(45)

Visual outcome three and six months after implantation of Acri.LISA 366D lenses

Ocena funkcji wzroku 3 i 6 miesięcy po wszczepieniu soczewki Acri.LISA 366D

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Streszczenie: Cel: ocena funkcji wzroku 3 i 6 miesięcy po operacji zaćmy z mikrocięcia (MICS) z wszczepieniem wieloogniskowej, hybrydowej soczewki Acri.LISA 366D.
Metody: trzy i sześć miesięcy po obuocznej operacji zaćmy metodą MICS u wyselekcjonowanych 20 pacjentów (40 oczu) oceniono chirurgicznie indukowany astygmatyzm (SIA – analiza wektorowa), obuoczną UDVA, UNVA i UIVA (logMAR), niezależność od okularów, czułość kontrastową (CS- CSV-1000), objawy subiektywne, stopień zadowolenia pacjenta (Type Questionnaire) i powikłania.
Wyniki: trzy i sześć miesięcy po zabiegu SIA wynosił kolejno 0,55 i 0,58 D. Trzy miesiące po operacji średnia obuoczna UDVA nie różniła się istotnie od tej, którą mierzono w 6. miesiącu (-0,10 $\pm$ 0,17 versus -0,14 $\pm$ 0,11; p = NS). Wszyscy pacjenci uzyskali bardzo dobrą funkcję wzroku do różnych odległości i byli całkowicie niezależni od okularów. Mezopowa CS do dali i fotopowa do dali i bliży mieściły się w granicach normy wiekowej i nie uległy zmianom. Niski stopień glare/halo wystepował u 75% pacjentów. Ogólnie poziom zadowolenia pacjentów był bardzo wysoki (9.05/10). Nie zaobserwowano powikłań pooperacyjnych.
Wnioski: zastosowanie wieloogniskowej soczewki Acri.LISA 366D u wyselekcjonowanych pacjentów z zaćmą przyniosło bardzo dobre wyniki funkcji wzroku, wysoki poziom zadowolenia pacjenta i niezależność od okularów.

Słowa kluczowe: operacja zaćmy z mikronacięcia (MICS), wszczep soczewki Acri.Lisa 366D, funkcja wzroku.

Summary: Purpose: To evaluate 3 and 6 months binocular visual outcomes after microincision cataract surgery (MICS) with implantation of multifocal, hybrid Acri.LISA 366D IOLs.
Material and methods: Three and six months after bilateral MICS with Acri.Lisa 366D implantation, 40 eyes of 20 patients were evaluated for surgical induced astigmatism (SIA – vector analysis), binocular UDVA, UNVA and UIVA (logMAR), spectacle independence, contrast sensitivities (CS-CSV-1000), subjective symptoms, patient satisfaction (Type Questionnaire) and complications.
Results: Three and six months after surgery, SIA was equal 0.55 D and 0.58 D subsequently. Three months postoperatively mean binocular UDVA did not differ significantly from the six-month follow-up (-0.10 $\pm$ 0.17 versus -0.14 $\pm$ 0.11; p = NS). All patients had very good spectacle-free visual function at all distances and were totally spectacle independent. Mesopic distance and photopic distance and near CS were within normal age-matched limits at both follow-ups and did not change during observation time. A low degree of glare/halo was detected in 75% of subjects. Overall patient satisfaction was very high (9.05/10). There were no postoperative complications.
Conclusions: Multifocal Acri.LISA 366D IOL implantation in selected cataract patients provides a very good visual outcome, a high level of patient satisfaction and spectacle-free visual function.

Key words: microincision cataract surgery, Acri.Lisa 366D IOl implantation, visual outcome.

Introduction

Microincision cataract surgery (MICS) with intraocular lens implantation through clear corneal incision smaller than 2 mm is a technique increasingly popular because provide to less induced astigmatism, fewer higher-order aberrations (1,2) and shorter rehabilitation time in comparison to standard cataract surgery. Another important advantage for the patient is multifocal IOL which give an oportunity to see well for near and distance without glasses. Nowadays, multifocal aspheric IOLs with a low addition improve also intermediate vision, reduced anwanted effects (glare, halo), increase the range of focus, improve image quality. Recently only few multifocal IOLs are available in the market that can be implanted through incision smaller than 2 mm. One of them is the hybrid (refractive – diffractive) multifocal Acri.Lisa 366D IOL (Zeiss) (Fig. 1) (Tab. I).

This hybrid IOL provide good near, intermediate and far vision under different light conditions (3). One of the significant factor which has influence on the patients' satisfaction after surgery with multifocal IOL implantation is neuroadaptation process. It selects an image related to the object that is being looked at and then supppresses the other image. It is commonly known that after multifocal IOL implantation neuroadaptation time last at least 3 months. In our experience with multifocal IOLs implantations the neuroadaptation time may be different for different lenses and last even up to one year (4,5).

Fig. 1. Acri.Lisa 366D lens.
Ryc. 1. Soczewka Acri.Lisa 366D.

Material/ Materiał	Hydrophylic acrylic (25%) with hydrophobic surface/ Hydrofilna akrylowa (25%) z hydrofobową powierzchnią
Optic design/ Model optyczny	Aspheric multifocal/ Asferyczna wieloogniskowa
Haptic/angulation/ Haptyka/zgięcie	plate /0°/ płaska/ 0°
Diameter (mm)/ Średnica (mm)	Optic/ Optyka 6 mm Total/ Całkowita 11 mm
Lens design/ Model soczewki	Single–piece diffractive, +3.75 D add at IOL plane/ jednoczęściowa dyfrakcyjna, dodatek +3.75 D
Light distribution/ Dystrybucja światła	% far/ % near % dal/ % bliż 65/35
Diopter range/ Zakres mocy	0.0 ± 32.00 D
A constant (ultrasound)/ Stała A	117.8
Diffractive rings (n)/ Pierścienie dyfrakcyjne	29
PCO prevention/ PCO zapobieganie	Square-edged optic and haptic/ kwadratowe brzegi optyki i haptyki

Tab. I. General IOL characteristics.
Tab. I. Ogólna charakterystyka soczewki.

To date, in the polish literature there was no published results describing clinical outcomes with a hybrid lenses Acri. Lisa 366D. That is why we carried out a study in which we implanted binocularly Acri.Lisa 366D lenses in selected cataract patients and evaluated their binocular outcomes three and six months post operation.

Material and methods

The study comprised 40 eyes of 20 patients (11 females, 9 males), with a mean of age of 55 ± 3.5 years undergoing cataract surgery (mean LOCS III, NO3, NC3) with implantation binocularly of Acri.Lisa 366D lenses (Zeiss).

Inclusion criteria were following: range of age – 40–70 years, bilateral cataract, pupil size between 3–6 mm in dim light condition, preoperative corneal astigmatism less than 1.50 D (Corneal Videokeratography, Zeiss), motivation for spectacle independence, tolerant patients, willing and able to comply with scheduled visits.

Exclusion criteria included ophthalmic disease, impaired ocular motility, pupil size < 3 mm in low light or > 6 mm in full light (Colvard pupillometer). Subjects were also exluded if they were satisfied with reading glasses, had unrealistic visual outcome expectations, a profession that demand visual precision, psychiatric disease, stroke, dyslexia, dissatisfaction with progresive glasses or the need for IOL power beyond available diopter range or ocular surgery complications.

Surgical technique

The same surgeon (L. W.) performed all biaxial MICS using the same faco machine (Infiniti, Alcon) in topical anesthesia (Alcaine). Two clear corneal 1.2 x 1.4 mm trapezoidal incisions at 2 and 10 o'clock were made with a 19-gauge steel knife and 5.0 mm diameter capsulorhexis was created. Before ultrasound phacoemulsification, manual nucleofractis with 2 phacochopers was performed. After removal of the nucleus and cortical material one incision was enlarged to 1.7 mm using trapezoidal knive 1.5 x 1.7 mm. The Acri. Lisa 366D IOL was implanted with an Acri-shooter A2-2000 injector set (Acri.Tec GmbH). Final incision size after IOL implantation was measure with a special caliper (Asico) and the mean was equal 1.68 ± 0.04 mm. Target refraction was emmetropia, and IOL power calculations were done using IOL Master (Carl Zeiss-Meditec, Jena, Germany – the software version 2005, A-constant recommended by the manufacturer with SRK-T formula). The second eye was operated 1 month after first one.

Outcome measures

Three and six months post surgery, the following examinations were performed: surgical induced astigmatism (SIA) by vector analysis, binocular uncorrected distance (UDVA), [ETDRS (4 m) charts] and near visual acuities (UNVA), [ETDRS (40 cm), uncorrected intermediate visual acuity (UIVA), [ETDRS (60 cm) charts], spectacle independence, binocular photopic (85 cd/m^2), mesopic (3 cd/m^2) distance (2.5 m) and binocular photopic (85 cd/m^2) near (35 cm) uncorrected CS [CSV-1000, F.A.C.T. – 1.5, 3, 6, 12, 18 cycles per degree (cpd)], subjective symptoms and patients satisfaction (modified TyPE Questionnaire described by Leyland et al.) (6).

Statistical analysis

Statistical analysis of the results was performed using Statistica software. Visual acuity, contrast sensitivity, postoperative refraction and patient satisfaction results 3 and 6 months post surgery were compared using the Wilcoxon test. A p value less than 0.05 was considered statistically significant.

Results

Three and six months after surgery SIA was equal 0.55 and 0.58 D, subsequently.

Visual acuity

Before operation, the mean preoperative binocular uncorrected distance visual acuity was logMAR 0.24 ± 0.25 D, mean

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preoperative binocular corrected distance visual acuity was logMAR 0.11 ± 0.19 D. Six eyes were hyperopic ranging from +1.0 D to +1.5 D, with a mean spherical equivalent +1.29 ± 0.25 D, 6 eyes were myopic ranging from -1.00 D to -4.00 D with a mean spherical equivalent of +2.79 ± 2.12 D. Remaining 8 eyes were emmetropic. For all eyes, the mean preoperative equivalent refraction was +1.23 ± 2.32 D.

Three months postoperatively, the mean binocular UDVA was logMAR -0.1 ± 0.17 D. Distance vision was improved only for one patient and was equal +1.25 D. The mean spherical equivalent was 0.06 ± 0.25 D. In the rest of patients binocular UDVA was 0.0.

The mean binocular UNVA was logMAR 0.02 ± 0.08 D. In one patient, near vision was improved by additional correction +2.00 D. In the rest of patients binocular UNVA was 0.0. The mean spherical equivalent for near was +0.1 ± 0.45 D.

The mean binocular UIVA was logMAR 0.29 ± 0.19. The binocular UIVA in 30% of patients was equal 0.1 or better. Intermediate vision was improved in 10` subjects with spectacle correction ranging from -0.50 D to +0.75 D (mean +0.09 ± 0.41). Binocular corrected intermediate visual acuity (CIVA) mean was logMAR 0.15 ± 0.18. Binocular CIVA in 70% of patients was equal 0.1 or better.

Six months after surgery, the mean binocular UDVA was logMAR -0.14 ± 0.11. No one patient needed spectacle correction for distance.

The mean binocular UNVA was logMAR 0.01 ± 0.05. In one patient near vision was better with spectacle correction +0.75 D. The mean of spherical equivalent was equal +0.04 ± 0.17.

The mean binocular UIVA was logMAR 0.28 ± 0.22. The binocular UIVA in 45% of patients was equal 0.1 or better. Intermediate vision improved in 8 subjects with spectacle correction ranging from -1.00 D to +0.75 D (mean – 0.52). Binocular CIVA mean was logMAR 0.13 ± 0.15. Binocular CIVA in 80% of patients was equal 0.1 or better.

Three and six months comparison

Uncorrected distance and near vision

Three and six months postoperatively, there was no significant differences in binocular UDVA (logMAR; 3 months: -0.1 ± 0.17; and 6 months: -0.14 ± 0.11; NS). Three months after surgery, the mean near vision was equal 0.02 ± 0.08 (logMAR) and did not differ significantly from those at 6 months (0.01 ± 0.05) (Tab. II).

Visual acuity mean/ Średnia ostrość wzroku	3 months/ 3 miesiące	6 months/ 6 miesięcy	p value/ p wartość
UDVA (logMAR)	-0.1 ± 0.17	-0.14 ± 0.11	NS
UNVA (logMAR)	0.02 ± 0.08	0.01 ± 0.05	NS
UIVA (logMAR)	0.29 ± 0.19	0.28 ± 0.22	NS

NS – statistically not significant/ nieistotny statystycznie.

Tab. II. Mean binocular UDVA, UNVA, UIVA three and six months post surgery.

Tab. II. Średnia obuoczna UDVA, UNVA, UIVA 3 i 6 miesięcy po operacji.

Uncorreceted intermediate vision

Three months after surgery, mean binocular UIVA was 0.29 ± 0.19 (logMAR) and did not change significantly at 6 months follow-up (0.28 ± 0.22) (Tab. II).

Spectacle independence

Three and six months after surgery, all examined patients were spectacle independent, even in some cases mentioned above spectacle correction improved visual acuity.

Contrast sensitivity

Three and six months post surgery, under various conditions (photopic – mean pupil size 3.45 ± 0.7, mesopic – mean pupil size 4.03 ± 0.7), contrast sensitivities were found to be within normal limits in comparison to the normal population in the range of 50 to 75 years old and did not change significantly between follow-ups (Tab. III) (Fig. 2–4).

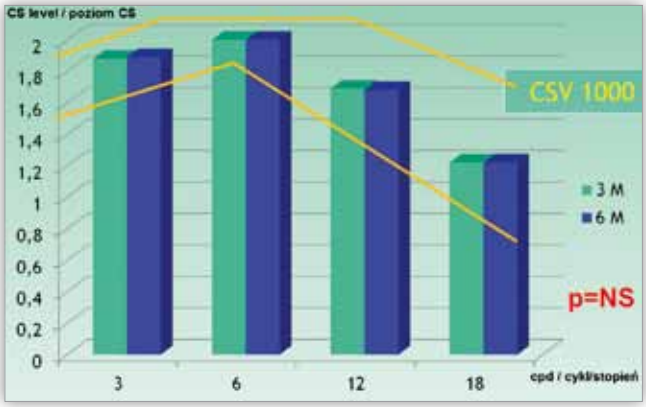

Fig. 2. Means of uncorrected binocular photopic distance CS three and six months after surgery, in comparison to the normal population in age of 50–75 years (yellow line).

Ryc. 2. Średnie obuoczne fotopowe CS do dali 3 i 6 miesięcy po operacji w porównaniu z wartościami u osób zdrowych w wieku 50–75 lat (żółta linia).

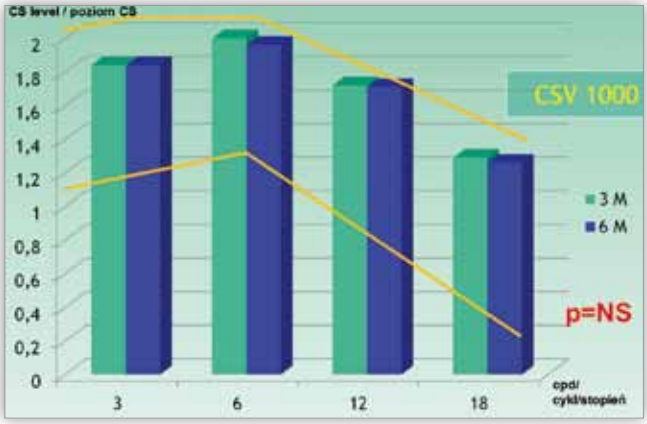

Fig. 3. Means of uncorrected binocular mesopic distance CS three and six months after surgery, in comparison to the normal population in age of 50–75 years (yellow line).

Ryc. 3. Średnia obuoczna mezopowa czułość kontrastowa do dali 3 i 6 miesięcy po operacji w porównaniu z wartościami u osób zdrowych w wieku 50–75 lat (żółta linia).

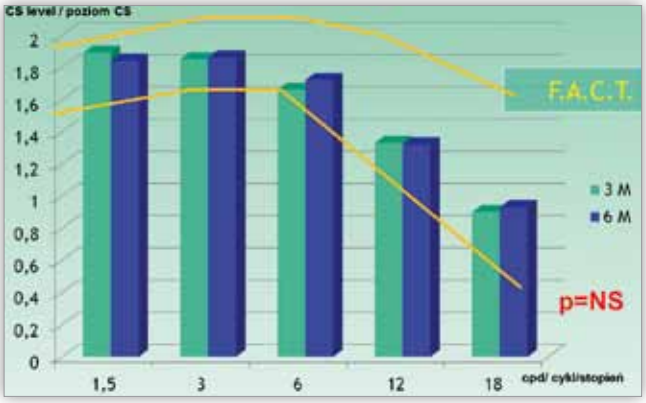

Fig. 4. Means of uncorrected binocular photopic near CS three and six months after surgery, in comparison to the normal population in age of 50–75 years (yellow line).

Ryc. 4. Średnia obuoczna fotopowa czułość kontrastowa do bliży 3 i 6 miesięcy po operacji w porównaniu z wartościami u osób zdrowych w wieku 50–75 lat (żółta linia).

Photopic distance/ Fotopowa do dali	3 months/ 3 miesiące	6 months/ 6 miesięcy	p value/ wartość p
3 cpd	1.88 ± 0.19	1.89 ± 0.17	NS
6 cpd	2.02 ± 0.26	2.00 ± 0.59	NS
12 cpd	1.69 ± 0.21	1.68 ± 0.34	NS
18 cpd	1.22 ± 0.26	1.22 ± 0.34	NS
Mesopic distance/ mezopowa do dali			
3 cpd	1.84 ± 0.22	1.84 ± 0.21	NS
6 cpd	2.11 ± 0.22	1.96 ± 1.01	NS
12 cpd	1.72 ± 0.26	1.71 ± 0.31	NS
18 cpd	1.29 ± 0.23	1.26 ± 0.34	NS
Photopic near/ Fotopowa do bliży			
1.5 cpd	1.89 ± 0.12	1.84 ± 0.18	NS
3 cpd	1.85 ± 0.20	1.86 ± 0.22	NS
6 cpd	1.66 ± 0.20	1.72 ± 0.25	NS
12 cpd	1.33 ± 0.26	1.32 ± 0.37	NS
18 cpd	0.90 ± 0.25	0.93 ± 0.39	NS

NS – statistically not significant/ nieistotny statystycznie

Tab. III. Mean uncorrected binocular photopic, mesopic distance and photopic near contrast sensitivity – three and six months comparison.

Tab. III. Średnia nieskorygowana czułość kontrastowa – obuoczna fotopowa, mezopowa do dali oraz fotopowa do bliży – porównanie po 3 i 6 miesiącach.

Subjective symptoms

Three and six months post surgery no significant daytime glare/halo was reported, however 75% of patients (15/20) reported low glare/halo perception mostly at night. No severe glare/halo was observed in any light conditions. In both follow-ups, level of work difficulties related to glare/halo was low and 6 months post operation was better in comparison to 3 months follow-up, albeit this difference was not statistically significant (0.45 ± 1.10 *vs* 0.70 ± 1.13, NS). The level of glare/halo perception was also low and stable during observation time (1.55 ± 1.35 *vs* 2.0 ± 2.15, NS) (Tab. IV).

Question/ Pytanie	Possible answers/ Możliwe odpowiedzi	3 months/ 3 miesiące	6 months/ 6 miesięcy	p
a. Work difficulty at near/ Trudności w pracy do bliży	(0 – 4)	0.20 ± 0.52	0.15 ± 0.67	NS
b. Work difficulty at distance/ Trudności w pracy do dali	(0 – 4)	0.60 ± 0.94	0.40 ± 0.82	NS
c. Work difficulty at intermediate/ Trudności w pracy do odległości pośredniej	(0 – 4)	0.80 ± 1.1	0.70 ± 1.1	NS
d. Work difficulty regarding glare/ halo/ trudności w pracy związane z „glare/halo"	(0 – 4)	0.70 ± 1.13	0.45 ± 1.1	NS
e. Level of glare/ halo perception/ poziom percepcji „glare/halo"	(0 – 4)	1.55 ± 1.35	2.0 ± 2.15	NS

NS – statistically not significant/ nieistotny statystycznie

Tab. IV. TyPE Questionnaire: work difficulties in near and far distance (a., b.); patient's perception of halo and glare/ patient´s disturbance by halo and glare (c., d.) – comparison of three and six months after surgery (range 0–4: 0 = none, 4 = strong/severe).

Tab. IV. Kwestionariusz TyPE Q: trudności w pracy do bliży i dali (a., b,); percepcja „halo" i „glare" / trudności związane z występowaniem „halo" i „glare" (c., d,) – porównanie 3 i 6 miesięcy po operacji (zasięg 0–4: 0 = żadne, 4 = silne/ciężkie).

Patient's satisfaction

In both follow-ups general satisfaction with visual performance, satisfaction with near and distance were very high (approximately 9/10) and stable. The satisfaction with intermediate vision was also high and almost equal in both follow-ups (7.65 ± 1.22 *vs* 7.80 ± 2.13, NS) but worse from the satisfaction with near and distance (Tab. V).

Six months after surgery, a work difficulties at near, intermediate and far distance improved slightly in comparison to the 3 months follow-up estimation, hovewer this difference was not statistically significant (Tab. V – a., b., c., d.).

Complications

No intra- or early postoperative complications were observed, and three and six months after surgery there were no postoperative complications.

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Question/ Pytanie	Possible answers/ Możliwe odpowiedzi	3 months/ 3 miesiące	6 months/ 6 miesięcy	p
a. General vision satisfaction/ Ogólne zadowolenie z widzenia	(0 – 10)	9.05 ± 0.88	9.0 ± 0.88	NS
b. Near vision satisfaction/ Zadowolenie z widzenia do bliży	(0 – 10)	8.73 ± 1.09	9.05 ± 0.89	NS
c. Distance vision satisfaction/ Zadowolenie z widzenia do dali	(0 – 10)	9.05 ± 0.99	9.40 ± 0.75	NS
d. Intermediate vision satisfaction/ Zadowolenie z widzenia pośredniego	(0 – 10)	7.65 ± 1.22	7.80 ± 2.13	NS

NS – statistically not significant/ nieistotny statystycznie

Tab. V. TyPE Questionnaire: patient's satisfaction (binocular, unaided vision) –comparison of three and six months after surgery (range 0–10: 0 = not satisfied et all, 10 = completely satisfied).

Tab. V. Kwestionariusz TyPE Q: satysfakcja pacjenta (obuoczne, nieskorygowane widzenie) – porównanie 3 i 6 miesięcy po operacji (zasięg 0–10: 0 = całkowicie niezadowoleni, 10 = całkowicie zadowoleni).

Discussion

In this study, we evaluated visual outcome of the Acri.Lisa 366D IOl. This hybrid (refractive-diffractive IOl) is designed for use in MICS and is independent of pupil size. Microincision cataract surgery do not provide to significant surgically induced astigmatism what was confirmed also in our study and is a cause of reduced corneal aberrations in comparison with standard coaxial phacoemulsification (7,8). Thus MICS is very usefull procedure if we deciding an implantation of multifocal IOLs. The Acri.Lisa 366D has an unequal light distribution (ie, 65% for distance and 35% for near vision for the refracted light). The reason for such distribution of light is that most patients prefer distance vision and that smallel amount of light for reading is sufficient for reading under normal light conditions. Another advantage of the Acri. Lisa 366D IOL is a reduction of unwanted effects, in particular halos, by producing 1 dominant image and 1 weaker image but smooths steps between the diffractive zones reduced glare (7).

Three and six months after surgery, in all patients (20/20) with implantations of Acri.Lisa 366D lenses very good uncorrected, binocular distance, near and intermediate visual acuities were obtained (Tab. II). There was no significant differences in mean of uncorrected visual acuities for distance, near and intermediate vision between follow-ups. Hovewer, in some cases six months after surgery improvement of visual acuity was obtained. In our study visual acuity outcomes for distance, intermediate and near vision were comparable to those reported by Alfonso et al. (9-11).

In our series of patients, 3 and 6 months after surgery binocular distance photopic, mesopic as well as near photopic CS was within normal limits in comparison with the normal population between 50 and 75 years old (12) and there was not significant differences between both follow-ups. Incoming light distribution to more than 1 focus what is present in multifocal IOLs theoretically and clinically decreases the contrast sensitivity (13). In our study CS results were within normal limits and were comparable to those described by others (9,10). Lack of significant differences in CS 3 and 6 months after surgery suggests that neuroadaptation process for new optical conditions in patients with implanted Acri.Lisa 366D is short and last only 3 months. The results of CS indicate that proposed concept of light distribution by producers in Acri.Lisa 366 D connected with it asphericity is a very good solution for the patients.

In our study, general patient satisfaction was very high and stable. Six months after surgery satisfaction from distance, intermediate and near vision improved slightly in comparison to 3 months after surgery, albeit this difference was not statistically significant (Tab. V) but work difficulties at distance, intermediate and at near diminished (Tab. IV).

In patients with multifocal IOLs visual phenomena like glare and halo are observed created by multiple out of focus images. In our study no patient has mentioned the symptoms to the surgeon before completing the questionnaire. No one patient had severe glare/halo. Low level and stable glare/halo perception was detected in 75% of patients 3 and 6 months post surgery only in low light conditions. Work difficulty regarding glare/halo were also low and unsignificantly reduced during observation time. Kajmak and Mester (14) reported in the similar percent of patients (80%) with halo but with mild level of perception. Can et al. (15) reported mild halo and glare problems in about 25% of patients. Alio et al. (3) reported night photic visual phenomenon in less than 10% of patients.

The results of our study and those described in the literature concerning with glare/halo showing only low or mild perception level of photic visual symptoms suggest that the design of the diffractive steps seen in Acri.Lisa 366D reduced significantly unwanted effects.

In our study, all patients accepted visual phenomena and none of them wanted the Acri.Lisa 366 D to be explanted.

What is worth to note, spectacle independence for distance, intermediate and distance vision was achieved in all subjects. Almost the same results of spectacle independence were obtained by others (15).

In conclusion, bilateral implantation of the microincision Acri.Lisa 366 D lenses provided very good outcomes and high level of patients satisfaction. So, we would recommend the MICS and this type of IOLs for the cataract surgeons and patients who want to be spectacle independent.

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