## RESEARCH

# Refractive stability following uncomplicated cataract surgery

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**Background:** Quality of life may be negatively impacted following cataract surgery if glasses prescription is delayed. This study aims to confirm the refractive stabilisation time in an Australian population to form the basis for suggesting an appropriate timeframe for spectacle prescription.

**Methods:** Participants (51 female and 35 male) were recruited one day after uncomplicated unilateral cataract surgery using a monofocal intraocular lens. Subjective refraction, automated refraction and central corneal thickness were measured at two, four and six weeks post-operatively. A short questionnaire assessing the impact of uncorrected near vision on daily activities was collected at two and four weeks.

**Results:** There was no significant change in the mean automated or subjective spherical equivalent refraction ( $p_{eq} < 0.001$ ), mean corneal thickness ( $p_{eq} < 0.001$ ), mean uncorrected distance visual acuity ( $p_{eq} < 0.001$ ) or mean uncorrected near visual acuity ( $p_{eq} < 0.001$ ) over the six-week study period. At week two, 59 per cent of patients stated that their uncorrected near vision affected their ability to perform daily tasks 'somewhat' or 'a lot', increasing to 75 per cent by week four.

**Conclusion:** Uncorrected near vision affected quality of life for most participants. All measured visual and ocular parameters were stable from two weeks post-operatively. Patients need not wait longer than this for spectacle prescription following uncomplicated unilateral cataract surgery.

Key words: cataracts, intraocular lens, refraction, stability

Advances in technology and surgical technique have made cataract surgery a rapid and safe procedure, allowing patients to return to routine activities soon after surgery. Foldable intraocular lenses (IOLs) and phacoemulsification permit increasingly smaller incisions, shorter operative times and decreased disruption to surrounding structures. It has been demonstrated that smaller incisions lead to faster refractive stability following IOL insertion and induce less corneal astigmatism, reducing stabilisation time and improving the clarity of uncorrected vision.<sup>1,2</sup>

Oshika and Tsuboi reported that while refraction did not stabilise for more than three months following surgery using an 11 mm incision, refraction stabilised within two weeks when a 3.2 mm incision was used.<sup>3</sup> This timeframe is supported by recent studies that report refractive stability can be achieved within one to two weeks when minimally invasive techniques are utilised.<sup>4–6</sup>

Patients who are not suitable for multifocal IOLs who elect to receive monofocal IOLs

require new reading or distance glasses post-operatively for complete visual rehabilitation. Current practice in Australia is to prescribe glasses four weeks after cataract surgery; a timeframe informed by historical refractive stabilisation time and also the structure of the public health funding system, Medicare. In the aftercare period following cataract surgery (generally accepted to be four weeks), optometrists are not permitted to claim reimbursement for services, including refraction, as it is considered post-operative care. As a result, patients often wait at least four weeks post-operatively for prescription of spectacles.

In light of recent studies, this delay has been questioned as uncorrected near or distance vision during the post-operative period may functionally impact the quality of life of patients and contribute to a loss of productivity.<sup>8,9</sup> The establishment of a timeframe for the stabilisation of refraction may also benefit patients experiencing significant post-operative refractive surprise who

require subsequent correction via procedures such as laser surgery.

This study seeks to determine the time required to achieve refractive stability in an Australian population following cataract surgery, and to assesses the impact of uncorrected near vision on the quality of life of patients during the post-operative period in an Australian population, in order to recommend changes to spectacle prescription practices.

#### Methods

All adults who underwent uncomplicated unilateral phacoemulsification and monofocal IOL insertion by a single ophthalmologist in a regional public hospital between 2 March 2016 and 24 November 2017 were considered for inclusion in the study. Patients were excluded if they had a preexisting ocular diagnosis such as glaucoma or if they had corneal, retinal or macular pathology. Patients were also excluded if

they experienced intra- or post-operative complications or required sutures.

# Surgical technique

All surgeries were performed by one surgeon (SA). Aspherical hydrophobic AcrySof IQ monofocal lenses (SN60WF, Alcon, Fort Worth, Texas, USA) were selected for each patient using a target refraction of  $0.00\pm0.25$  D. Due to financial constraints in the public health system, toric lenses were used only for patients with pre-operative astigmatism of 1.50 D or greater. The surgery was performed either under local anaesthesia using topical 0.5 per cent proxymetacaine hydrochloride drops or a two per cent lignocaine sub-tenon block, or under general anaesthesia as per patient election.

Two side ports were made using a 1 mm ophthalmic knife (MSL10, MANI Inc., Utsunomiya, Japan), viscoelastic was injected and a 2.3 mm main incision was made at 180 degrees using a 2.3 mm ophthalmic knife (MSL23, MANI Inc.). A continuous curvilinear capsulorrhexis measuring approximately 5 mm was performed using a 0.5  $\times$ 16 mm cystotome (581,610, Beaver-Visitec International, Waltham, Massachusetts, USA). After hydrodissection, phacoemulsification of the nucleus and aspiration of the cortex were performed. The IOL was inserted into the bag, viscoelastic was aspirated and antibiotic (1 mg/mL cephazolin) was injected intracamerally. Wounds were hydrated and checked for leaks, and a subconjunctival injection of approximately 0.2 mL of dexamethasone (4 mg/mL) was administered.

### Post-operative care

Patients were commenced on a regime of ciprofloxacin, prednisolone acetate/phenylephrine hydrochloride and diclofenac sodium for four weeks to be administered four times a day.

## **Clinical examination**

Eligible patients were recruited on day one post-operatively following uncomplicated unilateral cataract surgery and provided informed consent prior to participation. A routine examination was conducted on this day including slitlamp examination to assess for post-operative inflammation, and visual acuity.

At two, four and six weeks post-operatively the following examinations were conducted: slitlamp examination, uncorrected near and distance visual acuity, automated refraction, subjective refraction, and central corneal thickness. Patients were asked one question to assess the impact of uncorrected near vision on daily activities at two and four weeks.

The protocol for this study was designed in accordance with the Declaration of Helsinki and was approved by the University of Wollongong/Illawarra Shoalhaven Local Health District Health and Medical Human Research Ethics Committee.

## **Equipment**

Visual acuity was measured using a Snellen chart (VistaVision DMD Med Tech, Turin, Italy). Ultrasound pachymetry (Pachmate, DHG 55, DGH Technology Inc., Exton, Pennsylvania, USA) was used to measure central corneal thickness, optical coherence tomography was performed on the macula and optic nerve head to monitor post-operative complications, and retinal changes (Cirrus 500 OCT-HD, Zeiss, Jena, Germany) and refraction was measured subjectively and with an autorefractor (iTrace, Tracey Technologies, Houston, Texas, USA). Subjective refraction was performed by an experienced optometrist.

## Statistical analysis

Automated refraction, subjective refraction, uncorrected distance and near visual acuity, and central corneal thickness were compared across the study time points using a linear mixed model. Differences were considered statistically significant when the p-values for the pairwise comparisons in the linear mixed model (p<sub>diff</sub>) were < 0.05.

Equivalence testing was performed to determine if there was no change across the study period. Subjective refraction, automated refraction, uncorrected distance and near visual acuity, and central corneal thickness were compared at each time point across the study period using the two onesided test to provide p-values for equivalence (peg). To demonstrate equivalence, the two one-sided test investigated the hypotheses that the difference was greater or less than predetermined equivalence limits (differences small enough to be considered clinically insignificant). The equivalence limits for this study were defined as  $\pm$  0.50 D for automated and subjective refraction,  $\pm$  30 µm for pachymetry and  $\pm$  0.2 logMAR for visual acuity. If both of these hypotheses were rejected it was possible to state that the values were equivalent. Values were considered equivalent when  $p_{eq}$  was  $\leq 0.05$ .

Correlation between subjective and automated refraction was calculated using a Pearson correlation test where p  $\leq 0.05$  indicates significant correlation. Chi-squared  $(\chi^2)$  tests were used to test for relationships between post-operative patient satisfaction (such as impact of uncorrected near vision on

everyday life), and pre-operative refraction (such as hyperopic, emmetropic or myopic) and surgical history (such as phakic or pseudophakic in the fellow eye). The relationship was considered significant if  $p \le 0.05$ .

## **Results**

A total of 92 patients enrolled in the study; six patients withdrew and their data are not presented here. A total of 86 people participated in the study (51 female and 35 male). Of these, 27 patients missed one or more follow-up appointments and the data of these patients were included in the analysis for the visits that they attended. Reasons for withdrawing and missing appointments included inconvenience, inability to arrange transport and illness. The mean patient age at time of surgery was 72.75 years (range 50–88 years). There were no post-operative complications reported.

# **Refractive stability**

There was no significant change in the mean automated ( $p_{eq} < 0.001$ ,  $p_{diff} = 1.00$ ) or subjective spherical equivalent refractive error ( $p_{eq} < 0.001$ ,  $p_{diff} = 1.00$ ) over the study period. The mean automated spherical equivalent refractive error was  $0.11 \pm 0.78$  D at week two, and decreased by 0.10 D to  $0.01 \pm 0.62$  D at week four before increasing by 0.90 D to  $0.10 \pm 0.57$  D at week six (Figure 1).

The mean subjective spherical equivalent refractive error was  $-0.27\pm0.54$  D at week two and increased by 0.01 D to  $-0.26\pm0.49$  D at week four and by a further 0.05 D to  $-0.21\pm0.48$  D at week six (Figure 2). There was a moderately strong positive correlation between subjective and automated spherical equivalent refractive error at six weeks postoperatively (R = 0.75, p < 0.001).

#### **Corneal thickness**

Corneal thickness was measured to monitor post-operative corneal swelling as corneal oedema can affect visual acuity. There was a small but non-significant decrease in the mean corneal thickness across the study period (p<sub>eq</sub> < 0.001) (Figure 2). The mean central corneal thickness was 559.10  $\pm$  42.24  $\mu m$  at week two and decreased by 5.05  $\mu m$  to 554.05  $\pm$  40.90  $\mu m$  at week four, and by a further 3.8  $\mu m$  to 550.25  $\pm$  39.85  $\mu m$  at week six (Figure 2).

#### Visual acuity

There was a small but non-significant improvement in the mean post-operative

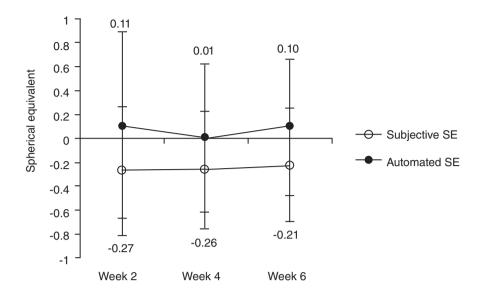


Figure 1. Automated (filled circles) and subjective (unfilled circles) spherical equivalent refractive error (SE) at two, four and six weeks following cataract surgery. Error bars represent  $\pm 1$  standard deviation.

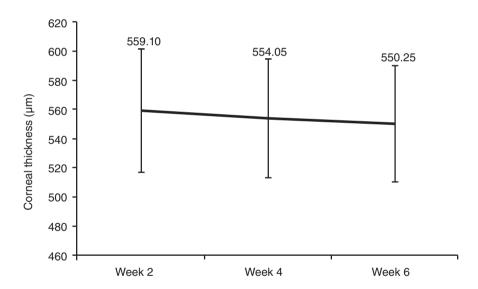


Figure 2. Corneal thickness (µm) at two, four and six weeks following cataract surgery. Error bars represent  $\pm 1$  standard deviation.

uncorrected distance visual acuity ( $p_{eq}$  < 0.001,  $p_{diff}$  = 0.360) and uncorrected near visual acuity ( $p_{eq}$  < 0.001,  $p_{diff}$  = 0.455) across the study period (Figure 3). Mean uncorrected distance visual acuity was  $-0.02 \pm 0.07$  logMAR at week two, and decreased by 0.023 to  $-0.04 \pm 0.08$  logMAR at week four and by 0.004 to  $-0.04 \pm 0.06$  logMAR at week six (Figure 3). Mean uncorrected near visual acuity was 0.44  $\pm$  0.20 logMAR at week two, and decreased by 0.02 to  $-0.41 \pm -0.18$ 

logMAR at week four and by 0.034 to  $0.42 \pm 0.19 \log$ MAR at week six.

By week two, 82.4 per cent of patients achieved uncorrected distance visual acuity of 6/6 or better, and this increased slightly to 85.7 per cent at week four (Figure 4). There was minimal change in the percentage of patients achieving 6/6 or better between weeks four and six (85.2 per cent). The percentage of patients achieving uncorrected distance visual acuity of 6/5 or better

continued to increase throughout the study period, increasing from 9.5 per cent at week two to 11.1 per cent by week four and to 14.8 per cent by week six (Figure 4). There was little or no change in the percentage of patients achieving uncorrected distance visual acuity 6/9 or better, or 6/12 or better throughout the study period, with all patients achieving uncorrected distance visual acuity 6/9 or better by six weeks post-operatively (Figure 4).

# **Quality of life**

Quality of life was assessed using a short questionnaire in order to determine the impact of uncorrected near vision on everyday activities. At week two, 61.1 per cent of those who responded stated that their uncorrected near vision was affecting their ability to do chores somewhat or a lot, with 11 patients indicating their vision was affecting their quality of life 'a lot', 33 responding 'somewhat', 28 responding 'not at all' and two giving no answer (Table 1).

At week four the respondents indicating their quality of life was affected 'somewhat' or 'a lot' increased to 81.7 per cent, with eight patients indicating their vision was affecting their quality of life 'a lot', 41 responding 'somewhat', 11 responding 'not at all' and five giving no answer (Table 1).

There was no relationship between reported quality of life and pre-operative refraction (whether the patient was hyperopic, myopic or emmetropic before surgery) ( $\chi^2 = 1.55$ , p = 0.818) or whether the patient was phakic or pseudophakic in the companion eye ( $\chi^2 = 3.77$ , p = 0.152).

#### **Discussion**

The aim of this study was to better understand current guidelines for spectacle prescription following cataract surgery in order to improve the quality of life for patients within the appropriate post-operative period. With cataract surgery being performed on younger, pre-retirement patients and with increased dependence on near vision in the digital age, optimising vision at the earliest opportunity would be of benefit. Stable refraction, visual acuity and corneal thickness were achieved within two weeks post-surgery for an Australian cohort receiving monofocal IOLs in the public health care system, suggesting that spectacles can safely be prescribed from two weeks post-

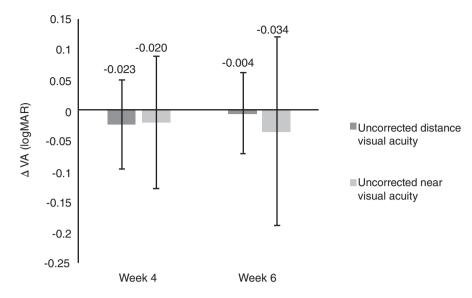


Figure 3. Change in uncorrected distance (UDVA) and near (UNVA) visual acuity from two weeks and then at four and six weeks following cataract surgery. Error bars represent  $\pm 1$  standard deviation.

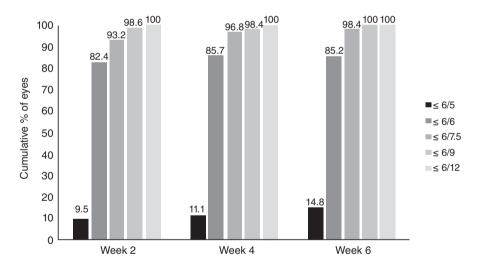


Figure 4. Cumulative percentage of patients achieving each visual acuity score or better at post-operative two, four and six weeks

Impact on quality of life	Week 2	Week 4
A lot	11 (15.3%)	8 (13.3%)
Somewhat	33 (45.8%)	41 (68.3%)
Not at all	28 (2.8%)	11 (18.3%)
No answer	2	5

Table 1. Patient responses to the quality of life questionnaire assessing the impact of uncorrected near visual acuity on everyday tasks. Responses are shown as raw numbers and as a percentage of total responses.

cataract surgery rather than the four weeks waiting period currently recommended.

Factors that are important in recovery of clear, stable vision post-cataract surgery include resolution of corneal oedema, intra-ocular inflammation, and stabilisation of corneal astigmatism.<sup>1</sup> With modern techniques of phacoemulsification and foldable IOLs becoming the current standard of care in the Australian health care setting, incision sizes have become smaller, and with smaller incisions comes less induced astigmatism that may take less time to stabilise.<sup>2</sup>

This study excluded patients who required corneal sutures as they can introduce higher amounts of astigmatism. However, any cataract surgery can induce refractive changes that can take time to stabilise. To determine the time it takes for refraction to stabilise, both automated and subjective refraction were measured. Subjective refraction was used as the primary outcome for this study as it is considered the gold standard for measurement of refraction and is the basis of spectacle prescription.<sup>10</sup> However, the process of subjective refraction is time-consuming and the accuracy is dependent on the skill of the clinician performing the refraction. Automated refraction provides a rapid and convenient measurement and generally correlates well with subjective refraction in pseudophakes with monofocal IOLs where accommodation is negligible.11

In this study, there was a moderately strong positive correlation between automated and subjective refraction (R = 0.75, p < 0.001), although automated refraction gave a more positive spherical equivalent at post-operative six weeks compared to subjective refraction (Figure 1). This suggests that although caution should be taken when using automated refraction to directly measure post-operative refraction, it offers an accurate and convenient method for monitoring post-operative refractive stability. However, automated refraction is not a suitable substitute for subjective refraction in the prescription of spectacles.

Although this study utilised spherical equivalent refraction which cannot distinguish between spherical and astigmatic error, the results show that both subjective and automated spherical equivalent refractive error remain stable from two weeks following surgery when minimally invasive surgical techniques are used (Figure 1). Similar findings of stable refraction within shorter time periods following surgery have

been reported in the literature by a number of other studies including Sugar et al.<sup>12</sup> and Caglar et al.<sup>4</sup> However, little literature is available regarding stabilisation times in the Australian context.

While this study does not directly compare stabilisation times following large and small incision procedures when performed within the Australian population, the results indicate a stabilisation time following small-incision surgery similar to that previously reported. To directly compare stabilisation times following large and small incision procedures performed within the Australian population, further studies will need to be performed.

There was a gradual but insignificant  $(p_{eq} < 0.001)$  decrease in mean corneal thickness across the study period (Figure 2), indicating that by week two, the corneal thickness had stabilised effectively in the study population. As pre-operative corneal thickness does not significantly differ from final post-operative thickness, 12 it may be used as an indication that refraction and visual acuity are likely to be stable when corneal thickness approaches pre-operative values. Pre-operative corneal thickness was not measured for this study as participants were recruited on day one following surgery. However, the stability in corneal thickness from weeks two to four suggests that any post-operative corneal oedema had resolved within two weeks following surgery.

Considering that corneal oedema can impact visual acuity, pachymetry is a safe, simple and useful measurement that may provide some objective measure to help determine when surgical outcomes have stabilised sufficiently to allow spectacle prescription, particularly for patients with ocular co-morbidity or post-operative complications. Although there was no correlation between change in post-operative corneal thickness and uncorrected distance visual acuity (p > 0.05), uncorrected visual acuity also remained stable from postoperative two weeks, with no change in uncorrected distance visual acuity or uncorrected near visual acuity over the study period (Figure 3). Furthermore, the proportion of patients achieving 6/6 uncorrected distance visual acuity or better peaked by four weeks post-operatively at 85.7 per cent and changed little from weeks four to six (Figure 4).

The benefits of early spectacle prescription include improved near vision and also

decreased anisometropia at distance.<sup>12</sup> This has implications for ocular comfort and allows for the patient to return to activities that require fine vision. In this case with a target refraction of emmetropia, care was taken pre-operatively to explain to the patients that their near vision was likely to be adversely affected for the four weeks until they were eligible to receive spectacles.

At weeks two and four, patients were asked if their uncorrected near vision was impacting on their ability to perform work duties, chores or hobbies. The majority of participants within this study reported that poor near vision negatively affected their ability to perform such tasks, with more patients reporting difficulty at later postoperative time points, for example at four weeks (81.7 per cent) versus two weeks (61.1 per cent) post-operatively (Table 1). Although it is unclear whether this trend is a result of increased frustration experienced by the patients or changes in the activities in which they participated, it does suggest that the impact on the quality of life becomes greater with time following surgery as their independence and productivity becomes affected.

Factors that may influence patient satisfaction include pre-operative refraction and previous cataract surgery. Myopes were counselled pre-operatively and were given a choice as to whether they preferred to have unaided distance or near vision, with most opting for emmetropia. Although such patients are generally happy with their distance vision, they often struggle to adjust to having poor uncorrected near vision. Additionally, patients who have only undergone surgery in one eye may develop anisometropia during the period between the surgeries, to which it may prove difficult to adapt. However, both these factors can be excluded as there was no relationship found with patient satisfaction (p > 0.05). This may be due to the absence of patients with high myopia or hyperopia in the cohort. Although such patients were not deliberately excluded from the study, the majority of patients had mild to moderate hyperopia or myopia, thereby potentially skewing the cohort toward patients who may experience more subtle changes in vision or may be more tolerant of anisometropia.

Some limitations have been identified for this study. Corneal thickness was not measured pre-operatively, which would have allowed any correlation between pre- and post-operative corneal thickness to be identified, elucidating whether corneal thickness could be used as a reliable measure of corneal or refractive stability.

Refraction was not recorded on day one following surgery. This meant that changes in refraction could not be measured within the first two weeks of the post-operative period, and that refraction may have stabilised even earlier than what is currently reported. However, there was no significant change in visual acuity from two to four weeks post-operatively, so it is reasonable to suggest that patients can be eligible for prescription of glasses from two weeks following surgery. It should also be noted here that refractive spherical equivalent does not directly correspond with visual acuity if the amount of astigmatic error is significant. Therefore, while stability in refractive spherical equivalent can be a good indication of visual stability, it cannot be used to infer visual outcomes.

Under current Australian Medicare guidelines, measurement of refraction and dispensing of spectacles does not attract reimbursement within the four weeks following surgery. This timeframe is based on reported recovery times following conventional large incision cataract surgery<sup>13</sup> and has not been revised as surgical advancements have occurred. These results show that using current surgical techniques, refraction, visual acuity and corneal thickness can be stable up to two weeks earlier than the current spectacle waiting period, and therefore the delay in spectacle prescription is unnecessary and may negatively impact quality of life in the post-operative period.

In conclusion, this study adds further evidence that the prescription guidelines may safely be revised to allow for the earlier prescription of reading glasses for patients receiving monofocal IOLs from two weeks following surgery, given there are no other ocular pathologies or complications.

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