



ReLEx SMILE

Minimally invasive vision correction – Information for patients



Seeing is living

Our eyes are our most important sensory organ. The human brain obtains over 80 % of its information via the sense of sight. Our eyes are our windows to the world. Seeing is recognizing. Seeing is experiencing. Seeing is independence and freedom. Seeing is living.

Well over half the world's population relies on glasses or contact lenses to see well. But many find that being dependent upon optical appliances interferes with their professional lives and leisure time.

Simply being able to see. Without glasses or contact lenses. Completely free of any optical appliances. This is now possible in increasing numbers of cases thanks to ongoing developments in medicine and technology. Refractive visual correction techniques have been scientifically recognized and clinically tested over the last few decades. They have come to represent an important alternative to traditional correction methods such as glasses and contact lenses.

ReLEX® SMILE is the new laser technique by ZEISS for the gentle correction of vision defects. It is a minimally invasive treatment method which combines the extensive experience and superior safety of traditional vision correction techniques with numerous innovative benefits, high precision levels and perceptibly greater comfort during the treatment itself.



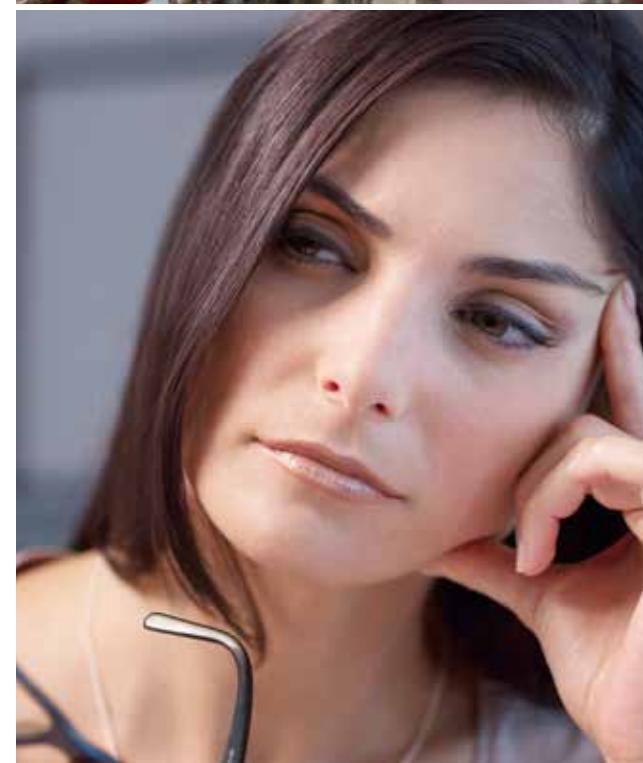
In and out of focus – Types of vision defect

The physical/optical principles behind the human eye are similar to those in a camera. The cornea and lens assume the role of the camera lens. They bundle the parallel incidental light rays and determine the focal distance. In an eye with normal vision, the light rays are focused so that the focal point is on the retina itself. The result is a sharply focused image. This is then transmitted via the optic nerve to the brain.

Nearsightedness is the most common vision defect worldwide. Almost half the global population is – to varying degrees – affected by it. In nearsighted people, the eye is too long in relation to its refractive power. Light rays are refracted by the cornea and the lens in such a way that the focal point lies in front of the retina. By the time the rays hit the retina itself, they are already drifting apart. The result is a retinal image which is out of focus. Distant objects appear blurred. Depending on the degree of vision defect, near objects are in sharp focus.

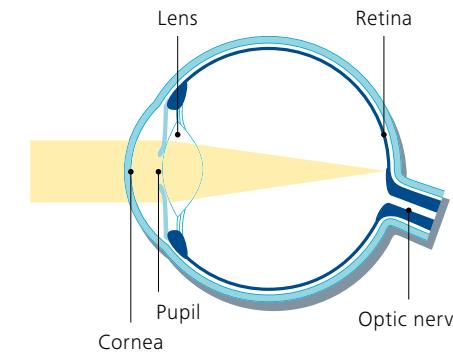
In farsighted people, the eye is too short in relation to the refractive power. Light rays are refracted by the cornea and the lens in such a way that the focal point is behind the retina. A blurred image is then created on the retina because the rays are not yet focused when they hit it. Up to a certain age this lack of refractive power can be compensated by changing the shape of the lens (accommodation). Depending on the extent of the farsightedness, objects which are close, and even distant ones in some cases, are no longer in sharp focus.

In people with astigmatism, the curvature of the cornea is uneven. The resulting refraction causes multiple focal points to be created. Objects both near and far appear skewed or distorted. Astigmatism can occur independently or be accompanied by farsightedness or nearsightedness.



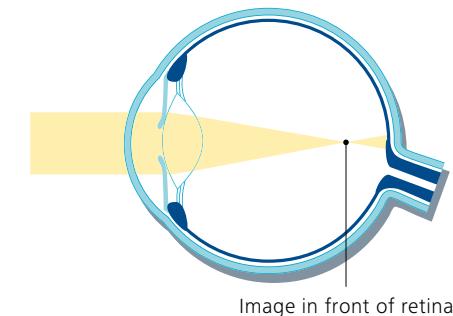
Normal vision (emmetropia):

Light rays are refracted by the cornea and the lens in such a way that the focal point is directly on the retina. Objects both near and far appear in sharp focus.



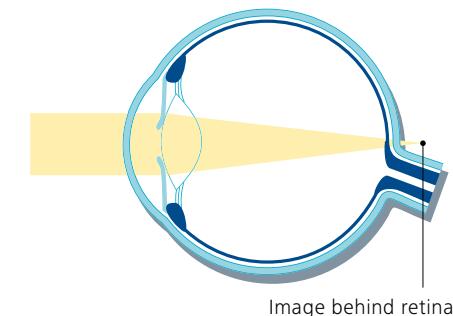
Nearsightedness (myopia):

Light rays are refracted by the cornea and the lens in such a way that the focal point is in front of the retina. Distant objects appear out of focus. Depending on the degree of myopia, near objects appear in sharp focus.



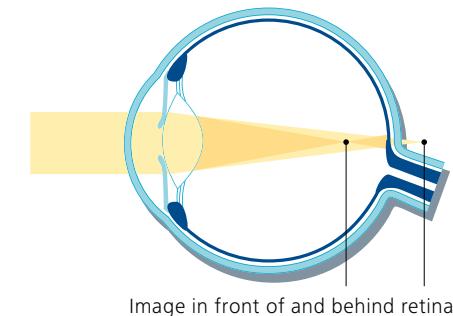
Farsightedness (hyperopia):

Light rays are refracted by the cornea and the lens in such a way that the focal point is behind the retina. Depending on the extent of the farsightedness, objects which are close, and even distant ones in some cases, appear out of focus.



Astigmatism

The irregular curvature of the cornea causes the light rays to be refracted into multiple focal points and not just one. Depending on the extent of the astigmatism, objects both near and far appear skewed and distorted.



A life without glasses – The different laser treatment options

Laser surgery techniques for refractive vision correction were well established, both scientifically and clinically, by the mid-80s. The basic principle behind all the methods is using a laser to model the outer corneal layer so that the focal point of the bundled incidental light is on the surface of the retina itself and not in front of or behind it.

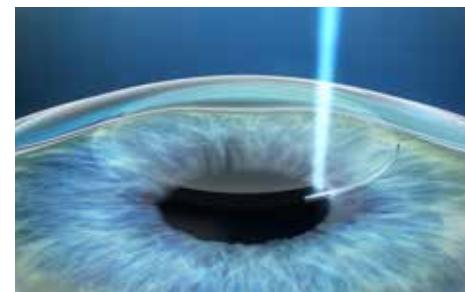
The original treatment methods, PRK and LASEK, manually removed the outer protective layer (epithelium) of the cornea before the laser surgery. The consequences often included post-operative pain and very slow recovery of visual acuity. As a consequence, laser surgery techniques which involved preparing a corneal flap (LASIK and Femto-LASIK) were then developed. Here, a mechanical cutting tool (microkeratome) or a femtosecond laser is used to create a thin flap of cornea which is just 120 micrometers thick. Almost a complete circle (270°) is cut in the upper layers of the cornea. The flap is then folded back like the cover of a book. Subsequently, the exposed corneal tissue is then ablated using an excimer laser in a separate stage of treatment. The greater the level of vision defect, the more tissue needs to be removed. In the final stage of treatment, the corneal flap is then folded back into its original position.

It then adheres in the original place over the coming weeks and months. The disadvantage is that the flap can shift or even tear off (flap displacement) as the result of rubbing or other physical contact after the operation.

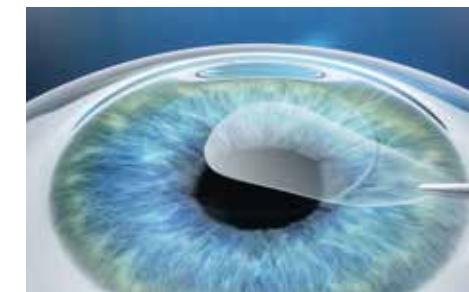
The ReLEx® SMILE principle: The high-precision VisuMax® femtosecond laser creates a small lens (lenticule) inside the intact cornea, the volume and form of which are determined by the degree of vision defect to be corrected. This lenticule is then removed in a minimally invasive procedure from the interior of the cornea through a small access measuring just a few millimetres. In contrast to earlier techniques, it is no longer necessary to fold back the cornea. There is no flap incision, the area of the incision is reduced to a minimum and the outer corneal layers remain more or less intact. All of which is made possible by a sensitive, precise and convenient treatment method.

The treatment steps

SMILE with VisuMax



Step 1:
In a single step the VisuMax femtosecond laser creates a thin lenticule and a small access measuring less than 4 mm in the intact cornea.



Step 2:
The surgeon removes the lenticule through the small access. There is minimal disruption to the biomechanics of the cornea. No flap needs to be cut.



Step 3:
The minimally invasive removal of the lenticule changes the shape of the cornea, correcting the refractive error of the eye.

Femto-LASIK



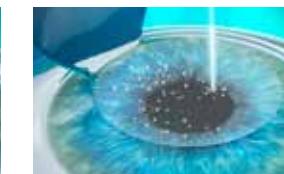
Step 1:
The femtosecond laser creates a corneal flap.



Step 2:
The patient is moved to the excimer laser.



Step 3:
The surgeon opens the flap and folds it back to expose the lower corneal layer (stroma) beneath.



Step 4:
The excimer laser ablates the pre-calculated amount of corneal tissue, point by point.



Step 5:
After the laser surgery is complete, the flap is returned to its original position. It then adheres in the original place over time.

Minimally invasive – with no flap incision

The benefits of ReLEx SMILE



In recent years minimally invasive diagnostic and treatment methods have set new standards in modern medicine. This is because minimally invasive very often means minimum discomfort for the patient. In its SMILE method ZEISS has developed a new technique for the minimally invasive laser correction of vision defects. This innovative treatment technique yields a whole range of benefits:

Flapless treatment

- No folding back of a corneal flap
- Lenticule preparation in the intact cornea
- Minimally invasive access measuring just a few millimeters (80 % less lateral incision than in LASIK and Femto-LASIK)
- Almost complete preservation of protective corneal layer (epithelium) and stabilizing outer corneal layers (Bowman's membrane)
- Maximum number of corneal nerves responsible for tear regulation remain intact
- Practically painless during and after the procedure

Entire treatment carried out using femtosecond laser (all-femto)

- Use of high-precision femtosecond technology
- Outstanding predictability of results, even in cases of severe myopia (> -7.00 D)
- Anatomically shaped contact glass avoids unnecessary compression of the cornea
- No loss of vision during treatment
- Noiseless and odorless treatment
- Stabilization of visual acuity typically within 14 days

Single-step treatment

- Entire laser correction in a single treatment step
- No device change during the operation
- Short procedure

Precise and sensitive treatment

VisuMax femtosecond laser

The specially developed laser system used for the SMILE procedure is the ZEISS VisuMax femtosecond laser. In Femto-LASIK surgery it has already impressed patients and physicians alike with its sophisticated technology, its precision and its reliability. SMILE using the VisuMax from ZEISS now permits accuracy down to nearest micrometer precision in the preparation of the lenticule within the intact cornea.

The high-precision femtosecond laser provides targeted correction of the vision defect while leaving the surrounding corneal tissue virtually unaffected.

A contact glass specially designed to match the individual anatomy of the cornea permits customized treatment in which the corneal tissue does not need to be unnecessarily compressed. This helps avoid temporary loss of vision caused by excessive intraocular pressure.

An ergonomically designed and functionally versatile patient supporting system provides extra comfort and relaxation during treatment. The position of the patient is continuously monitored during the laser procedure and automatically adjusted and corrected, if necessary.



Other things you might like to know about ReLEx SMILE

What makes SMILE with VisuMax so special?

Unlike in all other laser eye surgery procedures, the corneal tissue is not ablated using an excimer laser. In ReLEx SMILE, proven femtosecond laser technology is the only technology used. A small lenticule is prepared inside the intact cornea using the femtosecond laser. This lenticule is removed through an access point just a few millimeters across. In fact, the cornea does not have to be opened at all – unlike with LASIK and Femto-LASIK. The technique is made possible by the unique precision and performance of the VisuMax® femtosecond laser made by ZEISS.

There is no flap in PRK or LASEK either. How do these procedures differ from SMILE?

In PRK and LASEK procedures, the top layer of the cornea (epithelium) is removed manually. The exposed deeper layers of the cornea are then ablated using an excimer laser. The disadvantages: there is significantly greater

pain after the operation, and the healing process and the stabilization of visual acuity take a relatively long time. PRK and LASEK are not recommended for the treatment of severe nearsightedness. The risk of scarring (haze) is significantly higher. SMILE combines the benefits of PRK and LASEK (no flap incision) with those of LASIK and Femto-LASIK (minimum discomfort and rapid restoration of visual acuity) – but without any of their disadvantages.

How much experience has gone into ReLEx SMILE?

The name ZEISS has stood for quality and precision in optics since 1846. In 1986 ZEISS unveiled the first excimer laser for refractive correction of the eye. Over the last 25 years the company has been at the forefront of advances in the laser correction of vision defects. Femtosecond technology has been extensively trialed and has proven its clinical value over many years. Refractive lenticule extraction has been performed in controlled

clinical studies since 2006. The first patients have already undergone 5 years of post-treatment monitoring. ReLEx SMILE is now being deployed in many countries worldwide as a standard treatment method.

How can I find out if I am suitable for SMILE?

As with all other vision correction methods, you will have to undergo a detailed eye examination. The nature and degree of ametropia, the curvature and thickness of the cornea, as well as many other factors play a role. Your ophthalmologist will advise you personally after conducting a detailed examination.

After ReLEx SMILE, how long will it be before I can see properly without glasses or contact lenses and return to my normal routine?

Every healing process is different. In most cases visual acuity is very good one or two days after the operation and stabilizes within two to three weeks. Following PRK or LASEK, by comparison, full recovery can take up to three months. After ReLEx SMILE, you will generally be able to drive, work and do sports without glasses or contact lenses just a few days following treatment.

What are the risks?

Like all medical techniques, ReLEx SMILE is not without side effects. Only your physician can explain the individual risks and possible side effects to you and decide whether treatment with ReLEx SMILE is the right option for you.





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We make it visible.