ReLEx is the new generation of corneal refractive procedures. It combines state-of-the-art femtosecond technology with high-precision lenticule extraction aiming at providing minimally invasive refractive corrections in a single system. Visual outcomes from Carl Zeiss Meditec with ReLEx smile, a refractive lenticule is created in the intact cornea and removed via a small incision. Without ablation and without creating a flap. The new refractive ReLEx smile procedure offers clear clinical benefits.

ReLEx smile
Small incision, lenticule extraction

• Single-step therapy
• Full flapless
• Femtosecond lenticule extraction
• Clear visual outcomes

ReLEx flex
Femtosecond lenticule extraction

• Single-step therapy
• Femtosecond cuts the incision and the flap for access
• The unique minimally invasive treatment for laser vision correction

The surgery is:
• Flapless – first-time flapless laser vision correction
• All-flap – Femtosecond lenticule cutting substitutes conventional flap creation
• Single-step – one laser device, one integrated procedure

Your local contact:

Surgical instruments:

Phone: +81 3 33 55 0331
Japan

Surgical Ophthalmology:

Phone: +49 7364 20 6000
Germany

The step towards minimally invasive laser vision correction.

ReLEx is the new generation of corneal refractive procedures. It combines state-of-the-art femtosecond technology with high-precision lenticule extraction aiming at providing minimally invasive refractive corrections in a single system. Visual outcomes from Carl Zeiss Meditec with ReLEx smile, a refractive lenticule is created in the intact cornea and removed via a small incision. Without ablation and without creating a flap. The new refractive ReLEx smile procedure offers clear clinical benefits.

ReLEx smile
Flapless, All-femto, Single-step.
Experience the unique minimally invasive treatment for laser vision correction

In a single step, the VisuMax creates a refractive lenticule and a small incision. The removal of the lenticule changes the shape of the cornea, creating the required change to the refraction.

The lenticule is removed through the small incision. The deterioration of the transparency of the cornea is termed “full flap cut”.

ReLEx is a LASIK without flap and PRK without pain.

The incision is minimally invasive with a flap-like access cut, instead of a full flap.

The flap-like access cut is opened manually via the flap-like access cut.

The apical corneal tip is now completely exposed, and the incision can be made by the femtosecond laser.
The following results were achieved within a controlled clinical study for ReLEx smile for the correction of myopia and astigmatism. 260 eyes with a prospective inclusion of ±2.00 D or better from three study centers (Denmark, India and Egypt) were analyzed and evaluated.

- 85 % of all patients achieved an uncorrected visual acuity of 20/20 or better.
- Stability with almost no regression
- For 97 % of patients, refractive outcome is within ±0.5 D
- High stability with negligible regression
- Good refractive outcome
- High patient satisfaction

Prof. Markus Buma (Germany) and Prof. Walter Sekundo (Germany) belong to the small group of principal investigators for the ReLEx® femtosecond laser and were deeply involved in the development of the lenticule extraction technique ReLEx. They have published the 1st year results of the ReLEx flex cases treated in 2006 in part of the approval study – including the first eye ever treated – and conclude:

- ReLEx is a safe and effective procedure for the treatment of myopia
- High stability with negligible regression
- Good refractive outcome
- High patient satisfaction

References

3. Dan Z. Reinstein, London Vision Clinic, United Kingdom, “Advantages of ReLEx flex as a refractive procedure”, International Refractive User Symposium, Hangzhou, 2012 (fold-out page)
8. Eui-Sang Chung, Samsung Medical Centre, Korea, “Would it be possible to operate ReLEx® flex?”, 2002 International Refractive Surgery Symposium, Hangzhou, 2012 (fold-out page)
9. W. Jaspers, E. Bleeker, N. Smaling, M. van der Willik, C. van den Broek, “Refractive outcomes within ±0.5 D for 97% of eyes. Excellent predictability, results very close to target refraction, even for high myopia and myopic astigmatism.” 269 eyes with a preoperative BCVA of 20/25 or better; 85% of all patients achieved uncorrected visual acuity of 20/20 and better after 3 months.
25. Dan Z. Reinstein, London Vision Clinic, United Kingdom, “Advantages of ReLEx flex as a refractive procedure”, International Refractive User Symposium, Hangzhou, 2012 (fold-out page)
29. Dan Z. Reinstein, London Vision Clinic, United Kingdom, “Advantages of ReLEx flex as a refractive procedure”, International Refractive User Symposium, Hangzhou, 2012 (fold-out page)
The procedure is highly accurate and very neutral in terms of spherical aberration and independent of the amount of correction.

Dr. Ekktet Chansue, TRSC International LASIK Center, Thailand, June 2012

Safety, stability, predictability and visual acuity of ReLEx smile
Clinical results by Ekktet Chansue

Dr. Ekktet Chansue is founder and Medical Director of the TRSC International LASIK Center in Bangkok, Thailand. He was recognized as “The first surgeon to perform LASIK in Thailand” and is performing ReLEx smile since early 2011. He presents his results with ReLEx smile from a study including 326 eyes, with an average patient age of 31 years (range 18 to 56) and a mean pre-op SEQ of -4.95 D ± 1.89 D (range -10.50 D to -1.00 D).

- Convincing visual outcomes: 92% of the patients have UDVA 20/20 or better after already one month (pre-op 98% of patients had CDVA of 20/20 or better)
- Refractive outcome of 100% of all eyes is within ± 1 D after 3 months
- Highly predictable results
- Very stable results with almost no regression
- BCVA at 6 months: 95% of eyes have gained one line or stayed unchanged, no eye lost 2 or more lines
ReLEx smile and Femto-LASIK
A comparison by Eui-Sang Chung

Prof. Eui-Sang Chung is the Chief of the cornea division in Samsung Medical Center in Seoul, Korea's largest ophthalmological clinic serving over 100,000 outpatients and performing 6,000 operations and is Associate Professor of Ophthalmology, Sungkyunkwan University School of Medicine. He was the first surgeon to start ReLEx Flex in Korea and has been doing ReLEx smile since June 2011. In his study he compares the results of ReLEx smile and Femto-LASIK and concludes:

- ReLEx smile is a safe, predictable and effective procedure for treating myopia and myopic astigmatism
- Results for safety and refractive outcome are comparable to Femto-LASIK

### Results: Refractive outcome (MR SEQ percent within attempted)

<table>
<thead>
<tr>
<th></th>
<th>ReLEx smile</th>
<th>LASIK</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diopters</td>
<td>≤ -1.0</td>
<td>100%</td>
</tr>
<tr>
<td></td>
<td>-1.0 &lt; ≤ -0.5</td>
<td>90%</td>
</tr>
<tr>
<td></td>
<td>-0.5 &lt; ≤ 0.5</td>
<td>80%</td>
</tr>
<tr>
<td></td>
<td>0.5 ≤ &lt; 1.0</td>
<td>70%</td>
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<tr>
<td></td>
<td>1.0 ≤</td>
<td>60%</td>
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</tbody>
</table>

#### Diagrams

- Diagrams demonstrating the difference between ReLEx smile (top) and LASIK (bottom) in how the two procedures affect the anterior corneal nerve plexus.

### Results: Safety (change in CDVA)

<table>
<thead>
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<td></td>
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<td>60%</td>
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#### Diagrams

- Mean corneal sensation for 38 eyes after ReLEx smile compared with the corneal sensation after LASIK averaged over nine published studies.

Postoperative dry eye
A comparison between ReLEx smile and LASIK

Prof. Dan Z. Reinstein started performing ReLEx smile in 2010 and describes one of the biggest advantages of the flapless ReLEx smile procedure to be the reduction of postoperative dry eye compared with that observed after PRK and LASIK. In ReLEx smile the anterior corneal anatomy is preserved and the anterior stromal nerve plexus is disrupted significantly less since there are no sidecuts created – no flap is created; this should result in fewer dry eye symptoms and a faster recovery of postoperative patient comfort as has been found in preliminary studies where corneal sensation recovered to baseline levels after 3 months.

The cornea is one of the most densely innervated peripheral tissues in humans with the majority of nerves located in the anterior stroma, Bowman’s layer and epithelium. In LASIK, the anterior stromal nerve plexus is disrupted by the creation of a flap with further nerves being severed by the excimer laser ablation (similarly in PRK). Postoperatively, this means that the patient may have dry eye symptoms and decreased corneal sensitivity while the nerves regenerate. A number of studies have reported that corneal sensation takes at least 6 months to recover to normal levels after LASIK.

### Results: Safety (change in CDVA)

<table>
<thead>
<tr>
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<tr>
<td></td>
<td>3.0 ≤</td>
<td>80%</td>
</tr>
<tr>
<td></td>
<td>4.0 ≤</td>
<td>70%</td>
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#### Diagrams

- Mean corneal sensation for 38 eyes after ReLEx smile compared with the corneal sensation after LASIK averaged over nine published studies.
**Biomechanical stability**

**Advantages of ReLEx smile as a refractive procedure**  

Dr. Cynthia Roberts is Professor of Ophthalmology and Biomedical Engineering at the Ohio State University. To compare the biomechanical consequences of ReLEx smile to a standard LASIK procedure, she and her colleagues (Abhijit Sinha Roy, PhD and William Joseph Dupps, Jr., MD, PhD of the Cleveland Clinic Foundation) generated a non-linear, anisotropic, fiber-dependent material model. Biomechanical properties were taken from the literature, including reduction in elastic modulus within the LASIK flap and at the interface. ReLEx smile was assumed to have less reduction in modulus as a function of the ratio of side cut and at the interface. ReLEx smile was assumed to have less reduction in elastic modulus within the LASIK flap

Biomechanical stability was calculated within the flap (LASIK) / cap area (ReLEx smile) arc length between LASIK and ReLEx smile. Stress distribution reduction in modulus as a function of the ratio of side cut and at the interface. ReLEx smile was assumed to have less reduction in elastic modulus within the LASIK flap

Dr. Cynthia Roberts is Professor of Ophthalmology and Biomedical Engineering at the Ohio State University.

**Methods with the following results:**

- ReLEx smile has stress distribution in the cap and the stromal bed that is much closer to the unoperated state (of equivalent thickness) than LASIK.
- LASIK has greatly reduced peak stress within the flap compared to the preoperative state due to cutting of many tension-bearing anterior lamellae (Middle upper row).
- LASIK has greatly increased peak stress at the level of residual stromal bed due to inability of the flap to carry the stress which is then transmitted into the corneal bed (Middle lower row).

**Biomechanical stability Superior differences of ReLEx smile over LASIK**

Profs. Cynthia Roberts, Ohio State University, USA, June 2012

- LASIK has greatly increased peak stress at the level of residual stromal bed due to inability of the flap to carry the stress which is then transmitted into the corneal bed (Middle lower row).

The absence of a flap will result in increased biomechanical integrity for two reasons:

- Anterior stromal lamellae are stronger than posterior stromal lamellae, therefore the postoperative cornea will be stronger after ReLEx smile as the anterior stromal lamellae remain intact. The opposite is true in LASIK where the biomechanical stability of the cornea effectively relies only on the residual posterior stromal lamellae.
- Vertical cuts (e.g. flap sidecut) have more biomechanical impact than horizontal cuts (Figure 2), meaning that the ReLEx smile procedure minimizes the biomechanical change to the cornea. This also allows the lenticule to be removed from deeper in the cornea to take further advantage of the stronger anterior stromal lamellae.

![Figure 1](Image 654x161 to 891x306)

Figure 1: Percentage increase in central corneal strain on human cadaver eyes after the creation of a LASIK flap, a sidecut only or delamination only at both 90 μm and 160 μm. Delamination only resulted in a lower increase in strain compared to the other procedures at both depths.

<table>
<thead>
<tr>
<th>Procedure</th>
<th>90 μm</th>
<th>160 μm</th>
</tr>
</thead>
<tbody>
<tr>
<td>LASIK Flap</td>
<td>9%</td>
<td>32%</td>
</tr>
<tr>
<td>Sidecut Only</td>
<td>9%</td>
<td>33%</td>
</tr>
<tr>
<td>Delamination Only</td>
<td>5%</td>
<td>5%</td>
</tr>
</tbody>
</table>

**Figure 2**: Percentage increase in central corneal strain on human cadaver eyes after the creation of a LASIK flap, a sidecut only or delamination only at both 90 μm and 160 μm. Sidecut and whole flap resulted in a similar increase in strain with significantly greater increase for the 160 μm depth. Increase in strain was the same at both depths when the delamination cut only was performed. Applying this finding to ReLEx smile, since no anterior corneal sidecut is created, there will be slightly less increase in corneal strain in ReLEx smile compared to thin flap LASIK and a significant difference in corneal strain compared to LASIK with a thicker flap.

Reference see page 11

**Reference see page 11**
A ReLEx smile Case
By Dan Z. Reinstein

Patient: Right eye of a 40 year old (Caucasian) male with high myopia.

Treatment planning: Central corneal thickness was 529 μm, lenticule thickness was 150 μm (intended correction was plano, 6-mm optical zone), cap thickness was 120 μm, to leave 259 μm of residual stroma. As no flap was created, there was also 65 μm of untouched anterior stroma, so the total stroma was 324 μm. A 3-mm supero-temporal incision was used to remove the lenticule.

Treatment summary:
- Superbly accurate refractive correction
- CDVA same as pre-op within first week
- UDVA same as pre-op CDVA
- Contrast sensitivity slightly improved
- Corneal sensation only slightly reduced at 1 day (compared with zero at 1 day after LASIK) and fully recovered by 1 month (compared with 6 months after LASIK)
- Large, well-centered optical zone on topography

Fluorescein slit lamp photo at the one day post-op in which the boundary of the lenticule can be seen to be well centered on the corneal vertex. The supero-temporal 3-mm incision can be seen.

Contrast sensitivity before and 3 months after ReLEx smile.

Atlas tangential curvature topography maps before (top left) and 3 months after (bottom left). The difference map is shown on the right demonstrating the well-centered 6-mm optical zone.

*outside approved treatment range, clinical study software was used

Prof. Dan Z. Reinstein, London Vision Clinic, United Kingdom, August 2012
Surface quality of extracted ReLEx smile lenticule using environmental SEM technique

The lenticule extracted from patients were preserved and prepared for imaging. Environmental or “wet” scanning electron microscopy was performed on lenticule anterior, posterior and edge surfaces.

- Very smooth cutting surface
- Lenticule removal without residual pieces
- High quality of surface and edges, appropriate for quality of vision
- Anterior and posterior lenticule cut refer to each other, appropriate for refractive correction

Lenticule

Anterior lenticule surface – low magnification

Posterior lenticule surface – low magnification

Anterior lenticule surface – high magnification

Edge and anterior surface of lenticule – high magnification