FIRST EXPERIENCE WITH FEMTOSECOND LASER PRESBYOPIA CORRECTION METHOD INTRACOR

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SUMMARY

FIRST EXPERIENCE WITH FEMTOSECOND LASER PRESBYOPIA CORRECTION METHOD INTRACOR

We report the first experience with presbyopia correcting femtosecond laser surgical procedure INTRACOR. This procedure is so far the only one that is made purely intrastromally without generating a wound connected to corneal surface or anterior chamber.

Presbyopia – caused by physiological aging and decreasing elasticity of the lens, impairs patient's accommodative ability. In the case of the method INTRACOR, presbyopia is corrected by steepening of corneal curvature in the central optical zone. Procedure is usually performed only in the non-dominant eye.

Methods: Intracor procedure was performed in 10 eyes of 10 patients (3 women and 7 men, aged 47–58 years). All procedures were performed with the femtosecond laser VICTUS (Bausch - Lomb, USA) in the non-dominant eye by an experienced surgeon.

Results: One-year follow-up. Mean monocular uncorrected near visual acuity (UNVA) improved from 0.2 ± 0.1 before surgery to 0.7 ± 0.3 after treatment (mean improvement of four lines). Mean near uncorrected binocular visual acuity (UNBVA) improved from a mean preoperative value of 0.23 ± 0.08 to a mean postoperative value of 0.8 ± 0.22 (mean improvement of about 5 lines). The mean monocular uncorrected distance visual acuity (UDVA) was 0.9 ± 0.1 before surgery and 0.8 ± 0.3 after treatment (average loss of 1 line). The mean binocular uncorrected distance visual acuity improved from 1.0 ± 0,1 to 1,3 ± 0.3 after surgery. All patients had improvements in near vision. In 3 patient, monocular distance vision improved, in 6 patient improved binocular distance vision. We observed statistically significant decrease (mean loss of 1 line) of monocular best corrected distance visual acuity (BCDVA). Patients subjectively reported satisfaction with the quality of vision achieved for near and distance and high levels of spectacle independence under good lighting conditions.

The results shows that INTRACOR method is well suitable for low hyperopic patients, who because of good distance visual acuity are not good candidates for refractive lens exchange with multifocal intraocular lens implantation.

Key words: presbyopia, Intracor, intrastromal, femtosecond laser

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INTRODUCTION

Correction of presbyopia is addressed as standard by the prescription of eye glasses for near vision or by the use of multifocal contact lenses (1).

Older methods of surgical correction of presbyopia include the monovision method, in which a refractive procedure (excimer laser, if applicable during cataract surgery) is used to create a condition in which one eye (usually the non-dominant) has myopic – minus refraction, whilst the dominant eye is emmetropic or slightly myopic (2). The procedures used for surgical correction of presbyopia always represent a certain risk. The main risk is the potential deterioration of visual acuity to distance or under worse light conditions, and in the night. This may cause problems especially in emmetropic or slightly hypermetropic patients, who have good uncorrected distance visual acuity. Also not entirely negligible are risks of intraocular procedures (presbyopic lens replacement – PRELEX), especially the risk of postoperative infection or retinal detachment (3, 4), as well as potential problems with night vision upon the use of multifocal intraocular lenses.

For these reasons, the ideal correction of presbyopia appears to be a surgical procedure which is minimally invasive, with a low risk of postoperative complications, rapid visual rehabilitation and minimal impact upon distance visual acuity. The Intracor method, which was introduced and first performed by Ruiz et al. (5, 6) partially meets these criteria. The Intracor method, by creating concentric circular intrastromal incisions, alters the biomechanical forces in the cornea, leading to increased curvature of the central part of the cornea, and thus increasing the depth of visual acuity. This leads to a dramatic improvement of near visual acuity in the operated eye, and also of binocular acuity (5, 6).

In this study we present our first experiences with the Intracor surgical method.

STUDY COHORT AND METHOD

The cohort consisted of 10 eyes of 10 patients (3 women, 7 men) aged between 47 and 58 years, with slight hypermetropia and concurrent presbyopia, who met the entrance criteria for surgery using the Intracor method. The observation period was 1 year.

According to the laser manufacturer (5), the indication criteria for a patient for Intracor are:

- +0.5 to +1.0 D spherical subjective refraction with maximum astigmatism 0.5 Dcyl or maximum spherical refraction +1.25 D without astigmatism,
- pachymetry more than 500µm in the centre of the cornea,
- addition to near vision +1.5D and more,
- corneal astigmatism max. 2Dcyl,
- keratometry min. 39D, max. 48D,
- angle kappa below 10 degrees.
- acceptance of applicable decrease of distance visual acuity (VA) in operated eye.

Preoperative examination covered an examination of uncorrected and corrected near and distance visual acuity, both monocular and binocular. Examination of refraction without and in cycloplegia (Unitropic gtt, Unimedpharma, Bratislava, Slovakia), corneal topography (SIRIUS, Schwind, Kleinostheim, Germany), including examination of the shape of the anterior and posterior surface of the cornea, pachymetric map, pupillometry, optical biometry, endothelial microscope, tonometry, Schirmer test and test for dominant eye.

After ensuring the patients had met the above-stated criteria and signed a detailed informed consent form, we performed a laser procedure with the use of a VICTUS femtosecond laser (Bausch – Lomb, USA). With regard to the different corneal thickness in individual patients, before surgery we entered the lowest pachymetry values of 1, 2, 3, 4 mm from the centre of the pupil into the laser software – we used the values obtained by a Sirius corneal topograph (Schwind, Kleinostheim, Germany).

The actual surgical procedure was performed under topical anaesthesia (Benoxi gtt, Unimedpharma, Bratislava, Slovakia). The first phase is the precise indication of the centre of the pupil on a slit lamp. Subsequently the eye is fixed by underpressure on the laser optic ("docking"). During the procedure pressure on the eye is monitored, as well as lateral forces, which prevents imprecision in the depth of the incision. Precise centring of the procedure (ideally to the point between the centre of the pupil and the first Purkynje image) after docking is performed under the control of an image from the laser camera, with the help of software. The actual laser procedure, which takes approx. 20 seconds, consists in the creation of five concentric incisions in the corneal stroma (with different heights of incision), which leads to a discrete arching and remodelling of the central sections of the cornea (fig. 1). A new mechanical balance is thus attained, which is created by intraocular pressure and forces within the interior of the cornea. Concentric circular rings are visible intrastromally in the centre of the cornea, initially filled with microscopic gas bubbles, which are absorbed during the course of a few hours (fig. 2, 3, 4). In OCT imaging of the cornea we can detect the incisions of the femtosecond laser (fig. 5). The visible communication with the anterior ocular chamber on the image is an optical artefact (optical reflection). The area of the central arching of the cornea (fig. 6) is visible on corneal topography following Intracor surgery.

The entire procedure, including indication of the eye, docking and creation of the incisions takes approximately 2 minutes.

A postoperative follow-up immediately after the procedure contained an examination on a slit lamp, photo documentation and examination of near and distance vision. Postoperative local treatment was Eflumidex gtt (Allergan, Irvine, USA) (3x daily for a period of 2 weeks) and artificial tears Hypromellose P gtt (Unimedpharma, Bratislava, Slovakia) according to requirement, usually only in the first days after surgery.

We performed further follow-up examinations on the 1st and 7th postoperative day, 1 month and 1 year after surgery.

After the procedure we evaluated monocular UNVA (uncorrected near visual acuity) and CNVA (corrected near visual acuity) in the operated (non-dominant) eye (table 1) and monocular UDVA (uncorrected distance visual acuity), CDVA (best corrected distance visual acuity) (table 2). We also evaluated uncorrected near binocular visual acuity (UNBVA) (table 3) and uncorrected distance binocular visual acuity (UDBVA) (table 4) before and after the procedure.

We statistically evaluated changes in VA using a Student T-test. We also recorded subjective patient satisfaction with the result of the operation after 1 year, the incidence of complications and the occurrence of disruptive secondary optic phenomena (at night), as well as the need to wear glasses for reading.

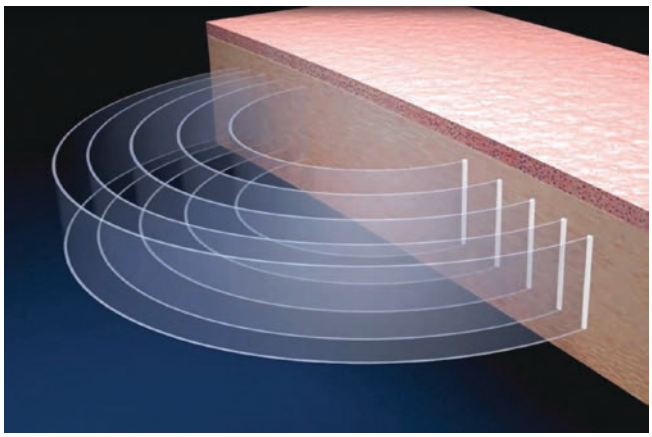


Fig. 1 Diagram of Intracor procedure

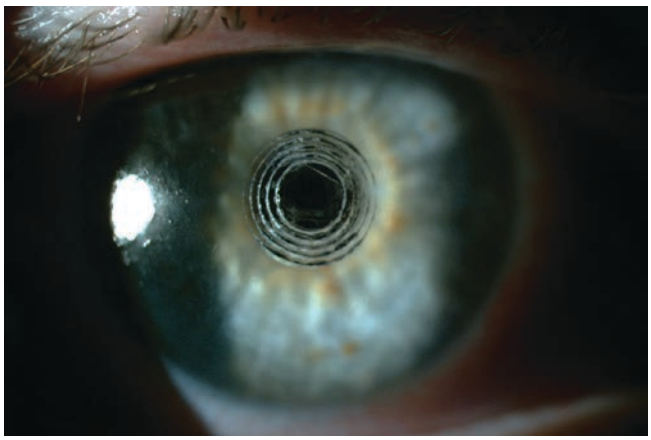


Fig. 2 Operated eye approx. 30 minutes after procedure

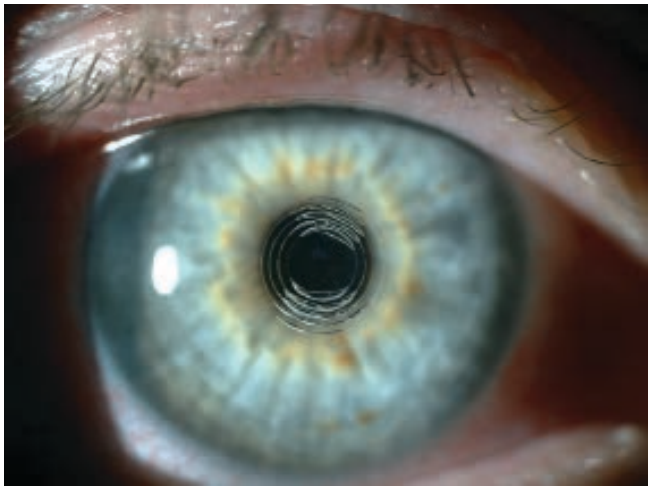


Fig. 3 Operated eye 1 hour after procedure

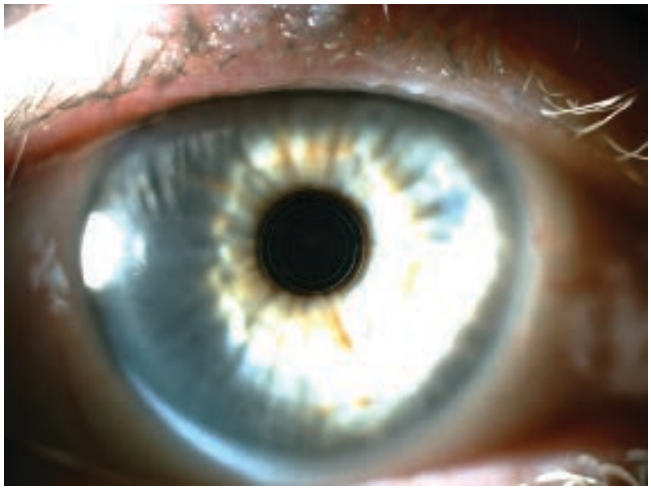


Fig. 4 Operated eye 1 year after procedure

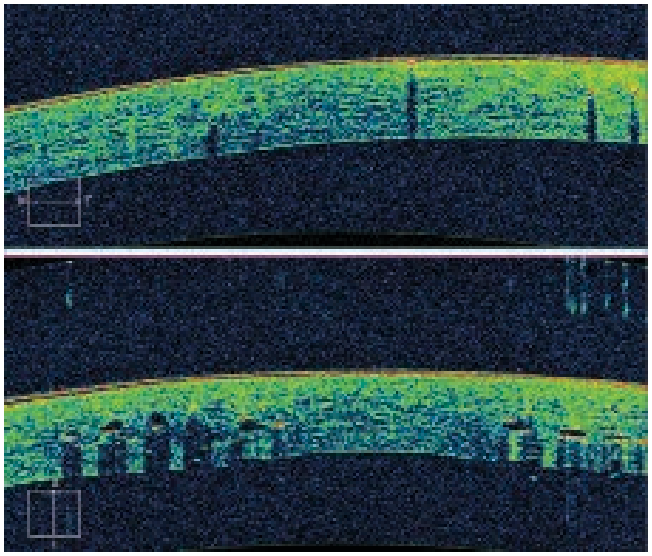


Fig. 5 OCT of centre of cornea first day after procedure. The apparent communication of incisions with anterior chamber is an artefact.

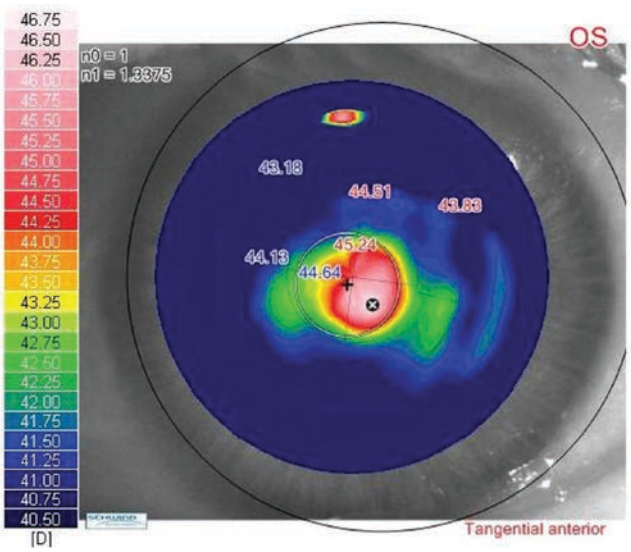


Fig. 6 Topography of cornea 1 month after procedure (increase of steepness in centre)

RESULTS

The results of surgery using the Intracor method are presented in the tables and graphs.

We did not record perioperative or postoperative complications in any case. Improvement of near vision appeared in patients usually after 90 minutes. One day after surgery the UNVA values substantially improved to an average value of 0.7 ± 0.3 (graph 1). Uncorrected near vision in the operated eye gradually improved further, we did not record deterioration in any case. Improvement of UNVA (uncorrected near VA monocularly) 1 year after surgery was marked and statistically significant ($p < 0.05$) – on average by 5.7 rows (minimum 2 rows, maximum 8 rows). Improvement of near VA binocularly was even more marked. We did not record signs of regression of the effect of surgery in any case (graph 2).

Distance VA was usually influenced only slightly, in fact in some cases an improvement was recorded. In one patient (patient no. 10) we recorded a more marked myopic shift (-1.25D) 1 year after surgery, which caused a decrease of uncorrected distance VA monocularly. The given condition did not cause the patient subjective complaints.

Before the procedure uncorrected distance VA in the operated eye was on average 0.9 ± 0.1. One year after surgery this was 0.8 ± 0.3 – the difference is not statistically significant (graph 3). Uncorrected distance VA in the operated eye improved in the case of 3 operated eyes, 1 eye was unchanged and in 6 eyes it decreased. One year after surgery we recorded a statistically significant reduction ($p < 0.05$) of best corrected distance VA monocularly (from 1.2 ± 0.1 to 1.0 ± 0.25).

By contrast,mean uncorrected distance binocular VA was 1.0 ± 0.1 before the procedure. One year after surgery it had improved significantly to 1.3 ± 0.3 (graph 4).

Binocular distance VA was unchanged in 3 eyes, improved in 6 eyes and deteriorated in 1 eye (by 1 row).

The patients stated that under photopic conditions near visual acuity was fully adequate for regular activities (reading newspapers, work with mobile telephone, reading bills in shops). 4 patients stated the use of glasses for near vision (in weak light). Perception of light phenomena at night (rings around lights) were stated by patients especially during the first 3 months, but did not cause greater complaints in any of the patients, including in the case of night driving.

Subjective patient satisfaction was high. 8 patients stated full satisfaction with the result of the procedure, 2 patients stated partial satisfaction.

All patients decided again in favour of the procedure, even with the knowledge of certain limitations.

DISCUSSION

The Intracor surgical method was designed, performed for the first time and published by Ruiz et al. (6, 7). Since that time a number of studies have been published, which present positive results of this intrastromal procedure (8, 9). In suitable patients it is possible to perform the procedure also bilaterally (10). Likewise, modification of the incisions also enables its use in emmetropic patients (11). Its advantage is an absence of a wound on the surface of the cornea, which reduces the risk of infection, is painless and has a practically immediate effect. This was confirmed also in our study, in which we did not observe any complications, and the effect was perceptible already after 90 minutes. A further advantage according to more recent published data is the absence of regression of the effect even after a longer observation period (12). This is so far confirmed also by our results.

The method also has certain disadvantages, which limit its wider use. These are partially the strict indication criteria and thus the smaller population of suitable patients, and also the financial demand factor of the femtosecond laser. In our case an advantage is the use of a VICTUS universal

Table 1 UNVA (uncorrected near VA) in operated eye before and after procedure and CNVA (corrected near VA) before procedure

	Preoperative		90 min.	1 day	1 week	1 month	1 year
	UNVA	CNVA	UNVA	UNVA	UNVA	UNVA	UNVA
Patient no. 1	0.1	1.0	1.0	0.8	1.0	0.5	0.5
Patient no. 2	0.32	1.0	0.4	0.63	1.0	1.0	1.0
Patient no. 3	0.2	1.0	0.4	0.5	0.63	0.8	0.8
Patient no. 4	0.2	1.0	0.5	0.8	0.63	0.8	0.8
Patient no. 5	0.2	1.0	0.8	0.8	0.63	0.8	0.8
Patient no. 6	0.2	1.0	0.5	1.0	1.0	1.0	1.0
Patient no. 7	0.2	1.0	0.6	0.5	0.2	0.2	0.4
Patient no. 8	0.2	1.0	0.4	0.5	0.5	0.4	0.5
Patient no. 9	0.2	1.0	1.0	1.0	0.9	1.0	1.0
Patient no. 10	0.32	1.0	1.0	1.0	1.0	1.0	1.0
Average	0.2 ± 0.1	1.0	0.6 ± 0.4	0.7 ± 0.3	0.7 ± 0.3	0.7 ± 0.3	0.7 ± 0.3

Table 2 Binocular near VA before and after procedure

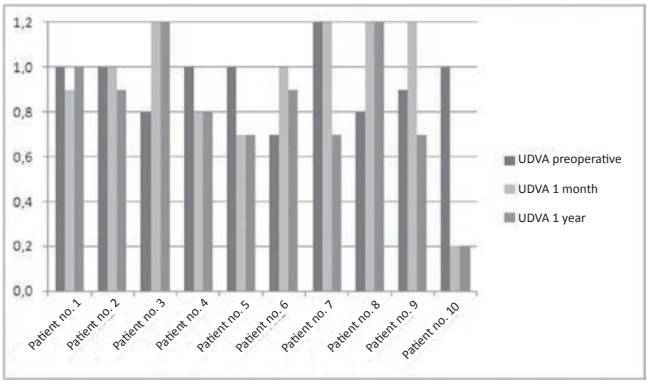
	Preoperative		90 min.	1 day	1 week	1 month	1 year
	UNBVA	CNBVA	UNBVA	UNBVA	UNBVA	UNBVA	UNBVA
Patient no. 1	0.1	1.0	1.0	1.0	1.0	0.5	0.5
Patient no. 2	0.32	1.0	0.8	0.63	1.0	1.0	1.0
Patient no. 3	0.2	1.0	0.4	0.5	0.63	0.5	0.63
Patient no. 4	0.2	1.0	1.0	0.8	0.8	0.8	0.8
Patient no. 5	0.2	1.0	1.0	1.0	0.5	0.8	0.8
Patient no. 6	0.2	1.0	0.5	1.0	1.0	1.0	1.0
Patient no. 7	0.3	1.0	0.8	0.5	0.8	0.8	0.5
Patient no. 8	0.2	1.0	0.4	0.5	0.4	0.5	0.5
Patient no. 9	0.2	1.0	1.0	1.0	1.0	1.0	1.0
Patient no. 10	0.4	1.0	1.0	1.2	1.0	1.0	1.0
Average	0.23 ± 0.08	1.0	0.8 ± 0.3	0.8 ± 0.23	0.8 ± 0.23	0.8 ± 0.21	0.8 ± 0.22

Table 3 UDVA (uncorrected distance VA) and CDVA (corrected distance VA) in operated eye before and after procedure

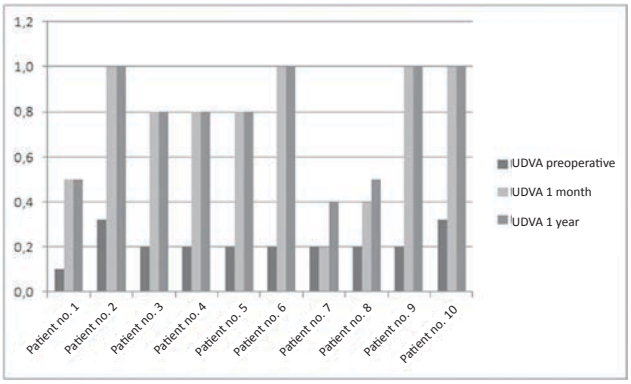
	Preoperative		90 min.	1 day	1 week	1 month	1 year	1 year
	UDVA	CDVA	UDVA	UDVA	UDVA	UDVA	UDVA	CDVA
Patient no. 1	1.0	1.2	0.4	0.8	0.9	0.9	1.0	1.0
Patient no. 2	1.0	1.50	0.5	1.5	0.8	1.0	0.9	1.5
Patient no. 3	0.8	1.2	0.8	1.2	1.0	1.2	1.2	1.2
Patient no. 4	1.0	1.2	0.7	0.5	0.6	0.8	0.8	1.0
Patient no. 5	1.0	1.2	0.6	0.6	0.7	0.7	0.7	0.7
Patient no. 6	0.7	1.2	0.8	0.6	0.8	1.0	0.9	1.0
Patient no. 7	1.2	1.2	0.6	1.0	1.0	1.2	0.7	0.9
Patient no. 8	0.8	1.2	1.2	1.5	1.5	1.2	1.2	1.2
Patient no. 9	0.9	1.0	0.8	1.0	1.2	1.2	0.7	0.9
Patient no. 10	1.0	1.0	0.5	0.3	0.3	0.2	0.2	0.6
Average	0.9 ± 0.1	1.2 ± 0.1	0.7 ± 0.2	0.9 ± 0.4	0.9 ± 0.3	0.9 ± 0.3	0.8 ± 0.3	1.0 ± 0.25

Table 4 Binocular distance VA before and after procedure

	Preoperative		90 min.	1 day	1 week	1 month	1 year
	UDBVA	CNDVA	UDBVA	UDBVA	UDBVA	UDBVA	UDBVA
Patient no. 1	1.0	1.2	1.0	2.0	0.5	2.0	1.0
Patient no. 2	1.0	1.5	0.8	1.5	1.0	1.0	2.0
Patient no. 3	0.8	1.2	0.8	1.5	1.5	1.2	1.2
Patient no. 4	1.2	1.2	0.8	1.2	1.2	1.2	1.2
Patient no. 5	1.0	1.2	1.0	1.2	1.5	1.0	1.0
Patient no. 6	1.0	1.2	0.8	1.0	1.0	1.0	1.2
Patient no. 7	1.2	1.2	1.5	1.2	1.5	1.2	1.0
Patient no. 8	0.8	1.2	1.5	1.2	1.5	1.2	1.5
Patient no. 9	0.9	1.0	1.5	1.0	1.5	1.0	1.5
Patient no. 10	1.0	1.0	0.8	1.2	1.0	1.0	1.5
Average	1.0 ± 0.1	1.2 ± 0.1	1.1 ± 0.3	1.3 ± 0.1	1.2 ± 0.5	1.2 ± 0.3	1.3 ± 0.3

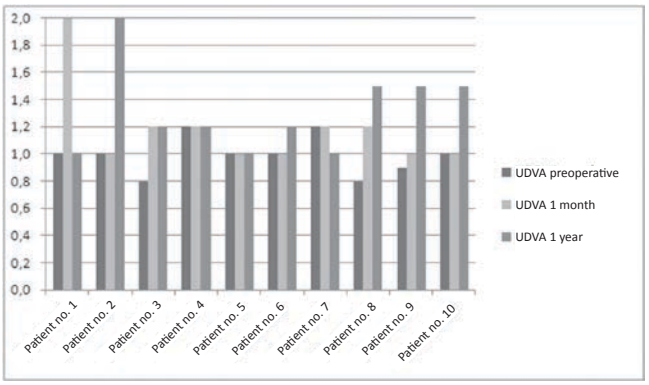


Graph 1 Uncorrected near VA in operated eye before and after procedure

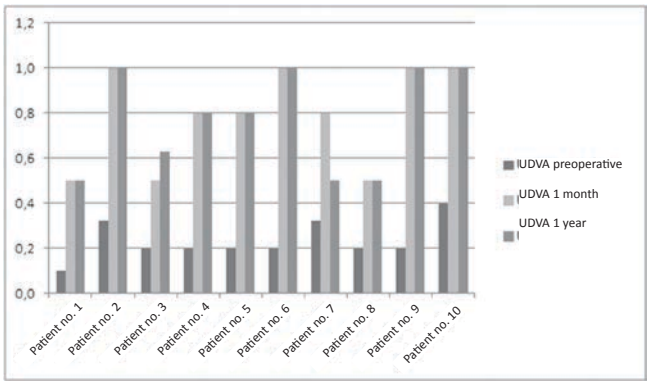


Graph 2 Uncorrected binocular near VA before and after procedure

platform laser, which enables use in several indications (cataract, LASIK, keratoplasty, INTRACOR). Further reasons may be concerns regarding a decrease of distance visual acuity and also insufficient effect regarding the monocularity of the procedure. These fears were not confirmed in our study. Likewise, fears concerning problems with night vision were



Graph 3 Uncorrected distance visual acuity in operated eye before and after procedure



Graph 4 Uncorrected binocular distance visual acuity in operated eye before and after procedure

also not confirmed.

In accordance with the data from the literature we also recorded a decrease of best corrected distance monocular VA, which was however unequivocally balanced with a concurrent improvement of uncorrected near binocular VA or even an improvement of distance VA. We explain the more pronounced myopic shift (-1.25 D) in the operated eye in patient no. 10 after 1 year with reference to the probably different biomechanical properties of the cornea. The myopic shift is not progressing further. In accordance with the majority of the studies published to date, in our patients also we recorded high subjective patient satisfaction with the result of the operation.

CONCLUSION

Our first experiences with correction of presbyopia using the INTRACOR method confirmed that upon adherence to the indication criteria this modern method brings excellent results with high subjective patient satisfaction. The procedure is genuinely quick, painless and excellently tolerated by patients. A large advantage is its very rapid effect, without the need for longer visual rehabilitation in the postoperative period and the absence of regression. The negative influence on UDVA is minimal, and even improvement is possible. The effect is sufficient for near activities under photopic conditions. Night vision is influenced by slight dysphotopsias (concentric rings around light sources), usually only in the first three months after surgery. Another advantage is that the method is suitable also for pseudophakic patients.

Our results demonstrate that the INTRACOR method is suitable for slightly hypermetropic patients, for whom refractive lens replacement with implantation of a multifocal intraocular lens is usually not suitable due to good distance visual acuity. The method thus extends our current possibilities for the correction of presbyopia.

LITERATURE

1. **Bischoff G.:** Compensation for presbyopia using contact lenses [German]. Ophthalmologe, 2006;103(8): 655–658, 660.
2. **Holzer MP, Rabsilber TM, Auffarth GU.:** Presbyopia correction using intraocular lenses [German]. Ophthalmologe, 2006; 103(8): 661–666.
3. **Fintelmann RE, Naseri A.:** Prophylaxis of postoperative endophthalmitis following cataract surgery: current status and future directions. Drugs, 2010; 70(11): 1395–1409.
4. **Semoun O, Bourcier T, Dupas B, et al.:** Early bacterial keratitis after presbyopic LASIK. Cornea. 2008; 27(1): 114–116.
5. Intracor Patient selection, Technolas PV, Munich.
6. **Ruiz LA, Cepeda LM, Fuentes VC.:** Intrastromal correction of presbyopia using a femtosecond laser system. J Refract Surg.2009; 25(10): 847–854.
7. **Ruiz, LA.:** Preliminary clinical results with 11-months follow-up of intrastromal correction of presbyopia (intraCORTM) using the FEMTEC® femtosecond laser system. Dostupné na: https://www.scribd.com/document/23193238/100373-Luis-Ruiz-White-Paper-0908-Final.
8. **Holzer M., Mannsfeld A., Ehmer A., Auffartht G.U.:** Early Outcomes of INTRACOR Femtosecond Laser Treatment for Presbyopia. J Refrac Surg [online], 2009, 25(10): 855–861.
9. **Holzer M.P, Knorz M.C., Tomalla M., Neuhann T.M., Auffarth G.U.:** Intrastromal Femtosecond Laser Presbyopia Correction: 1-year Results of a Multicenter Study. J Refrac Surg [online], 2012, 28(3): 182–188.
10. **Khoramnia R., Holzer M.P., Fitting A., Auffartth G.U., Rabsilber T.M.:** Funktionelle Ergebnisse nach Korrektur der Presbyopie mittels bilateraler intrastromaler Femtosekundenlaserbehandlung. Der Ophthalmologe [online], 2013, 110(12): 1163–1170.
11. **Thomas B.C., Fitting A., Auffarth G.U., Holzer M.P.:** Femtosecond Laser Correction of Presbyopia (INTRACOR) in Emmetropes Using a Modified Pattern. J Refrac Surg [online], 2012, 28(12): 872–878.
12. **Khoramnia R., Fitting A., Rabsilber T.M., Thomas B.C., Auffartth G.U., Holzer M.P.:** Intrastromal femtosecond laser surgical compensation of presbyopia with six intrastromal ring cuts: 3-year results. Brit J Ophthalmol [online], 2015, 99(2): 170–176.