

Received: 2018.02.26

Accepted: 2018.05.16

Published: 2018.09.17

# Effect of Phacoemulsification on Visual Acuity and Macular Morphology in Patients with Wet Age-Related Macular Degeneration

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Statistical Analysis C  
Data Interpretation D  
Manuscript Preparation E  
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**Source of support:** Departmental sources

**Background:** This article discusses the effectiveness of phacoemulsification cataract surgery with intraocular lens implantation in patients with wet age-related macular degeneration in the inactive phase of the disease.


**Material/Methods:** Forty-nine patients (50 eyes) aged  $78.94 \pm 5.54$  years, previously treated with intravitreal injections of anti-vascular endothelial growth factor agents, were qualified for a prospective, randomized 12-month study. The participants were divided into 2 groups. Group I consisted of 25 patients (25 eyes) who were subjected to phacoemulsification cataract surgery. Group II consisted of 24 patients (25 eyes) who were not subjected to phacoemulsification cataract surgery despite having a lens opacity of grade II or higher according to the Lens Opacities Classification System.

**Results:** After 12 months of follow-up, patients in group I gained on average 8.04 letters ( $p < 0.001$ ). Furthermore, 20% of the eyes had a significant improvement in best corrected visual acuity of  $\geq 15$  Early Treatment of Diabetic Retinopathy Study Chart letters. Patients in group II lost on average 1.96 letters ( $p > 0.05$ ). No significant differences between central retinal thickness values in either group ( $p > 0.05$ ) were noted. The mean number of intravitreal injections of anti-vascular endothelial growth factor agents during the study was  $2.64 \pm 1.98$  in group I and  $2.92 \pm 2.40$  in group II ( $p > 0.05$ ).

**Conclusions:** Phacoemulsification performed in eyes with wet age-related macular degeneration during the inactive phase of the disease significantly improves visual acuity. In addition, it does not significantly influence the frequency of intravitreal injections of anti-vascular endothelial growth factor agents or disease activity.

**MeSH Keywords:** **Injections, Intraocular • Phacoemulsification • Vascular Endothelial Growth Factors • Wet Macular Degeneration**

**Full-text PDF:** <https://www.medscimonit.com/abstract/index/idArt/909652>

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## Background

The opacification of the lens, as in age-related macular degeneration (AMD), is currently one of the most common ophthalmologic pathologies [1,2]. The pathogenesis of cataract is multifactorial, and it has many mechanisms in common with AMD [3–8]. AMD significantly worsens functional parameters such as visual acuity (VA) and permanently damages macular morphology. In the wet form of the disease, there is a rapid deterioration of vision, and pathological choroidal neovascularization (CNV) develops in the macula [9–11]. Wet AMD is a chronic pathology requiring repetitive treatment with intravitreal injections of anti-vascular endothelial growth factor (VEGF) agents [12,13]. Phacoemulsification is a surgical procedure used to remove cataract [2]. It is perceived as a risk factor for blood-retina barrier damage and inflammatory cascade initiation. These are potential mechanisms affecting the state of the macula and the course of degeneration [7,8,14]. Surgical interventions increase the permeability of blood vessels, which may cause intra-retinal macular edema even after uncomplicated phacoemulsifications [7,8]. Proinflammatory cytokines induce angiogenesis, which is crucial for both induction and perpetuation of CNV [9]. Moreover, the intraocular pressure fluctuations that occur during cataract surgery change both the morphology and function of the macula [7,8]. Cataract removal increases retinal exposure to light, including ultraviolet (UV) light and blue spectrum light, which are absorbed by clouded lenses [15,16]. Studies in animal models and tissue cultures showed that short-wavelength light has a negative effect on the function of retinal pigment epithelium (RPE) and photoreceptors [17,18]. To avoid retinal damage, intraocular lenses (IOL) with UV and blue light filters are commonly used, particularly in patients with AMD or with an increased AMD risk [6,19,20].

The aim of the study was to assess the effect of phacoemulsification cataract surgery followed by posterior chamber IOL implantation on visual acuity and macular morphology in patients with wet AMD in the inactive phase of the disease over 12 months after surgery.

## Material and Methods

Forty-nine patients (50 eyes) diagnosed with wet AMD and aged  $78.94 \pm 5.54$  years were qualified for a prospective, randomized 12-month study. The patients had been previously treated with intravitreal injections of anti-VEGF agents (ranibizumab and/or bevacizumab). To qualify for the study, patients had to be over 50 years old and lack an active degenerative process confirmed by optical coherence tomography (OCT) and fluorescein angiography. They also had to have a cataract in the examined eye, with a minimum score of NO2/NC2/C2/P2 according

to the Lens Opacities Classification System (LOCS) III. There were 2 local inclusion criteria for the study: 1) a best corrected visual acuity (BCVA) between 34 and 74 letters according to the standardized Early Treatment of Diabetic Retinopathy Study Chart (ETDRS) (equivalent to 0.1–0.5 on the Snellen scale, and 1.0–0.3 on the logMAR scale) and 2) a lesion size not exceeding 12 MPDG DA (Macular Photocoagulation Study Group Disc Areas) [21,22].

The general exclusion criteria were: 1) stroke of the central nervous system or myocardial infarction during the last 6 months and 2) unstable arterial hypertension and ischemic heart disease. The local exclusion criteria were: 1) irreversible damage to the fovea (subretinal scar or geographical atrophy); 2) hemorrhage in the macula occupying at least 50% of the lesion; 3) retinal detachment; 4) a history of vitreoretinal or anti-glaucoma surgery or keratoplasty; 5) retinal photocoagulation in less than 1 month; 6) a history of macular photocoagulation; 7) unregulated or advanced glaucoma; 8) an active infection of the eyeball or eye-protective apparatus; 9) past or active uveitis; and 10) significant degenerative changes of the peripheral retina.

This research project was approved by the Bioethical Commission of the Military Medical Institute in Warsaw (Resolution No. 10/WIM/2013).

Two study groups were selected during randomization. Group I consisted of 25 patients (25 eyes) aged  $80.04 \pm 4.47$  years who were subjected to phacoemulsification cataract surgery. There were 15 women (60%) and 10 men (40%). There were 9 right eyes (36%) and 16 left eyes (64%). Fifteen eyes (60%) were diagnosed with type I wet AMD (occult form) and 10 eyes (40%) were diagnosed with type II wet AMD (classic form). The mean number of anti-VEGF injections received prior to the beginning of the study was  $5.52 \pm 2.99$  and the mean injection treatment period prior to study enrollment was  $17.24 \pm 15.23$  months.

Group II consisted of 24 patients (25 eyes) aged  $77.84 \pm 6.44$  years, who were not subjected to phacoemulsification cataract surgery despite having a lens opacity of grade II or higher according to the LOCS. There were 13 women (54%) and 11 men (46%). There were 8 right eyes (32%) and 17 left eyes (68%). Sixteen eyes (64%) were diagnosed with type I wet AMD and 9 (36%) eyes were diagnosed with type II wet AMD. The mean number of anti-VEGF injections prior to study enrollment was  $4.40 \pm 2.06$ . The mean injection treatment period was  $12.24 \pm 7.88$  months.

Both groups were homogeneous in terms of sex, age, affected eye (right or left), type of wet AMD (occult or classic), and average number of injections before enrollment in the study ( $p > 0.05$ ).

The baseline functional and morphological parameters were recorded for each group. In group I, BCVA was  $55.16 \pm 10.04$  ETDRS letters. The mean central retinal thickness (CRT) was  $237 \pm 94.80$   $\mu\text{m}$ . In group II, BCVA was  $59.24 \pm 6.80$  ETDRS letters. CRT was  $281 \pm 108.11$   $\mu\text{m}$ .

The 25 eyes from group I underwent phacoemulsification with intraocular implantation of an aspheric, monofocal, UV and blue light filtering, acrylic, foldable, single-piece, posterior chamber lens (AcrySof IQ SN60WF; Alcon Laboratories, Inc.). In both groups, CNV activity parameters were assessed during monthly control visits, after which a decision was made to either inject anti-VEGF agents or perform further follow-up. A relapse in disease activity was defined by several factors: 1) a decrease in BCVA of at least 5 ETDRS letters in the presence of subretinal fluid, intra-retinal edema, or a central retinal thickness increase of 100  $\mu\text{m}$  or higher; 2) the occurrence of a new CNV focus; 3) the occurrence of hemorrhages in the macula with confirmed disease activity; 4) the persistence of fluid or intra-retinal edema in the OCT at the next follow-up visit after injection; and 5) the progression of RPE detachment parameters. Patients were treated with either ranibizumab or aflibercept, which are registered by the Food and Drug Administration (FDA) and European Medicines Agency (EMA) for the treatment of wet AMD. Treatment was carried out on a monthly basis until CNV activity was inhibited.

Statistical analysis was performed within each group to compare the baseline values of BCVA and CRT to those obtained in the following time control points, as well as at the end of the 12-month follow-up period. Statistical analysis was also performed to assess differences between the groups.

The groups were compared in terms of BCVA and CRT values at individual time points, as well as over time; the number of required injections of anti-VEGF agents; and the change in ETDRS letters at monthly control points and after 12 months of follow-up.

All the results were collected in the database using Microsoft Excel 2003.

### Statistical analysis

Statistica 12.0 (StatSoft Poland) was used for the statistical analysis of the data. To verify the normality of the distribution of the variables, the Kolmogorov-Smirnov and Shapiro-Wilk tests were used. The *t* test was used to compare sets of 2 means, either at different time points within 1 group or between the groups. For comparisons involving more than 2 means, an analysis of variance (ANOVA) was performed, followed by the Bonferroni post hoc test to determine the statistical significance of the differences between the means. The

repeated-measures ANOVA was used for variables within the same group, while a one-way ANOVA was used for comparisons between groups. For the comparison of variables with a non-normal distribution, the Kruskal-Wallis ANOVA was used. The Mann-Whitney U test was used to compare the medians between the groups. To determine the relationship between discrete variables, the chi-squared test was conducted. Statistical significance was considered at *p* values <0.05.

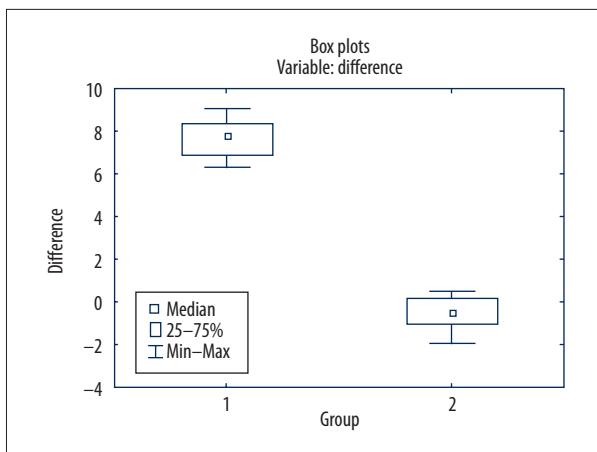
### Results

In the eyes subjected to phacoemulsification cataract surgery (group I), a significant improvement of 9.08 letters was observed in the mean BCVA at 1 month after the surgery compared to the initial value (*p*<0.001). The tendency was maintained at subsequent time control points (*p*<0.001). After 12 months of follow-up, the difference from the initial BCVA in patients from group I was 8.04 letters (*p*<0.001). A significant BCVA improvement of  $\geq 15$  ETDRS letters was observed in 20% of the eyes. In 44% of the eyes, there was an improvement in BCVA of  $>5 < 15$ . BCVA was considered stable when there was a deterioration or an improvement of up to 5 letters. BCVA improvement or stabilization occurred in 96% of the eyes. In 1 eye (4%), there was a decrease in BCVA of 13 letters due to scar formation in the macula.

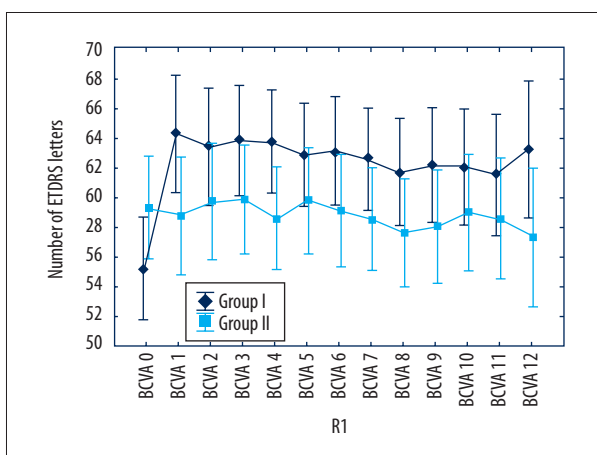
In group II, patients lost on average 1.96 letters compared to the initial BCVA value (*p*>0.05). No significant BCVA improvement was seen in this group. Stabilization of BCVA occurred in 80% of the eyes (20 cases), while in the remaining 20% (5 eyes) there was a decrease in BCVA. In 3 of the 5 eyes that experienced a decrease in BCVA, more than 15 letters were lost. In 2 of these, a scar developed in the macula, while in the third there was atrophy of the pigment epithelium and outer layers of the retina. In the remaining 2 eyes, decreased BCVA was associated with an increase in lens opacity (Figure 1).

The results of the ANOVA conducted for repeated BCVA measurements within each group (F test) revealed that the means from the consecutive control points were not significantly different in either group I or group II (*F*=2.12, *p*=0.15). Post hoc analysis revealed a significant difference between all consecutive BCVA values and the baseline BCVA measurement only in group I (*p*<0.0001). The results from the Mann-Whitney U test with continuity correction showed that in each control point, the mean number of ETDRS letters gained in group I was significantly higher than in group II (*U*=0, *p*<0.001) (Figure 2).

Statistical analysis revealed no significant differences between baseline CRT values and those of consecutive observation points in either group (*p*>0.05). In Group I, at the final control point, there was an insignificant increase in the average CRT value



**Figure 1.** Comparison of changes in the mean value of ETDRS letters gained between group I and group II. The y-axis represents the average number of ETDRS letters gained.

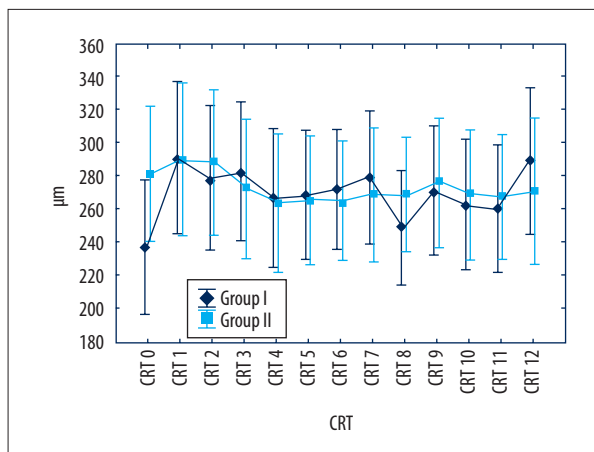


**Figure 2.** Calculated materiality levels between the mean output BCVA (in the number of ETDRS letters) and averages obtained at subsequent intervals (ANOVA/Bonferroni test). Group I deep-blue curve, group II light-blue curve.

to  $289.20 \pm 125.73 \mu\text{m}$  ( $p > 0.05$ ). In group II, an insignificant decrease in the average CRT value to  $270.92 \pm 91.79 \mu\text{m}$  ( $p > 0.05$ ) was noted at the final control point. The observed CRT fluctuations were related to the recurrences of CNV activity and the formation of scars and retinal atrophy.

The results of the ANOVA for repeated CRT measurements (F test) revealed that the means from the consecutive control points were not significantly different between each other either in group I or group II ( $F = 0.01$ ,  $p = 0.90$ ) (Figure 3).

The mean number of injections of anti-VEGF agents during the study was  $2.64 \pm 1.98$  in group I and  $2.92 \pm 2.40$  in group II. Statistical analysis revealed that this difference was not statistically significant ( $p > 0.05$ ). In both groups, the average number



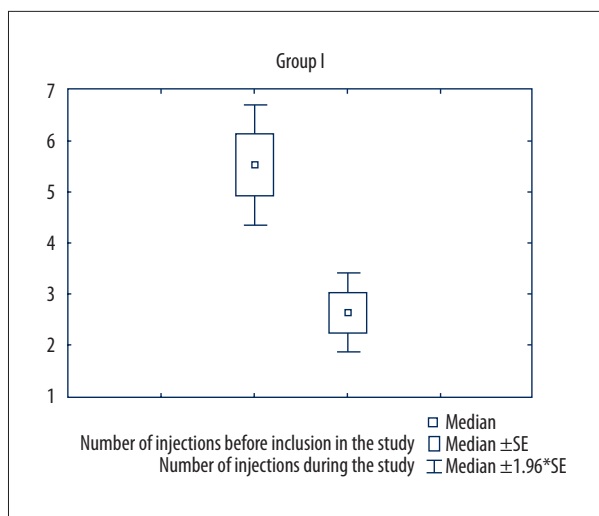
**Figure 3.** Calculated materiality levels between the mean output CRT in  $\mu\text{m}$  and the changes over time (ANOVA/Bonferroni test). Group I deep-blue curve, group II light-blue curve.

of injections received before enrollment in the study was significantly higher than the number of injections received during the study ( $p < 0.05$ ) (Figures 4, 5, Table 1).

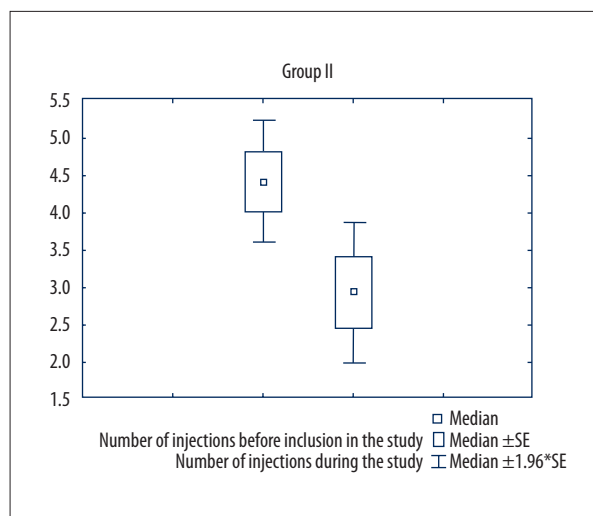
No serious adverse events associated with phacoemulsification or anti-VEGF agents administration were observed. In group I, all phacoemulsifications were uncomplicated.

## Discussion

The improvement in VA that is observed after removal of the opaque lens can be prolonged and last for many years after surgery. Mönestam and Lundqvist, based on a longitudinal cohort study among 810 patients, found that despite the gradual deterioration of vision in eyes with AMD during 10 years of follow-up, a significant VA improvement was maintained compared to the preoperative value. They stressed that the main reason for vision deterioration in eyes with AMD is primarily the natural course of the disease and not the ophthalmological procedure [23]. Therefore, patients with AMD may benefit from phacoemulsification cataract surgery. Recent epidemiological cross-sectional studies with at least 5-year follow-up data [24–26] did not find a negative association between cataract surgery and AMD, although such an association was observed among white patients in earlier studies, such as the Beaver Dam Eye Study and the Blue Mountain Eye Study [27,28]. The different findings from the recent and earlier cross-sectional studies could be due to the improvements in cataract surgery (phacoemulsification), better preoperative assessment of the macula (OCT), and differences in study populations. In report number 25 of the Age-Related Eye Disease Study (AREDS), no direct influence of cataract surgery on the risk of AMD progression was found within a 5-year period [29]. Furthermore,



**Figure 4.** Comparison of the average number of injections in the period before inclusion with the average number of injections during group I observations ( $t=3.73$ ;  $p<0.05$ ).



**Figure 5.** Comparison of the average number of injections in the period before inclusion with the average number of injections during group II observations ( $t=2.16$ ;  $p<0.05$ ).

**Table 1.** Comparison of the number of injections before and during the study between groups.

Variable	Group I	Group II	t*	p**
Average number of injections before assay	5.52±2.99	4.40±2.06	1.54	0.13
Average number of injections during the test	2.64±1.98	2.92±2.40	-0.45	0.65

\* t-value; the size of the difference relative to the variation in sample data. \*\* p-value; probability value. The significance level is 0.05.

report number 27 of the AREDS assessed the effect of phacoemulsification cataract surgery on VA in patients with various stages of AMD. It revealed that the patients achieved a significant improvement in mean VA, which persisted for at least 18 months after surgery [30]. Similarly, among 1232 eyes treated surgically due to cataract, report 5 of the AREDS 2 showed a significant improvement in VA across all AMD severity groups ( $p<0.0001$ ). The eyes with advanced AMD (central geographic atrophy, neovascular disease, or both;  $n=324$ ) gained 6.8 letters [31].

In a meta-analysis of 2 randomized controlled trials [32,33] and 2 case-control studies [34,35] published in 2015, Kessel et al. confirmed a significant improvement in VA (of 6.5–7.5 letters) following phacoemulsification in patients with AMD. They also reported no improvement in VA within a follow-up period of 6–12 months in patients that did not undergo surgery. In addition, there were no signs of an increased risk of progression from dry AMD to wet AMD after surgery [36]. Furthermore, in the third phase of the registration studies for ranibizumab (ANCHOR and MARINA), phacoemulsification was found to be safe and to provide functional benefits to eyes treated for wet AMD [37]. Four months after cataract surgery, VA in the ranibizumab-treated eyes improved by a mean of 10 letters,

which was not significantly different from the improvements observed in the fellow or sham eyes.

In a retrospective analysis involving 312 eyes with AMD, Stock et al. found a significant VA improvement after cataract surgery. However, VA improvement was significantly higher in the control group, which was composed of eyes without retinal pathologies ( $n=3871$ ). VA improvement was influenced by its preoperative value. In patients with VA of 20/40 or higher, the result was comparable to the group without pathological changes in the central retina. The study did not specify the type of AMD, only that no patient underwent cataract surgery during the active period of wet AMD [38].

Apart from epidemiological cross-sectional studies, meta-analyses, and cohort studies, several smaller studies, similar to our randomized study in both the number of patients and study duration, have investigated the relationship between cataract surgery and AMD. Saraf et al. performed a retrospective study of the effects of cataract surgery on BCVA, CRT, and the number of anti-VEGF injections in 2 groups of patients with wet AMD [39]. In total, 40 eyes underwent cataract surgery and the other 42 eyes did not. They confirmed that cataract surgery improves vision without contributing to the progression



of wet AMD. VA, which was comparable in both groups at baseline, was significantly higher in patients after cataract surgery compared with those who did not undergo surgery ( $0.23 \pm 0.65$  vs.  $0.11 \pm 0.59$  logMAR improvement;  $p=0.049$ ) [39]. Lee et al., among patients with wet AMD previously treated with anti-VEGF injections, retrospectively reviewed medical records of 39 eyes after cataract surgery [40]. The baseline VA was  $1.02 \pm 0.58$  logMAR, and it improved significantly 1 month ( $0.81 \pm 0.62$  logMAR;  $p<0.001$ ) and 6 months ( $0.85 \pm 0.64$  logMAR;  $p=0.001$ ) after surgery. In the study by Tabandeh et al. (30 eyes of 28 patients), VA improved significantly after cataract surgery ( $0.17 \pm 0.54$  logMAR;  $p=0.01$ ) [41] and perioperative macular adverse events did not occur. In a retrospective, non-comparative, interventional case-series study of 16 eyes with wet AMD, Muzyka-Wozniak observed a significant improvement in VA after phacoemulsification (mean, 3 logMAR lines); moreover, VA remained stable during a median follow-up of 14 months (range, 7–28) [42].

Our analysis showed a significant improvement in BCVA compared to the initial value in the group of patients who underwent cataract surgery, as soon as the first control point. At 1 month after phacoemulsification, the patients had gained an average of 9.08 ETDRS letters. Twelve months after the surgery, they had gained 8.04 ETDRS letters compared to baseline BCVA. Our analysis also revealed that phacoemulsification did not significantly affect the central retina.

In our study, there were no significant differences in CRT values from baseline throughout the follow-up in either group ( $p>0.05$ ). Grixti et al., in a retrospective analysis of 30 eyes with wet AMD treated with anti-VEGF injections, reported a significant increase in median CRT after phacoemulsification (203  $\mu$ m, preoperatively; 238  $\mu$ m, 1 month after surgery;  $p<0.05$ ); the median CRT returned to the baseline value 3 months after surgery (212.5  $\mu$ m;  $p=0.38$ ) [43]. In our study, among patients who underwent phacoemulsification, the average CRT value did not increase significantly at the end of follow-up ( $p>0.05$ ). In contrast, Saraf et al. reported that the mean CRT increased significantly in the eyes treated surgically but not in the untreated eyes ( $265.4 \pm 98.4$   $\mu$ m vs.  $216.4 \pm 58.3$   $\mu$ m;  $p=0.011$ ) [39]; the surgically treated eyes were more likely to develop new or worse cystoid changes after the study midpoint (54.2% vs. 28.1%;  $p=0.048$ ). Thus, Saraf et al. recommended using anti-inflammatory drops early and for a long time in the perioperative period in patients with wet AMD who undergo phacoemulsification [39].

To assess the incidence of recurrence of neovascular membrane activity, we examined the number of intravitreal injections of anti-VEGF agents received during the follow-up period. The patients received an intravitreal ranibizumab or aflibercept on a *pro re nata* (PRN) treatment strategy in recurrence of disease activity. Our analysis showed that the number of

injections received before enrollment in the study was significantly higher than the number received during the study in both groups of patients. In the aforementioned study of Saraf et al., there was no significant difference in the mean number of anti-VEGF injections administered 6 months before phacoemulsification ( $2.31 \pm 1.40$  injections) and 6 months after the procedure ( $2.30 \pm 1.45$  injections,  $p=0.921$ ) [39]. In the control group, there was also no significant difference in the average number of injections administered 6 months before the control point ( $3.0 \pm 1.45$  injections) and 6 months after it ( $2.57 \pm 1.45$  injections,  $p=0.057$ ). There was also no significant difference in the change in the average number of injections between groups ( $p=0.233$ ). Kessel et al. conducted a study involving 89 eyes with wet AMD, and they also did not find a statistically significant difference between the number of injections 6 months before the surgery (1.5 injections) and 6 months after it (1.7 injections,  $p=0.25$ ) [36]. In our study, the average number of injections in group I was  $5.52 \pm 2.99$  before the study and  $2.64 \pm 1.98$  during the follow-up ( $p<0.05$ ). In group II, an average of  $4.40 \pm 2.06$  injections were administered in the pre-study period and  $2.92 \pm 2.40$  ( $p<0.05$ ) were administered during the follow-up. The smaller number of injections during the follow-up period could be due to a longer treatment time before the start of this study compared to the duration of the follow-up period. Comparison of the mean number of injections before and after the study did not show statistically significant differences between the groups ( $p>0.05$ ), showing that phacoemulsification had no significant effect on the activity of wet AMD and did not cause the need to increase the number of intravitreal injections of anti-VEGF agents. Similar results were published by Grixti et al., Muzyka-Wozniak, and Tabandeh et al., who showed that the number of anti-VEGF injections did not increase after surgery [41–43]. In our study, disease activity was evaluated every month. Such frequent controls allow for early detection of relapse and prompt administration of the drug on a PRN basis [44]. Some of the participants in this study had been previously treated for wet AMD during remission of CNV activity. The mean duration of treatment was  $17.24 \pm 15.23$  months in group I, and  $12.24 \pm 7.88$  months in group II. This may explain the relatively low number of necessary injections in both groups. An important factor in predicting the recurrence of CNV activity is the length of remission periods preceding surgery. Lee et al. confirmed that a longer the period of CNV inactivity before the surgery was associated with less frequent recurrences [40]. Rappoport et al., in their 6-month-long study based on retrospective chart review of 42 eyes (38 patients), noticed that the number of anti-VEGF reinjections after phacoemulsification was lower in eyes that did not show CNV activity before surgery than in eyes with active disease (56% vs. 80%) [45]. The length of remission prior to cataract surgery may be an important factor to consider when establishing the eligibility criteria for treatment in the case of patients with coexistence of cataract and wet AMD.

In all patients in group I, UV and blue light filtering, acrylic, posterior chamber, intraocular lenses were implanted, which is a standard procedure in our institution in patients with wet AMD. Although implantation blue light filtering lenses during phacoemulsification is common, there is little evidence that supports a protective effect of such filters on the retina [46–48].

The study, which was the first single-center, randomized study in Poland among patients with wet AMD who underwent phacoemulsification, has certain limitations. The number of patients included in the study was relatively small. The study was done before introduction of reimbursed AMD treatment, which increased the availability of this treatment and standardized it. The present findings can be used in practice in other centers in Poland that treat patients with wet AMD. We analyzed the effects of phacoemulsification in patients with AMD over a

period of 12 months, like most previous studies with similar patient numbers. Because wet AMD is a chronic disease, studies with longer follow-up could provide more information on AMD progression after phacoemulsification.

## Conclusions

Phacoemulsification performed in eyes with wet AMD during the inactive phase of the disease significantly improves visual acuity. Moreover, phacoemulsification does not significantly change the need for intravitreal anti-VEGF injections, disease activity, and macular morphology. Larger studies among Polish patients with wet AMD who undergo phacoemulsification are needed; for instance, an analysis of the electronic database of patients who receive reimbursed treatments.

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