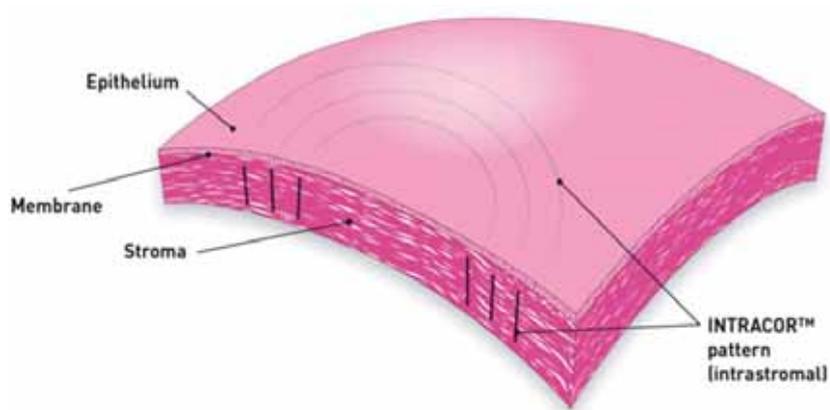
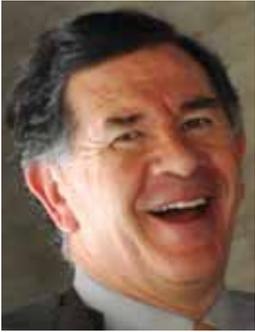


# INTRACOR™



An excerpt from the presentations by Dr Luis Ruiz and Dr Mike Holzer and the Round Table discussion moderated by Dr Wing-Kwong Chan in the





**Luis Antonio Ruiz, M.D.**

Centro Oftalmológico Colombiano, Bogotá  
Colombia

Dr Ruiz was the first surgeon to quantify the feasibility of non-invasive intrastromal corrections with the first phase focusing on the non-invasive correction of presbyopia. To date, he has treated about 1,300 eyes with INTRACOR™.

INTRACOR™ is an intrastromal correction using the TECHNOLAS® Femtosecond Workstation (Technolas® Perfect Vision GmbH, Germany) which reshapes the cornea by inducing a redistribution of biomechanical forces, with the combination of new, completely intrastromal ablation patterns leading to the desired refractive effect.

Because it is purely intrastromal, there is no incision of the epithelium, endothelium, or Bowman's or Descemet's membrane, ensuring the safety of the INTRACOR™ procedure, with excellent healing and minimal risk of infection (Figure 1).

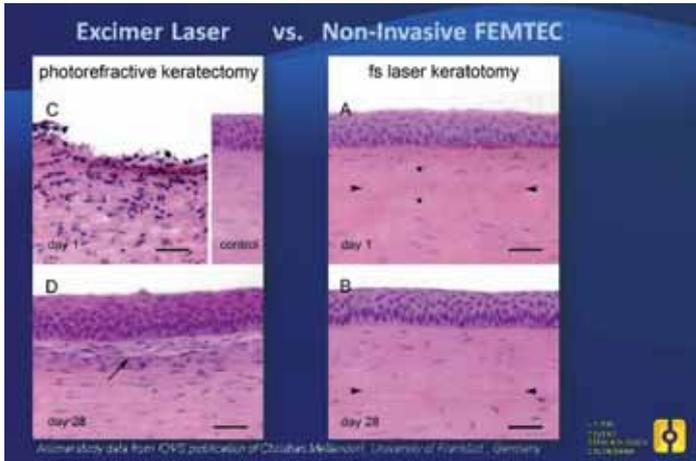


Figure 1. Intrastromal approach ensures excellent healing: excimer laser versus non-invasive approach

Finite Element Modeling (FEM) using a spatial 3-dimensional grid adapted to the individual curvature of the cornea is used to predict the impact of the intrastromal ablations on the biomechanical response and to ensure the accuracy of the procedure. Importantly, the cornea must be as stress-free as possible during treatment, in order to allow precise 3-dimensional modeling of the femtosecond laser pulses.

The intrastromal rings created during the INTRACOR™ presbyopia procedure make the corneal surfaces increasingly hyper-prolate, with steepening of the central portion, in order to improve near vision, while both maintaining and improving the distance vision that the patient had prior to surgery.

To ensure eye fixation with minimal biomechanical impact for a high level of predictability, a curved interface is used between the eye and the femtosecond laser (Figure 2). This has the advantage of not modifying the shape of the cornea or increasing intraocular pressure (IOP) due to flattening of the cornea, further improving accuracy in both the anterior and posterior parts of the cornea.



Figure 2. Eye fixation with minimal biomechanical impact ensures a high level of predictability

**Evaluation study**

Since October 2007, an evaluation study of INTRACOR™ for presbyopia has been conducted at the Centro Oftalmológico Colombiano, Bogotá. The analysis consists of 128 eyes with at least 6 months of follow up, following the same profile without previous surgery or pseudophakia, in order to assess the accuracy, stability and safety of the INTRACOR™ procedure.

Twenty of the 128 eyes have now had a follow up time of 17 to 18 months. The patients had a mean age of 52.8 years (range 44-67) with an average duration of control of 9.5 months (range 6-18 months).

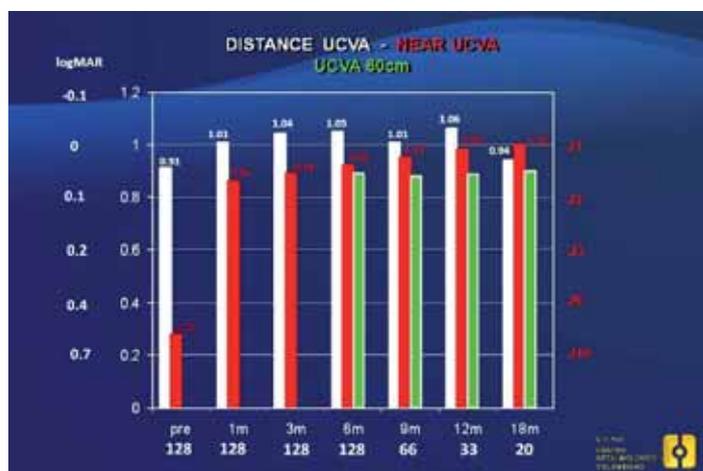


Figure 3. Pre and Post-operative Visual Acuities

Figure 3 shows the pre-operative patient visual acuities and post-operative visual outcomes at different follow up visits in terms of distance uncorrected visual acuity (UCVA, shown in white), near UCVA (red), and intermediate UCVA at 60 cm (green). Distance and intermediate UCVA have not only been maintained, but also improved, while post-operative near UCVA has improved significantly.

In the analysis of cumulative near UCVA less than 20% of patients saw J6 or better pre-operatively, whereas more than 90% of them were seeing J2 or better following the INTRACOR™ procedure.

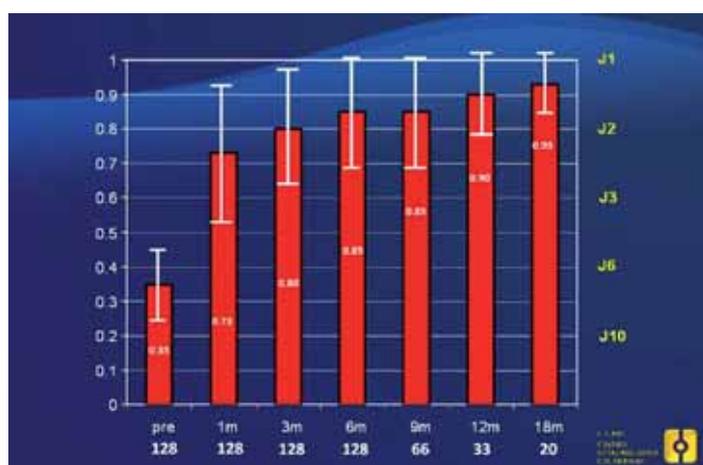


Figure 4. Distance Corrected Near Vision

For the distance correction, the patients retained very good near vision, as depicted in Figure 4.

Pre-operatively, 92.2% of the patients had J5 or worse uncorrected near visual acuity (UCNVA), while 97.6% had UCNVA J3 or better after 6 months. Simultaneous distance vision of 20/25 or better and near vision J3 or better was seen in 93.8% of the eyes at 6 months. Patients were therefore extremely satisfied with their results, having achieved very good distance vision and excellent near vision.

The mean sphere, which was 0.47D pre-operatively, was -0.11D in 20 of the patients who had follow up of 18 months, while MRSE went from a pre-operative mean of 0.27D to -0.31D in the same period. The mean refractive cylinder remained unchanged.

### Accuracy and stability

After 6 months, 91.4% of eyes were within  $\pm 0.50D$  sphere. It was noted that no astigmatism was induced or corrected. For the control group of patients between 1 and 6 months, the change in average sphere is plano; between 6 and 12 months, the change is -0.07D and in the last group, the change is -0.11D.

### Safety

The INTRACOR™ procedure was found to be safe, with almost all patients (99.2%) having an excellent best spectacle corrected visual acuity (BSCVA) of at least 20/20, while just one patient (1.5%) lost one line of vision.

### Wavefront analysis

The excellent visual outcomes of the patients following INTRACOR™ are reflected in the results of the wavefront analysis. Figure 5 depicts the improvement between levels of pre- and post-operative mean and higher-order RMS, demonstrating that not only aberrations are being corrected, but also that no aberrations are being induced by the INTRACOR™ procedure.

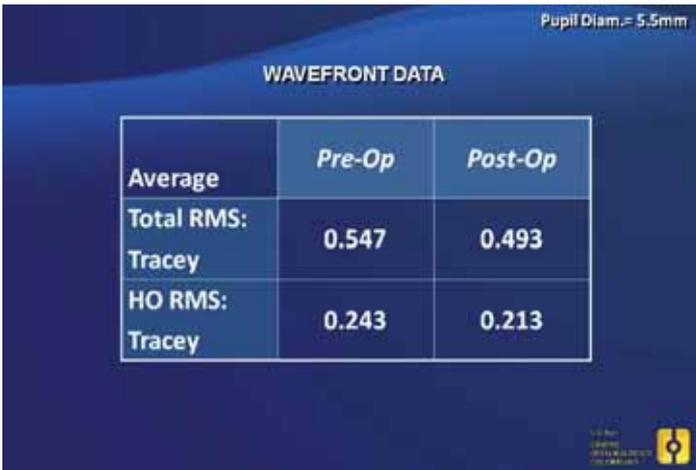


Figure 5. Pre and post-operative RMS

Pre- and post-operative spherical aberrations are shown in Figure 6. Spherical aberrations need to be induced during the correction of presbyopia. However, when there are low or weak levels of HOAs, balancing them with lower order aberrations such as sphere is beneficial.

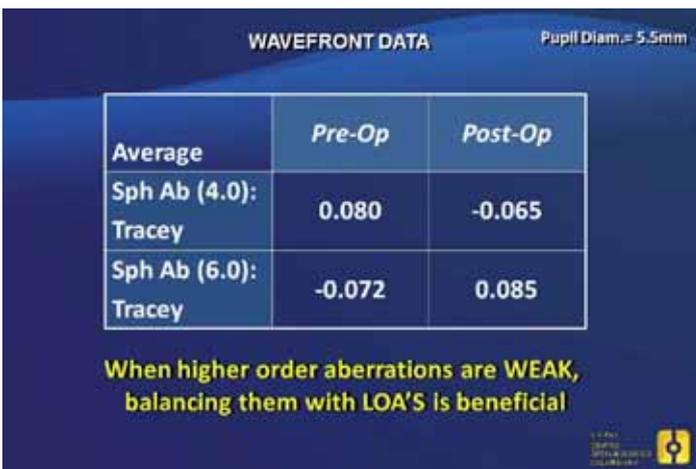


Figure 6. Pre and post-operative Spherical Aberrations

### Contrast sensitivity

Under photopic conditions, no change was observed in contrast sensitivity (Figure 7), although post-operative can sometimes be better than pre-operative contrast sensitivity. Similarly, pre- and post-operative contrast sensitivity under mesopic conditions was more or less the same.

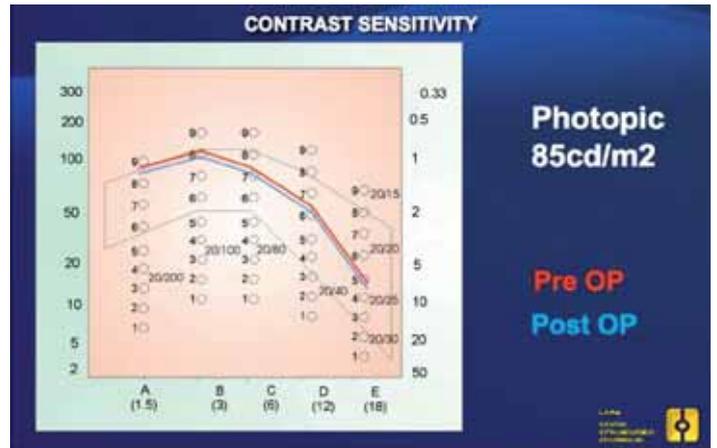


Figure 7. Contrast Sensitivity

In summary, INTRACOR™ is a minimally invasive procedure that shows very promising results in the correction of presbyopia without significant long-term downsides observed after 19 months. Due to the totally intrastromal ablation pattern, complications such as infections can be avoided.

INTRACOR™ treatment is an effective solution for correction of problems such as presbyopia. Vision correction is now possible in the least invasive way imaginable: purely intrastromally, without a flap.





### Mike P Holzer, M.D.

University of Heidelberg  
Germany

*Dr Holzer is a faculty member of Cataract, Corneal and Refractive Surgery at the International Vision Correction Research Centre, Department of Ophthalmology, University of Heidelberg, Germany. He is one of the clinical investigators for the INTRACOR CE study.*

Presbyopia is an extremely common condition, affecting the entire population over the age of 50 years. Until recently, laser procedures for the correction of presbyopia have been associated with certain limitations, in particular the creation of an opening into the cornea and removal of the epithelium in order to apply laser ablation to the deeper stromal tissue.

INTRACOR™ (intrastromal correction of presbyopia) is a new intrastromal femtosecond laser procedure in which the laser beam is focused directly into the mid-stroma, with consecutive rings being formed without dissecting or cutting the corneal epithelium or Bowman's or Descemet's membrane, leading to a change in post-operative corneal refraction.

INTRACOR™ successfully reshapes the cornea and redistributes the biomechanical forces necessary for the correction of presbyopia, with the corneal surface being flattened or steepened according to the applied pattern of stromal ablations. The cut design and stromal depth algorithm depend on the degree of refractive error to be corrected.

A major advantage of INTRACOR™ concerns the rapid time of the procedure, which lasts approximately 20 seconds. While gas bubbles that form in the cornea during the early stages of the ablative procedure cause blurring of the patient's vision during the first 2 to 3 hours post-operatively, the cornea clears as these bubbles dissolve, distance visual acuity returns and the majority of patients experience a gain in near visual acuity as early as the first post-operative day.

Because the structural integrity of the cornea is maintained, INTRACOR™ is associated with a minimal risk of infection and there is rapid promotion of wound healing.

Early promising results with INTRACOR™ were presented last year at the Royal Hawaiian Eye meeting in Kona, Hawaii, by Dr Luis Antonio Ruiz from Bogotá, Colombia, who invented the innovative non-invasive procedure.

To date, Dr Ruiz and his team have treated more than 1500 eyes with INTRACOR™. The University of Heidelberg is currently participating in a prospective multicenter European study to further examine the safety and stability of this novel treatment and to obtain CE approval.

### Study results

The ongoing prospective study, which is being conducted at the University of Heidelberg, is evaluating the INTRACOR™ procedure in 25 presbyopic patients (age range, 48-66 years) who required a minimum near visual acuity addition of 2.00D or more and received the treatment in their non-dominant eye.

The 25 patients had a pre-operative mean uncorrected distance visual acuity (UCDVA) of  $0.11 \pm 0.11$  logMAR.

The femtosecond laser surgery, performed with the TECHNOLAS® Femtosecond Workstation (Technolas® Perfect Vision GmbH, Germany) was done under topical anesthesia. First, the line of sight was marked on the cornea. The laser treatment

comprising of five intrastromal rings with a predefined distance from each other were then created within 20 seconds.

During the first few hours post-operatively, the intrastromal rings expand due to cavitation gas that accumulates during the procedure. However, just 1 day post-operatively, these rings were hardly detectable at the slit lamp. These post-operative findings were seen in all patients and are depicted in Figure 8.



Figure 8. INTRACOR™ post-operative findings

Parameters investigated in the trial included uncorrected and corrected near and distance visual acuity using a logarithmic visual acuity 'new EDTRS chart,' corneal topography, endothelial cell count, biometric measurements and contrast sensitivity testing.

Among the 25 patients treated, the mean UCVA increased from 20/100 (logMAR 0.7) to 20/30 (logMAR 0.26) within 3 months post-operatively, with this difference being statistically significant ( $P < 0.01$ ) (Figure 9). These findings confirm those of Dr Ruiz's earlier results.

The mean distance sphere changed from  $+0.75 \pm 0.23D$  pre-operatively to  $+0.15 \pm 0.31D$  at 3 months post-operatively, while the cylinder showed minimal difference. Uncorrected and best corrected distance visual acuities were stable over 3 months. UCVA improved from  $0.70 \pm 0.60$  to  $0.26 \pm 0.21$  logMAR, distance corrected NVA improved from  $0.59 \pm 0.12$  to  $0.23 \pm 0.18$  logMAR, and best corrected NVA was unchanged after 3 months.

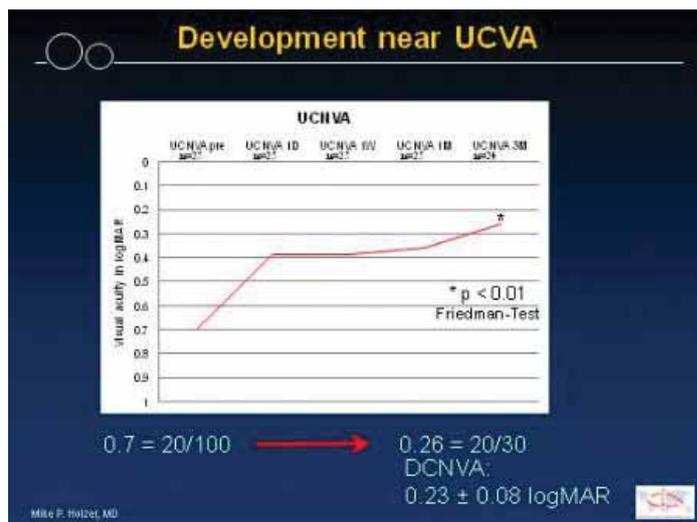


Figure 9. Post-operative near UCVA

The endothelial cell count did not show significant differences before and after surgery, corneal topography showed slight refractive changes, and post-operative straylight measurements were well within the normal age range.

In summary, the INTRACOR™ presbyopia correction procedure showed good outcomes, with minimal risk of infection and no weakening of the cornea, in contrast to many other refractive surgical procedures. Further refractive treatments with INTRACOR™, which include low myopia, hyperopia and astigmatism, are presently under investigation.





Moderator:  
**Wing-Kwong Chan, M.D.**

*Eye & Retina Surgeons  
Singapore*

*Dr Chan practises general ophthalmology, cataract surgery and sub-specializes in laser vision correction surgery with LASIK, epi-LASIK, sub-Bowman's keratomileusis and advanced surface ablation with the latest excimer and femtosecond laser technology for the correction of myopia and astigmatism.*

Speaker:  
**Luis Antonio Ruiz, M.D.**

*Centro Oftalmológico  
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Colombia*

Speaker:  
**Mike Holzer, M.D.**

*University of Heidelberg  
Germany*

**PRINCIPLE OF INTRACOR™**

**Dr Chan:** How does the TECHNOLAS® Femtosecond Workstation differ from the other femtosecond lasers available today that makes it special to correct presbyopia?

**Dr Holzer:** The most important feature is the unique curved patient interface which keeps corneal deformation to a minimum. Once the eye is connected to the TECHNOLAS® Femtosecond Workstation, there is less stress on the cornea with less suction pressure in contrast to complete applanation. Therefore the tissue can be cut or separated more precisely, in contrast to a totally flat applanation. Other femtosecond systems, apart from Visumax, require applanation of the cornea with a flat contact interface, which compresses the cornea and induces higher IOP. **Unlike the other competing systems, which are optimized for flap applications** and working at one depth, the INTRACOR™ system is optimized to work at different depths throughout the treatment. So it is a different area of optimization to other treatment applications.



**Dr Ruiz:** The curved patient interface does not flatten the cornea. The laser's cuts are also curved, following the stromal lamella, leading to more precise cuts through the naturally curved cornea.

**Dr Chan:** After the INTRACOR™ presbyopic treatment, where does the ablated tissue go?

**Dr Holzer:** When you treat the cornea with the femtosecond laser, there is cavitation and the ablated tissue evaporation. However, with INTRACOR™ treatment, there is not really a cut; but a separation of the corneal tissue.

## INTRACOR™ Round Table Discussion

**Dr Chan:** So is it like a femtosecond laser procedure, with evaporation of small bubbles of basically carbon dioxide and water, within a day?

**Dr Holzer:** The stromal tissue is converted into gas bubbles which will disappear within 1 - 2 hours, with no real physical debris being formed. No tissue is removed; no flap is created; the anterior and posterior surfaces of the cornea remain intact; and the procedure does not disturb the epithelium or Bowman's layer.

### TREATMENT INDICATIONS

**Dr Chan:** What is the maximum refractive error that can be treated with INTRACOR™ for hyperopia combined with presbyopia?

**Dr Ruiz:** At the moment, we are able to correct up to +2.75D.

**Dr Chan:** Can INTRACOR™ treat myopia and if so, how many diopters?

**Dr Ruiz:** So far, we have treated patients up to -3.00D. We can treat astigmatism up to 2.00D but the outcomes are not as accurate as for those patients with a half diopter less than that.

**Dr Chan:** For the INTRACOR™ procedure, where do you center the treatment?

**Dr Ruiz:** **The treatment will be centered with the patient's line of sight.** The first Purkinje's reflex is seen and marked on the cornea, with the treatment centration being based on this marking.

**Dr Chan:** The interesting thing is that although you mark on the cornea that is still curved, sometimes when you applanate down with a flat interface,

you may distort the centration. The advantage of the curved interface is that it allows for a more accurate centration compared to a flat applanation interface. The curved interface also allows for the patient to maintain visual sight during the entire procedure, thus maximizing patient comfort.

**Dr Chan:** Is there any effect on IOP after the INTRACOR™ procedure?

**Dr Ruiz:** None of the patients that we have treated have had a marked elevation of IOP post-operatively. In the normal range of patients, we have seen no difference whether the IOP is 10 mmHg or 20 mmHg pre-operatively. Based on the normal IOP, the results have been very stable.

**Dr Chan:** How about applanation tonometry?

**Dr Ruiz:** It has no significant effect.

**Dr Chan:** Does pupil size have any effect on the INTRACOR™ procedure?

**Dr Ruiz:** We have found that the procedure is not pupil-dependant and we do not see any difference.

### CONTRA-INDICATIONS

**Dr Chan:** What are the contra-indications of INTRACOR™?

**Dr Ruiz:** The contra-indications are similar to those with LASIK, including patients with irregular corneas due to keratoconus, corneal scars etc.

**Dr Chan:** Will you consider a patient who has a borderline topography for the INTRACOR™ procedure?

**Dr Ruiz:** If there is some kind of irregularity observed in the topography, we will definitely not recommend the patient to go for the INTRACOR™ procedure.

## TREATING CATARACT PATIENTS

**Dr Chan:** Can the INTRACOR™ procedure be done in patients with early cataracts, or should you wait until after the cataract procedure has been done?

**Dr Ruiz:** I will treat the cataract first and once there is stable refraction with emmetropia, perform the INTRACOR™ procedure. We have treated four cases of post-cataract patients with INTRACOR™ and they are doing quite well after 8 to 10 months.

**Dr Chan:** After the INTRACOR™ procedure, if you implant an IOL – I assume it is a monofocal lens first – would the effect still be there? Would the patient still have his original reading ability? Say if someone had the INTRACOR™ procedure for presbyopia and they developed a cataract 5 years later, you take out the cataract and you put in an IOL, would that patient still have the INTRACOR™ effect?

**Dr Ruiz:** Yes, we have done a 6-month follow up in four eyes which had IOL implanted after the INTRACOR™ procedure and they are still able to see well.

**Dr Chan:** How about IOL power calculation for cataract surgery after INTRACOR™? Say a patient who is emmetropic, went for INTRACOR™ and 10 years later, needed cataract surgery?

**Dr Ruiz:** The IOL calculation will not be affected since we usually take the K readings at about 4 mm. We perform a normal calculation with the pre- and post-K values and they are similar.

## TREATING POST-REFRACTIVE SURGERY PATIENTS

**Dr Chan:** How does the INTRACOR™ procedure work in post-LASIK patients who have had their cornea thinned out after myopia treatment and are now emmetropic?

**Dr Ruiz:** We have performed INTRACOR™ on 30 post-LASIK eyes and found that most are over-corrected. We are now investigating the reasons behind this over-correction, one of which could be the flap. If we go deeper below the flap to perform the intrastromal procedure, it may have much more effect. We have also done LASIK for these over-corrected patients and they do very well. Due to the observed over-correction, we will certainly need more time to analyze the algorithms, ring patterns and depth for post-LASIK eyes.

**Dr Chan:** Can INTRACOR™ be done in post-RK operated eyes?

**Dr Ruiz:** We have done 20 or 30 such eyes and the results have been excellent – almost as good as the results with virgin eyes, unless there was a very high degree of myopia pre-operatively. If the cornea is too flat, we have less success, but within 1 to 4D of myopia corrected with RK, the results have been great.



## INTRACOR™ & PRESBYLASIK

**Dr Chan:** What is the difference between INTRACOR™ and presbyopic LASIK?

**Dr Ruiz:** PresbyLasik leaves the cornea with different curves centrally and peripherally, which creates aberrations. The INTRACOR™ procedure barely affects the corneal surface; the topography afterwards shows a very even surface, which may explain why patients experienced less or no disturbances, compared with PresbyLasik patients. Secondly, with INTRACOR™, no important nerves in the cornea are cut, as no flap is created. Therefore the eye does not lose any sensitivity and dry eye syndrome is not an issue.

**Dr Chan:** What is the difference between the post-operative outcomes with INTRACOR™ and those with PresbyLasik correction?

**Dr Ruiz:** There is a distinct difference in contrast sensitivity. In my experience, the downside of PresbyLasik is that patients lose a lot of contrast sensitivity. Of the thousands of patients operated on so far, **I have never seen a PresbyLasik patient with 20/15 vision and yet could read J1 or J2, unlike the INTRACOR™ patients.**

## STABILITY

**Dr Chan:** How long does the INTRACOR™ effect last?

**Dr Ruiz:** So far, the INTRACOR™ clinical data up to a follow up time of about 2 years have been very stable.

**Dr Holzer:** Regarding stability, we observed that the follow up data between 1 week and 6 months remain the same in both under-performers and those who were spot-on. So it seems the results are stable over that period of time.

**Dr Ruiz:** My explanation for the stability is that the change in the anterior asphericity and the posterior asphericity is basically the same proportion. When you measure the change in asphericity at 1 day, 1 week, 1 month, 3 months, 6 months, it will be the same. But with LASIK, for example, the anterior change is completely different after the first week because a lot of myopia is being induced – it is completely different.

## RETREATMENTS

**Dr Chan:** What is the strategy for INTRACOR™ re-treatment for under-performers? Do you cut extra rings or deeper rings?

**Dr Ruiz:** We make adjustments to the nomogram which include many factors, such as the number and depth of the rings, the optical zone, the distance between the rings, etc.

## MYOPIC CORRECTION

**Dr Chan:** Can myopia correction be combined with the INTRACOR™ presbyopia correction procedure, by having both the INTRACOR™ rings and the RK-like cuts?

**Dr Ruiz:** That is exactly what we are doing now; combining both the radial cuts for myopia with the rings for presbyopia. That is why, for example, if a patient is emmetropic and presbyopic, we must do radial incisions, because a minimal amount of at least half a diopter of myopia is induced, which must be compensated for. I find this works really well in emmetropes, where the myopia is induced then compensated for with radial cuts.

**Dr Chan:** Are the RK cuts done together with the rings?

**Dr Ruiz:** Yes, within the same procedure.

## OUTCOMES

**Dr Chan:** After the INTRACOR™ procedure, will patients encounter any problems with glare and halos or driving at night?

**Dr Ruiz:** In the early post-operative period, some patients may see and even count the halos, but they are not bothered by these disturbances when driving at night.

**Dr Holzer:** I agree, even though patients may experience glare and halos, they do not seem to be disturbed to the extent of having to abstain from certain activities.

**Dr Chan:** The reason we are bringing up these problems of glare and halos may be because we tend to associate the principle of INTRACOR™ to be similar with some of these multifocal IOLs which uses diffraction rings. What Dr Ruiz has invented with the INTRACOR™ procedure is not based on diffraction rings; it is actually **changing the shape of the cornea and making it slightly more hyper-prolate**, as a way of correcting for presbyopia.

**Dr Chan:** Are there any concerns such as any risk of ectasia?

**Dr Ruiz:** No, but if Descemet's membrane were touched, there would be a high risk of ectasia.

**Dr Chan:** Is there any significant loss of biomechanical strength, which might cause instability with thinner, softer corneas?

**Dr Holzer:** The minimally invasive treatment is performed directly into the stroma without the need for any tissue removal or cutting the cornea. Therefore the structural integrity of the cornea is maintained. We further justified this by using an ocular response analyzer and found no significant changes in the corneal resistance factor and hysteresis of the cornea.

**Dr Ruiz:** So far, no major difference has been seen in outcomes of a patient with a pre-operative hysteresis of 11 compared to one with a hysteresis of 9.5. The INTRACOR™ procedure itself has a minimal effect on corneal hysteresis, unlike LASIK, which can reduce hysteresis from 9.5 to 6; INTRACOR™ has not reduced hysteresis by more than 0.2 or 0.3. Unfortunately, to date there is no agreement about exactly what hysteresis is measuring. However, it is the only tool available for gauging how strong the cornea is pre-operatively versus post-operatively. The difference compared to LASIK is striking.

**Dr Chan:** How often do you use the ocular response analyzer?

**Dr Ruiz:** At 1 day post-operatively, then at every follow up: 1 month, 3 months, 6 months, 1 year, and 18 months.





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