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Postoperative stability of refractive error after cataract surgery

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Abstract

Aim. The goal of the present study is to determine how much time must pass after a cataract surgery with no complications to achieve a sufficiently stable refraction.

Subjects and methods. We measured the postoperative refraction of 61 pseudophakic subjects (mean age: 74.32 ± 7.11 years) five times with an autorefractor. The subjects had undergone unilateral cataract surgery and the time intervals for the measurement went from one day to eight weeks after the operation. In order to obtain the spherical equivalent (SE) and the cylinder power, the difference from each measurement and the last measurement in the seventh or eighth week post-surgery was taken. The Friedman test for paired samples was used to see if there were any significant differences in spherical equivalent and cylinder power in the 5 measurements taken. In addition, two repeated measurements were taken on one eye of 16 phakic subjects with good ocular health pertaining to a similar age group to determine the measurement uncertainty of the autorefractor (± 1.96 SD for the measured value differences).

Results. In the case of the spherical equivalent, we found no statistically significant difference between the individual repeated test series. The cylinder power was significantly higher on the first day after the operation than during all subsequent appointments, but then showed no significant difference between all measurements taken during the examinations after the first day. The differences in the spherical equivalent between one measurement and the reference measurement (7 - 8 weeks after the surgery) resulted in 95 % confidence intervals (± 1.96 SD) of approximately ± 2.00 dioptres (D) on the first day post-surgery and lay between ± 1.20 D and ± 0.80 D in post-surgery weeks 1, 3 and 5. The corresponding confidence intervals for the cylinder power were ± 2.00 D on the first day post-surgery and lay between ± 1.27 D and ± 0.88 D in post-surgery weeks 1, 3 and 5. The statistical dispersion of the spherical equivalent and the cylinder power decreased slightly as the time from the surgery increased. We estimated a measurement uncertainty for automated refractometry performed on older phakic eyes of ± 0.80 D for the spherical equivalent and ± 1.16 D for the cylinder power.

Conclusion. The refractive power of a pseudophakic eye can be determined with sufficient certainty after one to three weeks after undergoing cataract surgery without complications. This means that optical aids to correct any residual refractive error or presbyopia can be prescribed earlier than before and, hence, the number of follow-up appointments required to measure a stable refraction can be reduced.

Keywords
Cataract, postoperative refraction, refraction measurement, repeated automated refractometry

Introduction

Cataract is one of the most common eye diseases. Around one million people living in Germany were reported having cataract in 2012, and an increase of around 25 % is forecast by 2030.[1] The predominant type of cataract in older eyes is cataracta seniles.

Cataract removal and the subsequent implantation of an artificial intraocular lens (IOL) is one of the most frequently performed surgeries. Every year, around 6,000 – 7,000 cataract surgeries are performed per one million inhabitants in Europe.[2] The preferred surgical method is the extracapsular cataract extraction (ECCE). During this procedure, the IOL is implanted in the lens capsule, which is left in the eye except for its frontal part. The folded IOL is inserted through a scleral tunnel incision near the limbus into the remaining capsular sack so that the IOL is fixed in the position of the natural lens. Foldable IOLs allow for very narrow incisions, enabling a sutureless healing process of the laceration. If both eyes must be operated, each eye is operated at different times to avoid serious bilateral complications.

Among other things, the refractive power of the implanted IOL depends on the axial length, the anterior chamber depth, the corneal radius and the expected lens position. Hence, various biometric measurements are necessary to determine the refractive power, as well as a target refraction, which, in most cases, will be emmetropia or a mild myopia. However, the refraction after surgery is affected by various factors and only reaches its final value after a few days or weeks. A reason for this can be the temporary swelling of the cornea caused by the surgery, even if this swelling is usually subdued by the viscoelastic medium administered during the operation.[3] Temporary changes in the axial length, the position of the IOL or the anterior chamber depth are also among the short-term factors that can primarily influence the spherical component of the postoperative refraction.[4] On the other hand, the size, position and healing process of the incision tend to influence the value and axis position of the postoperative astigmatism.[5] Furthermore, the capsular sack may shrink after cataract surgery, which, in turn, can lead to a dislocation of the IOL and, thus, increase any higher-order optical aberrations.[6] A cause for a medium-term change in postoperative refraction is the not uncommon Irvine-Gass syndrome, which is characterized by cystoid macular oedema appearing between the sixth and tenth week after the operation.[7]

It is the impression of the authors of this study that the eye clinics and ophthalmological practices that perform cataract surgeries establish different time frames for the stabilisation of the refractive power. It usually takes up to eight weeks after the surgery to determine a final refraction and prescribe optical aids. The determination of the exact time after the extraction of a cataract and the implantation of an IOL when the refraction is stable enough to prescribe optical aids to correct any remaining refractive errors or presbyopia is a controversial topic in the literature. Some authors state that a stable refraction is achieved one week after the surgery,[8-10] while other studies ascertain that this time is only enough to stabilise the spherical component of the refraction.[11] Others have observed changes of up to one dioptre within the first four to six weeks post-surgery.[7]

It is therefore the aim of this study to determine the earliest possible time after surgery in which a stable refraction is reached.

Subjects and Methods

35 female and 26 male (n = 61) pseudophakic subjects with an average age of 74.23 ± 7.11 years and a postoperative visual acuity of 0.64 ± 0.25 on the day after the surgery were included in this study. All of them underwent cataract surgery at the same medical facility (St. Barbara Eye Clinic in Hamm-Heessen) and had five subsequent follow-up appointments to determine their refraction one day after the surgery, approximately one week after the surgery, approximately three weeks after the surgery, approximately five weeks after the surgery and a final examination in the seventh or eighth week after the surgery. All subjects had a bilateral operation; however only the eye operated first was considered in this study. In all cases (29 right eyes; 32 left eyes), a posterior chamber intraocular lens with spherical power and a UV filter (SA60AT, Alcon) was implanted. Four different surgeons carried out the operations. They made a superior or supero-temporal scleral tunnel incision up to 3 mm wide on all subjects.

The exclusion criteria included a visual acuity $V_{CC} < 0.1$ on the first day post-surgery, acute ocular inflammation or other surgical complications, preoperative scars or corneal dystrophies and macular oedema (wet AMD, Irvine-Gass syndrome). Subjects with fixation problems, for example due to nystagmus or amblyopia, were also excluded.

On each of the five appointments, the objective refraction was determined with three repeated measurements using an ARK-760A autorefractor (Nidek Co., LTD, Japan). The mean values for cylinder and axis output by the device and rounded off in 0.25 D steps were included in the study protocol.

In order to evaluate the measured values statistically, we established the following (null) hypothesis: the postoperative refraction measured at different time intervals does not differ from the reference value determined on the final examination (i. e.: the refraction on the seventh or eighth week after surgery). The null hypothesis is rejected if the level of significance (p-value) falls below 5 %.

Using the refraction measurements (sphere, cylinder, axis), we calculated the spherical equivalent (SE = sph + (0.5 × cyl)) and the difference between the principal meridians (given as the minus cylinder). The axis values were ignored for the purpose of this study since the meridian position of postoperative astigmatism has a smaller effect compared to its magnitude.

The procedure conducted in this study is also based on the assumption that any refraction changes are due to the healing process and that the refraction must, therefore, become more stable with time. Based on this, we took the values of the final examination (on the seventh to eighth week post-surgery) as reference values. We then calculated the difference between the SE and cylinder values measured at any of the four postoperative time intervals (1 day, 1 week, 3 weeks, 5 weeks) and the respective final examination (week 7 or 8). For example, if the SE on the first day after surgery was -2.00 D and eight weeks later -1.50 D, the difference would then be -0.50 D. This means that, out of the five series of measurements of spherical equivalent and cylinder, we calculated four measurement series, each with the difference of the measured value and that of the final examination. We used the Shapiro-Wilk test to check if the series with the measured value differences were normally distributed and Levene's test to see if it was homoscedastic. Both tests gave negative results. We thus conducted a non-parametric analysis of variance (Friedman test) to test the hypothesis using the software IBM SPSS.

In analogy to other studies, we then proceeded to calculate the standard deviation (SD) and the 95 % confidence intervals for repeated measurements (± 1.96 SD) for the measured value differences, regardless of the fact that none of the series of measurements followed a normal distribution. The 95 % confidence interval represents the range in which the probability of finding a measured value difference between two repeated measurements is 95 %.[12] This interval can be used to estimate whether the difference between two measurements can be explained by the measurement uncertainty of the autorefractor used or it is in fact due to a real change in the variable to be measured.

In order to estimate the measurement uncertainty of the autorefractor used in this study, the refraction of 16 healthy (phakic) test subjects with a similar age distribution was measured twice in a row. We used the Shapiro-Wilk test to check if the differences between spherical equivalent and cylinder measurements 1 and 2 were normally distributed and, assuming it was the case, we calculated the respective standard deviation (SD) and the 95 % confidence intervals for repeated measurements (± 1.96 SD), the latter representing an estimated value of the measurement uncertainty of the autorefractor used in the study.

Results

Figure 1 shows the distribution of the values of the SE and the cylinder power at the time of the final examination in the seventh to eighth week after the operation. It can be seen that the values of both the SE and the cylinder power are close to zero in the majority of cases, however both components of the refractive error present a clinically significant scatter. While the values of the SE show an approximately symmetrical distribution around zero, all cylinder values present a skewed distribution and are in the negative range due to the minus cylinder notation used here. The median of the SE is -0.37 D (min = -3.75 D; max = +2.00 D), whereas the median of the cylinder is -0.75 D (min = -5.25 D; max = 0.00 D).

Figure 2 shows the central tendency and dispersion of the difference between the values of the refraction measured at the different postoperative time intervals and those determined during the final examination. It can be seen that the medians for all time samples are close to zero, but the statistical dispersion (range and interquartile range) is greatest on the first day after the operation. Outliers are present in both figures (marked with a circle if their distance to the box is greater than 1.5 times the interquartile range; marked with an asterisk if their distance to the box is greater than 3 times the interquartile range). These were deliberately included in the data set, since they can be understood as minor in most cases and, to a certain extent, correspond to what is to be expected in the practice of cataract surgery. It is also worth noting that especially the series of measurements corresponding to the fifth week after surgery shows a skewed distribution (median lies off-centre).

The Friedman variance analysis for dependent samples using all five measurement series (including the final examination) for the SE and the cylinder values showed that the SE does not vary significantly between the series of measurements ($p > 0.05$). In contrast, the cylinder values showed a significant difference ($p = 0.01$) between the series of measurements. If we do a pairwise comparison, the differences exist only between the first day after surgery and all subsequent appointments. There is no significant difference ($p < 0.05$) between weeks 1 and 8 after the surgery.

Figure 3 shows the absolute values for the deviation of the SE and the cylinder, analogously to **Figure 2**. The medians and the whiskers on both figures show that the deviations from the final refraction value are greatest on the first day post-surgery and, after about one week, differ only slightly from the subsequent postoperative weeks.

Table 1 shows the 95 % confidence intervals for the difference of all measured values of the refraction to the reference value (the refraction value measured on the seventh to eighth week post-surgery). The confidence intervals are calculated from the standard deviation of the difference in measurements between two repeated measurements. They are shown here for practical reasons and for comparison with other studies, although the values cannot be assumed to be normally distributed in any of the eight series of measured value differences, as is required to perform this calculation (Shapiro-Wilk test $p < 0.05$ for all the repeated series of measurements for both SE and cylinder). The last column shows the 95 % confidence intervals for the difference in measurements of two consecutive test refraction measurements in healthy subjects of a similar age group. They correspond to an estimated value for the measurement uncertainty of the autorefractor used in this study when employed to determine the refractive power of older eyes.

Discussion

The aim of the present study is to determine the postoperative point in time in which a sufficiently stable refraction is reached. We assume that a sufficiently stable refraction is reached if at least two refraction measurements taken several days apart can be regarded as the same on average and if their difference to a reference value can be explained solely by procedural or physiological observational errors.

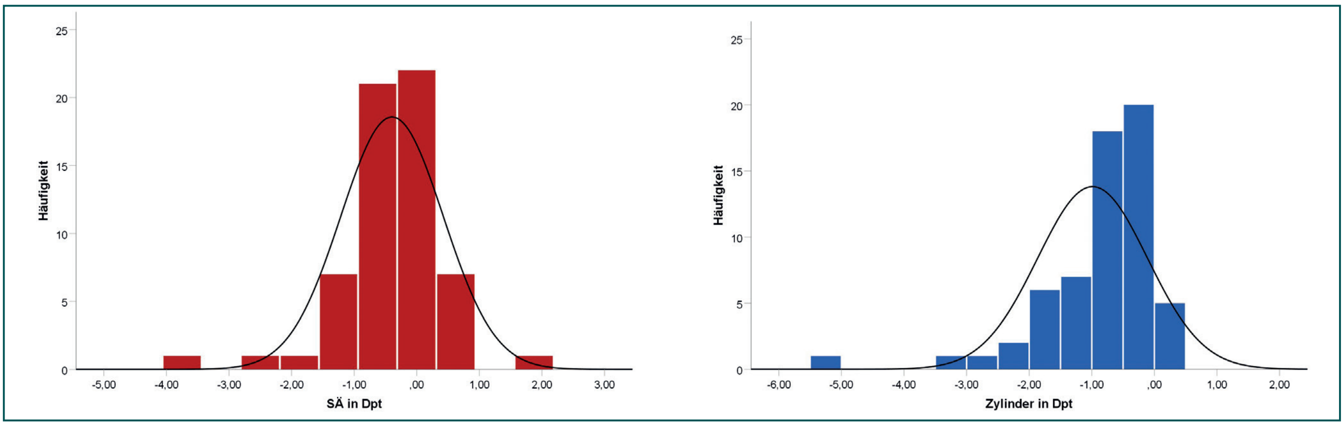

Figure 1: *Distribution of the refraction values at the time of the final examination (n = 61).*

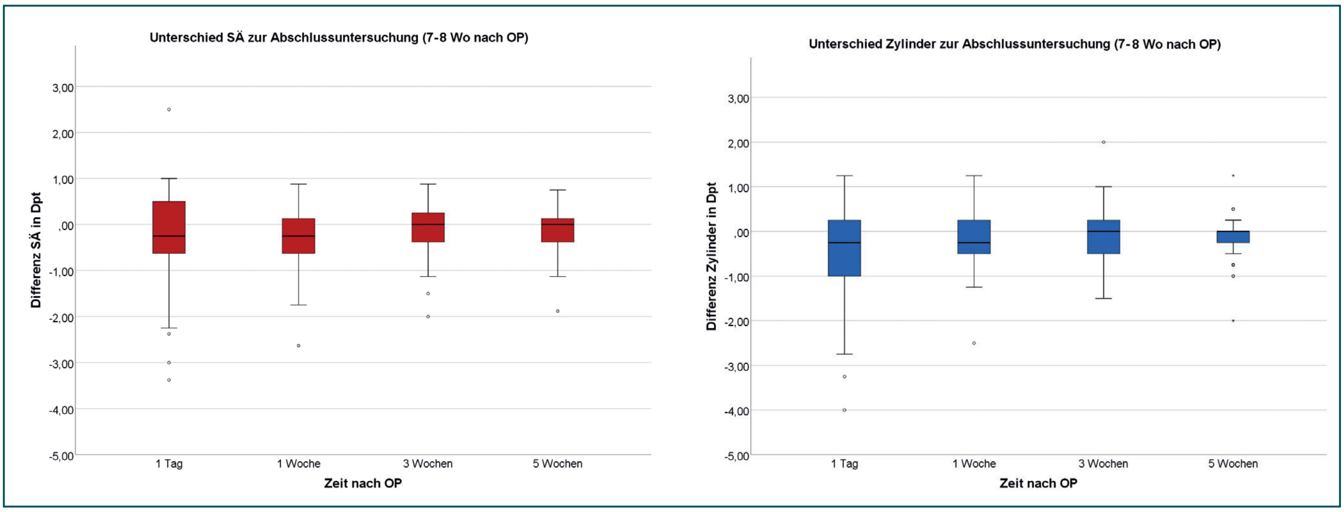

Figure 2: *Difference between the values of the spherical equivalent (left) and cylinder (right) between different follow-up appointments and the final examination (n = 61). The horizontal lines mark the position of the median, the boxes contain the two inner quartiles and the whiskers show the range. Circles are used to mark data points, whose distance from the box is more than 1.5 times the interquartile range. Asterisks are used to mark data points, whose distance from the box is more than 3 times the interquartile range.*

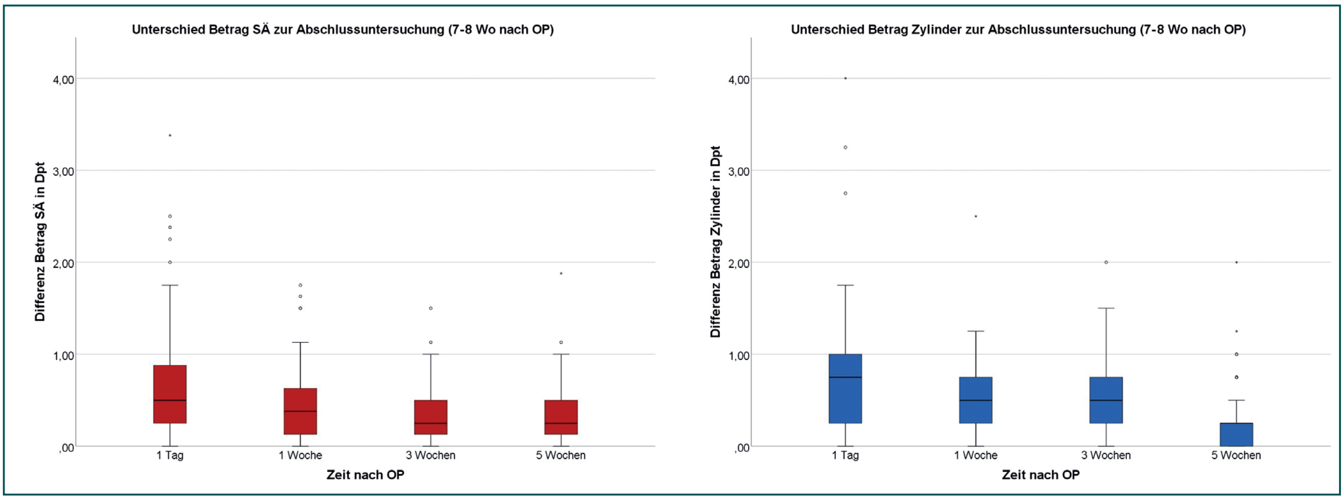

Figure 3: *Difference between the absolute values of the spherical equivalent (left) and cylinder (right) between different follow-up appointments and the final examination, shown as absolute values. The horizontal lines mark the position of the median, the boxes contain the two inner quartiles and the whiskers show the range. Circles are used to mark data points, whose distance from the box is more than 1.5 times the interquartile range. Asterisks are used to mark data points, whose distance from the box is more than 3 times the interquartile range.*

Table 1: 95 % confidence intervals for measured value differences between two repeated objective refraction measurements. The refraction determined in the seventh to eighth postoperative week was taken as a reference. The right column (control) shows the 95 % confidence interval (CI) for the refraction measurements of healthy patients from a similar age group obtained using the same refractometer used in this study.

	1 day after surgery	1 weeks after surgery	3 weeks after surgery	5 weeks after surgery	Control
95 % CI for SE (± 1.96 SD)	± 1.96 D	± 1.20 D	± 1.07 D	± 0.95 D	± 0.80 D
95 % CI for cylinder (± 1.96 SD)	± 2.00 D	± 1.26 D	± 1.27 D	± 0.88 D	± 1.16 D

Figure 1 shows that even the refraction values from the eighth week post-surgery have a large dispersion around zero (the ideal value). There are several reasons why the SE deviates from zero. On the one hand there are measurement errors, rounding, the use of imprecise mathematical models when calculating the refractive power of the IOL or the healing process itself. On the other, this deviation could also be due to differences in the target refraction. For example, in patients exhibiting moderate to severe myopia before surgery, the target refraction is often set at a mild myopia, since, before the operation, the patient is used to seeing nearby objects more sharply than those further away and it is deemed better for the patient if this is also the case post-surgery. Meanwhile, the deviations from zero of the cylinder power depend, among other things, on the corneal astigmatism, which can be altered by the incision during cataract surgery, but cannot be neutralised.[5,13] The skewed distribution of the values of the cylinder power can be explained by the fact that all values are given as minus cylinders and most eyes only presented with a low postoperative astigmatism.

The results from the Friedman variance analysis show that the SE exhibits no significant difference (bias) and that the cylinder power only shows a significant difference for the measurements taken on the first day after the surgery. It can, hence, be deduced that no myopia or hyperopia develops during the healing process, but rather a higher astigmatism immediately after the operation. This can be explained, for example, by the effect of the incision on the corneal astigmatism and the healing process that follows.[5] The spread of the SE and cylinder values presented in **Figure 2** and **Figure 3** and the different positions of the medians in **Figure 3** show that the time after a cataract surgery affects the refraction. As expected, the spread and median positions are higher shortly after the operation but stabilise to a nearly constant level after approximately one week.

A closer look at the literature can help us understand whether the dispersion of the measured value differences between two refraction measurements has a physiological or procedural origin or, rather, can be attributed to a real change in the refraction of the test subjects. In the case of automated refractometry of healthy younger eyes, measurement uncertainties between ± 0.3 D and ± 0.4 D (95 % confidence interval) are often given for both SE and cylinder.[14-18] In this case, the measurement uncertainty depends on the method, the time lapse between measurements and the population examined.[17] It is also determinant, at least in the case of automated refractometry of younger eyes, whether cycloplegic drugs are used to measure the refractive error of the eye.[18]

Only a few relevant studies are available on the measurement uncertainty in older phakic or pseudophakic eyes. For example, Leinonen et al. give a measurement uncertainty of approximately ± 0.75 D for the SE and approximately ± 1.00 D for the cylinder when subjective refraction is performed on older phakic or pseudophakic eyes and explain the greater dispersion compared to younger eyes with the, on average, lower visual acuity in older eyes.[19] Reeves et al. present differences outside of a ± 0.50 D range in 25 % of the eyes during repeated autorefractor measurements of pseudophakic eyes. In contrast to the present study, however, these data only refer to a single measurement time after the surgery.[20]

Table 1 shows that the range (95 % confidence interval) for the measured value differences for the first postoperative day is approximately ± 2.00 D for both the SE and the cylinder and is significantly lower in all other subsequent measurements. In the case of the SE, the range shows a decreasing trend as the time from the surgery increases. Nevertheless, the range of the measurements from the fifth postoperative week is still slightly above the estimated measurement uncertainty for the refractometer used in this study. In the case of the cylinder power, the range remains the same for post-surgery weeks 1 and 3 while dropping slightly below the estimated measurement uncertainty in week 5. It should be emphasised, however, that the ranges for both SE and cylinder are around twice as large as stated elsewhere for younger eyes, even after three or more postoperative weeks (see above). This also roughly applies to the measurement uncertainty of the refractometer used, which was determined using subjects of a similar age group but with healthy eyes. The study conducted by Leinonen et al. presents a similar magnitude for the measurement uncertainty in the SE and cylinder of older eyes.[19] However, this quantity was measured subjectively and, therefore, cannot be compared directly. While Leinonen et al. assumed that the reduced visual acuity in many of the older subjects was the cause of the greater measurement uncertainty, other explanations must be found for objective measurements. These include age-dependent miosis, which leads to a 2 mm average reduction in pupil diameter in 70-year-olds compared to 20-year-olds[21] and, therefore, may cause inaccurate autorefractor measurements. It remains to be studied whether the precision of other devices or methods for measuring refraction depend to a lesser extent on the pupil diameter than the Nidek autorefractor used here.

Regarding the aim of this study, the decisive variable is the point in time at which the dispersion of the measured value differences can be accepted as sufficiently small or sufficiently stable. Based on the statistical dispersion shown in Figure 2 and Figure 3 and the intervals listed in Table 1, a sufficiently stable refraction can be assumed approximately on the third week post-surgery. It is also worth noting that the dispersion of the measurements of the first week after surgery is only slightly larger and could be accepted clinically. In this respect, the results presented here support the recommendation of other authors that a sufficiently accurate refraction measurement is already possible after seven days[9-11] or two weeks[4] post-surgery. However, it can also be argued that not even seven or eight weeks after the surgery are enough to reach a stable target refraction, since other authors state that the refractive power is only sufficiently stable after 90 days.[22]

The significance of this study lies in the relatively high number of test subjects, the comparatively high number of series of measurements and in the seamless recording of data of the examined subjects. On the other hand, one of the possible points of criticism is that axis changes in cylinder power were not taken into account. In order to do this, an analysis of vector components is necessary.[23] However, vector data for astigmatism is much more difficult to interpret than the cylinder magnitude and axis, which is why we did not perform a recalculation for this study. It should also be noted that the healing process and the postoperative astigmatism not only depend on the size and location of the incision, but possibly also on the type of IOL implanted. Strictly speaking, the results are only relevant if the surgical technique and IOL type are the same, as was the case here. Furthermore, this study does not take into account to what extent the best-corrected visual acuity V_{CC} stabilises after cataract surgery. Visual acuity and refraction are particularly independent of one another if the refraction is determined using an objective procedure. However, it can also be argued that refraction can only be accurately measured using a subjective method. Nonetheless, this argument can be questioned using the fact that the precision of modern autorefractors is at least equal[18] or even superior to a subjective refraction measurement.[15]

Conclusion

The present study shows, in agreement with other authors, that the refraction of a pseudophakic eye can be determined with sufficient clinical accuracy already one to three weeks after an uncomplicated cataract surgery. This means that optical aids to correct any residual refractive error or presbyopia can be prescribed earlier than before and, hence, the number of follow-up appointments required to measure a stable refraction can be reduced.

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