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Multifocal diffractive intraocular lenses in cataract surgery – preliminary report

Wieloogniskowe dyfrakcyjne soczewki wewnątrzgałkowe w chirurgii zaćmy – doniesienie wstępne

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Summary: Purpose: evaluation of the efficacy of multifocal, diffractive intraocular lenses in cataract surgery.
Material and Methods: 20 eyes in 10 patients, mean age 64 ±9 years, included in the study, undergoing phacoemulsification of the cataract with implantation of diffractive MIOL (AcrySof ReSTOR, SA60D3, Alcon). Follow-up was performed for a period of 6 months. Postoperative evaluation performed five times included: visual acuity for distance and near without and with best correction, contrast sensitivity, patient satisfaction in 10-grade scale, degree of independence from glasses and frequency of lighting effects.
Results: After 6 months from surgery uncorrected distance visual acuity ≥1.0 was achieved in 55% of operated eyes (6/11), and the best corrected in 91% (10/11). Uncorrected near visual acuity in 2-6 months after surgery was achieved in all patients. Contrast sensitivity for spatial frequencies in the range 12 and 18cdg was decreased, but in 6 cdg was normalized after 6 months of observation, and in 3 cdg was normal. Subjective patient satisfaction in 10-grade scale was on average in the first day after surgery 7.9 points and after 6 months 9.3. The necessity to use glasses (30%) and lighting effects had no bearing on subjective patient satisfaction perception.
Conclusions: Multifocal diffractive lens implants are able to restore good visual acuity independent of distance and is effective and safe method in cataract surgery.

Słowa kluczowe: wieloogniskowe soczewki wewnątrzgałkowe, dyfrakcyjne soczewki wewnątrzgałkowe, operacje zaćmy.
Key words: Multifocal intraocular lens, diffractive intraocular lens, cataract surgery.

Introduction:

First surgeries to implant intraocular lenses were performed in 1949 by Herold Ridley (1). Since that time dynamic development of microsurgery as well as introduction of new materials and biomedical technologies made it possible to perform effective and safe operations and restoring fast full visual acuity. Nowadays standard in cataract surgery is monofocal intraocular lens implant, which results in loss of near vision.

The idea of diffractive cataract surgery is more important in recent years. This is a new method especially for people with active lifestyle, which is capable to correct inducted by cataract surgery presbyopia and reduce or eliminate dependence on glasses.

One of the surgical methods to correct presbyopia with the use of monofocal intraocular lenses is to create monovision conditions. This involves creation in the dominant eye emmetropic conditions to use for far and in the other eye correction in the range from –1.5 to –3.0 D for near. It is important to emphasize that about 30% of patients are unable to tolerate monovision, due to loss of binocular vision, which is in direct correlation with the degree of anisometropy (2,3,4). The next step in the development of presbyopia correction was introduction of diffractive or multifocal intraocular lenses (MIOL). First surgeries with MIOLs, originally as models of 2-3 zones, were performed already in 1986 (5). Amongst currently used MIOLs there are two basic types: refractive lenses and diffractive lenses. Diffractive lenses are characterized by quick achievement of near vision, and also less frequent side effects in the form of lighting phenomena in comparison to refractive lenses (4,6,7).

The aim of this study is evaluation of effectiveness of multifocal, diffractive intraocular lens implants in cataract surgery. Analysis of visual acuity, contrast sensitivity and subjective satisfaction of patients, lighting side effects and dependence on glasses was performed.

Material and Methods

Studied material includes post-surgical evaluation after 20 phacoemulsification of senile cataracts and multifocal, diffractive intraocular lenses implants (AcrySof ReSTOR, SA60D3, Alcon). The implant surgeries of MIOLs were performed in both eyes in all patients about four weeks apart between procedures. It was a group of 4 men and 6 women, 49 to 74 years old (mean 64 ±9).

Diagnosis of bilateral cataract was the requirement for operation and inclusion in the study. Qualification of patients for MIOL implants besides typical ophthalmologic exam included extensive interview to assess motivation towards MIOL implant, desire to get independent of glasses and level of daily

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activity. All patients received information about surgical therapy of cataract, MIOL specification, possible complications, and specifically about necessity of neuroadaptation to new vision system and consciously consented to surgery as well as post-surgical evaluation. Exclusions from MIOL implants were narrowed to ophthalmic pathology that could influence achievement of good visual acuity and included irregular astigmatism, corneal cone, corneal decompensation, severe dry eye syndrome, eccentric, non reactive pupil, diabetic retinopathy, macular degeneration, high risk of retinal detachment, poorly controlled glaucoma, previous laser or other eye surgery, monofocal intraocular lens in one eye and required power of MIOL beyond availability. Calculation of MIOL power was done by ultrasonograpphic measurement of the eyeball axis by the contact method with the use of SRK/T formula (constant A=118.2). The goal of the refraction was scheduled for emmetropic (±0.25 D). The same surgeon performed all surgical procedures. In one patient, because of bilateral with the rule astigmatism at the level 1.8-2.0 D limbal relaxing incision (LRI) was done at the same time.

In the study protocol, post-surgical evaluation was scheduled five times in the following intervals from the surgery: 1 day, 1 week, 1 month, 2 months and 6 months. Protocol of the study included examination of distance and near visual acuity with Snellen tables without correction (UCVA) and with the best correction (BCVA), tonometry, examination of anterior chamber with the slit lamp, ophthalmoscopy, corneal topography, and subjective evaluation of the quality of vision and satisfaction level graded from 1 (minimal satisfaction) to 10 (maximal), dependence on glasses and side effects (like effect "halo", lighting phenomena and difficulty in adaptation to the new visual system). Additionally in every patient with visual acuity ≥1.0 (Snellen), the curve of contrast sensitivity was determined with table CSV-1000.

Results

In subject group pre-operation mean uncorrected distance visual acuity was 0.3 ±0.18 and 0.5 ±0.26 with the best correction. Range of pre-operation refraction in spherical equivalent was from –3.5 to +4.0 D.

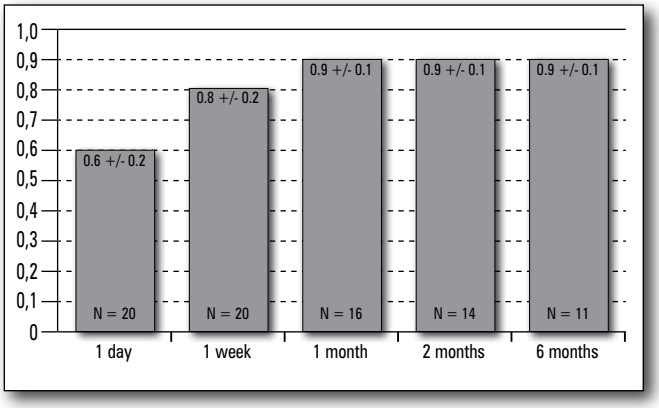

Fig. 1. Mean uncorrected distance visual acuity in particular periods after surgery.
Ryc. 1. Średnia ostrość wzroku do dali bez korekcji w poszczególnych okresach po zabiegu.

Uncorrected distance visual acuity (UCVA) after 1 day post-surgery was in the range 0.3-1.0 (mean 0.6 ±0.2), after 1 week 0.6-1.0 (mean 0.8 ±0.2), and subsequently after 1-6 months 0.7-1.0 (mean 0.9 ±0.1). Results of the uncorrected distance visual acuity are shown in figure 1.

Full uncorrected visual acuity (UCVA) ≥1.0 1 day after operation were achieved by 10% (2/20) of the operated eyes, after 1 week 40% (8/20), after 1 month 50% (8/16), after 2 months 50% (7/14), and after 6 months 55% (6/11). The best corrected distance visual acuity (BCVA) ≥1.0 after 1 week was noticed in 65% (13/20) of the operated eyes, and after 6 months in 91 % (10/11) respectively. Specific information is shown in table 1.

Uncorrected near visual acuity at the level 0.5 according to Snellen chart 1 day after operation was found in 45% (9/20) of the operated eyes, after 1 week in 75% (15/20), after 1 month in 94% (15/16) of the operated eyes, and after 2-6 months in all the patients (figure 2)

	UCVA					BCVA				
	1 day (n=20)	1 week (n=20)	1 mnth (n=16)	2 mnths (n=14)	6 mnths (n=11)	1 day (n=20)	1 week (n=20)	1 mnth (n=16)	2 mnths (n=14)	6 mnths (n=11)
≥ 1.0	10%	40%	50%	50%	55%	20%	65%	81%	86%	91%
0.9	–	10%	25%	–	36%	10%	5%	13%	7%	–
0.8	20%	15%	19%	29%	9%	15%	15%	6%	7%	9%
0.7	5%	25%	6%	21%	–	15%	15%	–	–	–
0.6	20%	10%	–	–	–	15%	–	–	–	–
0.5	15%	–	–	–	–	15%	–	–	–	–
0.4	25%	–	–	–	–	10%	–	–	–	–
0.3	5%	–	–	–	–	–	–	–	–	–

Tab. I. Results of distance uncorrected visual acuity (% of eyes operated) (UCVA) and the best corrected (BCVA) in particular periods after surgery.
Tab. I. Wyniki ostrości wzroku do dali (% ogółu operowanych oczu) bez korekcji (UCVA) i z najlepszą korekcją (BCVA) w poszczególnych okresach po zabiegu.

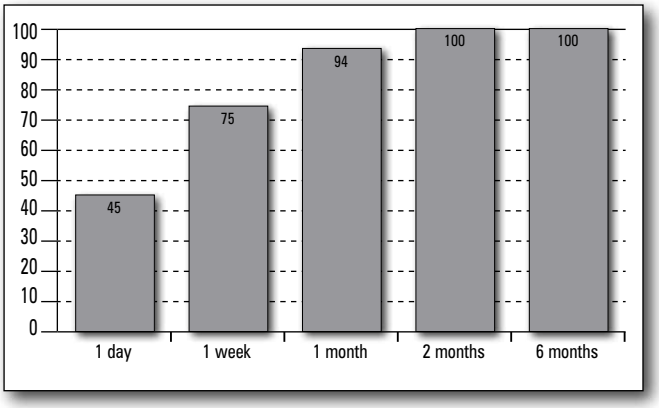

Fig. 2. Percentage of eyes with uncorrected near visual acuity at the level 0.5/30 cm (according to Snellen chart) in particular periods after surgery.

Ryc. 2. Procentowy udział oczu z ostrością wzroku do bliży na poziomie 0,5/30 cm (Snellen) bez korekcji w poszczególnych okresach po zabiegu.

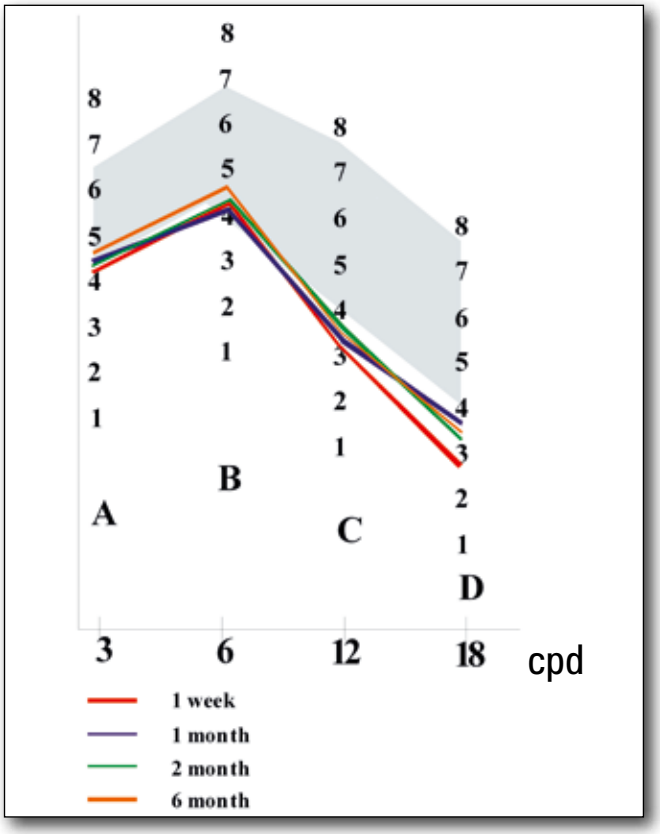

Fig. 3. Contrast sensitivity values in particular periods after surgery according to table CSV-1000.

Ryc. 3. Wyniki czułości kontrastu w poszczególnych okresach po zabiegu na podstawie tablicy CSV-1000.

One month after operation in 31% (5/16) of the operated eyes mean spherical equivalent was +0.45 ±0.11 D (range to +0.5 D), and after 6 months +0.25 ±0.47 D (range from -0.25 to +0.75 D).

In the intraoperative time and immediately after no essential side effects connected to MIOL implant were observed. Intraocular pressure during the study was never recorded higher than 21 mmHg in all patients. Examination of the anterior chamber with slit lamp did not show misplacement of MIOL. Warping

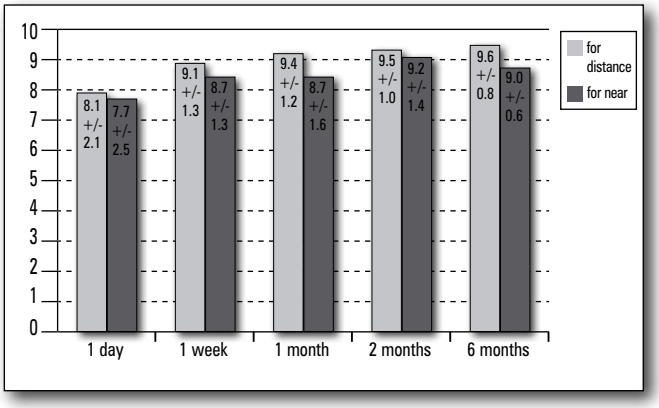

Fig. 4. Subjective level of patient satisfaction in 10 grade scale in particular periods after surgery.

Ryc. 4. Subiektywny poziom satysfakcji pacjentów w 10-stopniowej skali w poszczególnych okresach po zabiegu.

of the posterior capsule was noted after 1 month from surgery in 44% (7/16) of the operated eyes.

Results of the contrast sensitivity are shown in figure 3.

General subjective level of the patient satisfaction using 10 grade scale was after 1 day 7.9 ± 2.3 pts, after 1 week 8.9 ±1.3, after 1 month 9.0 ±1.4, after 2 months 9.4 ±1.2, and after 6 months 9.3 ±0.8 pts. Subjective near visual acuity was slightly lower but statistically insignificant in comparison with distance visual acuity in particular steps of observation ($p>0.05$) (figure 4).

History data showed that 3 out of 10 operated patients were using intermittently glasses for reading, generally with being tired in the evening hours or during precision required vision for near sight.

4 out of 10 patients reported lighting phenomena around artificial light sources, but it was substantially reduced in 1-4 weeks after implantation of MIOL in the second eye. Patients reported lighting intensity as moderate or low without essential interference on quality of vision. In 6 out of 10 studied after MIOL implantation in both eyes it appeared "halo" phenomenon during reading in the evening hours, described by patients as "shadow" of the letters or diplopia.

Discussion

In our work we concluded, that distance uncorrected visual acuity ≥0.8 [≥20/25 Snellen, ≥0.1 log MAR] after 2 months from MIOL implant was achieved in 79% (11/14) of the operated eyes, and after 6 months 100% of the operated eyes. These results point out that multifocal, diffractive intraocular lenses implants enables good distance visual acuity. In the available bibliography there are a very few publications evaluating effectiveness and post-operation period after implants of diffractive lenses of the type AcrySof ReSTOR. In the recently published work by Roch KM et al. evaluation of visual acuity, aberration and contrast sensitivity after AcrySof ReSTOR lens implant was performed as well as 3 types of monofocal lenses. In evaluation of visual acuity after 2 months of observation in 90% of the eyes (45/50) with diffractive lenses ≥20/25 [≥0.8 Snellen] best-corrected visual acuity (BCVA) was achieved (8). Our own study, although using small group of patients shows that all the

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patients after 2 months achieved distance BCVA ≥0.8. For proper interpretation of the results it is important to consider time frame of the visual acuity correction in the post-operation period. Therefore the best reference should be comparison of the visual acuity in analogical time compartments. Unfortunately in many papers the final evaluation of the visual acuity is presented, after observation period that is frequently variable. It is directly connected with neuroadaptation process to the new visual system, which lasts about 3 months (9). It seems, that earlier analyses mirror only the time necessary for full adaptation, but reliable evaluation should involve longer observation period. Walkow T. et al. present such data in paper with the use of different than AcrySof ReSTOR diffractive lens (10). In this work it was shown, that after 12 months distance uncorrected visual acuity (UCVA) ≥0.8 was achieved in 73.4% (47/64) of the studied eyes, and best corrected visual acuity (BCVA) >0.8 in all patients. Interesting communication is the work by Slagsvold with multiyear (7.9 ±1.3 years) observation period after diffractive lens implant 3M (11). Despite the fact, that during such a long observation period, quality of visual acuity in older group of patients (78.1 ±6.8 years) may be influenced by many systemic factors, the author found distance uncorrected visual acuity (UCVA) ≥0.8 in 69.9% of the eyes (53/76).

For a full assessment of the neuroadaptation process it is important to know time to achieve correction of the visual acuity with differences for distance and near. In own material we noticed difference in the dynamic of correction of the visual acuity for distance in comparison to near. Uncorrected distance visual acuity ≥1.0 1 day after surgery was achieved by only 10% of the operated eyes, but near visual acuity at the level 0.5 according to Snellen chart was achieved by 45% of the operated eyes. Results after 1 week are 40% for distance and 75% for near, and after 1 month 94-100% of the operated eyes achieve 0.5 (Snellen chart) uncorrected near visual acuity, and 50-55% uncorrected distance visual acuity, and corrected 81-91%. Our results may suggest that neuroadaptation process for near in that kind of lenses is more rapid. In the available literature there is no data on dynamic return of visual acuity after MIOL implant type AcrySof ReSTOR. Communication evaluating dynamic improvement in the visual acuity for near is work by Alio JL. et al. comparing diffractive lens TwinSet with accommodative and refractive lenses (7). In this communication after 12 months observation period it was determined that return to near visual acuity was faster with diffractive lens than any other. Achievement of better visual acuity for near as compared to distance could be interpreted in connection to construction of the optical part of diffractive MIOL, comprised of central 3.6 mm zone of diffractive rings with added power for near.

Another problem that we assessed in our work was contrast sensitivity. According to some communications, implants of every type MIOL result in decrease in contrast sensitivity (3,13,14). In our material we determined, that within 12 and 18 cdg contrast sensitivity values are diminished in the entire 6 months observation period. Lowering of the contrast sensitivity in frequency range from 6 to 18 cdg was noted by Slagsvold, who was evaluating diffractive lenses 3M, however results were assessed after about 7.9 years from the surgery (11). Analyzing results within frequency 6 cdg we noted substantial improvement of contrast sensitivity between second and sixth months of observation. In turn contrast sensitivity values for frequency 3 cdg remained in the age referenced norm. Stated improvement of the contrast sensitivity could be the effect of neuroadaptation and points at, that optimal time for reliable assessment of contrast sensitivity is 6 months after surgery. Similar conclusions were suggested in the work by Montes-Mico et al. evaluating contrast sensitivity for refractive model of MIOLs. He also noticed improvement in the contrast sensitivity in the period from 3 to 6 months after MIOL implant (12).

Subjective satisfaction level of patients was very high already in the first week after MIOL implant. So high satisfaction level in the studied group was not connected with the necessity of use of the glasses for near by 3/10 patients. The remainder of patients (70%) in the 6 months observation period never used glasses. This data is close to the ones obtained by Walkow et al., according to whom 80.6% of operated patients never used glasses (10). Slightly worse results were obtained after implant of diffractive lenses 3M, where in the group of 72 patients only 39 (54.2%) never used glasses (11). Subjectively worse evaluation for near in our group was influenced by lighting side effect "halo" in 60% of operated patients during reading.

Side effects like flashes observed in this work in 4/10 patients estimated as mild or moderate did not have any influence on subjective assessment of vision quality. Reduction of lighting effects in comparison to refractive MIOLs may stem from gradual connection of optical elements in diffractive central part of the lens and from refractive peripheral zone.

We emphasize, that our observations are preliminary and for reliable comparison the number of patients should be higher and observation period should be longer.

Conclusions

The use of diffractive MIOL allows achievement of good visual acuity independent from distance with slight advantage for near as a result of faster return of visual acuity.

Contrast sensitivity after implant of diffractive MIOL is decreased in the range of higher frequencies, but it normalizes for lower frequencies in 6 months observation period.

After implant of diffractive MIOL patient satisfaction was high, independent from few lighting phenomena and sporadic correction with glasses.

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