Original Article

Initial experience with three-dimensional heads-up display system for cataract surgery – A comparative study

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Purpose: To compare the complication rates, surgical time and learning curve using the 3-D Heads up display system in comparison with the conventional microscope for routine cataract surgery. **Methods**: Consecutive consenting adults with uncomplicated cataract were offered phacoemulsification using the 3-D Heads up display system (ARTEVO 800 Carl Zeiss Meditec) or the conventional microscope (Zeiss Lumera 700) by two experienced surgeons. Surgical time, measured from start of corneal incision to removal of microscope from the surgical field and complication rates were compared between the groups. **Results**: Of the 343 eyes enrolled, 100 (29%) underwent surgery using the 3-D Heads up display system. The surgical time for 3-D Heads up display system was significantly higher in the 3-D group (8.4 ± 2.1 vs. 6.5 ± 1.8 minutes, $P < 0.001$). There were no group differences in surgical complications (2% in 3-D vs. 2.5% in conventional microscope, $P = 0.28$). Comparing across 4 quartiles within the 3-D group, the mean surgical time was slightly higher during the 1st quartile ($n = 25$, 9.1 ± 1.9 minutes) compared to the last quartile ($n = 25$, 8.2 ± 1.9 minutes) ($p = 0.17$). Complications in the 3-D group occurred only in the initial 50% of cases. Seven (7%) cases in the 3-D group were converted to conventional binocular microscope of which 3 each were due to difficulty in depth perception and low illumination while one was due to intraoperative pupillary constriction. **Conclusion**: Phacoemulsification with the 3-D Heads up display system takes longer time but offers excellent visualization, ergonomics and safety compared to conventional microscopes. Experienced surgeons should be able to adapt easily after their first 50 surgeries.

Key words: Conventional microscope, phacoemulsification, viewing system, 3-D Heads up display system

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Cataract surgery has seen a lot of progress in recent years and is now considered as a refractive surgery. Improvements in surgical techniques, intraocular lens technology, improved phaco-dynamics and kinetics, and the recent introduction of the femtosecond laser platforms have all contributed to improved outcomes for patients.[1] However, the operating field, on which so much depends, has mainly been reliant on the surgical microscope with its binocular viewing systems that require surgeons to adapt their neck and back to get the most precise view. Ergonomics during long operating hours has been a challenge for ophthalmologists for a long time and has led to the development of several issues with neck and back pain within the community.[2,3]

Heads – up ophthalmic surgery, first developed more than 2 decades ago,[4] has matured sufficiently over the past few years and is being increasingly adopted by ophthalmologists.[5-13] This offers many advantages including maintenance of an ergonomic posture for the surgeon, excellent 3-D visualization of the surgical field and lower illumination that helps patient cooperation during topical surgery. Many authors have published their experience with the Ngenuity visualization system (Alcon, USA) with most of the data from vitreoretinal surgeons.[6,10,11,13] A large retrospective series showed that Ngenuity is as efficient and safe as a conventional binocular microscope for performing the cataract surgery.[12] However, there is not enough research on utilization of these systems for anterior segment surgeries, especially in cataract surgery.[8,9,12]

Additionally, most studies lack adequate number of patients and comparison with conventional microscopes to make robust recommendations. The learning curve with these newer systems, for an experienced phaco-surgeon has also not been well documented till date.

The 3-D Heads up display system used in our study, (Artevo 800 3-D Carl Zeiss Meditech, USA) is a new 3-D digital visualization system launched about a year back that helps surgeons perform heads up ophthalmic surgery. It offers real time stereoscopic imaging of the surgical field on a 55-inch, OLED 4K display screen. This system promises real colours, better resolution, a good depth of focus and optimum visualization with low light intensity for patient comfort.

In this study, we present our experience of the first 100 cataract surgeries operated using the 3-D Heads up display system in comparison with surgeries performed using the conventional binocular surgical microscope.

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Methods

This was a prospective, comparative, parallel assignment, non–randomized, open label study performed at a tertiary eye hospital in Western India. The study was approved by the institutional ethics committee and followed the tenets of the Declaration of Helsinki. All participants signed an informed consent before enrolment.

All consecutive adult patients with uncomplicated cataract scheduled to undergo routine phacoemulsification surgery between 3rd February and 21st March 2020 were included in the study. Eyes with pupils <4 mm in size, requiring toric IOLs and those with posterior polar cataract and pseudo-exfoliation were also considered eligible for enrolment. We excluded eyes with compromised corneal clarity, subluxated cataracts, obvious phacodonesis and eyes with previous ocular surgery such as parsplana vitrectomy, glaucoma filtration surgery etc., That may compromise surgical performance. Consenting patients were offered surgery using the 3-D Heads up display system (Artevo 800 Carl Zeiss Meditech, USA) after explaining the pros and cons of the new system. If patients did not consent for the 3-D system, they underwent surgery with the conventional binocular microscope. Recruitment was stopped when we reached our predefined target of 100 surgeries using the 3-D Heads up display system.

All participants underwent a comprehensive preoperative work-up including best corrected visual acuity (BCVA), slit lamp evaluation and cataract grading using the lens opacification classification system (LOCSIII),[14] maximum pupillary size after mydriasis, dilated fundus evaluation, ocular biometry and ultrasound pachymetry. Phacoemulsification was performed under topical anaesthesia for all participants, using a temporal clear corneal incision, with the Stellaris Phacoemulsification machine (Baush and Lomb, USA). Surgeries were performed by two experienced surgeons (ASK, JAK), each performing more than 2000 surgeries per year for the past 5 years. During surgery, parameters recorded were the type of incision (biplanar vs. triplanar), pupillary size using callipers, shape of the circular capsulorhexis margin (regular vs. irregular) as judged by a neutral observer (XYZ), occurrence of capsulorhexis run-off to the periphery requiring retrieval, complications during surgery, location of the IOL (in the bag vs. sulcus), need for a tunnel suture and need for supplemental subtenon's anaesthesia.

The surgery time from start of the corneal incision to removal of the microscope from the surgical field was noted by the neutral observer. Similarly, the Effective Phaco Time (EPT in seconds) as displayed on the phacoemulsification machine console was also noted. In the surgeries using the 3-D Heads up display system the observer also noted the conversion to the conventional binocular microscope anytime during surgery. At the end of each surgery, the surgeon was asked to fill the NASA workload index,[15] which assesses work load on six scales including mental demand, physical demand, temporal demand, performance, effort and frustration levels. Increments of high, medium and low estimates for each point result in 21 gradations on the scales. The higher the summary score, the greater the difficulty and effort required in executing the task. The surgeon was also asked to comment on their surgical experience and any aspects of surgery they were not comfortable with, in an open-ended fashion. Subjective responses were categorized into issues relating to the illumination and depth perception for analysis.

Postoperative evaluation was done on the first day after cataract surgery and the degree of striate keratopathy was noted along with the pachymetry to document corneal edema in comparison with preoperative values.

Statistical analysis

All continuous variables were expressed as means with standard deviation and all group differences were analysed using the student t test or the Wilcoxon's Ranksum test. The Shapiro-Wilk test was used to assess the normality of distribution. All categorical variables were expressed as proportions (n, %) and group differences were analysed using the Chi square or the Fischer's exact test.

Visual acuity was converted to logarithm of minimum angle of resolution (logMAR) and change in visual acuity before surgery and on postoperative day1 was analysed using the paired t test. In order to document the learning curve, eyes that underwent surgery using the 3-D Heads up display system were divided into 4 equal groups (quartiles) based on the performed date such that the first quartile had the earliest surgeries and the last quartile had the latest surgeries. Group wise comparisons across quartiles was made using the analysis of variance (ANOVA) in case of continuous variables and the Chi square or Fischer's exact for categorical variables.

All data were entered in Microsoft Excel and statistical analysis was performed using STATA 12.1 I/c (Stata Corp, Fort Worth, Texas, USA). All P values < 0.05 were considered statistically significant.

Results

We enrolled 343 eyes of 343 eligible patients during the study period of which 100 (29%) underwent surgery using 3-D Heads up display system and the remaining 243 (71%) had surgery using the Conventional Microscope. The mean age of participants was 66.1 + 7.9 years and 173 (50%) participants were men.

A comparison between various demographic, clinical and surgical parameters between eyes that underwent surgery using the 3-D Heads up display system vs. the conventional binocular microscope is shown in Table 1. There were no differences in the preoperative characteristics between groups. There were 4 eyes with mature cataract of which two were operated under the 3-D Heads up display system and two using the binocular microscope, all of which were uneventful. The surgical time was significantly higher in the 3-D Heads up group [Fig. 1] (1.96 minutes higher in 3-D Heads up display system, 95% CI = 1.5 – 2.3 minutes, $P < 0.001$), even after adjusting for EPT, grade of nuclear sclerosis, and complications. Capsulorhexis run off was seen in two eyes (2%) in the 3-D Heads up group but none on the binocular group, though this was only marginally significant [Table 1]. The mean surgeon workload score was significantly higher in the 3-D Heads up group suggesting higher overall difficulty levels [Table 1]. There were no group differences with respect to surgical complications and post-operative outcomes such as striate keratopathy, corneal edema and BCVA on postoperative day 1 [Table 2].

Eyes that underwent surgery using the 3-D Heads up display system (n = 100) were divided into 4 equal groups (n = 25 in each) with the 1st quarter representing the initial cases and the last 25 representing the most recent cases. Comparing across quarters [Table 3] we found that the mean surgical time was slightly higher during the 1stquartile [Fig. 2] and reduced by almost 1 minute per case after that, but this was not statistically significant. Most surgeries continued to take more than 8 minutes in the 3-D Heads up group. The surgical time taken in the fourth quartile (8.2 ± 1.9 minutes) was still significantly

Table 1: Comparison Between Demographics, Clinical and Surgical Parameters in Eyes that Underwent 3-D Heads Up Display vs. Conventional Microscope

Variable	Conventional Microscope (*n*=243)	3-D Heads Up Display Group (*n*=100)	*P*
Age	65.8±7.6	66.2±8.5	0.71
Gender (% men)	122 (50%)	51 (51%)	0.89
Surgeon 1: ASK	102 (42%)	51 (51%)	0.13
Surgeon 2: JAK	141 (58%)	49 (49%)	
Clinical Characteristics			
Cataract >NS grade 3	104 (43%)	35 (35%)	0.18
Posterior polar cataract	1 (<1%)	1 (1%)	0.12
Preop BCVA	0.83±0.48	0.75±0.44	0.12
Central corneal thickness (m)	504±25	502±25	0.38
Pupil size			0.51
<4 mm	5 (2%)	4 (4%)	
4-6 mm	67 (28%)	28 (28%)	
>6 mm	171 (70%)	64 (64%)	
Surgical Parameters			
Surgery under peribulbar block	2 (1%)	0	0.50
Incision			
Biplanar	233 (96%)	99 (99%)	0.18
Triplanar	10 (4%)	1 (1%)	
Epitrate used	10 (4%)	6 (6%)	0.45
Irregular rhexis	15 (6%)	6 (6%)	0.95
Rhexis run off	0	2 (2%)	0.08
EPT (seconds)	7.13±10.6	6.27±9.5	0.46
Surgical time (minutes)	6.5±1.8	8.4±2.1	<0.001
IOL position			
In bag	244 (99%)	99 (99%)	0.76
In sulcus	1 (<1%)	1 (1%)	
Iris Claw	1 (<1%)	0	
Toric IOL implanted	8 (3%)	9 (9%)	0.08
Sutured incision	2 (1%)	0	0.50
Surgeon workload score	29.2±13.5	35.8±14.2	<0.001

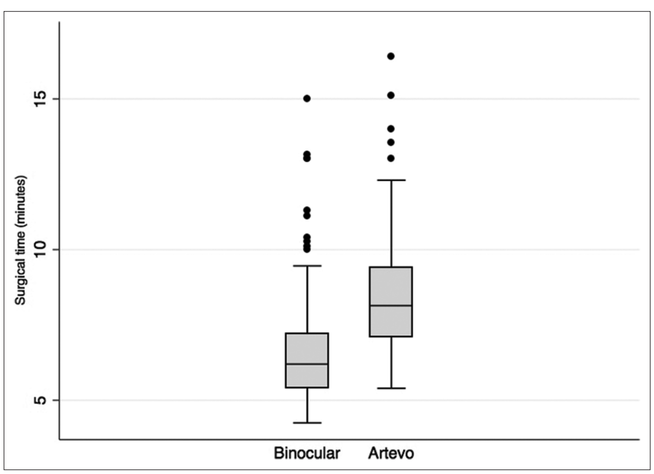

Figure 1: Box and Whisker Plot Showing Median Surgical Time in the Conventional Microscope and 3-D Heads Up Display Group, along with Interquartile Range and Outliers

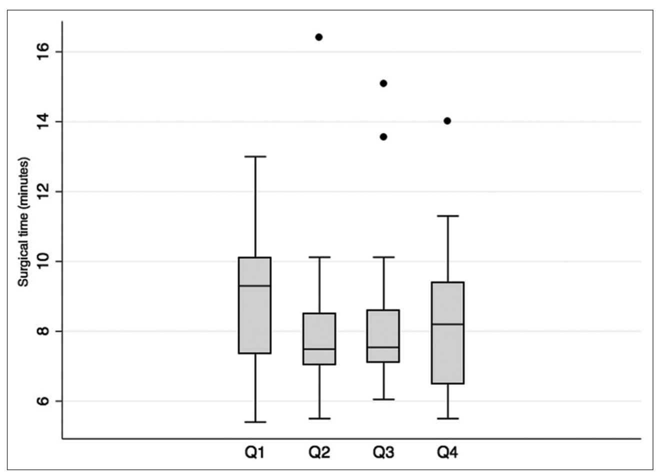

Figure 2: Box and Whisker Plot Showing Median Surgical Time Across the Four Quartiles within the 3-D Heads Up Display Group (n = 25 in each Quartile), along with Interquartile Range and Outliers

greater than time to perform surgery using the conventional microscope ($p = 0.003$). However, the surgeon workload score showed significant reduction over time suggesting increasing ease of surgeon with experience [Table 3].

In terms of complications, one nucleus drop occurred in the 1st quartile and one zonular dialysis happened in the 2nd quartile. There were no other complications and no significant differences in rates of complications across

Table 2: Comparison of Complications and Post-Op Parameters in Eyes that Underwent 3-D Heads Up Display Group vs. Conventional Microscope

Variable	Conventional Microscope (*n*=243)	3-D Heads Up Display Group (*n*=100)	*P*
Intra-Operative Complications			
PCR	4 (2%)	0	
Nucleus drop	0	1 (1%)	0.28
Iris prolapse	1 (<1%)	0	
Ragged incision	1 (<1%)	0	
Zonular dialysis	0	1 (1%)	
Postoperative Day 1			
BCVA (logMAR)	0.40±0.27	0.41±0.34	0.61
IOP	21.1±6.1	21.3±5.9	0.84
DCCT** (m)	46±28	45±21	
Striate keratopathy			
Grade 1	29 (12%)	17 (17%)	0.12
Grade 2	55 (23%)	11 (11%)	
Grade 3	36 (15%)	14 (14%)	
Grade 4	8 (3%)	5 (5%)	

**DCCT calculated as postop CCT-preop CCT

Table 3: Comparison Between the Four Quartiles Based on Date of Surgery (Learning Curve)

Variable	Q1 (*n*=25)	Q2 (*n*=25)	Q3 (*n*=25)	Q4 (*n*=25)	*P*
Age	65.6±9.1	64.6±7.6	66.5±9.2	68.2±7.3	0.48
% Men	7 (28%)	15 (60%)	12 (48%)	17 (68%)	0.08
Preop BCVA	0.69±0.33	0.63±0.30	0.73±0.45	0.88±59	0.68
Surgical time	9.1±1.9	8.0±2.1	8.3±2.1	8.2±1.9	0.17
Irregular rhexis	4 (16%)	0	2 (8%)	0	0.06
Rhexis run off	1 (4%)	0	1 (4%)	0	0.56
Complications					
PCR	0	0	0	0	0.42
Nucleus drop	1	0	0	0	
Zonular dialysis	0	1	0	0	
BCVA on POD1	0.38±0.25	0.41±0.36	0.41±0.34	0.44±0.41	0.99
Converting to Binocular	3 (12%)	1 (4)	1 (4%)	2 (8%)	0.64
Difficulty with 3-D Heads up display group					
Low illumination	3 (12%)	0	1 (4%)	1 (4%)	0.39
Difficult depth perception	2 (8%)	1 (4%)	0	1 (4%)	
Surgeon workload score	45.8±12.5	41.8±17.3	36.9±15.2	28.6±7.3	0.03

quarters. Of the 100 cases, the surgeons experienced problems with visualization in 9 cases (9%), of which 5 were due to low illumination and 4 were due to depth perception. Of these 9 cases, 7 were converted to the conventional binocular microscope (78%) of which 3 conversions occurred in the 1st quarter, 1 each in the 2nd and 3rd quarters and 2 in the 4th quarter [Table 3]. Conversions were due to low illumination in the 3 eyes and difficulty in depth perception in the 3 eyes while one was due to intraoperative pupillary constriction.

In the 3-D Heads up display system group, the eye that experienced nucleus drop did not have any predisposing factors such as a small pupil or PPC and the surgeon did not report any problems with visualization. The IOL was placed in the sulcus after a thorough anterior vitrectomy under the 3-D Heads up display system, and the nucleus was removed via a parsplana approach after 24 hours with good visual outcome. Similarly, in the eye that had zonular dialysis, the surgeon reported difficulties in depth perception and resorted to converting to the conventional microscope to manage the dialysis with a capsular tension ring and placed the IOL in the bag, without the need for a vitrectomy and with good visual outcome.

On comparing between surgeons, we found no differences in the pre and intra-operative parameters. The overall surgical time was also similar between surgeons (7.3 + 1.9 min for ASK vs. 6.8 + 2.0 minutes for JAK, $P = 0.21$). Both surgeons took longer time while operating on the 3-D Heads up display system (ASK = 8.5 ± 1.9 minutes and JAK = 8.2 ± 2.1 minutes) compared to the binocular microscope (ASK = 6.8 + 1.7 minutes and JAK = 6.3 + 1.8 minutes). The surgeon workload score was also similar between surgeons with both having higher difficulty while using the 3-D Heads up display system (37.3 ± 13.4 for ASK vs. 34.3 ± 14.8 for JAK, $P = 0.29$). There were no other differences between surgeons in terms of complications and postoperative outcomes such as BCVA and striate keratopathy.

Discussion

In this study, we found that surgeries performed under the 3-D Heads up display system (ARTEVO 800, Carl Zeiss Meditec, U. S. A) by an experienced cataract surgeon took more time compared to the Conventional Microscope. Surgeons experienced problems with either illumination or depth perception in 9% of the cases. Slightly more complications occurred in the initial 25 cases and more conversions from 3-D Heads up display system to binocular microscope also occurred in the first 25 cases. The surgeons' comfort improved significantly with experience over the first 100 cases.

The 3-D Heads up display system, apart from offering excellent visualization, an ergonomic surgical posture, and better patient comfort, also provides access to real time intraoperative OCT imaging of the surgical field, which can be very advantageous while performing endothelial surgeries, visualizing the integrity of the posterior capsule, confirming the proper positioning of the IOL in the bag and identifying incision related problems on table.

Conversion from the digital to the conventional visualization using binocular optics is also quite simple. Additionally, it also allows superimposition of pre-operative data points on the large LED screen without disturbing the surgical field of view, an excellent teaching tool, offers data storage on a compliant cloud based server and lends itself to research easily. We did not observe any significant lag between intraocular manoeuvres and the images transmitted to the screen.

The colour of tissues was also as natural as seen with the conventional microscope and we found no problems with performing the capsulorhexis in most cases, including the eyes with mature cataracts. We also observed that the sharpness of focus was not lost even on higher magnifications, even while performing capsulorhexis.

Depth perception and low illumination were encountered in about 10% of the cases and many were in the first 50 cases. Similarly, conversions to conventional microscope were greater in the first 50 cases and both complications i.e., nucleus drop and zonular dialysis occurred within the first 50 cases. In our opinion, an experienced cataract surgeon without any prior exposure to heads-up surgery should be able to adapt after the first 25 cases and become comfortable after the initial 50 cases, after which complications are extremely rare. This was also corroborated with significant improvement in the comfort of doing surgery assessed using a standardized assessment scale.

In a large retrospective series, Weinstock *et al*.[12] also showed very low complication rates using the Heads – up Ngenuity system (12/1673 cases, 0.72%) compared to 0.77% using the conventional microscope. Nariai *et al*.[8] reported that with real-time digital processing and automated brightness control, the 3D Ngenuity system reduced ocular surface illumination by 50% thereby reducing patient's photophobia. This may improve patient cooperation and help reduce complication rates too.

We did not observe any significant lag between intraocular manoeuvres and the images transmitted to the screen. Similar findings were reported by Kaur *et al*.,[16] comparing the 3D Ngenuity system (80 milliseconds) with that to the Artevo 800 visualization system (less than 50 milliseconds).

We also found that surgeries using the 3-D Heads up display system took about 2 minutes more to complete for both surgeons. However, Weinstock *et al*.,[12] reported no differences in surgical time across the Ngenuity (6.48 ± 1.15 minutes) and conventional microscope (6.52 ± 1.38). Most other studies using the Ngenuity for anterior and posterior segment surgeries do not show any differences in time taken for surgery across these groups.[17,18] However, most other studies do not provide a quartile-wise split in surgical times and complication rates, making it difficult to see the learning curve. On comparing surgical times across quartiles, we find that both surgeons took about 1 minute lesser after the first 25 cases, suggesting improving adaptability and comfort while operating as experience increases, a fact also seen with the surgical comfort scale assessment. We suspect that the lack of wet lab training and a cautious approach in the beginning by both surgeons, mainly to avoid complications, lead to more surgical time.

The fact that the EPT was slightly shorter in the 3-D Heads up display system group shows that surgeons took more time for other steps such as incision creation, capsulorhexis and IOL implantation. However, we did not record the time required for each of these manoeuvres and hence are unable to firmly comment on any one step that required more time. However, we suspect that capsulorhexis may have required the maximum time when performing the earlier cases, since it requires maximum depth perception.

The drawbacks of the study are the lack of a strict random allocation and masking, and lack of documentation of patient comfort in terms of illumination levels and pain or discomfort during surgery and lack of formal documentation of the surgeon's posture. The strengths are the relatively large sample size, presence of a comparison group using the Conventional Microscope and documentation of the learning curve of two experienced surgeons performing high volume cataract surgery. To the best of our knowledge, this is the largest series comparing surgical safety and efficacy using this 3-D Heads up visualization system.

Conclusion

In conclusion, surgeries with the heads up display system provides excellent 3-D visualization with good depth perception and real time imaging without time lags. However, it takes about 2 minutes more on an average, to finish routine cataract surgery. An experienced surgeon should be comfortable with the heads up display system after negotiating the initial 50 cases. Further studies using a randomized study design are required to understand usefulness and widen applications of 3-D Heads-up cataract surgery. A cost-benefit analysis is also essential to justify the added costs of visualization systems before they are adopted on a wider scale in resource-poor settings globally.

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Conflicts of interest

There are no conflicts of interest.

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