(58)

Cataract surgery with bilateral multifocal ReZoom intraocular lens implantation – comparison of 3 and 12 months follow-up

Operacja zaćmy z obuocznym wszczepem soczewek wieloogniskowych ReZoom – porównanie wyników 3 miesiące i 12 miesięcy po operacji

Lubiński Wojciech, Gronkowska-Serafin Jolanta, Podborączyńska-Jodko Karolina, Karczewicz Danuta

Clinic of Ophthalmology, Pomeranian Medical University, Szczecin, Poland
Head: Professor Danuta Karczewicz MD, PhD

Summary:

Purpose: To evaluate the visual outcome, spectacles independence, contrast sensitivity (CS), subjective symptoms, patient satisfaction and complications three and 12 months after cataract surgery with bilateral ReZoom multifocal refractive intraocular lens (IOL) implantation.

Patients and methods: This study comprised 40 eyes of selected 20 patients who had uneventful cataract surgery with bilateral implantation of ReZoom (AMO) multifocal IOL. Three and 12 months after bilateral surgery binocular uncorrected, the best corrected distance, near and uncorrected intermediate visual acuities (VA), spectacle independence, the best corrected binocular distance (with and without glare), near photopic CS, subjective symptoms, patient satisfaction and complications were evaluated.

Results: Three and 12 months after surgery all patients had binocular uncorrected distance visual acuity (VA) of 0.5 or better; the best corrected distance VA was 1.0 in all cases. Three months after surgery, the mean binocular uncorrected intermediate VA was J4.10. The mean binocular uncorrected and the best corrected near VA were J3.10 and J1.70 respectively.

Total spectacle independence and independence for distance, intermediate and near vision were achieved in 65%, 100%, 95% and 70% of patients respectively. The best corrected binocular distance and near CS were within normal limits. The most frequent subjective symptoms were mild glare and halo (65% – 13/20 of patients).Total vision satisfaction was very high (9.6/ 10). There were no postoperative complications.

One year after surgery, statistically significant improvement occurred in the best distance corrected near VA ($p<0.04$), photopic distance best corrected CS without glare for 12 cycl/deg ($p<0.03$) and in the level perception of glare/halo ($p<0.02$) in comparison to the results from 3 months follow-up. The rest of analyzed parameters was unchanged. No complications were noticed except posterior capsule opacification in four patients one year after surgery who needed YAG laser treatment.

Conclusion: Bilateral ReZoom multifocal IOL implantation was effective in selected cataract patients, providing very good uncorrected distance, intermediate, and near visual acuities as well as very high level of patient satisfaction.

Longer than three months of the neuroadaptation time after bilateral surgery is necessary to obtain significantly better visual function results.

Słowa kluczowe: operacja zaćmy, ReZoom IOL implantacja, funkcja wzroku, objawy subiektywne, zadowolenie pacjentów, powikłania.
Key words: cataract surgery, ReZoom IOL implantation, visual outcome, subjective symptoms, patient satisfaction, complications.

Introduction

Today cataract surgery with the implantation of a multifocal IOLs can be also refractive procedure designed to patients who want to be spectacle independent. Multifocal IOLs are thought to engage the simultaneous vision principle in which separate near and distance images are superimposed on the retina. The brain selects the image it wants to see. However, the patients with multifocal IOLs have to accept the visual side effects that may occur like halo and glare, especially at night. Multifocal IOLs provide good uncorrected visual acuity for all distances, they are better than monofocal IOLs and presbyopic human lens. In 1997 FDA approved the Array SA40N refractive, multifocal IOl which opened a new area in the field of cataract surgery and presbyopic correction. Numerous studies' results and also our experiences (1,2,3) have demonstrated safety and effectiveness of the Array IOl in correcting vision for different distances. In 2005 year FDA approved a second-generation multifocal, refractive IOL – ReZoom (Advanced Medical Optics). The refractive surface is based on the hydrophobic acrylic platform incorporating the OptiEdge design. The ReZoom (6 mm optics diameter) is a three-piece, distance dominant and zonal-progressive lens with wide range of diopters power ranging from +6.0 D to +30.0 D. The five concentric, refractive zones provide multifocal vision: zones 1,3,5 are distance dominant;

zones 2 and 4 are near dominant, and an aspheric transition between zones provides balanced intermediate vision. When compared with the Array IOL, the distance and near zone areas of the Rezoom IOL have been modified to decrease unwanted halos in low light conditions without affecting good distance and near vision (4). One of the important issue of multifocal IOL implantation is neural adaptation for patients to adapt to changes in the optical component of the visual system. The longer phase of neural adaptation that can take from several moths to a year has been demonstrated in trials of aspheric versus spherical IOLs, multifocal IOls and refractive corneal surgery (5-9). In those studies, the patient satisfaction level was much better at the end of 1 year than a few weeks after surgery, even though there has been no optical change during this period. Optimal neural adaptation time necessary for receiving the best visual function results after bilateral ReZoom lenses implantation is not known. That is why the goal of our study was to evaluate and compare the visual outcome, spectacle independence, contrast sensitivity, subjective symptoms, patient satisfaction and complications three and twelve months after cataract surgery with bilateral ReZoom multifocal refractive intraocular lens implantation.

Patients and methods

Forty eyes of selected 20 patients (women/ men – 8/12; mean age 57.9 ± 7.8 years; mean of the best corrected distance visual acuity – 0.7±0.3; mean of spherical equivalent (SE) – -0.3 D ± 1.2 D) undergoing uneventful cataract (mean LOCS III NO3, NC3) surgery with bilateral implantation of ReZoom (model NXG1) multifocal IOL. The second eye was operated 4 weeks after first one. Inclusion criteria were: range of age 40-70 years, bilateral cataract, preoperative keratometric cylinder less than 1.0 D, no preexisting pathology other than cataract, no myopia and patient's motivation for spectacle independence. The target refraction was emmetropia or low hyperopia (0 to +0.25 D). Lens power was assess with ultrasound or IOL Master. For IOL power calculation the SRK/ T or Hoffer Q were used.

Surgical technique

Cataract surgery (divide and conquer or phacoaspiration technique for lens extraction) was performed by one surgeon in topical anesthesia (Alcaine) through temporal, clear corneal incision (2.8-3.0 mm). Capsulorhexis diameter was approximately 5 mm. Multifocal ReZoom IOL was implanted using an unfolder into the capsular bag.

Outcome measures

Three months and one year after binocular cataract surgery with ReZoom implantation ophthalmological evaluation was performed including: binocular uncorrected and best corrected distance VA, binocular uncorrected intermediate (60 cm) VA, binocular uncorrected and distance corrected near visual acuity at 30 cm (UCDVA, BCDVA – Snellen Chart; UCIVA, and UCNVA, BCNVA – Jaeger Chart) and complications. Photopic (an illumination of 85 cd/ m^2), binocular, best distance corrected contrast sensitivity (with and without glare) was measured with spatial frequencies 3, 6, 12, and 18 cycles per degree (CSV-1000 test, VectorVision). Absolute values of log contrast sensitivity were obtained for each patient, and the spatial frequency and means and standard deviations were calculated. Patients were asked to grade spectacle independence, subjective symptoms and visual satisfaction.

Patient's satisfaction was assessed using a subjective TyPE questionnaire (10).

Statistical analysis

Statistical analysis of the results was performed using Statistica software. The visual acuity, contrast sensitivity, postoperative refraction and patient's satisfaction results 3 and 12 months after surgery were compared using Wilcoxon test. A p value less than 0.05 was considered statistically significant.

Results

Three and one year after surgery, the mean spherical equivalent was +0.20 D ± 0.50 D and +0.20 D ± 0.40 D, respectively. This difference was not statistically significant.

Distance vision

Three months postoperatively, the mean binocular uncorrected distance visual acuity (UCDVA) was 0.97 ± 0.10 (range 0.5-1.0). Binocular UCDVA of 1.0 (20/20) was achieved in 85% of patients, 0.8 (20/25) or better in 100% patients.

One year after surgery, the mean binocular UCDVA was 0.94 ± 0.14 (range 0.6-1.0) and this value did not differ significantly from binocular UCDVA three months postoperatively (Fig. 1).

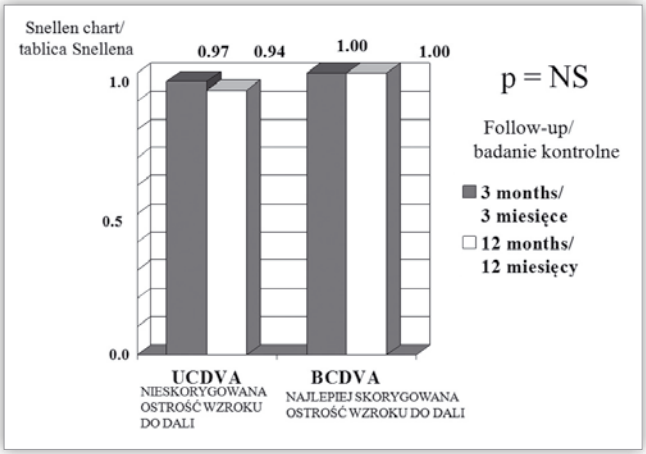

Fig. 1. Distance uncorrected and the best corrected binocular visual acuity 3 and 12 months after surgery (n = 20 patients).
Ryc. 1. Nieskorygowana i najlepiej skorygowana obuoczna ostrość wzroku do dali 3 miesiące i 12 miesięcy po operacji (n = 20 pacjentów).

Three months postoperatively, the mean binocular best corrected distance visual acuity (BCDVA) was 1.0 ± 0.00. All patients achieved BCDVA of 1.0 (20/20) which continued up to twelve months after surgery.

Near vision

Three months after surgery, the mean binocular uncorrected near visual acuity (UCNVA) was J3.10 ± 2.50 (range J10-J1). Binocular UCNVA of J1 or better was achieved in 45%, of J2 or better in 65% and of J4 or better in 75% of patients. All patients had UCNVA of J10 or better.

ISSN 0023-2157 Index 362646

One year after surgery, the mean binocular UCNVA was J2.20 ± 2.14 (range J8-J1) and was better in comparison to 3 months follow-up result (J2.20 ± 2.14 versus J3.10 ± 2.50), albeit this difference was not statistically significant (Fig. 2).

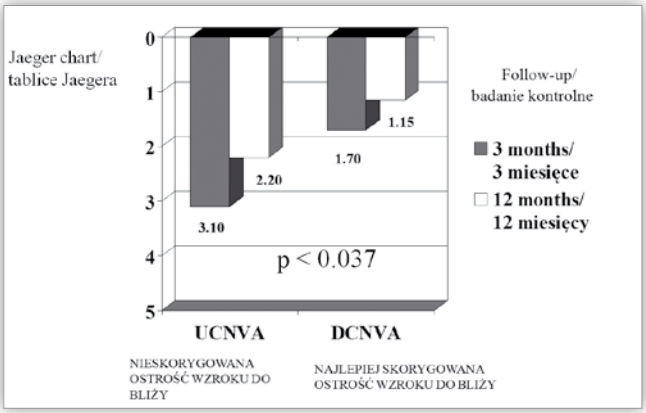

Fig. 2. Uncorrected and the best distance corrected binocular near visual acuity 3 and 12 months after surgery (n = 20 patients).
Ryc. 2. Nieskorygowana i najlepiej skorygowana obuoczna ostrość wzroku do bliży 3 miesiące i 12 miesięcy po operacji (n = 20 pacjentów).

Three months postoperatively, the mean binocular distance corrected near visual acuity (DCNVA) was J1.70 ± 1.16 (range J6-J1). Binocular DCNVA of J1 or better was achieved in 60%, of J2 or better in 85%. All patients had DCNVA of J4 or better.

One year after surgery, the mean DCNVA was J1.15 ± 0.37 (range J2-J1) and was significantly better in comparison to three months follow-up result (J1.15 ± 0.37 versus J1.70 ± 1.16; p<0.037) (Fig. 2). Binocular DCNVA of J1 was achieved in 85% of patients. All patients had DCNVA of J2 or better.

Intermediate vision

Three months after surgery, the mean binocular uncorrected intermediate visual acuity (UCIVA) was J4.8 ± 2.45 (range J10-J1). Binocular UCIVA of J2 (20/25) or better was achieved in 30% of patient, of J4 (20/32) or better in 50%, J6 (20/40) or better in 80%. No patients had uncorrected intermediate acuity worse than J10.

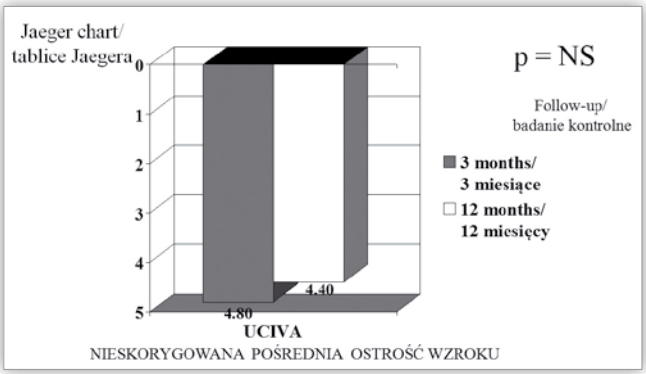

Fig. 3. Uncorrected binocular intermediate visual acuity 3 and 12 months after surgery (n = 20 patients).
Ryc. 3. Nieskorygowana obuoczna pośrednia ostrość wzroku 3 miesiące i 12 miesięcy po operacji (n = 20 pacjentów).

One year after surgery, the mean binocular UCIVA was J4.4 ± 2.39 (range J10-J1) and was better in comparison to 3 month follow-up result (J4.4 ± 2.39 versus J4.8 ± 2.45) but this difference was not statistically significant (Fig. 3).

Spectacle independence

Three months after surgery, all patients (20/20) were spectacle independent for distance vision, 95% (19/20) for intermediate vision, 70% (14/20) for near vision. On the survey, 65% (13/20) patients did not wear spectacles for regular daily activities. Twelve months after surgery, level of spectacle independence was the same (Fig. 4).

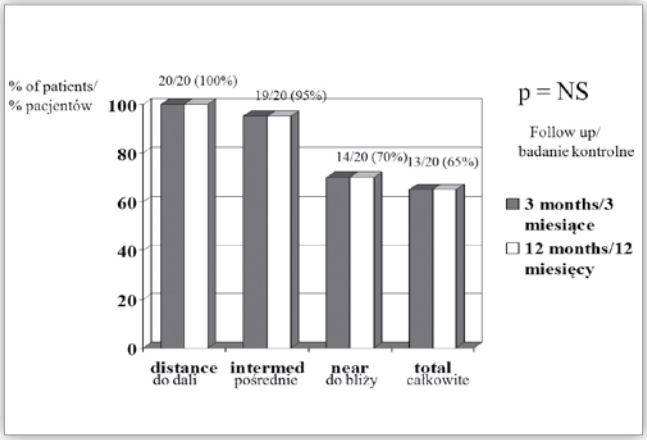

Fig. 4. Spectacle independence 3 and 12 months after surgery (n = 20 patients).
Ryc. 4. Niezależność od okularów 3 miesiące i 12 miesięcy po operacji (n = 20 pacjentów).

Contrast sensitivity

Three and 12 months after surgery, mean of binocular photopic CS for distance (with and without glare) was between normal limits in comparison to normal population in age of 50-75 years (11).

One year postoperatively, the mean of the best corrected binocular distance photopic CS without glare was significantly better at 12 cpd (1.71 ± 0.12 versus 1.83 ± 0.12; p<0.026). At 3, 6 and 18 cpd contrast sensitivity 3 and 12 months postoperatively did not differ significantly (Tab. I).

Spatial frequency (cpd) (mean + SD)/ Częstotliwość przestrzenna (cykli na stopień) (średnia ± SD)	3 months postoperatively/ 3 miesiące po operacji	12 months postoperatively/ 12 miesięcy po operacji	p (Wilcoxon test) p/ (test Wilcoxona)
3	1.96 + 0.12	1.93 + 0.08	p = NS
6	2.07 + 0.14	2.15 + 0.07	p = 0.049 (NS)
12	1.71 + 0.12	1.83 + 0.12	P = 0.026
18	1.23 + 0.17	1.13 + 0.16	P = NS

Tab. I. Comparison of the mean best corrected binocular distance photopic contrast sensitivity without glare 3 and 12 months after surgery (n = 20 patients).
Tab. I. Porównanie średniej najlepiej skorygowanej obuocznej fotopowej czułości kontrastowej do dali bez olśnienia 3 miesiące i 12 miesięcy po operacji (n = 20 pacjentów).

Three and 12 months after surgery, the mean of the best corrected binocular distance photopic CS with glare were not altered (Tab. II).

Spatial frequency (cpd) (mean + SD)/ Częstotliwość przestrze nna (cykli na stopień) (średnia ± SD)	3 months postoperatively/ 3 miesiące po operacji	12 months postoperatively/ 12 miesiące po operacji	p (Wilcoxon test)/ p (test Wilcoxona)
3	1.75 + 0.17	1.78 + 0.09	p = NS
6	1.92 + 0.12	1.92 + 0.09	p = NS
12	1.55 + 0.19	1.55 + 0.11	p = NS
18	1.11 + 0.20	0.99 + 0.15	p = NS

Tab. II. Comparison of the mean best corrected binocular distance photopic contrast sensitivity with glare 3 and 12 months after surgery (n = 20 patients)

Tab. II. Porównanie średniej najlepiej skorygowanej obuocznej fotopowej czułości kontrastowej do dali z olśnieniem 3 miesiące i 12 miesięcy po operacji (n = 20 pacjentów).

Subjective symptoms

Glare

In the one year follow-up, the frequency of patients without glare was almost the same in comparison to the three months after surgery 75% (15/20) versus 70% (14/20). Severe glare was not observed. One year after surgery, improvement in glare severity perception was detected. There was no moderate glare. In one patient moderate glare completely disappeared, in two subsequent patients moderate glare was reduced to mild glare.

Halo

One year after surgery reduction in perception of halo was seen. No halo reported 40% (8/20) of patients and this result was better in comparison to 3 months after surgery 20% (4/20) of patients. One year postoperatively there was no severe halo and the frequency of moderate halo was reduced in comparison to three months postoperatively – 5% (1/20) versus 25% (5/20) of patients. In two patient moderate halo was reduced to mild halo; in one subsequent patient moderate halo disappeared.

Twelve months after surgery, reduction of work difficulties connected with glare/ halo was observed in comparison to 3 months follow-up (0.35 ± 0.49 versus 0.60 ± 0.82), albeit this difference was not statistically significant. One year postoperatively statistically significant reduction of the glare/ halo level perception was obtained (0.75 ± 0.55 versus 1.40 ± 0.99; $p<0.018$). What is worth to note, the level perception of glare/ halo as well as work difficulties connected with glare/halo were low.

Patient Satisfaction

One year after surgery total vision satisfaction was very high and did not differ significantly from those seen 3 months after surgery (9.65 ± 0.58 versus 9.60 ± 0.82; p = NS). Satisfaction from distance and near vision as well as work difficulties in the near and distance 3 and 12 months after surgery were on the same levels.

Complications

Three months after surgery there was no postoperative complications. One year postoperatively, the only complication was significant posterior capsule opacification (PCO) in 4 patients treated successfully by Nd: YAG capsulotomy.

Discussion

Our experiences with bilateral ReZoom IOL implantation suggest that this procedure is effective and safe in selected cataract patients, providing good or very good vision at all distances, a high patients satisfaction and low complication rate what is consistent with data from other studies (12-16).

Much less is known about optimal neural adaptation time necessary for receiving the best visual function results after bilateral multifocal lenses implantation.

The results of the study performed by Goes F. (17) suggest that neural adaptation in majority of patients occurs within the first 6 weeks after surgery, some may require more than 3 months. Some patients continues to improve distance, intermediate and near vision for at least 6 month after multifocal IOl implantation. A minority of patients (less than 5%) never adapt. Another studies indicate that reasonable adaptation time to multifocal IOLs may take up to one year (18). Knowledge about optimal neuroadaptation time after multifocal IOL implantation is very important from clinical point of view. The patients should know, when they can expect reduction or disappearance of photic phenomena, surgeons should know when to suggest explantation of the multifocal IOL.

That is why the goal of our study was to determine a possible changes in visual function between 3 and 12 months after cataract surgery with multifocal ReZoom IOL implantation.

Twelve months postoperatively, we did not observe significant changes in binocular UCDVA, BCDVA, UCNVA, UCIVA and spectacle independence in comparison to 3 months follow-up (Fig. 1-4). Significant difference was found when we compared results of binocular DCNVA. One year after surgery significant improvement of binocular DCNVA (Fig. 2) was achieved ($p<0.037$) in comparison to the results 3 months after surgery.

One year after surgery, total vision satisfaction was unchanged but decrease of frequency and severity of unwanted subjective symptoms were obtained (perception level of glare/ halo and work difficulties connected with glare/ halo) in comparison to 3 months follow-up.

When we analysed binocular photopic distance contrast sensitivity with and without glare (Tables I, II), twelve months postoperatively significant improvement was obtained only for the binocular BCDVA without glare for 12cpd. The other parameters of CS were not altered.

One year postoperatively, the only complication was mild posterior capsule opacification in 4 patients which was a cause of the quality of vision reduction (hazy vision). We decided to perform Nd: YAG capsulotomy because we knew that our patients were initially happier with their vision. The PCO was treated successfully by Nd: YAG capsulotomy. YAG laser capsulotomy may need to be performed much earlier in patients with multifocal IOLs because of the specialized optics.

Summarising our results, the improvement of visual function (especially better near vision and reduced frequency and level of glare/ halo) was detected 12 months after bilateral ReZoom implantation in comparison to 3 months – follow-up.

Probably, the main cause of this improvement is neural adaptation which takes more than 3 months for patients with ReZoom IOls implantation.

The neural adaptation is a process that take place as the brain adapts over time to changes in the visual information be-

ISSN 0023-2157 Index 362646

ing supplied by the eye's optical component. The main role in neural adaptation plays the 'software' localized in the occipital cortex of the human brain which works as the best image enhancing-computer. Neural adaptation allows patients to detect higher quality images than we can expect from multifocal IOLs.

The mechanism involved in the neuroadaptation to MIOLs hve not been adequately studied. There is no understanding of the adaptation processes that occur possibly due to the change in refractive needs in pseudophakes. Neuroplasticty is known to occur with changes in synapses (synaptogenesis) and neuronal connections as well as by the generation of the new nerve cells (neurogenesis) (19). The dopaminergic systems in the brain hs been shown to play important role in the neuroadaptation process (20).

There are two types of temporal neural adaptation: quick phase (few seconds or minutes) and longer phase lasting from several months to a year. The longer phase of neural adaptation has been demonstrated in trials of aspheric versus spherical IOLs, multifocal IOls and refractive corneal surgery (5-9). In these studies, the patients' satisfaction level was much better at the end of 1 year than in few weeks after surgery. Complaints of halos, glare and dysphotopsia were common in the early postoperative period. By the end of the year the majority of the patients with multifocal IOls were happy with their vision and were adapted to new optical conditions.

Those observations are in agreement with the results obtained in our study which suggest that neuroadaptation time longer than several months after bilateral ReZoom IOL implantation is necessary to obtain significantly better visual function results.

Patients satisfaction with multifocal IOLs is difficult to predict. Assessing personality traits, expectations, exclusion of patients with eyes disease other than cataract, and signs of early memory impairment or neurologic disease may be beneficial in obtaining desired outcomes.

Total spectacle independence in patients with multifocal IOLs implantation may be achieved with advanced technology of these lenses and with further better understanding of neural adaptation process as well. Discovery of the objective methods of neural adaptation measurement is necessary for appropriate patients' selection for multifocal IOL implantation.

References:

1. Javitt JC, Steinert RF: *Cataract extraction with multifocal intraocular lens implantation: a multinational clinical trial evaluating clinical, functional, and quality of-life outcomes.* Ophthalmology 2000, 107(11), 2040-2048.
2. Sen HN, Sarikkola A-U, Uusitalo RJ et al.: *Quality of vision after AMO Array multifocal intraocular lens implantation.* J Cataract Refract Surg 2004, 30, 2483-2493.
3. Lubiński W, Gronkowska J, Barnyk K, Szych Z, Karczewicz D: *Visual function and complications after cataract surgery with bilateral multifocal intraocular lens implantation.* Klin Oczna 2007, 7-9, 261-266.
4. Lane SS, Morris M, Nordan L, Packer M et al.: *Multifocal intraocular lenses.* Ophthalmol Clin N Am 2006, 19, 89-105.
5. Holladay JT: *Quality of vision. Essential optics for the cataract and refractive surgeon.* Chapter 10. Understanding neural adaptation. Slack Incorporated 2007, 115-122.
6. Pesudovs K: *Involvement of neural adaptation in the recovery of vision after laser refractive surgery.* J Refract Surg 2005, 21, 144-147.
7. Mester U, Hunold W, Wesendahl T, Kaymak H: *Functional outcomes after implantation of Tecnis ZM900 and Array SA40 multifocal intraocular lenses.* J Cataract Refract Surg 2007, 33, 1033-1040.
8. Montes-Mico R, Alio JL: *Distance and near contrast sensitivity function after multifocal intraocular lens implantation.* J Cataract Refract Surg 2003, 29, 703-711.
9. Schallhron SC, Kaupp SE, Tanzer DJ et al.: *Pupil size and quality of vision after Lasik.* Ophthalmology 2003, 110, 1606-1614.
10. Leyland MD, Langan L, Goolfee F, Lee N, Bloom PA: *Prospective randomized double-masked trial of bilateral multifocal, bifocal or monofocal intraocular lenses.* Eye 2002, 16, 481-490.
11. Pomerance G, Evans D: *Test-retest reliability of the CSV-1000 contrast test and its relationship to glaucoma therapy*. Invest Ophthalmol Vis Sci 1994, 35(9), 3357-3361.
12. Chiam PJT, Chan JH, Haider SI et al: *Fuctional vision with bilateral ReZoom and ReSTOR intraocular lenses 6 months after cataract surgery.* J Cataract Refract Surg 2007, 33, 2057-2061.
13. Pepose JS, Quazi MA, Davies J et al: *Visual performance of patients with bilateral vs combination Crystalens, ReZoom, and ReSTOR intraocular lens implants.* Am J Ophthalmol 2007, 144, 347-357.
14. Palmer AM, Faina PG, Albelda AS et al: *Visual function with bilateral implantation of monofocal and multifocal intraocular lenses: a prospective, randomized, controlled clinical trial.* J Refract Surg 2008, 24, 257-264.
15. Chang DF: *Prospective functional and clinical comparison of bilateral ReZoom and ReSTOR intraocular lenses in patients 70 years or younger.* J Cataract Refract Surg 2008, 34, 934-941.
16. Żelichowska B, Rękas M, Stankiewicz A et al.: *Apodized diffractive versus refractive multifocal intraocular lenses: Optical and visual evaluation.* J Cataract Refract Surg 2008, 34, 2036-2042.
17. Goes FJ: *Neural adaptation and multifocal visual outcome.* Cataract and Refractive Surgery Today Europe 2008, 3, 32-33.
18. Coffman TM: *How I see with the ReZoom. Mastering refractive IOLs. The art and science.* Slacke Incorporated 2008, chapter 83, 317-318.
19. Pepin SM: *Neuroadaptation of presbyopia – correcting intraocular lenses.* Curr Opin Ophthalmol 2008, 19, 10-12.
20. Levesque D, Rouillard C: *Nur77 and retinoid X receptors: crucial factors in dopamine- related neuroadaptation.* Trends Neurosci 2007, 30, 22-30.

The study was originally received 20.04.2009 (1135)/
Praca wpłynęła do Redakcji 20.04.2009 r. (1135)
Accepted for publication 30.10.2009/
Zakwalifikowano do druku 30.10.2009 r.

Adres do korespondecji (Reprint requests to):
Wojciech Lubiński MD, PhD
Clinic of Ophthalmology
Pomeranian Medical University
Powstańców Wlkp. 72 Str.
70-111 Szczecin
e-mail:Lubinski@pro.onet.pl