



Breath-O
correct®

Japan Quality
Orthokeratology Contact Lens

Professional Fitting and Information Guide



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This guide is intended for eye care professional.
Please read carefully before use and keep
this information for future use.

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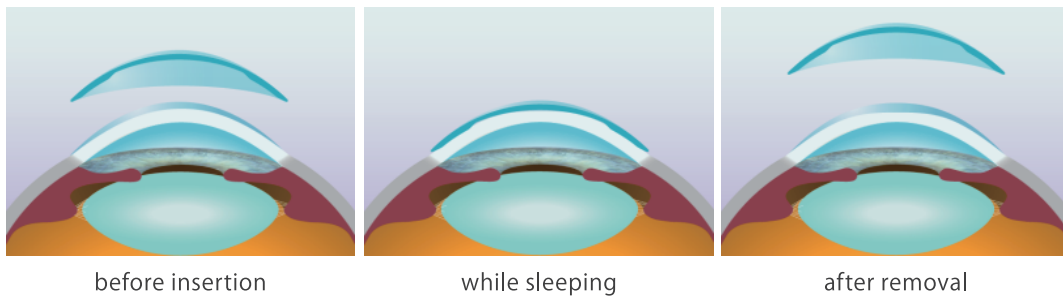
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Introduction

Principle of Orthokeratology treatment

Corneal topography is reshaped by direct wear of the contact lens on the anterior segment of the eye. After removal, unaided vision is improved.



Intended use

Breath-O Correct is indicated for overnight wear for myopia and myopic astigmatism. It reshapes the cornea, and provides improved vision after removing lens.

Indications

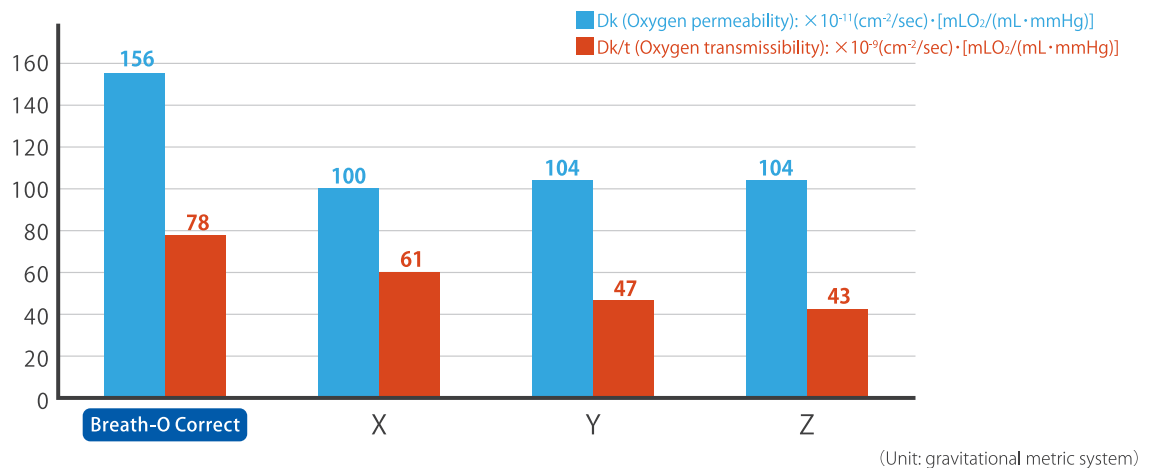
Vision correction for myopia or myopic astigmatism (spherical power is between -1.00 D and -4.00 D and cylindrical power is $\frac{1}{2}$ or less of the spherical power. However, in case of inverse astigmatism, the cylindrical power is $\frac{1}{2}$ or less of the myopic power, and the astigmatism power is -0.75 D or less).

Product description

Lens material

► Supply of oxygen to the cornea

Breath-O Correct's material (Dk/t 78) guarantees high-Level safety for overnight lens wearers.



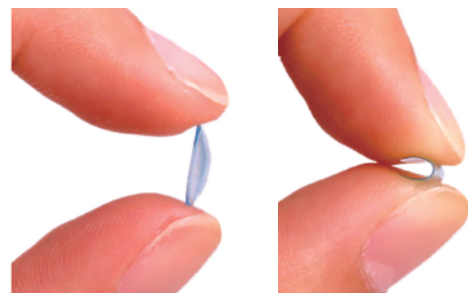
► High durability

The flexible material is based on Toray's original polymer technology.

The components retain strength and the lens bends flexibly in response to impacts from outside to prevent cracking.



Impact test, 6.9g iron ball dropping from 150 cm height.



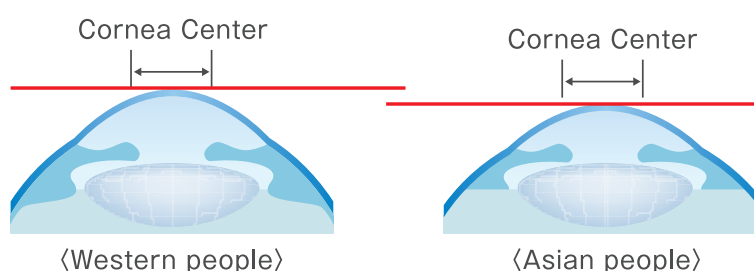
► Composition

Fluoride-containing methacrylate compound
Silicon-containing methacrylate compound

Lens design

► Corneal shape comparison

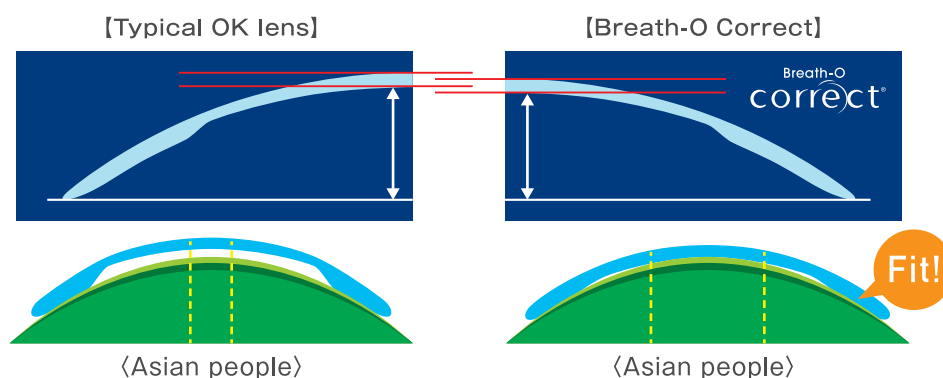
Corneas of Asian people tend to be relatively flatter than those of Western people.



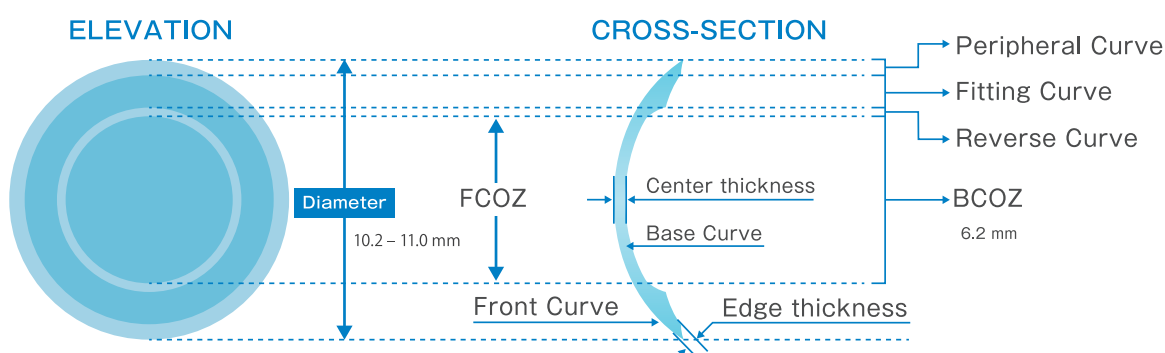
(Motozumi Itoi et al, 1996, Comparison of corneal shape between Japanese and Americans)

► Shallow sagittal depth and wide optical zone

Breath-O Correct is specially designed for Asian people whose corneas are flatter, shallower sagittal depth makes wider optical zone.



► Lens structure



Product description

Prescription procedure

► Prescription procedure



► Screening

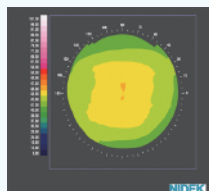
■ Easy Calculation

$$(\text{Flatter meridian}) - (\text{Target power}) \geq 39.00$$

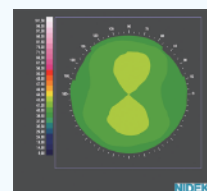
e.g. When flatter meridian is 43.00D, target power less than -4.00D has higher effectiveness.

■ Estimation from Topography pattern

Applicable eye that lens can be positioned in the center of cornea.



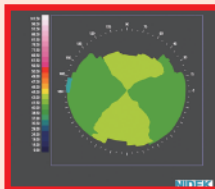
Gentle proptosis
(corneal vertex is located in center of cornea)



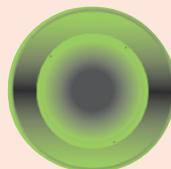
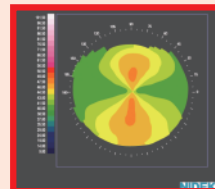
Partially astigmatism with the rule



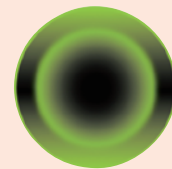
Non-applicable eye that cannot be well centered.



Astigmatism with the rule
overall likea rugby ball



High astigmatism with the rule



► Choice of first trial lens spec

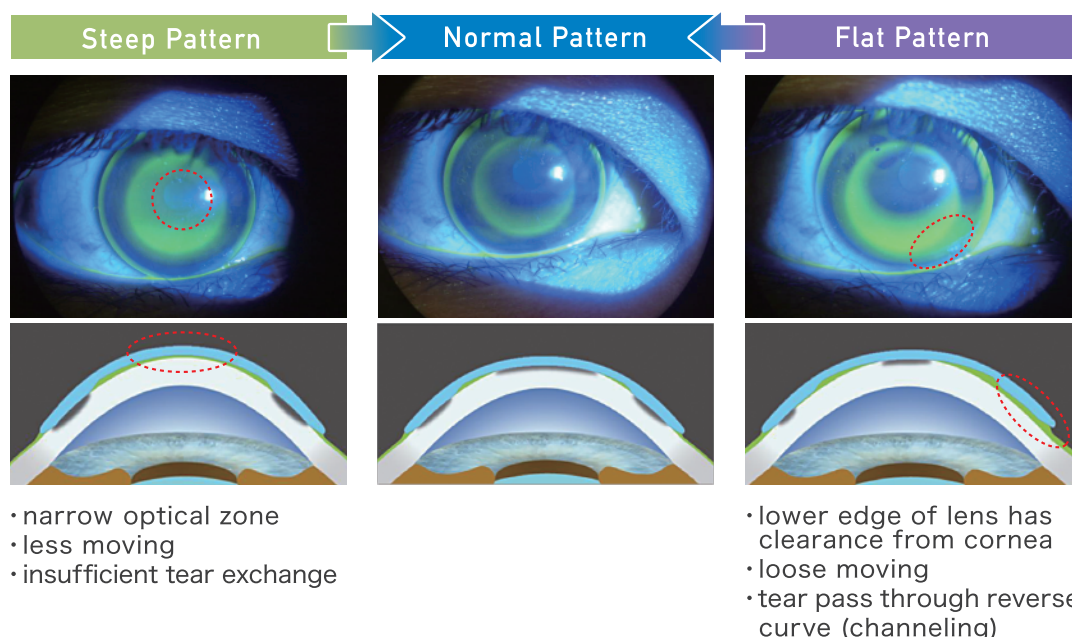
Breath-O Correct has wide range 60 pieces of trial lens, choose Fitting curve/ Target power/ Diameter as following procedure.

- Step 1 Determine the **Fitting curve** referring Avg. of KRT data,
- Step 2 Calculate the difference of the fitting curve and flatter meridian,
- Step 3 Determine the **Target power** by adding the difference (step2) to the myopia power,
- Step 4 **Diameter** is 10.6 mm.

► Judgement

Criteria for fitting condition after 15 minutes of lens wear.

- Lens is properly centered.
- Lens moves 1-2 mm at blinking.
- A proper doughnut pattern is achieved, and also the optical zone as wide as 3 mm.
- Vision correction needed by patient should be obtained and stable, and wearing feeling is comfortable.



► Additional correction

After fitting the appropriate trial lens, required additional power will be added on the trial lens target power.

► Patient's instruction

Refer to instructions for use, be sure to consult the patient regarding lens handling and lens care.

Product description

Regular examinations

► Recommended schedule



Parameters for examinations

- Interview
- Examination of anterior segment of the eye and funduscopy
- Measurement of corneal topography
- Objective refraction test
- Measurement of corneal endothelial cell (at least 2,000/mm²)
- Tonometry
- Visual acuity test
- Fitting test (confirmation of the lens centering, etc.)
- Examination of appearance of the lenses

Clinical outcome

► Post marketing surveillance in Japan

In relation to the registered cases of 159 eyes, the cases of 153 eyes were subject to safety evaluations and the cases of 86 eyes were subject to effectiveness evaluations.

Summary of surveillance

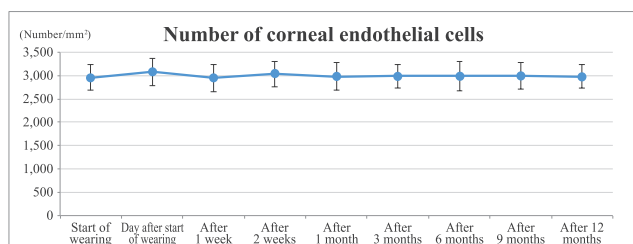
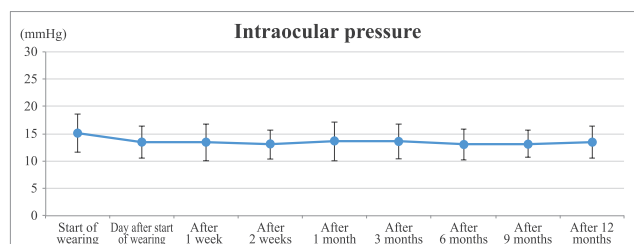
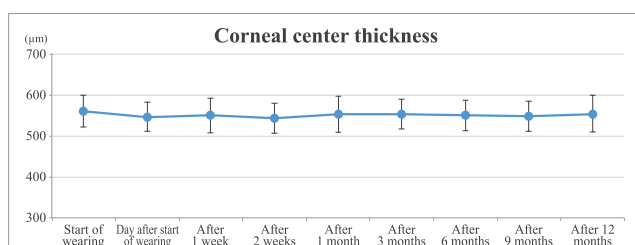
Subject and eligibility	77 patients (Male: 40, Female: 37), 153 eyes
Institutions	5 clinics
Evaluation term	2012.7 – 2014.4
Age prescribed	8 to 55 years old (Avg. 23.7 +/- 12.14 years old)
Average myopia power	-0.50 to -6.50 D (-2.82 +/- 1.32 D)
Average cylindrical power	0.00 to -2.75 D (-0.42 +/- 0.54 D)
Average spherical equivalent power	-0.50 to -7.25 D (-3.02 +/- 1.40 D)

► Safety

With the cases of 153 eyes subject to safety evaluations, adverse events were expressed with 9 of the eyes. Among these, there were 4 eyes where a causal relationship with the product concerned could not be denied but all were known and recovery has been confirmed with each case.

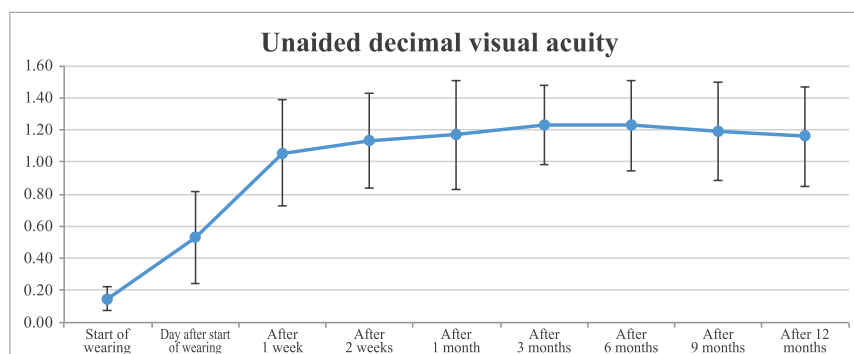
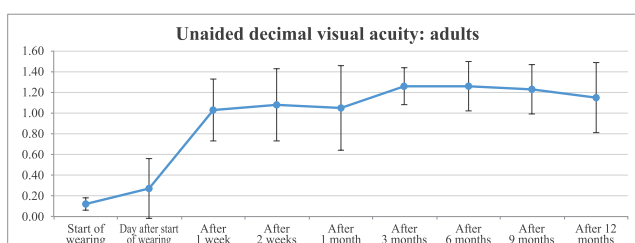
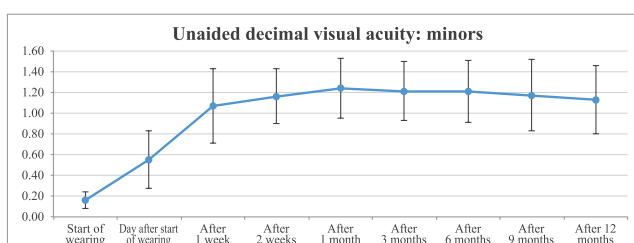
In addition, dirt on the lens was an issue related to maintenance and management and this was resolved by requesting the ophthalmologist to provide guidance on proper use.

Classification	Details	Number of expressions (percentage)
Ocular disorder	Superficial keratopathy	1 (0.7%)
	Bulbar conjunctiva hyperemia	1 (0.7%)
	Annular corneal iron deposition	2 (1.3%)
	subtotal	4 (2.6%)
Abnormality	Dirt on the lens	2 (1.3%)
Expression rate of abnormality, etc.		6 (3.9%)



► Validity

With the effectiveness evaluation results, performance was favorable as the efficacy ratio of the unaided visual acuity evaluation (definition of effectiveness: 0.7 or more) was 95.4% after 3 months from the start of wearing the product and 92.5% after 12 months. Meanwhile, even in the transition of unaided visual acuity, visual acuity of 1.0 or above was obtained after 1 week from the start of wearing the product.



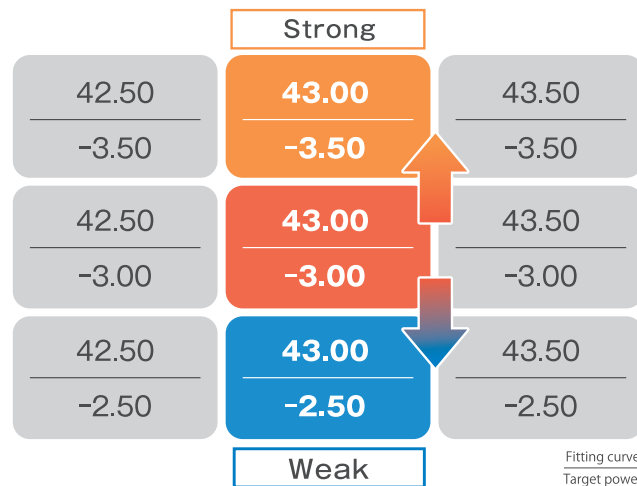
Trouble shooting

Trouble shooting

- ▶ If patient can not obtain required vision correction although fitting condition is well

Change target power strong or weak.

(Fitting curve is not required to change in case only target power is changed.)

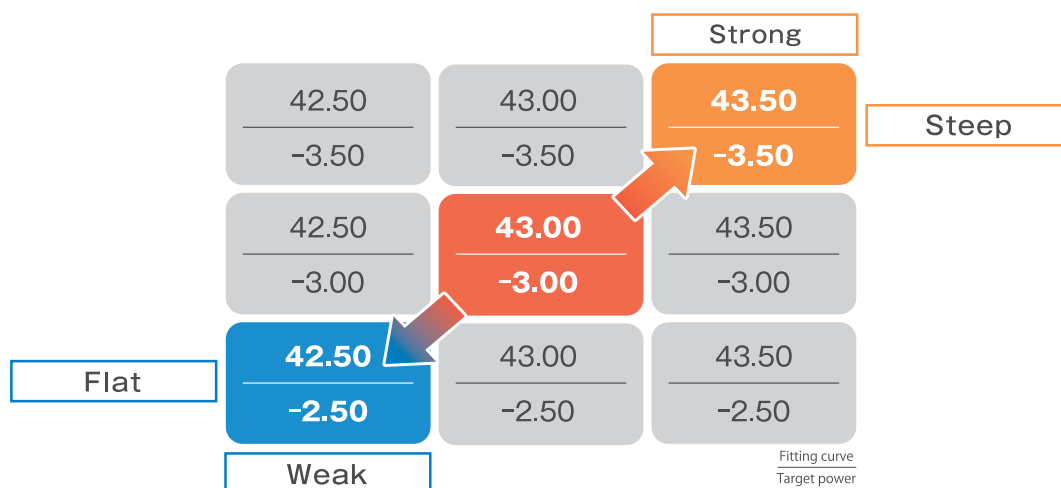


- ▶ If fitting condition is not stable

Change fitting curve steep or flat.

When making fitting curve 1step flat, target power should be 1 step weak.

When making fitting curve 1step steep, target power should be 1 step strong.



- ▶ If stable fitting is not obtained even after changing fitting curve

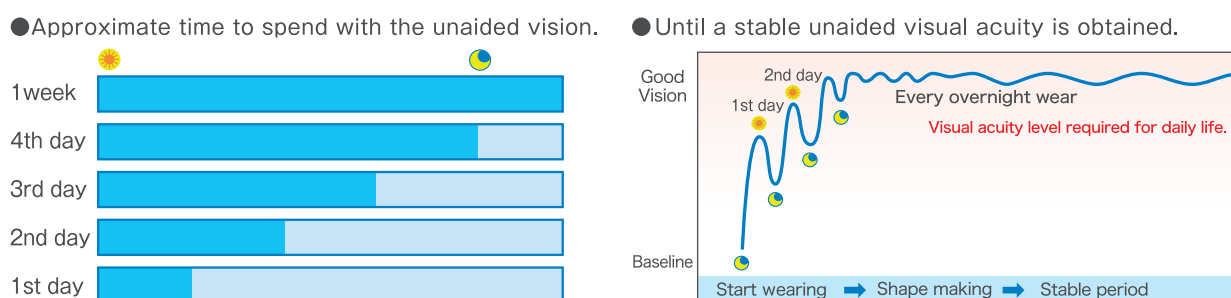
Choose 1 step bigger diameter.

(Target power and fitting curve are not required to change in case diameter changes)

FAQ

Q1 How many days will it take to get stable unaided vision?

A. Although there are individual differences, unaided vision is gradually improved day by day, and become stable after 1 week from starting in most cases.



Q2 How many hours are required to sleep with lens wear overnight?

A. At least 5 hours are recommended.

Q3 How long is the lifetime of Breath-O Correct?

A. Same as typical RGP lens (2 years as a guide), examination of lens appearance should be conducted at regular examination to see if continuous usage of the lens can be. When continuous use is difficult, take necessary actions such as replacing the lens.

Q4 What color is applied to Breath-O Correct?

A. Only blue is available. To confirm lens specifications marked on each lens when distinguish the lens of left or right.



Fitting curve 41.50 D
Target power -2.50 D
Diameter 10.6 mm

Q5 Is the effectiveness of Breath-O Correct made from unique flexible material enough for reshaping the cornea?

A. Some clinical studies were conducted in Japan so far, safety and effectiveness of Breath-O Correct and its material are validated through the tests.

Q6 What is the solution recommended?

A. Solutions can be used for Breath-O Correct as long as the compatibility is evaluated.

Possible range of order

► Diameter

10.2mm	10.6mm	11.0mm
	●	

● Standard

► Fitting curve × Target power

Fitting curve (D) (0.50 interval)	Target refractive correction power (D) (0.50 interval)														
	-1.00	-1.50	-2.00	-2.50	-3.00	-3.50	-4.00	-4.50	-5.00	-5.50	-6.00	-6.50	-7.00	-7.50	-8.00
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