Supplement to June 2010

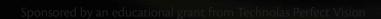
Cataract & Refractive Surgery

Presbyopia

EUROPE

True Solutions for Presbyopia With Laser Technology

Capturing the growing presbyopia market sector.



Technolas Perfect Vision: True Solutions for Presbyopia With Laser Technology

echnolas Perfect Vision (Munich, Germany) was formed through a joint venture between the refractive business of Bausch + Lomb (Rochester, New York) and the femtosecond laser developer 20/10 Perfect Vision AG (Heidelberg, Germany) in 2009. Truly focusing on the laser vision correction industry, Technolas Perfect Vision (TPV) has a full range of expertise in both femtosecond and excimer refractive businesses, with many innovations focused on the correction of presbyopia. This supplement to CRST Europe addresses the company's existing INTRACOR treatment as well as introduces its forthcoming excimer laser solutions for presbyopia.

FEMTOSECOND LASER INTRASTROMAL TREATMENT FOR PRESYBOPIA

INTRACOR is an intrastromal femtosecond laser treatment to correct presbyopia. Luis Antonio Ruiz, MD, of Bogotá, Columbia, performed the first INTRACOR procedures in the world in 2007; he is the co-inventor of the procedure. Following a subsequent prospective multicenter study in Germany, INTRACOR received the Conformité Européenne (CE)-Mark for the treatment of presbyopic hyperopia in April 2009. The CE study was performed by Mike P. Holzer, MD, and Gerd U. Auffarth, MD, both of Heidelberg; Michael C. Knorz, MD, of Mannheim; Mark Tomalla, MD, of Duisburg; and Tobias Neuhann, MD, of Munich. Included in this supplement is a summary of 12month CE data and 2-year follow-up data, respectively presented by Professor Knorz and Dr. Ruiz during TPV's Alliance meeting in Boston at the American Society of Cataract and Refractive Surgery (ASCRS) meeting.

Since the commercial availability of INTRACOR in Europe in late 2009, more than 1,500 procedures have been performed using the TPV Femtosecond Workstation 520F. Dan Alexandre Lebuisson, MD, of Paris, provides his insight into the key steps for the successful commercial launch of INTRACOR. Lastly, Carlos Gutiérrez Amorós, MD, of Coruña, Spain, discusses his study on performing INTRACOR on pre-phaco and pseudophakic patients.

FUTURE INNOVATIONS: FORTHCOMING EXCIMER SOLUTION FOR PRESBYOPIA

In tangent to TPV's femtosecond laser solution for presbyopia, the company has developed an advanced and innovative algorithm to correct presbyopia using its excimer laser platform.

A European multicenter study on this corneal excimer solution for presbyopia involves a binocular procedure that provides LASIK vision correction for patients with presbyopia and a mid-to-high refractive error. Developed by Jean Jacques Chaubard, MD, of Nice, France, this binocular solution integrates near and distance treatments. The distance correction uses the tissue-saving algorithm for hyperopia, and the near central addition is asymmetric according to the dominance of the eyes.

A European study evaluating this presbyopic excimer treatment is in its final stages of completion. The study participants in this prospective, multicenter, bilateral study on 80 to 100 patients are Dr. Chaubard; Jorge Castanera, MD, PhD, of Barcelona, Spain; Antoine Roure, MD, of Nice, France; and Dominique Pietrini, MD, of Paris. "According to the data of the current status of our clinical study, we can state that the algorithm used for the presbyopic correction by the excimer laser delivers the desired outcomes in relation to gain of near visual acuity and distance correction as well as safety. In parallel to the refractive data, the evaluation of patient satisfaction based on the questionnaire supports the statement about the efficacy of the algorithm," Dr. Chaubard said. Clinical study results will be presented at the European Society of Cataract and Refractive Surgeons (ESCRS) meeting in Paris.

LOOKING AHEAD: FURTHER IMPROVING OUTCOMES

Based upon TPV's growing INTRACOR experience and data from the excimer presbyopia study, TPV is looking to combine the best of both worlds, aiming to further improve outcomes and patient satisfaction.

12-Month Conformité Europeénne Data on INTRACOR

Results from this European multicenter study are promising.

BY MICHAEL C. KNORZ, MD

t the age of 51 years old, I can now say with understanding that presbyopia is a nuisance. My eyes get tired when I read, and I have developed trouble seeing at near. For several years, I have been searching for a presbyopia treatment that will not only help my patients with presbyopia, but one that will also help me. I believe I have found the answer. The INTRACOR (Technolas Perfect Vision, Munich, Germany) treatment is contained inside the cornea using a femtosecond laser, and in my opinion, it is the ideal treatment for presbyopia.

The femtosecond laser creates five stacked cylinders of different heights inside the cornea, starting above Descemet's membrane and ending approximately 100 µm below Bowman's membrane. The innermost diameter of the cylinder is 1.8 mm in the Conformité Européenne (CE)-certified version.

In my opinion, [INTRACOR] is the ideal treatment for presbyopia.

Because this is a purely intrastromal procedure, there is no risk of infection. How it works is that the intraocular pressure pushes the innermost part of the cornea slightly forward, to create a small change in position (5–8 μ m), and resulting in central steepening of the cornea without inducing any change to the periphery and mid-periphery. This effect is like adding a plus lens to the cornea. Additionally, there is an induction of negative spherical aberration, which

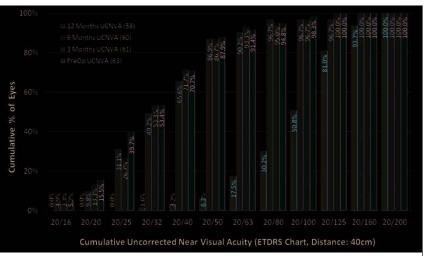


Figure 1. Preoperative to 12-months postoperative cumulative near UCVA.

is important because it increases patients' depth of focus and allows them to see better at near. As a small side effect, it also induces approximately -0.50 D of myopia.

The procedure lasts less than 30 seconds. Visually, some gas bubbles are present within the rings. Visual quality will be slightly reduced immediately postoperatively; however, the gas bubbles disappear within the first hour and vision will improve.

MULTICENTER STUDY

I am currently participating in the European multicenter study of INTRACOR, which to date includes results from 63 patients, 58 of whom have at least 12 months of follow-up, from four sites in Germany. Treatments were performed in the nondominant eye only and completed between July and October 2008. Patients (age, 55.4 \pm 6.2 years) had a preoperative manifest refraction of 0.74 \pm 0.37 D sphere and -0.29 \pm 0.24 D cylinder.

Because INTRACOR induces a little myopia, we selected patients who were slightly hyperopic preoperatively to avoid myopia postoperatively. We expected to see a positive shift in the postoperative cumulative near UCVA (Figure 1), and that is what our results

Courtesy of Mike P. Holzer, MD; Michael C. Knorz, MD Mark Tomalla, MD; and Tobias Neuhann, MI

INTRACOR: 2-YEAR DATA SHOW GOOD LONG-TERM STABILITY

By Luis Antonio Ruiz, MD

I have the honor and distinction of being the first surgeon to perform noninvasive intrastromal corrections with INTRACOR (Technolas Perfect Vision, Munich, Germany). Two years after my initial treatments, patients are still stable. This procedure shows great promise for the treatment of presbyopia in our aging population.

To date, I have treated nearly 2,000 eyes with INTRACOR, 282 of which have at least 6 months' follow-up, 214 of which have at least 12 months' follow-up, and 94 of which have at least 24 months' follow-up. The average length of follow-up is 16.22 months (range, 6–29 months), and the average age of patients is 53.55 years (range, 43–70 years). This article will focus on those patients with at least 24 months of follow-up; data from this subset of patients demonstrate good long-term stability of INTRACOR.

Preoperatively, many patients are plano presbyopes. With regard to distance UCVA, many patients went from 20/20 preoperatively to 20/16 postoperatively. Additionally, at 24 months postoperatively, most patients are reading J1. It is important to note that INTRACOR does not induce any cylinder, as it is an astigmatically neutral procedure.

The great thing about INTRACOR is that it provides patients with excellent near, intermediate, and distance vision without the need for spectacle correction. Preoperatively, 77.6% of patients were J6 or worse. But at 2 years, 100% of patients are J3 or better, 96.8% are J2 or better, and 74.47% are J1 or better (Figure 1). It is there-

fore clear that INTRACOR improves near vision, and it does so without sacrificing distance vision (Figure 2).

The most crucial message that surgeons want to know is: What is the long-term stability of INTRACOR? In my study, 54% of patients (51 eyes) were within ±0.50 D of intended correction early on. By 24 months, 92% were within ±0.50 D of intended correction. In 86% of patients, the refractive change was 0.50 D or less, with 94% of patients maintaining the same change from month 1 as they have at month 24. Between 12 and 24 months, 98.9% of patients have less than 0.50 D of change, indicating completely stable results. No patient had more than 1.00 D of change, and the mean change at 2 years is 0.02 D.

Regarding safety, no patient lost more than 1 line of BCVA,

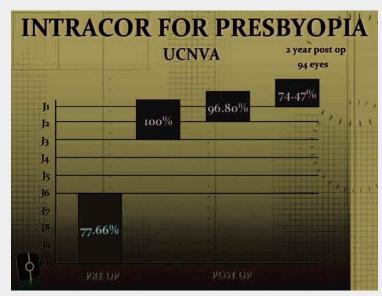


Figure 1. All patients showed improvement in near UCVA.

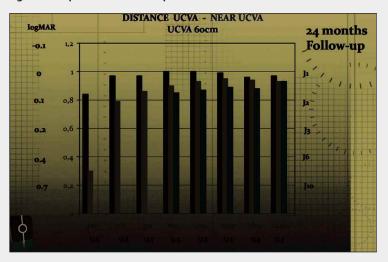


Figure 2. Distance and near UCVA, pre- and postoperatively.

and 80% of patients increased by 1 line of BCVA. This is impressive, because we are dealing with patients who have good preoperative vision, and in fact 99.21% of my patients had preoperative BCVA between 20/20 and 20/15. Results at 2 years indicate that long-term stability is excellent, and I expect that the stability will be maintained over time.

Luis Antonio Ruiz, MD, is the Scientific Director at the Centro Oftalmológico Colombiano, Bogotá, Columbia. Dr. Ruiz states that he has received a research grant sponsored by Technolas Perfect Vision. He may be reached at tel: +57 236 00 00; e-mail: luisantonio.ruiz@gmail.com.



have consistently shown. At 12 months postoperatively, 40% of patients are seeing 20/25 or better, 50% are seeing 20/30 or better, and 70% are seeing 20/40 or better at near. On average, the gain of lines of visual acuity at 12 months is 4.7 lines at near. This is a tremendous gain of near UCVA, which we have shown to be stable from the first stage to 12 months (Figure 2). The other good news is that this treatment provides a wow factor. Patients see well at near as soon as 1 or 2 hours postoperatively.

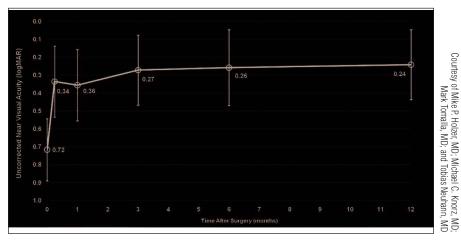


Figure 2. Stability of near UCVA, up to 12 months.

The pre- to postoperative change in distance UCVA was minimal, which is mostly because the procedure does induce a small amount of myopia. However, it is important to note that distance UCVA did not decrease in this patient population. The good news is that, regarding distance BCVA, most patients were within ±1 lines. A small number of patients even gained 1 or 2 lines; however, there was one patient who lost 2 lines of distance BCVA.

The other good news is that this treatment provides a wow factor. Patients see well at near as soon as 1 or 2 hours postoperatively.

CONCLUSION

Although the results for distance BCVA do not improve significantly after INTRACOR, patients gain a lot of near vision postoperatively, which is important to this presbyopic population. Today, the clear indication for INTRACOR is presbyopic hyperopes between 0.50 D to 1.25 D.

It is important to remember that, in this study, only the nondominant eye was treated; however, at the end of 12-month follow-up, 60% of patients indicated that they would like to undergo treatment in the dominant eye. The other 40% of patients were happy with the vision in their first eye.

The two main side effects of INTRACOR are that the treatment induces slight myopia (-0.50 D) and that 90% of patients see rings around lights while driving at night. These rings are nothing like those induced by a multifocal IOL, however, and patients have minimal complaints.

In fact, these rings typically disappear between 6 weeks and 3 months postoperatively. The positive effects of INTRACOR include the central steepening of the cornea, the induction of negative spherical aberration, and the significant increase of depth of focus. Such benefits outweigh the side effects, and patients seem to be happy with their postoperative outcomes.

At 12 months, results are stable and there is nearly no loss of distance BCVA. I do believe that INTRACOR is a very promising procedure, and it should secure a distinct position in the marketplace for presbyopia treatments.

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Strategy and Results for Offering INTRACOR

Follow three simple steps to incorporate intrastromal correction.

BY DAN ALEXANDRE LEBUISSON, MD

n the past, there was substantial room for improvement in presbyopia treatments. Now, with the availability of INTRACOR (Technolas Perfect Vision, Munich, Germany), patients can undergo an intrastromal correction that induces significant improvements in near visual acuity. Although surgeons are alert to the promise of INTRACOR, it is still too early for patients to have the same level of awareness. For this reason, developing a strategy to commercialize INTRACOR is the first order of business when integrating these treatments into your practice. This article will discuss my early experience commercializing INTRACOR at the Clinique de la Vision in Paris.

Approximately 90% of emmetropic patients do not wish any traditional presbyopia correction with spectacles or contact lenses. These are the patients who will enter your clinic seeking alternative treatments. In addition to IOL correction strategies and the limited methods of laser vision correction for presbyopia, we can now offer patients INTRACOR to correct their presbyopia.

There is no question that as cataract surgery and refractive surgery continue to merge, the future growth of our field will be dependent on presbyopia correction. With the mean age of our population increasing, and with these patients having higher demands and heavier expectations compared with previous generations, presbyopia correction will become a larger percentage of the procedures we perform in the next 5 to 10 years. Additionally, the mean age for patients undergoing laser vision correction in 2009 was 37.8 years. Therefore, we have a large pool of patients to choose from, with one group of patients who are viable candidates for presbyopia correction with INTRACOR: low hypermetropic patients of at least one eye.

COMMERCIALIZING INTRACOR

The question is: How do we commercialize presbyopiacorrection procedures, when in many countries across Europe, direct-to-consumer medical marketing is forbidden? In France for instance, medical doctors cannot advertise and only general medical information is authorized in the media. We must find other methods of relaying information to patients with presbyopia, so that they understand that options for correction extend beyond spectacles and contact lenses. They must be made aware of all platforms of presbyopia correction. This strategy translates into successful surgeries and happy patients.

At our center, which is the main refractive surgery clinic in France, we have the ability to offer patients all forms of presbyopia correction. We present each option in a manner that provides patients with enough confidence to make an educated decision. We also explain that although refractive surgery is not reimbursed by the social health care system and is included in the free-market economic health regulations, if the patient has private insurance, part of the cost may be reimbursed. France is the first country to offer private insurance in addition to the socialized health care available to French residents. The range of reimbursement may be anywhere between 20% and 80%; patients are more likely to receive reimbursement if they are older.

GOALS FOR GROWTH

Each center must set realistic goals for growth. Our goal over the next few years is to increase ammetropic laser surgery rates, with annual rate increases currently hovering between 3% and 5%. We also hope to increase the number of presbyopic procedures we perform, expand the conventional indications for presbyopia surgery, and be among the first centers to invest in new technologies.

In 2009, we purchased the TECHNOLAS 520F femtosecond laser in order to perform INTRACOR. We do not use any direct marketing or advertising, we do not offer any discounts or credits, and we do not bundle presbyopia correction into a refractive package pricing strategy. We charge a premium price (€2,000/eye), because it is a premium procedure. At this cost, we will break even on our investment in the 520F laser after 200 INTRACOR procedures. Some surgeons may be hesitant to price this procedure so high, but patients who are 45 years of age or older tend to have more disposable income and are willing to spend €2,000 on a procedure that will improve their quality of life. We have found that



Figure 1. Prospective patients for INTRACOR.

offering INTRACOR at our center has provided us with an edge over competitors; the procedure is starting to create its own buzz, and patients will gravitate toward the center that offers it. The results INTRACOR offers patients are not only impressive, but stable as well.

STRATEGY

There are three main steps that must be taken to successfully commercialize INTRACOR.

Step one. Our first step after adding INTRACOR into the presbyopia-correction strategies we offer was to inform every ophthalmologist working at the Clinique de la Vision about the procedure. Surgeons were invited to attend educational sessions and live surgeries. We offered training sessions to those who were interested in learning the INTRACOR technique; surgeons who did not undergo training were asked to inform their patients about the procedure, referring them to a colleague in the event that the patient was interested. We also trained surgeons on the strategies involved in explaining INTRACOR to potential patients and family members who accompanied patients to the visit.

Step two. The second step is dealing with the patients. The patient's introduction to INTRACOR will largely influence his decision to undergo the procedure or opt for another presbyopia-correcting treatment. First, it is important for patients to understand that INTRACOR does not make their presbyopia disappear but rather decrease the symptoms of presbyopia. Second, patients must know that INTRACOR is possible

in part because of the evolution of femtosecond laser technology. As such, the procedure is fast, easy, predictable, precise, ergonomic, and secure. With these key words, patients are able to grasp the complete range of benefits offered by INTRACOR.

But how do patients find out about INTRACOR? We have chosen to post a 2-minute video on our Web site. Beside the Internet, the telephone is the first opportunity we have to communicate with the patient. Staff answering the phones must understand their importance in the process of lead tracking. They should also understand all surgical options, including presbyopiacorrection strategies like INTRACOR, and be able to describe them to the interested patient. Personnel who are in the position of communicating with the patient over the phone or once the patient enters the clinic should be available to answer any questions they may have and must orient the patient to what options are best for him. The biggest point to remember is that the staff is available to guide the patient, but it is the patient who must make the final decision.

Patients seem to understand that femtosecond lasers are a precise technology. Most are willing to undergo procedures that incorporate femtosecond technology. The biggest fear patients have today is the loss of distance vision after presbyopia correction; however, most studies of INTRACOR have shown a low level of decreased long-distance visual acuity postoperatively.

Step three. The next step of commercializing INTRACOR is learning the indications for surgery, for which there are three criteria: the patient must have good cooperation between their eyes, prospective candidates must have no sign of cataract, and patients must be presbyopic. Using these criteria, approximately 25% of patients are eligible for INTRACOR, with 20% choosing to undergo the procedure. For example, we performed 72 cases of INTRACOR in the first 4 months of offering it at our clinic (Figure 1).

CONCLUSION

INTRACOR is a new refractive principle used for the correction of presbyopia. It is a safe and effective procedure that is gaining popularity. Incorporating it into your practice will increase the surgical perimeter you are able to offer. Our patients enter the clinic knowing what INTRACOR is and, in many cases, asking for it. Until your clinic gets to this point, follow the steps outlined above to commercialize INTRACOR. Your conversion rates will flourish, and patients will be happier than ever.

Dan Alexandre Lebuisson, MD, is the Medical Director of the Clinique de le Vision, Paris. Dr. Lebuisson states that he has no financial interest in the companies mentioned. He may be reached at e-mail: lasik@orange.fr.



Experience With INTRACOR in Special Presbyopia Cases

Combining INTRACOR and phacoemulsification is safe and effective for refractive surgery patients who require good distance and near visual acuity.

BY CARLOS GUTIÉRREZ AMORÓS, MD; BERTA RUIZ, DOO; PATRICIA GÓMEZ, DOO; AND MARCOS ANTELO, DOO

he correction of presbyopia by femtosecond-created intrastromal incisions (INTRACOR; Technolas Perfect Vision, Munich, Germany) has been shown to be effective, safe, and stable in the medium term. Since January 2009, we have performed 91 INTRACOR procedures in 57 patients (mean age, 53 years; range, 45–77 years), including 34 procedures in ideal phakic patients (Conformité Européene study criteria), seven in pseudophakic patients, and 24 as pre-phaco procedures. Our detailed results follow.

Given patients' growing demand for complete and permanent correction of their refractive errors, including presbyopia, we have created a new technique combining the INTRACOR procedure for presbyopia correction with extraction of the clear crystalline lens or cataract during phacoemulsification. Following a full preoperative examination, the technique usually consists of performing bilateral INTRACOR followed by phacoemulsification of the crystalline lens 1 or 2 weeks later to correct the refractive error.

We implant toric and/or spherical IOLs with this combined procedure. To calculate the strength of the IOLs, we use standard formulas (SRK-T, Haigis, HofferQ, or Holladay) and keratometry and biometry data prior to INTRACOR (in eyes that have not undergone surgery).

INTRACOR RESULTS IN PSEUDOPHAKIC PATIENTS

All pseudophakic patients we have treated with INTRACOR experience improved near visual acuity with almost no affect on their distance visual acuity (Figure 1). Additionally, a high percentage of patients have a reduction in spectacle dependence. From my point of view, INTRACOR in pseudophakic patients is a highly fruitful procedure, improving near visual acuity and eliminating the need for glasses.

INTRACOR AND PHACO OUTCOMES

We have performed the new combination treatment of INTRACOR and phacoemulsification in 24 eyes (13 patients), with a mean follow-up of 4 months (range, 1 week to 12 months). We implanted the iSymm (Hoya, Tokyo) or the toric AcrySof (Alcon Laoratories, Inc., Fort Worth, Texas) in this population. Of these patients, six had an opaque crystalline lens and seven

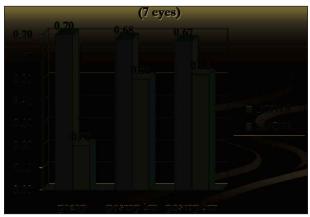


Figure 1. Distance and near UCVA in pseudophakic patients treated with INTRACOR.

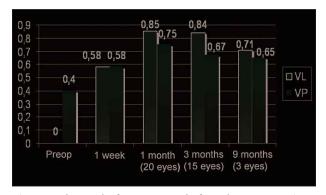


Figure 2. The results for INTRACOR before phaco surgery in 24 eyes of 13 patients are promising. (VL = distance UCVA;VP = near UCVA)

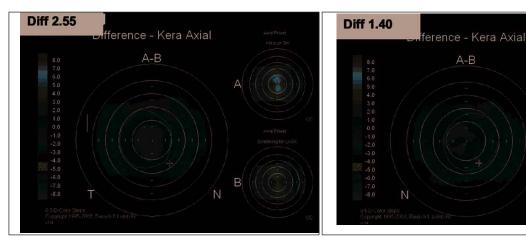


Figure 3. Case No. 1: Post- and preoperative difference maps for the right and left eye.

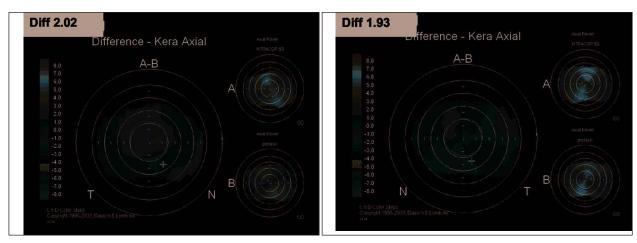


Figure 4. Case No. 2: Post- and preoperative difference maps for the right and left eye.

had a clear crystalline lens.

The logarithmic visual acuity chart 2,000 was used for distance visual acuity; for near vision, the Jaeger chart was used. Preoperative data were as follows: mean spherical refractive error, -0.88; mean cylindrical refractive error, -1.92; mean distance UCVA, 20/200; and mean near UCVA, 20/60 (J7).

Four months after surgery, the mean data were: distance UCVA, 20/25; and near UCVA, J3 (Figure 2). A total of 53.3% of patients had a distance UCVA of 20/20; 20% of 20/25; and 19.9% of 20/32. Forty percent of patients had a near UCVA of J1 and 59.9% of J2.

Of the 13 treated patients, 90% resumed their normal activities within 2 weeks postoperatively, and the level of satisfaction with the result of the procedure was high in most patients. No patient who underwent INTRACOR followed by phacoemulsification required glasses for distance vision or to read a newspaper. In good light, 95% were able to read J2. There were no significant refractive surprises, no IOLs that required lens exchange, and no retreatments required for residual refractive errors.

In our experience, and compared with multifocal

No patient who underwent INTRACOR followed by phacoemulsification required glasses for distance vision or to read a newspaper.

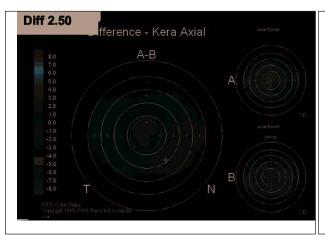
lenses, INTRACOR followed by phacoemulsication results in an improvement in intermediate vision, more rapid adjustment, less glare and halos, slightly inferior near vision (J3 vs J1), and much less impact of residual refractive defects as well as the opacity of the posterior capsule on the quality of vision.

After 1 year of experience, total and final refractive correction combining INTRACOR and phacoemulsification is excellent, making this a safe and effective combination procedure.

CASE STUDIES

Below are three case studies of patients we have treated with INTRACOR and phacoemulsification.

Case No. 1. A 52-year-old woman requested refractive



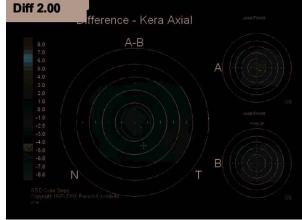


Figure 5. Case No. 3: Post- and preoperative difference maps for the right and left eye.

surgery because of poor vision and an increase in diopters. Her preoperative refraction was: OD +5.50 -1.75 X 5°, with 20/25 visual acuity and add +1.75 J1; OS +5.50 -3.50 X 45°, with 20/32- visual acuity and add +1.75 J1. One week after INTRACOR followed by phacoemulsification with implantation of a toric IOL, her UCVA was: OD 20/32 (J2) and OS 20/50- (J3). At 6 months postoperative, her UCVA was: OD 20/32 (J2) and OS 20/40 (J2). Binocularly, she was 20/25 and J2 (Figure 3).

We currently recommend INTRACOR and phacoemulsification to patients who request refractive surgery and good distance and near visual acuity.

Case No. 2. A 50-year-old woman who requested refractive surgery due to poor adjustment to progressive glasses had a preoperative refraction of: OD -9.50 -4.25 X 30°, with 20/40 visual acuity and add +1.50 J1; OS -5.50 -3.75X 155°, with 20/32- visual acuity and add +1.50 J1. One week after INTRACOR and phacoemulsification with implantation of a toric IOL, her UCVA was: OD 20/32 (J2) and OS 20/25 (J2). One month postoperative, her UCVA was: OD 20/25 (J2) and OS 20/25 (J2). Binocularly, she was 20/25 and J1 (Figure 4). Case No. 3. A 75-year-old woman with initial sub-

capsular cataract requested surgery because of poor tolerance of glasses. Her preoperative refraction was: OD +3.25 -1.00 X 100°, with a visual acuity of 20/20 and add +3.00 J1; OS +3.25 -0.75 X 80°, with a visual acuity of 20/20 and add +3.00 J1. In this case, an aspherical IOL was implated after INTRACOR and phacoemulsification. One week postoperative, her UCVA was: OD 20/40 (J3) and OS 20/32 (J4), and 1 month postoperative it was OD 20/25 (J2) and OS 20/25 (J2). Binocularly, she was 20/25 and J1 (Figure 5).

CONCLUSION

We currently recommend INTRACOR and phacoemulsification to patients who request refractive surgery and good distance and near visual acuity, because of its efficacy, its good results, and its high level of patient satisfaction. We have had very few unsatisfied patients at our center.

Carlos Gutiérrez Amorós, MD, is the Medical Director of COGMA, La Coruña, Spain. He states he has no financial interest in the products or companies mentioned. He may be reached at email: cogma@cogma.net.



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Frequently Asked Questions on INTRACOR

How does the TECHNOLAS 520F differ from other femtosecond lasers that makes it suitable for treating presbyopia?

- Unique curved interface, which keeps corneal deformation to a minimum.
 This allows for precise 3D cutting.
- · Less stress with less suction.
- Unlike other systems, which are optimized for flap applications and are working at one depth (2D), the 520F is optimized to work at different depths throughout the treatment.
- Laser cuts are curved, following the stromal lamellae and leading to more precise cuts through the naturally curved cornea.

2. What causes the corneal change and treatment of presbyopia?

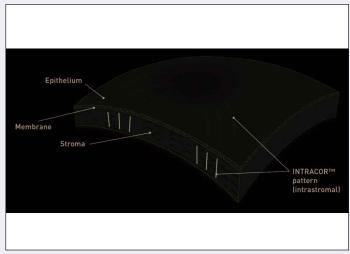
 The biomechanical change, which interacts with intraocular pressure, pushes the innermost part of the cornea slightly forward, resulting in central steepening of the cornea.

3. What are the current indications for INTRACOR?

 For the moment, TPV recommends treating presbyopic patients who are slightly hyperopic.
 Surgeons achieve the best results with manifest refractive spherical equivalent (MRSE) between +0.25 to 1.00 D, with no more than 0.50 D of astigmatism.

4. What is the long-term effect of INTRACOR?

- At present, the longest range of follow-up extends to 2.5 years, with very stable results.
- Long-term results are stable because the anterior corneal fibers are not affected. Additionally,
 Descemet and Bowman are not touched.



5. Would you recommend bilateral treatment as a standard?

- INTRACOR has been designed as a bilateral procedure
- For starting surgeons, TPV recommends treating the nondominant eye first and the second eye 2 to 4 weeks later, if distance vision of first eye has not been compromised.
- · For experienced surgeons:
 - TPV recommends bilateral treatment for all patients with MRSE in the range of +0.75 to 1.25 D
 - For patients with MRSE between 0.50 and 0.75 D,
 TPV recommends to simulate the myopic shift of -0.50 D (or -0.75 D as a worst-case simulation) with contact lenses. If the patient agrees with the distance vision, the bilateral INTRACOR treatment is advised.
 - For patients between 0.00 and 0.50 D, TPV recommends a monocular treatment. First conduct a contact lens trial for a few days to decipher if the patient supports the induced monovision. If he does not support monovision, TPV recommends not to treat.