Original Article

Evaluation of the World Health Organization outcome standards at the early and late post-operative visits following cataract surgery

Jay J Meyer[1,2], Neil L Murray[1,3]
[1]Fred Hollows Foundation New Zealand, Auckland, New Zealand
[2]New Zealand National Eye Centre, Faculty of Medical and Health Sciences, University of Auckland, Auckland, New Zealand.
[3]Rotorua Eye Clinic, Rotorua, New Zealand

Abstract

Introduction: This study was conducted to determine whether the World Health Organization (WHO) visual acuity standards are correlated between the early and late early post-operative periods following phacoemulsification (phaco) and small incision extracapsular cataract surgery (SICS). Secondary aims were to compare visual outcomes and complications following SICS and phaco.

Methods: Retrospective cohort study following phaco and SICS performed by one surgeon. Primary outcome measures included uncorrected visual acuity (UCVA) and best corrected visual acuity (BCVA) at the early (≤72 hours) and late (≥21 days) post-operative visits. Secondary outcome measures included complications and astigmatism.

Results: 705 eyes were studied (509 phaco, 196 SICS). The correlation for UCVA between early and late follow-up examinations was higher for phaco (r_s=0.58) compared to SICS (r_s=0.45, p=0.04) while correlation for BCVA was similar (phaco, r_s=0.52; SICS, r_s=0.47; p=0.44). At the early post-operative visit, a higher proportion in the phaco group achieved ≥6/18 UCVA (81.5% phaco vs 64.8% SICS, p<0.0001) and BCVA (87.8% phaco vs 73.5% SICS, p<0.0001). At the late post-operative visit, a higher proportion following phaco also achieved ≥6/18 UCVA (93.9% phaco vs 85.2% SICS, p=0.0004) and BCVA (96.9% phaco vs 91.3% SICS, p=0.004). After exclusion of eyes with pre-existing ocular comorbidities, a similar proportion had ≥6/18 late UCVA (98.9% phaco vs 96.9% SICS, p=0.22) and BCVA (100% phaco vs 99.2% SICS, p=0.27).

Conclusions: Early and late post-operative WHO visual acuity levels are correlated, but not equivalent, following both phaco and SICS. In eyes without comorbidities, similar final visual outcomes can be achieved after phaco and SICS.

Key words: Astigmatism, Phacoemulsification, MSICS, SICS, Small incision cataract surgery.

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Corresponding author
Jay J. Meyer, MD, MPH
Department of Ophthalmology
Private Bag 92019, University of Auckland
Auckland, New Zealand.
Tel.: 64 9 373 7599 ext 86712
Fax: 64 9 367 7173
E-mail: jay_meyer@rocketmail.com

Introduction

Cataract is the leading cause of blindness worldwide, accounting for half of all cases (Pascolini & Mariotti, 2010). The only cure is surgery although access to surgery is not equitably available worldwide as the majority of those blind due to cataracts live in the developing world (Brian & Taylor, 2001; Pascolini & Mariotti, 2010). Cataract surgery outcomes and complication rates may be suboptimal in some regions of the world (Thapa et al, 2011; Nangia et al, 2011; Huang et al, 2011; Zhao et al, 2010). An important component of quality assurance is the auditing of surgical results. However, monitoring surgical outcomes in developing settings may be limited by low post-operative follow-up rates (Limburg et al, 2005; Huang et al, 2011).

The World Health Organization (WHO) has promoted a qualitative outcome standard of "good" uncorrected visual acuity of ≥6/18 in 80% of post-operative patients. This standard relies on visual acuity being tested between discharge and 12 weeks post-operatively (WHO, 1998). In areas with low return of patients for post-operative exams, one option is to use early acuity when comparing visual acuity results to the proposed standard, as the majority of patients are usually available or return for post-operative day one examinations. Correlation between visual acuity at the first post-operative exam and final acuity was found in a large, multicenter study although analysis by method of cataract extraction was not reported (Congdon et al, 2013).

The primary aim of this study was to determine whether early post-operative visual assessment at the WHO standard levels was predictive of final visual acuity following small incision cataract surgery (SICS) and phacoemulsification (phaco) in a developed setting with a high rate of return for final follow-up. The secondary aims were to compare the visual outcomes and complications following SICS and phaco.

Subjects and Methods

This was a retrospective cohort study of all consecutive eyes undergoing cataract surgery between 1 January, 2011 and 30 September, 2014 by one of the study authors (NLM) in New Zealand. Eyes were only included if they received an early post-operative examination within 72 hours and a late post-operative examination ≥21 days following surgery. Eyes were excluded if visual acuity could not be accurately measured or the refractive target was not within 1.5 D of emmetropia. Written informed consent was obtained from all subjects, and the tenets of the Declaration of Helsinki were followed. This study was approved by the Lakes District Health Board Research and Ethics Committee, New Zealand.

Preoperative testing included visual acuity, refraction, slit lamp and fundus examinations. Biometry measurements were performed using the IOLMaster (Carl Zeiss Meditec, Dublin, CA, USA). When axial length measurements could not be obtained using the IOLMaster, measurements were taken using an A-scan ultrasound (Tomey AL1000, Nagoya, Japan) by applanation. Pre-operative and post-operative keratometry measurements were taken using the IOLMaster. Denser cataracts based on a grading system (Thylefors et al, 2002) (WHO/PBD nuclear grade 3, mature or hypermature) were routinely removed using SICS whereas all others received phaco. The surgeon was experienced in both techniques. The same type of foldable, single-piece, acrylic intraocular lens (IOL) (Tecnis ZCB00, Abbott Medical Optics, Santa Ana, CA, USA) was used for all cases.

Phaco surgery was performed through a 2.6mm temporal clear corneal incision by sculpting the nucleus, cracking it into segments, and phacoemulsifying until it was completely removed. Cortex was removed using an automated irrigation/aspiration hand piece. Viscoelastic was injected followed by the

IOL in the capsular bag. The viscoelastic was removed and cefuroxime was injected intracamerally. Sutures were not routinely used to close the incision.

SICS was performed through a temporal conjunctival peritomy and a frown-shaped scleral incision located approximately 2mm posterior to the limbus. A sclerocorneal tunnel was created with an external opening of 5 to 8mm (depending on the size of the nucleus) and internal opening of up to 9mm. The anterior capsule was stained with trypan blue dye in cases with a poor red reflex. A side port was created and the anterior chamber was filled with viscoelastic. A large, continuous, curvilinear capsulorrhexis was torn with relaxing incisions as needed. Hydrodissection was performed and the nucleus was expressed and rotated out of the capsular bag. The nucleus was extracted using a Simcoe irrigation/aspiration cannula placed through the wound behind/underneath the nucleus to express it through the incision. The Simcoe cannula was used to remove cortex. The capsular bag was filled with viscoelastic followed by placement of the IOL within the capsular bag. The viscoelastic was removed, conjunctiva reapproximated, and cefuroxime given intracamerally.

Primary outcome measures included: uncorrected visual acuity (UCVA) and best corrected visual acuity (BCVA) at the early (≤72 hours) and late (≥21 days) post-operative visits. A visual acuity chart at 6m was used. Early BCVA was estimated using pinhole visual acuity and late BCVA was determined by non-cycloplegic refraction. Secondary outcome measures included intraoperative and post-operative complications.

Visual acuity data were log-transformed (LogMAR). The Spearman's rank correlation coefficient (r_s) was used to assess the correlation between early and late post-operative visual acuity. The Fisher r-to-z transformation was used to determine the significance of the difference between correlation coefficients. The Fisher's exact test was used to compare proportions. To compare means of normally distributed data, the Student's t-test was used, while the Mann-Whitney U test was used to compare non-normally distributed data. Data were analysed using SPSS version 19 statistical software (SPSS Inc., Chicago, IL, USA) and Microsoft Office Excel 2010 (Redmond, Washington, USA).

Results

During the study period, 912 eyes underwent phaco or SICS. Of these, 11 received the early post-operative exam more than 72 hours following surgery, 5 did not return for follow-up after the first post-operative visit, and 179 eyes (113 phaco, 66 SICS) received the final examination within 21 days following surgery. Additionally, 8 eyes did not receive an IOL targeting emmetropia (within 1.5 D), acuity was unable to be accurately assessed for 3 eyes, and 1 eye received intracapsular cataract extraction. A total of 705 eyes met the inclusion criteria, of which 509 underwent phaco and 196 SICS. Patients undergoing SICS were older (mean 76.5 ±12.1 years) compared to those that underwent phaco (mean 73.0 ±10.8 years) ($p<0.001$; Table 1).

Preoperatively, eyes in the SICS group had worse corrected visual acuity compared to the phaco group ($p<0.0001$; Table 2).

The mean time between surgery and the early post-operative visit was 1.2 ±0.6 days after phaco and 1.1 ±0.3 days after SICS ($p<0.001$). The median time between surgery and the late post-operative visit was 43 days following phaco and 40 days following SICS ($p=0.07$). Pre-operative and post-operative biometric and refractive measurements are shown in table 3.

Axial length measurements were performed using A-scan ultrasound for 5.5% of eyes that underwent phaco and 38.5% SICS ($p<0.001$) with the remainder obtained using the

IOLMaster. Mean keratometry values were not significantly different pre-operatively or post-operatively. Mean post-operative keratometric cylinder was slightly higher in the SICS group although mean refractive cylinder was not statistically different. In the phaco group, the spherical equivalent of the refraction at the late post-operative visit was within 0.5 D, 1.0 D, and 2.0 D of intended for 81.2%, 95.1%, and 99.4% of eyes; and in the SICS group for 74.5%, 94.5%, and 99.5% of eyes, respectively.

The correlation for UCVA between early and late follow-up examinations was higher for phaco (r_s=0.58; p<0.001) compared to SICS (r_s=0.45; p<0.001) (phaco vs. SICS, p=0.04). The correlation for early and late follow-up measurements of BCVA was similar: phaco (r_s=0.52; p<0.001) and SICS (r_s=0.47; p<0.001) (phaco vs. SICS, p=0.44).

A higher proportion of eyes obtained a good visual outcome (6/18 or better) at the late post-operative visit compared to the early visit in both the phaco and SICS groups. A lower proportion of eyes had a borderline (between 6/18 and 6/60) or poor (less than 6/60) visual outcome at the late post-operative visit in the phaco and SICS groups. Over 50% of eyes with <6/60 visual acuity (corrected and uncorrected) of at the early visit had improvement to 6/60 or better at the later visit. The trend of improved uncorrected and corrected visual acuity over time was seen in both the phaco and SICS groups (Table 4).

At the early post-operative visit, a higher proportion of the phaco group obtained 6/18 or better for UCVA (81.5% phaco vs 64.8% SICS, p<0.0001) and BCVA (87.8% phaco vs 73.5% SICS, p<0.0001). At the late post-operative visit, a higher proportion of the phaco group also achieved 6/18 or better for UCVA (93.9% phaco vs 85.2% SICS, p=0.0004) and BCVA (96.9% phaco vs 91.3% SICS, p=0.004). The final mean uncorrected logMAR visual acuity in the phaco group was 0.18 (20/30) compared to 0.29 (20/39) in the SICS group, (p=0.001). The final mean corrected logMAR visual acuity was 0.08 (20/24) in the phaco group and 0.17 (20/30) in the SICS group (p=0.006).

In the phaco group, 29.7% had pre-existing ocular comorbidities felt to impact the vision compared to 33.2% of the SICS group (p=0.36). The major ocular comorbidities of the phaco group were: age related macular degeneration (58.9%), diabetic maculopathy (12.6%), amblyopia (9.3%), epiretinal membrane (6.6%), glaucoma (4.0%), retinal vein occlusion (2.6%), and 1% or less due to other conditions. The ocular comorbidities of the SICS group were: age related macular degeneration (61.5%), epiretinal membrane (12.3%), corneal scar (6.2%), amblyopia (4.6%), glaucoma (4.6%), diabetic maculopathy (3.1%), and 1% or less due to other conditions. After exclusion of those eyes with pre-existing ocular comorbidities, there were similar proportions of eyes with 6/18 or better final UCVA (98.9% phaco vs 96.9% SICS, p=0.22) and BCVA (100% phaco vs 99.2% SICS, p=0.27).

In the phaco group, there were three intraoperative complications (2 posterior capsular ruptures, 1 retained nuclear lens fragment in anterior chamber) and 5 eyes with post-operative complications (5 cystoid macular oedema). In the SICS group, there were 2 eyes with intraoperative complications (1 posterior capsular rupture, 1 iris trauma) and 5 eyes with post-operative complications (2 endophthalmitis, 1 retinal detachment, 2 cystoid macular oedema). Of the 4 eyes with final BCVA <6/60 following phaco, all had pre-existing ocular disease that accounted for the poor vision (2 macular degeneration, 2 central retinal vein occlusion). Of the 8 eyes with final BCVA <6/60 following SICS, 7 had a pre-existing ocular disease that accounted for the decreased vision (4 macular degeneration, 1 central retinal vein occlusion, 1 prior stroke, 1 phacomorphic glaucoma). One patient had a

poor final visual outcome following SICS due to post-operative endophthalmitis. There were no cases of corneal decompensation in either group.

Analysis of the eyes excluded due to late post-operative follow-up occurring prior to 21 days (n=179) was performed. There were no significant differences in the proportions of eyes with visual acuity of ≥6/18, <6/18 to 6/60, and <6/60 when comparing excluded eyes to non-excluded eyes within the phaco and SICS groups.

Table 1: Demographic characteristics of patients

Gender	**All patients (n=705)**	**Phaco (n=509)**	**SICS (n=196)**
Female	390 (55%)	276 (54%)	114 (58%)
Age Group (years)			
≤50	27 (3.8%)	23 (4.5%)	4 (2.0%)
51-60	65 (9.2%)	51 (10.0%)	14 (7.1%)
61-70	163 (23.1%)	124 (24.4%)	39 (20.0%)
≥71	450 (63.8%)	311 (61.5%)	139 (70.9%)

Table 2: Pre-operative visual acuity with and without correction

Pre-operative Visual Acuity				
	Phaco (n=509)		**SICS (n=196)**	
	Uncorrected	**Corrected**	**Uncorrected**	**Corrected**
<6/60	70 (13.8%)†	27 (5.3%)*	100 (51.0%)†	83 (42.3%)*
<6/18 to 6/60	199 (39.0%)	105 (20.6%)*	79 (40.3%)	72 (39.8%)*
≥6/18	240 (47.2%)†	377 (74.1%)*	17 (8.7%)†	41 (5.6%)*

*p<0.0001 when comparing proportion of eyes with corrected acuity level in phaco group with SICS group.
†p<0.0001 when comparing proportion of eyes with uncorrected acuity level in phaco group with SICS group

Table 3: Pre-operative and post-operative mean biometric and refractive measurements

	Phaco	**SICS**	**p-value**
Axial Length	23.69 ± 1.29 mm	23.43 ± 0.96 mm	0.005
Mean Pre-op Keratometry values	43.83 ± 1.60 D	43.88 ± 1.46 D	0.70
Mean Pre-op Keratometric Cylinder	1.10 ± 0.86 D	1.14 ± 0.89 D	0.62
Mean Post-op Keratometry values	43.67 ± 1.60 D	43.80 ± 1.45 D	0.31
Mean Post-op Keratometric Cylinder	1.06 ± 0.85 D	1.21 ± 0.85 D	0.04
Mean Post-op Refractive Cylinder	0.98 ± 0.78 D	1.09 ± 0.78 D	0.10

Table 4: Uncorrected and corrected visual acuity at early and late post-operative visits

Uncorrected	**Phaco (n=509)**			**SICS (n=196)**		
Visual Acuity	**Early**	**Late**	**P-Value**	**Early**	**Late**	**P-Value**
<6/60	16 (3.1%)	4 (0.8%)	0.0110	20 (10.2%)	9 (4.6%)	0.0520
<6/18 to 6/60	78 (15.3%)	27 (5.3%)	<0.0001	49 (25%)	20 (10.2%)	0.0002
≥6/18	415 (81.5%)	478 (93.9%)	<0.0001	127 (64.8%)	167 (85.2%)	<0.0001
Corrected Visual Acuity						
<6/60	15 (2.9%)	4 (0.8%)	0.0181	19 (9.7%)	8 (4.1%)	0.0443
<6/18 to 6/60	47 (9.2%)	12 (2.4%)	<0.0001	33 (16.8%)	9 (4.6%)	<0.0001
≥6/18	447 (87.8%)	493 (96.9%)	<0.0001	144 (73.5%)	179 (91.3%)	<0.0001

Discussion

The world's growing and aging population will result in a continued increase in the number of individuals blind from cataracts in areas with low surgical coverage. There is a need for not only an increase in the number of cataract surgeries performed, but also for improvements in the quality of surgery in order to optimize outcomes in many parts of the world. The evaluation of outcomes in the developing world should employ benchmark standards that are evidence-based and relevant. The data from this study add to the limited current literature describing visual outcomes over time following SICS and allow comparison with a reference population undergoing phacoemulsification.

There was moderate correlation between early and late post-operative UCVA in both the SICS and phaco groups. Eyes in the phaco cohort met the previously proposed standard for a "good" surgical outcome (>80% with 6/18 or better) at both the early and late visits. However, eyes in the SICS cohort only reached this standard at the late post-operative visit. This suggests that the use of this standard would not be an appropriate metric when evaluating early (within 3 days) post-operative visual acuity following SICS.

The PRECOG study was a large, multi-center, multi-national study that found a similar, but slightly higher degree of correlation for early and late UCVA (Congdon et al, 2013). There are, however, some notable differences between PRECOG and the present study. The PRECOG study included pooled data from cataract extraction performed by SICS (63%), phaco (21%) and ECCE (16%) and excluded eyes with visually significant comorbidities diagnosed preoperatively. Late post-operative visual acuities (corrected) were missing for 10% of eyes. Also, PRECOG defined the lowest level of vision as 6/60 or worse, whereas "poor" vision is less than 6/60 according to the definition from the WHO (WHO, 1998) and also used in this study.

Previous data has shown that less than half of some patient populations return for follow-up unprompted (Limburg et al, 2005). While the use of early visual acuity could be used as a metric for evaluating results following SICS, the results of this study suggest that different criteria should be used when evaluating early and late acuity since the acuity levels at these time periods show correlation, but are not equivalent. A study in rural Indonesia also found that a significantly lower percentage of eyes obtained a visual acuity of 6/18 or better on the first post-operative day compared to the final visit, although 20% did not return for the final examination (Bani et al, 2012). The current study had a high post-operative follow-up rate (>99%), as only five of 915 eyes were excluded for lack of follow-up.

There are limited data comparing SICS to phaco with the available reports limited to a handful of trials, mainly in settings where high volume SICS is routinely performed on mature cataracts. Analysis of pooled results from these trials showed that phaco, in the short term, may result in similar BCVA and better UCVA compared to SICS (Riaz et al, 2013). There are no long term data from randomized, controlled trials comparing the techniques although posterior capsule opacification may be higher and reduce the long term vision following SICS (Ruit, 2007). A randomized trial in Nepal used an "expertise-based trial design" whereby patients were randomized to an expert in either surgical technique (Wormald, 2007). A unique and key feature of the current study is that the sole surgeon is proficient in both phaco and SICS techniques, having had extensive and ongoing experience performing SICS (Murray & Murray, 2009). A limitation of this study is the retrospective nature and lack of randomization to phaco or SICS, which limits the comparability of the two groups and surgical techniques.

The early and late visual outcomes (both uncorrected and corrected) were better for the phaco group compared to the SICS group. This finding is not unexpected given that more dense cataracts were removed using the SICS technique and the older mean age and higher proportion of co-existing ocular pathology of this cohort. When eyes with pre-existing ocular pathology were excluded, there were no significant differences in the final uncorrected and corrected acuity levels between the two groups. Slightly more keratometric astigmatism was measured post-operatively in the eyes following SICS. Surgically induced astigmatism has been shown to be slightly higher following SICS compared to phaco in some studies (George et al, 2005; Cook et al, 2012; Venkatesh R, 2012).

A common cause of poor outcomes in developing countries is post-operative refractive error (Thapa et al, 2011; Nangia et al, 2011; Huang et al, 2011; Limburg et al, 2005; Zhao et al, 2010). The WHO standards for evaluating vision following cataract surgery specify different visual acuity cutoffs for "available" correction and "best" correction (WHO, 1998). The visual acuity measured with available correction (the presenting vision) is often interpreted as the uncorrected visual acuity since many patients cannot afford or do not have access to spectacles for distance correction. Because of the reduced likelihood of post-operative vision being optimized with distance spectacles in the developing world, it is important to obtain the best possible refractive results. A UK study has promoted a post-operative refractive benchmark of >85% within 1.0 D following phaco (Gale et al, 2009). There is no such benchmark for SICS.

A strength of this study is the relatively low amount of post-operative refractive error in the studied eyes. Greater than 90% of all eyes (phaco and SICS) achieved a spherical equivalent refraction within 1.0 D of the target (emmetropia was targeted for >98%), easily meeting the UK phaco benchmark. This was despite A-scan ultrasound axial length measurement being necessary for over one-third of the eyes receiving SICS. Because of the relatively low amounts of post-operative refractive error in this study, the lower visual acuity levels at the early post-operative visit compared to those of the late visit can be mostly attributed to the trauma of surgery followed by recovery.

Patients were not excluded on the basis of visually significant ocular comorbidities diagnosed preoperatively or post-operatively. We chose to not exclude eyes with concomitant ocular disease as many of these diseases are not detectable preoperatively due to a limited view of the fundus. The inclusion of all patients, regardless of pre-existing ocular disease, also provides a better representation of outcomes that could be realistically expected or obtained for a general population. Pre-existing eye disease was the main vision-limiting factor post-operatively for eyes in this study and the visual outcomes from this study may not be generalizable to other populations with significantly different rates of ocular comorbidities.

Another limitation of our study results was the exclusion of eyes of patients who did not have a "late" post-operative visit after 3 weeks, as some patients routinely returned just within three weeks. Further subgroup analysis did not identify any significant differences in visual acuity levels of this excluded group when compared to non-excluded eyes. The late post-operative visit after three weeks was chosen because visual acuity has been shown to be relatively stable after three weeks following extracapsular cataract extraction and SICS (Bani et al, 2012).

The data in this study describe a "best-case scenario" as there was good follow-up (unprompted), biometry equipment to

obtain accurate and precise measurements, standardized surgery (one surgeon proficient in both techniques), a low complication rate, modern operating equipment and supplies (i.e. viscoelastic), a wide selection of IOL powers, and standardized visual acuity measurement. Additionally, the surgery was performed in a health system where surgery can be provided free of charge, reducing affordability selection bias. This study adds to the limited current literature by describing early and late visual and refractive outcomes following SICS, referenced to phaco outcomes, and may be of value as benchmarks. Also, the data support the validity of the PRECOG study's correlation between early visual acuity assessment and unprompted late assessment.

Conclusions

Early and late post-operative visual acuity levels are moderately correlated following both phaco and SICS. If using the previously proposed WHO standard for a "good" UCVA outcome (>80% with 6/18 or better), the late visit data may be more appropriate following SICS given worse correlation between early and late visits in this cohort. The use of this outcome standard may be appropriate at either the early or late visits following phaco given better correlation between the early and late visits. In eyes without significant comorbidities, similar final visual outcomes can be attained after phaco and SICS.

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