessive intermediate bearing with inadequate edge lift.

3. Characteristics of a Flat Lens

A flat lens will often position high under the upper lid or drop rapidly when released from the lid. This lens may be comfortable for the patient, but often provides poor vision. The fluorescein pattern will show central bearing or touch when the lens is centered on the eye. Horizontal decentration or movement may also indicate a flat lens.

4. Fluorescein Evaluation

The fluorescein pattern should indicate good tear exchange with an alignment lens-to-cornea relationship. The presence of the ultraviolet (UV) light absorber in the Oxfore®100 (hexafocon A) Contact Lens material requires the addition of a yellow Wratten filter modification of the Slit Lamp and Burton lamp to visualize the fluorescein pattern adequately.

The following evaluations apply to all Semi-scleral and Scleral lens designs:

1. Characteristics of a Well-Fit Lens

A good fit positions centered over the cornea or may lag slightly inferiorly. There is little or no movement of the lens with blinking. The lens completely vaults the cornea and the limbus. The fitting zone of the lens settles into the conjunctiva and aligns to the sclera.

2. Characteristics of a Tight Fitting Lens

A tight lens usually shows blanching of the bulbar conjunctival blood vessels as they pass under the fitting zone of the lens. There may be impingement of the larger blood vessels resulting in localized conjunctival congestion and inflammation. There may be no fluorescein/tear flow under the lens.

3. Characteristics of a Flat Fitting Lens

A flat fitting lens will have an area of corneal touch or bearing. This will usually result in localized epithelial staining in the area of lens bearing. This lens may initially be comfortable for the patient, but wear time is usually reduced due to increased discomfort with normal lens wear. The fluorescein pattern will show bearing or touch at the apex of the cornea, or where the elevation of the cornea is highest. Edge lift off may also indicate a flat fitting lens.

4. Fluorescein Evaluation

The fluorescein tear flow test will demonstrate tear flow behind a semi-scleral or scleral lens. Fluorescein is applied to the front surface of a lens that has settled for the appropriate time (usually 20-30 minutes or longer). Fluorescein can be seen as it percolates behind the contact lens and colors the fluid in the chamber between the lens and the cornea. This is best seen and evaluated using an optic section and white light at high intensity.

The fluorescein pattern can also be evaluated by adding fluorescein to the fluid in the bowl of the lens during lens application to the eye. The patient is instructed to position his/her head parallel to the floor and to look directly down.
The bowl of the lens is filled with non-preserved saline. A fluorescein strip is dipped into the saline, adding fluorescein to the solution. The lens is placed on the eye and allowed to settle for several minutes. The fluorescein pattern can be evaluated

using cobalt blue light and a yellow Wratten filter. The lens is allowed to settle on the eye for 20-30 minutes or longer and the fluorescein pattern is again evaluated.

This method of lens evaluation will demonstrate areas of bearing, alignment and clearance. To estimate the amount of lens clearance, the practitioner must use an optic section and white light. Estimation of the fluid layer thickness can be made by referencing the thickness of the fluorescein colored green fluid in the optic section to the known thickness of the contact lens also seen in the optic section.

The presence of the ultraviolet (UV) light absorber in the Oxfore®100 (hexafocon A) Contact Lens material requires modification of the Burton lamp to visualize fluorescein patterns adequately.

5. Bubble Evaluation
Immediately upon lens insertion, inspection of the fit for bubbles trapped under the lens is made. If any are present, the lens is removed and reapplied. A properly placed lens will not have bubbles present in the fluid layer after insertion.

FITTING PROCEDURE:

General Information

Oxfore®100 (hexafocon A) rigid gas permeable contact lenses may be fitted for daily wear or extended wear using the standard techniques for rigid contact lenses. A diagnostic lens fitting procedure is recommended, although not always required.

When placed on the human cornea, the Oxfore®100 rigid gas permeable contact lens acts as a refracting medium to focus light rays upon the retina.

Clinical studies have demonstrated that rigid gas permeable contact lenses manufactured from these fluorosilicone acrylate contact lens materials are safe and effective for their intended use. However, the clinical studies may not have included all design configurations or lens parameters that are presently available in these materials. Consequently, when selecting an appropriate lens design and parameters, the eye care practitioner must consider all factors that affect lens performance and ocular health. The potential impact of these factors must be weighed against the patient's needs. Therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored.

Pretrial Examination

A complete contact lens examination should be carried out including general health, previous contact lens history, refraction, keratometry and slit lamp examination. Patients who have evidence of any disease affecting the cornea or conjunctiva, acute or subacute inflammation of the anterior segment of the eye, insufficiency of the lacrimal secretion, corneal hypoesthesia, any disease or infection which will affect the eye or be exacerbated by the wearing of contact lenses are not candidates for wearing these lenses.

FITTING PROCEDURE – SPHERICAL AND ASPHERIC

Selection of Patients

Patients should be individuals who require a daily wear or extended wear lens; are not-aphakic; and, have non-diseased eyes. Patients should have a refractive error which does not exceed 20.00 diopters of myopia and 12.00 diopters of hyperopia for daily wear, or 8.00 diopters of hyperopia for extended wear; and, who may exhibit corneal astigmatism up to 4.00 diopters. Patients predisposed to excessive edema or staining may not be suitable.

Diagnostic Lens Fitting Procedure

Fitting is recommended to be carried out with the aid of diagnostic lenses. Nearly every patient begins with a 9.2 mm trial lens. The exceptions would be patients who have keratometer readings below 41.00 D or above 45.00 D. If the corneal reading is below 41.00 D and the patient appears to have an exceptionally large cornea and palpebral fissure, begin with a 9.6 mm diameter lens. This is rare. Alternatively, if a patient has a keratometer reading which is greater than 45.00 D or has an unusually small palpebral aperture, begin the fitting with an 8.8 mm diameter lens.

The base curve of the lens may be found in Table 1. From the keratometer readings, find the flattest K and steepest K. Enter the table on the left with the corneal cylinder (ΔK) value and follow across to the first diagnostic lens base curve to be used.

Table 1:

Corneal Cylinder (ΔK)	Lens Base Curve
Plano	0.25 D flatter to on flat K
0.25 – 0.75 D	on flat K to 0.25 D steeper
1.00 – 1.75 D	0.25 D steeper to 0.75 D steeper
>2.00 D	0.75 D steeper to 1.00 D steeper

Place the diagnostic lens on the patient's cornea. Wait approximately 10 minutes for tearing to subside. Check the lens for positioning and movement. Ideally, the lens will ride up with the blink and then quickly drop to a position that is near the center of the cornea. If the lens should drop to the lower limbus or position eccentrically, remove the lens and replace it with a lens that is 0.4 mm larger. If centering is still not achieved, use a diagnostic lens that is 0.25 D steeper.

The power for the final lens may be most accurately determined by an over refraction with the diagnostic lens in place. This may be carried out with either a trial frame or refractor. Allow approximately 15 minutes for the lens to settle on the patient's eye before performing the over refraction. Only the spherical power needs to be determined in order to arrive at the final correction.

When the optimum over refraction has been obtained, the correction should be added to the power of the diagnostic lens to arrive at the final prescription.

EXAMPLE:	Over refraction	-1.25 D
	Diagnostic Lens	(+) -3.00 D
	Lens Power Ordered	-4.25 D

A patient's lens power requirement may be determined without diagnostic lenses by:

1. Converting the spectacle Rx to minus cylinder form.
2. Adjusting the spectacle Rx for vertex distance.
3. Using the sphere power only.

The selection of the Oxfore®100 rigid gas permeable contact lens may be aided by an examination of the fluorescein pattern. The ideal fluorescein pattern shows a definite green central area with some darkening near the periphery of the optic zone. The peripheral curve area should show a definite green band. The most important faulty lens fluorescein pattern to be detected is a corneal seal at the intermediate lens position. The fluorescein pattern shows a dark touch ring that runs completely around the contact lens in the intermediate zone. The larger the lens the greater is the tendency for this to happen. It also occurs most frequently when the optic zone of the contact lens is greater than an 8.0 mm diameter. Hence, a lens design with an optic zone of 8.0 mm or less is usually preferred.

NOTE: Evaluation of fluorescein patterns for lenses manufactured in materials with the UV absorber is best accomplished using a slit lamp or Burton Lamp with a Wratten filter over the light source.

A 9.6 mm (large) lens may be needed for patients who have a problem of flare with smaller diameter contact lenses. The flare may occur if the patient has either a very large pupil or if the smaller lens rides off the center of the cornea. Fortunately, flare is only an occasional problem with the 9.6 mm lens because the peripheral curve and edge are specifically designed to minimize the flare problem.

Some patients develop problems of staining, which are due to an optic zone that is too large. A 7.8 mm optic zone is large enough to avoid flare in nearly every contact lens patient. If the patient requires an even larger lens than the 9.2 mm diameter, choose the 9.6 mm diameter lens but keep the optic zone at 8.0 mm in all but the most unusual cases. In this way some tear pumping is achieved in nearly every case and avoids the corneal punctate staining that is due to inadequate lens pumping.

FITTING PRECEDURE – MONOCENTRIC BIFOCAL

Patient Selection

Patients should be selected who require a daily wear lens; are not-aphakic; and, have non-diseased eyes. Patients should have a refractive error which does not exceed 20.00 diopters of myopia and 12.00 diopters of hyperopia; and, who may exhibit corneal astigmatism up to 4.00 diopters and up to +4.00 diopters of add power. Patients predisposed to excessive edema or staining may not be suitable.

Power Compensation

Higher plus power spectacle prescriptions at distance require higher plus distance and add powers, while higher minus power spectacle prescriptions require less minus power and less add powers in bifocal contact lenses.

Prism

The purpose of the prism is to orient the lens, give a low reading position, and provide a supporting edge at the bottom to enable upward displacement by the lower lid.

DISTANT POWER	PRISM
>+8.00	1.00
+4.00	1.25
+2.00	1.50
Plano	1.75
-2.00	2.00
-4.00	2.25
-6.00	2.50
>-8.00	2.75

Seg Height

The average seg height is determined by the diagnostic lens selection and fitting evaluation.

Diagnostic Lens Fitting Procedure

Fitting is recommended to be carried out with the aid of diagnostic lenses. A suggested diagnostic lens set follows.

Base Curves	7.30 to 8.20 mm (.10 mm steps)
Size	9.2 mm
Optic Zone	7.8 mm
Power	-3.00 diopters
Add	+2.00 diopters
Prism Ballast	1.50 diopters
Seg. Height	4.3 mm

The base curve of the lens may be found in Table 2. From the keratometer readings, find the flattest K and steepest K. Find the corneal cylinder (□K) value in the left column and follow across, this is the first diagnostic lens base curve to be used.

Table 2:

Corneal Cylinder (ΔK)	Lens Base Curve
Plano	0.75 D flatter to 0.50 D flatter
0.25 - 0.75 D	0.50 D flatter to 0.25 D flatter
1.00 - 1.75 D	0.25 D flatter to on flat K
>2.00 D	Not more than 0.25 of difference steeper cylinder

Place the diagnostic lens on the patient's cornea. Wait approximately 10 minutes for tearing to subside and check the lens for positioning and movement. Ideally, the lens will ride up with the blink and then quickly drop to a position that is near the center of the cornea. If the lens should drop to the lower limbus or position eccentrically, remove the lens and replace it with a lens that is 0.4 mm larger. If centering is still not achieved use a diagnostic lens which is 0.50 D steeper.

The lens should translate up, with down gaze, so that the segment is within the visual axis for reading. The prism ballast should not rotate greater than 20 degrees nasally, and seg height, in primary gaze, should be even or slightly above lower pupillary margin. If the lens rotates excessively, a larger prism diopter ballast will be necessary.

The power for the final lens may be most accurately determined by an over refraction with the diagnostic lens in place. This may be carried out with either a trial frame or refractor. Allow approximately 15 minutes for the lens to settle on the patient’s eye before performing the over refraction. Only the spherical power needs to be determined in order to arrive at the final correction.

When the optimum over refraction has been obtained, the correction should be added to the power of the diagnostic lens to arrive at the final prescription.

EXAMPLE:		
	Over refraction	-1.25 D
	Diagnostic Lens	(+) -3.00 D
	Lens Power Ordered	-4.25 D

The selection of the Oxfore®100 rigid gas permeable bifocal contact lens may be aided by an examination of the fluorescein pattern. The ideal fluorescein pattern shows a definite green central area with some darkening near the periphery of the optic zone. The peripheral curve area should show a definite green band. The most important faulty lens fluorescein pattern to be detected is a corneal seal at the intermediate lens position. The fluorescein pattern shows a dark touch ring that runs completely around the contact lens in the intermediate zone. The larger the lens the greater is the tendency for this to happen. It also occurs most frequently when the optic zone of the contact lens is greater than an 8.0 mm diameter. Hence, a lens design with an optic zone of 8.0 mm or less is usually preferred.

NOTE: Evaluation of fluorescein patterns for lenses manufactured in materials with the UV absorber is best accomplished using a slit lamp or Burton Lamp with a Wratten filter over the light source.

A larger lens may be needed for patients who have a problem of flare with smaller diameter contact lenses. The flare may occur if the patient has either a very large pupil or if the smaller lens rides off the center of the cornea. Fortunately, flare is only an occasional problem with the 9.6 mm lens because the peripheral curve and edge are specifically designed to minimize the flare problem.

Some patients develop problems of staining, which are due to an optic zone that is too large. A 7.8 mm optic zone is large enough to avoid flare in nearly every contact lens patient. If the patient requires an even larger lens than the 9.2 mm diameter, choose the 9.6 mm diameter lens but keep the optic zone at 8.0 mm in all but the most unusual cases. In this way some tear pumping is achieved in nearly every case and avoids the corneal punctate staining that is due to inadequate lens pumping.

FITTING PROCEDURE – CONCENTRIC BIFOCAL

Patient Selection

Patients should be selected who require a daily wear lens; are not-aphakic; and, who have non-diseased eyes. Patients should have a refractive error which does not exceed 20.00 diopters of myopia and 12.00 diopters of hyperopia; and, who may exhibit corneal astigmatism up to 4.00 diopters and up to +4.00 diopters of add power. Patients predisposed to excessive edema or staining may not be suitable.

Power Compensation

Higher plus power spectacle prescriptions at distance require higher plus distance and add powers, while higher minus power spectacle prescriptions require less minus power and less add powers in bifocal contact lenses.

Seg Diameter

The average seg diameter is determined by the diagnostic lens selection and fitting evaluation.

Diagnostic Lens Fitting Procedure

Fitting is recommended to be carried out with the aid of diagnostic lenses. A suggested diagnostic lens set would be as follows.

Base Curves	7.30 to 8.20 mm (.10 mm steps)
Size	9.2 mm
Optic Zone	7.8 mm
Power	-3.00 diopters
Add	+2.00 diopters
Add Diameter	2 to 4 mm

The base curve of the lens may be found in Table 3. From the keratometer readings, find the flattest K and steepest K. Find the corneal cylinder (ΔK) value in the left column and follow across, this is the first diagnostic lens base curve to be used.

Table 3:

Corneal Cylinder (ΔK)	Lens Base Curve
PLANO	0.25 D flatter to on flat K
0.25 - 0.75 D	On flat K to 0.25 steeper
1.00 - 1.75 D	0.25 D steeper to 0.50 D steeper
2.00 - 2.75 D	0.50 D steeper to 0.75 D steeper
> 2.75 D	0.25 D steeper to 1.00 D steeper

Place the diagnostic lens on the patient's cornea. Wait approximately 10 minutes for tearing to subside and check the lens for positioning and movement. Ideally, the lens will ride up with the blink and then quickly drop to a position which is near the center of the cornea. If the lens should drop to the lower limbus or position eccentrically, remove the lens and replace it with a lens that is 0.4 mm larger. If centering is still not achieved use a diagnostic lens which is 0.25 D steeper.

The power for the final lens may be most accurately determined by an over refraction with the diagnostic lens in place. This may be carried out with either a diagnostic frame or refractor. Allow approximately 15 minutes for the lens to settle on the patient's eye before performing the over refraction. Only the spherical power needs to be determined in order to arrive at the final correction. Both distance and near acuity should be checked.

When the optimum over refraction has been obtained, the correction should be added to the power of the diagnostic lens to arrive at the final prescription.

EXAMPLE:	Over refraction	-1.25 D
	Diagnostic Lens	(+) -3.00 D
	Lens Power Ordered	-4.25 D

The selection of the Oxfore®100 rigid gas permeable bifocal contact lens may be aided by an examination of the fluorescein pattern. The ideal fluorescein pattern shows a definite green central area with some darkening near the periphery of the optic zone. The peripheral curve area should show a definite green band. The most important faulty lens fluorescein pattern to be detected is a corneal seal at the intermediate lens position. The fluorescein pattern shows a dark touch ring that runs completely around the contact lens in the intermediate zone. The larger the lens the greater is the tendency for this to happen. It also occurs most frequently when the optic zone of the contact lens is greater than an 8.0 mm diameter. Hence, a lens design with an optic zone of 8.0 mm or less is usually preferred.

NOTE: Evaluation of fluorescein patterns for lenses manufactured in materials with the UV absorber is best accomplished using a slit lamp or Burton Lamp with a Wratten filter over the light source.

A larger lens may be needed for patients who have a problem of flare with smaller diameter contact lenses. The flare may occur if the patient has either a very large pupil or if the smaller lens rides off the center of the cornea. Fortunately, flare is only an occasional problem with the 9.60 mm lens because the peripheral curve and edge are specifically designed to minimize the flare problem.

FITTING PROCEDURE – ASPHERIC BIFOCAL

Patient Selection

Patients should be selected who require a daily wear lens; are not-aphakic; and, have non-diseased eyes. Patients should have a refractive error which does not exceed 20.00 diopters of myopia and 12.00 diopters of hyperopia; and, who may exhibit corneal astigmatism up to 4.00 diopters and up to +4.00 diopters of add power. Patients predisposed to excessive edema or staining may not be suitable.

Diagnostic Lens Fitting Procedure

Fitting is recommended to be carried out with the aid of diagnostic lenses. A suggested diagnostic lens set follows.

Base Curves	7.30 to 8.20 mm (.10 mm steps)
Size	9.2 mm
Optic Zone	7.8 mm
Power	-3.00 diopters
Add	+2.00 diopters

The base curve of the diagnostic lens should be 2.75 diopters steeper than the flattest keratometer reading.

EXAMPLE:	K Reading	42.50 x 43.50
	+2.75 Steep	2.75
	Diagnostic Lens Base Curve	45.25 = 7.456 mm

Place the diagnostic lens on the patient's cornea. Wait approximately 10 minutes for tearing to subside and check the lens for positioning and movement. Ideally, the lens will ride up with the blink and then quickly drop to a position that is near the center of the cornea. If the lens should drop to the lower limbus or position eccentrically, remove the lens and replace it with a lens that is 0.4 mm larger. If centering is still not achieved, use a diagnostic lens that is 0.50 D steeper.

The power for the final lens may be most accurately determined by an over refraction with the diagnostic lens in place. This may be carried out with either a diagnostic frame or refractor. Allow approximately 15 minutes for the lens to settle on the patient's eye before performing the over refraction. Only the spherical power needs to be determined in order to arrive at the final correction. Both distance and near acuity should be checked.

With the diagnostic lenses on the eyes, place the over refraction in a diagnostic frame for both eyes. (The use of a phoropeter is not recommended for this test.)

- Add a +0.50 sphere to both sides of trial frame and ask the patient to read the near point card. Then ask the patient to read the 20/20 line on the distance chart (not how clearly he can read).
- Continue adding +0.25 at a time until the patient cannot read all of the 20/20 line.
- If the patient can read most of the 20/20 line, and at least J-3 on the near point card, the total power of the contact lens power and the power of diagnostic lenses from the trial frame should be ordered.

When the optimal over refraction has been obtained, the correction should be added to the power of the diagnostic lens to arrive at the final prescription.

EXAMPLE:	Over refraction	-1.25 D
	Diagnostic Lens	(+) -3.00 D
	Lens power ordered	-4.25 D

The selection of the Oxfore®100 rigid gas permeable bifocal contact lens may be aided by an examination of the fluorescein pattern. The ideal fluorescein pattern shows a definite green central area with some darkening near the periphery of the optic zone. The peripheral curve area should show a definite green band. The most important faulty lens fluorescein pattern to be detected is a corneal seal at the intermediate lens position. The fluorescein pattern shows a dark touch ring that runs completely around the contact lens in the intermediate zone. The larger the lens the greater is the tendency for this to happen. It also occurs most frequently when the optic zone of the contact lens is greater than an 8.0mm diameter. Hence, a lens design with an optic zone of 8.0mm or less is usually preferred.

NOTE: Evaluation of fluorescein patterns for lenses manufactured in materials with the UV absorber is best accomplished using a slit lamp or Burton Lamp with a Wratten filter over the light source.

A larger lens may be needed for patients who have a problem of flare with smaller diameter contact lenses. The flare may occur if the patient has either a very large pupil or if the smaller lens rides off the center of the cornea. Fortunately, flare is only an occasional problem with the 9.60 mm lens because the peripheral curve and edge are specifically designed to minimize the flare problem.

FITTING PROCEDURE – TORIC

Patient Selection

Patients should be selected who require a daily wear lens; are not-aphakic; and, who have non-diseased eyes. Patients should have a refractive error that does not exceed 20.00 diopters of myopia and 12.00 diopters of hyperopia; and, who may exhibit corneal astigmatism up to 6.00 diopters.

Diagnostic Lens Fitting Procedure

The base curve of the lens may be found in Table 4. From the keratometer readings, find the flattest K and steepest K. Find the corneal cylinder (ΔK) value in the left column and follow across, this is the first diagnostic set to be used.

Table 4:

Corneal Cylinder (ΔK)	Diagnostic Set
1.00 – 2.50	2 Diopter Diagnostic Set
2.75 – 4.00	3 Diopter Diagnostic Set
4.25 – Up	4 Diopter Diagnostic Set

Place the diagnostic lens on the patient's cornea. Wait approximately 10 minutes for tearing to subside and check the lens for positioning and movement. Ideally, the lens will ride up with the blink and then quickly drop to a position that is near the center of the cornea. If the lens should drop to the lower limbus or position eccentrically, remove the lens and replace it with a lens that is 0.4 mm larger. If centering is still not achieved, use a diagnostic lens that is 0.50 D steeper.

Other Diagnostic Lens Procedure

Select a bitoric diagnostic lens that provides alignment bearing and positions the lens slightly beneath the upper lid. Allow approximately 15 minutes for the lens to settle on the patient's eye before performing the over refractions. Perform a sphero-cylinder over refraction, adding the sphere power from the over refraction to the flattest meridian of the diagnostic lens.

EXAMPLE:	Diagnostic Lens	42.00 x	44.00
		-1.00	-2.00
	Over refraction	-2.00	
	Order	-3.00	-2.00

If the cylinder finding is -0.50 or less, order cylinder power of diagnostic lens.

EXAMPLE:	Diagnostic Lens	42.00 x	44.00
		-1.00	-2.00
	Over refraction	PL	-0.50
	Order	-1.00	-2.00

If cylinder finding is -0.75 or larger, and the axis is at or near the diagnostic lens axis, add the minus cylinder power to the steep meridian of the diagnostic lens.

EXAMPLE:	Diagnostic Lens	42.00 x	44.00	
		-1.00	-2.00	
	Over refraction	PL	-1.00	x 180
	Order	-1.00	-3.00	

The selection of the Oxfore®100 rigid gas permeable toric contact lens may be aided by an examination of the fluorescein pattern. The ideal fluorescein pattern shows a definite green central area with some darkening near the periphery of the optic zone. The peripheral curve area should show a definite green band.

NOTE: Evaluation of fluorescein patterns for lenses manufactured in materials with the UV absorber is best accomplished using a slit lamp or Burton Lamp with a Wratten filter over the light source.

A larger lens may be needed for patients who have a problem of flare with smaller diameter contact lenses. The flare may occur if the patient has either a very large pupil or if the smaller lens rides off the center of the cornea. Fortunately, flare is only an occasional problem.

Initial Lens Evaluation

Movement:

Blink induced lens movement should show downward lens movement with the lid motion (average 1 mm) and then upward with the lid motion (average 1 mm) as with a standard gas permeable contact lens. During the interblink period the lens should have little or no motion (average less than 1 mm). Lens designs over 11.5 mm diameter may exhibit little or no movement.

Positioning:

The lens should position centrally or slightly inferiorly as it will tend to migrate to the steepest cornea area. Lens designs over 11.5 mm diameter will most always position centrally.

Characteristics of a Tight (too steep) Lens:

- A lens that is too tight will show reduced movement upon blinking. Bubbles may be detected behind the lens. For lens designs over 11.5 mm diameter the presence of bubbles may not indicate a poor fitting lens.

Characteristics of a Loose (too flat) Lens:

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

Trial Lens Fitting :

Trial lens fitting is recommended whenever possible. Trial lens fitting allows a more accurate determination of lens specifications for the lens fit and power. Choose the first lens according to the base curve selection criteria for the specific lens design. Trial lenses are essential in fitting patients whose corneal topography is distorted.

Trial Lens Procedure

Select a trial lens and place the lens upon the eye. Evaluate the lens using white light for the following:

Centering

Lenses may not center well due to the unusual corneal topography in patients with keratoconus. Often the lens will position inferiorly over the steepest corneal area.

Movement

Lens movement should be equivalent to or slightly less than a standard RGP lens.
Evaluate the fluorescein pattern. The fluorescein pattern should show a lens with either mild apical clearance or “feather touch” (alignment) over the steepest conical area. In the periphery there should be another area of alignment and near the edge a thin band of pooling.
The fluorescein pattern provides the best method for monitoring the fit of the contact lens over time.

Special Follow-up Care:

With lenses in place on the eyes, evaluate fitting performance to assure that the criteria of a well-fitted lens continue to be satisfied. The fluorescein pattern provides a guide to lens adaptation. If the lens demonstrates reduced movement, consider exchanging for another of flatter base curve. Usually, a lens with a 0.50 diopters flatter base curve should be the next choice with variations from this based on the judgment of the eye care practitioner.

A lens with excessive movement should be replaced with another that is 0.50 diopters steeper base curve.

After lens removal, conduct a thorough biomicroscopy examination to detect the presence of unusual vertical corneal striae in the posterior central cornea and/or corneal neovascularization. Note: some vertical striae are typical in advanced stages of keratoconus. The presence of these conditions may be indicative of excessive corneal edema.

The recommended schedule for follow-up visits is the same as standard lenses.

- NOTE: Practitioners should consult their finishing lab for available keratoconus, pellucid marginal degeneration, and post-surgical lens designs. The design parameters must meet the parameters specified in the product labeling.

FOLLOW-UP CARE FOR ALL LENSES

- Follow-up examinations, as recommended by the eye care professional, are necessary to ensure continued successful contact lens wear. An unscheduled visit may be indicated whenever the wearer reports a change in vision, ocular discomfort, or redness of the eye.
- Prior to a follow-up examination, the contact lenses should be worn for at least four continuous hours and the patient should be asked to identify any problems which might be occurring related to contact lens wear.

- With lenses in place on the eyes, evaluate fitting performance to assure that characteristics of a well-fit lens continue to be satisfied for the appropriate lens design. Examine the lenses closely for surface deposition and/or damage.
- After the lens removal, instill sodium fluorescein into the eyes and conduct a thorough biomicroscopy examination.
- The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization is indicative of excessive corneal edema.
- The presence of corneal 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 characteristics of a well-fit lens are not satisfied during any follow-up examination, the patient should be re-fitted with a more appropriate lens.

IN-OFFICE CARE OF TRIAL LENSES

Eye care professionals should educate contact lens technicians concerning proper care of trial lenses.

Each Oxfore®100 (hexafocon A) Contact Lens is shipped non-sterile. Hands should be thoroughly washed and rinsed and dried with a lint free towel prior to handling a lens.

CAUTION: NON-STERILE, CLEAN AND CONDITION LENSES PRIOR TO USE.

RECOMMENDED INITIAL WEARING SCHEDULE

The wearing schedules should be determined by the eye care practitioner. Patients tend to over wear the lenses initially. The eye care practitioner should emphasize the importance of adhering to the initial maximum wearing schedule. Regular checkups, as determined by the eye care practitioner. are also extremely important.

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

Oxfore®100 (hexafocon A) Contact Lenses are indicated for daily wear. The maximum suggested wearing time for daily wear lenses is:

During Waking Hours*

Day	Hours
1	4-8
2	6-10
3	8-14
4	10-15
5	12-all waking hours
6 and after -	all waking hours

*If the lenses continue to be well tolerated.

Lenses should be removed daily for cleaning and disinfecting (according to lens care system instructions) before wearing.

CLINICAL ASSESSMENT:

a. Vision should be crisp and clear after the blink.
b. The eye should be white and quiet.

Temporary discomfort may be caused by a foreign body under the lens surface. The lens should be removed, rinsed and reinserted. If the discomfort persists, the patient should consult the eye care professional before returning to lens wear.

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 may not be a good candidate for monovision with the Oxfore®100 (hexafocon A) Contact Lens. Occupational and environmental visual demands should be considered. If the patient requires critical vision (visual

acuity and stereopsis) it should be determined by trial whether this patient can function adequately with monovision. Monovision contact lens wear may not be optimal for such activities as:

(1) visually demanding situations such as operating potentially dangerous machinery or performing other potentially hazardous activities; and

(2) driving automobiles (e.g., driving at night). Patients who cannot pass their state driver's license requirements with monovision correction should be advised to not drive with this correction OR may require that additional overcorrection be prescribed.

B. Patient Education
All patients do not function equally well with monovision correction. Patients may not perform as well for certain tasks with this correction as they have with bifocal reading glasses. Each patient should understand that monovision, as well as other presbyopic contact lenses, or other alternatives, 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 "sight eye." Have the patient point to an object at the far end of the room. Cover one eye. If the patient is still pointing directly at the object, the eye being used is the dominant (sighting) eye.

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

B. Refractive Error Method

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

C. Visual Demand Method

Consider the patients' 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 a 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 -2.25 diopters myopic in the right eye and -1.50 diopters myopic in the left eye may have the right eye corrected for distance and the left uncorrected for near.

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

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

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

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

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

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

6. Adaptation

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

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

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

7. Other suggestions

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

- Having a third contact lens (distance power) to use when critical distance viewing is needed.
- Having a third contact lens (near power) to use when critical near viewing is needed.
- Having supplemental spectacles to wear over the monovision contact lenses for specific visual tasks may improve the success of monovision correction. This is particularly applicable for those patients who cannot meet state licensing requirements with a monovision correction.
- Make use of proper illumination when carrying out visual tasks.

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

- Reverse the distance and near eyes if a patient is having trouble adapting.
- Refine the lens powers if there is trouble with adaptation.
- Accurate lens power is critical for presbyopic patients.
- Emphasize the benefits of the clear near vision in straight ahead and upward gaze with monovision.

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

All patients should be supplied with a copy of the Patient Instructions for Oxfore®100 (hexafocon A) Contact Lenses.

SEMI-SCLERAL AND SCLERAL LENS FITTING GUIDELINES:

1. Pre-Fitting Examination

The flatter keratometry reading (Flat K) and amount of corneal astigmatism should be determined. If corneal topography is done, note the steepest area on the map and the temporal quadrant. Using the Elevation map determine the highest point on the cornea. Measure the corneal limbal size. If accurate corneal measurements are not possible, choose a steep lens.

Looking from the side, estimate the sagittal height of the cornea and adjacent sclera.

2. Lens Diameter Selection

Select the appropriate lens diameter based on the condition of the eye and the available parameters. Select a lens diameter that will be able to vault the cornea and limbus and have an adequate diameter fitting zone beyond the limbus (probably 1-2 mm). Large HVID corneas may require 18 mm diameter lenses whereas normal and small HVID corneas probably will be well fit with a 16 mm diameter lens.

3. Base Curve Selection

Lenses designed to vault the cornea and limbus are most easily fit using the sagittal height of the cornea and the sagittal depth of the contact lens. Achieving clearance over the cornea and limbus is most easily determined using a trial lens set based on lenses with increasing amounts of sagittal depth.

A properly fit base curve will vault over the cornea avoiding all corneal touch. There should be no bubbles under the lens. Bubbles captured under the lens are most probably due to air capture during lens application to the eye. Remove the lens and reapply.

1. Lens Power Selection

Lens power can best be determined by adding the spherical value of the over-refraction to the trial lens power.

2. Fluorescein Examination

The fluorescein examination can best be conducted by placing the fluorescein into the cup of the lens prior to insertion. Evaluation of a trial lens that has apical touch is the best way to determine the proper sag. If central bearing is noted, the sag value should be increased by 0.1 mm for every 1.0 mm of touch. The optimal fit will be obtained with the minimum sag value that vaults the cornea with no apical bearing. The ideal pattern aligns the cornea with no bubbles at the limbus or under the optical cap.

The following evaluations apply to all Semi-scleral and Scleral lens designs:

a. Characteristics of a Well-Fit Lens

A good fit positions centered over the cornea or may lag slightly inferiorly. There is little or no movement of the lens with blinking. The lens completely vaults the cornea and the limbus. The fitting zone of the lens settles into the conjunctiva and aligns to the sclera. Bubbles should not be observed under the lens at any location (very small bubbles less than 0.10 mm can be ignored). There should not be any conjunctival impingement or excessive edge lift.

b. Characteristics of a Tight-Fitting Lens

A tight lens usually shows blanching of the bulbar conjunctival blood vessels as they pass under the fitting zone of the lens. There may be impingement of the larger blood vessels resulting in localized conjunctival congestion and inflammation. There may be no fluorescein/tear flow under the lens.

c. Characteristics of a Flat Fitting Lens

A flat fitting lens will have an area of corneal touch or bearing. This lens may initially be comfortable for the patient, but wear time is usually reduced due to increased discomfort with normal lens wear. The fluorescein pattern will show bearing or touch at the apex of the cornea, or where the elevation of the cornea is highest. Edge lift off may also indicate a flat fitting lens. A lens fit with this appearance may result in localized epithelial staining in the area of lens bearing.

d. Fluorescein Evaluation

The fluorescein pattern can be evaluated by adding fluorescein to the fluid in the bowl of the lens during lens application to the eye. The patient is instructed to position his/her head parallel to the floor and to look directly down. The bowl of the lens is filled with non-preserved saline. A fluorescein strip is dipped into the saline, adding fluorescein to the solution. The lens is placed on the eye and allowed to settle for several minutes. **(Note: The presence of the ultraviolet (UV) light absorber in the Oxfore®100 (hexafocon A) Contact Lens material requires the addition of a yellow written filter modification of the Slit Lamp and Burton lamp to visualize fluorescein pattern adequately.)** The fluorescein pattern can be evaluated using cobalt blue light with either instrument. The lens is allowed to settle on the eye for 20-30 minutes or longer and the fluorescein pattern is again evaluated. This method of lens evaluation will demonstrate areas of bearing, alignment and clearance. To estimate the amount of lens clearance, the practitioner must use an optic section and white light. Estimation of the fluid layer thickness can be made by referencing the thickness of the fluorescein-colored green fluid in the optic section to the known thickness of the contact lens also seen in the optic section.

The fluorescein tear flow test will demonstrate tear flow behind a semi-scleral or scleral lens. Fluorescein is applied to the front surface of a lens that has settled for the appropriate time (usually 20-30 minutes or longer). Fluorescein can be seen as it percolates behind the contact lens and colors the fluid in the chamber between the lens and the cornea. This is best seen and evaluated using an optic section and white light at high intensity.

e. Bubble Evaluation

Immediately upon lens insertion, inspection of the fit for bubbles trapped under the lens is made. If any are present, the lens is removed and reapplied. A properly placed lens will not have bubbles present in the fluid layer after insertion.

The periphery should be evaluated once the ideal corneal clearance has been achieved. The edge should be adjusted if there is excessive edge lift or conjunctival impingement.

1. **Troubleshooting**
   - Corneal edema: This can be caused by excessive corneal vaulting, poor tear flow or increased lens thickness or a combination of all these factors. The sag value should be re-evaluated to obtain the minimum sag that vaults with no apical bearing. Peripheral conjunctival impingement may be another possible cause for edema. The Peripheral curves (PCs) should be flattened with maintenance of the appropriate sag.
   - Lens Awareness: This can be caused by excessive edge lift, due to the PCs being too flat or the sag being too low. The first step would be to determine whether the sag is appropriate. In many cases, the edge will improve when the sag is increased. If the sag is correct, steepening or flattening of the periphery may correct the problem.
   - SPK: This may be caused by any apical bearing or a sensitivity to the solution used to fill the lens cup.
   - Decreased visual acuity: If patients complain of decreased visual acuity after 8-10 hours of wear, have the patient clean, disinfect and reinsert the lens after a few hours of wear.
   - Excessive redness: This may be a sign that the lens is fitting too tightly, the patient is using preserved solutions to apply the lens to the eye, or there is meridional tightness of the lens fit.

2. **Patient Instructions**

   Patients should be instructed in the procedures for inserting and removing the lens. Patients may find it easiest to use the tripod insertion method. Place the lens between the thumb, index and middle finger for insertion. The patient should be instructed to completely fill the cup of the lens with the recommended non-preserved solution, avoiding any bubbles. While facing downward toward a table top, the completely filled lens should be placed onto the eye as the patient looks directly at the center of the lens using the other hand and a free finger on the hand with the lens to retract the eyelids away from the eye. Immerse the cornea into the bowl of fluid, gently applying the lens to the cornea. Do not push the lens onto the cornea - this will create negative pressure under the lens creating a tight-fitting lens. Gently release eye lids. Check for bubbles. The lens should feel comfortable and the vision should be clear as the excessive fluid is expelled from the eye.

   Patients may be instructed to irrigate the lens with rewetting drops and massage the lens prior to blinking the lens out or to remove it with a contact lens suction cup.

   Instructions for removal of the lens with a suction cup:

   Place the suction cup near the edge of the lens in the 6 o'clock position. Gently rotate the lens nasally and temporally to ensure the lens is movable. Lift the lens upward and outward, holding the eye lids away from the cornea. If the lens does not easily release from the eye, repeat lens rotation on the eye and rotate the suction cup superiorly and lift the lens out and down from the eye. Alternate as needed until the lens easily releases from the eye.

HANDLING OF OXFORE®100 (HEXAFOCON A) CONTACT LENSES:

Conventional lens placement and removal applies to Oxfore®100 (hexafocon A) Contact Lenses. Please instruct the patient how to place and remove the lens. Make sure the patient is able to put on the lenses and remove them before the patient leaves your office.

PATIENT LENS CARE DIRECTIONS:

Eye care professionals should review with the patient lens care directions, including both basic lens care information and specific instructions on the lens care regimen recommended for the patient:

GENERAL LENS CARE (To First **Clean and Rinse, Then Disinfect** Lenses)
Basic Instructions:

- Always wash and rinse hands before handling contact lenses.
- Always use **fresh unexpired** lens care solutions.
- Use the recommended chemical (not heat) system of lens care. Carefully follow instructions on solution labeling. Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. **Do not alternate or mix lens care systems unless indicated on solution labeling**.
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting lenses. Do not put lenses in the mouth.
- Lenses should be **cleaned, rinsed, and disinfected** each time they are removed. **Cleaning and rinsing** are necessary to remove mucus and film from the lens surface. **Disinfecting** is necessary to destroy harmful germs.
- Always remove, clean, rinse, enzyme (as recommended by the eye care professional) and disinfect lenses according to the schedule prescribed by the eye care professional. The use of an enzyme or any cleaning solution **does not substitute for disinfection.**

The lens care products listed below are recommended by Paragon Vision Sciences, Inc. for use with the Oxfore®100 (hexafocon A) Contact Lens. See Package Insert for other products that may be used with this lens. Eye care professionals may recommend alternate solutions that are appropriate for the patient's use with his or her lens. Care should be taken not to mix solutions from different companies and/or care systems unless specifically instructed to do so by the eye care professional.

Table 5: Lens Care

Solution Purpose	Lens Care System Chemical (not heat) disinfection
Cleaning	Menicon Unique pH® Multi-Purpose Solution, Boston Advance® Cleaner, or Boston Simplus® Multi-Purpose Solution
Rinsing	Menicon Unique pH® Multi-Purpose Solution, Boston Advance® Conditioning Solution, Boston Simplus®, Sterile Saline Solution or other solution recommended by your eye care professional.
Disinfection/Storage	Menicon Unique pH® Multi-Purpose Solution, Boston Advance® Conditioning Solution, Boston Simplus® or other solution recommended by your eye care professional.
Lubrication/Rewetting	Boston Rewetting Drops
Periodic Protein Cleaning	Menicon Progent Protein Remover for Rigid Gas Permeable Contact Lenses
Insertion of semi-scleral & scleral lenses	Sterile Non-preserved Solution or as recommended by your eye care professional

- **Note:** Some solutions may have more than one function, which will be indicated on the label. Read the label on the solution bottle and follow instructions.
- **Clean** one lens first (always the same lens first to avoid mix-ups) with a recommended cleaning solution. **Rinse** the lens thoroughly with recommended solution to remove the cleaning solution, mucus, and film from the lens surface, and put that lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.
- **After cleaning**, disinfect lenses using the system recommended by the manufacturer and/or the eye care professional.
- To store lenses, disinfect and leave them in the closed/unopened case until ready to wear. If lenses are not to be used immediately following disinfection, the patient should be instructed to consult the package insert or the eye care professional for information on storage of lenses.
- After removing the lenses from the lens case, empty and rinse the lens storage case with sterile contact lens solution as recommended by the lens case manufacturer (never use tap water); then allow the lens case to air dry. When the case is used again, refill it with storage solution. Replace lens case at regular intervals as recommended by the lens case manufacturer or your eye care professional.
- Eye care professionals may recommend a **lubricating/rewetting** solution which can be used to wet (lubricate) lenses while they are being worn to make them more comfortable.
- Oxfore®100 (hexafocon A) Contact Lenses cannot be heat (thermally) disinfected.

Chemical (Not Heat) Disinfection

- Clean the contact lenses with a recommended cleaning solution and thoroughly rinse them with a recommended rinsing solution.
- After cleaning, to disinfect, carefully follow the instructions accompanying the disinfecting solution in the care regimen recommended by the lens manufacturer or the eye care professional.
- Thoroughly rinse lenses with a fresh saline solution or other solution recommended for rinsing before inserting and wearing or follow the instructions on the disinfection solution labeling.
- Do not heat the disinfection solution and lenses.
- Leave the lenses in the unopened storage case until ready to put on the eyes.
- Caution: Lenses that are chemically disinfected may absorb ingredients from the disinfecting solution that may be irritating to the eyes. A thorough rinse in fresh sterile saline solution (or follow the instructions on the disinfection solution labeling) prior to placement on the eye should reduce the potential for irritation.

CARE FOR A STICKING (NON-MOVING) LENS:

If the lens sticks (stops moving), the patient should be instructed to apply a few drops of the recommended lubricating or rewetting solution directly to the eye and wait until the lens begins to move freely on the eye before removing it. If non-movement of the lens continues after 10 minutes, the lens edge should be gently manipulated using the eyelid (do not touch the lens directly), and the patient should immediately consult the eye care professional.

HOW SUPPLIED:

Each Oxfore®100 (hexafocon A) Contact Lens is shipped non-sterile in an individual plastic container. Follow the manufacturer's instructions on the disinfecting solution label.

The plastic container, packing slip or invoice is marked with the information for base curve, diopter power, diameter, center thickness, color, UV-absorber, lot number, hydration date and other required parameters specified by the design.

REPORTING OF ADVERSE REACTIONS:

All serious adverse experiences and adverse reactions observed in patients wearing Oxfore®100 (hexafocon A) Contact Lenses should be reported to:

Paragon Vision Sciences
2120 W. Guadalupe Rd.
Gilbert, AZ 85233-2810

1-800-528-8279
1-480-892-7602
1-480-926-7369 FAX
www.paragonvision.com

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