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Outcome of the Manual Small Incision Cataract Surgery at the Base Hospital and Improved Surgical Eye Camps in Nepal: A Prospective Observational Comparative Study

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Abstract

A prospective observational comparative case study on the outcome of manual small incision cataract surgery (SICS) at the base hospital and improved surgical eye camps in FarWestern region in Nepal was conducted during June and November 2010. A total of 445 cataract patients aged above or equal to 40 years without coexisting ocular pathologies were recruited and operated with SICS. Patients were examined on the first day of surgery and followed up after one week and again after 4 to 6 weeks. The uncorrected and best corrected visual acuity (VA) with pinhole was recorded on day one and after one week. Refraction and kerotometry was done at 4 to 6 weeks follow up. Comparison of the uncorrected and best corrected postoperative visual acuity at base hospital with surgical eye camps was done at 4 to 6 weeks. Of the 221 cases operated at base hospital 189 (85.5%; 95% Confidence Interval (CI): 80.9 - 90.2) and of the 224 cases operated at camps 202 (90.2%; 95% CI: 86.3 - 94.1) were available at the follow up period of 4 to 6 weeks. The VA improved significantly at one week and 4 to 6 weeks follow up in both the groups. A comparative analysis of two surgical set-ups showed no significant difference of uncorrected (p = 0.400) and best corrected (p = 0.580) VA in the operated eye at 4 to 6 weeks follow up time respectively. The surgical complications were low in both the settings; 8 out of 221 (3.6%; 95% CI: 1.2 – 6.1) at base hospital and 3 out of 224 (1.3%; 95% CI: 0.0 – 2.8) in camps and did not differ significantly (p = 0.580). Cataract surgery at surgical eye camps with improved settings offers safe and noticeably good outcome, equivalent to that of the hospital set-up if the appropriate surgical protocol is maintained and surgery is performed by an experienced ophthalmic surgeon in the western region in Nepal.

Keywords: Manual small incision cataract surgery; Eye camps; Visual outcome; Prospective comparative study; Nepal

Introduction

Cataract is the leading cause of blindness globally, except in the few most developed countries, despite improvement in the cataract surgical techniques and cost-effective intervention programs [1,2]. It was estimated that 314 million people are visually impaired worldwide; 45 million of them were blind due to different causes, and 39.1% of the global blindness was due to cataract [1,2]. Increasing life expectancy and low uptake of cataract surgical services in the developing countries contribute to the increased burden of untreated cataract patients.

Cataract still remains the leading cause of blindness in Nepal. According to the National Blindness Survey conducted in Nepal during the years 1980 and 1981, the prevalence of blindness was estimated to be 0.84% (best corrected VA<3/60 in the better eye), with cataract being the leading cause of blindness accounting for 66.8% of the total blindness [3]. Another study conducted in the Gandaki zone of Nepal reported the prevalence of blindness (presenting VA <6/60 in the better eye) of 2.6% in the population aged \geq 45 years and the cataract accounted for 61% of the total blindness. Another study conducted in the Lumbini zone in Chitwan district of Nepal reported the prevalence of blindness of 4.6% among of \geq 50 years old and again cataract comprised of 48% of it [4]. Studies reported earlier from Nepal showed that Extracapsular cataract surgery (ECCE) performed in eye camps gave unacceptable outcomes because of a high rate of capsular rupture and posterior capsular opacification [5].

Due to the geographical variation, poor socioeconomic conditions and poor transportation facilities, less accessibility and affordability of eye care services by the rural population and in particular less privileged community, offering the eye care services through hospital-based facility is a great challenge in countries like Nepal. Most of the rural population living in Nepal is widely scattered among the mountains and hilly villages, which are accessible by only foot. Community based outreach activities can be a good alternative solution for the elimination of avoidable blindness in such scenario. Most eye hospitals in the country provide surgical eye care services in the remote districts through surgical eye camps which are the only alternative. Most of the camps conducted in Nepal are predominantly provide the cataract surgery of type Manual Small Incision Cataract Surgery (SICS) with intra ocular lens implantation (IOL). Randomized controlled studies conducted earlier from India reported that SICS which involves the removal of nucleus through a scleral tunnel through a 6.5 mm incision offered the effective rehabilitation of cataract patients [6,7]. Though phacoemulsification has become the biggest surgical achievement of the last two decades, majority of surgeons in developing world are still not practicing it due to its limitations such as long and risky process and it requires expensive and complex equipments [8].

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Received August 13, 2011; Accepted September 06, 2011; Published September 10, 2011

Citation: Bhatta RC, Krishnaiah S, Pant BP, Sapkota YD (2011) Outcome of the Manual Small Incision Cataract Surgery at the Base Hospital and Improved Surgical Eye Camps in Nepal: A Prospective Observational Comparative Study. J Clinic Experiment Ophthalmol 2:186. doi:10.4172/2155-9570.1000186

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In many countries surgical eye camps are uncommon and not the standard practice and there is a debate on the continuation of the surgical camps. Hospital based randomized clinical trial of Phacoemulsification versus SICS conducted earlier in Nepal reported that SICS may be a more appropriate procedure for the treatment of advanced cataracts in the developing world [9]. The present study was designed to determine if the visual outcome and surgical complications of SICS performed in eye camps are comparable with that of base hospital set up in Nepal.

Materials and Methods

A prospective observational comparative study following a cataract surgical intervention was conducted in the Far Western region of Nepal. Ethics approval was obtained from the Institutional Research Review Board of the Nepal NetraJyothiSangh, Kathmandu, Nepal and the Institutional Review Board of L V Prasad Eye Institute, Hyderabad, India prior to the commencement of the study. The study was conducted in accordance with the tenets of the Helsinki declaration during the period June and November 2010. Written informed consent was obtained from all the participants after explained to them about the purpose of the study. A total of 224 patients were selected from three surgical eye camps and 221 patients were selected from the base hospital on the first day after surgery using the inclusion and exclusion criteria that explained in one of the following sections.

Study areas

One base hospital namely Geta Eye Hospital in Kailali and three surgical eye camps in the Far Western region of Nepal were selected for the purpose of the study. Three surgical eye camps selected for the study were in two hilly remote districts namely Dadeldhura and Doti of the Far Western region of Nepal. The three surgical eye camp sites were: one higher secondary school, second one the Red Cross Society and the third on was a government district hospital where temporary operation theaters were prepared for surgery. These areas chosen for the study purpose would roughly reflect the socioeconomic distribution of the entire population in such a way that the study findings can be generalized to the entire Nepal.

Inclusion and exclusion criteria

The study has included the patients operated for cataract using the SICS procedure and aged above or equal to 40 years, agreed to participate in the study and gave their informed consent, and surgeries performed by an experienced Ophthalmologist. The study excluded the patients who had been operated for complicated cataract, traumatic cataract, uveitic cataract, combined procedures, operated with secondary IOL implantation and other ocular co-morbidities which may affect the visual outcome.

Ophthalmic examination

One Ophthalmologist, one Ophthalmic Officer, two Ophthalmic Assistants and two paramedical staff were involved in the study. All patients were operated by the same ophthalmologist in both the settings to avoid the intra-surgeon variation. The experienced Ophthalmologist examined the patients using the slit lamp biomicroscope, direct ophthalmoscope and flashlight as appropriate. The details on demographic information and examination that included pre-operative visual acuity assessment, keratometry readings, axial length, intraocular lens power and the other clinical data required were recorded in a pre-designed World Health Organization (WHO) recommended cataract surgery record format from the surgical record cards. At the base hospital and at the surgical eye camps, study patients were examined on the first day of surgery by an Ophthalmologist under a slit lamp biomicroscope. Visual acuity was assessed by ophthalmic assistants using the Snellen's vision chart at a 6 meter distance, using pinhole for testing corrected visual acuity. Patients were discharged on the first day at the surgical eye camps and on the second day at the base hospital after counseling for postoperative care and follow-up following routine procedures. Patients at both the settings were followed up with a thorough examination and visual acuity was assessed after one week and again at 4 to 6 weeks of post-surgery. At the 4 to 6 weeks followup, patients were checked with refraction using a streak retinoscope and subjectively. Keratometry was performed in all cases to evaluate the change in corneal astigmatism.

Patients operated at both the settings who were unable to come to the follow-up visits at one week and again at 4 to 6 weeks were examined at home with the portable equipment and or were brought to the clinic and examined.

Definitions

The visual outcome was considered to be poor if the VA <6/60 in the operated eye, visual outcome was considered to be border line if the VA <6/18 to 6/60 in the operated eye and patient was considered to have good visual outcome if VA was between 6/6 and 6/18.

Statistical analysis

The sample size was determined for this study with the assumption that 80% good visual outcome from the surgical camps and with an improvement of an outcome of 10% at the base hospital, the required sample size was estimated to be 222 each at the base hospital and at the surgical camp that has 80% power with 95% confidence level and 10% drop out rate. The data analysis was performed with SPSS version 16.0 software for windows (SPSS, Chicago, IL, USA). Visual outcome comparisons were performed using uni-variable analysis of either chi-square test or Fisher's exact test was used as appropriate. For comparison of preoperative and postoperative visual outcomes for the same patient, McNemar's chi-square test was used. Comparison of continuous variables between groups was done by using the independent sample t-test. A two tailed p value of <0.05 was considered to be statistically significant.

Results

The mean age of the patients at the base hospital was 64.1 ± 9.7 , the age ranged from 40 to 90 years and the mean age at the surgical eye camps was 65.8 ± 9.4 and the age ranged from 40 to 99 years. The age did not differ significantly between the groups (p = 0.061). There were 129 (58.4%) females operated at the base hospital and 136 (60.7%) females at the surgical eye camps and the gender difference (p = 0.684) was not significant (Table 1).

Of the 221 patients operated at the base hospital, 117 (52.9%) had pre-operative presenting poor VA of <6/60 and 109 (49.3%) had poor visual acuity after best correction (Figure 1). Patients operated at the surgical camps, a total of 141 (62.9%) out of 224 had pre-operative presenting poor VA and 132 (58.9%) had poor VA after best correction (Figure 1). The presenting and best corrected visual acuity was significantly different between the groups (p = 0.030 and p < 0.0001) respectively.

At the base hospital of the 221 patients operated, 187 (84.6%) had uncorrected good visual acuity in the operated eye and after correction with pinhole, improved in 214 (96.8%) patients on the first day of surgery. Of the 224 study patients operated at the surgical eye camps,

Characteristics	Base Hospital N (%)	Surgical eye camps N (%)	P value
Age group (yrs) 40 - 49 50 - 59 60 - 69 70 - 79 ≥ 80	13 (5.9) 30 (13.6) 103 (46.6) 64 (29) 11 (5)	8 (3.6) 24 (10.7) 102 (45.5) 70 (31.3) 20 (8.9)	0.061
Total	221 (100)	224 (100)	
Gender Male Female	92 (41.6) 129 (58.4)	88 (39.3) 136 (60.7)	0.684
Total	221 (100)	224 (100)	





Figure 1: Percent of patients with preoperative visual acuity operated in two different locations of surgical setups.



194 (86.6%) had uncorrected good visual acuity and, after correction improved in 213 (95.1%) on the first day of surgery. The uncorrected and best corrected visual acuity was not significantly different between the patients at hospital and surgical campson the first day of surgery (p = 0.740 and p = 0.370) respectively.

A total of 212 of the 221 (95.9%) patients were followed up at one week and 189 (85.5%) at 4 - 6 weeks of surgery at base hospital. A total of 216 of 224 (96.4%) patients at one week and 202 (90.2%) patients at

4 to 6 weeks were followed up at surgery camps. At one week follow-up at base hospital, 201 of the 212 (94.8%) patients achieved uncorrected good VA. Improved VA was noticed in 209 (98.6%) patients after best correction with pinhole, and 190 (88%) of 216 had uncorrected good VA and improved vision in 215 cases (99.5%) of the best correction with pinhole at surgical eye camps. On comparing the two groups, significant difference was found in uncorrected visual acuity (p = 0.001), no significant difference was found after best correction with pinhole (p = 0.370).

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Of the 189 patients, 160 (84.7%) had uncorrected good VA, with improved to 186 (98.4%) after best correction at the base hospital, whereas 178 (88.1%) of 202 had uncorrected good VA and 200 (99.0%) had best corrected good VA at the surgical camps at 4 - 6 weeks postoperatively (Figure 2). Only one patient of 189 (0.5%) uncorrected and best corrected at base hospital had poor outcome (VA <6/60) and no one at the camps at 4 - 6 weeks follow up had poor outcome. There was no statistical significant difference between both the groups of uncorrected (p = 0.400) and best corrected (p = 0.580) VA in the operated eye respectively.

At the base hospital preoperative good presenting VA in the better eye was found in 83 of 221 cases (37.6%) and best corrected good VA in 98 (44.3%), whereas 99 of 224 (44.2%) preoperative cases had presenting good VA and 134 (59.8%) had best corrected good VA in the better eye at the eye camp group (Figure 3). After 4 – 6 weeks follow up of surgery 171 of 189 (90.5%) had uncorrected and 177 (98.9%) best corrected good VA in the better eye at hospital, whereas it was 192 of 202 (95.0%) and 201 (99.5%) at eye camps, respectively (Figure 4). The preoperative presenting as well as best corrected VA was significantly different between the groups (p = 0.030 and p = 0.000), respectively. There was no significant difference in both the groups of the uncorrected and best corrected VA in the better eye at 4 – 6 weeks postoperative follow-up (p = 0.210) and (p = 0.950) respectively, which shows that the operated patients where almost equally benefited at both the setups.

Preoperative presenting VA improved significantly at 4 – 6 weeks post-operative follow-up at both the groups. Of the 117 patients with presenting VA < 6/60 preoperatively, 100 (85.5%) improved to \geq 6/18 at the base hospital and of the 141 patients with presenting VA < 6/60 preoperatively, 120 (85.1%) improved to \geq 6/18 post operatively at 4-6 weeks at eye camps. The preoperative best corrected VA <6/60 improved \geq 6/18 in 100% cases at the base hospital and preoperative best corrected VA <6/60 improved to \geq 6/18 in 97.7% patients at the 4 –



Figure 3: Percent of patients with preoperative visual acuity in the better eye at two different locations of surgical setups.



Figure 4: Percent of patients with postoperative visual acuity in the better eye at two different locations of surgical setups at 4 - 6 weeks post surgery.

Diopter	Base hospital	Surgical eye camps	
	n (%)	n (%)	
14 -18	13 (5.9)	7 (3.1)	
18.5-19.5	10 (4.5)	13 (5.8)	
20-20.5	26 (11.8)	30 (13.4)	
21-21.5	41 (18.6)	36 (16.1)	
22-22.5	60 (27.1)	55 (24.6)	
23-23.5	44 (19.9)	42 (18.8	
24-24.5	18 (8.1)	23 (10.3	
>25	9 (4.1)	18 (8)	
Total	221 (100)	224 (100)	

 Table 2: Details on intraocular lens power in both the study settings.

Astigmatism in diopter	Preoperative		4 to 6 weeks follow-up	
	Base hospital	Surgical eye camps	Base hospital	Surgical eye camps
	n (%)	n (%)	n (%)	n (%)
<0.5	24 (10.9)	20 (9)	4 (2.3)	5 (3.8)
0.5 - 1.0	99 (44.8)	115 (51.3)	24 (13.6)	16 (12.3)
1.25 - 2.0	72 (32.6)	71 (31.7)	68 (38.6)	39 (30)
2.25 - 3.0	21 (9.5)	15 (6.7	55 (31.3)	38 (29.2)
> 3.25	5 (2.3)	3 (0.9)	25 (14.2)	32 (24.6)
Total	221 (100)	224 (100)	176 (100)	130(100)

 Table 3: Corneal astigmatism in diopter at preoperative and 4 to 6 weeks postoperative in both the settings.

6 weeks at eye camps. At postoperative 4-6 weeks follow-up presenting VA was not significantly different between the base hospital and camps (p = 0.897). For the patients who did not attend 4 – 6 weeks follow-up, either first follow-up or VA finding at the time of discharge were taken as a final VA.

Table 2 shows the intraocular lens details at the both settings. The mean intraocular lens power was 21.72 ± 1.81 and ranged from 14-27 diopters at the base hospital, while at surgical eye camps the mean intraocular lens power was 22.03 ± 1.9 and ranged from 14.5-28 diopters. The intraocular lens power was not statistically significantly different between both the settings (p=0.12).

Table 3 depicts the preoperative and postoperative corneal astigmatism in diopters for different cut off values. The mean corneal astigmatism by keratometry reading of pre-operative patients at the

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base hospital was 1.18 ± 0.78 , ranging from 0-4.25 diopters. At surgical eye camps it was 1.11 ± 0.68 , ranging from 0-5.25 diopters. At 4-6 weeks follow-up the mean corneal astigmatism at base hospital patients was 2.12 ± 0.99 , ranging from 0.25-5.25 diopters and at surgical eye camps it was 2.39 ± 1.29 , ranging from 0.25-8 diopters. Corneal astigmatism was not statistically significantly different in pre-operative cases, but borderline significantly different postoperatively between the base hospital and eye camps — p=0.38 and p=0.07, respectively (Table 3). Figure 5 explains the comparative analysis of percent postoperative corneal astigmatism in different cut offs of diopter in both the study settings.

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Intra-operative and post-operative surgical complications were extremely low at both the settings — 8 of 221 (3.62%) at the base hospital and 3 of 224 (1.34%) at surgical eye camps. Capsule rupture with vitreous loss occurred in 2 cases and capsule rupture without vitreous loss in one case at the hospital whereas it was one each at the surgical camps. One case at the hospital group found retinal detachment on 4-6 weeks of follow-up; there was no case of endophthalmitisat both the settings (Table 4). There was no statistically significant difference found in their complication rates between both the setting (p=0.58).

Discussion

Surgical technology for cataract surgery is growing rapidly and in developing countries the manual small incision cataract surgery (MSICS) is recommended as a procedure of choice, as it gives similar outcomes as phacoemulsification with low costs, less complications and is less time consuming. Accessibility and affordability are the major significant barriers for uptake of surgical service in the developing countries. To overcome these barriers for the elimination of avoidable blindness due to cataract, outreach activities such as surgical camps can be the most effective alternative where the latest manual small incision cataract surgery is applicable. We had selected MSICS as a surgical



Figure 5: Percent corneal astigmatism of 4 to 6 weeks postoperative in both the settings.

Complications	Base hospital n (%)	Surgical camps n (%)
Capsule rupture without vitreous loss	1 (0.45)	1 (0.45)
Vitreous loss	2 (0.90)	1 (0.45)
Retained lens matter	1 (0.45)	0
Striate Keratopathy	2 (0.90)	0
Hyphema	1 (0.45)	1 (0.45)
Retinal detachment	1 (0.45)	0
Total complications	8 (3.62)	3 (1.34)
Total operated cases	221	224

 Table 4: Intra-operative and post-operative complications of cataract surgery in both the study settings.

procedure as it is commonly used at our hospital and other hospitals within the Nepal like in other developing countries. Both the groups had an almost equal number of study cases; there was no significant difference in the age groups and gender at both the settings, which facilitated for good comparison and its validity.

In this study there was a significant difference in preoperative presenting visual acuity in both the groups. This was due to the higher proportion of poor VA patients that were operated at camps accepting waiting time since they were unable to afford hospital based services. In the remote areas more patients with poor VA benefited from camps and both the groups achieved good sight restoration.

This prospective comparative case series study results showed both the groups acquired excellent and almost similar visual outcome at first day, one week and at 4 to 6 weeks post-surgery. A significant difference was not found between both the settings on the first day, one week and 4 to 6 weeks post-surgery, except uncorrected VA at one week follow-up. A significant difference was found in uncorrected VA atone week follow up between both the settings, which might be due to the difference in astigmatism developed which improved after pin hole correction and recovered at 4 to 6 weeks follow up time. The visual outcome of the study was comparable with hospital based clinical trials and interventional case study results of phacoemulsification and MSICS done in Nepal, India and Pakistan [7-10]. This result was achieved because of the similar surgical protocols followed at both the settings including preoperative calculation of intraocular lens power using biometry, surgery under a good quality microscope, well experienced surgeon, use of standard surgical procedures and maintenance of sterilization procedures.

Patients at both the settings were counseled well at discharge for postoperative care as well as for follow up visits after the one week and again at 4 to 6 weeks. Patients who were unable to attend at one week and at 4 to 6 weeks for follow up visits were brought to the primary eye center or hospital for the standard follow up examination. Patients who were even unable to come to the clinics were examined at their respective homes using the portable equipment. This was helpful to cover good proportion of the operated patients for the follow up and postoperative care at both the settings, which was not the standard practice at the traditional surgical eye camps.

Earlier a few studies were done on the comparison of the surgical outcome of cataract surgery at the base hospital versus surgical eye camps either by ICCE or ECCE + IOL techniques, but to our knowledge, no comparative study was done on the manual small incision cataract surgery procedure between these two settings. A comparative study done earlier in India showed the best corrected VA after six weeks as 82.7% versus 43.8% at the base hospital and the peripheral eye camps, respectively [11]. But the surgical techniques were different in both the settings - ICCE at camps and ECCE with intraocular lens implantation after biometry in 58% cases at the base hospital, which might be resulted in a difference in outcome. A similar comparative study done in south India showed best corrected good VA to be 88.3% after 3 months follow up at the base hospital and 73.4% at eye camps where the surgical technique was ICCE with aphakic correction which was not in routine practice now and the surgery at the hospital was done under a microscope, but not mentioned so at the camps [12]. A study by Balent and colleagues [13] showed that 38.3% of the SICS group at a surgical eye camp had 6/18 or better presenting VA after 8 weeks follow up and accepted the limitations of the slit lamp examination, which was done only on severe complicated cases after identifying by flashlight examination and preoperative pathologies masked by mature and hyper-mature cataract that may be the causes of a less good outcome. Evaluation of visual outcome of cataract surgery in an Indian eye camps study showed 87.9% of the ECCE with IOL group had best corrected VA 6/18 or better at 6 weeks follow up, but in the same study patients operated with ICCE had 78.1% best corrected good VA [14]. This difference observed was may be due to different definitions of case detection methods and selection criteria, surgical technique, and postoperative care which played on important role in the visual outcome.

The preoperative mean corneal astigmatism did not differ significantly in both groups. However, the mean corneal astigmatism after 4 to 6 weeks follow up was borderline significantly different between both the groups. Further studies are required with long term follow up at both the base hospital and surgical camp to determine the actual difference in astigmatism. Our study findings of the preoperative and postoperative astigmatism differences were in accordance with previously published study [10]. Our finding of the difference in postoperative astigmatism was slightly higher than the previously published study by Gogate and his colleagues [7], which might be due to the superior approach in surgical procedure carried out in all cases including patients who had preoperative against the rule astigmatism in this study.

The intra-operative and postoperative complications were extremely low and the complication rate was not significantly different between both the settings. However, at the base hospital surgical complications were slightly higher than that at camps which might be due to coexisting ocular pathologies. Capsule rupture with vitreous loss was found in two (0.9%) cases and capsule rupture without vitreous loss was found in one (0.4%) case at the hospital, whereas it was one (0.4%) each at surgical camps. Only one patient had anterior chamber intraocular lens implanted due to posterior capsule rupture and vitreous loss in patients operated at the base hospital. One case operated at the base hospital had retinal detachment at 4 to 6 weeks follow up and was not noticed on the first day and at one week follow up, and had good VA upto one week of follow up. The cause of retinal detachment was not known. One patient operated at the base hospital had retained lens matter and cortical wash was performed on first day of surgery. One patient operated at the hospital and one patient at the camp got hyphema, it become absorbed spontaneously and there was no case of endophthalmitisat both the settings. It was too early to get the posterior capsular opacification as our last follow up was at 4 to 6 weeks.

Our findings of surgical complications at both the settings were comparable with the clinical trial study conducted previously in Nepal [9]. However, our findings on complications were less than the previously conducted clinical trial in India [7], which reported the complications of 6% posterior capsular rent and 1% iridocyclitis postoperatively in the MSICS group. Another study of high volume suture less intraocular lens surgery in a rural eye camp in India showed a 3.2% intra-operative and 3.9% postoperative complications of which 1.1% posterior capsular rent and 0.8% vitreous loss occurred in MSICS group [13], which was slightly higher than our study.

The strength of this study was having followed up the possible maximum number of patients for evaluation of post-operative visual outcomes. The number achieved was close to the minimum required number for the study. This was made possible wherein the patients who were unable to visit on follow-up by their own were visited by ophthalmic assistant involved in study at their home and brought them for eye examination either at hospital or primary eye center. However,

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the postoperative visual outcomes of these patients were similar in comparison to those patients who visited on their own. Based on this study and our previous experience in this studied area, it can be speculated that the other few patients who lost follow-up could either have similar outcomes as observed in this study or they did not feel need of examination as because of their better visual outcome.

The limitation of our study was short duration of follow up which did not reveal the long term postoperative complications like posterior capsular opacification, corneal decompensation and change in astigmatism. Another limitation is that patients were not selected randomly from different surgical eye camps and at the base hospital but all eligible patients were agreed to participate in the study. We could not count the endothelial cells and measurement of central corneal thickness due to lack of appropriate equipment and resources.

Acknowledgements

The authors wish to thank the Health Ministry of Nepal and Nepal Netra Jyoti Sangh for funding this study and all the patients who volunteered and participated in the study.

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