OBJECTIVE ASSESSMENT OF POSTOPERATIVE RESULTS OF INTRAOCULAR LENSES

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SUMMARY

Purpose: To prospectively compare postoperative results of two premium intraocular lenses EnVISTA (Bausch and Lomb) and AcrySof IQ (Alcon), focussing on glistenings and posterior capsule opacification. The evaluation of glistenings was done using Image J software and posterior capsule opacifications were quantified with OSCA system.

Methods: Twenty patients (7 men and 13 women) with bilateral cataract were included. EnVista intraocular lens (IOL) was implanted in one eye and AcrySof IQ IOL in the second eye of each patient. Objective evaluation methods were used for assessment. Glistenings was quantified with ImageJ software and PCO using the Open-Access Systematic Capsule Assessment (OSCA) system (Devised by Aslam TM, Edinburgh, United Kingdom). Complete ophthtalmological evaluation including evaluation after pupil dilatation was done and digital images of intraocular lenses were obtained. The results of 2-, 4-, 6- and 12-month follow-up were compared.

Results: Twenty patients were analyzed 2 months, 16 patients 4 months, 14 patients 6 months and 13 patients 12 months after cataract surgery. There was only minimal difference in best corrected visual acuity between EnVista and AcrySof group. The glistenings in the EnVista IOLs was objectively lower than in the AcrySof IOLs during whole follow-up period. In contrast to PCO, in eyes with AcrySof IOL was lower PCO score.

Conclusion: Development of new materials and techniques of cataract surgery is the topic of ophthtalmologists worldwide. Reduction of glistenings and PCO is one of the main aims, objective measurements is important part of assessment of postoperative results after cataract surgery.

Key words: glistenings, posterior capsule opacification, EnVista, AcrySof IQ, Image J software, OSCA system

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INTRODUCTION

The aim of this study was to assess postoperative results with a focus on glistenings and posterior capsule opacification (PCO) in the case of the premium intraocular lenses (IOL) EnVISTA (Bausch and Lomb) and AcrySof IQ (Alcon), with the use of objective assessment methods.

With regard to intraocular lenses, the term glistenings refers to the phenomenon created by micro-vacuoles filled with fluid that form inside the optics of soft intraocular lenses, when the IOL comes into an aqueous environment (fig. 1). The influence on visual function is controversial, explantation due to glistenings is described only very rarely (8, 20, 22). Posterior capsule opacification is defined as a complex of changes in the region of the lens capsule, leading to its opacification (1), in which the main role is played by the migration and proliferation of epithelial cells of the human lens between the artificial intraocular lens and the lens capsule. Posterior capsule opacifications may again deteriorate the patient's vision after cataract surgery. The assessment of glistenings and PCO can be performed by subjective, subjective-objective (semi-quantitative) or objective methods. In our study we quantified glistenings using the computer program Image J and quantified posterior capsule opacifications using the objective software OSCA system.

METHOD

In total 20 patients with bilateral cataracts were included in the study, specifically 7 men and 13 women with an average age of 71.5 years, within the range of 58 to 79 years. The patients underwent uncomplicated cataract surgery in both eyes at the Department of Ophthalmology of the University Hospital in Hradec Králové. An EnVista IOL was implanted in one eye and an AcrySof IQ IOL in the other. The patients were operated on by one of three experienced surgeons. A standard ophthalmological examination including autorefractometer, determination of best corrected visual acuity and examination of the posterior segment in artificial mydriasis (Unitropic 1% gtt, Neosynephrine 10% gtt) was performed preoperatively, as well as 2, 4, 6 and 12 months after cataract surgery. Postoperatively we photographed the IOL at follow-up examinations, focusing on glistenings on a slit lamp with an inbuilt CSO Epsilon Lyrae camera. The slit lamp was set to 25x enlargement, with a beam width of 2 mm, maximum length, at an angle of 45 degrees with maximum light intensity. Photographs were taken after focusing on the micro-vacuoles in the intraocular lens. The entire region of the posterior capsule was documented after focusing on PCO in retroillumination. Assessment of glistenings and PCO was performed using objective software.

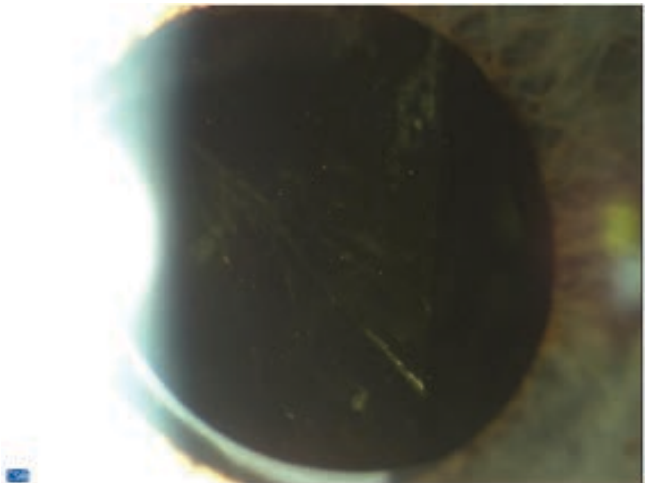


Fig. 1 Glistenings in the intraocular lens are detectable as whitish spots in the foreground, in the background are fine posterior capsule opacifications, the posterior capsule is slightly folded

For the objectivisation of glistenings we used the Image J program, which is open-source software issued by the National Institutes of Health (NIH) in 2010. We proceeded according to the methodology described in the study by the authors J. Colin and I. Orignac: Glistenings on Intraocular Lenses in Healthy Eyes: Effects and Associations, Journal of Refractive Surgery 2010, 36: 1398-1420. The aim was to determine the number of micro-vacuoles per unit of surface. In our study the surface was set at 300 x 300 pixels (approx. 3 x 3 mm) in the optical axis, since configuration in units of length was very difficult. First of all it was necessary to adjust the photography – after bordering of the central zone of the IOL with glistenings, colour inversion was performed, as well as conversion to 8 bit format, subtraction of background, contrast adjustment and finally calculation of points of diameter up to 0.001 mm2.

We evaluated posterior lens opacifications (PCO) using OSCA software. We used Single Analysis, since PCOs were not covered by artificial light reflexes, equalisation and segmentation were performed, removal of background, removal of light areas and swapping bright areas and fading bits such as edges of IOL etc. We attained this by clicking with the mouse from top to bottom on the columns offering these processes, which are presented vertically on the left in the active window of this program. Finally the OSCA score for PCO for the entire optic part of the IOL was calculated automatically.

For comparison we used a Paired Hotelling's T-Square with a randomisation test (Edgington), based on 10 000 permutations. This test enables a comparison of several variables at once. If there was no difference of the lenses in the given variable, then the average difference of the values is equal to zero, and this applies for all the compared variables. The zero hypothesis for the aforementioned test was therefore that all the average differences are equal to zero (in our cases differences in glistenings, CVA and OSCA score for pairs of lenses). The alternative hypothesis was that at least one average difference is not equal to zero.

RESULTS

Two months after surgery 20 patients were examined, four months after 16 patients, six months 14 patients and twelve months after surgery 13 patients. In the EnVista group preoperative corrected visual acuity was 0.62 (0.4-0.8) and in the AcrySof Group 0.62 (0.2-0.8). The postoperative results are summarised in the table (table 1). Postoperative corrected visual acuity increased to an average value of 0.85 and remained stable in both observed groups (graph 1).

Glistenings were evaluated by the Image J program, and are expressed in the numbers of points with a size of < 0.001 mm2 on a surface of approx. 3 x 3 mm (square of 300 x 300 pixels). An increase in glistenings was recorded in both intraocular lenses between the 2nd and 4th month and between the 6th and 12th month. By contrast, between the 4th and 6th months a reduction occurred, again in both the observed IOLs (graph 2).

Posterior capsule opacifications (PCO) were assessed by the OSCA system and are expressed numerically by the OSCA score. In eyes with an EnVista intraocular lens a progressive slight increase in PCO was recorded over time, whereas in eyes with an AcrySof IOL the OSCA score fluctuated and throughout the entire period was lower than in the case of the EnVista IOL (graph 3). Over the course of 12 months no YAG capsulotomy was performed in the observed group.

After 2 months the p-value of the randomised test was 0.058, i.e. it was not demonstrated that at least one average difference was other than zero. After 4 months the p-value of the randomised test was 0.190, i.e. it was not demonstrated that at least one average difference was other than zero. After 6 months the p-value of the randomised test was 0.012, i.e. on a 5% level of significance it is possible to assert that at least one average difference was other than zero. This difference is in the values of the OSCA parameter, where the EnVista values are higher than the AcrySof values (the p-value of the randomised test for this variable was 0.010). After 12 months the p-value of the randomised test was 0.023, i.e. on a 5% level of significance it is possible to assert that at least one average difference was other than zero. This difference is in the values of the parameter of glistenings, where the EnVista values are higher than the AcrySof values (the p-value of the randomised test for this variable was 0.006).

Visual acuity of eyes with an AcrySof IQ IOL and an EnVista IOL was comparable throughout the entire postoperative observation period. In the EnVista IOL the incidence of glistenings throughout the observation period was lower than in the AcrySof IQ IOL, and one year after surgery the difference was statistically significant. By contrast, in eyes with an AcrySof IQ IOL a lower incidence of posterior capsule opacifications was recorded, with the largest difference after 6 months. We did not record complaints with different colour of intraocular lenses in both eyes in any of our patients.

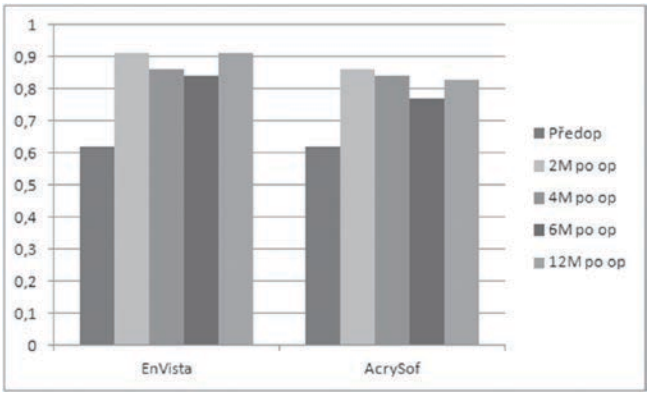
DISCUSSION

Glistening of soft IOLs is one of the potential postoperative complications. Although its influence on quality of vision

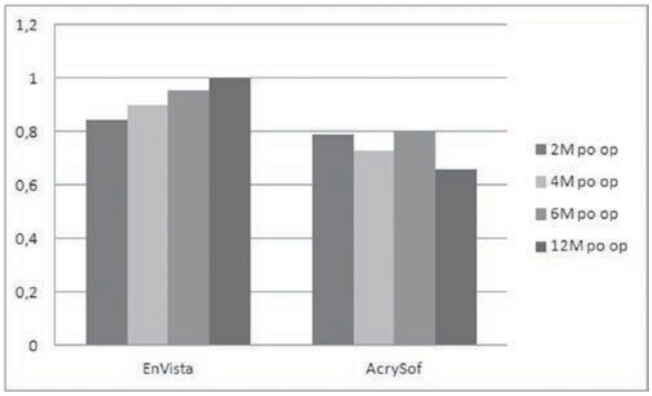
Table 1 Postoperative results of CVA, glistenings and OSCA score. The results are presented in the form of averages – above and minimum/maximum value – below

	2 months postop.		4 months postop.		6 months postop.		12 months postop.	
IOL	EnVista	AcrySof	EnVista	AcrySof	EnVista	AcrySof	EnVista	AcrySof
KZO	0,91 0,8 –1,0	0,86 0,6–1,0	0,86 0,7–1,0	0,84 0,6–1,0	0,84 0,7–1,0	0,77 0,6–1,0	0,91 0,8–1,0	0,83 0,5–1,2
Glistenings	42,71 2–170	79,93 4–274	93,73 8–244	164,53 24–538	67,33 13–174	131,00 30–387	109,60 23–184	179,00 70–296
OSCA	0,85 0,61–1,58	0,79 0,28–2,10	0,90 0,33–1,65	0,73 0,22–2,59	0,95 0,48–1,35	0,80 0,52–1,46	1,00 0,34–1,85	0,66 0,40–1,50

Key: IOL – intraocular lens, CVA – corrected visual acuity, OSCA – Open-access Systematic Capsule Assessment, postop. - postoperatively

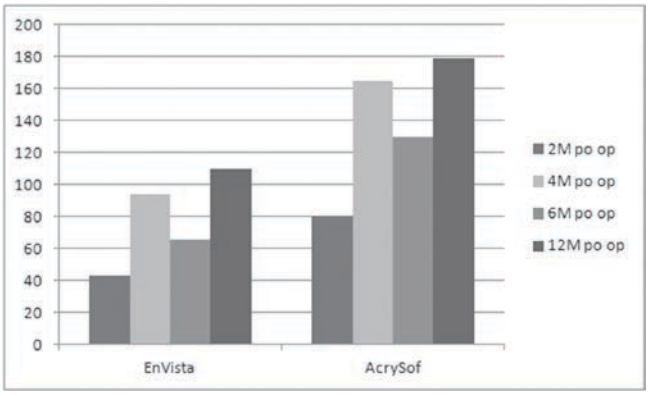


Graph 1 Best corrected visual acuity preoperatively and 2, 4, 6 and 12 months after implantation of EnVista and AcrySof intraocular lenses
Key: preop. - preoperatively, postop. - postoperatively, M – months



Graph 3 Postoperative results of posterior capsule opacifications assessed by OSCA program in eyes with EnVista and AcrySof intraocular lenses

is not large, it is necessary to ensure that its development is prevented. Factors influencing the incidence of glistenings include the composition of the material of the intraocular lens, the technique of production and processing, such as the process of sterilisation and exposure of IOL to temperature fluctuations, and last but not least also packaging of the IOL. Glistening is also contributed to by careless handling of the intraocular lens and also folding of the lens (8). Most often this is described in the case of hydrophobic acrylate IOLs (5, 22, 17). The development of glistening is accentuated by glaucoma, concurrent use of local medication and conditions leading to a breach of the haemato-ocular barrier. However, not all opacities in the intraocular lens are caused by micro-vacuoles filled with fluid, and therefore not all opacities can be evaluated as glistenings. In the case of breach of the haemato-ocular barrier changes also occur in the concentrations of proteins and lipids, and the accumulation of phospholipids on the optic of the IOL, which facilitates the penetration of hydrophobic substances. The possibility of objectivisation of glistenings is important, especially upon a comparison of the results of different studies. Micro-vacuoles can be compared thanks to the different refractive index (water – polymer). The size of the micro-vacuoles is stated from 1 to 20 µm, most frequently around 10 µm diameter (3, 20). Larger micro-vacuoles are observed upon higher temperature fluctuation in which an IOL is present, since the temperature increases the loose volume in the acrylate and facilitates the formation of vacuoles filled with fluid. They are dispersed throughout the entire optics. For evaluation of glistenings it is necessary to obtain quality photography of the IOL in large scale enlargement and maximum lighting. Semi-quantitative methods are used in assessment, and recently also a method using the computer program Image J. The most frequently used



Graph 2 Postoperative results of glistenings assessed using the Image J program in EnVista and AcrySof intraocular lenses

semi-quantitative method is assessment of glistenings according to the number of micro-vacuoles per millimetre of volume, the author of which is professor Miyata (13). An absence of micro-vacuoles is indicated by 0, degree 1 represents the presence of micro-vacuoles up to a total number of 50-mm3, the limit for degree 2 is 100 micro-vacuoles/mm3 and degree 3 is a number of 200 micro-vacuoles/mm3 or more. It is also possible to assess glistenings according to the number of micro-vacuoles in a field with a beam size of 10 x 2 mm, in which degree 0 represents less than 10 and degree 4 more than 40 micro-vacuoles in the field (22). In our study we used the Image J program, which is freely accessible software, for objectivisation of glistenings. The aim was to determine the number of micro-vacuoles per unit of surface. This method was described in the study conducted by professor Colin et al. (5). Upon quantification of glistenings using this technique we encountered a number of technical difficulties, for example upon configuring the surface in units of length. In our study the surface was set at 300 x 300 pixels (approx. 3 x 3 mm) in the optical axis, since configuration in units of length was very difficult. The use of computer software in science and research is increasingly widespread, and in future will be essential. We present this method as a further possibility for the assessment of glistenings, even if we are aware that its specificity, validity, sensitivity and repeatability has not yet been sufficiently verified.

We consider the greatest limitation of the Image J program to be the difficulty of obtaining perfect digital photographs with focus on glistenings, determination of the surface for assessment (difficult in mm, possible in pixels), the risk of including also other opacities of the IOL or PCO. In hydrophobic acrylates further phenomena are also described, namely "surface light scattering" or subsurface nano glistenings (3, 4). EnVISTA intraocular lenses are presented as glistenings -free. A reduction of glistenings is achieved thanks to special material ensuring balanced hydration of the intraocular lens, as well as quality packaging. In our study the EnVista intraocular lens manifested a low degree of glistenings throughout the entire observation period, whereas in the case of the AcrySof intraocular lens a higher incidence of glistenings was observed, which is in accordance with other studies (7, 9, 10). There was also fluctuation in the incidence of glistenings during the course of our observation, in which a stabilisation to slight reduction took place following the primary increase in glistenings, with a subsequent further increase, which had already been documented also in other studies (20).

The hydrophobic acrylate intraocular lens AcrySof is considered the referential IOL in studies of glistenings, as well as in examination of posterior capsule opacifications (10). Posterior capsule opacifications after cataract surgery cloud the posterior capsule, and in addition to the negative impact on satisfaction of patients with cataract surgery, later treatment of secondary cataract also has social, economic and medical consequences. Solution of PCO causing deterioration of vision depends on the type of opacification. The most frequent treatment is Nd: YAG laser capsulotomy, less frequently suction of mainly proliferative type in the form of Elschnig's pearls (11, 14). Thorough cleansing of the posterior capsule from LEC, perfect fixation of the IOL in the lens capsule and perfect anterior circular continual capsulorhexis (ACCC) with edge on the IOL has a fundamental influence on preventing the occurrence and development of PCO. For reduction of PCO the intraocular lens should be produced from biocompatible and adhesive material, which reduces the proliferation and migration of LEC by adhering firmly to the posterior capsule, and should be of maximum optic size, which ensures good contact with the posterior capsule and circular capsulorhexis, as well as a sharp edge of the optics and haptics. Factors which cannot be influenced or can be influenced only with difficulty include factors that are dependent on the patient. An important role is played by age – the younger the patient, the greater the risk of incidence of PCO and ocular and metabolic pathology (16) in the patient. Assessment of PCO is performed with the help of subjective, subjective-objective and objective techniques. The most frequently used are subjective-objective techniques, in which subjective assessment is combined with computer processing of digital photography. For assessment of PCO the most appropriate methods are those in which the subjective interference of the investigator is reduced to the lowest possible level. Also important for assessment is the quality of the obtained digital photo documentation with maximum elimination of potential artefacts (2, 11). As yet none of the methods is capable of assessing capsules after laser YAG – capsulotomy, which leads to a distortion of the outcomes of measurement. In our study we used the objective system OSCA. Open-access Systematic Capsule Assessment, presented by professor Aslam, is a freely accessible objective technique, which takes into account opacities close to the centre of the optical part of the lens and which have a greater influence on visual acuity. This system is based on "texture analysis". The outcome is the "OSCA score", which produces values from 0 to 15. Opacities that do not have an influence on visual acuity or only a minimal influence are assessed by a lower value than those in the centre (2, 15, 19).

The AcrySof SA60AT intraocular lens is a soft acrylate lens for which a significantly lower incidence of secondary cataract is described following implantation than in the case of PMMA and silicon IOLs (6). The bioactive material of the optical part of the AcrySof lens creates an enclosed system with the edge of the anterior capsule, and as a result posterior capsule opacification is generally not of a higher degree (12, 18, 21). This was confirmed also during our observation.

CONCLUSION

In our study we demonstrated a lower incidence of glistenings in the EnVista intraocular lens throughout the entire observation period in comparison with the AcrySof IQ IOL. By contrast, a lower incidence of posterior capsule opacifications was recorded in eyes with an AcrySof IQ IOL.

The development of new materials and cataract surgery technologies remains at the forefront of interest of ophthalmologists worldwide. The reduction of glistenings and PCO is one of the aims of cataract surgery, and as a result the objectivisation of these conditions is an important component of the observation of postoperative results.

LITERATURE

1. **Adámková H. Novák J.:** Sekundární katarakta, její prevence a léčba. Část první: Prevence vzniku sekundární katarakty. Čes a slov Oftal, 62; 2006: 230–236.
2. **Aslam, TM., Patton, N., Rose, ChJ.:** OSCA: a comprehensive open-access system of analysis of posterior capsular opacification, BMC Oftalmol, 6; 2006: 30.
3. **Beheregaray S., Yamamoto, T., Hiraoka T. et al.:** Influence on visual function of forward light scattering associated with subsurface nanoglistenings in intraocular lenses. J Cataract Refract Surg, 40; 2014: 1147–1154.
4. **Bessen-Miyajima H., Minami K., Yoshino M., et al.:** Sufrace light scattering and visual function of diffractive multifocal hydrophobic acrylic intraocular lenses 6 years after implantation. J Cataract Refract Surg, 39; 2013: 1729–1733.
5. **Colin J., Orignac I.:** Glistenings on Intraocular Lenses in healthy Eyes: Effects and Associations. J Refract Surgery, 36; 2010: 1398–1420.
6. **Congdon, N.:** Three-year study compares acrylic and silicone IOLs. Ophthalmology Times. 1997, 15, 14-15. a Mandle, M. Acrylic lenses cause less posterior capsular opacification than PMMA or silicone. Ocular Surgery News, 8; 1996: 9.
7. **Deepinder K.D., Mamalis N., Olson R.J., et al.:** Visual significance of glistenings seen in the AcrySof intraocular lens. J Cataract Refract Surg, 22; 1996: 452–457.
8. **Gunenc U., Oner H., Tongal S.:** Effects on visual function of glistenings and folding marks in AcrySof intraocular lenses. J Cataract Refract Surg, 27; 2001: 1611–1614.
9. **Hayashi K., Hirata A., Yoshida M., et al.:** Long-Term Effect of Surface Light Scattering and Glistenings of Intraocular Lenses on Visual Function. Am J Ophthalmol, 154; 2012: 240–251.
10. **Chang A., Behndig A., Ronbeck M., et al.:** Comparison of posterior capsule opacification and glistenings with 2 hydrophobic acrylic intraocular lenses: 5- to 7-year follow-up. J Cataract Refract Surg, 39; 2013: 694–698.
11. **Jirásková, N., Rozsíval, P.:** Metody hodnocení zkalení zadního pouzdra po operaci katarakty. Čes. a slov. Oftalmol, 60; 2006: 155–157.
12. **Linnola, R.J.:** Sandwich theory: Bioactivity-based explanation for posterior capsule opacification. J. Cataract. Refract. Surg, 23; 1997: 1539–1542.
13. **Miyata A., Yaguchi S.:** Equilibrium water content and glistenings in acrylic intraocular lenses. J Cataract Refract Surg, 30; 2004: 1768–1772.
14. **Nekolová, J., Pozlerová, J., Jirásková, N. et al.:** Pooperační výsledky expandibilní nitrooční čočky ACQUA (Mediphacos). Čes a Slov Oftalmol, 64; 2008: 87–90
15. **Nekolová, J., Jirásková, N., Pozlerová, J., Rozsíval, P.:** Three-year follow-up of posterior capsule opacification after AquaLase and NeoSoniX phacoemulsification. Am J Ophthalmol, 148; 2009: 390–395.
16. **Nekolová, J., Pozlerová J., Jirásková N., Rozsíval P.:** Opacity zadního pouzdra u pacientů s diabetes mellitus 2. typu. Čes. a slov. Oftal, 64; 2008: 193–196
17. **Pagnoulle Ch., Bozukova D., Gobin L., et al.:** Assessment of new-generation glistening-free hydrophobic acrylic intraocular lens material. J Cataract Refract Surg, 38; 2012: 1271–1277.
18. **Spalton, D.J., Maxwell, W.A.:** Acrylic lenses minimize PCO progression: British study. Ocular Sugery News, 14; 1996: 34.
19. **Stepanov, S., Nekolová, J., Jirásková, N., Rozsíval, P.:** Long-term follow-up of posterior capsule opacification after AquaLase and NeoSoniX phacoemulsification, Biomed Pap Med Fac Univ Palacky Olomouc Czech repub, v tisku.
20. **Tognetto D et al.:** Glistenings in foldable intraocular lenses. J Cataract Refract Surg, 18; 2002: 1211–1216.
21. **Ursell, P.G., Spalton, D.J., Pande, M.V., Hollick, E.J., Barman, S., Boyce, J., Tilling, K.:** Relationship between intraocular lens biomaterials and posterior capsule opacification. J. Cataract Refract. Surg, 24; 1998: 352–360.
22. **Werner, L.:** Glistenings and surface light scattering in intraocular lenses. J Cataract Refract Surg, 36; 2010:1398-1420.