PACKAGE INSERT

Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lens

IMPORTANT

Please read carefully and keep this information for future use.

This package insert 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.

CAUTION: Federal Law Prohibits Dispensing Without a Prescription

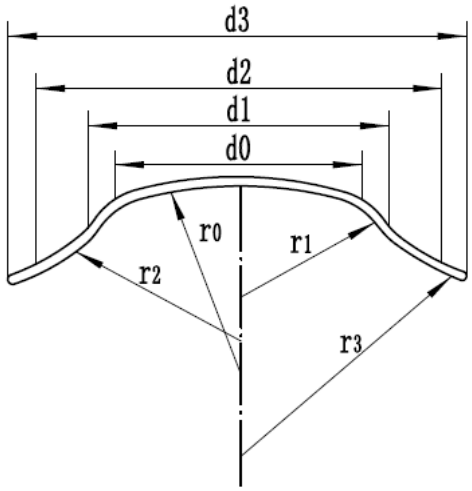
Nonsterile. Clean and condition lenses prior to use.

DESCRIPTION

The Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lens is a lathe cut contact lens manufactured from the rigid gas permeable material roflufocon E, which is a fluorosilicone acrylate contact lens material registered with the United States Adopted Names (USAN) Council.

The Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lens is designed with anti-geometric shape. The lens consists of four arcs (or curves): base arc, reverse arc, fitting arc and side arc. The basal arc region, located in the center and relatively flat in shape, is the treatment area and exerts slight pressure on the cornea. The second is the inverted arc region, which is steeper and provides space for corneal epithelium and tear fluid. The fitting arc zone is then used to provide pressure in the middle and periphery of the cornea and improve center positioning. The lateral arc is the site of tear exchange.

Figure 1 Schematic Diagram of Shaft Section of Orthokeratology



Where,
r_0 ——BC Base Arc Radius;
r_1 —— Reverse Arc Curvature Radius;
r_2 ——Adaptive Arc Curvature Radius;
r_3 ——Edge Arc Curvature Radius;
d_0 ——Base Arc Diameter;
d_1——Reverse Arc Diameter;
d_2——Adaptive Area Diameter;
d_3——Total Diameter;

The Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lens incorporates a visibility tint to make the lens more visible for handling. The tinted lenses are available in blue and gray and contain one or more of the following color additives: D&C Green No.6, C.I. Solvent yellow No. 18, and FD&C Red No. 17.

LENS PARAMETERS AND PROERTIES

Table #1 - Delight (roflufocon E) Lens Parameters and Properties

Parameter or Property	Specification	Tolerance Limit
Radius of Base Arc Curvature	7.50-9.93 mm, Step Size 0.01mm	±0.05 mm
Total Diameter	9.60-11.60 mm, Step Size 0.10 mm	±0.10 mm
Central Thickness	0.15-0.30 mm, Step Size 0.01 mm	±0.02 mm
Back Focal Power F'v	$\|F'v\| \leq 5.00D$ $5.00D < \|F'v\| \leq 10.00D$	±0.12D ±0.18D
Prismatic Power (Residual)	$\|F'v\| \leq 6.00D$ $\|F'v\| > 6.00D$	±0.25cm/m ±0.50cm/m
Oxygen Permeability	94×10^{-11} (cm^2/s) [$mLO_2/(mL\cdot hPa)$] @35℃	± 20%
Refractive Index	1.432	± 0.001
Specific Gravity	1.15	-
Light Transmittance	94 %	± 5%
Contact Angle	46°	± 15%
Water Absorption	Less than 0.5% by weight	-

ACTIONS

The Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lens produces a temporary reduction of myopia by changing the shape (flattening) of the cornea, which is elastic in nature. Flattening the cornea reduces the focusing power of the eye, and if the amount of corneal

flattening is properly controlled, it is possible to bring the eye into correct focus and completely compensate for myopia.

The posterior surface of regular contact lenses generally aligns with the central cornea and rests directly on the corneal tear layer. Regular contact lenses are designed to cause little or no effect on the cornea but Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lens is designed to purposely flatten the shape of the cornea by applying slight pressure to the center of the cornea when the patient is asleep.

After the lens is removed, the cornea retains its altered shape for all or most of one's waking hours. The lenses are designed to be worn overnight with removal during the following day. The Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lens must be worn at night on a regular schedule to maintain the orthokeratology effect, or the myopia will revert to the pretreatment level.

INDICATIONS

The Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lens is indicated for use in the reduction of myopic refractive error in non-diseased eyes. The lens is indicated for overnight wear for the temporary reduction of myopia up to 4.00 diopters (manifest spherical equivalent) in eyes with astigmatism up to 1.50 diopters. The lenses may only be disinfected using a chemical disinfection system.

Note: To maintain the Orthokeratology effect overnight lens wear must be continued on a prescribed schedule. Failure to do so can affect daily activities (e.g., night driving), cause visual fluctuations, and changes in intended correction.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE YOUR Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lens when any of the following conditions exist:

- Acute and sub-acute inflammations 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 tears (dry eyes)
- Corneal hypoesthesia (reduced corneal sensitivity).
- Any systemic disease which may affect the eye or be exacerbated by wearing contact lenses.
- Allergic reactions of ocular surfaces or adnexa which 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 contact lens.
- Any active corneal infection (bacterial, fungal or viral).

- If eyes are red or irritated.

WARNINGS

The practitioner should provide this warning to the patient.

Incorrect use of contact lenses and lens care products can 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.

EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION; IF THE PATIENT EXPERIENCES:

- **Eye Discomfort,**
- **Excessive Tearing,**
- **Vision Changes,**
- **Loss of Vision,**
- **Redness Of The Eye,**
- **Or Other Problems with their Eyes,**

THEY SHOULD BE INSTRUCTED TO IMMEDIATELY REMOVE THE LENSES, AND PROMPTLY CONTACT THEIR EYE CARE PRACTITIONER.

The risk of ulcerative keratitis has been shown to be greater among wearers of extended wear lenses than among wearers of daily wear lenses. The risk among extended wear lens wearers increases with the number of consecutive days that lenses are worn between removals, beginning with the first overnight use. This risk can be reduced by carefully following directions for routine lens care, including cleaning the storage case. Additionally, smoking increases the risk of ulcerative keratitis for contact lens wearers. It is recommended that contact lens wearers see their eye care practitioners twice each year or, if directed, more frequently.

Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lens is to be worn overnight with removal during all or part of each following day. Wearing the lenses continuously (extended wear) presents increased risk, which increases with the number of consecutive days that the lenses are worn between removals. Although the lens is prescribed for use only overnight wear with removal during waking hours, and although the safety risks of overnight wear with removal upon wakening may not be as great as with extended wear, there is still increased risk beginning with the first overnight period.

To avoid serious eye infections, vision loss or blindness, please be aware of the following warnings…

- **Inadequate rubbing, rinsing, and disinfecting of your lenses may cause serious eye infections, vision loss or blindness. Failure to complete the recommended lens rubbing and rinsing times in the labeling to adequately disinfect lenses and reduce the risk of contact lens infection can cause severe infection, vision loss or blindness.**

- **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.**

- **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.**

- **Do not expose your contact lenses to water while you are wearing them.**

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

- **Do not use your multi-purpose solution beyond the expiration and/or discard date because it could result in contamination of the solution and can lead to severe infection, vision loss or blindness.**

- **Do not store your lenses or rinse your lens case with water or any non-sterile solution. Only use fresh multi-purpose solution (or sterile saline solution) so you do not contaminate your lenses or lens case.**

Overnight orthokeratology lenses in adults have been shown to induce optical aberrations, increase corneal irregularity and ocular high-order aberrations and reduce the eye's contrast sensitivity function to a degree correlated with myopic correction achieved, even in clinically successful orthokeratology cases. This may cause bothersome symptoms in vision, such as double vision, glare, halos, blurring, and night vision problems.

PRECAUTIONS

Eye care Practitioner

Clinical studies have demonstrated that Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lenses 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 the material. Consequently, when selecting an appropriate lens design and parameters, the eye care practitioner should consider all factors that affect lens performance and the patient's 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 weighed against the patient's need for refractive reduction; therefore, the continuing ocular health of the patient, and lens performance on the eye should be carefully monitored by the prescribing eye care practitioner.

Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lenses are supplied non-sterile in an individual plastic case. The lenses are shipped dry and must be cleaned and conditioned prior to use.

Patients with limbal stem cell deficiency may need to be monitored more closely to prevent progression of the disease; and if any progression of the disease is noted, contact lens wear may have to be reduced or terminated.

Patient

Patients should be informed of the following precautions

Solution Precautions

- Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions with the contact lenses.
- Do not heat the wetting/soaking solution and lenses.
- Always use fresh unexpired lens care solutions.
- Always follow directions in the package inserts of the contact lens solutions used
- Use only a chemical lens care system. Use of a heat (thermal) lens care system can cause damage by warping Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lens..
- Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
- Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.
- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored).

Handling Precautions

- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-base cosmetics are less likely to damage lenses than oil-base products.

- Be certain that fingers or hands are free of foreign material before touching the contact lenses. Microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.

- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in this booklet and those prescribed by the eyecare practitioner.

- Always handle the lenses carefully and avoid dropping them.

- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use. Pour the lens into your hand.

- Do not touch the lens with fingernails.

- To minimize lens warpage during cleaning, the lenses should be cleaned in the palm of the hand rather than between the thumb and fingers.

Lens Wearing Precautions

- CAUTION: Non-sterile. Clean and condition lenses prior to use.

- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking Lens in the "Instructions for Wearers" booklet. The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, patients should immediately consult with the eye care practitioner.

- Never wear contact lenses beyond the period recommended by the eye care practitioner.

- Avoid, if possible, all harmful or irritating vapors and fumes when wearing lenses.

- If aerosol products such as sprays are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.

Lens Case Precautions

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

Topics to Discuss with the Eyecare Practitioner

- Ask your eyecare practitioner about wearing your lenses during sporting activities.
- Always contact your eyecare practitioner before using any medicine in your eyes.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of your eyes. You should be instructed as to a recommended follow-up schedule.

Who Should Know That the Patient is Wearing Contact Lenses

- Inform your doctor (health care practitioner) about being a contact lens wearer.
- Always inform your employer of being a contact lens wearer. Some jobs may require the use of eye protection equipment or may require that you not wear contact lenses.

ADVERSE EFFECTS (PROBLEMS AND WHAT TO DO)

Patients should be informed that the following problems might occur:

- Eyes stinging, burning, itching (irritation), or other eye pains.
- Comfort is less than when lens was first placed on eye.
- Feeling of something 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, double vision, rainbows, glare or halos around objects
- Night vision problems
- Decreased contrast sensitivity
- Sensitivity to light (photophobia)
- Dry eyes

Please refer to the Clinical Study Section of this package insert for adverse effects observed during the study.

If the patient notices any of these conditions, the patient should be instructed to **IMMEDIATELY REMOVE THE LENSES.**
The patient should be advised to follow these instructions:

- 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 practitioner.

- If the lens has dirt, an eyelash, or other foreign objects on it, or the problem stops and the lens appears undamaged, thoroughly clean, rinse and disinfect the lens; then reinsert it.

- If the problem continues, **IMMEDIATELY** remove the contact lenses and consult the eye care practitioner.

When any of the above problems occur, a serious condition such as **Acanthamoeba Keratitis**, infection, corneal ulcer, neovascularization, iritis, persistent stromal edema or GPC (giant papillary conjunctivitis) may be present. The patient should be instructed to keep the lens off the eye and seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage including corneal scarring, opacification, blindness or loss of eye.

CLINICAL STUDY DATA

A clinical study was conducted to establish a reasonable assurance of safety and effectiveness of the Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lens to temporarily reduce myopic refractive error compared with a control lens. A summary of the clinical study is presented below.

INTRODUCTION

This trial was a multi-center, randomized, open label, and positive parallel controlled clinical trial. The target enrollment was 258 patients with binocular myopia. The selected subjects were randomly assigned to the experimental group and the control group to wear the trial product and the controlled product respectively. Subjects in the control group were treated with rigid gas permeable contact lenses for overnight orthokeratology produced by Euclid Systems Corporation, and those in the experimental group were treated with the Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lens produced by Tianjin Mastervision Technology Co., Ltd. Follow-up visits were carried out over 12 months of wearing the contact lenses.

DEMOGRAPHIC INFORMATION

The clinical trial was structured to recruit participants across three distinct age categories: 8-12 years, 13-18 years, and over 18 years. This stratification was implemented to facilitate comparative analysis of clinical outcomes and assess equivalency across age groups. Consequently, the mean age of enrolled subjects was calculated at 17.7 years.

The gender distribution among participants demonstrated a higher proportion of female subjects compared to male subjects: 74.19% female and 25.81% male in the treatment group, 54.69% female and 45.31% male in the control group, and 64.29% female and 35.71% male overall. Gender was not considered a significant variable in the study design.

The clinical investigation was conducted in China, with the majority of participants identified as Chinese Han nationality (92.32% in the test group, 93.75% in the control group). This distribution closely corresponds to the demographic composition reported in the 2020 National

Population Census, which indicated that Han nationality represents 91.1% of the population. Ethnicity was not considered a factor in the trial design.

Table 2. Demographic Information

	Index	Test group	Control group	Total
Age (years)	N(Missing)	124(0)	128(0)	252(0)
	Mean(Sd)	18.24(8.85)	17.21(8.01)	17.71(8.43)
	Median	14.92	14.82	14.89
	Ql,Q3	11.64,24.69	10.99,23.17	11.44,24.06
	Min, Max	8.60,39.62	8.00,39.89	8.00,39.89
Gender	Male n (%)	32(25.81%)	58(45.31%)	90(35.71%)
	Woman n (%)	92(74.19%)	70(54.69%)	162(64.29%)
	Total (missing)	124(0)	128(0)	252(0)
Ethnic group	Han Chinese n (%)	112(90.32%)	120(93.75%)	232(92.06%)
	Other n (%)	12(9.68%)	8(6.25%)	20(7.94%)
	Total (missing)	124(0)	128(0)	252(0)

This table presents a demographic analysis of refractive parameters, indicating the number of patients with different spherical diopters distributed across various ranges of corneal astigmatism at the baseline.

Table 3. The Distribution of Baseline Myopic Refractive Errors

	Pretreatment Myopia (Spherical Diopters)													
	≤1.0 D		1.25 to 2.00 D		2.25 to 3.00 D		3.25 to 4.00 D		4.25 to 5.00 D		Not Report		Totals	
Corneal Astigmatism	n/%		n/%		n/%		n/%		n/%		n/%		n/%	
	Test	Control	Test	Control	Test	Control	Test	Control	Test	Control	Test	Control	Test	Control
0.00	0 (0.0%)	0 (0.0%)	1 (0.9%)	0 (0.0%)	2 (1.1%)	0 (0.0%)	1 (0.6%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (0.8%)	1 (0.2%)
< 0.12	0 (0.0%)	0 (0.0%)	1 (0.9%)	1 (0.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	1 (0.2%)
0.12 to 0.50	0 (0.0%)	1 (7.7%)	5 (4.6%)	8 (7.4%)	9 (5.0%)	8 (4.4%)	4 (2.3%)	8 (4.7%)	0 (0.0%)	1 (11.1%)	7 (31.8%)	3 (13.6%)	25 (5.0%)	29 (5.8%)
0.5 to 0.62	0 (0.0%)	0 (0.0%)	2 (1.9%)	0 (0.0%)	3 (1.7%)	4 (2.2%)	4 (2.3%)	2 (1.2%)	1 (11.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	10 (2.0%)	6 (1.2%)
0.62 to 1.00	2 (15.4%)	1 (7.7%)	6 (5.6%)	17 (15.7%)	15 (8.3%)	18 (9.9%)	14 (8.2%)	12 (7.0%)	0 (0.0%)	1 (11.1%)	4 (18.2%)	5 (22.7%)	41 (8.1%)	54 (10.7%)
1.00 to 1.12	0 (0.0%)	0 (0.0%)	3 (2.8%)	2 (1.9%)	1 (0.6%)	8 (4.4%)	5 (3.0%)	3 (1.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	9 (1.8%)	13 (2.6%)
1.12 to 1.50	2 (15.4%)	1 (7.7%)	7 (6.5%)	9 (8.3%)	9 (5.0%)	8 (4.4%)	12 (7.0%)	6 (3.5%)	0 (0.0%)	0 (0.0%)	1 (4.6%)	0 (0.0%)	31 (6.2%)	24 (4.8%)

	Pretreatment Myopia (Spherical Diopters)													
	≤1.0 D		1.25 to 2.00 D		2.25 to 3.00 D		3.25 to 4.00 D		4.25 to 5.00 D		Not Report		Totals	
Corneal Astigmatism	n/%		n/%		n/%		n/%		n/%		n/%		n/%	
	Test	Control	Test	Control	Test	Control	Test	Control	Test	Control	Test	Control	Test	Control
1.50 to 1.62	0 (0.0%)	1 (7.7%)	1 (0.9%)	1 (0.9%)	1 (0.6%)	0 (0.0%)	5 (2.9%)	3 (1.8%)	0 (0.0%)	1 (11.1%)	0 (0.0%)	0 (0.0%)	7 (1.4%)	6 (1.2%)
1.62 to 2.00	0 (0.0%)	1 (7.7%)	0 (0.0%)	3 (2.8%)	3 (1.7%)	4 (2.2%)	5 (2.9%)	3 (1.8%)	0 (0.0%)	1 (11.1%)	0 (0.0%)	0 (0.0%)	8 (1.6%)	12 (2.4%)
> 2.00	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.1%)	0 (0.0%)	4 (2.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	6 (1.2%)	0 (0.0%)
Not Report	2 (15.4%)	2 (15.4%)	19 (17.6%)	22 (20.4%)	38 (21.0%)	48 (26.5%)	42 (24.6%)	37 (21.6%)	3 (33.3%)	1 (11.1%)	2 (9.1%)	0 (0.0%)	106 (21.0%)	110 (21.8%)
Totals	6 (46.2%)	7 (53.9%)	45 (41.7%)	63 (58.3%)	83 (45.9%)	98 (54.1%)	96 (56.1%)	75 (43.9%)	4 (44.4%)	5 (55.6%)	14 (63.6%)	8 (36.4%)	248 (49.2%)	256 (50.8%)

Percentage = number of eyes within both the corneal astigmatism range and myopia range, divided by the total number of eyes within the myopia range.

ACCOUNTABILITY

Of the 280 subjects enrolled in the PMA clinical trial, data from 215 participants (76.8%) were available for analysis at the 12-month follow-up assessment.

The study was conducted across three investigational sites, enrolling a total of 280 subjects, with 140 allocated to the experimental arm and 140 to the control arm. Of these, 215 subjects completed all required follow-up visits (109 in the experimental group and 106 in the control group). A total of 65 subjects discontinued participation, with 21 withdrawals attributed to inability to obtain study lenses, and 10 subjects were excluded from the analysis.

Table. 4 ACCOUNTABILITY

	Initial		Month 1		Month 3		Month 6		Month 9		Month 12	
	T	C	T	C	T	C	T	C	T	C	T	C
Available for Analysis (in Window) (n/N[1]) %	262 (46.79%)	258 (46.07%)	240 (42.86%)	242 (43.21%)	232 (41.43%)	232 (41.43%)	226 (40.36%)	230 (41.07%)	216 (38.57%)	226 (40.36%)	212 (37.86%)	218 (38.93%)
Discontinued	16	22	18	16	6	8	4	2	4	0	2	4
Lost to Follow-up	2	0	4	0	2	2	2	0	6	4	2	4
% (n/N[2]) Accountability	262 (46.95%)	258 (46.24%)	240 (43.32%)	242 (43.68%)	232 (42.18%)	232 (42.18%)	226 (41.24%)	230 (41.97%)	216 (40.15%)	226 (42.01%)	212 (39.85%)	218 (40.98%)

n = total number of eyes in the specified column category at that visit

N^1 = total number of eyes enrolled (560)

N^2 = total number of eyes enrolled (560) – total number of eyes lost to follow-up

OVERNIGHT WEAR SAFETY SUMMARY

Discontinued Eyes

Table. 5 DISCONTINUED EYES TABULATED BY COMPLETED VISITS AND REASONS FOR DISCONTINUATION WITH INCIDENCE RATES																
	Initial		Month 1		Month 3		Month 6		Month 9		Month 12		Aggregated Discontinued		subtotal	Randomization Set N=560
	C	T	C	T	C	T	C	T	C	T	C	T	C	T		% Incidence
1. Poor Scotopic Vision	0	0	0	2 (0.4%)	0	2 (0.4%)	0	0	0	0	0	0	0	4 (0.7%)	*4*	0.71%
2.Positive Slit Lamp Findings (SLF)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	*0*	0.00%
3.Adverse Reaction	0	0	2 (0.4%)	0	0	2 (0.4%)	0	0	0	0	0	0	2 (0.4%)	2 (0.4%)	*4*	0.71%
4.Lens Position	0	0	0	0	0	0	0	0	0	0	0	0	0	0	*0*	0.00%
5.Discomfort	0	0	0	2 (0.4%)	0	0	0	2 (0.4%)	0	0	0	0	0	4 (0.7%)	*4*	0.71%
6.Handling Problems	4 (0.7%)	2 (0.4%)	2 (0.4%)	2 (0.4%)	0	0	0	0	0	0	0	0	6 (1.1%)	4 (0.7%)	*10*	1.79%
7.Disinterest	0	0	4 (0.7%)	0	0	0	0	0	0	0	2 (0.4%)	0	6 (1.1%)	0	*6*	1.07%
8.Lost to Follow-up	2 (0.4%)	0	4 (0.7%)	0	2 (0.4%)	2 (0.4%)	2 (0.4%)	0	6 (1.1)	4 (0.7%)	2 (0.4%)	4 (0.7%)	14 (2.5%)	10 (1.8%)	*28*	5.00%
9.None Given	8 (1.4%)	14 (2.5%)	6 (1.1%)	2 (0.4%)	4 (0.7%)	4 (0.7%)	4 (0.7%)	0	0	0	0	2 (0.4%)	26 (4.6%)	22 (3.9%)	*44*	7.86%
10.Other	4 (0.7%)	6 (1.1%)	4 (0.7%)	8 (1.4%)	2 (0.4%)	0	0	0	4 (0.7%)	0	0	2 (0.4%)	14 (2.5%)	16 (2.9%)	*30*	5.36%
(Other Specify)	4[a] (0.7%)	4[a] (0.7%) 2[b] (0.4%)	4[a] (0.7%)	8[a] (1.4%)	2[a] (0.4%)				4[a] (0.7%)			2[c] (0.4%)				
Subtotal	18 (3.2%)	22 (3.9%)	22 (3.9%)	16 (2.9%)	8 (1.4%)	10 (1.8%)	6 (1.1%)	2 (0.4%)	10 (1.8%)	4 (0.7%)	4 (0.7%)	8 (1.4%)	68 (12.1%)	62 (11.1%)	*130*	23.21%

percentage = n/N

[a] personal [b] exclusion [c] work related

Proportion of the subjects whose BCVA decreased by 1 line, 2 lines or above in comparison to the baseline after 1-day, 1-week, 2-weeks, 30-days, 3-months, 6-months, 9-months and 12-months of treatment (presented in Snellen or Log MAR VA) are summarized below.

Table 6. Decrease in BCVA

BCVA Decrease by						
	1 line		**2 lines**		**> 2 lines**	
	Test	**Control**	**Test**	**Control**	**Test**	**Control**
1 Day	37 (7.1%)	42 (8.1%)	5 (1.0%)	3 (0.6%)	1 (0.2%)	0 (0%)
1 week	11 (2.2%)	20 (4.0%)	0 (0%)	5 (1.0%)	0 (0%)	1 (0.2%)
2 weeks	14 (2.8%)	23 (4.7%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
1 month	11 (2.3%)	26 (5.4%)	0 (0%)	4 (0.8%)	0 (0%)	0 (0%)

3 months	11 (2.4%)	12 (2.6%)	3 (0.6%)	1 (0.2%)	0 (0%)	1 (0.2%)
6 months	11 (2.4%)	8 (1.8%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
9 months	9 (2.0%)	10 (2.2%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
12 months	17 (4.0%)	11 (2.6%)	3 (0.6%)	0 (0%)	1 (0.2%)	0 (0%)

Note: percentage = number of eyes with decreased vision/total number of eyes examined at follow-up.

Wearing Time

Patients were required to wear the device for more than eight hours per day according to the Instructions for Use.

Intraocular Pressure (IOP)

At 1 month and 12 months after wearing, the comparison of intraocular pressure between the experimental group and the control group showed that there was no clinically relevant difference between the two groups.

EFFECTIVENESS OUTCOMES

Table 7. UCDVA STRATIFIED BY PRETREATMENT MYOPIA (FAS 12 months)

UCDVA	**Pretreatment Myopia (Spherical Diopters)**													
	≤1.0 D		1.25 to 2.00 D		2.25 to 3.00 D		3.25 to 4.00 D		4.25 to 5.00 D		Not Report		Total	
	n/%		n/%		n/%		n/%		n/%		n/%		n/%	
	Test	Control	Test	Control	Test	Control	Test	Control	Test	Control	Test	Control	Test	Control
20/20 or better	4 (66.7%)	5 (71.4%)	25 (55.6%)	33 (52.4%)	49 (59.0%)	39 (39.8%)	49 (51.0%)	26 (34.7%)	0 (0%)	2 (40.0%)	8 (57.1%)	5 (62.5%)	135 (54.4%)	110 (43.0%)
20/25 or better	4 (66.7%)	5 (71.4%)	31 (68.9%)	37 (58.7%)	60 (72.3%)	57 (58.2%)	63 (65.6%)	38 (50.7%)	1 (25.0%)	3 (60.0%)	9 (64.3%)	6 (75.0%)	168 (67.7%)	146 (57.0%)
20/32 or better	4 (66.7%)	6 (85.7%)	34 (75.6%)	41 (65.1%)	62 (74.7%)	61 (62.2%)	69 (71.9%)	42 (56.0%)	1 (25.0%)	3 (60.0%)	10 (71.4%)	6 (75.0%)	180 (72.6%)	159 (62.1%)
20/40 or better	4 (66.7%)	6 (85.7%)	35 (77.8%)	44 (69.8%)	65 (78.3%)	67 (68.4%)	72 (75.0%)	45 (60.0%)	1 (25.0%)	3 (60.0%)	11 (78.6%)	6 (75.0%)	188 (75.8%)	171 (66.8%)
20/80 or better	5 (83.3%)	6 (85.7%)	35 (77.8%)	46 (73.0%)	67 (80.7%)	80 (81.6%)	76 (79.2%)	49 (65.3%)	1 (25.0%)	3 (60.0%)	12 (85.7%)	8 (100%)	196 (79.0%)	192 (75.0%)
20/200 or better	5 (83.3%)	7 (100%)	38 (84.4%)	50 (79.4%)	68 (81.9%)	84 (85.7%)	82 (85.4%)	52 (69.3%)	1 (25.0%)	3 (60.0%)	12 (85.7%)	8 (100%)	206 (83.1%)	204 (79.7%)
Not Report	1 (16.7%)	0 (0%)	7 (15.6%)	13 (20.6%)	15 (18.1%)	14 (14.3%)	14 (14.6%)	23 (30.7%)	3 (75.0%)	2 (40.0%)	2 (14.3%)	0 (0%)	42 (16.9%)	52 (20.3%)
Total eyes	6 (100%)	7 (100%)	45 (100%)	63 (100%)	83 (100%)	98 (100%)	96 (100%)	75 (100%)	4 (100%)	5 (100%)	14 (100%)	8 (100%)	248 (100.0%)	256 (100%)

Percentage = number of eyes with uncorrected distance visual acuity (UCDVA) within a specified range and within the myopia range, divided by the total number of eyes within the myopia range.

Table 8**.** Refractive Change from Baseline Visit (FAS 12 months vs. baseline)

	Pretreatment Myopia (MRSE)													
	≤1.0 D		1.25 to 2.00 D		2.25 to 3.00 D		3.25 to 4.00 D		4.25 to 5.00 D		Not Report		Totals	
Refractive Change	n/%		n/%		n/%		n/%		n/%		n/%		n/%	
	Test	Control	Test	Control	Test	Control	Test	Control	Test	Control	Test	Control	Test	Control
0.00	0 (0.0%)	0 (0.0%)	1 (0.9%)	2 (1.9%)	3 (1.7%)	3 (1.7%)	2 (1.2%)	2 (1.2%)	0 (0%)	0 (0%)	0 (0.00%)	0 (0.00%)	6 (1.2%)	7 (1.4%)
Decreases														
＜0.12	1 (7.7%)	0 (0%)	1 (0.9%)	0 (0%)	0 (0%)	1 (0.6%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (0.4%)	1 (0.2%)
0.12 to 0.50	2 (15.4%)	2 (15.4%)	6 (5.6%)	3 (2.8%)	10 (5.5%)	7 (3.9%)	10 (5.9%)	3 (1.8%)	0 (0.0%)	0 (0.0%)	2 (9.1%)	3 (13.6%)	30 (6.0%)	18 (3.6%)
0.5 to 0.62	0 (0.0%)	0 (0%)	0 (0.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
0.62 to 1.00	2 (15.4%)	4 (30.8%)	7 (6.5%)	13 (12.0%)	4 (2.2%)	5 (2.8%)	9 (5.3%)	2 (1.2%)	0 (0.0%)	1 (11.1%)	3 (13.6%)	3 (13.6%)	25 (5.0%)	28 (5.6%)
1.00 to 1.12	0 (0%)	0 (0%)	0 (0.0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
1.12 to 1.50	0 (0.0%)	0 (0%)	7 (6.5%)	12 (11.1%)	15 (8.3%)	12 (6.6%)	4 (2.3%)	7 (4.1%)	0 (0.0%)	0 (0.0%)	3 (13.6%)	0 (0.0%)	29 (5.8%)	31 (6.2%)
1.50 to 1.62	0 (0.0%)	0 (0%)	0 (0.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
1.62 to 2.00	0 (0.0%)	0 (0%)	4 (3.7%)	7 (6.5%)	13 (7.2%)	14 (7.7%)	3 (1.8)	4 (2.3%)	0 (0%)	0 (0%)	3 (13.6%)	0 (0%)	23 (4.6%)	25 (5.0%)
＞2.00	0 (0.0%)	0 (0%)	0 (0%)	0 (0%)	11 (6.1%)	28 (15.5%)	39 (22.8%)	26 (15.2%)	0 (0.0%)	2 (22.2%)	1 (4.6%)	2 (9.1%)	51 (10.1%)	58 (11.5%)
Not Report	1 (7.7%)	0 (0%)	15 (13.9%)	18 (16.7%)	23 (12.7%)	23 (12.7%)	21 (12.3%)	31 (18.1%)	4 (44.4%)	2 (22.2%)	2 (9.1%)	0 (0%)	66 (13.1%)	74 (14.7%)
Totals	6 (46.2%)	6 (46.2%)	40 (37.0%)	53 (49.1%)	76 (42.0%)	90 (49.7%)	86 (50.3%)	73 (42.7%)	4 (44.4%)	5 (55.6%)	14 (63.6%)	8 (36.4%)	226 (44.8%)	235 (46.6%)
Increase														
＜0.12	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
0.12 to 0.50	0 (0%)	0 (0%)	3 (2.8%)	7 (6.5%)	1 (0.6%)	1 (0.6%)	4 (2.3%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	8 (1.6%)	8 (1.6%)
0.5 to 0.62	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
0.62 to 1.00	0 (0%)	0 (0%)	0 (0%)	1 (0.9%)	0 (0%)	3 (1.7%)	3 (1.8%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (0.6%)	4 (0.8%)
1.00 to 1.12	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
1.12 to 1.50	0 (0%)	0 (0%)	1 (0.9%)	0 (0%)	1 (0.6%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (0.4%)	0 (0%)
1.50 to 1.62	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
1.62 to 2.00	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (0.6%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (0.2%)	0 (0%)
＞2.00	0 (0%)	1 (7.7%)	0 (0%)	0 (0%)	1 (0.6%)	1 (0.6%)	1 (0.6%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (0.4%)	2 (0.4%)
Not Report	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Totals	0 (0%)	1 (7.7%)	4 (3.7%)	8 (7.4%)	4 (2.2%)	5 (2.8%)	8 (4.7%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	16 (3.2%)	14 (2.8%)

Percentage = number of eyes within the refractive change range and within the myopia range, divided by the total number of eyes within the myopia range.

Table 9. STABILITY OF MANIFEST REFRACTION STRATIFIED BY DIOPTRIC GROUP（FAS）

	9 and 12 Months n/N (%)

Change in Spherical Diopters	≤1.0 D		1.25 to 2.00 D		2.25 to 3.00 D		3.25 to 4.00 D		4.25 to 5.00 D		Not Report	
	n/N (%)		n/N (%)		n/N (%)		n/N (%)		n/N (%)		n/N (%)	
	Test	Control	Test	Control	Test	Control	Test	Control	Test	Control	Test	Control
≤1.0 D	5 (38.5%)	7 (53.9%)	34 (31.5%)	47 (43.5%)	58 (32.0%)	69 (38.1%)	69 (40.4%)	43 (25.2%)	0 (0.0%)	2 (22.2%)	6 (27.3%)	8 (36.4%)
1.00 to 1.50 D	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.9%)	4 (2.2%)	7 (3.9%)	3 (1.8%)	2 (1.2%)	1 (11.1%)	1 (11.1%)	0 (0.0%)	0 (0.0%)
1.50 to 2.00 D	0 (0.0%)	0 (0.0%)	1 (0.93%)	0 (0.0%)	2 (1.1%)	4 (2.2%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.6%)	0 (0.0%)
2.00 to 2.50 D	0 (0.0%)	0 (0.0%)	1 (0..93%)	0 (0.0%)	0 (0.0%)	2 (1.1%)	2 (1.2%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
2.50 to 3.00 D	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
3.00 D	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.9%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (4.6%)	0 (0.0%)
Not Report	1 (7.7%)	0 (0.0%)	9 (8.3%)	13 (12.0%)	18 (9.9%)	15 (8.3%)	21 (12.3%)	28 (16.4%)	3 (33.3%)	2 (22.2%)	6 (27.3%)	0 (0.0%)
Totals	6 (46.2%)	7 (53.9%)	45 (41.7%)	63 (58.3%)	83 (45.9%)	98 (54.1%)	96 (56.1%)	75 (43.9%)	4 (44.4%)	5 (55.6%)	14 (63.6%)	8 (36.4%)
Mean Difference	-0.29	-0.29	-0.24	-0.11	-0.27	-0.08	-0.43	-0.01	0.75	0.25	0.13	-0.82
SD	0.39	0.99	0.80	0.92	1.19	1.10	1.35	1.10	0.00	0.28	1.63	0.71
95% CI	(-0.71, 0.53)	(-2.53, 1.85)	(-0.63, 0.16)	(-0.50, 0.25)	(-0.70, 0.15)	(-0.39, 0.30)	(-0.88, 0.01)	(-0.49, 0.46)	(,,.)	(-0.43, 0.93)	(-2.46, 2.71)	(-1.93, 0.31)

Note that for n/N(%), n = number of eyes with both baseline manifest refractive range and change in spherical diopter range, and N = total number of eyes within baseline manifest refractive range.

SUMMARY OF KEY SAFETY & EFFECTIVENESS VARIABLES

Table 10. Summary of Key Safety & Effectiveness Variables (N=Eyes)

Criteria	1 Month		3 Months		6 Months		9 Months		12 Months	
	Test	Control	Test	Control	Test	Control	Test	Control	Test	Control
n	248	256	248	256	248	256	248	256	248	256
UCVA 20/20 or better	164 (66.13%)	133 (51.95%)	162 (65.32%)	125 (48.83%)	172 (69.35%)	136 (53.13%)	146 (58.87%)	133 (51.95%)	135 (54.44%)	110 (42.97%)
UCVA 20/40 or better	218 (87.90%)	211 (82.42%)	208 (83.87%)	188 (73.44%)	206 (83.06%)	196 (76.56%)	192 (77.42%)	181 (70.70%)	188 (75.81%)	171 (66.80%)
The number of eyes in different spherical diopter range										
±0.50 D	91 (36.69%)	94 (36.72%)	83 (33.47%)	91 (35.55%)	76 (30.65%)	93 (36.33%)	54 (21.77%)	83 (32.42%)	45 (18.15%)	77 (30.08%)
± 1.00 D	143 (57.66%)	162 (63.28%)	125 (50.40%)	131 (51.17%)	121 (48.79%)	135 (52.73%)	104 (41.94%)	136 (53.13%)	80 (32.26%)	117 (45.70%)
± 2.00 D	196 (79.03%)	209 (81.64%)	186 (75.00%)	190 (74.22%)	186 (75.00%)	181 (70.70%)	164 (66.13%)	178 (69.53%)	148 (59.68%)	175 (68.36%)
± 3.00 D	214 (86.29%)	222 (86.72%)	208 (83.87%)	206 (80.47%)	203 (81.85%)	198 (77.34%)	186 (75.00%)	194 (75.78%)	186 (75.00%)	196 (76.56%)

Change in spherical diopters	Baseline-1month – Mean Dif (SD)		Month 1 – 3 Mean Dif (SD)		Month3 – 6 Mean Dif (SD)		Month6 – 9 Mean Dif(SD)		Month9 – 12 Mean Dif (SD)	
0.12 to 1D	1.07 (0.51) n=5	0.93 (0.68) n=7	0.00 (0.32) n=6	-0.30 (0.52) n=7	-0.15 (0.41) n=6	0.14 (1.08) n=7	-0.18 (0.35) n=5	-0.22 (0.66) n=7	-0.25 (0.69) n=5	-0.28 (0.99) n=7
1.25 to 2.00D	1.09 (0.89) n=36	1.29 (0.61) n=52	-0.03 (0.69) n=43	-0.10 (0.65) n=58	-0.01 (0.84) n=43	-0.05 (0.71) n=53	-0.18 (0.53) n=41	-0.22 (0.85) n=48	-0.23 (0.79) n=36	-0.11 (0.99) n=50
2.25 to 3.00D	1.72 (1.12) n=68	1.89 (1.23) n=81	-0.20 (1.46) n=75	0.00 (1.22) n=82	-0.11 (0.96) n=71	-0.06 (1.12) n=80	-0.03 (0.82) n=69	-0.10 (1.08) n=80	-0.28 (1.19) n=65	-0.05 (1.09) n=83
3.25 to 4.00D	2.59 (1.56) n=83	2.47 (1.24) n=58	-0.17 (1.72) n=83	-0.26 (1.55) n=57	0.06 (1.12) n=81	-0.12 (1.32) n=52	-0.31 (0.77) n=74	0.03 (1.34) n=48	-0.43 (1.35) n=75	-0.01 (1.08) n=47
>4.0D	0(0) n=0	3.59 (1.74) n=4	-0.50 (2.41) n=3	-0.38 (0.10) n=4	-1.33 (2.02) n=3	0.19 (0.39) n=4	-0.75 (0) n=1	-0.54 (0.19) n=3	1.50 (0) n=1	0.50 (0.55) n=3

	Treat, n=248	Control, n=256
Serious Adverse Event***	0	2
Loss of BSCVA > 2 lines***	2	2
BSCVA worse than 20/40***	1	1
Increase of> 1 D Coreal Cyl***	0	3

In the clinical investigation, the Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lens was evaluated in the test group over a 12-month follow-up period. Safety and effectiveness outcomes were assessed in 248 treated eyes at scheduled follow-up visits from Month 1 through Month 12. This table corresponds to the FAS data set.

The UCVA rows represent the number of eyes that attained an uncorrected visual acuity (UCVA) of 20/20 or better and 20/40 or better at various follow - up time points.
The percentages in parentheses represent the proportion of the number of eyes in this group to the total number of eyes in the experimental and control groups within the FAS data set.

The MRSE change (from baseline) (±0.50D, ±1.00D, ±2.00D, ±3.00) rows represent the number of eyes with spherical refractive error changes of 0.50D or less, 1.00D or less, 2.00D or less, and 3.00D or less at different follow - up time points.
The percentages in parentheses represent the proportion of the number of eyes in this group to the total number of eyes in the experimental and control groups within the FAS data set.

The MRSE changes in refractive ranges represent the different groups based on the distinct refraction results at baseline. The horizontal data represent the mean and standard deviation of spherical diopter changes in eyes during different follow - up periods;
"n" represents the number of data.

Safety outcomes in the test group showed no serious adverse events. Two treated eyes experienced a loss of best-corrected visual acuity (BSCVA) of greater than 2 lines, one treated eye had BSCVA worse than 20/40, and no treated eyes had an increase in corneal cylinder greater than 1.00 D. Among the four subjects across both study groups with loss of greater than 2 lines of BSCVA, one corrected to 20/20 at study completion, one corrected to 20/20 before study withdrawal, one discontinued without follow-up recheck after a recorded acuity of 20/63, and one had BSCVA of 20/50 at study completion. Investigators reported no associated complications, adverse events, or slit-lamp abnormalities at the final study visit.

FITTING

For a description of fitting techniques, refer to the **Fitting Guide for Dilight™ (roflufocon E) Overnight Orthokeratology Lenses**. Copies of the fitting guide are available from:

Tianjin MasterVision Technology Co., Ltd.
1st Floor No.15 Building. No. 89 Heyuan Road,
Jing-jin Technology Valley, Wuqing District,
Tianjin. P.R. China
+862260913521
[Insert Toll-Free U.S. Number]
http://www.mastervision.cn/

RECOMMENDED WEARING SCHEDULE

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

Wearing Schedule: On the initial night of wearing (first overnight wear), lenses should be inserted at a time early enough to achieve 8 to 10 hours of closed eye wearing time (sleep). A well fit lens provides for centration with the eye closed. The effects of lid interaction on blinking and gravity may result in lens decentration during open eye wear. The patient should place the lens(s) in their eye 15 to 20 minutes before going to sleep.

Be aware “when in doubt, take it out”. It is important that the new wearer not sleep in a lens that has a significant foreign body sensation. In the event of foreign body sensation, instruct the patient to remove the lens, clean and re-wet it; and again place the lens in the eye. If the sensation continues, remove the lens. The lens should not be worn.

Appointment Schedule: The patient should report for follow-up evaluation the morning after the first overnight wear. The visit is best scheduled within a few hours of awakening and the patient should report with lenses in place. This visit provides an excellent opportunity to evaluate lens centration and potential lens adherence.

Upon the absence of clinical signs and complications, the patient may be instructed to continue overnight wear of the lenses until the next scheduled follow-up visit.

An alternate daytime wear schedule may be offered at the practitioner’s discretion.

Myopic Reduction Maintenance Lens (Retainer Lens) Schedule

After a period of several days, or when the eyecare practitioner is satisfied that the patient has adapted to the Dilight™ (roflufocon E) Overnight Orthokeratology Lenses, the eyecare practitioner may optimize the wearing schedule for an individual patient to monitor the duration of visual improvement. This may continue as long as the patient can see clearly. When it is found that the patient experiences a visual decrement following lens removal, the schedule of overnight wear must be modulated to maintain visual performance.

LENS CARE DIRECTIONS

The lens care products listed below are recommended for use with the Dilight™ (roflufocon E) Overnight Orthokeratology Lenses.

Chemical Lens Care System

CLEAR CARE® Cleaning & Disinfecting Solution by Alcon
And
Unique pH® Multi-Purpose Solution by Menicon Co., Ltd

The directions found in the package inserts from these products should be followed. Failure to adhere to these procedures may result in the development of serious ocular complications. A patient should not switch from one care system to another unless it has been determined by the eye care practitioner that this is necessary. Do not mix or alternate the disinfection and storage systems unless so indicated on the product label.

Inform the patient of the following lens care suggestions:

- Always wash and rinse your hands before handling your contact lenses

- Never use tweezers or other tools to remove your lenses from the lens container. Pour the lens into your hand.
- Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lenses must be both cleaned and disinfected each time you remove them. One procedure does not replace the other. Cleaning is necessary to remove mucus and film from the lens surface. Disinfecting is necessary to destroy harmful germs. To minimize lens warpage during cleaning, the lenses should be cleaned in the palm of the hand rather than between the thumb and fingers.
- Clean one lens first. The recommended procedure is to always clean the same lens first to avoid mix-ups. Rinse the lens thoroughly to remove the cleaning solution. Place the lens into the correct storage chamber and fill the chamber with the recommended disinfecting solution as recommended by your eye care practitioner. Clean and rinse the other lens in the same manner and place it in its chamber.
- Tightly close the top of each chamber of the lens storage case.
- To disinfect your lenses, leave them in the solution for at least the period indicated on the product label.
- Leave the lenses in the closed storage case until you are ready to put them in your eye.

LENS CASE CLEANING AND MAINTENANCE

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 discouraged. If air drying, be sure that no residual solution remains in the case before allowing it to air dry.

ENZYME CLEANING

The eye care practitioner may recommend enzyme cleaning. Enzyme cleaning does not replace routine cleaning and disinfecting. The patient should carefully follow the instructions in the enzymatic cleaning labeling.

EMERGENCIES

If chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes, the patient should flush eyes immediately with tap water and then remove lenses promptly. The patient should **CONTACT THE EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.**

HOW SUPPLIED

Each lens is supplied non-sterile in an individual plastic case. The case, packing slip or invoice is marked with the base curve, power in diopters, diameter, center thickness, color, and Lot #.

REPORTING OF ADVERSE REACTIONS:

All serious adverse experiences and adverse reactions observed in patients wearing or experienced with the lenses should be reported immediately to the manufacturer.

Manufactured by

Tianjin MasterVision Technology Co., Ltd.
1st Floor No.15 Building. No. 89 Heyuan Road,
Jing-jin Technology Valley, Wuqing District,
Tianjin. P.R. China
[Insert Toll-Free U.S. Number]
http://www.mastervision.cn/

℞ : Prescription Use Only;

 : Use-by date;

: Batch code;

 : Date of manufacture;

 : Consult instructions for use;

Printed YYYY-MM-DD

PATIENT INFORMATION BOOKLET
FOR POTENTIAL USERS OF

Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lens

CAUTION: Federal Law Prohibits Dispensing Without a Prescription

Nonsterile. Clean and condition lenses prior to use.

List of Contents

Introduction

The information in this booklet is to help you decide whether or not to be fitted with the Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lens. Orthokeratology is a fitting procedure that temporarily corrects or greatly reduces nearsightedness (known by the medical name, myopia) with or without astigmatism after contact lenses have been removed. By temporary, it is meant that the contact lenses are worn while sleeping (overnight) and then removed upon awakening; whereupon the nearsightedness remains corrected or greatly reduced for all or most of your waking hours. The exact time period over which the myopia remains corrected varies with each patient. Generally, Dilight™ (roflufocon E) Overnight Orthokeratology Lenses must be worn each night to maintain the effect.

How the Eye Functions

The eye is very much like a camera and must be in good focus to see objects clearly. The focusing power of the eye comes from two eye structures, the cornea and the lens.

The cornea is the clear, bubble-like structure on the front of the eye, where light first enters the eye. It provides about two thirds of the eye's focusing power, and the lens inside the eye provides the other third. In a normal eye, light focuses at the retina, at the back of the eye, which acts like the film in a camera. Some eyes focus, or refract, the light too much, so that the images of distant objects are formed in front of the retina, and the image on the retina is blurred, producing myopia.

Myopia usually starts in childhood and gets progressively worse through adolescence. It normally stops increasing by the late teens, but it can sometimes continue to get worse into the mid-twenties.

How the Dilight (roflufocon E) Overnight Orthokeratology Contact Lens Functions

The Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lens produces a temporary reduction of myopia by changing the shape (flattening) of the cornea, which is elastic in nature. Contact lenses rest directly on the cornea, separated only by a layer of tears, and can influence the corneal shape. Regular contact lenses are designed to nearly match the shape of the cornea and thereby cause little or no flattening effect.

Dilight™ (roflufocon E) Overnight Orthokeratology Lenses are designed to purposely not match the shape of the cornea but instead apply slight pressure to the center of the cornea, in a design known as reverse geometry.

Pressure is produced when the lens is less curved than the cornea, which places more of the lens weight on the center of the cornea. If the cornea is flattened, this reduces the focusing power of the eye, and if the amount of corneal flattening is sufficient, it is possible to bring the eye into

correct focus and compensate for myopia. After the lens is removed, the cornea retains its altered shape for all or part of the remainder of the day.

Dilight™ (roflufocon E) Overnight Orthokeratology Lenses are indicated for patients who desire to have time periods during the day in which they do not need to wear their contact lenses, but still be able to see clearly. Some patients are content to wear their contact lenses for normal activities during part of the day and remove them for evening activities.

These contact lenses for Orthokeratology produce a temporary reduction of all or part of your myopia. The amount of reduction will depend on many factors, including the amount of your initial myopia, the elastic characteristics of your eye and the way that the contact lens fits your eye.

Alternative ways to Correct Myopia

Myopia can be corrected by any method that reduces the focusing power of the eye. The most common methods of reduction are by glasses or regular daily wear or extended wear contact lenses. These represent a means of correcting myopia only during the time that the glasses or regular contact lenses are worn, with no lasting effect on the myopia. Other methods of correcting myopia involve various surgical procedures such as LASIK.

Risk Analysis

There is a small risk involved when any contact lens is worn. It is not expected that the Dilight™ (roflufocon E) Overnight Orthokeratology Lenses will provide a risk that is greater than other overnight wear rigid gas permeable contact lenses. The most common patient symptoms concerned poor distance vision and flare/ghosting (visual disturbances). The incidence of these symptoms tends to decrease over time in orthokeratology treatment, and they will go away if lens wear is discontinued.

The two most common side effects which occur in general rigid contact lens wearers are corneal edema and corneal staining. It is anticipated that these two side effects will also occur in some wearers of Dilight™ (roflufocon E) Overnight Orthokeratology Lenses. Other side effects, which sometimes occur in all hard lens wearers, are pain, redness, tearing, irritation, discharge, or abrasion of the eye. These are usually temporary conditions if the contact lenses are removed promptly and professional care is obtained. When overnight orthokeratology lenses dislocate during sleep, transient distorted vision may occur the following morning after removal of the lenses. This distortion may not be immediately corrected with spectacle lenses. The duration of the distorted vision would rarely be greater than the duration of the daily visual improvement normally achieved with the lenses.

In rare instances, there may occur permanent corneal scarring, and resulting permanent decreases in vision may occur. The risk of serious problems (such as corneal ulcers and vision loss) is greater when lenses are worn overnight. In addition, studies have shown that smoking increases

the risk of corneal ulcers, for those who wear lenses overnight. You should carefully discuss the benefits and risks of overnight wear lenses with your eye care professional. You should remove your contact lenses if any abnormal signs are present.

Indications

The Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lens is indicated for use in the reduction of myopic refractive error in non-diseased eyes. The lens is indicated for overnight wear for the temporary reduction of myopia up to 4.00 diopters (manifest spherical equivalent) in eyes with astigmatism up to 1.50 diopters. The lenses may only be disinfected using a chemical disinfection system.

Note: To maintain the Orthokeratology effect overnight lens wear must be continued on a prescribed schedule. Failure to do so can affect daily activities (e.g., night driving), cause visual fluctuations, and changes in intended correction.

Precautions

General

Clinical studies have demonstrated that Dilight™ (roflufocon E) Overnight Orthokeratology Lenses 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 the material. Consequently, when selecting an appropriate lens design and parameters, the eye care practitioner should consider all factors that affect lens performance and the patient's ocular health; including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.

The potential impact of these factors on the your ocular health should be weighed against the need for refractive reduction; therefore, your continuing ocular health, and lens performance on the eye should be carefully monitored by the prescribing eye care practitioner.

Dilight™ (roflufocon E) Overnight Orthokeratology Lenses are supplied non-sterile in an individual plastic case. The lens is shipped dry and must be cleaned and conditioned prior to use.

Patient

You should be aware of the following precautions

Solution Precautions

- Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions with the contact lenses.
- Do not heat the wetting/soaking solution and lenses.
- Always use fresh unexpired lens care solutions.
- Always follow directions in the package inserts of the contact lens solutions used.
- Use only a chemical lens care system. Use of a heat (thermal) lens care system can cause damage by warping Dilight™ (roflufocon E) Overnight Orthokeratology Lenses.
- Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
- Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.
- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored).

Handling Precautions

- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-base cosmetics are less likely to damage lenses than oil-base products.
- Be certain that your fingers or hands are free of foreign material before touching your contact lenses. Microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in this booklet and those prescribed by your eyecare practitioner.
- Always handle your lenses carefully and avoid dropping them.
- Never use tweezers or other tools to remove your lenses from the lens container unless specifically indicated for that use. Pour your lens into your hand.
- Do not touch the lens with your fingernails.
- To minimize lens warpage during cleaning, the lenses should be cleaned in the palm of the hand rather than between the thumb and fingers.

Lens Wearing Precautions

- CAUTION: Nonsterile. Clean and condition lenses prior to use.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking Lens in the *Instructions for Wearers Booklet*. The lens should move freely on the

eye for the continued health of the eye. If non-movement of the lens continues, you should immediately consult your eye care practitioner.
- Never wear your contact lenses beyond the period recommended by your eye care practitioner.
- Avoid, if possible, all harmful or irritating vapors and fumes when wearing lenses.
- If aerosol products such as sprays are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.

Lens Case Precautions

- Contact lens cases can be a source of bacterial growth. To prevent contamination and to help avoid serious eye injury, always empty, clean, and rinse the lens case with fresh, sterile rinsing solution and allow to air dry. Do not use water.
- Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or eyecare practitioner.

Discuss these topics with your eye care practitioner:

- During initial weeks of treatment, some patients may experience changes in vision that may require temporary alternate corrective eyewear. This should be discussed with your eye care practitioner.
- Wear of contact lenses during sporting activities
- Use of any medication in your eye(s).
- Importance of adhering to the recommended follow-up schedule to assure the continuing health of your eyes.
- Informing your doctor (health care practitioner) about being a contact lens wearer
- Informing your employer of being a contact lens wearer. Some jobs may require the use of eye protection equipment or may require that you not wear contact lenses during work hours.
- Patients with limbal stem cell deficiency may be at additional risk of progression of the disease with contact lens wear, and that it is especially important for them to ensure that they see their eyecare provider for all recommended follow-up care.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE YOUR Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lens when any of the following conditions exist:

- Acute and sub-acute inflammations 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 tears (dry eyes)
- Corneal hypoesthesia (reduced corneal sensitivity).
- Any systemic disease which may affect the eye or be exacerbated by wearing contact lenses.

- Allergic reactions of ocular surfaces or adnexa which 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 contact lens.
- Any active corneal infection (bacterial, fungal or viral).
- If eyes are red or irritated.

Warnings

Incorrect use of contact lenses and lens care products can result in serious injury to the eye. It is essential that you follow the eye care practitioner's directions and all labeling instructions for proper use of contact lenses and lens care products. Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision. If you experience eye discomfort, excessive tearing, vision changes, or redness of the eye, immediately remove the lenses and do not wear them until instructed to do so by the eye care practitioner. All contact lens wearers must see their eye care practitioner according to the schedule given to them.

Dilight™ (roflufocon E) Overnight Orthokeratology Lenses are to be worn overnight with removal during all or part of each following day. Wearing the lenses continuously (extended wear) presents increased risk, which increases with the number of consecutive days that the lenses are worn between removals. Although the lens is prescribes only for overnight wear with removal during waking hours, and although the safety risks of overnight wear with removal upon awakening may not be as great as with uninterrupted extended wear, there is still increased risk beginning with the first overnight period.

WARNING

The risk of ulcerative keratitis has been shown to be greater among wearers of extended wear lenses than among wearers of daily wear lenses. The risk among extended wear lens wearers increases with the number of consecutive days that lenses are worn between removals, beginning with the first overnight use. This risk can be reduced by carefully following directions for routine lens care, including cleaning the storage case. Additionally, smoking increases the risk of ulcerative keratitis for contact lens wearers. It is recommended that contact lens wearers see their eye care practitioners twice each year or, if directed, more frequently.

To avoid serious eye infections, vision loss or blindness, please be aware of the following warnings…

- **Inadequate rubbing, rinsing, and disinfecting of your lenses may cause serious eye infections, vision loss or blindness. Failure to complete the recommended lens**

rubbing and rinsing times in the labeling to adequately disinfect lenses and reduce the risk of contact lens infection can cause severe infection, vision loss or blindness.

- **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.**
- **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.**

- **Do not expose your contact lenses to water while you are wearing them.**
- **If your lenses have been submersed in water when swimming in pools, lakes, or oceans, you should discard them and replace them with a new pair. Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. Ask your eye care professional for recommendations about wearing your lenses during any activity involving water.**
- **Do not use your multi-purpose solution beyond the expiration and/or discard date because it could result in contamination of the solution and can lead to severe infection, vision loss or blindness.**
- **Do not store your lenses or rinse your lens case with water or any non-sterile solution. Only use fresh multi-purpose solution or sterile saline solution so you do not contaminate your lenses or lens case.**

Even when functioning effectively, overnight contact lenses can result in certain vision issues for adults. These may include distortion of vision, making the cornea (the transparent front part of the eye) uneven, and leading to complications such as double vision, glare, halos, blurry sight, and difficulty seeing at night. The degree of nearsightedness corrected by these lenses correlates with the likelihood of experiencing these side effects.

ADVERSE EFFECTS

You should be informed that the following problems might occur:

- Eyes stinging, burning, itching (irritation), or other eye pains.
- Comfort is less than when lens was first placed on eye.
- Feeling of something 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 you notice any of the above, **IMMEDIATELY REMOVE YOUR 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 your eye. Place the lens in the storage case and contact your eye care practitioner.
- If the lens has dirt, an eyelash, or other foreign objects on it, or the problem stops and the lens appears undamaged, you should thoroughly clean, rinse and disinfect the lens; then reinsert it.
- If the problem continues, you should **IMMEDIATELY** remove the contact lenses and consult your eye care practitioner.

When any of the above problems occur, a serious condition such as **Acanthamoeba Keratitis**, infection, corneal ulcer, neovascularization, iritis, persistent stromal edema or GPC (giant papillary conjunctivitis) may be present. You should be instructed to keep the lens off the eye and seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.

CLINICAL STUDY DATA

A clinical study was conducted to establish a reasonable assurance of safety and effectiveness of the Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lens to temporarily reduce myopic refractive error compared with a control lens. A summary of the clinical study is presented below.

INTRODUCTION

This trial was a multi-center, randomized, open label, and positive parallel controlled clinical trial. The target enrollment was 258 patients with binocular myopia. The selected subjects were randomly assigned to the experimental group and the control group to wear the trial product and the controlled product respectively. Subjects in the control group were treated with rigid gas permeable contact lenses for overnight orthokeratology produced by Euclid Systems Corporation, and those in the experimental group were treated with the Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lens produced by Tianjin Mastervision Technology Co., Ltd. Follow-up visits were carried out over 12 months of wearing the contact lenses.

DEMOGRAPHIC INFORMATION

The clinical trial was structured to recruit participants across three distinct age categories: 8-12 years, 13-18 years, and over 18 years. This stratification was implemented to facilitate comparative analysis of clinical outcomes and assess equivalency across age groups. Consequently, the mean age of enrolled subjects was calculated at 17.7 years.

The gender distribution among participants demonstrated a higher proportion of female subjects compared to male subjects: 74.19% female and 25.81% male in the treatment group, 54.69%

female and 45.31% male in the control group, and 64.29% female and 35.71% male overall. Gender was not considered a significant variable in the study design.

The clinical investigation was conducted in China, with the majority of participants identified as Chinese Han nationality (92.32% in the test group, 93.75% in the control group). This distribution closely corresponds to the demographic composition reported in the 2020 National Population Census, which indicated that Han nationality represents 91.1% of the population. Ethnicity was not considered a factor in the trial design.

Table 2. Demographic Information

	Index	Test group	Control group	Total
Age (years)	N(Missing)	124(0)	128(0)	252(0)
	Mean(Sd)	18.24(8.85)	17.21(8.01)	17.71(8.43)
	Median	14.92	14.82	14.89
	Ql,Q3	11.64,24.69	10.99,23.17	11.44,24.06
	Min, Max	8.60,39.62	8.00,39.89	8.00,39.89
Gender	Male n (%)	32(25.81%)	58(45.31%)	90(35.71%)
	Woman n (%)	92(74.19%)	70(54.69%)	162(64.29%)
	Total (missing)	124(0)	128(0)	252(0)
Ethnic group	Han Chinese n (%)	112(90.32%)	120(93.75%)	232(92.06%)
	Other n (%)	12(9.68%)	8(6.25%)	20(7.94%)
	Total (missing)	124(0)	128(0)	252(0)

This table presents a demographic analysis of refractive parameters, indicating the number of patients with different spherical diopters distributed across various ranges of corneal astigmatism at the baseline.

Table 3. The Distribution of Baseline Myopic Refractive Errors

	Pretreatment Myopia (Spherical Diopters)													
	≤1.0 D		1.25 to 2.00 D		2.25 to 3.00 D		3.25 to 4.00 D		4.25 to 5.00 D		Not Report		Totals	
Corneal Astigmatism	n/%		n/%		n/%		n/%		n/%		n/%		n/%	
	Test	Control	Test	Control	Test	Control	Test	Control	Test	Control	Test	Control	Test	Control
0.00	0 (0.0%)	0 (0.0%)	1 (0.9%)	0 (0.0%)	2 (1.1%)	0 (0.0%)	1 (0.6%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (0.8%)	1 (0.2%)
< 0.12	0 (0.0%)	0 (0.0%)	1 (0.9%)	1 (0.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	1 (0.2%)
0.12 to 0.50	0 (0.0%)	1 (7.7%)	5 (4.6%)	8 (7.4%)	9 (5.0%)	8 (4.4%)	4 (2.3%)	8 (4.7%)	0 (0.0%)	1 (11.1%)	7 (31.8%)	3 (13.6%)	25 (5.0%)	29 (5.8%)

	Pretreatment Myopia (Spherical Diopters)													
	≤1.0 D		1.25 to 2.00 D		2.25 to 3.00 D		3.25 to 4.00 D		4.25 to 5.00 D		Not Report		Totals	
Corneal Astigmatism	n/%		n/%		n/%		n/%		n/%		n/%		n/%	
	Test	Control	Test	Control	Test	Control	Test	Control	Test	Control	Test	Control	Test	Control
0.5 to 0.62	0 (0.0%)	0 (0.0%)	2 (1.9%)	0 (0.0%)	3 (1.7%)	4 (2.2%)	4 (2.3%)	2 (1.2%)	1 (11.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	10 (2.0%)	6 (1.2%)
0.62 to 1.00	2 (15.4%)	1 (7.7%)	6 (5.6%)	17 (15.7%)	15 (8.3%)	18 (9.9%)	14 (8.2%)	12 (7.0%)	0 (0.0%)	1 (11.1%)	4 (18.2%)	5 (22.7%)	41 (8.1%)	54 (10.7%)
1.00 to 1.12	0 (0.0%)	0 (0.0%)	3 (2.8%)	2 (1.9%)	1 (0.6%)	8 (4.4%)	5 (3.0%)	3 (1.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	9 (1.8%)	13 (2.6%)
1.12 to 1.50	2 (15.4%)	1 (7.7%)	7 (6.5%)	9 (8.3%)	9 (5.0%)	8 (4.4%)	12 (7.0%)	6 (3.5%)	0 (0.0%)	0 (0.0%)	1 (4.6%)	0 (0.0%)	31 (6.2%)	24 (4.8%)
1.50 to 1.62	0 (0.0%)	1 (7.7%)	1 (0.9%)	1 (0.9%)	1 (0.6%)	0 (0.0%)	5 (2.9%)	3 (1.8%)	0 (0.0%)	1 (11.1%)	0 (0.0%)	0 (0.0%)	7 (1.4%)	6 (1.2%)
1.62 to 2.00	0 (0.0%)	1 (7.7%)	0 (0.0%)	3 (2.8%)	3 (1.7%)	4 (2.2%)	5 (2.9%)	3 (1.8%)	0 (0.0%)	1 (11.1%)	0 (0.0%)	0 (0.0%)	8 (1.6%)	12 (2.4%)
> 2.00	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.1%)	0 (0.0%)	4 (2.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	6 (1.2%)	0 (0.0%)
Not Report	2 (15.4%)	2 (15.4%)	19 (17.6%)	22 (20.4%)	38 (21.0%)	48 (26.5%)	42 (24.6%)	37 (21.6%)	3 (33.3%)	1 (11.1%)	2 (9.1%)	0 (0.0%)	106 (21.0%)	110 (21.8%)
Totals	6 (46.2%)	7 (53.9%)	45 (41.7%)	63 (58.3%)	83 (45.9%)	98 (54.1%)	96 (56.1%)	75 (43.9%)	4 (44.4%)	5 (55.6%)	14 (63.6%)	8 (36.4%)	248 (49.2%)	256 (50.8%)

Percentage = number of eyes within both the corneal astigmatism range and myopia range, divided by the total number of eyes within the myopia range.

ACCOUNTABILITY

Of the 280 subjects enrolled in the PMA clinical trial, data from 215 participants (76.8%) were available for analysis at the 12-month follow-up assessment.

The study was conducted across three investigational sites, enrolling a total of 280 subjects, with 140 allocated to the experimental arm and 140 to the control arm. Of these, 215 subjects completed all required follow-up visits (109 in the experimental group and 106 in the control group). A total of 65 subjects discontinued participation, with 21 withdrawals attributed to inability to obtain study lenses, and 10 subjects were excluded from the analysis.

Table. 4 ACCOUNTABILITY

	Initial		Month 1		Month 3		Month 6		Month 9		Month 12	
	T	C	T	C	T	C	T	C	T	C	T	C
Available for Analysis (in Window) (n/N[1]) %	262 (46.79%)	258 (46.07%)	240 (42.86%)	242 (43.21%)	232 (41.43%)	232 (41.43%)	226 (40.36%)	230 (41.07%)	216 (38.57%)	226 (40.36%)	212 (37.86%)	218 (38.93%)
Discontinued	16	22	18	16	6	8	4	2	4	0	2	4
Lost to Follow-up	2	0	4	0	2	2	2	0	6	4	2	4
% (n/N[2]) Accountability	262 (46.95%)	258 (46.24%)	240 (43.32%)	242 (43.68%)	232 (42.18%)	232 (42.18%)	226 (41.24%)	230 (41.97%)	216 (40.15%)	226 (42.01%)	212 (39.85%)	218 (40.98%)

n = total number of eyes in the specified column category at that visit

N^1 = total number of eyes enrolled (560)

N^2 = total number of eyes enrolled (560) – total number of eyes lost to follow-up

OVERNIGHT WEAR SAFETY SUMMARY

Discontinued Eyes

Table. 5 DISCONTINUED EYES TABULATED BY COMPLETED VISITS AND REASONS FOR DISCONTINUATION WITH INCIDENCE RATES

	Initial		Month 1		Month 3		Month 6		Month 9		Month 12		Aggregated Discontinued		subtotal	Randomization Set N=560
	C	T	C	T	C	T	C	T	C	T	C	T	C	T		% Incidence
1. Poor Scotopic Vision	0	0	0	2 (0.4%)	0	2 (0.4%)	0	0	0	0	0	0	0	4 (0.7%)	*4*	0.71%
2.Positive Slit Lamp Findings (SLF)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	*0*	0.00%
3.Adverse Reaction	0	0	2 (0.4%)	0	0	2 (0.4%)	0	0	0	0	0	0	2 (0.4%)	2 (0.4%)	*4*	0.71%
4.Lens Position	0	0	0	0	0	0	0	0	0	0	0	0	0	0	*0*	0.00%
5.Discomfort	0	0	0	2 (0.4%)	0	0	0	2 (0.4%)	0	0	0	0	0	4 (0.7%)	*4*	0.71%
6.Handling Problems	4 (0.7%)	2 (0.4%)	2 (0.4%)	2 (0.4%)	0	0	0	0	0	0	0	0	6 (1.1%)	4 (0.7%)	*10*	1.79%
7.Disinterest	0	0	4 (0.7%)	0	0	0	0	0	0	0	2 (0.4%)	0	6 (1.1%)	0	*6*	1.07%
8.Lost to Follow-up	2 (0.4%)	0	4 (0.7%)	0	2 (0.4%)	2 (0.4%)	2 (0.4%)	0	6 (1.1)	4 (0.7%)	2 (0.4%)	4 (0.7%)	14 (2.5%)	10 (1.8%)	*28*	5.00%
9.None Given	8 (1.4%)	14 (2.5%)	6 (1.1%)	2 (0.4%)	4 (0.7%)	4 (0.7%)	4 (0.7%)	0	0	0	0	2 (0.4%)	26 (4.6%)	22 (3.9%)	*44*	7.86%
10.Other	4 (0.7%)	6 (1.1%)	4 (0.7%)	8 (1.4%)	2 (0.4%)	0	0	0	4 (0.7%)	0	0	2 (0.4%)	14 (2.5%)	16 (2.9%)	*30*	5.36%
(Other Specify)	4[a] (0.7%)	4[a] (0.7%) 2[b] (0.4%)	4[a] (0.7%)	8[a] (1.4%)	2[a] (0.4%)				4[a] (0.7%)			2[c] (0.4%)				
Subtotal	18 (3.2%)	22 (3.9%)	22 (3.9%)	16 (2.9%)	8 (1.4%)	10 (1.8%)	6 (1.1%)	2 (0.4%)	10 (1.8%)	4 (0.7%)	4 (0.7%)	8 (1.4%)	68 (12.1%)	62 (11.1%)	*130*	23.21%

percentage = n/N

[a] personal [b] exclusion [c] work related

Proportion of the subjects whose BCVA decreased by 1 line, 2 lines or above in comparison to the baseline after 1-day, 1-week, 2-weeks, 30-days, 3-months, 6-months, 9-months and 12-months of treatment (presented in Snellen or Log MAR VA) are summarized below.

Table 6. Decrease in BCVA

BCVA Decrease by						
	1 line		**2 lines**		**> 2 lines**	
	Test	**Control**	**Test**	**Control**	**Test**	**Control**
1 Day	37 (7.1%)	42 (8.1%)	5 (1.0%)	3 (0.6%)	1 (0.2%)	0 (0%)
1 week	11 (2.2%)	20 (4.0%)	0 (0%)	5 (1.0%)	0 (0%)	1 (0.2%)

2 weeks	14 (2.8%)	23 (4.7%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
1 month	11 (2.3%)	26 (5.4%)	0 (0%)	4 (0.8%)	0 (0%)	0 (0%)
3 months	11 (2.4%)	12 (2.6%)	3 (0.6%)	1 (0.2%)	0 (0%)	1 (0.2%)
6 months	11 (2.4%)	8 (1.8%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
9 months	9 (2.0%)	10 (2.2%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
12 months	17 (4.0%)	11 (2.6%)	3 (0.6%)	0 (0%)	1 (0.2%)	0 (0%)

Note: percentage = number of eyes with decreased vision/total number of eyes examined at follow-up.

Wearing Time

Patients were required to wear the device for more than eight hours per day according to the Instructions for Use.

Intraocular Pressure (IOP)

At 1 month and 12 months after wearing, the comparison of intraocular pressure between the experimental group and the control group showed that there was no clinically relevant difference between the two groups.

between the two groups.

EFFECTIVENESS OUTCOMES

Table 7. UCDVA STRATIFIED BY PRETREATMENT MYOPIA (FAS 12 months)

UCDVA	**Pretreatment Myopia (Spherical Diopters)**													
	≤1.0 D		1.25 to 2.00 D		2.25 to 3.00 D		3.25 to 4.00 D		4.25 to 5.00 D		Not Report		Total	
	n/%		n/%		n/%		n/%		n/%		n/%		n/%	
	Test	Control	Test	Control	Test	Control	Test	Control	Test	Control	Test	Control	Test	Control
20/20 or better	4 (66.7%)	5 (71.4%)	25 (55.6%)	33 (52.4%)	49 (59.0%)	39 (39.8%)	49 (51.0%)	26 (34.7%)	0 (0%)	2 (40.0%)	8 (57.1%)	5 (62.5%)	135 (54.4%)	110 (43.0%)
20/25 or better	4 (66.7%)	5 (71.4%)	31 (68.9%)	37 (58.7%)	60 (72.3%)	57 (58.2%)	63 (65.6%)	38 (50.7%)	1 (25.0%)	3 (60.0%)	9 (64.3%)	6 (75.0%)	168 (67.7%)	146 (57.0%)
20/32 or better	4 (66.7%)	6 (85.7%)	34 (75.6%)	41 (65.1%)	62 (74.7%)	61 (62.2%)	69 (71.9%)	42 (56.0%)	1 (25.0%)	3 (60.0%)	10 (71.4%)	6 (75.0%)	180 (72.6%)	159 (62.1%)
20/40 or better	4 (66.7%)	6 (85.7%)	35 (77.8%)	44 (69.8%)	65 (78.3%)	67 (68.4%)	72 (75.0%)	45 (60.0%)	1 (25.0%)	3 (60.0%)	11 (78.6%)	6 (75.0%)	188 (75.8%)	171 (66.8%)
20/80 or better	5 (83.3%)	6 (85.7%)	35 (77.8%)	46 (73.0%)	67 (80.7%)	80 (81.6%)	76 (79.2%)	49 (65.3%)	1 (25.0%)	3 (60.0%)	12 (85.7%)	8 (100%)	196 (79.0%)	192 (75.0%)
20/200 or better	5 (83.3%)	7 (100%)	38 (84.4%)	50 (79.4%)	68 (81.9%)	84 (85.7%)	82 (85.4%)	52 (69.3%)	1 (25.0%)	3 (60.0%)	12 (85.7%)	8 (100%)	206 (83.1%)	204 (79.7%)
Not Report	1 (16.7%)	0 (0%)	7 (15.6%)	13 (20.6%)	15 (18.1%)	14 (14.3%)	14 (14.6%)	23 (30.7%)	3 (75.0%)	2 (40.0%)	2 (14.3%)	0 (0%)	42 (16.9%)	52 (20.3%)

UCDVA	Pretreatment Myopia (Spherical Diopters)													
	≤1.0 D		1.25 to 2.00 D		2.25 to 3.00 D		3.25 to 4.00 D		4.25 to 5.00 D		Not Report		Total	
	n/%		n/%		n/%		n/%		n/%		n/%		n/%	
	Test	Control	Test	Control	Test	Control	Test	Control	Test	Control	Test	Control	Test	Control
Total eyes	6 (100%)	7 (100%)	45 (100%)	63 (100%)	83 (100%)	98 (100%)	96 (100%)	75 (100%)	4 (100%)	5 (100%)	14 (100%)	8 (100%)	248 (100.0%)	256 (100%)

Percentage = number of eyes with uncorrected distance visual acuity (UCDVA) within a specified range and within the myopia range, divided by the total number of eyes within the myopia range.

Table 8**.** Refractive Change from Baseline Visit (FAS 12 months vs. baseline)

	Pretreatment Myopia (MRSE)													
	≤1.0 D		1.25 to 2.00 D		2.25 to 3.00 D		3.25 to 4.00 D		4.25 to 5.00 D		Not Report		Totals	
Refractive Change	n/%		n/%		n/%		n/%		n/%		n/%		n/%	
	Test	Control	Test	Control	Test	Control	Test	Control	Test	Control	Test	Control	Test	Control
0.00	0 (0.0%)	0 (0.0%)	1 (0.9%)	2 (1.9%)	3 (1.7%)	3 (1.7%)	2 (1.2%)	2 (1.2%)	0 (0%)	0 (0%)	0 (0.00%)	0 (0.00%)	6 (1.2%)	7 (1.4%)
Decreases														
＜0.12	1 (7.7%)	0 (0%)	1 (0.9%)	0 (0%)	0 (0%)	1 (0.6%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (0.4%)	1 (0.2%)
0.12 to 0.50	2 (15.4%)	2 (15.4%)	6 (5.6%)	3 (2.8%)	10 (5.5%)	7 (3.9%)	10 (5.9%)	3 (1.8%)	0 (0.0%)	0 (0.0%)	2 (9.1%)	3 (13.6%)	30 (6.0%)	18 (3.6%)
0.5 to 0.62	0 (0.0%)	0 (0%)	0 (0.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
0.62 to 1.00	2 (15.4%)	4 (30.8%)	7 (6.5%)	13 (12.0%)	4 (2.2%)	5 (2.8%)	9 (5.3%)	2 (1.2%)	0 (0.0%)	1 (11.1%)	3 (13.6%)	3 (13.6%)	25 (5.0%)	28 (5.6%)
1.00 to 1.12	0 (0%)	0 (0%)	0 (0.0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
1.12 to 1.50	0 (0.0%)	0 (0%)	7 (6.5%)	12 (11.1%)	15 (8.3%)	12 (6.6%)	4 (2.3%)	7 (4.1%)	0 (0.0%)	0 (0.0%)	3 (13.6%)	0 (0.0%)	29 (5.8%)	31 (6.2%)
1.50 to 1.62	0 (0.0%)	0 (0%)	0 (0.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
1.62 to 2.00	0 (0.0%)	0 (0%)	4 (3.7%)	7 (6.5%)	13 (7.2%)	14 (7.7%)	3 (1.8)	4 (2.3%)	0 (0%)	0 (0%)	3 (13.6%)	0 (0%)	23 (4.6%)	25 (5.0%)
＞2.00	0 (0.0%)	0 (0%)	0 (0%)	0 (0%)	11 (6.1%)	28 (15.5%)	39 (22.8%)	26 (15.2%)	0 (0.0%)	2 (22.2%)	1 (4.6%)	2 (9.1%)	51 (10.1%)	58 (11.5%)
Not Report	1 (7.7%)	0 (0%)	15 (13.9%)	18 (16.7%)	23 (12.7%)	23 (12.7%)	21 (12.3%)	31 (18.1%)	4 (44.4%)	2 (22.2%)	2 (9.1%)	0 (0%)	66 (13.1%)	74 (14.7%)
Totals	6 (46.2%)	6 (46.2%)	40 (37.0%)	53 (49.1%)	76 (42.0%)	90 (49.7%)	86 (50.3%)	73 (42.7%)	4 (44.4%)	5 (55.6%)	14 (63.6%)	8 (36.4%)	226 (44.8%)	235 (46.6%)
Increase														
＜0.12	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
0.12 to 0.50	0 (0%)	0 (0%)	3 (2.8%)	7 (6.5%)	1 (0.6%)	1 (0.6%)	4 (2.3%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	8 (1.6%)	8 (1.6%)
0.5 to 0.62	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
0.62 to 1.00	0 (0%)	0 (0%)	0 (0%)	1 (0.9%)	0 (0%)	3 (1.7%)	3 (1.8%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (0.6%)	4 (0.8%)
1.00 to 1.12	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
1.12 to 1.50	0 (0%)	0 (0%)	1 (0.9%)	0 (0%)	1 (0.6%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (0.4%)	0 (0%)
1.50 to 1.62	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
1.62 to 2.00	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (0.6%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (0.2%)	0 (0%)
＞2.00	0 (0%)	1 (7.7%)	0 (0%)	0 (0%)	1 (0.6%)	1 (0.6%)	1 (0.6%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (0.4%)	2 (0.4%)

Not Report	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Totals	0 (0%)	1 (7.7%)	4 (3.7%)	8 (7.4%)	4 (2.2%)	5 (2.8%)	8 (4.7%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	16 (3.2%)	14 (2.8%)

Percentage = number of eyes within the refractive change range and within the myopia range, divided by the total number of eyes within the myopia range.

Table 9. STABILITY OF MANIFEST REFRACTION STRATIFIED BY DIOPTRIC GROUP（FAS）

	9 and 12 Months n/N (%)											
Change in Spherical Diopters	≤1.0 D		1.25 to 2.00 D		2.25 to 3.00 D		3.25 to 4.00 D		4.25 to 5.00 D		Not Report	
	n/N (%)		n/N (%)		n/N (%)		n/N (%)		n/N (%)		n/N (%)	
	Test	Control	Test	Control	Test	Control	Test	Control	Test	Control	Test	Control
≤1.0 D	5 (38.5%)	7 (53.9%)	34 (31.5%)	47 (43.5%)	58 (32.0%)	69 (38.1%)	69 (40.4%)	43 (25.2%)	0 (0.0%)	2 (22.2%)	6 (27.3%)	8 (36.4%)
1.00 to 1.50 D	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (1.9%)	4 (2.2%)	7 (3.9%)	3 (1.8%)	2 (1.2%)	1 (11.1%)	1 (11.1%)	0 (0.0%)	0 (0.0%)
1.50 to 2.00 D	0 (0.0%)	0 (0.0%)	1 (0.93%)	0 (0.0%)	2 (1.1%)	4 (2.2%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.6%)	0 (0.0%)
2.00 to 2.50 D	0 (0.0%)	0 (0.0%)	1 (0..93%)	0 (0.0%)	0 (0.0%)	2 (1.1%)	2 (1.2%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
2.50 to 3.00 D	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
3.00 D	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.9%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (4.6%)	0 (0.0%)
Not Report	1 (7.7%)	0 (0.0%)	9 (8.3%)	13 (12.0%)	18 (9.9%)	15 (8.3%)	21 (12.3%)	28 (16.4%)	3 (33.3%)	2 (22.2%)	6 (27.3%)	0 (0.0%)
Totals	6 (46.2%)	7 (53.9%)	45 (41.7%)	63 (58.3%)	83 (45.9%)	98 (54.1%)	96 (56.1%)	75 (43.9%)	4 (44.4%)	5 (55.6%)	14 (63.6%)	8 (36.4%)
Mean Difference	-0.29	-0.29	-0.24	-0.11	-0.27	-0.08	-0.43	-0.01	0.75	0.25	0.13	-0.82
SD	0.39	0.99	0.80	0.92	1.19	1.10	1.35	1.10	0.00	0.28	1.63	0.71
95% CI	(-0.71, 0.53)	(-2.53, 1.85)	(-0.63, 0.16)	(-0.50, 0.25)	(-0.70, 0.15)	(-0.39, 0.30)	(-0.88, 0.01)	(-0.49, 0.46)	(.,.)	(-0.43, 0.93)	(-2.46, 2.71)	(-1.93, 0.31)

Note that for n/N(%), n = number of eyes with both baseline manifest refractive range and change in spherical diopter range, and N = total number of eyes within baseline manifest refractive range.

SUMMARY OF KEY SAFETY & EFFECTIVENESS VARIABLES

Table 10. Summary of Key Safety & Effectiveness Variables (N=Eyes)

Criteria	1 Month		3 Months		6 Months		9 Months		12 Months	
	Test	Control	Test	Control	Test	Control	Test	Control	Test	Control
n	248	256	248	256	248	256	248	256	248	256
UCVA 20/20 or better	164 (66.13%)	133 (51.95%)	162 (65.32%)	125 (48.83%)	172 (69.35%)	136 (53.13%)	146 (58.87%)	133 (51.95%)	135 (54.44%)	110 (42.97%)

UCVA 20/40 or better	218 (87.90%)	211 (82.42%)	208 (83.87%)	188 (73.44%)	206 (83.06%)	196 (76.56%)	192 (77.42%)	181 (70.70%)	188 (75.81%)	171 (66.80%)
The number of eyes in different spherical diopter range										
±0.50 D	91 (36.69%)	94 (36.72%)	83 (33.47%)	91 (35.55%)	76 (30.65%)	93 (36.33%)	54 (21.77%)	83 (32.42%)	45 (18.15%)	77 (30.08%)
± 1.00 D	143 (57.66%)	162 (63.28%)	125 (50.40%)	131 (51.17%)	121 (48.79%)	135 (52.73%)	104 (41.94%)	136 (53.13%)	80 (32.26%)	117 (45.70%)
± 2.00 D	196 (79.03%)	209 (81.64%)	186 (75.00%)	190 (74.22%)	186 (75.00%)	181 (70.70%)	164 (66.13%)	178 (69.53%)	148 (59.68%)	175 (68.36%)
± 3.00 D	214 (86.29%)	222 (86.72%)	208 (83.87%)	206 (80.47%)	203 (81.85%)	198 (77.34%)	186 (75.00%)	194 (75.78%)	186 (75.00%)	196 (76.56%)
Change in spherical diopters	Baseline-1month – Mean Dif (SD)		Month 1 – 3 Mean Dif (SD)		Month3 – 6 Mean Dif (SD)		Month6 – 9 Mean Dif(SD)		Month9 – 12 Mean Dif (SD)	
0.12 to 1D	1.07 (0.51) n=5	0.93 (0.68) n=7	0.00 (0.32) n=6	-0.30 (0.52) n=7	-0.15 (0.41) n=6	0.14 (1.08) n=7	-0.18 (0.35) n=5	-0.22 (0.66) n=7	-0.25 (0.69) n=5	-0.28 (0.99) n=7
1.25 to 2.00D	1.09 (0.89) n=36	1.29 (0.61) n=52	-0.03 (0.69) n=43	-0.10 (0.65) n=58	-0.01 (0.84) n=43	-0.05 (0.71) n=53	-0.18 (0.53) n=41	-0.22 (0.85) n=48	-0.23 (0.79) n=36	-0.11 (0.99) n=50
2.25 to 3.00D	1.72 (1.12) n=68	1.89 (1.23) n=81	-0.20 (1.46) n=75	0.00 (1.22) n=82	-0.11 (0.96) n=71	-0.06 (1.12) n=80	-0.03 (0.82) n=69	-0.10 (1.08) n=80	-0.28 (1.19) n=65	-0.05 (1.09) n=83
3.25 to 4.00D	2.59 (1.56) n=83	2.47 (1.24) n=58	-0.17 (1.72) n=83	-0.26 (1.55) n=57	0.06 (1.12) n=81	-0.12 (1.32) n=52	-0.31 (0.77) n=74	0.03 (1.34) n=48	-0.43 (1.35) n=75	-0.01 (1.08) n=47
>4.0D	0(0) n=0	3.59 (1.74) n=4	-0.50 (2.41) n=3	-0.38 (0.10) n=4	-1.33 (2.02) n=3	0.19 (0.39) n=4	-0.75 (0) n=1	-0.54 (0.19) n=3	1.50 (0) n=1	0.50 (0.55) n=3

	Treat, n=248	Control, n=256
Serious Adverse Event***	0	2
Loss of BSCVA > 2 lines***	2	2
BSCVA worse than 20/40***	1	1
Increase of> 1 D Coreal Cyl***	0	3

In the clinical investigation, the Dilight™ (roflufocon E) Overnight Orthokeratology Contact Lens was evaluated in the test group over a 12-month follow-up period. Safety and effectiveness outcomes were assessed in 248 treated eyes at scheduled follow-up visits from Month 1 through Month 12. This table corresponds to the FAS data set.

The UCVA rows represent the number of eyes that attained an uncorrected visual acuity (UCVA) of 20/20 or better and 20/40 or better at various follow - up time points.
The percentages in parentheses represent the proportion of the number of eyes in this group to the total number of eyes in the experimental and control groups within the FAS data set.

The MRSE change (from baseline) (±0.50D, ±1.00D, ±2.00D, ±3.00) rows represent the number of eyes with spherical refractive error changes of 0.50D or less, 1.00D or less, 2.00D or less, and 3.00D or less at different follow - up time points.
The percentages in parentheses represent the proportion of the number of eyes in this group to the total number of eyes in the experimental and control groups within the FAS data set.

The MRSE changes in refractive ranges represent the different groups based on the distinct refraction results at baseline. The horizontal data represent the mean and standard deviation of spherical diopter changes in eyes during different follow - up periods;
"n" represents the number of data.

Safety outcomes in the test group showed no serious adverse events. Two treated eyes experienced a loss of best-corrected visual acuity (BSCVA) of greater than 2 lines, one treated eye had BSCVA worse than 20/40, and no treated eyes had an increase in corneal cylinder greater than 1.00 D. Among the four subjects across both study groups with loss of greater than 2 lines of BSCVA, one corrected to 20/20 at study completion, one corrected to 20/20 before study withdrawal, one discontinued without follow-up recheck after a recorded acuity of 20/63, and one had BSCVA of 20/50 at study completion. Investigators reported no associated complications, adverse events, or slit-lamp abnormalities at the final study visit.

Maintaining Effects Dilight™ (roflufocon E) Overnight Orthokeratology Lenses

The long-term wear of Dilight™ (roflufocon E) Overnight Orthokeratology Lenses does not eliminate the need to continue wearing contact lenses to produce the reduction in myopia. After the cornea has been changed by wearing these contact lenses, you must continue overnight wear of the lenses to maintain the results. Usually the treatment lenses will continue to be the lenses worn after successful treatment. In unusual circumstances, new lenses may be prescribed that are Myopic Reduction Maintenance Lenses or Retainer Lenses. Such Retainer Lenses would be only a slight modification of the patient's prescription.

The wearing schedule for Dilight™ (roflufocon E) Overnight Orthokeratology Lenses or Retainer Lenses may vary from the schedule prescribed during treatment. In cases of low pretreatment myopia, the effect may last for more than one day.

Glossary

Adnexa:	Tissues near the eye
Adverse effects:	Undesirable effects
Aphakia:	Eye that does not have a lens structure
Astigmatism:	Eye condition in which one or more surfaces of the cornea or lens has a shape that is not round but more like that of a football
Best Spectacle Corrected Visual Acuity:	Best vision you can achieve wearing glasses in your exact prescription under optimum viewing conditions
Contact Lens Sticking:	Lack of movement of a contact lens on the cornea
Cornea:	The clear, bubble-like structure on the front of the eye, where light first enters the eye.
Corneal abrasion:	Loss of cells on the corneal surface due to mechanical trauma
Corneal edema:	Accumulation of fluid in the cornea
Corneal hypoesthesia:	Partial loss of sensitivity to touch in the cornea
Corneal staining:	Bright areas on the cornea where dye collects. Indicates an abrasion or other disturbance of the cornea
Corneal ulcer:	Small area of tissue loss in the cornea
Disinfection:	Destruction of bacteria and viruses but not some spores
Diopter:	Unit of power for glasses or contact lenses
Enzyming contact lenses:	Placing contact lenses in a solution that contains an enzyme that dissolves proteins on the surface of the lens
Hypoesthesia:	Reduced corneal sensitivity to touch
Iritis:	Infection of the iris or colored portion of the eye
Lacrimal secretion:	Generation of tears
Manifest Refraction Spherical Equivalent:	A measure of vision correction requirements (in diopters), which combines your myopia and your astigmatism
Myopia:	Medical term for nearsightedness
Myopic Reduction Maintenance Lens:	A modification of the orthokeratology contact lens design in which the central portion of the lens applies just enough pressure to the cornea to maintain the

	corneal flattening achieved but with no additional corneal flattening
Neovascularization:	New vessel growth in the cornea
Orthokeratology:	Contact lens fitting procedure that temporarily reduces myopia after contact lenses have been removed
Refract:	Bending of light in order to make it focus
Refractive anomalies:	Eye conditions leading to blurred vision including myopia (nearsightedness), hyperopia (farsightedness) and astigmatism
Retainer Lenses:	Another name for the Myopic Reduction Maintenance Lens
Retina:	Structure at the back of the eye that receives the light image
Rewetting contact lenses:	Placing a solution in the eye while contact lenses are worn that acts as an artificial tear to wet the lens
Sticking lens:	Lens on the cornea that does not move.

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