

Misa Lens Scleral Lens Fitting



The fitting of full- and mini Misa® lenses

FITTING · MANAGEMENT · INSTRUCTIONS

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System description and basic principles of Misa® lenses

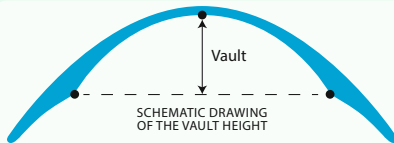
The fitting of scleral lenses is based on different principles than the fitting corneal lenses. Corneal lenses are based on the fact that the contact lens and the cornea are geometrically parallel. This determines how the contact lens acts on the cornea. The practitioner is free to choose any form of geometry and nowadays there are a lot of different options available. Besides a wide range of spherical curves with different radii, contact lenses with aspheric curves are available, where the radius and eccentricity can be specified. This makes it possible to have variations in various directions: not only rotation symmetrical, but also meridian or quadrant specific. Fluorescein should always be used to assess the lens fit.



The scleral lens should rest on the sclera, the cornea should be free of touch by creating an umbrella over the (diseased) cornea. Furthermore, the tear reservoir between the cornea and the contact lens should not be excessive: optimal is approximately 0.25 mm (about half the cornea thickness).



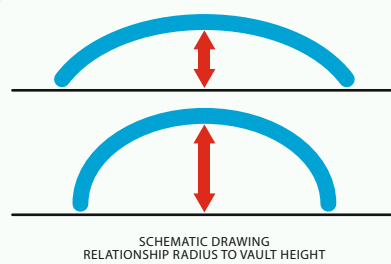
In scleral lenses the height of the lens is much more important than the choice of radius. This height is called the sagitta height or the **vault** height. With the Misa® lenses, the term vault height is used.



The vault height is the height difference between the inside apex of the lens and the point where the lens lands on the sclera and turns into the scleral zone. The vault height of a spherical segment is determined by the radius and diameter of that spherical segment. When the radius of the spherical segment changes, the vault height will also change. In existing scleral lens systems the height of the lens is determined by the composition of spherical curves: a steeper radius creates a larger vault height compared to a flatter radius on the same segment with the same diameter.

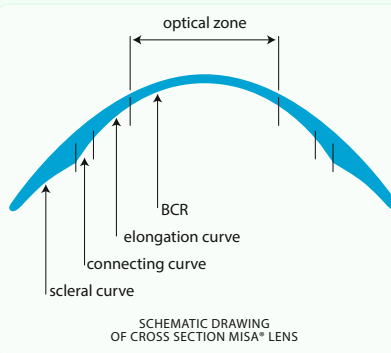
Therefore, in existing scleral systems the practitioner has to be very experienced to choose the right composition of curves that:

- 1 Ensures the exact height.
- 2 Provides the most suited shape that corresponds with the shape of the eye.

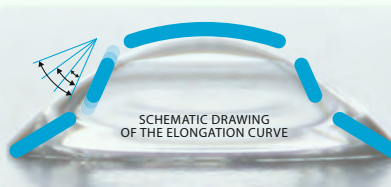


As a result of this fitting complexity scleral lenses never became widely used. The Misa® lens system took away the complexity of fitting scleral lenses:

- the fitting procedure has been greatly simplified and become predictable and transparent
- it is possible to work with smaller diameters.



The Misa® lens is constructed in a way that whenever the vault height is determined; the shape, radius and diameter of the lens can be freely changed without affecting that height. When changing the BCR, or when changing the size of the scleral aperture diameter, the resulting differences in height will immediately be compensated by the so called: **Elongation curve**. Where a change in the lens would in theory make the vault height higher or lower, the elongation curve will compensate this in a way that the vault height remains the same. The first step in fitting a Misa scleral lens is to find the optimal vault height with the trial set. After this, the practitioner is free to choose any BCR or landing zone.



2 Trialset Misa® lenses

The Misa trial set consists of 16 trial lenses. 8 mini scleral lenses and 8 full scleral lenses with different sagittal heights and scleral curves. With the composition it's possible to fit practically all cases.

Type	LZ	DM	BCR	Vault	Power	SC	SC2
Mini Misa	Normal	17.0	7.80	3.500	-2.00	13.50	0.75
Mini Misa	Normal	17.0	7.80	3.750	-2.00	13.50	0.75
Mini Misa	Normal	17.0	7.80	3.750	-2.00	13.50	1.50
Mini Misa	Normal	17.0	7.80	3.750	-2.00	13.50	2.25
Mini Misa	Normal	17.0	8.80	3.500	-2.00	13.50	0.75
MiniMisa	Wide	17.0	7.80	3.750	-2.00	13.50	Standard
Mini Misa	Wide	17.0	7.80	3.750	-2.00	13.50	Steep1
Mini Misa	Wide	17.0	7.80	3.750	-2.00	13.50	Steep2
Misa	Wide	20.0	7.80	3.500	-2.00	13.50	0.50
Misa	Wide	20.0	7.80	3.750	-2.00	13.50	1.00
Misa	Wide	20.0	7.80	4.000	-2.00	13.50	0.50
Misa	Wide	20.0	7.80	4.000	-2.00	13.50	1.00
Misa	Wide	20.0	7.80	4.000	-2.00	13.50	1.50
Misa	Wide	20.0	7.80	4.250	-2.00	13.50	0.50
Misa	Wide	20.0	7.40	4.500	-2.00	13.00	0.50
Misa	Wide	20.0	7.40	4.500	-2.00	13.00	1.00



Delivery options Misa® lenses

3

Delivery options Misa® lenses

Vault heights	2500 micron to 5500 micron in steps of 125 micron
Landing Zone	13.0 mm. Normal 14.0 mm. Wide 15.0 mm. Extra Wide
Power	S-20.00 D to S+20.00 in steps of 0.25 D. Powers higher than +/- 20 D in consultation with Microlens
Optical zone	8.00 mm
BCR	6.00 mm. to 9.90 mm. in steps of 0.10 mm.
Total diameter	18.5 mm, 20.0 mm, 21.5 mm and 23.0 mm
Scleral curve	12.5 to 15.0 mm spline curve. in steps of 0.25 mm.
Front Toric	-0.75 to -4.75 in steps of 0.50 D 1 degree accurate
Toric scleral curve	up to diameter 20.0 mm: 0.50 to 1.50 mm, in steps of 0.25 mm. up to diameter 21.5 mm: 0.50 to 1.00 mm, in steps of 0.25 mm. up to diameter 23.0 mm: 0.50 mm
Centre Thickness	500 micron

Delivery options Misa mini lenses

Vault heights	2500 micron to 5500 micron in steps of 125 micron
Landing Zone	13.0 mm. Normal 14.0 mm. Wide 15.0 mm. Extra Wide
Power	S-20.00 D to S+20.00 in steps of 0.25 D. Powers higher than +/- 20 D in consultation with Microlens.
Optical zone	8.00 mm.
BCR	6.00 mm. to 9.90 mm. in steps of 0.10 mm.
Total diameter	16.5 mm, 17.0 mm, 17.5 mm
Scleral curve	12.5 to 15 mm. spline curve in steps of 0.25 mm.
Front Toric	-0.75 to -4.75 in steps of 0.50 D 1 degree accurate
Toric scleral curve	0.75 to 2.25 mm, in steps of 0.25 mm.
Centre Thickness	300 micron

Materials:

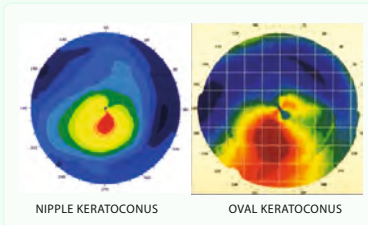
Optimum Extreme
Boston XO2
Tyro 97



The indications and fitting of the Misa® lens and Mini Misa® lens

The introduction of the smaller scleral lens, the Misa® Mini lens, has broadened the application possibilities of scleral lenses:

- The appearance of the lens is more appealing for the user. The diameter of the lens is only slightly larger than a soft contact lens. An important psychological reason for the willingness to wear scleral lenses. Candidates for scleral lenses often have eye pathology with a long history of treatment, surgery and a wide range of contact lens fittings. This frustrating history can make the patients and the people close to them sceptical to start a new adventure, it is important to consider this, as commitment is very important in fitting scleral lenses.
- Patients usually experience high comfort with both the Misa® lens and the Mini Misa® lens. Mechanical stress is often an important cause of failure in RGP contact lens fitting. The stress-free wearing of scleral lenses does not give this problem. We even observe the user extending the prescribed wearing time because of this absence of mechanical stress. This does not have to be a problem with a healthy cornea, but when a weaker unhealthy cornea is involved a higher risk of 'overwear' exists, which can result in lens intolerance or lens related conjunctival and corneal problems.
- Scleral lenses have a sealed fit. Therefore, there is a closed reservoir of fluid between the cornea and the lens. This reservoir provides nutrition to the cornea and will contain metabolic waste products after a certain amount of time. Because of this the scleral lenses should be removed after a few hours and the solution should be refreshed (replaced). With vulnerable corneas, removal and reinsertion after 4 to 5 hours is advised. The wearer may consider this as a constraint, nevertheless it is important to communicate the importance of compliance and the dangers of overwear.



The indications for the application of Misa® lenses are extensive:

Keratoconus

The vast majority of Misa® lenses are fitted on keratoconic corneas. Scleral lenses are suited for all categories of Keratoconus:

- Keratoconus, Oval and Nipple
- Keratoglobus
- Pellucid Marginal Degeneration

The Misa® lenses achieve excellent results with all grades of keratoconus. With lower degrees and smaller protrusions the Mini Misa® lens will perform well. With higher degrees of keratoconus it is probably more likely to fit the Misa® lens. With Keratoglobus sometimes vault heights over 5.00 are used. Microlens provides special trial lenses for these fittings.

Trauma and irregular astigmatism

In eyes with irregular corneas resulting in reduced optical quality a scleral lens would be the first choice to restore visual acuity. Soft contact lenses are often not capable of restoring the visual acuity completely and it is difficult to create a good and comfortable fit with RGP lenses. The eye geometry, with the exception of the affected cornea, is often not significantly different.

After surgery and intercorneal ring segments

Misa® lenses can be used after all types of keratoplasty. When the visual acuity or quality of vision after surgery is insufficient for normal functioning of the patient, a scleral lens can be fitted to improve visual acuity. Depending on the age and vulnerability of the graft, the wearing time of the lenses can be determined.

After inserting intercorneal ring segments the visual acuity will improve, but this can functionally insufficient. Scleral lenses can be used to improve the optical quality of the eye.

Refractive surgery

Misa® lenses can be used after refractive surgery:

- To correct corneal ectasias which can develop after a long period of time
- If the surgery creates unwanted refractive errors or aberrations which need to be corrected.

Corneal degenerations and dystrophies

Many of patients suffer from distorted vision before they are suitable for a cornea transplant. With scleral lenses the visual acuity can often be restored sufficiently, resulting in postponing or refrain from surgery. The same applies for corneal dystrophies with interfering corneal opacities. These can be less disruptive after the application of sclera lenses and visual acuity can be (partially) restored.

Dry eye management

A special application for scleral lenses is the dry eye management. Scleral lenses create a reservoir of fluid between the cornea and lens. This often results in patients experiencing relief or even resolving of their complaints. It is an increasingly popular option with Keratitis Sicca.

High Refractive Errors

High myopic and astigmatic refractive errors can be optically corrected with RGP contact lenses. The mechanical stress in the eye, caused by the movement of the (thick) lens on the cornea, often gives comfort problems and can cause an unstable vision. A Mini Misa® lens has minimal movement and should not cause any mechanical stress, and will therefore be more comfortable to wear. In contrast to the corneal lens, the scleral lens has to be removed during the day and the solution should be refreshed.

The fitting procedure of Misa® and Mini Misa® lenses

Misa® lenses or Mini Misa® lenses?

Generally the Misa® lens (diameter 20.0 mm or larger) has a more stable fit and more fit/alignment possibilities than the Mini Misa® lens (diameter 16.5).

- In case of keratoconus: the Mini Misa® can be chosen with lower grades of protrusion or ectasia
- With older eyes, looser conjunctivas, looser eyelids or larger eyelid fissures, the full scleral version is recommended (Misa®).
- When patients have an initial fear of the full scleral lens because of its size or encounter problems with insertion, start with the Mini Misa® lens.

Step 1: Determination of the appropriate Vault

The first step of the fitting procedure is to determine the appropriate vault height using the trial set of the Misa® system.

With normal eye- and cornea geometries (where the lens will typically be used for dystrophies, dry eye cases and high refractive errors) the vault height will be smaller/lower: 3.25 or 3.50 mm

Lower grades of keratoconus usually have a vault height between 3.25 and 3.75 mm. The higher grades of keratoconus normally have a greater vault height (4.00 to 5.00 mm). In cases of keratoconus globus sometimes an extremely large vault height (above 5.00 mm) will be required, in this case it is advised to contact Microlens about the possibilities and optional extra trial lenses.

With vault heights above 4.25 mm a full Misa® lens should be fitted. The bearing of the mini Misa® can be insufficient with vault heights that high. Vaults heights above 4.25 mm can be ordered with the mini Misa®. Please contact Microlens when this is necessary.

Insert the lens with the expected vault height. The lens should be filled with saline and fluorescein as explained in the 'Insertion and removal' chapter.

Primarily check if there is enough clearance between the lens and the cornea with a slitlamp and cobalt blue light. If there is touch in the center of the lens and cornea (and in some cases the edge of the lens will not land on the sclera all the way around and air bubbles arise) the vault height is too low. Another trial lens with a higher vault should be inserted the same way. Repeat this procedure until the lens is found that:

- Has no touch
- The edge of the lens lands on the sclera all the way around
- The patient is experiencing little to no comfort problems (lenses with corneal touch and incorrect alignment with the sclera will in most cases give comfort problems).



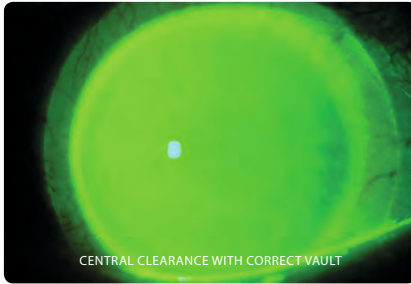
KERATOCONUS GLOBUS



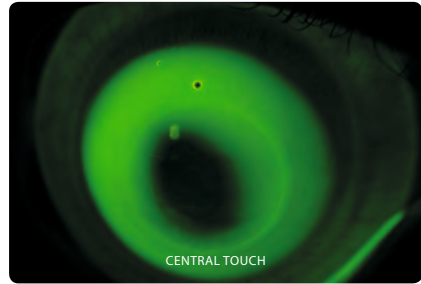
THICKNESS TEAR FILM SEEN WITH SLIT LAMP

PHOTO: LOT - UZA





The thickness of the tear film between the lens and cornea can be estimated using an optic section. It's possible to compare the green colored tear film and the cornea. At the apex the clearance should be about 0.25 mm (approximately half the cornea thickness). At no point central or peripheral should the lens touch the cornea!



When the first trial lens has no touch and a good landing on the sclera, insert another trial lens with a smaller vault height. Repeat this until a lens is inserted that gives touch. Go one step back to the previous lens and check the thickness of the tear film.

Air bubbles:

During insertion, especially with less experienced practitioners, air bubbles can arise underneath the lens. Smaller air bubbles (less than 1.0 mm in diameter) can be left during the fitting procedure. If the air bubbles are bigger than 1.0 mm in diameter the lens should be reinserted because the air bubble has an effect on your evaluation of the lens fitting. When air bubbles repeatedly arise during insertion a solution with higher viscosity should be tried.

If air bubbles still arise using a higher viscosity solution it is possible that the lens fit is incorrect. Air bubbles centered underneath the lens can indicate a vault that is too high or a BCR that is too steep. Air bubbles in the periphery of the cornea can be an indication that the BCR is to flat (see step 2: Determination of the BCR).

Air bubbles that arise during wearing are caused by a scleral curve that does not seal sufficiently. This can have multiple causes, which will be discussed in step 5: Determination of the scleral curve.



PHOTO: LOT - CHU LIEGE



PHOTO: LOT - CHU LIEGE

Step 2: Determination of the appropriate base curve radius (BCR)

BCR determination with Misa® has a greater tolerance margin compared to corneal contact lenses. With RGP lenses it is possible and often necessary to have curvature steps of 0.05 mm. With the Misa® lenses and Mini Misa® lenses we advise to take steps of 0.20 mm.

The BCR determination is important to:

- Ensure that the lens does not touch the vulnerable cornea anywhere, especially peripheral
- Get the best possible alignment of the lens with the cornea and sufficient clearance in the peripheral cornea and limbal area
- Possibly change the final lens power

Most of the lenses in the trial set have a BCR of 7.80 mm. These lenses will be used in most cases. There are lenses in the trial set that have a BCR of 8.30 and 8.80 mm. These are fitted with normal or extremely flat cornea values or for eyes that have gone through refractive surgery.

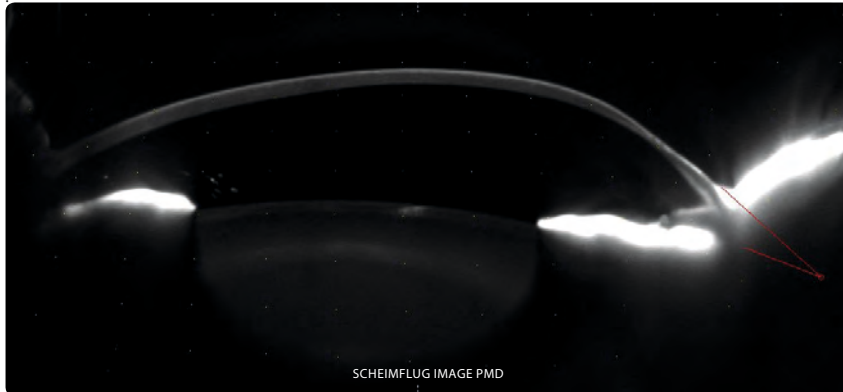
The general BCR fitting rule of the Misa® (for normal cornea K-values) is 0.20 mm flatter than the flattest apex K-value.

With keratoconus the apex K-value is not a useful value because in most cases it is much steeper than the peripheral cornea. If you would choose a lens with a BCR that is only 0.20 mm flatter than the flattest K-value of the apex there is a high risk of peripheral touch. 7.80 mm is in many cases the correct BCR (80% of the ordered Misa® lenses have a BCR of 7.80 mm). In keratoconus cases, the peripheral K-values (sagittal at 30°) are much more relevant for BCR determination. For all these reasons corneal topography is essential when fitting Misa® lenses. When the peripheral K-values are relatively steep, air bubbles can arise in the periphery with a BCR of 7.80 mm because there is too much clearance. To prevent this, a steeper BCR should be chosen (7.50 or 7.30 mm).

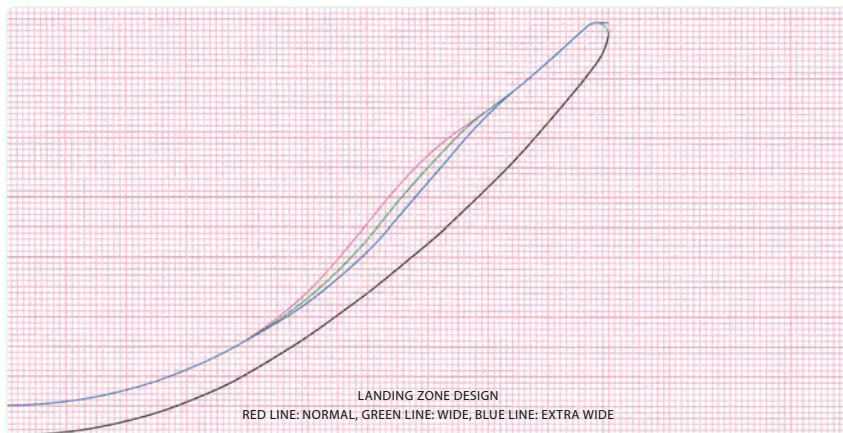
In some cases of keratoconus the peripheral curvature of the cornea can be rather flat. To prevent peripheral touch, a flatter BCR should be chosen (8.00 or 8.30 mm). In cases of PMD sometimes it is also necessary to choose a flatter BCR because of the protrusion far in the periphery of the cornea.

Perfect parallel alignment is difficult to achieve in irregular cornea's. Always try to make it as parallel as possible. Larger differences in clearance create larger pulling and pushing forces on the lens and this will result in more stress for the eye.

When Conjunctivochalasis (most of the times this is in one quadrant) occurs it can be helpful to steepen the BCR. The steepening can only be done if there is enough space in the other three quadrants. Conjunctivochalasis almost always occurs due to scleral curve alignment problems.



Step 3: Determination of the scleral aperture diameter (landing zone)



Once the vault height and BCR have been determined, it is important to determine the diameter of the lens zone that will 'dome' over the cornea; this is called the scleral aperture diameter or **landing zone**. The landing zone is the part of the lens that lands on the sclera and should be outside the limbal area. There should always be enough clearance between the lens and the limbal area.

- The **Normal** aperture diameter/landing zone is 13.0 mm
- When the cornea diameter is larger than average (>11.3 mm) a larger landing zone is required (13.5 mm) and can be ordered as the **Wide** version
- In some cases an even larger landing zone is needed. The **Extra Wide** version, it has an aperture diameter of 14.0 mm

When extra limbal clearance is needed, or it is necessary to maximize the tear volume behind the lens a wider landing zone can be chosen in combination with a flatter BCR.

The full Misa® lens is available in three landing zones: **Normal**, **Wide** and **Extra Wide**. All are available in combination with each (total) lens diameter.

The Mini Misa® lens is also available in the **Normal**, **Wide** and **Extra Wide** version but with preset minimal lens diameters to guarantee enough support on the sclera. With the full Misa® lenses the support of the scleral curve is sufficient with any diameter chosen. With the Mini Misa®, the support of the scleral curve is sufficient if the diameter of the lens is 16.5 mm with a **Normal** landing zone. If the landing zone of 16.5 mm lens would be changed to **Wide**, the scleral curve would not offer sufficient support. To guarantee the necessary support by the scleral curve, all Mini Misa® lenses with a **Wide** landing zone require a lens diameter of 17.0 mm. When an **Extra Wide** landing zone is required, the lens diameter will be 17.5 mm.

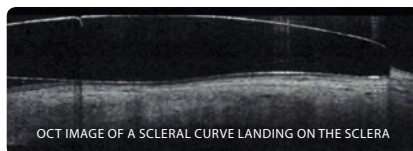


PHOTO: LOT - CHU LIEGE



Step 4: Determination of the lens diameter

The Mini Misa® trial lenses have a diameter of 16.5 mm, the full Misa® lenses 20.0 mm. These diameters can be retained with almost all the Misa® fits.

The Mini Misa® lenses have preset diameters, 16.5 mm for the **Normal** landing zone, 17.0 mm for the **Wide** landing zone and 17.5 mm for the **Extra Wide** landing zone. As told at step 3, these preset diameters of the Mini Misa® are required to guarantee enough support by the scleral curve. If there is still doubt as to whether the scleral curve of the Mini Misa® gives the sufficient amount of support a full Misa® lens should be chosen.

The full Misa® lenses can be ordered with a diameter of 20.0, 21.5 and 23.0 mm. In most cases a 20.0 mm diameter is the primary choice. Only when more stability is required due to:

floppy eyelids, extremely loose conjunctiva and large eyelid fissures, a larger diameter sometimes is required.

NB: The vault height will always remain the same, regardless of BCR, diameter or landing zone changes. When inserting the ordered lens with modified parameters, the central clearance between apex and lens will remain the same as with the trial lens.

Step 5: Determination of the scleral curve

The first four steps of fitting the Misa® can be determined soon after insertion of the trial lens. The vault height, BCR, landing zone and diameter can be measured within 15 minutes after insertion. The scleral curve cannot be determined with short-term assessment. The relation between the scleral curve and the eye is only visible after a longer period of wearing (the longer the better). The scleral curve supports entirely on the sclera. The difficulty is that there is no equipment that can measure the shape and curvature of the sclera. New developments are at hand, with new generation OCT's and other shape profilers. In the future it will be possible to measure the shape of the sclera. Fitting the scleral curve will never be a standard measurement because of the eyelids and soft conjunctiva. Each conjunctiva reacts differently to a scleral lens, the only way to determine the reaction between the two is with slitlamp examination.

The scleral curve of the Misa® trial lenses have a spline curve (the curvature flattens slightly towards the edge) with the equivalent of 13.5 mm sagittal radius. The scleral curve range is 12.5 mm to 15.0 mm in steps of 0.25 mm. Statistics show that in 75% of the eyes a scleral curve of 13.5 mm will suffice.

The other 25% require an alternate scleral curve, either a:

- Steeper curve
- Flatter curve
- Non-rotation symmetrical curve
- Non-rotation symmetrical with steeper curves
- Non-rotation symmetrical with flatter curves

For good assessment of the scleral curve, the lens should be worn at least 45 minutes (unless it is clear that the scleral curve is too flat directly after insertion). If the scleral curve is too flat the lens will not seal and air bubbles will arise underneath the lens due to slight eye movement or lens manipulation. If this situation arises, another trial lens with a scleral curve at least 0.50 mm steeper should be ordered. With that trial lens it should be possible to determine the scleral curve.

When assessing the scleral curve after a wearing time of about an hour there are some indications that should be seen as reasons to change the scleral curve:

1 Comfort

When there is good alignment between the scleral curve and sclera the patient will have a comfortable first experience with the trial lens. After a longer period of time the wearer will be able to tell you:

- When the lens feels to tight, then there is probably need for a flatter scleral curve
- If there are any pressure points, they can often tell where these points are in the eye. In this situation, ask the patient where the pressure points are 'clockwise'. It can be an indication for a non-rotation symmetrical curve.

2 Rotation

Placing your finger lightly on the inferior part of the lens and manually rotating the lens can assess rotation. Every lens has an engraving that can be easily seen with a slitlamp. With the help of this engraving it is possible to assess the amount of rotation. The rotation should occur easily without too much force. The conjunctiva should not move whilst rotating the lens.



3 Pressure

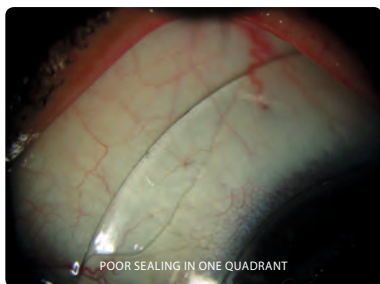
This is another way to assess if the scleral curve fit. Place a finger on the sclera just underneath the lens (sometimes necessary to have the patient look up). Put slight pressure on the sclera and assess if it is possible to get some air underneath the lens. This should be possible without a lot of pressure. When a lot of pressure is necessary to get air underneath the lens, the scleral curve is to steep and has to be flattened. When a very slight amount of pressure causes air to get underneath the lens, the scleral curve may be too flat. The scleral curve should not always be made steeper in this case, only when air bubbles can get within the landing zone should the scleral curve made steeper.

Fluoresceine will help assessing the scleral curve. insert a large amount of fluoresceine on top of the lens and assess where it has easy access underneath the lens edge.



4 Non-rotation symmetrical curve

When the lens is sealing poorly in one meridian but is positioned correctly in the other, a non-rotational symmetrical scleral curve is required. The same is sometimes required when only one quadrant is sealing poorly. In the trial set multiple Misa® non-rotational symmetrical curve lenses are included. These lenses have a greater vault height (4.00 mm), which makes it possible to properly assess the non-rotational symmetrical curve on most eyes.



POOR SEALING IN ONE QUADRANT

PHOTO: LOT - CHU LIEGE

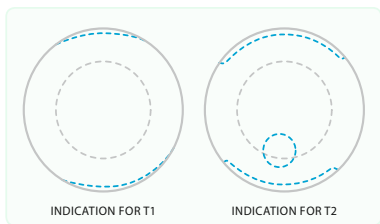
The toric lenses have two lines engraved in the direction of the flattest curve. Always record where the markings are located. In this way you will be able to see if the lens fit is stable. The markings are also necessary to calculate what front toric axis has to be ordered.

If in doubt whether a non-rotation symmetrical lens is needed, try the **T1** (0.50 mm difference) version first. If the lens has sealing 360° around, it is the correct curve. Is there still a poor sealing in one or more areas, try the **T2** (1.00 mm) version. When these two toricities aren't sufficient a **T3** (1.50 mm) is available. It can be ordered if needed.

The trial set contains one Mini Misa® toric trial lens. This **T1** version has a difference in curvature of 0.75 mm. The **T2** (1.50 mm difference) version is not in the trial set. When the Mini Misa® toric does not seal sufficiently in one meridian or quadrant the Mini Misa **T2** version should be ordered.

It is possible that there are pressure points in one meridian or quadrant. In this case, a non-rotation symmetrical version is needed. One of the meridians should be made flatter or steeper. For instance, if there is impingement at the edge of the lens on the nasal and temporal side with a trial lens (13.5 mm sc) a non-rotational symmetrical curve of 14.0 mm should be ordered. This will have two curvatures of 14.0/13.5 with the full Misa® T1 and 14.0/ 13.25 with the Mini Misa® T1.

In practice it has appeared that the larger the diameter of the applied scleral lens, the sooner a meridian specific curve will be required. Compare the percentages in the accompanying illustrations about non-rotational symmetric statistics in full Misa® and Mini Misa® lenses. The lens should stabilize in the same direction (check the markings) after blinking a couple of times. If the lens keeps rotating or stabilizes in different directions the toricity is not correct or a larger diameter is required. This is especially important when ordering a front toric power.



INDICATION FOR T1

INDICATION FOR T2

5 Blanching

A common complication while fitting scleral lenses is blanching. Blanching is always the result of poorly aligned scleral curve and leads to obstruction of the blood vessels in the conjunctiva. When this arises at the base of the scleral curve near the landing zone the scleral curve is too flat and should be steepened. If this occurs at the edge of the lens the scleral curve should be made flatter.

There are several measuring techniques (Scheimflug and OCT), which can be of great value when fitting scleral lenses. If possible use these devices to assess the clearance and alignment of the scleral lens and get an even bigger success rate.

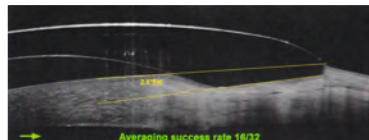


BLANCHING

PHOTO: LOT - UZA

6 Angulation

Although the scleral curve has almost the same curvature as the sclera it doesn't always mean that the alignment is optimal. In a small percentage of cases the angle between the two is not aligned, with impingement in the limbal area as a result (OCT image 1). This poor alignment will not give complaints initially, but can result in limbal redness, poor wearing time or even pain complaints. In some cases these complaints will not start before weeks or even months of wearing the Misa scleral lens.



Averaging success rate 16/32

OCT image 1 limbal impingement

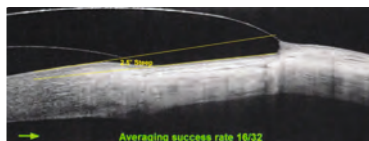
To resolve this problem it is possible to change the angle between the elongation curve and scleral curve of the mini Misa lens in 2.5 degrees steps. This is called the **angulation** parameter.



Averaging success rate 32/32

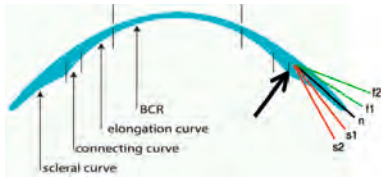
OCT image 2 perfect alignment

In OCT image 2 the angle is changed 2.5 degrees with perfect alignment as a result. Would we change the angle a further 2.5 degrees it will result in poor alignment again with impingement at the edge of the lens (OCT image 3).



Averaging success rate 16/32

OCT image 3 conjunctival impingement



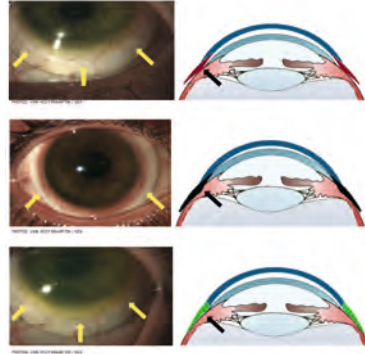
The angulation can be ordered in four types:

- Steep 1 (S1): 2.5 degrees steeper
- Steep 2 (S2): 5 degrees steeper
- Flat 1 (F1): 2.5 degrees flatter
- Flat 2 (F2): 5 degrees flatter

When to change the angle?

When limbal impingement as seen in the top illustration is visible during the fitting session, a steep 1 angulation should be fitted. If the steep 1 is not fitted, the result after multiple hours of wear can be, as seen in the middle illustration. If the angle is correct a fit as in the lower illustration should be seen.

If the steep 1 angle still gives limbal impingement a steep 2 should be considered. But be careful not to make the angle too steep or impingement will occur at the edge of the lens.



Step 6: Determination of the lens power

The determination of the lens power is the same as with RGP lenses. Use a trial frame and lenses and not a phoropter. With a trial frame it is easier to examine the patients reaction like pinching and blinking. The power of the trial Misa® lenses is -2.00 dpt. The -2.00 dpt. should be added to your over-refraction (do not forget to calculate the corneal vertex distance).

- The over-refraction is only accurate when the correct vault height is used. Central touch or too much clearance can influence the measurement.
- When a lens is ordered with a different BCR, this has to be compensated in the lens power following the SAM/FAP rule (Steeper Add Minus/ Flatter Add Plus, 0.50 dpt. for every 0.10 mm change).

Aberrations and toric powers

Scleral lenses are mainly used in eyes with complex eye surfaces, irregular astigmatisms, and many aberrations. By giving the eye a completely 'new' optical clear anterior surface the visual acuity will improve dramatically. However,

sometimes a toric refractive error will remain. Front toric options are available. in a range of -0.75 to -4.75 dpt., in steps of -0.50 dpt., 1 degree accurate.

Front toric powers are **only available** with non-rotational symmetrical scleral curve due to the stabilisation of the lens.

To order a front toric power, the spherical and toric over refraction should be sent to Microlens together with the location of the markings on the toric lens. Or the crosscylinder tool of the **Design your Fit®** program can be used

Experience shows that the vision will recover dramatically when using Misa® lenses. In approximately one in five wearers, the recovered visual acuity will be 80-90% of the maximum acuity achieved using cylindrical correction. A lot of these wearers have no problems wearing additional glasses correcting the remaining cylindrical power (if the extra 10-20% visual acuity is required).



Insertion and removing Misa® lenses by the practitioner

For many patients, the fitting and first time insertion of scleral lenses is an unpleasant and tense experience. That's why it is important that the practitioner manipulates the lens easily. It is wisely to first practice the insertion with colleagues before working with patients. The fitting procedure should be done in a quiet and save ambience where the patient feels comfortable.

Misa® lenses, from the trial set, as well as the Rx lenses, are stored and delivered dry. Because of the dry storing it is possible that the wettability of the material is not optimal after first time insertion. To avoid dry spots on the lens after insertion the lens should be cleaned with a non-abrasive cleaning solution. After the cleaning the lens should be rubbed in with high viscose insertion solution.

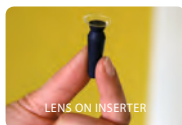
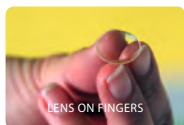
The insertion of the lens



- 1 The patient should sit on a stool in the middle of the room with enough space for the practitioner to move around him. Because fluorescein is used give the patient a towel to avoid staining.



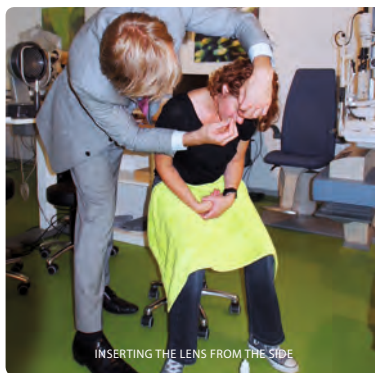
- 4 Let the patient lean forward until his face is horizontal and his nose more or less perpendicular to the floor. Put an item, for example a solution bottle, between the feet of the patient. This should be the patient's focusing point during insertion to minimize eye movement.



- 2 There are two ways to hold the scleral lens when inserting it. The first one is keeping thumb, index finger and middle finger together and place the lens on the three fingers (held as a tripod). The second way is to place the lens on a DMV inserter and hold the inserter in position with thumb and index finger.



- 3 The lens should be completely filled with solution and fluorescein when inserting it. Use a multipurpose solution or saline. In the beginning when the patient is not yet used to the procedure, it is easier to use a solution with a higher viscosity to avoid air bubbles. Use one or two drops of liquid fluorescein or fluorescein strips can be dipped in the insertion solution.



- 5 When inserting the lens in the patient's right eye it's easiest to hold the lens with the right hand. Bend over from the side and with the left index or middle finger pull up the upper eyelid at the base of the lashes. With the index finger of the right hand the lower eyelid should be pulled down to make the eyelid fissure as big as possible. Use the ring finger when holding the lens with three



fingers. If the DMV inserter is used, hold the lower eyelid with the middle finger. When the eyelid fissure is big enough the Mini Misa® lens can be placed gently on the eye. With the full Misa® scleral lens first put a part of the lens under the upper eyelid and then place the lens gently on the eye. The lens has to be in a more or less horizontal position to avoid air bubbles beneath the lens once placed on the eye.

When it is certain the lens settles on the eye, the eyelids can be released. When inserting a lens in the left eye, it's best to insert the lens with the left hand and hold the upper eyelid with the right hand in the same manner as the right eye.

Some practitioners prefer to kneel down in front of the patient to carry out the procedure from that position. When inserting the lens like this always use a DMV inserter.



MANIPULATING THE EYELIDS



INSERTING LENS WITH INSERTER

Air bubbles

If the lens has more or less the right 'fit' the lens will be hardly felt. After insertion check directly, preferably with a cobalt blue penlight, if the lens settles well and no air bubbles are behind the lens. If there is an air bubble: remove the lens and reinsert it.

When air bubbles arise after each insertion:

- Be sure that the insertion procedure is done well (horizontal position of the lens completely filled with solution)
- Be sure the patient is looking in the correct direction, focussed on the item between the feet
- Check if the vault height or radius of the lens are adequate
- Use a solution with a higher viscosity



CHECKING FOR AIR BUBBLES WITH COBALT BLUE PENLIGHT

The removal of the lens

Capillary forces are holding the lens on the eye. To remove the lens from the eye that capillary force should be broken.

Use a plunger/remover used for normal rigid lenses and wet the lens with saline or solution for inserting GP's. With the full Misa® a DMV inserter can be used.

Place the plunger on the inferior or temporal edge of the lens. Lift the edge of the lens with the help of the plunger to break the capillary force and the lens can be easily removed from the eye. In some cases, especially if the scleral curve doesn't have a good alignment, the capillary forces are so strong and the suction force of the plunger will not be enough to overcome these and remove the lens. When this occurs, let the patient look up slightly and place your thumb on the sclera underneath the lens. Perform some pressure on the sclera while pulling on the lens with the plunger.



REMOVE THE LENS WITH INSERTER



REMOVE THE LENS BY EYE LID MANIPULATION

Never place the plunger centrally on the lens and try to force it out.

This method works for the Mini Misa® lens as well as the full Misa® lens.

The full Misa® lens can be removed in another way as well. This is because the edge thickness is different and can be manipulated by the eyelids. Let the patient look up slightly and pull the lower eyelid to the temporal side. This will make it tighter and possible to get the eyelid underneath the lens edge. Lift the lens edge with the eyelid to break the capillary forces and the lens will come out of the eye easily.



Patient information about Misa® scleral lenses

This brochure will give complementary information about scleral lenses. It will not replace the information your lens practitioner or ophthalmologist gives you. They know your specific eye problems and needs.

Why scleral lenses?

Scleral lenses are mainly fitted on eyes that have health issues. They can be seen as a prosthetic device for the front part of the eye. Scleral lenses can restore the visual acuity or solve comfort problems.

There are many indications why scleral lenses are fitted. The most important and common ones are:

- 1 When glasses or other contact lenses can't restore the vision enough, scleral lenses can be the solution. The insufficient visual acuity is the result of an irregular shaped cornea (the transparent part of the eye). This irregularities can have multiple causes:
 - Keratoconus
 - Genetic cornea diseases
 - Inflammations (viral/bacterial)
 - Cornea diseases through allergies or dermatitis
 - Cornea dystrophy
- 2 To optimize the visual acuity after surgery such as cornea transplants. In some cases scleral lenses are used to correct eyes that underwent refraction surgery.
- 3 With reduced vision caused by trauma to the eye which resulted in cornea irregularity.
- 4 Due to several reasons the tear-layer can be insufficient. When the cornea isn't completely covered with a tear-layer it can desiccate and cause severe complaints, such as extended irritation, pain and even vision loss. With the reservoir of solution behind the scleral lens, the complaints can be reduced.
- 5 Scleral lenses are also fitted to increase the eyelid fissure if somebody has a drooping or falling eyelid.
- 6 There is a non-medical use for scleral lenses as well. Because the lens makes the eye completely dust free and do not fall out while swimming. People that work in very dusty environments or practicing water sports intensively use them.

How do scleral lenses work?

Scleral lenses, in contrast to RGP or soft lenses, do not touch the cornea. They vault over the cornea and land on the white sclera. Between the cornea and the lens is a fluid reservoir. The fluid reservoir will:

- Mask irregularities of the cornea, the optical performance of the cornea will be a lot better. The visual acuity can increase drastically.
- Act like a liquid bandage to relieve extremely dry or diseased corneas.

The first thing most people notice is their size. They are bigger than normal soft or rigid lenses. The big advantage of this

bigger size is the possibility to stay clear of the very sensitive cornea and only touch the less sensitive white sclera. This is also the reason they are made of rigid plastics. Because the lens does not touch the cornea the initial comfort is really good and almost everybody can get accustomed to them in a short period of time.

Are there different kinds of scleral lenses?

The principle of scleral lenses is very old. It was the first kind of lens ever invented for correcting the vision. The first ones were made over a hundred years ago, not from plastics but glass blown.

Just a couple of years ago their great potential was re-discovered and they got a lot more attention, especially in the medical applications. There were a couple of reasons why this happened:

- 1 The measurement and scanning devices became a lot better. Mapping the shape of the cornea became more detailed.
- 2 Technological advancements made it possible to produce lenses more easily and precisely.
- 3 Material developments made it possible to make lenses of extremely high oxygen permeability.

The patient's biggest recognition was probably the new possibilities in size. The **Misa scleral** lens has an average diameter of 20 mm. The **Mini Misa scleral** lens has a diameter of 16.5 mm, which is almost the same size/diameter as a soft contact lens. Insertion or removal of the Mini Misa scleral lens is not that big of a problem anymore. The Misa scleral lens, which is slightly larger, asks a bit more practice the first few days.

Which lens is best suited for a certain eye can not be said in advance and is determined during the fitting session.





How are scleral lenses fitted?

An ophthalmologist gives the indication for the use of scleral lenses. An internal or external working medical eye care specialist does the fitting procedure. There can be a separate appointment for the fitting.

During the fitting, several lenses are tried, until finally is determined what the most appropriate lens will be. A good prognosis can be given about the expected visual acuity.

The fitting procedure usually takes an hour and a half or longer.

Once the appropriate lens or lenses have been determined, they can be manufactured on prescription by the laboratory. An appointment for instruction about learning how to use, take care and how to treat the lenses will be made.

When the instruction is successful, the lenses can be taken home. A wearing schedule will be given, specifying how many hours the lenses can be worn each day. Depending on the indication and health of your eyes the wearing schedules is different for everyone else. It may take several days to even weeks before the lenses can be worn all day long.

The first follow up will be after one to two weeks as indicated by the medical eye care specialist. Often the ophthalmologist will want to do some check ups as well. Take into account that a couple of appointments will be necessary the first couple of weeks. In later stages this will be once every few months depending on how the wearing goes.

Can the lenses be worn all day long?

Yes, in most indications these lenses can be worn all day. With a limited number of indications this will be different.

However, the lenses should be taken out every 4 to 6 hours to be reinserted with new solution. At subsequent follow-ups it will be determined whether it remains necessary or not. But the medical eye care specialist is always the one who makes that decision.

Scleral lenses can not be worn overnight, a small nap during the day normally is no problem. The lenses should always be removed in the evening before going to bed.

Scleral lenses, depending on the material, should be replaced every one or two years, in that way the clarity and accuracy can be ensured.

To whom should I direct my questions about scleral lenses?

Scleral lenses are not generally well known. Also, your regular optician or eye care specialist is usually not familiar. Therefore it is best to focus your questions to your ophthalmologist or your eye care specialist that has fitted your scleral lenses.



Instruction on the treatment of scleral and mini scleral lenses

Hygiene

The type of lens that you will be wearing only touches the eye on the whites, while it will stay clear of the cornea. The scleral lens is fitted because of different, usually medical reasons. Especially with these (mostly unhealthy) eyes hygiene is very important to prevent infections or complications. Therefore, always follow the rules of hygiene when handling the lens:

- 1 Effectively and thoroughly wash your hands with warm water and non-perfumed disinfecting soap.
- 2 Dry your hands, if possible, with a lint-free towel or tissues.
- 3 Always check the expiration date of the cleaning and insertion solution. The date shouldn't be exceeded. After opening of the bottle, the solution can only be used temporarily. In most cases, this is indicated on the bottle. If it is not indicated, the solution can be used until two months after opening when stored at room temperature.
- 4 Beside daily lens care, the lens case should be cleaned on a daily basis as well. After inserting the lenses in the morning, rinse the lens case with insertion solution and let it dry upside down.

Lens material

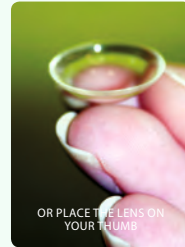
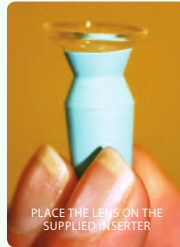
The scleral lenses are fabricated from highly oxygen permeable materials. The materials should also meet high standards of "wettability", clarity and accuracy of shape. For these reasons the plastics that are used aren't as robust as some other plastics. You should always handle the lenses carefully. Always use lint-free tissues to rub the lenses. Normal standard tissues could scratch the surface of the lens. When handling the lens, try to do this above a table.

Lens solutions

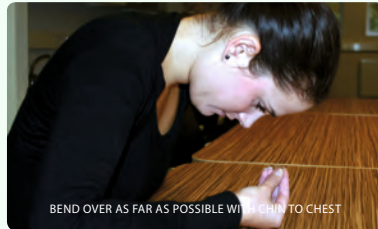
With the scleral lenses you need three types of solutions, which your practitioner will prescribe. A cleaner is for cleaning the lenses. With cleaning solution you can remove grease and protein deposits from the surface before putting the lenses away in the lens case. The second one is a storing and rinsing solution, normally used for RGP lenses. This is the solution to rinse the lenses after cleaning and in which the lenses are stored to disinfect when the lenses are not worn. The third solution is the insertion solution. This has to be conservative free saline because the solution you put in the lens will stay in between the lens and the cornea for as long as you wear the lenses.

The insertion of the lens

For insertion, although a lot of people use them, you do not necessarily need a mirror. Be sure to take place behind a table where you have the space to bend over because the face has to be horizontal when inserting the lens.



- 1 Remove the lens from the lens case and place it on the supplied inserter or on your thumb, index and middle finger. Fill the lens completely with saline.



- 2 Bend over as far as possible with chin to chest, look at the lens with the face parallel to the table surface. If you use a mirror look at your eyes in the mirror and try to keep focussed on the same point during the insertion. Make sure that the lens is held horizontal filled with solution.



- 3 If you insert the lens with your right hand, first pull up the upper eyelid with the left index and middle finger at the base of the lashes. be sure you have a strong hold because especially in the beginning the strong blinking reflex will make the insertion more difficult. With the ring finger of the hand you hold the lens, pull down the lower eyelid.



- 4 Try to keep focussing on the same point while bringing the lens closer to the eye and gently place it on there. It is easiest to first place the lens underneath the upper eyelid and keep pushing slightly while the other hand places the lower eyelid over the edge of the lens.
- 5 Gently release the lens and eyelids and check the vision with the lens. When the vision is poor it is possible an air bubble is underneath the lens. You can also check for air bubbles with a mirror and good light. When an air bubble arises the lens should be re-inserted because it will decrease the vision and comfort.

Removal of the lens

There are two ways to remove the Misa lenses.

The first way can be done with both the full Misa® and Mini Misa® lenses.



- 1 Use the supplied scleral lens plunger.
- 2 Pinch the plunger and place it on the bottom side of the lens (on the boundary of the cornea and white of the eye).
- 3 Make a tilting movement upwards, this way air can get underneath the lens and the lens will easily come out.

With the Mini Misa® a plunger/remover used for normal rigid lenses is preferable.

Never place the plunger centrally on the lens and try to force it out.



The full Misa® lens can be removed in another way as well.

- 1 Take place behind a table and look straightforward with your chin pointing upwards a little bit.
- 2 Pull up the upper eyelid with your middle finger until it is above the lens edge.
- 3 Now make the eyelid tighter by pulling it to the temporal side. The eyelid will get underneath the lens edge and the lens will come loose from the eye.
- 4 Catch the lens with your other hand or let it drop on a soft towel placed before you on the table.

Cleaning and storage of the lens

- 1 After removing the lenses they should be cleaned to discard the protein and fat deposits that build up on the lens surface during wearing.
- 2 Put a few drops of cleaner on the lens and rub both sides for at least 30 seconds with thumb and index finger.
- 3 Rinse the lens with the RGP lens solution. Make sure all the cleaner solution is washed of the lens.
- 4 Store the lens in the supplied lens case. Make sure the case is filled with RGP lens solution that is refreshed every day. The lens should be completely covered with the solution for thorough disinfection.

Follow up appointment

Scleral lenses are only fitted by a limited amount of specialists. This lens type is completely different to all other lenses. Most opticians and other specialist don't have the knowledge to solve complications or even check the fitting of the scleral lenses.

- When you have questions, always ask them to your scleral lens practitioner.
- Always visit your pre-arranged follow up appointments.
- When there is doubt about something, don't hesitate to contact your practitioner.

Wearing schedule

Dependable on the indication, your practitioner will give you a wearing schedule. Keep to the schedule because over-wear of the lenses is a big health risk for the eye.

The solution between the lens and eye will stay there until the lens is removed from the eye. This solution is the most important supplier of nutrients to the cornea. Dependable on the health of the cornea, re-insertion is sometimes necessary to refresh the solution. When starting wearing Misa® scleral lenses, the lenses should be re-inserted every 4-6 hours until your practitioner says otherwise.

Your wearing schedule is:

First day: 2 hours

Every next day hours longer

Refresh solution after hours

Your next follow up appointment is:

date hour

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