



# A Multicenter Audit Of Phacoemulsification Cataract Surgery Outcome at Menilik II Referral Hospital Andbiruh Vision Specialized Eye Clinic, Addis Ababa, Ethiopia

Abraham Y\*

Department of Ophthalmology, Addis Ababa University College of Health Sciences School of Medicine, Ethiopia

\*Corresponding author: Dr. Yonas Abraham, Department of Ophthalmology, Addis Ababa University College of Health Sciences School of Medicine, H. No. 2321, Bole Road, Bole Sub City, Ethiopia, Tel: +25191157312; Email: yonimed120@gmail.com

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## Abstract

**Aim:** To assess visual outcome and complication rates in patients who underwent Phacoemulsification for cataract at Menilik II Referral Eye Hospital and Biruh Vision Specialized Eye Care Center, Addis Ababa.

**Study Design and Methods:** A Prospective Interventional Study assessing visual outcome in 262 eyes of 240 patients who had Phacoemulsification with foldable posterior chamber intraocular lens implantation done for cataract by 3 different Ophthalmic Surgeons. Visual acuity was assessed pre-operatively, on the first Post-operative week and fourth to sixth Post-operative weeks. Refraction was done the fourth to sixth -operative weeks.

**Results:** Good visual outcome of 6/18 or better was obtained in 90.5%, 93.9% at first and four to six postoperative weeks respectively. Best corrected visual acuity of 6/18 or better was achieved in more than 96.9% at four to six postoperative periods. Overall Intra-operative & Post-operative Complication rates were 6.1% and 4.18% respectively. Poor outcome was seen in 2 cases that developed Pseudophakic Bullous Keratopathy (PBK) after surgery.

**Conclusion:** The study has shown that Phacoemulsification gives us good postoperative visual acuity at the immediate and intermediate postoperative intervals. It has also shown that the procedure has low intra-op and post-op complication rates.

**Keywords:** Cataract; Phacoemulsification; Complications; Visual outcome

## Abbreviations

BCVA: Best Corrected Visual Acuity; DFE: Dilated Fundus Exam; IOL: Intraocular Lens; IOP: Intraocular Pressure; PCO: Posterior Capsular Opacity; PCT: Posterior Capsular Tear; PBK: Pseudophakic Bullous Keratopathy; PPV: Pars-Plana Vitrectomy; PKP: Penetrating Keratoplasty; PI: Peripheral Iridectomy; RD: Retinal Detachment; SICS: Small Incision Cataract Extraction; SLE: Slit Lamp Exam; UCVA: Uncorrected Visual Acuity; VA: Visual Acuity; YAG: Yttrium Aluminum Garnet.

## Introduction

Globally, it is estimated that approximately 1.3 billion people live with some form of distance or near vision impairment. With regards to distance vision, 188.5 million have mild vision impairment, 217 million have moderate to severe vision impairment, and 36 million people are blind [1]. With regards to near vision, 826 million people live with a near vision impairment [2]. Africa accounts for 15 % of world's blindness [1]. The prevalence of cataract is on the rise since people are living longer every decade [1]. The World Health

Organization (WHO) estimated that 20 million persons are blind from cataract worldwide, making it the leading cause of visual loss [3]. By the year 2020, the projected number of persons with blinding cataract will exceed 40 million worldwide [4]. WHO categorized visual outcome following eye surgery as Good, Borderline and Poor [5]. It has also recommended and set targets aimed at achieving good uncorrected visual acuity in at least 80% of surgeries and poor in less than 5%, and corrected visual acuity of good in 90% of surgeries and poor in less than 5% by 2 months after surgery [5].

In Ethiopia the prevalence of blindness is 1.6% and low vision is 3.7%; [6]. Due to cataract:

- 1.2 million (42.3%) are severely visually impaired
- More than half million people (49.9%) are blind

Cataract surgery is one of the most practiced means of restoring vision for those with vision impairment. In recent years the number of people who undergo cataract surgery has increased rapidly [7]. However, the quality of surgery remains a problem that should be addressed [7] and there is a need for increased attention on the quality of visual outcome [8,9] and it is one of the three important strategic issues in Cataract blindness control, the others being volume and cost [8]. A key focus to provide high quality of surgery is the outcome of the procedure. In cataract surgery this is measured predominantly using visual acuity [9]. And to control the quality doing surgical audit is one method recommended [10]. Cataract surgery technique changed during the past four decades. It has moved from intracapsular to Extracapsular procedure [11]. Smaller incision Phacoemulsification have become the standard type in developed countries and along with this improved IOL materials and designs has come well suited with the smaller incision [11]. Superior manual small incision is the operation of choice in many developing countries including Ethiopia [12].

The main issue in Phacoemulsification cataract surgery is its minimal use in low income countries because of the cost [12]. It could be cost effective in low income countries in a way that it returns patients to their functional life quicker, reduces number of visits to eye care centers, less need for spectacle use & Posterior Capsular Opacity (PCO) treatment [13]: Performing surgical audit is one of the methods of quality control [14]. The present outcomes of cataract surgery in Africa do not meet the recommendations of WHO in some instances. Phacoemulsification brings in less astigmatism, shorter recovery time, best UCVA postoperatively [15]. A retrospective cataract audit has been done on outcome of Extra capsular cataract surgery in the past [16]. There is also an ongoing audit research on outcome of small incision cataract surgery. This will be the first prospective audit of Phacoemulsification cataract surgery in Ethiopia

to our knowledge. So, this research will be a benchmark for the next researcher in an effort to improve the outcome of Phacoemulsification cataract surgery in our country.

## Methods & Materials

A Multicenter prospective interventional study was conducted between Feb 2017- Mar 2018 G.C. on patients who have undergone Phacoemulsification surgery at Menilik II referral Hospital and Biruh vision specialized eye clinic. The research & publication committee of department of ophthalmology, CHS, AAU & IRB approved this research, and consent was obtained from all the participants after explaining the relevance of the study. The surgery was done by 3 experienced ophthalmic surgeons.

After recruitment, all the patients were subjected to interviews and evaluation was done by the principal investigator. The information collected included demographic data, clinical presentation (Complaint, Past Ocular History or Surgery, History of DM or HTN). VA was taken using Snellen chart at 6meters. IOP was recorded using Tono-pen AVIA® by Reichert technologies, after instilling Tetracaine 0.5% before dilating the pupil. A detailed Slit lamp Examination of the anterior segment was done. Posterior segment examination was aided using an aspheric condensing lens 78/90D (when indicated Ocular US was done). Intra-op & post-op complication were noted. Post op examinations were held at 1<sup>st</sup> post-op day, 1<sup>st</sup> post-op week & 4<sup>th</sup>- 6<sup>th</sup> post-op week. Post-op refraction, if any, was one at 4<sup>th</sup>- 6<sup>th</sup> Post-op week. Any intervention done during post-op follow up was also recoded.

## Inclusion Criteria

All consecutive cataract patients who underwent Phacoemulsification Cataract surgery at Menilik II and Biruh vision specialized eye clinic from Feb 2017- Mar 2018 G.C. for the study group.

## Exclusion Criteria

Any patient who is diagnosed with other ocular co morbidities before the operation that might affect surgery outcome (Advanced Glaucoma, Retinal Detachment (RD), Macular Hole (MH) stage 2 and above, Age related macular Degeneration (AMD), Corneal Opacities (CO) at or near the visual axis...) between Feb 2017- Mar 2018 G.C. and any patient who is lost from follow-up before six weeks following the operation.

## WHO Postoperative Visual Acuity Outcome Measurement of

Good outcome was ranging from 6/6 - 6/18 of visual acuity,

Borderline outcome <6/18- 6/60 and Poor outcome <6/60 was used.

- **Best corrected visual acuity (BCVA):** VA in examined eye with best possible correction or pinhole
- **Uncorrected visual acuity (UCVA):** VA in the examined eye without best correction

Causes of poor visual outcome following surgery was recorded as due to Selection if related to preexisting concurrent eye diseases that had an impact on Post-op VA, Surgery if it is due to intraoperative or immediate post-operative complications, Spectacles if due to inadequate optical correction Post-operatively and Sequelae if it was related to late post-operative complications.

Axial length (AL) was categorized as short if <22 mm, normal between 22-24.5 mm), and long if >24.5 mm. Phacoemulsification cataract surgery is a procedure in which an ultrasonic device is used to break up and then remove a cloudy lens or cataract, from the eye to improve vision.

### Surgical Procedure

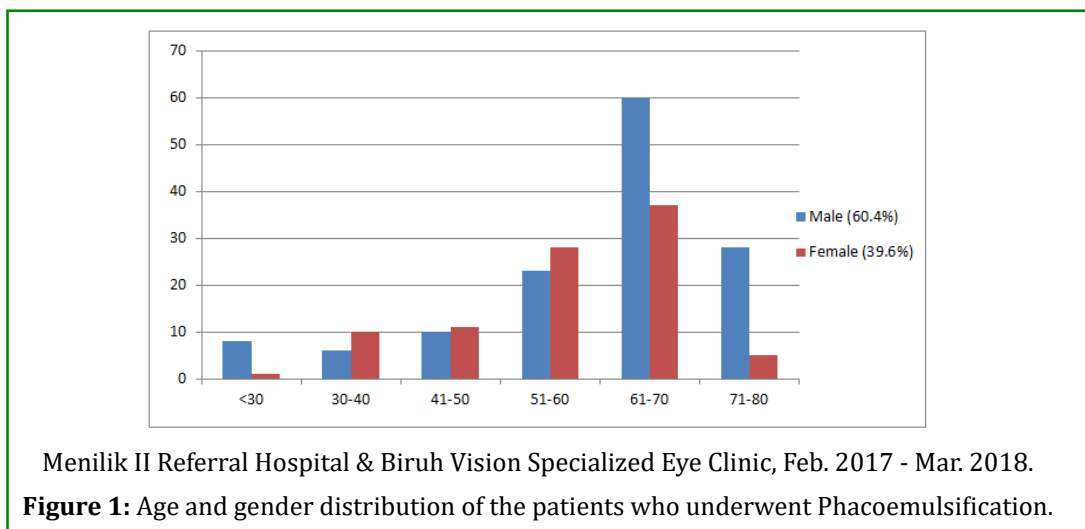
Patients were first given Anesthesia (General, Local and Topical Anesthesia) under aseptic technique. Then using 15° blade Paracentesis was done with subsequent Injection of Trypan blue for highlighting anterior lens capsule. Using Viscoelastic material anterior chamber was deepened. Incision (Limbus, Sclera, and Clear Corneal) was done to construct surgical wound followed by Continuous Curvilinear

Capsulorhexis (CCC). Hydrodelination & Hydrodissection was done using balanced salt solution (BSS). Emulsification of cortex & Nucleus was done using different techniques followed by Irrigation & Aspiration of lens material. Anterior Chamber was refilled with Viscoelastic Device and Acrylic foldable IOL was implanted into the capsular bag. Removal of Viscoelastic material was done and surgical wound was checked for leakage. Sub conjunctival plus Topical Steroid - Antibiotic Medication was given and eye was patched.

Different types of Phacoemulsification /machines were used in the two centers, Oretli - CataRhex 3 - Phacoemulsification System at Menilik II referral Hospital and Laureate (Alcon) with infinity hand piece at Biruh Vision Specialized eye care center. Statistical analysis was done using SPSS version 24.0. Frequencies in percentage, mean, and tables will be used for univariate analysis and  $p < 0.05$  will be used as cut off point for statistical significance.

### Results

262 eyes of 240 patients aged between 23 and 82 years with mean age  $60.79 \pm 10.5$  years were recruited for the study. The right eye was operated in 143 (54.6%) of cases. One Hundred forty five (60.4%) were males while 117 (39.6%) were females, giving a male to female ratio of 1.52:1. Most patients 196 (74.8%) were between the age of 51 - 80 years (Figure 1).



Three eyes had Axial Hyperopia and eleven eyes had Axial Myopia. The types of Cataract were Posterior Sub-Capsular in 49.6%, Cortical in 17.6%, Nuclear 15.6%, Age Related Mature Cataract in 16.8% and Developmental in 0.4% of cases.

Most eyes, 63.7% (167) had preoperative visual acuity of

>6/60. With 93.9% (246) having Uncorrected Visual Acuity in the range 6/6 - 6/18 by the 4-6th Post-op week after cataract surgery by Phacoemulsification (Table 1). The most common placement of IOL was in the capsular bag 251 (95.8%) of cases followed by Sulcus 8 (3.1%) and Anterior Chamber 3 (1.1%). IOL power change from biometry readings was seen in 40 cases. 2 had -1D  $\Delta$ , 13 had -0.5D  $\Delta$ , 21 had +0.5D  $\Delta$ , 3 had

+1.0 Δ and 1 had +2.0 Δ. Of the 40 with IOL power change, 2 cases were associated with alternative placement of IOL - 1

Sulcus & 1 Anterior chamber IOL (p=0.857).

	6/6-6/18	6/24-6/60	<6/60	Total
Pre-Op VA	62	105	95	262
1 <sup>st</sup> POW	237 (90.5%)	18 (6.8%)	7 (2.7%)	262
4 <sup>th</sup> /6 <sup>th</sup> POW UCVA	246 (93.9%)	11 (4.2%)	5 (1.9%)	262
4 <sup>th</sup> /6 <sup>th</sup> POW BCVA	254 (96.9%)	6 (2.3%)	2 (0.8%)	262

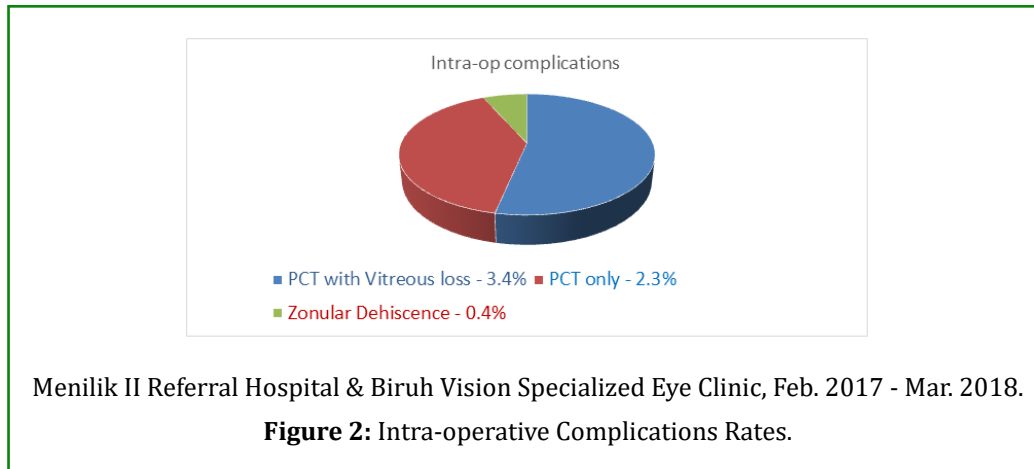
POD: Post-Operative Day; POW: Post-Operative Week; UCVA: Uncorrected Visual Acuity; BCVA: Best Corrected Visual Acuity.

**Table 1:** Distribution of visual acuity among patients in the pre and post- operatively periods.

Menilik II Referral Hospital & Biruh Vision Specialized Eye Clinic, Feb. 2017 - Mar. 2018.

The overall intra-op complication rate was 16 (6.1%) of which Posterior Capsular Tear (PCT) with vitreous loss 9

(3.4%) was the commonest (Figure 2).



In the post-op period complication rate was around 4.18% (n=11). Posterior Capsular Opacity (PCO) (1.14%) was the commonest Complication seen (Table 2). Of the 6 with

borderline outcome only 1 had post-operative complications - PCO. All (2) eyes with poor outcome had post-op complication (PBK) was statistically significant (p<0.001).

Complications	Number (%)
Retained Cortex	1 (0.38%)
Lens dislocation	1 (0.38%)
PCO	3 (1.14%)
Pupillary Block	1 (0.38%)
Hyphema	1 (0.38%)
CME	1 (0.38%)
RD	1 (0.38%)
PBK	2 (0.72%)
Total	11(4.18%)

Menilik II Referral Hospital & Biruh Vision Specialized Eye Clinic, Feb. 2017 - Mar. 2018.

**Table 2:** Post-operative complication Rates.

There was statistically significant association between Post-op complication and Post-op VA (Table 3).

Post-op Comp	Post-op BCVA (6 <sup>TH</sup> POW)			P- Value	Total (%)
	6/6-6/18	6/18-6/60	<6/60		
No	247	5	0	<0.001	252
Retained Cortex	1	0	0		1
Lens dislocation	1	0	0		1
PCO	2	1	0		3
Pupillary Block	1	0	0		1
Hyphema	1	0	0		1
CME	1	0	0		1
PBK	0	0	2		2
Total	254	6	2		

Menilik II Referral Hospital & Biruh Vision Specialized Eye Clinic, Feb. 2017 - Mar. 2018.

**Table 3:** Association between Final BCVA & Post-op Complication.

None of the patients with Spectacle correction had Poor Outcome (P = 0.34). After Refraction in the 4-6<sup>th</sup> POW results showed a range of Sphere -0.5 - +2.00 with Cylinder ranging from -2.50 - 0.00. Of the 16 Patients with Intra-op complications: 15 had good, 1 had Borderline & None had Poor Outcome. (P=0.938) Of those Operated, 12 eyes had Co-Morbidity (4 had refractive errors, 4 had mild Diabetic Retinopathy, 3 had Early Primary Open Angle Glaucoma & 1 had Stage 1 Macular Hole) but none had poor outcome which was statistically significant (p=<0.001). Three surgeons participated in this Study. Surgeon one (S<sub>1</sub>), Surgeon Two (S<sub>2</sub>) & Surgeon three (S<sub>3</sub>) did surgeries on 149, 51 & 60 eyes respectively.

On the 4-6<sup>th</sup> POW UCVA outcome showed S<sub>1</sub> had Good 94.7%, Borderline 4% & Poor 1.3%, with S<sub>2</sub> having Good on

94.3%, Borderline 5.7% & Poor 1.3% and S<sub>3</sub> having Good 96.6%, Borderline 0% & Poor 3.4% with P-Value - 0.237. BCVA outcomes on 4-6<sup>th</sup> POW showed S<sub>1</sub> had Good 96%, Borderline 4% & Poor 0%, with S<sub>2</sub> having Good 98.1%, Borderline 1.9% & Poor 0% and S<sub>3</sub> having Good 96.6%, Borderline 0% & Poor 3.4% with P-Value - 0.069. Intra-op Complication rates were 6.6%, 5.7% & 2.6% for S<sub>1</sub>, S<sub>2</sub> and S<sub>3</sub> respectively with (P-Value - 0.954).

Post-op Complication rates was 2.6% for S<sub>1</sub>, 5.7% for S<sub>2</sub> and 6.9% for S<sub>3</sub> which was statistically significant (P-Value - 0.020). YAG capsulotomy, YAG PI & PPV (1 each) was done for eyes with PCO, Pupillary Block & RD respectively. Those with CME & PBK (1 each) were given Bevacizumab injection (1X) & 5% NaCl solution. Two Centers were involved in the study. Table 4 shows comparisons between the two:

		Menilik II Referral Hospital	Biruh Vision Specialized Clinic	P-Value
Patient No.		51	211	
Pre-op VA	6/6-6/18	3	60	
	6/24-6/60	12	94	
	<6/60	36	57	
Cataract Type	PSC	112	14	
	Cortical	34	12	
	Nuclear	27	16	
	ARMC	35	9	
	Developmental	1	0	
Intra-op Comp.		3(5.9%)	13(6.2%)	0.981

IOL Power Δ		14(27.5%)	26(12.3%)	0.148
Post-op Comp.		4(7.8%)	8(3.8%)	<0.001
4-6 <sup>th</sup> POW BCVA	6/6-6/18	44(86.3%)	203(96.2%)	0.005
	6/18-6/60	4(7.8%)	7(3.3%)	
	<6/60	3(5.9%)	1(0.5%)	

Menilik II Referral Hospital & Biruh Vision Specialized Eye Clinic, Feb. 2017 - Mar. 2018.

**Table 4:** Comparison between Menilik II Referral Hospital & Biruh Vision Specialized Eye Clinic.

## Discussion

An audit will enable us better understand our strength, reveal our weakness areas & will ultimately improve our Service. It will help to match the growing visual demands of our population. A prospective audit of Phacoemulsification surgery has not been done in Ethiopia previously. Males accounted to 60.4% (145) with F: M being 1:1.52. This ratio was different from studies in New Zealand 2015 by Bia ZK, et al. [16] (F: M 1:1) & F: M 1.33:1 in India by Venkatesh R, et al. [17]. This could be due to Females still being economically dependent on Males which is one of the barriers to cataract uptake identified in previous studies [18]. Around 65.3% of eyes operated had a Pre-op VA better than 6/60. This was comparable to studies in New Zealand [16] 61% & 69.4% in UK in 2015 [19]. This was different from a study done by A Hennig A, et al. [20] in Nepal with pre-op VA <6/60 to be 16.1%. This could be explained by the location of our study which is the capital of Ethiopia & subsequently indicates that the visual demands of our Population are increasing as the number of office workers is on the rise.

At the 4-6<sup>th</sup> Post-op week the UCVA showed 93.9% had good, 4.2% had Borderline & 1.9 % had poor visual outcome. Lower outcomes were seen in a Study by Venkatesh R, et al. [17] in India that found the UCVA outcome to be 87.6% good, 11.5% Borderline and 6.9% with poor visual outcome. BCVA in this study at 4-6<sup>th</sup> Post-op week revealed 96.9% had Good, 2.3% Borderline & 0.8% Poor Outcome. Better outcome was seen in a study by Ventakesh R, et al. [17] which showed BCVA outcome was Good 99.1%, Borderline 0.9% & 0% had Poor visual outcome. And a comparable outcome was seen in a study done by Lundstrom M, et al. [21] with BCVA outcome of Good in 97.1%, Borderline in 2.1% and poor outcome in 0.9%. These results are in accordance to the standards of cataract surgery quality required by any Ophthalmic Surgical center. And the Visual outcome result differences could possibly be explained by the differences in Experience & equipment quality.

The overall intra-op complication rate was 6.1% with PCT ± Vitreous loss being the commonest at 3.4%. Higher results were found in the New Zealand study 9.6% with PCT ±

Vitreous loss the commonest at 4.4% [16]. Similar results were found in an audit in Australia 6.39% Complication rate with PCT ± Vitreous loss at 4.22% [22]. It was lower in studies India at 2.2% all of which was PCT ± Vitreous loss [17], in the UK which was 3.0% with PCT± Vitreous loss the commonest 1.8% [19] & was 0.89% with PCT 0.6% in Aravind eye Hospital India [23]. These differences could possibly be explained by differences in Surgeons' experiences as well as differences in Equipment Quality. In the post-op period complication rate was around 4.18% with PCO the commonest at 1.14%. Higher rates were seen in the New Zealand study at 8.2% with SK 1.0 % [16]; in the India study with 10.7% with all having SK [17] & the UK study 5.8% [19]. The rate was lower in Nepal at 2.89% [20]. As this was a Multicenter Study differences in Equipment & Experience levels might have played a role in these varying rates with the Studies mentioned above. Capsular placement of IOL was 95.8%, with Sulcus placement in 3.1%. Of the 14 cases with PCT ± vitreous loss 10 had IOL placement outside of the capsular bag (7 Sulcus & 3 ACIOL). Similarly in the New Zealand study IOL placement was 96% in the bag, 2.8% in the Sulcus, 0.2% ACIOL & left Aphakic in 1% [16] of cases which is comparable to our results. But it was quite lower in a study in Nepal ACIOL was inserted in 0.17% of cases, the rest in Capsular bag 99.83% [20].

These differences are due to the fact there was variance in the rate of PCT as well as Zonular Dehiscence between the Studies. A possible explanation could be the fact that there are high numbers of patients with Pseudoexfoliation Syndrome in our country. Out of the 40 cases in which IOL power was changed from Biometry calculations Only 2 of the cases had IOL change associated with PCT± vitreous loss (1 ACIOL & 1 Sulcus IOL placement). The remaining 38 with IOL change didn't have a complication at all. There is no much Data on IOL change in most countries. The main reason for our finding is unavailability of wide range of IOL powers. Only a small portion was associated with Intra-op Complications. Those Patients with Poor outcome had PBK. Both didn't have any Ocular Co-morbidities and vision didn't improve after Refraction. Long-term VA & outcomes are not known in this study as it lasted only up to 4-6weeks with possible different figures if it was extended more (6-12 months). The likely

cause of their Poor outcome is due to Surgery (Because of Unknown Operation time or Amount of PHACO energy used or it could be due to Age (70-80yr & >80 yr) and baseline Endothelial count was not present. A difference between the three Surgeons in respect to Visual Outcomes & intra-op complications was observed. This could be due to the fact the differences in Patient numbers, difference in techniques used & experience levels though it was not statistically significant. Post-op complication rate difference between the Surgeons was Statistically Significant ( $P= 0.02$ ) as it may be associated with experience levels & equipments used.

When comparing the two eye centers where the research took place, statistically significant ( $p<0.001$ ) results was seen in Post-op complication rate difference 7.8% (Menilik II referral Hospital) & 3.8% & Biruh Vision Specialized Clinic. 4-6<sup>th</sup> POW BCVA result difference for Menilik II referral Hospital (Good - 86.3%, Borderline - 7.8% & Poor - 5.9%) & Biruh Vision Specialized Clinic (Good - 96.2%, Borderline - 3.3% & Poor - 0.5%) was statistically significant ( $P=0.005$ ). This difference may be due to differences in Equipment in the two centers. And even though there was a difference between the two centers in Intra-op Complication rate & IOL power change it was not statistically significant ( $P=0.981$  &  $P = 148$ ) respectively.

## Conclusion

The results are comparable to reports from other international institutions and provide an additional benchmark in an era of changing populations, expectations, and the associated demand for cataract surgery. Intra-op & Post-op Complication rates were relatively low. In this study, leading factors contributing to poor outcome were possibly related to surgery.

## Limitation of the Study

The longest follow-up time in this study is 6 weeks postoperatively from three postoperative visits. Long-term visual outcomes of our patients were not audited. Unavailability of wide range of IOL power might have affected the visual Outcomes of some patients.

## Recommendation

Further studies that outline visual outcome in relation to Refractive Error should be done. Focus should be given to increase the choice of wide IOL power. Programs to integrate Phacoemulsification cataract surgery into resident's surgical training in our teaching hospitals is needed because this study has shown it is safe & effective.

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