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## ReLEX smile

### Flapless. All-femto. Single-step.

Experience the unique minimally invasive treatment for laser vision correction



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We make it visible.

## ReLEX

### The step towards minimally invasive laser vision correction

» ReLEX is LASIK without flap and PRK without pain. «  
**Dr. Rupal Shah**, New Vision Laser Centers, India, September 2011

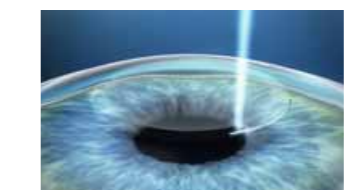
ReLEX is the new generation of corneal refractive procedures. It combines state-of-the-art femtosecond technology with high-precision lenticule extraction aiming at providing minimally invasive refractive correction in a single system: VisuMax® from Carl Zeiss. With ReLEX smile a refractive lenticule 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.

**The surgery is:**

- **Flapless** – creating a small incision rather than a full flap
- **All-femto** – femtosecond lenticule cutting substitutes excimer tissue ablation
- **Single-step** – one laser device, one integrated procedure

### ReLEX smile

Small incision lenticule extraction



In a single step, the VisuMax creates a refractive lenticule and a small incision of less than 4 mm in the intact cornea – virtually regardless of the ambient conditions or corneal structure.



The lenticule is removed through the small incision. The deterioration of the biomechanics of the cornea is minimal. No flap is cut.

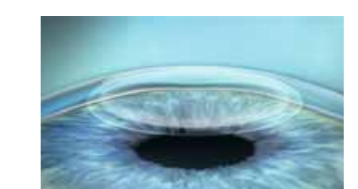


The removal of the lenticule changes the shape of the cornea, creating the required change to the refraction.

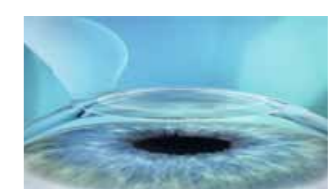
ReLEX smile is a further development of the ReLEX flex technique. ReLEX flex only distinguishes by the fact that for lenticule extraction a flap-like access cut is created instead of a small incision.

### ReLEX flex

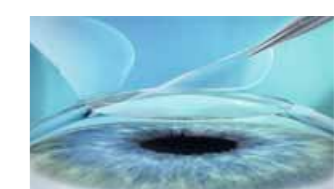
Femtosecond lenticule extraction



In a single step, the VisuMax creates the lenticule and the flap-like access cut in the otherwise intact cornea. The surgeon benefits from the smaller incision diameter in comparison to that of a LASIK procedure.



The flap-like access cut is opened and folded back.



The lenticule is removed manually via the flap-like access cut.



The upper corneal layer is now flipped back. The changed form of the cornea corrects the refraction error.

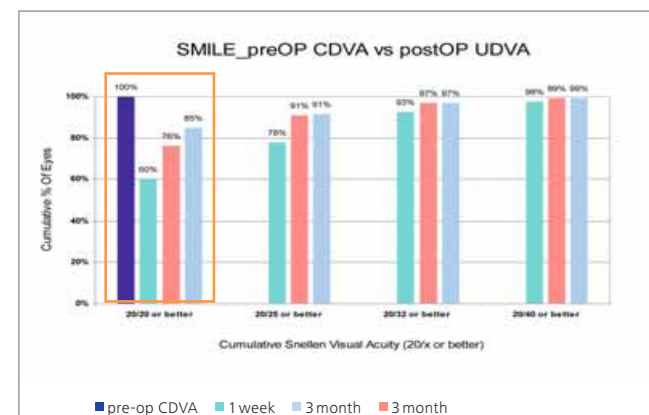
## ReLEx smile Multicenter study results<sup>2</sup>

» ReLEx is an interesting and an exciting new paradigm shift in refractive surgery that we are going to be able to be part of. «

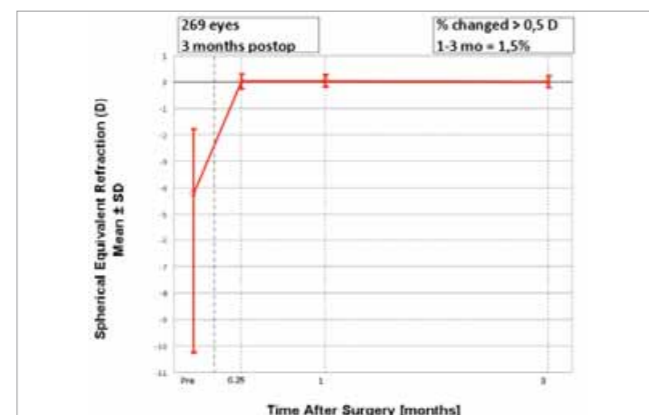
Dr. Rupal Shah, New Vision Laser Centers, India, June 2012

The following results were achieved within a controlled clinical study for ReLEx smile for the correction of myopia and astigmatism. 269 eyes with a preoperative BCVA of 20/20 or better from three study centers (Denmark, India and Egypt) were analyzed and evaluated.

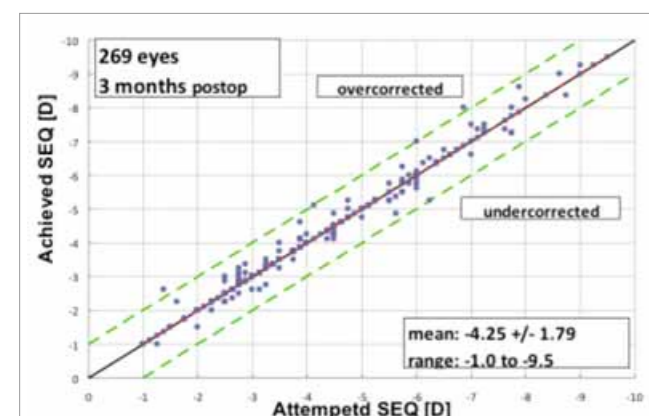
- 85 % of all patients achieved uncorrected visual acuity of 20/20 and better after 3 months
- Stability with almost no regression
- Results are very close to target refraction
- For 97 % of eyes refractive outcome is within +/- 0,5 D



**Effectiveness:** Visual outcome shows high rates of 20/20 UDVA.



**Stability:** Almost no regression over time.



Excellent predictability, results very close to target refraction, even for high myopic corrections

<sup>2</sup> Reference see page 11

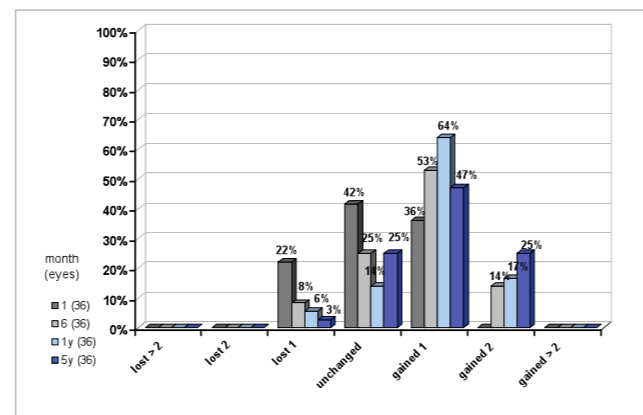
## ReLEx flex Long-term study results<sup>3</sup>

» Our 5-years results confirm ReLEx flex to be a predictable, safe and stable procedure for correction of myopia and myopic astigmatism. «

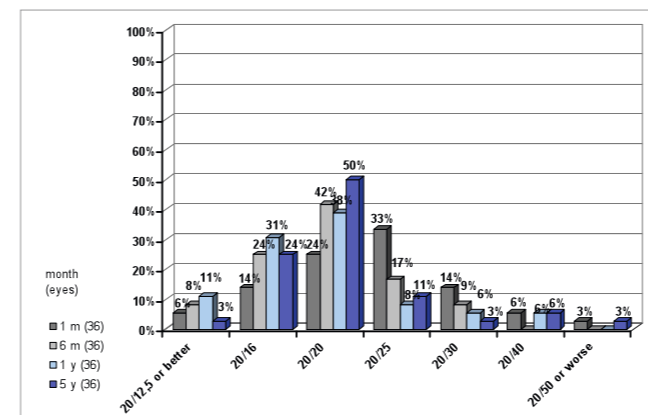
Prof. Walter Sekundo, Department of Ophthalmology, Philipps University Marburg, Germany, August 2012

Prof. Marcus Blum (Germany) and Prof. Walter Sekundo (Germany) belong to the small group of principal investigators for the VisuMax<sup>®</sup> femtosecond laser and were deeply involved in the development of the lenticule extraction technique ReLEx. They have published the 5-year results of the initial ReLEx flex cases treated in 2006 as part of the approval study – including the first eyes ever treated – and conclude:

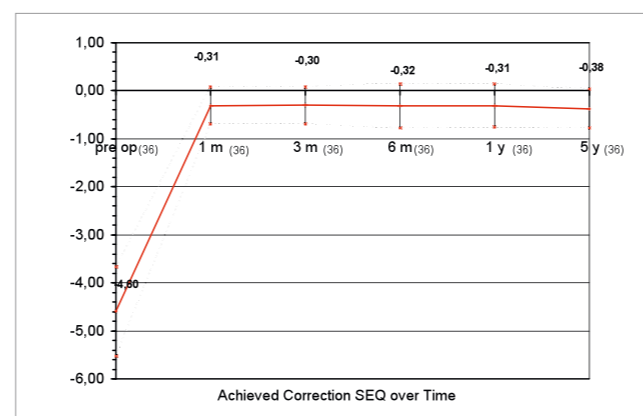
- ReLEx is a safe and effective procedure for treatment of myopia
- High stability with negligible regression
- Good refractive outcome
- High patient satisfaction



**Safety:** Change in CDVA: 97 % of eyes no loss of lines; 72 % of eyes even gained lines



**Efficacy:** 77 % of eyes achieved UCVA of 20/20 or better; 88 % of eyes have an UCVA of 20/25 or better



**Stability:** Almost no regression over time.

Please note that the treatments were aimed for slight undercorrection

<sup>3</sup> Reference see page 11

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- Source 2 Jesper Hjortdal, Rupal Shah, Osama Ibrahim, Controlled Multicenter Study, data on file, 2011 (fold-out page)
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- Source 15 Cynthia Roberts, Ohio State University, "Biomechanical advantages of ReLEx smile as a refractive procedure", International Refractive User Symposium, Cyprus, 2012, personal communication 2012 (page 6)
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- Source 19 Dan Z. Reinstein, London Vision Clinic, United Kingdom, personal communication 2012 (page 8, 9)
- Source 20 Sonia Yoo, Bascom Palmer Eye Institute, USA, Lenticule Imaging Project: Surface Quality of Extracted SMILE Lenticules Using "Environmental" SEM Technique, AAO Orlando 2011, CZM Evening Symposium (page 10)

# Safety, stability, predictability and visual acuity of ReLEx smile

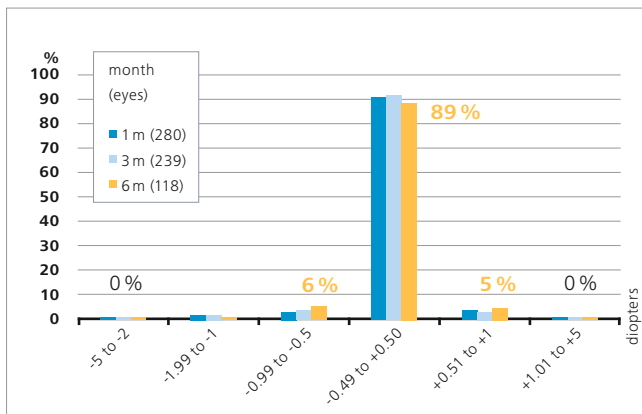
Clinical results by Ekket Chansue<sup>1</sup>

» The procedure is highly accurate and very neutral in terms of spherical aberration and independent of the amount of correction. «

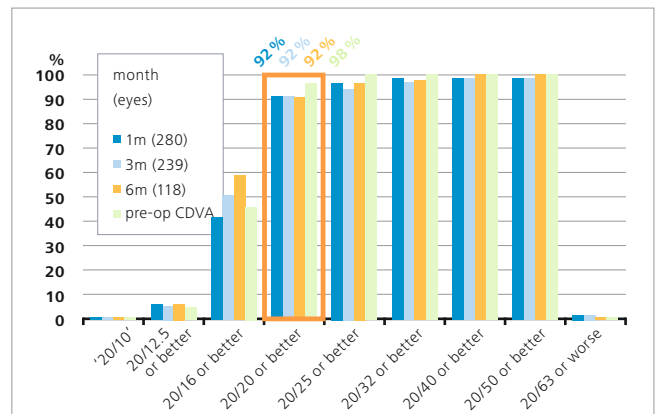
Dr. Ekket Chansue, TRSC International LASIK Center, Thailand, June 2012

Dr. Ekket 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  $\pm$  1.89 D (range -10.50 D to -1.00 D).

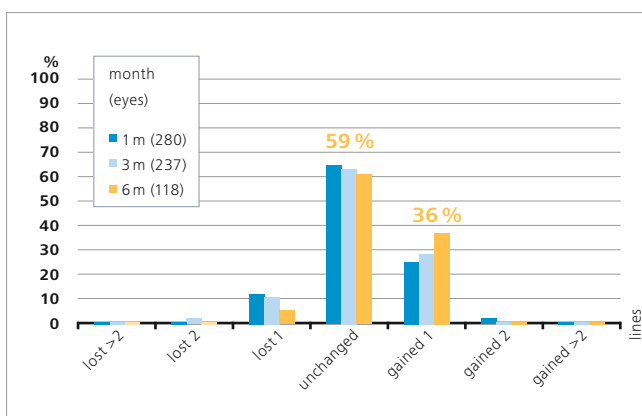
- Convincing visual outcomes: 92 % of the patients have UDVA 20/20 or better after already one month (pre-op 98 % of patients had CDVA of 20/20 or better)
- Refractive outcome of 100 % of all eyes is within  $\pm$  1 D after 3 months
- Highly predictable results
- Very stable results with almost no regression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



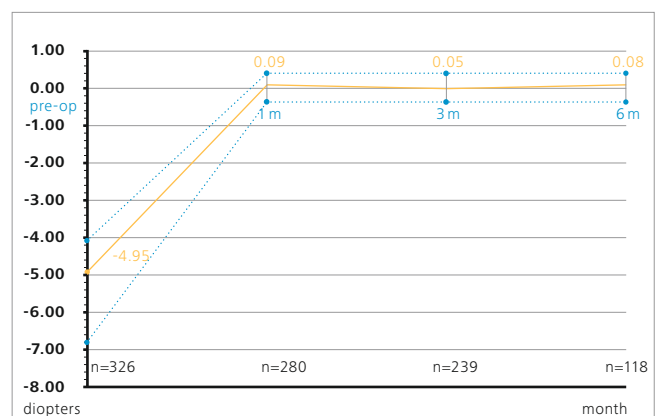
Refractive outcome: percentage within attempted



Effectiveness: pre-op CDVA vs. post-op UDVA



Safety: change in CDVA



Stability

<sup>1</sup> Reference see page 11

# ReLEx smile and Femto-LASIK

## A comparison by Eui-Sang Chung<sup>4</sup>

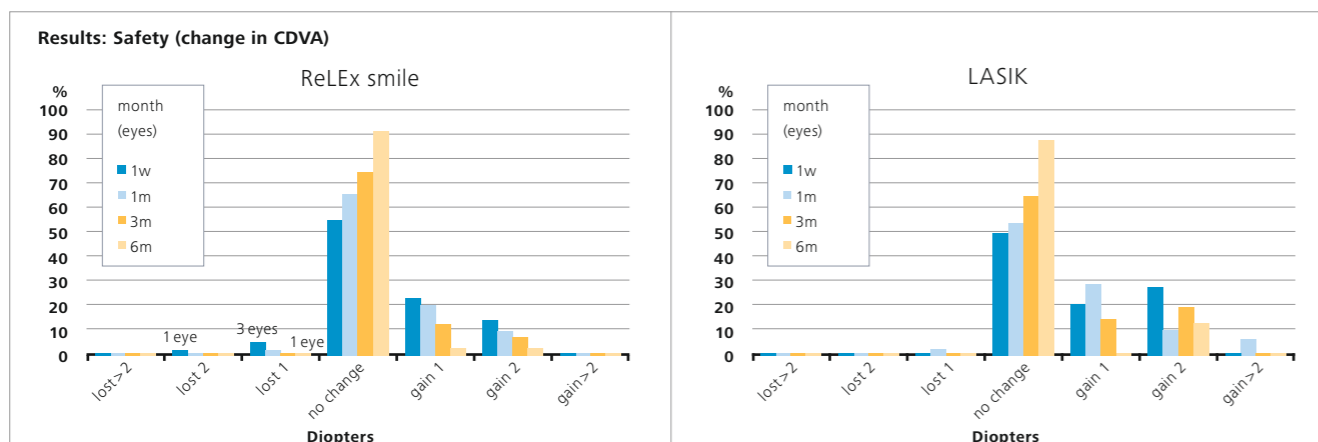
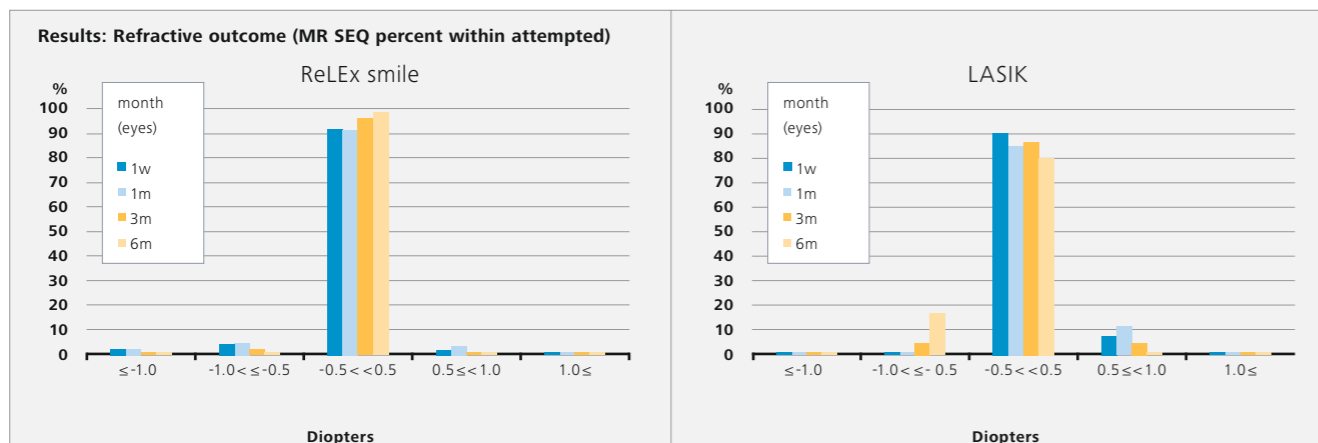
Prof. Eui-Sang Chung is the Chief of the cornea division in Samsung Medical Center in Seoul, Korea's largest ophthalmological clinic serving over 100,000 outpatients and performing 6,000 operations and is Associate Professor of Ophthalmology, Sungkyunkwan University School of Medicine. He was the first surgeon to start ReLEx smile 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 is the right direction of Laser Vision Correction. «

Prof. Eui-Sang Chung, Samsung Medical Center, Seoul, Korea, May 2012

- 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

	ReLEx smile	LASIK
Age (years)	29.55 ± 5.59 (19 ~ 41)	28.67 ± 6.30 (18 ~ 37)
MRSE (diopters)	-5.01 ± 2.55 (1.40 ~ 11.625)	-5.71 ± 2.26 (1.925 ~ -10.125)
Eyes	81 eyes of 41 patients	38 eyes of 28 patients



<sup>4</sup> Reference see page 11

# Postoperative dry eye

## A comparison between ReLEx smile and LASIK<sup>5</sup>

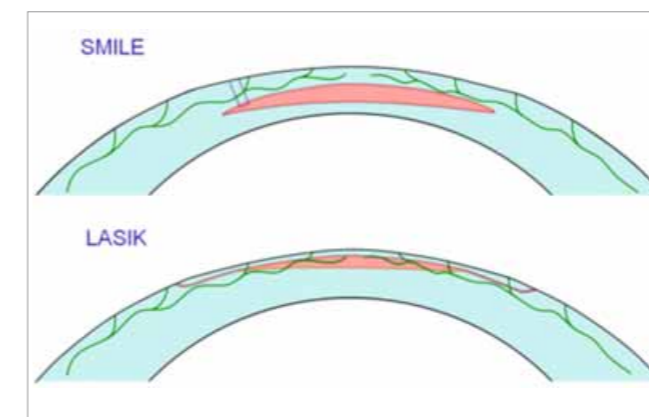
Prof. Dan Z. Reinstein started performing ReLEx smile in 2010 and describes one of the biggest advantages of the flapless ReLEx smile procedure to be the reduction of postoperative dry eye compared with that observed after PRK and LASIK. In ReLEx smile the anterior corneal anatomy is preserved and the 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.

» Leaving the anterior stromal nerve plexus of the cornea intact makes ReLEx smile into the least traumatic corneal refractive procedure ever – our studies appear to confirm drastically reduced dry eye side effects compared to LASIK. «

Prof. Dan Z. Reinstein, London Vision Clinic, United Kingdom, June 2012

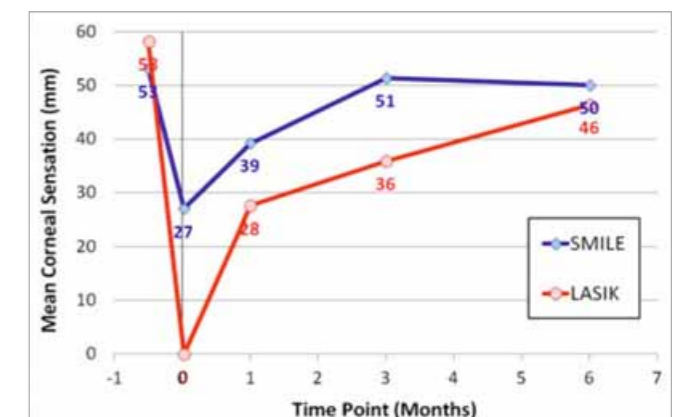
- ReLEx smile reduced postoperative dry eye compared to that observed after LASIK and PRK
- Faster recovery of corneal sensation to baseline level observed after ReLEx smile
- Significantly less disruption of anterior stromal nerve plexus with ReLEx smile compared to LASIK

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.<sup>6-14</sup>



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

<sup>5-14</sup> Reference see page 11



Mean corneal sensation for 39 eyes after ReLEx smile compared with the corneal sensation after LASIK averaged over nine published studies.

# Biomechanical stability

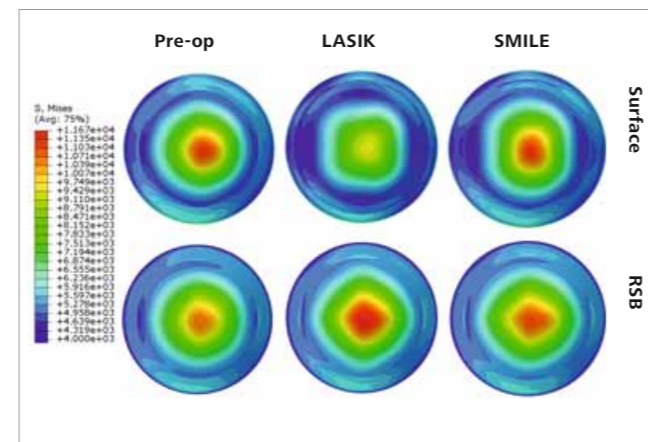
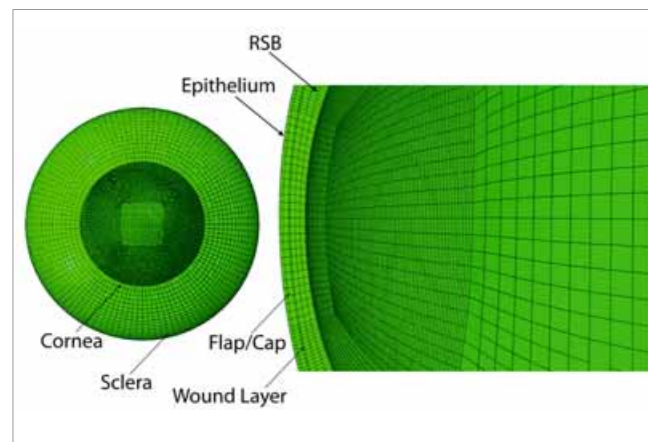
## Advantages of ReLEx smile as a refractive procedure<sup>15</sup>

» The biomechanical aspects of ReLEx smile are very exciting. Our model confirms that the biomechanical stability of the anterior corneal layer is much less affected with ReLEx smile compared to LASIK due to the innovative approach of minimizing the number of anterior lamellae that are cut. «

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

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 arc length between LASIK and ReLEx smile. Stress distribution was calculated within the flap (LASIK)/cap area (ReLEx smile) and within the stromal bed and compared between both 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 stromal bed (Middle lower row)



The top row shows the stress maps in the anterior corneal layers near the surface in an unoperated state (left), after making a LASIK flap (middle), and after a ReLEx smile cap (right). The bottom row shows the corresponding stress maps at the level of the residual stromal bed (RSB). Note that ReLEx smile is closer to pre-op than LASIK.

<sup>15</sup> Reference see page 11

# Biomechanical stability

## Superior differences of ReLEx smile over LASIK<sup>16</sup>

» ReLEx smile represents the ultimate dream of Prof Jose Ignacio Barraquer Moner: minimally invasive keratomileusis. «

Prof. Dan Z. Reinstein, London Vision Clinic, United Kingdom, June 2012

Prof. Dan Z. Reinstein is convinced that the extra biomechanical stability provided by this flapless minimally invasive procedure will bring a number of benefits.

Figure 1 shows diagrams of intact stromal lamellae after LASIK and ReLEx smile highlighting the anterior lamellae that remain intact after ReLEx smile. Residual stromal thickness (RST) calculations are shown for a 500 µm cornea with a 100 µm ablation/lenticule and 120 µm flap/cap thickness. The LASIK RST of 280 µm consists only of posterior stroma, whereas the ReLEx smile RST has the same 280 µm of posterior stroma, but also has 70 µm of anterior stroma, which makes a total of 350 µm of stroma. However, since anterior stroma is 50 % stronger than posterior stroma, a further 35 µm (50 % of the 70 µm of anterior stroma) can be added to make an effective total of 385 µm.

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

- Anterior stromal lamellae are stronger than posterior stromal lamellae<sup>17</sup>, 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<sup>18</sup> (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.

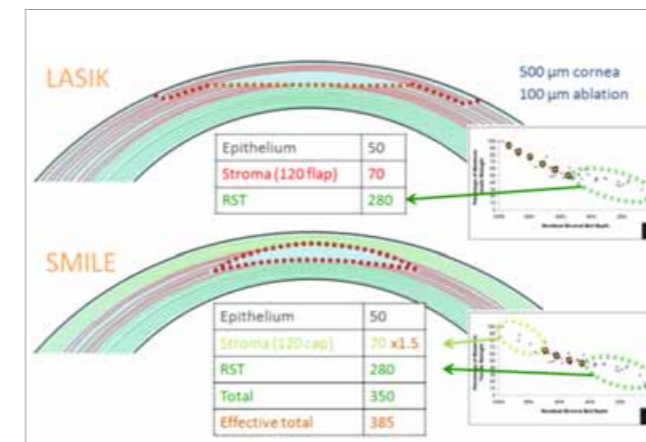


Figure 1

	90 µm	160 µm
LASIK Flap	9 %	32 %
Sidecut Only	9 %	33 %
Delamination Only	5 %	5 %

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.<sup>18</sup>

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.

<sup>16-18</sup> Reference see page 11

# A ReLEX smile Case

By Dan Z. Reinstein<sup>19</sup>

» This patient trains the military in high security lock mechanisms; he was told that laser couldn't help him. Thanks to the enhanced biomechanics of ReLEX smile he was made 20/20 from -10D in one shot. «

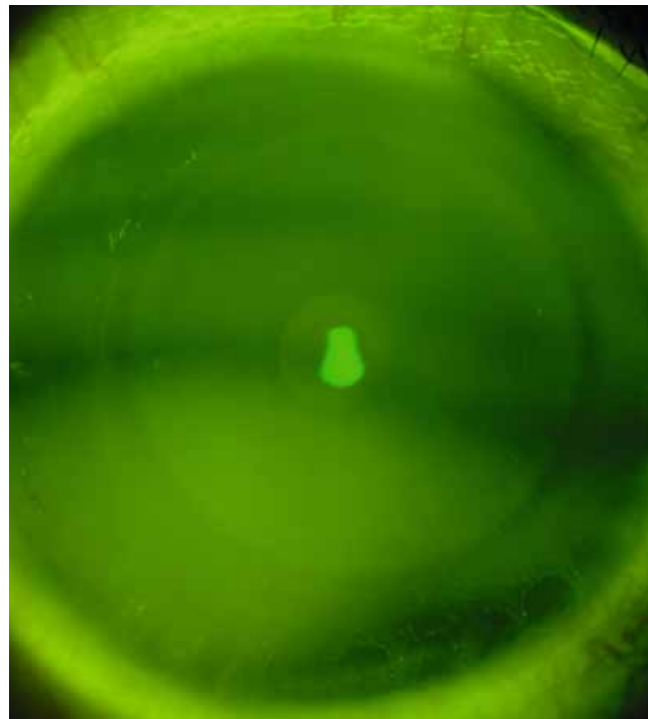
Prof. Dan Z. Reinstein, London Vision Clinic, United Kingdom, August 2012

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

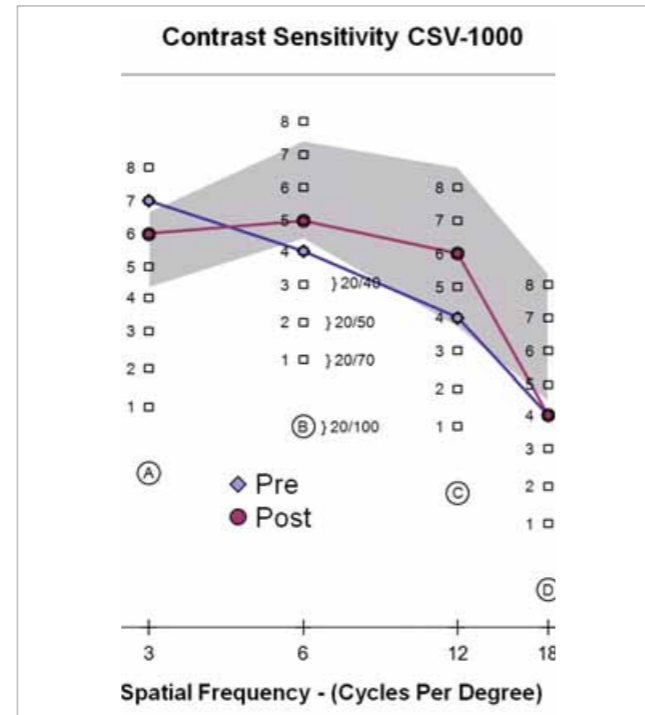
**Treatment planning:** Central corneal thickness was 529 µm, lenticule thickness was 150 µm (intended correction was plano, 6-mm optical zone), cap thickness was 120 µm, to leave 259 µm of residual stroma. As no flap was created, there was also 65 µm of untouched anterior stroma, so the total stroma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

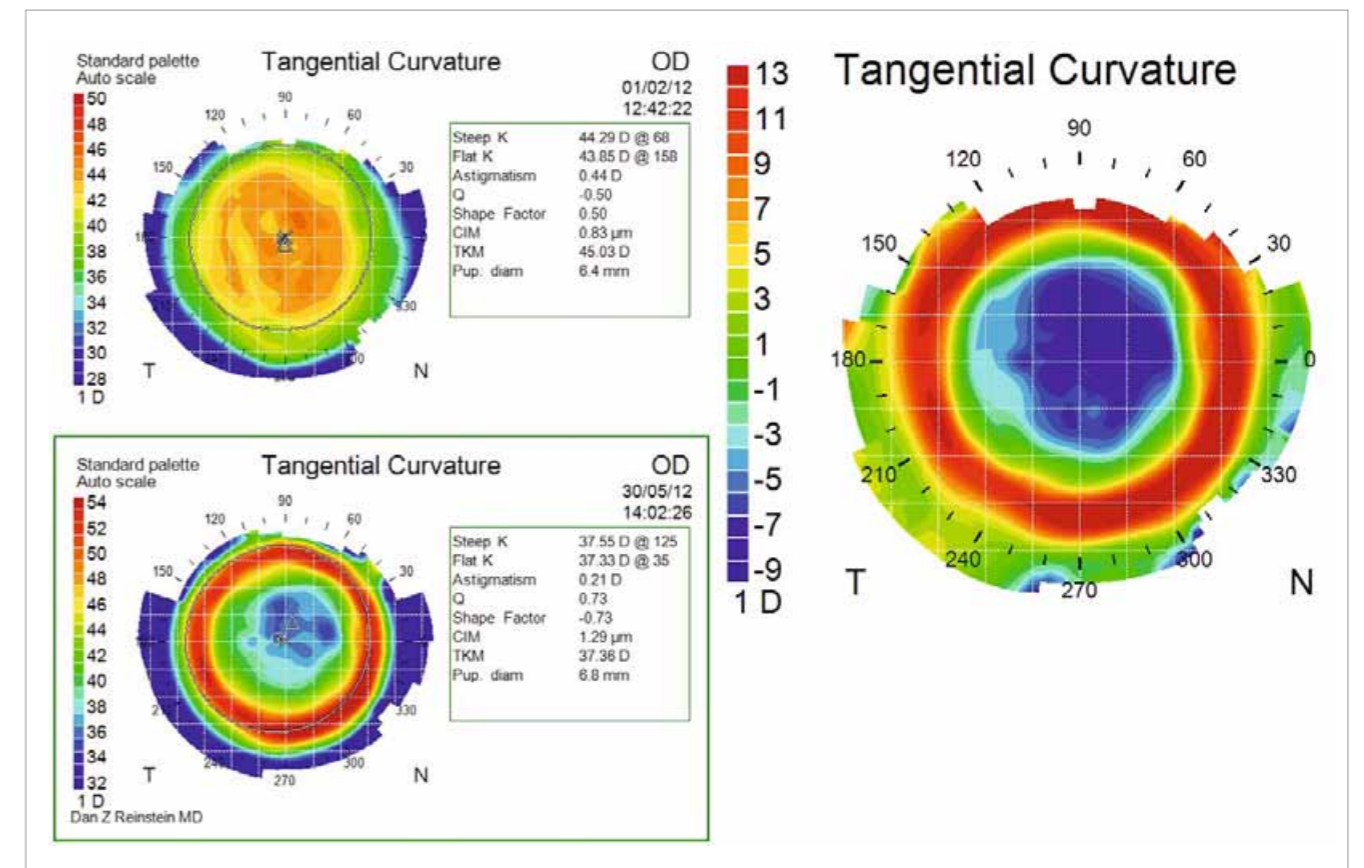


Fluorescein slit lamp photo at the one day post-op in which the boundary of the lenticule can be seen to be well centered on the corneal vertex. The supero-temporal 3-mm incision can be seen.



Contrast sensitivity before and 3 months after ReLEX smile.

	Pre-op	1 day	1 week	1 month	3 months
Manifest refraction	-10.25* -0.50 x 118 (target plano)	+1.25 -0.50 x 15	+0.50 -0.25 x 30	+0.50 -0.75 x 75	+0.50 -0.50 x 74
CDVA	20/16	20/20	20/12.5	20/16	20/16
UDVA	-	20/20	20/16	20/16	20/16
Contrast sensitivity	Low normal range	Slightly better than pre-op	Slightly better than pre-op	-	Slightly better than pre-op
Corneal sensation	60	40	50	60	60



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

<sup>19</sup> Reference see page 11

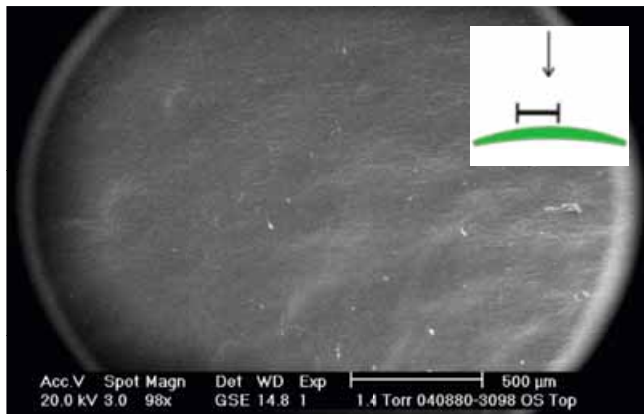
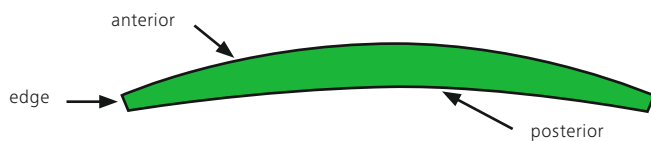
# Surface quality of extracted ReLEx smile lenticule

using environmental SEM technique<sup>20</sup>

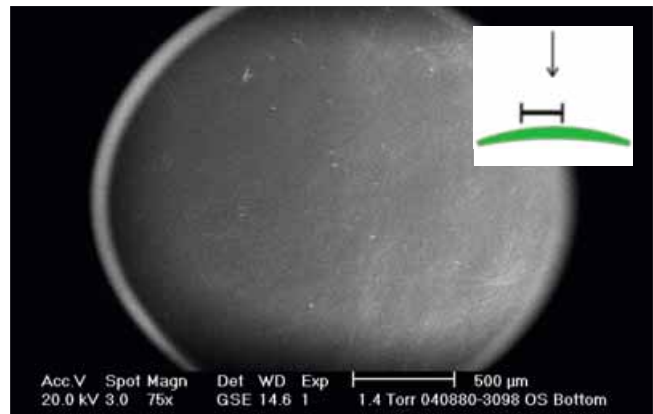
The lenticule extracted from patients were preserved and prepared for imaging. Environmental or “wet” scanning electron microscopy was performed on lenticule anterior, posterior and edge surfaces.

- 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

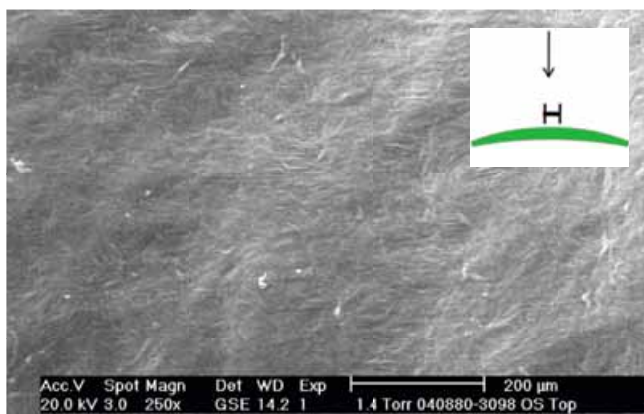
## Lenticule



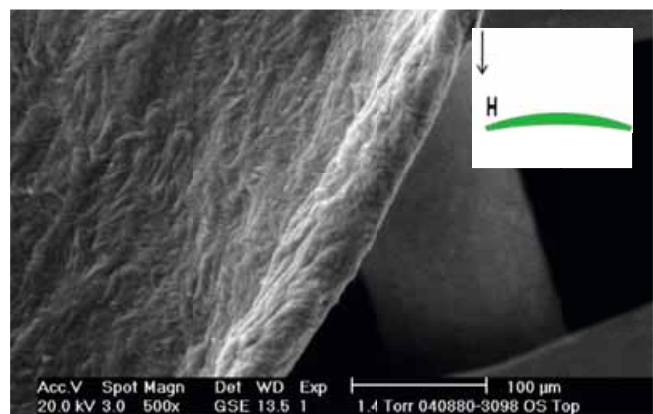
Anterior lenticule surface – low magnification



Posterior lenticule surface – low magnification



Anterior lenticule surface – high magnification



Edge and anterior surface of lenticule – high magnification

<sup>20</sup> Reference see page 11