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Professional paper

First Results of Intracor Procedure in Croatia

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A B S T R A C T

This study reports early outcomes of a cohort of presbyopic patients treated with Intracor. The study took place from December 2010 to May 2011 and was conducted in University Eye Hospital »Svjetlost«, Zagreb, Croatia. 95 eyes were enrolled in this prospective clinical trial (49 patients with non dominant eye and 23 with bilateral treatment). All patients gave informed consent prior to enrollment. Follow up consisted of uncorrected and corrected distant and near visual acuity, record of topographic changes, visual disturbances and patient satisfaction at 1 week, 1 and 3 months after the surgery. In this study Intracor procedure presented as both safe and effective with all eyes gaining several lines of uncorrected near visual acuity (UNVA), and achieving good uncorrected distant visual acuity(UDVA) as well. UDVA was affected by a mild myopic shift, which was effective in reducing mild preexisting hyperopia in some patients but led to a mild myopic outcome in previously emmetropic patients. Statistically significant improvement in UDVA and UNVA was observed in all time points. At 3 months of postoperative follow up all patients gained several lines of UNVA with monocular UNVA Jaeger system 1.67±0.28. UDVA showed slight improvement over time and initial myopic shift showed tendency of slight decrease with all patients achieving 1.0. Overall patients satisfaction was very high (98%) with only a few (3 patients, 5 eyes) reporting mild halo and glare at 3 months postop.Intracor procedure has proven its short term safety and efficacy in treating presbyopia. However, longer follow up period is needed.

Abbreviations: *UNVA – uncorrected near visual acuity, UDVA – uncorrected distant visual acuity*

Key words: *Intracor, presbyopia, femtosecond laser*

Introduction

Since the begining in 1949, refractive surgery has been evolving at fast pace with the development of different techniques from Jose Ignacio Baraquer's freeze keratomileusis to customized ablations.[1,2] Corneal refractive procedures, among which LASIK is the most popular, for myopia, hyperopia and astigmatism has proven to be successful and safe for many years. However, the biggest challenge of modern refractive surgery is successful treating of presbyopia. In 2005, the estimated global impact of presbyopia was affecting 1.04 billion people with over half of these not having adequate near vision correction.[3]

Nowdays, the most common way of treating presbyopia is spectacle and contact lens prescription. Refractive field had numerous attempts in treating presbyopia such as conductive keratoplasty, monovision procedures, multifocal corneal ablations (Presbylasik), intracorneal inlays (Acufocus), clear lens extraction with multifocal or acomodative intraocular lens implantation, phakic multifocal intraocular lenses, and anterior ciliary sclerotomy. Despite numerous efforts, numerous limitations have prevented widespread acceptance of most of these techniques. Concerns regarding regression of effect, impact on distant visual acuity, optical and visual distortion, anisometropia with monovision, and the inherent risks with invasive techniques played a limiting role.

With the introduction of femtosecond laser technology in the field of corneal surgery new minimally invasive techniques for presbyopia correction evolved by applying femtosecond laser pulses to the corneal stroma. They offer a painless and faster postoperative recuperation than surface ablation techniques without the need of cutting flaps. In October 2007, the first treatments of presbyopia using TECHNOLAS femtosecond laser (Technolas Perfect Vision GmbH, Munich, Germany) were performed by Luis Ruiz, MD, in Bogota, Columbia. In 2008, he presented his initial results of a procedure that changes the biomechanical forces of the cornea leading to multifocal cornea.4

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Patients and Methods

95 eyes were enrolled in this prospective clinical study (49 patients with non dominant eye and 23 with bilateral treatment). The study took place in University Eye Hospital »Svjetlost« in Zagreb from December 2010 to May 2011.

Inclusion criteria were patients more than 45 years of age, planopresbyopia or mild hyperopia up to 1D in spherical equivalent, cylindar up to 0.50D, near addition more or equal to +1.50D, best corrected distance visual acuity (CDVA) more than 0.6, pachimetry measurement more or equal to 500μm and keratometry readings between 39 and 48D.

Exclusion criteria were myopia, hyperopia more than 1D, cylinder more than 0.50D, topographical changes that indicate any kind of corneal irregularities succeptable for keratoconus, previous corneal refractive surgery, opaque media, corneal scars in the treatment zone, any previous or current ocular pathology like uveitis, glaucoma or evolving retinal disorders.

All patients underwent standard preoperative examination. Uncorrected distant visual acuity (UDVA) and CDVA (manifest and cycloplegic refraction) uncorrected and corrected near visual acuity (UNVA and CNVA), intraocular pressure (IOP), slit lamp examination and fundus examination were performed. Corneal topography (Wavelight Oculyzer, Germany), biometry (IOL Master, Carl Zeiss International, germany), endothelial cell count (CSO Specular Microscope, Italy) and aberometry (L80 WAVE+, France) were also obtained.

All patients underwent thorough preoperative councelling and were informed about the treatment and possible results. Patients were informed about variable response to treatment: possibility of following treatment side-effects, no near vision improvement, near vision deterioration with time, myopic shift, loss of up to 2 Snellen lines of distant vision, and night vision disturbances (halo/glare) which deteriorate with time. All patients gave informed consent prior to the surgery and enrollment in the study.

The Intracor procedure was performed by three surgeons using the TECHNOLAS femtosecond laser system (Technolas Perfect Vision 520F, Munich, Germany).

Patients were first treated on their nondominant eye, dominant eye was treated 4 weeks later if needed. Indications for treatment of the second eye were: unsatisfactory near vision or poor tolerance of Intracor induced monovision (fatigue and diplopia while reading).

Follow up included measurement of UDVA, CDVA, UNVA and CNVA, record of topographic changes, visual disturbances and patient satisfaction at 1 week, 1 and 3 months after the surgery.

On the day of surgery, all patients were given the following preoperative medications: oxybuprocaine hydrochloride 0.4% eye drops, benzodiazepine (5mg) and ibuprofen (400mg) pills. At first, non treated eye was covered. Under the microscope the patient was asked to fixate the light. The point of light reflex on the cornea was marked. After marking the cornea, patient was moved under the surgical microscope and asked to fixate red light. After centering, the eye was connected to the femtosecond laser using the TECHNOLAS specific curved patient interface device and five purely intrastromal consecutive rings around the line of sight were cut with the laser beam. The depth of these cuts as well as the energy used and spacing follows a proprietary nomogram that includes pachymetry data. The treatment time was approximately 20 seconds. The following postoperative medication regimen was recommended: 1 drop of tobramycin/dexamethasone 4 times daily for 2 weeks and artificial tears 6–8 times daily for one month. Before leaving the clinic, all patients were examined at the slit lamp where the corneal rings showed dilation due to cavitation gas that typically occurs during femtosecond laser treatment. On the following day, the gas had escaped in all eyes and only fine circular lines were noted in the stroma.

Results

72 patients aged from 46 to 63 years (average 54.22± 4.22) with preoperative monocular UDVA of 0.68±0.23, and binocular UDVA of 0.83±0.18 were included in the study. Their preoperative monocular UNVA was in Jaeger system (J) 7.21±2.96 and binocular UNVA was J5.81± 2.96. Average preoperative correction was 0.59±0.38 D and preoperative cylinders were 0.21±0.29 D. Binocular CDVA was 1.0±0.01 and binocular CNVA was J 1.0, preoperatively. Mean preoperative corneal thickness was 550.57±30.75 mm. 23 patients (46 eyes) underwent binocular intracor procedure, while the remaining 49 patients (49 eyes) underwent monocular procedure on their non-dominant eye.

Follow up was at 1 day, 1 week, 1 month and 3 months after surgery and included measurement of monocular and binocular UDVA, BDVA, UNVA and BNVA as well as corneal topographic changes and overall patients satisfaction.

On the first postoperative day monocular UDVA was 0.87±0.13, and binocular UDVA was 0.94±0.08. ($p \leq 0.05$ vs preop, student t-test). CDVA was 1.00±0.01. UNVA was J2.19±1.00 for monocular and J1.88±0.79 for binocular vision ($p \leq 0.05$ vs preop, student t-test). CNVA was J1.02±0.20, respectively.

At week 1 postop, monocular UDVA was 0.90±0.12 versus binocular UDVA of 0.97±0.07. CDVA was 1.00± 0.04. Monocular UNVA was J2.28±1.05, while binocular UNVA was J1.96±1.00. CNVA was J1.02±0.13J ($p \leq 0.05$ vs preop, student t-test).

After 1 month, results were following: monocular UDVA of 0.95±0.08 ($p \leq 0.05$ vs 1 week, student t-test) and binocular UDVA of 0.97±0.04. CDVA was 1.00. Monocular UNVA was J2.07±1.00 and binocular UNVA was J1.80±1.20. CNVA was J1.01±0.07.

3 months following the procedure, monocular and binocular UDVA were 1.0±0.00, as well as CDVA($p \leq 0.05$

TABLE 1.
COMPARISON OF MONOCULAR AND BINOCULAR UNCORRECTED AND CORRECTED DISTANCE AND NEAR VISUAL ACUITY (UDVA-UNCORRECTED DISTANCE VISUAL ACUITY, UNVA IN JAEGER(J)-UNCORRECTED NEAR VISUAL ACUITY, CDVA-BEST CORRECTED DISTANCE VISUAL ACUITY AND CNVA IN JAEGER(J)-BEST CORRECTED NEAR VISUAL ACUITY) IN ALL PATIENTS WHO UNDERWENT INTRACOR PROCEDURE THROUGHOUT TIME. (*P]0,05 VS PREOPERATIVE, STUDENT T TEST).

Preop							
Monocular				Binocular			
UDVA	UNVA	CDVA	CNVA	UDVA	UNVA	CDVA	CNVA
0.68±0.23	7.21±2.96	1.0±0.01	1.00±0.0	0.83±0.18	5.81±2.96	1.0±0.01	1.00±0.0
1day							
Monocular				Binocular			
UDVA	UNVA	CDVA	CNVA	UDVA	UNVA	CDVA	CNVA
0.87±0.13*	2.19±1.31*	1.00±0.01	1.02±0.20	0.94±0.08*	1.88±1.24	1.00±0.01	1.02±0.20
1wk							
Monocular				Binocular			
UDVA	UNVA	CDVA	CNVA	UDVA	UNVA	CDVA	CNVA
0.90±0.12*	2.28±2.05*	1.00±0.04	1.02±0.13	0.97±0.07*	1.96±1.93	1.00±0.04	1.02±0.13
1 Mo							
Monocular				Binocular			
UDVA	UNVA	CDVA	CNVA	UDVA	UNVA	CDVA	CNVA
0.95±0.08*	2.07±1.33*	1.00±0.00	1.01±0.07	0.97±0.04*	1.80±1.20	1.00±0.00	1.01±0.07
3 Mo							
Monocular				Binocular			
UDVA	UNVA	CDVA	CNVA	UDVA	UNVA	CDVA	CNVA
1.0±0.00*	1.67±0.3*	1.0±0.00	1.00±0.00	1.0±0.00*	1.5±0.0*	1.0±0.00	1.00±0.00

vs 1 week, vs 1 month, student t-test). Monocular UNVA was J1.67±0.28, while binocular UNVA was slightly better with J1.50±0.00. CNVA was J1.00±0.00, respectively (Table 1 and Figure 1A, B).

We compared binocular UDVA and UNVA between patients that underwent monocular Intracor procedure an those who underwent binocular treatment. At month 3 of follow up, average binocular UDVA in monocular treated patients was 0.97±0.03, while in binocular treated patients was 1.00±0.00, which was statistically significant (p≤0.05 student t-test). Binocular UNVA in monocular group was J1.63±0.49, and in binocular group J1.5± 0.00, which showed no statistical significance, although overall trend throughout follow up time was in favour of binocular treated patients (Table 2, Figure 2A, B).

Changes in corneal topography were also recorded (True Net Power, Wavelight Oculyzer, Germany) at 1 week, 1 and 3 months postoperatively. At 1 week postop average increase in central corneal power was 0,9 (ranging from 0 to 2.4D), at 1 and 3 month average change was 0.8D (ranging at 1 month from 0.1 to 2.3, and at 3 months from 0 to 2.3).

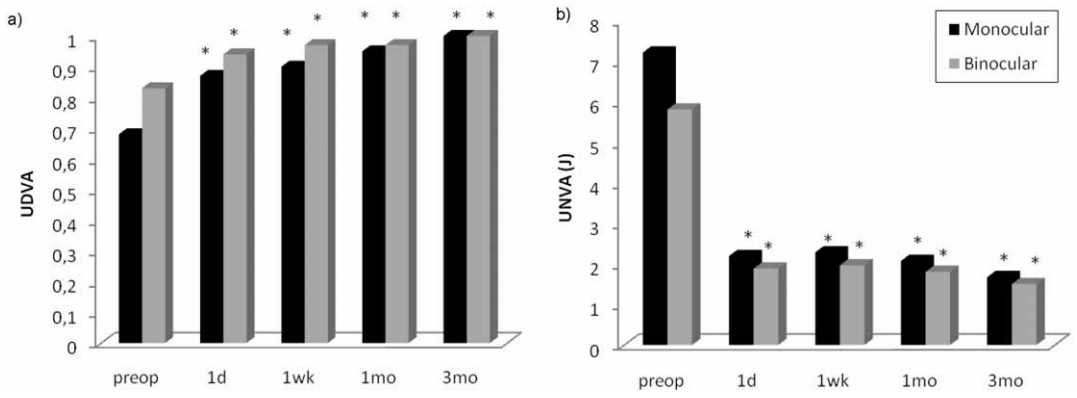

*Fig. 1. A) Overall monocular and binocular uncorrected distance visual acuity (UDVA) in patients that underwent Intracor procedure throughout follow up time.; B) Overall monocular and binocular uncorrected near visual acuity in Jaeger (UNVA(J)) throughout follow up time. (*P≤0.05 vs preoperative; student t-test).*

TABLE 2.

COMPARISON OF BINOCULAR UNCORRECTED DISTANCE (UDVA) AND NEAR VISUAL ACUITY (UNVA) IN JAEGER(J) BETWEEN PATIENTS THAT UNDERWENT MONOCULAR AND BINOCULAR PROCEDURE. (*P≤0,05 BETWEEN GROUPS; STUDENT T TEST).

1day			
Monocular procedure		Binocular procedure	
UDVA	UNVA	UDVA	UNVA
0.93±0.08	1.87±1.32	0.95±0.08	1.9±1.17
1 wk			
Monocular procedure		Binocular procedure	
UDVA	UNVA	UDVA	UNVA
0.95±0.048	1.79±1.19	0.99±0.10	2.11±2.43
1 Mo			
Monocular procedure		Binocular procedure	
UDVA	UNVA	UDVA	UNVA
0.97±0.05	1.63±0.99	0.98±0.03	1.98±1.36
3Mo			
Monocular procedure		Binocular procedure	
UDVA	UNVA	UDVA	UNVA
0.97±0.03	1.63±0.49	1±0.00*	1.5±0.00

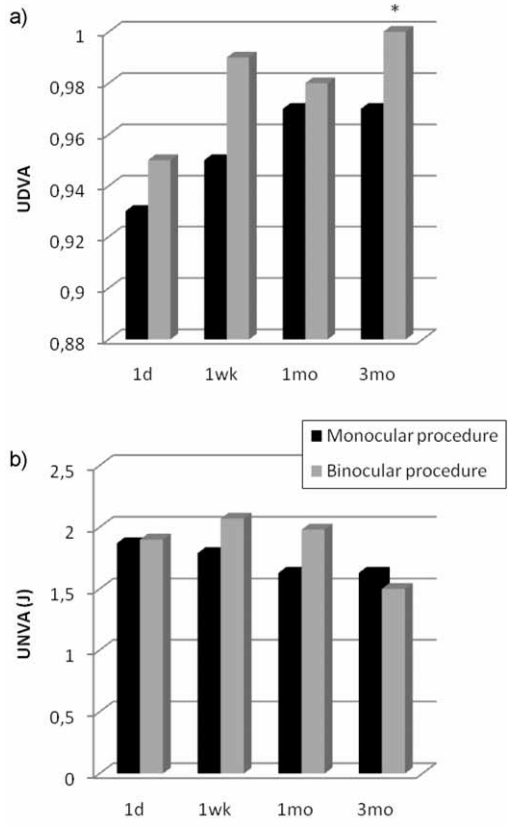

*Fig. 2. A) Comparison of binocular uncorrected distance visual acuity (UDVA) and B) uncorrected near visual acuity (UNVA(J) between patients that underwent monocular and binocular Intracor procedure. (*p≤0.05 between groups; student t-test.)*

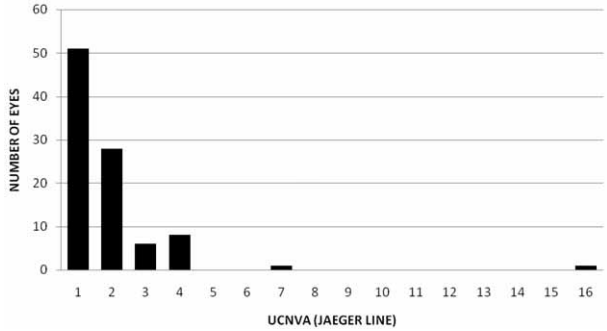

Fig. 3. Near vision distribution in patients that underwent Intracor procedure at 1 month postop.

51 eyes (52.94%) were able to read J1, 28 eyes (29.41%) were able to read even smaller letter than newsprint (equal to J2) and only 6 eyes (5.88%) treated were able to read newsprint only size (equal to J3). However, 2 eyes showed only slight improvement in near visual acuity (J16 and J7) and 8 eyes (7.84%) showed improvement in near visual acuity of J5 (Figure 3).

Discussion

Successful surgical managment of presbyopia is the main frontier of modern refractive surgery. Intracor as a minimally invasive and purely intrastromal procedure is highly alluring and its potential is under close investigation. According to Ruiz, femtosecond laser system (Technolas Perfect Vision GmbH) delivers a completely intrastromal customized pattern of laser pulses into the cornea to induce a local reorganization of the biomechanical forces and change in corneal shape. The basic pattern for presbyopic correction is a series of femto--disrruptive cylindrical rings that are delivered beginning within the posterior stroma, at a variable distance from Descemet's membrane, and extending anteriorly through the mid stroma to an anterior location at a predetermined, fixed distance beneath Bowman's layer. The net effect is a central steepening of the anterior corneal surface that produces multifocal hyperprolate corneal shape with an ideal, pupil-dependent aberration pattern. The variable refractive power of the cornea enhances the depth of focus, improving near vision, while maintaining distance vision at nearly the same acuity and photopic refraction[5].

The concept of the Intracor procedure is highly attractive for management of presbyopia. However, potential disadvantages of a new procedure must also be considered and studied. One of the main concerns with any new procedure is that of safety and long term stability. Intracor as completly intrastromal procedure offers safety in terms of possibility of ocular infection however long term effects on corneal stability have to be more evaluated. According to other authors and our own clinical experience the procedure has no significant impact on corneal stability and topographical changes that are observed in form of central corneal steepening with current technologies,

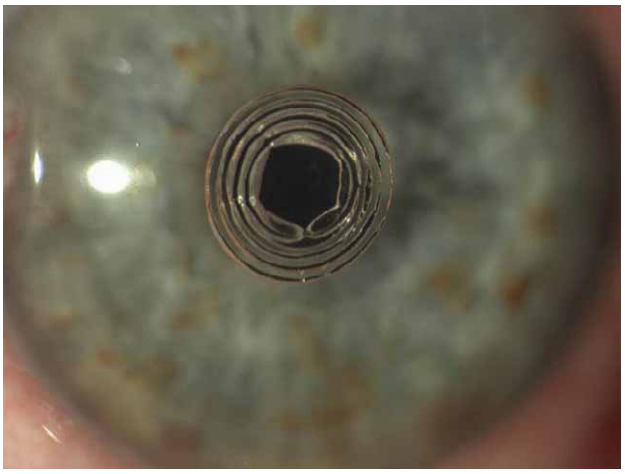

Fig. 4. Cornea immediately after Intracor procedure.

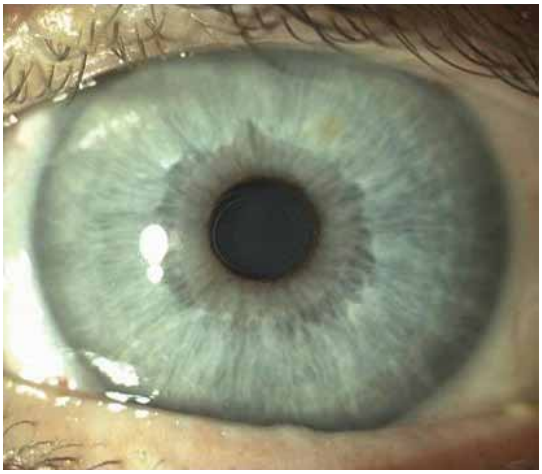

Fig. 6. Cornea one day after Intracor procedure.

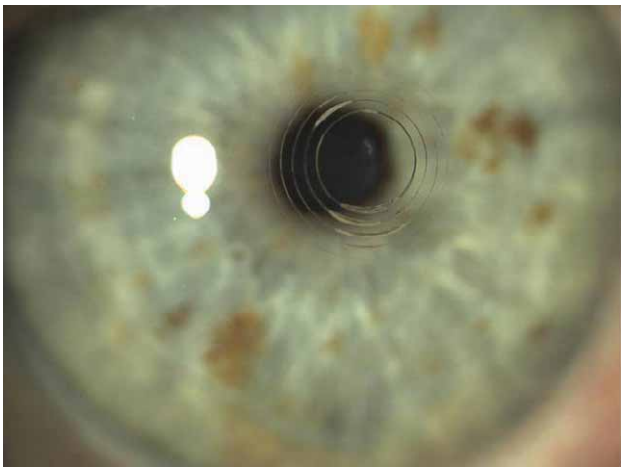

Fig. 5. Cornea two hours after Intracor procedure.

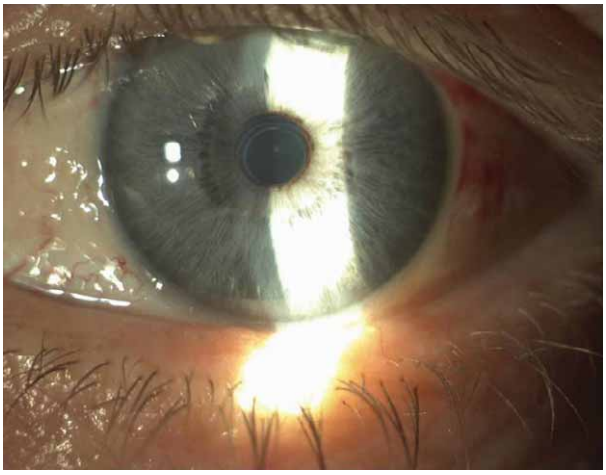

Fig. 7. Cornea one week after Intracor procedure.

eg, corneal topography, are minimal and do not always correlate with the visual acuity.[6,7] In our study avarage change in central corneal curvature was 0.9D (ranging from 0D to 2.4D) at 1 week postop, at 1 months avarage steepening was 0.8D (ranging from 0.1D to 2.3D) and remained stable through the follow up. We were not able to make any correlation between the changes in corneal curvature and visual acuity. It is possible that current technology can not always detect minimal changes on the anterior and posterior surface of the cornea and further investigation is needed.

Negative side effects seen to date are minimal with a slight disturbance of visual acuity during the early postoperative hours due to the cavitation gas bubbles located in the cornea (Figure 1). These resolve over the following hours, and on the first postoperative day, most patients achieve good distance and near visual acuity.[6] (Figure 2,3,4). According to other authors and our own clinical expirience on our patients who underwent Intracor procedure, few patients (17 patients, 10 with monocular treatment, 7 with binocular treatment) complained on visual disturbances such as halo and glare. Complaints of halos diminished over time, and at 3 months after surgery a few patients noticed them (3 patients, 1 with monocular treatment, 2 with binocular treatment).

In this study Intracor procedure presented as both safe and effective with all eyes gaining UNVA, and achieving good UDVA as well. UDVA was affected by a mild myopic shift, which was effective in reducing mild preexisting hyperopia in some patients but led to a mild myopic outcome in previously emmetropic patients. Statistically significant improvement in UDVA and UNVA was observed in all time points. At the 3 months postoperative follow up all patients gained several lines of UNVA with monocular UNVA of 1.67±0.28J. UDVA showed slight improvement over time and initial myopic shift showed tendency of slight decrease with all patients achieving 1.0.

In this study several patients 23 patients (31.94%) underwent binocular Intracor treatment with one month

difference between the operation of two eyes. Indication for the treatment of the other eye was unsatisfactory near vision improvement and fatigue during reading. It was interesting to notice that patients with binocular treatment presented with statistically significant better results of UDVA than patients with monocular treatment while there was no statisticaly significant difference in results in UNVA. However, patients reported higher satisfaction, less fatigue and better reading speed after the treatment of the other eye.

Our initial results of the Intracor procedure are stimulating for further research on femtosecond laser treatment of other refractive errors such as myopia, hyperopia, and astigmatism. It is a promising procedure, with safe, effective, and favorable visual results that seem to improve during the first 3 months of follow-up. According to Jaeger chart testing, the procedure has significant potential to improve near vision by several lines,with progressive improvement in eyes followed up to and beyond the first 3 months[5]. Having in mind the fast development of refractive surgery there is a need for longer follow up study on Intracor procedure.

In our study, patients showed corneal refractive changes with steepening of the central cornea. Difference maps (True Net Power) taken from Wavelight Allegro Oculyzer showed mild increase in central corneal curvature of 0.77D at one month after surgery and 0.85D after surgery with average value 0.77D after 3 months ranging from –2.4 to 3 D.

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PRVI REZULTATI INTRACOR METODE U HRVATSKOJ

SAŽETAK

Prikazani su rezultati praćenja pacijenata sa presbiopijom koji su se podvrgnuli Intracor metodi u Klinici Svjetlost u Zagrebu. Ova studija je obuhvaćala 95 očiju od kojih je 49 pacijenata operiralo samo nedominantno oko, dok su ostala 23 pacijenta operirala oba oka. Cilj rada je bio istražiti nekorigiranu i najbolje korigiranu vidnu oštrinu na daljinu i blizinu, promjene na reljefu rožnice, smetnje vida te zadovoljstvo pacijenata učinjenim zahvatom. Pacijenti su praćeni u prvom tjednu nakon operacije te nakon 1. i 3. mjeseca poslije učinjenog zahvata. U ovoj studiji Intracor metoda pokazala se kao sigurna i uspješna. Na svim operiranim očima došlo je do značajnog poboljšanja nekorigirane vidne oštrine na blizinu, a postignuta je i zadovoljavajuća nekorigirana vidna oštrina na daljinu. Primjećena je blaga miopizacija pacijenata na daljinu, što se pokazalo blagotvornim u pacijenata sa blagom preoperativnom hipermetropijom, dok su emetropni pacijenti iskusili blagu miopizaciju. Statistički značajno poboljšanje nekorigirane vidne oštrine na blizinu i daljinu primjećeno je kroz cijeli postoperativni period. 3 mjeseca postoperativno prosječna monokularna vidna oštrina na blizinu bila je Jaeger 1,67±0,28. Nekorigirana vidna oštrina pokazala je blago poboljšanje tokom cijelog postoperativnog perioda, a miopski pomak smanjenje, te su nakon 3 mjeseca svi pacijenti monokularno vidjeli 1,0. Sveukupno zadovoljstvo pacijenata bilo je iznimno visoko, te je svega nekoliko pacijenata nakon tri mjeseca primjećivalo halo i glare (3 pacijenta, 5 očiju). Intracor je minimalno invazivna, sigurna i efikasna metoda u zbrinjavanju pacijenata sa presbiopijom.