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Visual outcomes, binocular vision and subjective accommodation after Crystalens HD accommodating intraocular lens implantation

Ocena ostrości wzroku, widzenia obuocznego i subiektywnej akomodacji po wszczepieniu soczewek akomodacyjnych Crystalens HD

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Abstract: Objective: To evaluate visual acuity, binocular vision and subjective accommodation in patients after Crystalens HD accommodating intraocular lenses (IOLs) or monofocal IOLs implantation.
Material and methods: 75 consecutive patients (aged 48 to 75 years) after bilateral cataract surgery with acrylic monofocal IOL (n = 36) or single-optic accommodating IOL (Crystalens HD) (n = 19) implantation and healthy presbyopic population (n = 20) were enrolled. Presence of asthenopic symptoms, diplopia and spectacle dependence was assessed. Orthoptic status, prism bar and amblyoscopic motor fusion, Frisby Near Stereotest, TNO and Titmus tests were performed. Convergence and subjective accommodation were evaluated using Krimsky-Prince rule.
Results: Asthenopic symptoms were present respectively in 36.1%, 15.8% and 35.0% of patients and spectacle dependency was reported by 86.1%, 21.1% and 85.0% of patients in subsequent groups. Negative fusional distance vergence means were 9.53 ± 5.53, 8.05 ± 3.66, 6.65 ± 5.33 respectively (p = .039). Negative fusional near vergence means were 26.53 ± 11.39, 28.68 ± 11.70, 20.75 ± 12.60 in subsequent groups (p = .001). Mean subjective right eye/ left eye accommodation was 5.01 ± 1.47/ 4.86 ± 1.72, 6.29 ± 2.33/ 6.02 ± 1.90, 4.13 ± 0.89/ 4.22 ± 1.3 respectively (p = .009). There were no statistically significant differences between groups in positive fusional vergence, stereoacuity and near point of convergence.
Conclusions: Bilateral accommodating IOL implantation provided full binocular vision in the majority of patients. Spectacle dependence and asthenopic symptoms were less frequent in patients with accommodating IOLs. Accommodating IOLs provided significantly better useful accommodation than monofocal IOLs.

Key words: accommodation, intraocular lens, pseudophakia.

Abstrakt: Cel: ocena stanu widzenia obuocznego u pacjentów po zabiegu obustronnej fakoemulsyfikacji zaćmy z wszczepieniem soczewek wewnątrzgałkowych akomodacyjnych Crystalens HD lub soczewek jednoogniskowych.
Pacjent i metody: badaniu poddano 75 pacjentów w wieku od 48 do 75 lat po obustronnym zabiegu usunięcia zaćmy z wszczepieniem soczewek jednoogniskowych (n = 36) lub soczewek akomodacyjnych (n = 19) oraz pacjentów z przezierną soczewką (n = 20). W badaniu uwzględniono: obecność objawów astenopijnych, dwojenia i zależności od soczewek okularowych oraz stan ortoptyczny, fuzję motoryczną, stereopsję, konwergencję i zakres subiektywnej akomodacji.
Wyniki: objawy astenopijne zgłaszało kolejno 36,1%, 15,8% i 35,0% pacjentów, a konieczność stosowania korekcji okularowej do bliży – 86,1%, 21,1% i 85,0% pacjentów w kolejnych grupach. Średnie wartości fuzji dywergencyjnej do dali wynosiły kolejno: 9.53 ± 5.53, 8.05 ± 3.66, 6.65 ± 5.33 (p = .039). Średnie wartości fuzji dywergencyjnej do bliży wynosiły: 26.53 ± 11.39, 28.68 ± 11.70, 20.75 ± 12.60 (p = .001) u pacjentów z poszczególnych grup. Średnie wartości subiektywnej akomodacji oczu prawego/ lewego wynosiły: 5.01 ± 1.47/ 4.86 ± 1.72, 6.29 ± 2.33/ 6.02 ± 1.90, 4.13 ± 0.89/ 4.22 ± 1.3 (p = .009). Nie było istotnych statystycznie różnic między grupami w zakresach fuzji konwergencyjnej, stereoskopowej ostrości wzroku i zakresie konwergencji.
Wnioski: obustronne wszczepienie soczewek akomodacyjnych Crystalens zapewniało pełne widzenie obuoczne u większości pacjentów. Pacjenci, u których zastosowano soczewki akomodacyjne, rzadziej niż pacjenci z pozostałych grup zgłaszali konieczność stosowania soczewek okularowych do bliży oraz objawy astenopijne. Soczewki akomodacyjne Crystalens zapewniały istotnie wyższą użyteczną akomodację niż soczewki jednoogniskowe.

Słowa kluczowe: akomodacja, soczewka wewnątrzgałkowa, rzekomosoczewkowość.

The goal of cataract surgery is not only to improve visual acuity without complications, but also to provide better quality of life, which may be achieved by correcting presbyopia at the same time. On the other hand, in some cases, otherwise

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uneventful cataract surgery may induce binocular vision dysfunctions such as diplopia (1–3) and ocular misalignment (4–6), which seriously decrease the quality of life.

The accommodating intraocular lens (IOL) implantation is one of surgical presbyopia-correcting methods. The assumption of single optic accommodating IOLs was a change of the refractive power by anterior movement and/or a change of thickness or curvature of the optics resulting from the ciliary muscle contraction. In practice, the axial shift is absent or not sufficient to achieve the real change of refractive power, which has been proved in several studies (7, 8). However, accommodating IOLs have some advantage over monofocal IOLs in near and intermediate vision outcomes, which is mainly attributed to pseudoaccommodation effects, such as increased depth of focus (9, 10).

The outcomes of implantation of accommodating IOLs are dependent on their biomechanics, but also on the neuromuscular control of accommodation plant. The stiffness and elasticity of the implant depend on its material and structure. On the other hand, the neuromuscular control of accommodation adapts to changing properties of the ageing crystalline lens (11). The properties of intraocular lenses are usually similar to the properties of crystalline lens of a young person, so the accommodative effort may be inadequate after IOL implantation. Although the presence of neural plasticity may provide 'recalibration' of accommodation plant opposite to physiological changes of its neuromuscular control while ageing, it might be less efficient than physiologically (11, 12).

Accommodation reflex is strictly connected with convergence reflex. Accommodation and convergence disorders may affect stereoacuity and binocular vision. There is a lot to learn about how the accommodation-convergence complex works in pseudophakic patients, especially after accommodating IOLs implantation.

Another factor that may influence stereopsis in patients with accommodating IOLs is dynamic aniseikonia. It may be connected with binocularly different accommodation values generated by implants of different refractive power, differences in the lens and the ciliary muscle interaction through the lens capsule and zonules or subsequent fibrosis (13). The information about the mechanisms affecting binocular vision after accommodating IOLs implantation may be valuable to improve present presbyopia-correcting methods in the future.

The aim of this study was to assess binocular vision and subjective accommodation in patients after binocular single-optic accommodating IOLs or monofocal IOLs implantation in comparison to presbyopic phakic population.

Methods

75 consecutive patients aged 48 to 75 (mean 62.4 ± 8.0 years) who underwent bilateral cataract surgery in the Department of Ophthalmology, Medical University of Lodz in years 2011–2012, were enrolled in the study. Study patients had a single-optic accommodating IOL (Crystalens HD) or acrylic monofocal IOL (Adapt AO or Acrysof SN60WF) implanted binocularly. In order to compare the results, presbyopic healthy patients with translucent crystalline lens were enrolled as a control group. Table I. shows the characteristics of the 3 groups. The study followed the tenets of the Declaration of Helsinki and was approved by the institutional ethics committee.

Surgical technique

Uneventful cataract surgeries were performed by four surgeons. Using topical anesthesia and a 2.8 mm or 1.8 mm clear corneal incision, standard phacoemulsification was performed and an IOL was implanted. 1% pilocarpine drop was administered intraoperatively in monofocal IOL group and 1% atropine was administered intraoperatively as well as the day after surgery in the accommodating IOL group. In the accommodating IOL group, the power of an implant was adjusted to achieve refraction of -0.25 D in the dominating eye and -0.75 D in the fellow eye.

Exclusion criteria

Postoperative exclusion criteria were: age over 75 years, distance corrected visual acuity (DCVA) of the worse eye more than .15 logMAR, the difference of DCVA between eyes below .70 logMAR, anisometropia higher than 2.0 D sphere or 1.0 D cylinder, eye diseases other than cataract, or previous surgery.

Examination

Examination was performed six weeks after cataract surgery of the second eye in all patients with accommodating or monofocal IOLs by the same doctor and in the same sequence. Self-constructed patient's questionnaire concerned near vision spectacles dependence, asthenopic symptoms such as eye strain or pain while reading, diplopia and concomitant eye diseases.

Monocular best distance-corrected visual acuity was measured at 5 meters using Snellen notation and then converted to logMAR units. In the case of astigmatism spherical equivalent was used. Ocular alignment was assessed by the cover/uncover test and alternate cover test in primary position. In case of heterophoria angle of deviation was measured using a standard prism bar and alternate cover test at distance

	Monofocal IOLs/ Soczewki jednoogniskowe	Accommodating IOLs/ Soczewki akomodacyjne	Phakic/ Pacjenci z soczewką własną
Number of patients/ Liczba pacjentów (n)	36	19	20
Mean age (y)/ Średnia wieku (lata) ± SD	63.8 ± 9.0	63.7 ± 6.7	58.6 ± 6.0
Sex (M/F)/ Płeć (M/K)	9/27	6/13	7/13
Mean time between 1st and 2nd eye surgery (mths)/ Średni czas pomiędzy zabiegami (miesiące) ± SD	28 ± 6.2	3 ± 1.2	-

Tab. I. Patients characteristics.
Tab. I. Charakterystyka pacjentów.

(5 meters) and near (40 centimeters). Subjective and objective angle of deviation was also assessed using major amblyoscope (Clement-Clarke) and macular pictures. Motor fusion was measured binocularly with the best correction using a standard prism bar. The break base-in and base-out measures at 5 meters and 40 centimeters were noted. Examination was always performed in the same sequence to avoid adaptation. Motor fusion was also assessed using major amblyoscope and macular pictures. Near stereoacuity was evaluated using three tests: Titmus test, Random Dot (TNO) and Frisby Stereotest. In Titmus test stereoacuity was measured with A, B and C pictures, equivalents of alternately 400, 200 and 100 seconds of arc. In TNO test stereoacuity was adequate to the number of the card that patient identified correctly. Frisby Stereotest was performed at 40 centimeters with a head and a plate fixed to avoid monocular clues. Stereoacuity was assessed according to the thickness of a plate on which patient identified a circle correctly. Near point of convergence was measured binocularly in centimeters using Krimsky Prince Near Point Accommodation Rule (Western Ophthalmics Corporation, Washington). Accommodation amplitude was measured in diopters with subjective push-up technique using Krimsky Prince Near Point Accommodation Rule, separately for each eye to avoid the influence of the convergence. The mean value of three measurements was noted.

Statistical analysis

Statistical analysis of the results was performed with IBM SPSS Statistics 20 (SPSS, Inc). The data were indicated descriptively (mean values, range, standard deviation, 95% confidence intervals, median values, interquartile range). Normal distribution of data was checked with Kolmogorov-Smirnov and Shapiro-Wilk tests. In case of normal distribution of data statistically significant differences between data samples means were determined using Student t-test. In cases in which the normality test failed, Mann-Whitney test was performed to compare parameters. For comparison of nonparametric data, Chi-square test was performed. For parameters, in which 3 groups were compared, Kruskal-Wallis test was performed. The *p* values below .05 were considered statistically significant for all comparisons.

Results

Spectacle dependence was reported by 86.1%, 21.1%, and 85.0% of patients and asthenopic symptoms were present in 36.1%, 15.8% and 35.0% of patients in three groups, respectively.

Table II shows the visual outcomes 6 weeks after surgery of the second eye in both IOL groups and in the control group. There were no statistically significant differences in corrected distance visual acuity (CDVA) between the groups. Spherical equivalent was significantly higher in the phakic group than in both IOL groups. There were no statistically significant differences in IOL power between monofocal and accommodating groups.

Cover test was positive in 1 patient (2.7%) with monofocal IOLs. Persistent diplopia and exotropia was present in this patient. In the remaining patients, cover test was negative and central fixation was confirmed. Distance heterophoria was assessed in 5.4% monofocal IOLs patients (2.7% was esophoric, 2.7% exophoric) and 5% phakic patients (esophoria). No distance heterophoria was observed in accommodating IOLs group. In examination at near heterophoria (exophoria) appeared in 26.3% of cases in accommodating IOLs group, 22.1% of cases in monofocal IOLs group (8.3% was esophoric, 11.1% was exophoric and 2.7% exotropic) and 15.0% in phakic group (5% esophoric and 10% exophoric). Table III shows orthoptic status of the enrolled patients.

Negative distance and near vergences were significantly higher in both groups with IOLs. No significant differences in positive vergence and fusional amblyoscopic vergences were noted. There were also no statistically significant differences in stereoacuity and near point of convergence. The amplitudes of accommodation were significantly higher in the accommodating IOL group. Table IV includes parameters of binocular vision in the 3 groups. No correlation was found between stereoacuity and IOL power difference in both monofocal and accommodating IOL groups.

	Mean/ Średnia ± SD			p
	Monofocal IOL/ Soczewki jednoogniskowe	Accommodating IOL/ Soczewki akomodacyjne	Phakic/ Pacjenci z soczewką własną	
CDVA				
Right eye/ Prawe oko (logMAR)	0.02 ± 0.09	0.02 ± 0.07	0.01 ± 0.07	.930
Left eye/ Lewe oko (logMAR)	0.01 ± 0.07	0.02 ± 0.06	0.02 ± 0.08	.643
SE				
Right eye/ Prawe oko (D)	-0.08 ± 0.91	-0.38 ± 0.47	1.01 ± 1.00	.000
Left eye/ Lewe oko (D)	-0.26 ± 0.77	-0.21 ± 0.29	0.68 ± 1.28	.000
IOL power difference/ różnica mocy wszczepów (D)	0.57 ± 0.56	0.50 ± 1.19	-	.096

CDVA = corrected distance visual acuity/ skorygowana ostrość wzroku do dali; SE = spherical equivalent/ ekwiwalent sferyczny; SD= standard deviation/ odchylenie standardowe

Tab. II. Postoperative visual outcomes at 6 weeks.
Tab. II. Ostrość wzroku po 6 tygodniach od zabiegu.

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	Monofocal IOL/ Soczewki jednoogniskowe	Accommodating IOL/ Soczewki akomodacyjne	Phakic/ Pacjenci z soczewką własną	p
Distance /near phoria/ kąt odchylenia do dali/ bliży				
Exophoria/ Egzoforia (n)	1/ 4	0/ 5	0/ 2	-
Orthophoria/ Ortoforia (n)	34/ 29	19/ 14	19/ 17	-
Esophoria/ Ezoforia (n)	1/ 3	0/ 0	1/ 1	-
Mean amblyoscopic phoria/ Średni kąt odchylenia w synoptoforze (°) ± SD	1.33 ± 3.60	2.16 ± 2.29	2.55 ± 2.11	.089

n = number of patients/ liczba pacjentów; ° = degrees of arc/ stopnie kątowe

Tab. III. Postoperative orthoptic status at 6 weeks.
Tab. III. Stan ortoptyczny po 6 tygodniach od zabiegu.

	Monofocal IOL/ Soczewki jednoogniskowe	Accommodating IOL/ Soczewki akomodacyjne	Phakic/ Pacjenci z soczewką własną	p
	Mean/ Średnia ± SD [median/ mediana]			
Positive fusional vergence/ Fuzja konwergencyjna				
Distance (prism diopters)/ Do dali (dioptrie pryzmatyczne)	15.72 ± 9.76 [12.00]	14.21 ± 6.10 [12.00]	15.95 ± 10.55 [15.00]	.979
Near (prism diopters)/ Do bliży (dioptrie pryzmatyczne)	26.53 ± 11.39 [25.00]	28.68 ± 11.70 [28.00]	20.75 ± 12.60 [20.00]	.086
Amblyoscopic (° arc)/ Badana w synoptoforze (stopnie kątowe)	16.03 ± 7.50 [15.50]	13.95 ± 7.38 [15.00]	17.70 ± 9.44 [22.50]	.228
Negative fusional vergence/ Fuzja dywergencyjna				
Distance (prism diopters)/ Do dali (dioptrie pryzmatyczne)	9.53 ± 5.53 [8.00]	8.05 ± 3.66 [8.00]	6.65 ± 5.33 [6.00]	.039
Near (prism diopters)/ Do bliży (dioptrie pryzmatyczne)	14.08 ± 5.35 [14.00]	13.11 ± 5.27 [12.00]	8.40 ± 4.52 [8.00]	.001
Amblyoscopic (° arc)/ Badana w synoptoforze (stopnie kątowe)	4.64 ± 1.85 [4.00]	5.00 ± 1.41 [5.00]	4.20 ± 1.61 [4.00]	.295
Stereoacuity/ Ostrość widzenia stereoskopowego				
Frisby (sec arc/ sekundy kątowe)	99.55 ± 53.19 [85.00]	78.82 ± 41.33 [55.00]	124.69 ± 118.58 [55.00]	.417
Random Dot (sec arc/ sekundy kątowe)	294.71 ± 150.18 [240.00]	230.00 ± 152.97 [240.00]	321.18 ± 145.34 [240.00]	.133
Titmus (sec arc/ sekundy kątowe)	184.38 ± 129.79 [100.00]	141.18 ± 100.37 [100.00]	187.50 ± 131.02 [100.00]	.395
NPC (cm)	9.36 ± 7.06 [7.00]	8.95 ± 4.08 [7.00]	12.2 ± 8.88 [7.00]	.462
Accommodation amplitude/ Amplituda akomodacji (D)				
Right eye/ Prawe oko	5.01 ± 1.47 [4.60]	6.29 ± 2.33 [5.40]	4.13 ± 0.89 [4.20]	.005
Left eye/ Lewe oko	4.86 ± 1.72 [4.40]	6.02 ± 1.90 [5.80]	4.22 ± 1.36 [4.20]	.009

NPC= Near Point of Convergence/ Punkt bliży konwergencji

Tab. IV. Postoperative binocular vision at 6 weeks.
Tab. IV. Parametry widzenia obuocznego po 6 tygodniach od zabiegu.

Discussion

Accommodating IOLs implantation may influence the complex mechanism of eyes alignment, binocular vision and patients' quality of life due to the changes in accommodation plant properties (14). Application of new generation presbyopia-correcting IOLs requires therefore not only an evaluation of vi-

sual acuity but also binocular vision status. The previous studies include stereoacuity and subjective or objective accommodation measurements. The present study evaluates a wide range of binocular vision parameters in a group of patients after binocular accommodating IOLs implantation in comparison to monofocal IOLs and a group of phakic patients. Study groups did not differ significantly in terms of age and postoperative visual acuity, which eliminates the influence of these factors on the study parameters.

Spectacle dependence and asthenopia were less frequent in the accommodating IOLs group in comparison to the monofocal IOLs and phakic groups. The main causes of asthenopic symptoms in pseudophakic patients are aniseikonia and heterophoria (15) which occur more often after monocular cataract extraction (16). In the current study, potential factors causing aniseikonia were postoperative refractive difference between eyes or IOL power difference generating dynamic aniseikonia. The mean values of spherical equivalent difference between eyes as well as IOL power difference did not differ significantly between study IOL groups. The second factor influencing asthenopia – heterophoria (especially near exophoria) was more frequent in accommodating IOLs group, but did not correspond with asthenopic symptoms in this group.

Persistent diplopia is an undesirable effect after successful cataract surgery and occurs in 0 to 3% of cases (2– 6, 17). Application of topical anesthesia instead of retrobulbar or peribulbar injection reduced the occurence of persistent diplopia to 0–0.21% (18). In the present study, persistent diplopia was observed in one patient with monofocal IOLs, probably due to previously existing heterophoria decompensation.

Golnik et al. found ocular misalignment after cataract surgery in 7% of cases (5). In a prospective study concerning a change in ocular alignment after cataract surgery Chung et al (6) found exophoria or exotropia in 26 of 160 patients. In 4 cases, there was a reduction of strabismus angle and in 5% of cases exophoria or exotropia occurred after surgery. The authors suggest sensoric deprivation or optical aberrations as potential causes of acquired strabismus. In the present study, the frequency of ocular misalignment was comparable with Golnic and Chung's findings in the monofocal IOLs group, whereas it was significantly lower in the accommodating IOLs group. The probable cause of this may be a shorter interval between surgical procedures in the accommodating than in the monofocal IOLs group. Discrepancies between distance and near ocular alignment results, especially in the accommodating IOLs group should be emphasized. In this group, 26.3% of patients were exophoric at near, while maintaining normal ocular alignment at distance. According to Schor (14), application of accommodating IOLs theoretically may increase accommodative effort, AC/A ratio and accommodative convergence that secondarily induces near esophoria and increases negative fusional vergence to maintain binocular vision. The present study does not fully confirm this hypothesis. We observed increased negative fusional vergence and near exophoria rather than esophoria in the accommodating IOLs group. The probable mechanism was a decrease of accommodating effort after accommodating IOL implantation due to elasticity of the implant which was higher than presbyopic crystalline lens.

Mean angle of deviation measured with major amblyoscope was esophoria and differed from distance values measured with cover test and prism bar. Although amblyoscopic pictures are placed in the so-called optical infinity, they are in fact situated closer which releases proximal convergence and may influence ocular alignment.

The mean positive fusional vergence values did not differ significantly between the groups. The mean negative fusional vergence values were statistically higher in both pseudophakic groups in comparison to phakic patients. Fusional amplitudes vary individually (19) or depend on age (20). Some authors like Seshadri (21) found lower positive fusional amplitudes in pseudophakic patients. Discrepancies between this results may be connected with low repeatability of fusional amplitudes measures and different test conditions (22).

Mean stereoacuity values did not differ significantly between the study groups, although they varied according to the stereotest (they were the best in Frisby Stereotest and the poorest in TNO test), which confirms Garnham and Sloper's findings (20). The present study shows it is necessary to take into account the type of stereotest while comparing stereopsis in patients with pseudophakia.

There was no correlation between stereoacuity and IOLs power difference. In Ale's study the difference in accommodation amplitude of 1.0 D was connected with aniseikonia on the level of 6% and compromises binocularity. In the present study, we did not observe dynamic aniseikonia-related changes in stereopsis due to the low IOL power differences.

There were no statistically significant differences between the groups in near point of convergence. The results show normal convergence in the study population and they were comparable with Garnham and Sloper's study (20).

The mean subjective accommodation amplitudes were significantly higher in the accommodating IOLs group in comparison with the other groups and they were also higher than results obtained by other authors (6.02–6.29 vs. 0.94-4.78 D) (23–26). In pseudophakic patients, subjective accommodation is a combination of real pseudophakic accommodation and pseudoaccommodation (i.e. corneal astigmatism, depth of focus) as the method used in our study does not allow to distinguish between real pseudophakic accommodation and pseudoaccommodation. In Crystalens HD lenses pseudoaccommodation is connected with a central optics construction enhancing positive spherical aberrations and thus the depth of focus (27). This effect is a total of dynamic aberrations which appear with the IOL's shape and position change during accommodative effort and static aberrations which are less desired as they decrease contrast sensitivity and distance vision quality. In comparison, monofocal aspheric IOLs with lower degree of optical aberrations are characterized with better contrast sensitivity but lower depth of focus and pseudoaccommodation value (28). Higher subjective accommodation results in the accommodating IOLs group might have been connected with higher pseudoaccommodation potential. Nevertheless, the differences in accommodation results prove that accommodating IOLs provided better useful accommodation than monofocal IOLs. They also provided better near vision quality than presbyopic translucent crystalline lens, which may be a premise for refractive lens exchange.

The limitations of the present study were lack of randomisation and prospective evaluation of study parameters. Study groups differed in intervals between procedures because of individual cataract progression which might influence binocular

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vision results (29). Prospective randomized clinical trial including the change of binocular vision parameters in time – before treatment, between procedures and after treatment, may be useful to define risk factors of binocular vision status deterioration in pseudophakic patients.

In conclusion, bilateral accommodating IOLs implantation provided full binocular vision in the majority of patients, there were no significant differences in mean stereoacuity between the groups. Spectacle dependence and asthenopic symptoms were less frequent in patients with accommodating IOLs. Accommodating IOLs provided significantly better useful accommodation than monofocal IOLs.

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