

Cataract & Refractive Surgery

EUROPE

TODAY

ReLEx smile

Flapless. All-femto. Single-step.



Laser vision correction beyond LASIK.

ReLEx smile

Flapless. All-femto. Single-step.

CONTENTS

- 4** A Winning Combination: Femtosecond Lasers and Flapless Laser Vision Correction

Reviewed by Walter Sekundo, MD

- 6** ReLEx Versus Femtosecond LASIK: A Comparison

By Osama Ibrahim, MD

- 8** ReLEx smile: An Outstanding Treatment for Low, Moderate, and High Myopia

By Rupal Shah, MD

- 11** My New Clinical Standard is ReLEx smile

By Jesper Hjortdal, MD, PhD

- 13** The Importance of ReLEx in Our Current Laser Vision Correction Business

By Ekket Chansue, MD

The Numerous Benefits of ReLEx

Impressive for low, moderate, and high myopic corrections.

ReLEx, a procedure that is exclusively used with the VisuMax femtosecond laser (Carl Zeiss Meditec, Jena, Germany), takes a major step toward minimally invasive laser vision correction surgery. Not only does ReLEx use tissue removal instead of tissue ablation, which is the method of correction used for LASIK and PRK techniques, but it further distinguishes itself from these techniques because only one laser system is used for the entire procedure.

By eliminating the need for complex nomograms and fluence tests, the ReLEx procedures significantly facilitates the refractive surgery workflow. ReLEx is wavefront-optimized from the outset, and the VisuMax femtosecond laser transfers the precalculated lenticule profile into the intact cornea. Very little induction of spherical aberration across the entire optical zone was observed. Additionally, surgical results are independent of corneal hydration and environmental conditions due to the use of femtosecond-cutting instead of ablation.

ReLEx is available in two options, ReLEx flex and ReLEx smile. ReLEx flex is designed to preserve biomechanical stability and achieve perfect positioning of the lenticule in a flap-like access cut. Both the lenticule cut and the access cut are created in a single step using optimized cut geometries, leaving a large part of the cornea untouched by the treatment. Meanwhile, ReLEx was advanced to the latest procedure ReLEx smile. Additionally to the known advantages, this new minimally invasive treatment ReLEx smile is characterized by extracting the lenticule through a small incision. Thus, ReLEx smile eliminates the need for cutting a flap or flap-like access as with ReLEx flex or other refractive treatment methods.

NUMEROUS BENEFITS

As the least invasive laser vision correction procedure available today, ReLEx has several benefits. For the surgeon, there is a time-saving benefit because the patient can be treated under one laser system. The second benefit of ReLEx is that there is no longer a need to ablate the tissue, eliminating an entire surgical step (Figure 1). Shorter treatment times and the accuracy of the lenticule extraction increase treatment efficiency, especially for high refractive errors.

The third benefit of ReLEx is that the VisuMax creates a lenticule within the intact cornea soundlessly and minimally



Figure 1. ReLEx has a shorter procedure time compared to Femto-LASIK.

invasively. The method is not only more comfortable for the patient, but it also minimizes the stress that he or she experiences. Fourth, high-precision optics of the VisuMax femtosecond laser enable an extremely focused laser beam, permitting very low laser pulse energy at a high shot frequency and tight spot spacing for precise cut control at exactly the desired corneal depth.

CONCLUSION

With the recent introduction of ReLEx, the VisuMax femtosecond laser system fulfils the mission for which it was originally designed: refractive correction with lenticule extraction.

This compilation of articles explores the benefits of ReLEx smile, the latest technique to facilitate lamellar extraction through a small incision, and recaps the rationale behind ReLEx flex. The surgeons who have contributed to this supplement—Walter Sekundo, MD; Osama Ibrahim, MD; Rupal Shah, MD; Jesper Hjortdal, MD, PhD; and Ekket Chansue, MD—have extensive experience with both techniques.

A Winning Combination: Femtosecond Lasers and Flapless Laser Vision Correction

With the right candidate, ReLEx provides many advantages over PRK or LASIK.

REVIEWED BY WALTER SEKUNDO, MD

Refractive surgery is still a relatively new frontier in ophthalmology. It began as a radical idea in the late 1980s and early 1990s but it quickly transformed into a trend that is acceptable worldwide and boasts impressive postoperative results. Today, millions of people undergo elective laser vision correction to fix refractive errors in the hopes of achieving spectacle independence. LASIK and PRK are exceptional procedures with outstanding safety and efficacy, but there are now other laser vision correction options for our patients.

One newer choice in refractive surgery is ReLEx, a less-invasive, highly precise form of laser vision correction that is performed completely inside the intact cornea with the VisuMax femtosecond laser (Carl Zeiss Meditec, Jena, Germany). This innovation allows the surgeon to create a 3-D cut within the cornea, intrinsically increasing predictability of refractive surgery due to less tissue destruction and better ambient conditions.

OVERVIEW

Marcus Blum, MD, of Erfurt, Germany, and I belong to a small group of principal investigators for the VisuMax femtosecond laser and have been using this platform for refractive surgery since 2007. We also helped develop the company's original lenticule extraction technique, femtosecond lamellar extraction (ReLEx flex). Now, Carl Zeiss Meditec has a successive lenticule extraction technique, ReLEx smile, using small incision lamellar extraction. This method has eliminated the need for flap creation. Instead of a corneal flap, the surgeon creates a small incision and manually extracts the intrastromal lenticule. For a video demonstration of ReLEx smile, visit <http://eyetube.net/?v=ginuh>.

The company has branded both techniques under the general name of ReLEx. This technique is unique to other laser procedures because it uses precise laser cutting patterns instead of ablation patterns typical of LASIK and PRK procedures. One advantage of ReLEx is that the same laser can be used throughout the entire procedure, saving time in the operating room and eliminating the need to move the patient between two laser platforms.

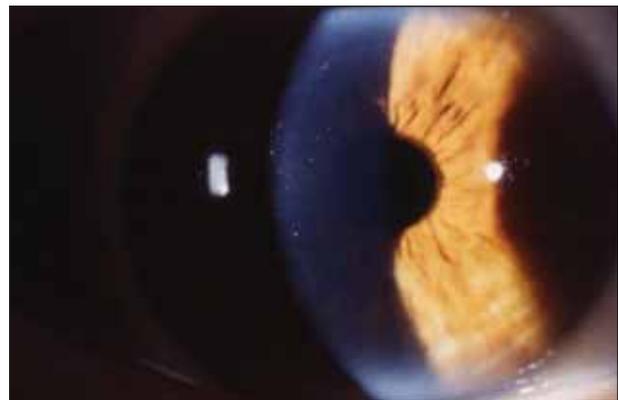


Figure 1. At 3-month follow-up after ReLEx smile, only a faint superior incision site is detectable at the slit lamp.

LASER QUALITY

By today's increasing standards of patient care, I feel that the VisuMax is the only machine that can be used for full refractive purposes. My initial experience is with ReLEx flex. In the beginning, I used the 200-kHz VisuMax femtosecond laser for this procedure, which includes creation of two cuts, one at the bottom and one at the top of the refractive lenticule. Once the lenticule is removed, the flap is repositioned and the procedure concludes.

ReLEx flex treatments with the 200-kHz laser were efficient and lasted between 50 and 60 seconds, depending on the lenticule and flap diameter. My surgical results were quite impressive. Of the more than 100 commercial patients I treated with the 200-kHz machine, all achieved a visual acuity of 20/40 or better at 1 month and roughly 80% were 20/20 or better by the last follow-up at 3 months.

In March 2011, I upgraded to the 500-kHz VisuMax, which has allowed me to achieve even more impressive results for my patients. Most notably, virtually all patients treated are 20/25 at 1 week and 20/20 unaided at the second follow-up at 1 month. Surgically, what I am most impressed with is the improved quality of the cut within the cornea and the speed of the treatment. With the

500-kHz engine, the treatment is done within 40 seconds. Thus, I have been able to reduce laser energy, leading to faster visual recovery. Now, I can also treat patients who I would have previously found unsuitable for this procedure with the 200-kHz laser, such as those who I did not feel could lay still for 60 seconds.

The more important issue, however, is that the 500-kHz laser also handles the corneal tissue more delicately, which combined with the quality of the corneal cut makes it easier to extract the lenticule. I performed ReLEx smile as a study procedure with the 200-kHz laser, but today it is my procedure of choice with the 500-kHz laser, in particular for moderate and high myopia.

Because of the increased stability of the achieved refractive correction, I can also perform ReLEx in patients with up to -10.00 D of myopia, which otherwise would have received a phakic IOL. In fact, this week I saw a patient 3 months after ReLEx smile for -9.50 D of myopia. He had an impressive distance UCVA of 20/12.5 and no night driving problems despite a 6.8-mm scotopic pupil.

INCISION SIZE

The nice thing about ReLEx smile is that there is no longer a need for the corneal flap. Therefore, this all-in-one laser procedure reduces the complications associated with the flap cut, including incomplete or irregular corneal flaps, thin or small corneal flaps, buttonholes, and free caps.

ReLEx smile can be performed using either one or two incisions. I prefer making two small incisions (3–5 mm) at the 12- and 6-o'clock positions. The use of two incisions enhances the flow of fluid within the eye when I flush the interface. These incisions can alternatively be created at the 3- and 9-o'clock positions, as is Professor Blum's technique, with the same result. Because the opening incisions are only 100 to 120 μm deep, they do not induce astigmatism. When only one incision is placed, a technique that Rupal Shah, MD, of India uses, a small pocket is created to extract the lenticule.

PATIENT COMFORT

I have found that patients are more comfortable during and after ReLEx versus femtosecond LASIK and surface ablation procedures, and I believe this is because the cuts

ReLEx currently has the most advantages for moderate and high myopia when compared with excimer-based procedures.

made during ReLEx flex, and especially ReLEx smile, are smaller than the surface manipulation with LASIK and PRK. Smaller cuts shorten the time it takes for the epithelium to heal (Figure 1). While the eye is healing, patients typically experience foreign body sensations; with ReLEx smile procedures, this lasts for no more than 2 to 3 hours as a minor discomfort in comparison to approximately 4 to 5 hours with LASIK and 2 to 3 days PRK.

During the entire procedure, the patient feels a little pressure. As shown in a study by Vetter et al,¹ treatment with the VisuMax femtosecond laser leads to the lowest increase in intraocular pressure as compared with other femtosecond lasers. Additionally, there is neither any central artery occlusion (ie, blackout of vision) nor the smell of the fumes typically created during excimer-based surgery.

ReLEx currently has the most advantages for moderate and high myopia when compared with excimer-based procedures. However, I am participating in a second ongoing study to test its efficacy for hyperopia. What we do know is that visual recovery, higher-order aberrations, and stability are excellent for moderate and high myopia, as shown in the comparative studies by Gertner and Hjortdal at a recent Carl Zeiss users' meeting held in Dubai. Hyperopia treatment has always been a more challenging terrain than myopia. However, our first results on hyperopic ReLEx are encouraging, and once we perfect a cut profile we hope to achieve results similar to the current excimer standards.

CONCLUSION

ReLEx is an exciting new realm in refractive surgery, and any reasonably skilled surgeon can achieve successful outcomes with this procedure. What I enjoy about ReLEx is being able to use the same femtosecond laser workplace for the nonrefractive cut and the surgical manipulation itself, and my patients enjoy the faster surgery and improved patient comfort. ■

Walter Sekundo, MD, is Professor and Chairman of the Department of Ophthalmology, Philipps University of Marburg, Germany. Professor Sekundo states that his research has been supported by Carl Zeiss Meditec. He may be reached at e-mail: sekundo@med.uni-marburg.de.



1. Vetter JM, Schirra A, Garcia-Bardon D, Lorenz K, Weingärtner WE, Sekundo W. Comparison of Intraocular Pressure During Corneal Flap Preparation Between a Femtosecond Laser and a Mechanical Microkeratome in Porcine Eyes. *Cornea*. 2011 Jul 26. [Epub ahead of print.]

WATCH IT NOW ON THE CATARACT SURGERY CHANNEL AT WWW.EYETUBE.NET

Using your smartphone, photograph the QR code to watch the video on Eyetube. If you do not have a QR reader on your phone, you can download one at www.getscanlife.com.



direct link to video:

<http://eyetube.net/?v=ginuh>



ReLEx Versus Femtosecond LASIK: A Comparison

As a new technique for laser vision correction, ReLEx is a single-step, single instrument operation.

BY OSAMA IBRAHIM, MD

ReLEx smile is a minimally invasive approach to laser vision correction. Instead of a corneal flap, which is mandatory for the execution of LASIK, an intrastromal lenticule is created with the femtosecond laser. The size and shape of the lenticule corresponds to the desired refractive correction in the intact cornea, and the incision is subsequently prolonged to the anterior corneal surface with a very small opening incision. ReLEx uses tissue removal instead of tissue ablation (Figure 1); it achieves a high precision of cutting that contributes to the predictability of the procedure.

COMPARING RESULTS

I have been using femtosecond LASIK for 5 years and ReLEx for 2 years now. In this time, we have performed ReLEx flex and ReLEx smile in approximately 200 eyes and 400 eyes, respectively. Like LASIK, ReLEx flex is performed with a corneal flap-like access cut; however, the flap created for ReLEx flex is smaller than the LASIK flap (Figure 2). Another difference is that, for ReLEx flex, after the flap is lifted, the lenticule is peeled off of the corneal bed rather than ablated. ReLEx smile is entirely different from LASIK, as there is no longer need to create a corneal flap. Instead, a small incision is made in the cornea and the lenticule is dissected and extracted through the incision.

As our experience with ReLEx grew over the course of the clinical study, we were able to titrate the energy levels of the VisuMax femtosecond laser (Carl Zeiss Meditec, Jena, Germany) as well as its spot distance and size to make the system more case specific. These adjustments have provided us with more repeatable and reproducible study results. Since then, we have also fine-tuned the lenticule geometry, resulting in more accurate astigmatic correction.

Comparing ReLEx smile to femtosecond LASIK, ReLEx smile has a slightly steeper learning curve, yet after mastering it, ReLEx smile became a much easier and shorter procedure. It is a single-step, single instrument operation, and therefore there is no need to move the patient between two lasers as there is during femtosecond LASIK. Additionally, laser treatment time (ie,

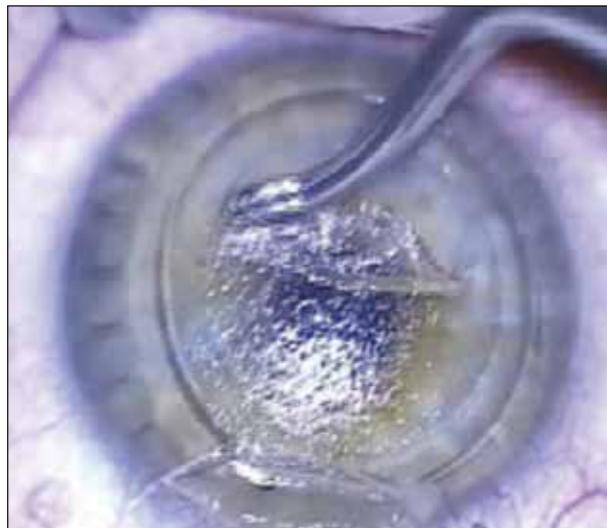


Figure 1. ReLEx uses tissue removal instead of tissue ablation.

time to create the lenticule) is nearly the same for all levels of myopic correction. For instance, I can treat -10.00 D of myopia in the same amount of time it takes me to treat -1.00 D of myopia, provided the eyes have the same cap diameter and optical zone.

The long-term results after ReLEx smile and LASIK are similar, but visual recovery can take a bit longer after ReLEx smile in some eyes. However, there is less incidence of dry eye after ReLEx smile compared with LASIK. One more important advantage for the use of ReLEx smile is that the incidence of strabismus and other flap complications have vanished.

SURGICAL ADVANTAGES

The major advantage of ReLEx smile is that there is no flap cutting involved, which we believe minimizes the induction of spherical aberration. Without the thread of spherical aberration, ReLEx smile patients are more likely to achieve better quality of vision than patients treated with an excimer laser, which is especially true for those with high myopia. We also believe that ReLEx smile offers better biomechanical stability than procedures employing flap creation, going along with less

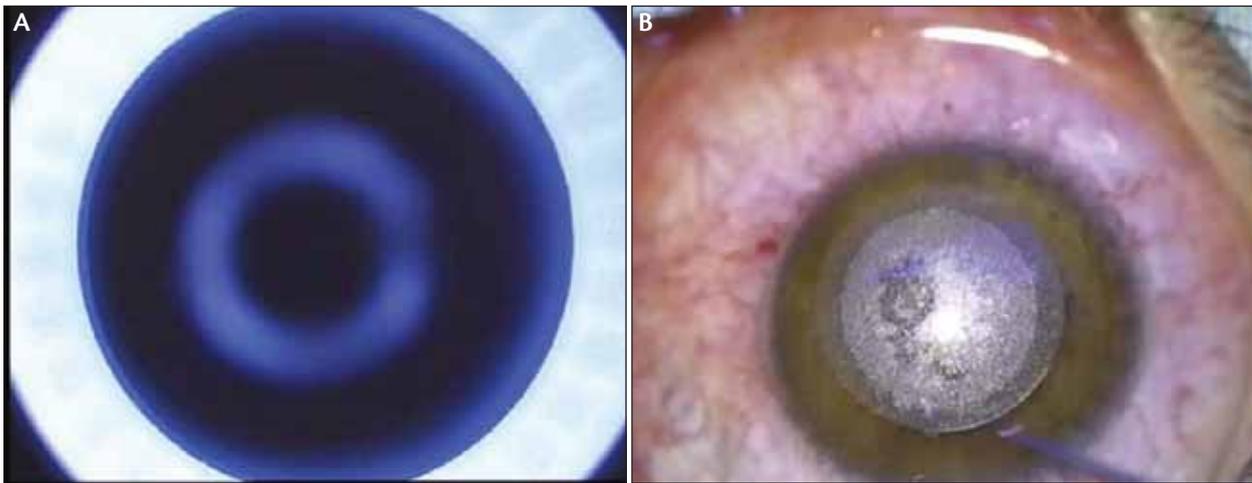


Figure 2. (A,B) The flap-like cut for ReLEx flex is smaller than the flap created for LASIK.

postoperative discomfort and less cases of dry eye. With no flap displacement, even after trauma, ReLEx smile is the best procedure for those who are involved in contact sports.

Unlike excimer-laser-based procedures, ReLEx smile uses a solid-state laser, and therefore there is no need for consumable gases or tight environmental humidity control. The VisuMax is a silent, soft, and gentle laser. It does not produce any smell, there is no vision blackout during the procedure, and the cornea is not forced into a nonphysiological planar shape. Thus, deformation and artifacts can be avoided in the cutting results, as well as unnecessarily high intraocular pressure (IOP).

THE PROCEDURE

The first step for ReLEx smile is to attach a disposable curved contact glass onto the laser aperture cone of the VisuMax femtosecond laser. The curved surface of the contact glass is designed to couple with the cornea after the VisuMax system self-calibrates the contact glass. Keratometry data can then be entered into the VisuMax software to account for the difference between the relaxed cornea and the contact glass curvature. This calculation allows the system to determine the ratio between the intended clinical treatment and the cap diameter on the relaxed eye as well as the incision diameter when cutting the eye coupled to the contact glass.

With the patient fixating on a flashing green light, the patient bed is repositioned so that the cornea comes into contact with the contact glass. At this time, the patient will notice a flashing fixation target in clear focus. This target uses the manifest refraction of each individual eye to align the target visibility. The bed is raised vertically while the surgeon observes the alignment of the contact glass application through the operating microscope and the side screen.

The cornea slightly applanates and centers, aiming

With ReLEx smile, deformation and artifacts can be avoided in the cutting results, as well as high intraocular pressure.

for the corneal vertex, and suction is applied. The eye is then immobilized with low corneal suction. The increase in IOP with the VisuMax is low enough for the patient to see throughout the procedure. The laser is activated when the surgeon presses on the foot pedal. After the lenticule and a small incision are created with the laser, the patient is moved to the observation microscope, where manual dissection is performed. This process starts with dissection of the upper surface (ie, cap) from the intrastromal lenticule. The lenticule is then dissected from the stromal bed and removed with a forceps through a 3- or 4-mm incision.

CONCLUSION

The evolution of refractive surgery is heading closer to preservation of corneal biomechanics. Increased safety was first achieved by creating thinner flaps; now, it goes one step further by using small incisions. ReLEx smile is the latest technique to follow this pattern of preserving corneal biomechanics. The most important point that refractive surgeons are aiming to achieve is aberration-free treatments. ReLEx smile is one step closer to this quest. ■

Osama Ibrahim, MD, is a Professor of Ophthalmology, Alexandria University, Egypt, and Chairman, Roayah Vision Correction Centers, Middle East. Dr. Ibrahim may be reached at e-mail: ibrosama@gmail.com.



ReLEx smile: An Outstanding Treatment for Low, Moderate, and High Myopia

I have treated more than 600 eyes with this minimally invasive technique.

BY RUPAL SHAH, MD

Of all the surgeons currently using ReLEx smile (Figure 1), I have completed the most cases to date. The reason that I choose this procedure time and time again is threefold. First, I feel it offers the most advantages to my patients in terms of the accuracy of refractive outcomes and safety. In fact, 99% of all eyes treated for myopia at our center are within ± 0.50 D of intended correction. While 30% of patients gain visual acuity after the procedure, less than 3% lose 1 or more lines of visual acuity. The advantages are particularly stark for high myopia. Second, ReLEx is a very time-efficient procedure, meaning that I am able to perform more procedures each day with the reassurance that I am selecting the best possible solution for my patients' refractive errors. Third, it is a unique procedure that is easily distinguishable from other laser vision techniques (no flap), which allows me to use a strategic marketing strategy.

My experience with ReLEx totals more than 1,500 procedures for the treatment of low, moderate, and high myopia (up to -10.00 D). There are two ReLEx techniques, femtosecond lamellar extraction (ReLEx flex) and small incision lamellar extraction (ReLEx smile), which are both minimally invasive and are performed with the VisuMax femtosecond laser (Carl Zeiss Meditec, Jena, Germany). The major difference between ReLEx flex and ReLEx smile is that a corneal flap is created prior to lenticule extraction in ReLEx flex only. I prefer ReLEx smile, because I no longer have to create and lift a flap in the cornea but rather just make a small corneal incision to excise the refractive lenticule.

ADVANTAGES

ReLEx smile offers many advantages:

- Postoperative discomfort for the patient is significantly less.
- The lack of a corneal flap eliminates the risk of a flap displacement, and so the amount of care that patients need to exercise is significantly less.
- Use of a small incision means that fewer corneal nerves are severed. This also leads to fewer issues after surgery, including dry eye.

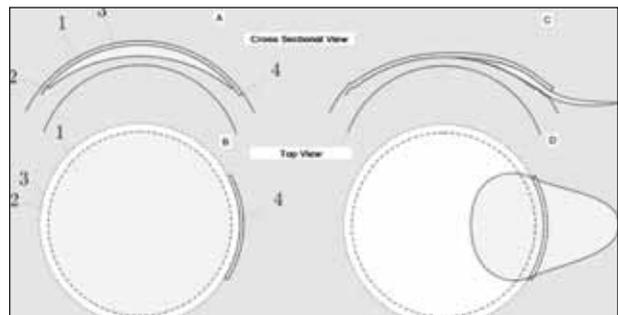


Figure 1. Schematic representation of the ReLEx smile procedure.

PATIENT SELECTION

I am happy that ReLEx smile is available for commercial purposes since I can now use this technique for all suitable patients independent from study participation. Before it was commercially available, I only performed ReLEx smile if patients agreed to participate in our current study, which precluded them to be available for at least 1 year of follow-up visits.

There are certain cases for which special attention must be given to patient selection for ReLEx, including if patients are too anxious; if they have astigmatism higher than the spherical component of myopia; or if they have more than -10.00 D of myopia, as this is still under investigation. In these patients, I typically perform LASIK, creating a flap with the femtosecond laser and ablating the corneal tissue with the excimer laser. However, the disadvantage with this treatment is that it takes more time, because I am moving the patients between two lasers.

TREATMENT RESULTS

As I said previously, I have extensive experience performing ReLEx treatments. Of the nearly 1,200 eyes for which I have at least 3-month follow-up, 29% have been for the treatment of low myopia, 50% for moderate myopia, and 21% for high myopia.

If I had to provide a quick snapshot of my results to date, I would say that visual outcomes after ReLEx have

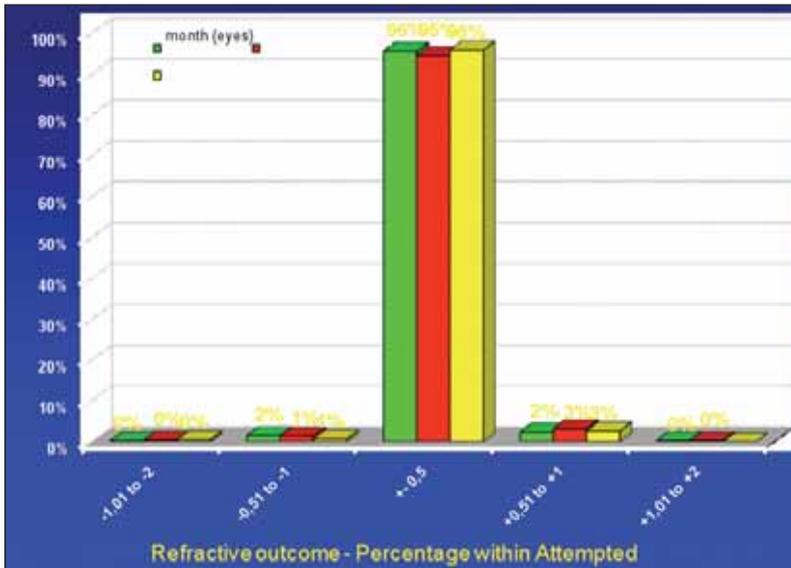


Figure 2. Refractive outcome after ReLEx for treatment of myopia and myopic astigmatism up to -10.00 D.

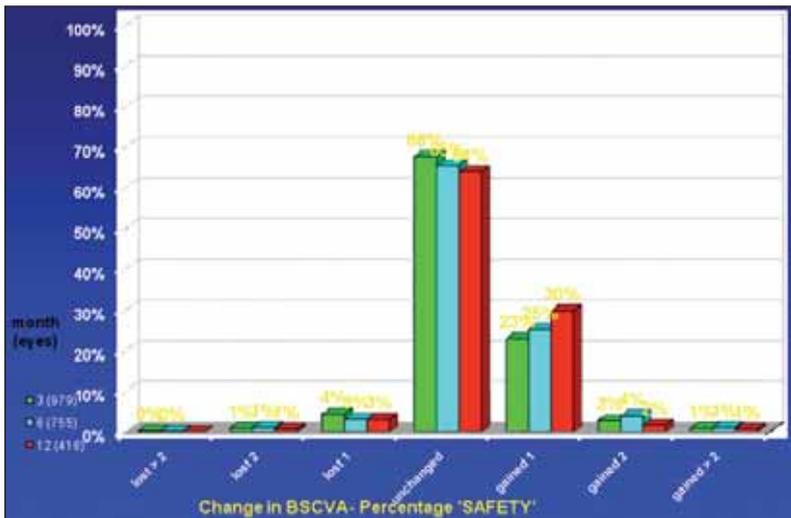


Figure 3. Safety of the ReLEx procedure, as expressed in the change in the numbers of lines of BCVA.

been equivalent to visual outcomes after LASIK in eyes with low myopia. Therefore, even if I have a -1.00 D treatment, I am not hesitant to perform a ReLEx procedure.

For eyes with moderate or high myopia, ReLEx has an edge over excimer laser treatments. Because the technique involves cutting a lenticule instead of ablating it, the results are less dependent on environmental factors including humidity and organic vapors. During ablation for high myopia, there is considerable drying of the corneal bed, with resultant scatter in the ablation rate. This causes the commonly observed increased scatter in the results of excimer laser LASIK once you start treating high myopia. Such increase in scatter is much less in ReLEx.

Within each of the three groups—low myopia, moderate myopia, and high myopia—at 3 months, 97%, 97%, and 90%, respectively, were within ± 0.50 D of intended correction (Figure 2). At 1 year, approximately 2% of eyes in the low myopia group and approximately 4% of eyes in the other two groups lost 1 or more lines of BCVA, but 25%, 29%, and 49%, respectively, gained 1 or more lines of visual acuity (Figure 3).

ADDED BENEFITS

As I see it, there are three distinct benefits that I have achieved by incorporating ReLEx into my surgical armamentarium: patient benefits, surgeon benefits, and marketing benefits.

Patient benefits. The beauty of ReLEx smile is that it builds on existing—and successful—laser vision techniques, and our results reflect that. In all three groups, more than 90% of eyes had a UCVA of 20/30 or better. Additionally, patient discomfort was minimized, and, in the majority of cases, pain was gone within the first few hours after surgery. Another benefit to ReLEx smile is that there is no risk of possible flap displacement from eye trauma or surgery at a later date. This is especially important for those patients who are involved in contact sports or jobs in which eye trauma is more likely.

Surgeon benefits. For me, two important surgical benefits of performing ReLEx smile are as follows. First, I can better maintain biomechanical stability. Second, this procedure causes fewer cases of dry eye. I make only a small incision in the cornea, and even the cap separation extends only up to 7 mm from the center of the cornea.

Both of these reasons should ensure that biomechanical stability is better maintained and that there are fewer cases of dry eye. Additionally, I save significant amount of time when performing ReLEx smile compared with Femto-LASIK—approximately 10 minutes per patient. I treat more than 1,000 patients a year, which means that I can conceivably save about 45 minutes on every working day.

Another aspect that I find beneficial is that I only have to purchase and maintain one laser instead of the two lasers that are needed for PRK or LASIK.

I save a significant amount of time when performing ReLEx smile compared with Femto-LASIK—approximately 10 minutes per patient.

Economically, this is the better set-up, because here in India we cannot up-charge the patient as much as what can be done in other countries, and it is hard for us to afford the maintenance and capital costs on two different laser systems.

Marketing benefits. We are in a very unique position, because we are one of the only centers that can offer blade-free, flap-free laser vision correction. This has provided patients with incentive to come into our center and find out more about ReLEx flex and ReLEx smile. Of course we still offer LASIK and PRK, as it is very important that the patient select the treatment that is right for him or her specifically, but I have noticed that more often patients prefer one of the two ReLEx techniques.

CONCLUSION

In the future, ReLEx procedures will be able to be performed through even smaller incisions than we use today. I have already attempted the use of 3-mm incisions in a number of ReLEx smile cases, and the results have been promising. The limiting factor at this point is the instruments we have to separate the lenticule in situ, which at this time are too large for smaller incision sizes. One solution may be the use of hydrodissection to separate the lenticule.

I feel very lucky to be among the first surgeons to use ReLEx in a large patient population. To date, I have noticed a surge in the number of patients who ask for ReLEx by name, and I look forward to growing my number of treated patients even more. It is truly an exciting time to be a refractive surgeon. ■

Rupal Shah, MD, practices at New Vision Laser Centers, Vadodara, India. Dr. Shah states that she is a consultant to Carl Zeiss Meditec. She may be reached at tel: +91 265 3058603; e-mail: rupal@newvisionindia.com.



My New Clinical Standard is ReLEx smile

Using this procedure in a high-volume clinic saves us from having to create a corneal flap.

BY JESPER HJORTDAL, MD, PhD

I work in an extremely high-volume, hospital-based clinic. In a typical day, I see up to 40 patients, treat a multitude of conditions, and correct various forms of refractive errors. My work is extremely rewarding—I find great joy in helping patients achieve better visual quality and in most cases spectacle independence—but it is also time-consuming, and anything I can do to safely reduce procedural times is helpful.

Approximately 16 months ago, we switched from using LASIK to lenticule extraction with ReLEx in the majority of my patients. We have performed approximately 900 procedures in this period. I have noticed a significant time-saving benefit.

Of the two available ReLEx procedures, femtosecond lamellar extraction (ReLEx flex) and small incision lamellar extraction (ReLEx smile), I prefer the latter because I no longer need to create a corneal flap to perform the refractive correction. For the past 4 months, I have been using ReLEx smile whenever possible, promoting it as my new clinical standard for refractive surgery. We have thus far performed approximately 400 ReLEx smile procedures.

DIFFERENCES

ReLEx is a simplistic but effective procedure that can today only be performed with the VisuMax femtosecond laser (Carl Zeiss Meditec, Jena, Germany); it is the only laser vision correction technique that uses a femtosecond laser to create a cut in the cornea and perform the refractive correction. With this technique, I am able to create the lenticule without ever having to break through the corneal surface. I typically use ReLEx for the treatment of high myopia, as this is the majority of patients who elect treatment due to reimbursement by the public health service. I treat patients with as much as -10.00 D. Below I describe the differences between both ReLEx procedures.

ReLEx flex. In the initial steps of the procedure, ReLEx flex is similar to LASIK in that a corneal flap is created and lifted; however, instead of ablating the tissue underneath the flap, the surgeon peels off a small refractive lenticule to provide the refractive correction. This is extremely easy to do, and after about 10 procedures I was comfortable with this technique.

ReLEx smile. The main difference between ReLEx flex

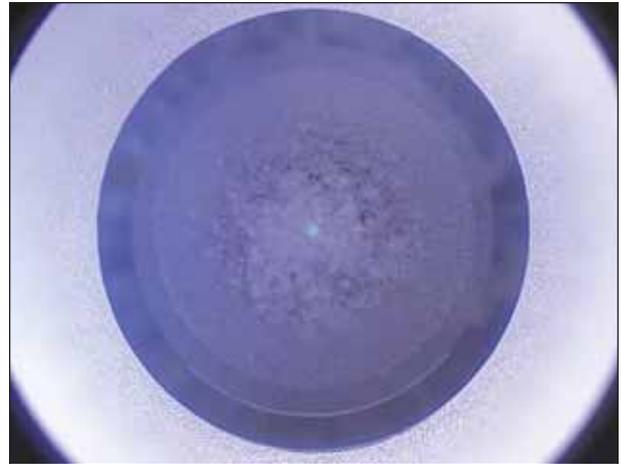


Figure 1. View through the operating microscope immediately before completion of a ReLEx smile laser treatment using the VisuMax femtosecond laser.

and ReLEx smile is that there is no longer a need for a corneal flap. Instead, a small tunnel incision is created and the refractive lenticule is extracted through the incision using a spatula. The learning curve is slightly longer with ReLEx smile, but by 20 cases I had the technique perfected.

PROCEDURAL ADVANTAGES

My typical ReLEx smile procedure, which lasts approximately 10 minutes, is outlined below:

- The patient is prepped for surgery by two drops of topical anesthesia and a lid speculum is inserted;
- Using the VisuMax femtosecond laser, an intrastromal lenticule is cut and a 3-mm incision is created at the 12-o'clock position. With a length of 500 μm , this small channel-like incision produces an entryway to the refractive lenticule (Figure 1); and
- The lenticule is loosened with a spatula and is manually extracted through the tunnel using a small forceps (Figure 2).

Surgically speaking, the ReLEx smile procedure has several advantages over excimer ablation techniques such as LASIK and PRK. Perhaps the largest is that I no longer have to create a preflap on the surface of the eye, meaning that I no longer have to worry about the complica-



Figure 2. Lenticule removal is completed through a small incision in the ReLEx smile procedure.

tions associated with a corneal flap, such as buttonholes and later flap dislocation. Additionally, there is minimal risk of epithelial growth under the flap, as only one small incision replaces the need for a flap, and there is more intact cornea compared with surface ablation procedures, which increases corneal stability.

Clinically speaking, the main advantages are that the procedure is shorter and follow-up shows less variations. I have seen less cases of patient discomfort, including dry eyes and foreign body sensation, and so far in my clinical experience with ReLEx smile I expect even less risk of corneal ectasia compared with LASIK. Regarding procedure time, I no longer have to move the patient from the femtosecond laser to the excimer laser, but rather I simply perform the cut and the refractive correction on the same patient bed at the VisuMax laser. There was a slight learning curve in which the procedure time was longer than it is for LASIK, but after I understood the ins and outs of the technique the surgical time decreased.

HIGHER-ORDER ABERRATIONS

We have begun to analyze higher-order aberrations before and after ReLEx and LASIK. Thus far, we have studied 3-month results for 100 patients, 50 of whom under-

ReLEx is the only laser vision correction technique that uses a femtosecond laser to create a cut in the cornea and perform the refractive correction.

went femtosecond LASIK and 50 of whom underwent ReLEx flex. Patients in the ReLEx flex group had fewer higher-order aberrations after surgery compared with femtosecond LASIK patients. Once we have longer-term results, we will repeat the same study using ReLEx smile patients. Since the process is similar to ReLEx flex, whereby the refractive lenticule is removed, we expect that the higher-order aberrations after ReLEx smile will be similar or even better than those after ReLEx flex.

How can this difference in higher-order aberrations after ReLEx flex and femtosecond LASIK be explained? We postulate that, with LASIK, once the flap is cut and following the excimer laser ablation, there tend to be small decentrations that can lead to coma. However, with the ReLEx procedures this is avoided because any and all cutting is done within the cornea. More research is needed to confirm this hypothesis.

CONCLUSION

ReLEx, and most specifically ReLEx smile, has become the new standard of care at our clinic for patients with high myopia. This treatment has many advantages over excimer ablation techniques, the most important two being a decreased number of higher-order aberrations after surgery compared with LASIK and the time it saves me in the operating room. ■

Jesper Hjortdal, MD, PhD, is the Director of Corneal and Refractive Surgery, Department of Ophthalmology, Aarhus University Hospital, Denmark. Professor Hjortdal states that he has no financial interest in the products or companies mentioned. He may be reached at e-mail: jesper.hjortdal@dadlnet.dk.



The Importance of ReLEx in Our Current Laser Vision Correction Business

Gradual incorporation of this technique has led to steady growth.

BY EKKTET CHANSUE, MD

ReLEx combines the latest femtosecond laser technology with an exact method for lenticule extraction within the intact cornea to achieve precise, accurate, and gentle vision correction. This procedure not only provides an easier approach to refractive correction, but it does so using just one device, the VisuMax femtosecond laser (Carl Zeiss Meditec, Jena, Germany). I transitioned to using ReLEx in July 2010 and have since performed approximately 600 procedures. This article reviews my personal motivation behind the switch to ReLEx, demonstrates the benefits of transitioning to ReLEx flex and subsequently ReLEx smile, and lastly offers my unique perspective of marketing the procedure.

PERSONAL MOTIVATION

I am continually striving to achieve better refractive results for my patients. Part of this equation is the willingness to consider incorporating new procedures into daily practice. Throughout my career as a refractive surgeon, I have made a habit of objectively analyzing any new procedure that I am curious about, and if it makes sense, I consider adopting it. For instance, in 1994, I was the first surgeon in Thailand to perform LASIK. Looking back to that period, the procedure was being performed by only a handful of surgeons around the world—it was even considered an aggressive approach by a lot of ophthalmologists. But my objective analysis of LASIK told me that it would help me to achieve better postoperative outcomes compared with radial keratotomy, PRK (with first-generation excimer lasers), and automated lamellar keratoplasty.

LASIK is commonplace today, but I believe that laser vision correction is evolving from excimer laser-based ablation procedures to microincision surgery procedures like ReLEx smile. Like any other procedure I have considered for routine use, I performed an objective analysis of ReLEx and determined it may perhaps be the most ideal way to perform laser vision correction.

The basis for the ReLEx procedure is the *Law of Thickness*, which was introduced by the late Jose Ignacio Barraquer, of Bogotá, Colombia, in 1949.¹ This is also the



Figure 1. (A) During ReLEx smile, the lenticule is removed through a 2-mm incision. (B) ReLEx smile: Postoperative day 1.

same principle for which numerous methods of laser vision correction—LASIK included—are based. However, ReLEx is unique to these other laser vision correction procedures because of the elegance with which the Law of Thickness is implemented. The beauty of ReLEx is its minimalistic approach to surgical correction. My incision size is now routinely between 2.0 and 2.5 mm long (Figure 1). You can say it is the cutting edge of refractive surgery because there is almost no cut edge.

BENEFITS

I gradually incorporated ReLEx into my practice over the past year, with a steady growth in the number of procedures I was performing. Currently, approximately half of my procedures are ReLEx surgeries. My initial experience (six eyes) was with ReLEx flex. I then transitioned to performing ReLEx with a continuously smaller incision size, still using the flex program on the VisuMax femtosecond laser. This is a helpful transition procedure based on ReLEx flex.

In July 2011, the ReLEx smile program was installed on our laser, and since then almost all of my cases have been done with this program. I have always been a firm believer in Dr. Barraquer's Law of Thickness, but only when I saw Rupal Shah, MD, of India, perform ReLEx smile did I realize that this is what LASIK wants to be when it grows up. ReLEx smile does what LASIK does—only better. There are minimal disturbances to the cornea, both structurally and physiologically. I see this procedure as the ultimate homage to Dr. Barraquer.

ReLEx flex and ReLEx smile procedures both have advantages. I prefer ReLEx smile, because I have found that, after surgery, these eyes tend to be more comfortable during the first night postoperative. Additionally, ReLEx smile eyes have the potential to be structurally stronger than ReLEx flex eyes, as there is no flap-edge cut by the laser. The benefit of such cut, however, is the ease with which you can go back and do enhancement surgery much in the same way as after LASIK.

STEPPING STONE

I use ReLEx smile whenever I can. When I do use ReLEx flex, I perform this technique with a small incision size while still using the flex program. ReLEx flex is a steppingstone, albeit an important one, to ReLEx smile. This procedure is a helpful step to optimize laser settings and to gain valuable experience learning the techniques required for this type of surgery. The ReLEx flex software also allows the surgeon to start performing a small-incision technique as described above by only making a small access cut even when the laser has created LASIK flap-like cuts. This serves as a training step for the surgeon to gain the confidence for progressing to ReLEx smile.

I can use the same preoperative process with ReLEx smile as we did for ReLEx flex and also for LASIK. We carefully explain the risks and benefits of each surgical option, and the patient has the freedom to make an informed decision. ReLEx has expanded the range of myopic treatment we can offer to patients. Historically, we have limited our myopic treatment to -10.00 D with LASIK, more from an optical quality standpoint. Now, with the superior optics that we see with ReLEx, we are treating cases above -10.00 D in the course of our clinical study, if pachymetry allows, with great results.

ReLEx has expanded the range of myopic treatment we can offer to patients.

Therefore, having ReLEx as a surgical option may increase the number of potential candidates for the future.

MARKETING SERVICES

As with any service I offer my patients, I truly believe in the ReLEx procedure. This is the first message that I tell patients. After that, it is mostly about providing clinical data and describing the procedure to the patient. I offer ReLEx to all patients who are candidates for the procedure, but it is important to let them choose the procedure that they feel is best suited. I do not like to think of it as marketing, but rather information gathering. I am able to offer a wider range of procedures to my patients. In the beginning, when there was not a lot of data on ReLEx, I made sure to point that fact out to the patient. Today, I feel very comfortable offering ReLEx to my patients.

It is not always easy to explain the procedure and make the patient understand completely, but one of the things patients like about ReLEx smile is that it uses a microincision and the vision correction cut is performed inside the intact cornea. Most people can identify with the benefits of minimally invasive procedures, as the whole of medical practice seems to be progressing. An analogy such as endoscopic surgery as opposed to laparotomy (in cholecystectomy, for example) is helpful.

CONCLUSION

Using ReLEx flex and ReLEx smile, I have been able to provide patients with a minimally invasive approach to laser vision correction that affords short treatment times and inherent accuracy, even in cases of high myopia. I have been able to expand my treatment range within the scope of the study well past the -10.00 D of myopia I could treat with LASIK, and I have done so safely and accurately using these techniques. ■

Ekket Chansue, MD, is the Medical Director at TRSC International LASIK Eye Center, Bangkok, Thailand. Dr. Chansue states that he has no financial interest in the products or companies mentioned. He may be reached at e-mail: echansue@lasikthai.com.



1. Barraquer JI. Queratoplastia refractiva. *Estudios Inform Oftalmol Inst Barraquer*. 1949;10:2-21.

The moment flapless surgery
becomes clearly visible: in a smile.
This is the moment we work for.



// ReLEx
MADE BY CARL ZEISS

Flapless. All-femto. Single-step. For the first time ever, advanced femtosecond technology and highly precise lenticule extraction are combined to perform minimally invasive corrections – with a single system: the VisuMax® from Carl Zeiss. Thereby, a refractive lenticule is created within the intact cornea and extracted through a small incision. The new flapless procedure offers clear advantages: minimal surgical impact on the corneal stability and excellent predictability of the refractive outcomes.

www.meditec.zeiss.com/ReLEx



We make it visible.

000000-1955-960