Original Article

Heads-up 3D viewing system in rhegmatogenous retinal detachment with proliferative vitreoretinopathy - A prospective randomized trial

Deeksha Rani, Atul Kumar, Parijat Chandra, Rohan Chawla, Nasiq Hasan, Divya Agarwal

Purpose: To compare the outcomes of vitreoretinal surgery in patients with primary and recurrent rhegmatogenous retinal detachment (RRD) with proliferative vitreoretinopathy (PVR) on 3 dimensional digitally assisted visualization system (3D-DAVS) and conventional analogue microscope (CAM). **Methods:** 68 patients with primary (50) and recurrent (18) RRD with PVR > C1 were included. One group underwent surgery on 3D-DAVS while the other on CAM. The parameters studied included detachment rate, best-corrected visual acuity (BCVA), duration of surgery, mean endo-illumination levels of 23 G (Gauge) micro incision vitrectomy system (MIVS) and microscope and satisfaction of surgeon and observers based on a framed questionnaire. The mean duration of follow up was three months. **Results:** 68 eyes of 68 patients with median age 52.5 (range 18–68) years were included. 50 had primary RRD and 18 had recurrent RRD. Detachment rate at the end of three months was comparable in both groups of primary ($P > 0.99$) and recurrent ($P = 0.21$) RRD. Mean duration of surgery in minutes for 3D DAVS and CAM group was 61.8 (±22.07) and 58.04 (±12.33), respectively, in primary RRD and 37.22 (±10.27) and 36.55 (±5.92), respectively, in recurrent RRD group. Mean endo-illumination in 3D DAVS (14.5%) group was half of that in CAM (34.17%) group. Surgeon and observer satisfaction scores were significantly higher for 3D DAVS group. **Conclusion:** 3D DAVS is a safe and effective modality or performing VR surgery in RRD with PVR. 3D DAVS allows lower endo-illumination levels provides superior surgeon ergonomics and offers better learning opportunities to the trainees.

Key words: 3D digitally assisted visualization system, endo-illumination, proliferative vitreoretinopathy, rhegmatogenous retinal detachment

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The current vogue in the present era is of digital visualization of ophthalmic microsurgeries. Among various modalities, the most intriguing is the three-dimensional (3D) visualization of ophthalmic surgery. 3D imaging can be classified as "active" visualization and "passive" visualization. In "active" visualization, high-speed consecutive images are shown to the eyes alternatively. A special pair of electronic glasses are worn by the observer that actively suppresses the image in the other eye. Head-mounted systems use the "active" system of 3D visualization. The current "Heads-Up" display systems use a "passive" system in which two images are mixed horizontally and then separated using polarized glasses so that each eye sees a slightly horizontally disparate image, which allows perception of depth. This system can be connected to a conventional analog microscope (CAM) and the image is projected on the screen. The surgeon now operates with a "Heads-Up" position wearing a pair of polarized glasses.

The binoculars of the microscope are removed and a high-resolution camera is attached at its place, which carries the visual signal through the fiberoptic transmission to a 55-inch 4K display that is kept at a distance of 1 to 1.5 meters from the surgeon. The screen displays a high definition image of a resolution of 2160 × 3840 pixels. The surgeon wears a pair of passive polaroid glasses that polarize the light entering each eye rendering 3D view of the image.

The proposed advantages consist of better ergonomics for the surgeon. Hours-long vitreoretinal (VR) surgeries in a "Heads down" position, peeking inside the binoculars of operating microscopes, have been an etiology for musculoskeletal disorders in many ophthalmic surgeons. This led to an increased prevalence of back pain and neck pain in surgeons ultimately leading to significantly reduced surgical longevity.[1,2]

The 3D-digitally assisted visualization system (3D DAVS) allows the surgeons to operate in a more comfortable and physiological "Heads-Up" position.[3] It also gives a magnified view of the intraoperative field so that all personnel in the operation room can see the same image as seen by the surgeon. This translates to superior learning opportunity to trainees and residents.[4,5] A specific advantage that is unique to vitreoretinal surgeries is the decreased requirement of endo-illumination with 3D DAVS. Higher degrees of endo-illumination have

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been reported to be associated with significant macular phototoxicity.[6] The image amplification system of 3D DAVS allows excellent visualization at half the endoillumination levels used on CAM.[7-9]

Various studies have been done in the past to assess the feasibility of performing vitreoretinal surgeries on 3D DAVS and have reported excellent outcomes, minimal complications, comparable surgical duration, and lower endoillumination.[10-22]

To the best of our knowledge, there has been no study that compares the outcomes of vitreoretinal surgeries in patients with rhegmatogenous retinal detachment (RRD) with proliferative vitreo retinopathy (PVR) by 3D DAVS and CAM. We conducted this study to evaluate the safety and efficacy of 3D "Heads Up" DAVS in primary or recurrent RRD with PVR and to determine the anatomical and functional outcomes of both entities.

Methods

This was a prospective, single center, unmasked, randomized control trial conducted at our center. The study was done as per the tenets of "Declaration of Helsinki". The clearance of the Institute Ethics Committee was obtained, and the trial was registered under the Clinical Trial Registry of India (CTRI/2020/04/024412).

The duration of enrolment of our study was from September 2018 to November 2019. During this period, 68 systemically stable phakic or pseudophakic patients (age >18 years) presenting to the outpatient department (OPD) and retina clinic at our center and diagnosed with primary (50) and recurrent (18) RRD with PVR > C1 (Updated Retina Society Classification of PVR, 1991), were enrolled provided they consented to participate and follow up. Patients suffering from other visually disabling disorders glaucoma, disc pallor, age-related macular degeneration, and corneal opacity were excluded from our study. Patients with traumatic or secondary RRD were also excluded.

Patients in both groups were randomized using computer-based software into two subgroups (allocation ratio 1:1). Subgroup 1 underwent surgery on 3D DAVS, while the other underwent surgery on CAM.

A detailed history regarding the onset of symptoms and past surgical or medical history was taken and recorded.

Routine ophthalmic examination like the assessment of best corrected visual acuity (BCVA), measurement of intraocular pressure (IOP), swinging flashlight test to document relative afferent pupillary defect (RAPD), and detailed slit lamp examination was done with pupil both dilated and undilated.

Dilated indirect ophthalmoscopy with peripheral indentation was done to document the extent of retinal detachment, the status of the macula, and exact localization of breaks and other peripheral treatable lesions and the findings were drawn on modified Amsler Dubois cartograph. Indirect ophthalmoscopy of the fellow eye was also done to screen for any peripheral treatable lesions and those lesions were appropriately managed (laser photocoagulation or cryotherapy). Ultra-wide field fundus photograph was also taken for documentation.

Patients who had visually significant cataract underwent phacoemulsification with posterior chamber intraocular lens (PCIOL) insertion two days before VR surgery. All patients with primary RRD and selected patients with recurrent RRD (who had previously not undergone primary belt buckle) underwent belt buckle followed by 23 G pars plana vitrectomy and silicone oil tamponade on constellation vitrectomy system (Alcon inc.).

Microscope illumination was set at 42% on 3D DAVS and 80% on CAM. Endo-illumination of the constellation was adjusted as per intraoperative visibility. 3D DAVS display was kept at 1 meter from the surgeon. Iris aperture of the camera was opened at 30% width and image display was kept at a gain of 1. White balance was adjusted before every surgery. All surgeries were performed by a single surgeon [Fig. 1].

The surgeon was middle-aged with no significant comorbidities that could bias the outcomes of the present study. Average no. of surgeries performed each day varied from 4 to 6, while the surgeries included in the study were normally sequenced between 1 to 3. Since all cases were operated by a single experienced surgeon, bias related to surgical expertize can be excluded.

Steps of VR surgery were identical in both groups. Silicone oil was used for endo-tamponade and strict postoperative face-down positioning was advised. Follow up examination was done on day 1, 1 week, 1 month and 3 months. The examination included assessment of BCVA, measurement of IOP, slit lamp examination for assessment of anterior chamber reaction, and indirect ophthalmoscopy for the assessment of the status of the retina.

After performing 10 surgeries each on both systems, the surgeon and 10 observers were asked to fill up the "Surgeon Satisfaction Score Sheet" and "Observer Satisfaction Score Sheet".

The surgeon's sheet contained 14 questions related to the quality of image, comfort of the surgeon, simplicity of use, a teaching tool, and ease of operating in terms of the absence of eye, back, and neck pain. The observer's score sheet had six questions related to the comprehension of the step being performed, understanding the anatomy, and overall satisfaction rate on the two systems. Answers were to be graded from 1 to 5 with 1 being the worst and 5 being the best.

The primary outcome studied was the anatomical success studied in terms of the redetachment rate at the end of three months. The secondary outcomes included BCVA, duration of surgery, endo-illumination, microscope illumination, complications, surgeon satisfaction score and observer satisfaction score.

Entire data was entered into an excel sheet and analyzed using Stata version 14.1. Comparison between 3D DAVS and CAM was done using "Mann- Whitney Test", "Chi-Square test" and "Fischer Exact test" as and when appropriate. Student's t-test was used to compare the improvement in BCVA and surgeon and observer satisfaction scores. The level of significance was set at P value <0.05.

Results

Baseline characteristics

68 eyes of 68 patients with median age 52.5 (range: 18–68) years were included in the study. Baseline characteristics in all subgroups were comparable and are presented in Table 1.

In the primary RRD group, more than half of the patients in both subgroups had not undergone any surgery in past. Approximately one-quarter of patients in both subgroups had undergone uneventful cataract surgery with placement of PCIOL in the capsular bag. The trend was similar in both subgroups of recurrent RRD. The severity of proliferative vitreoretinopathy was also similarly divided into all subgroups [Fig. 2].

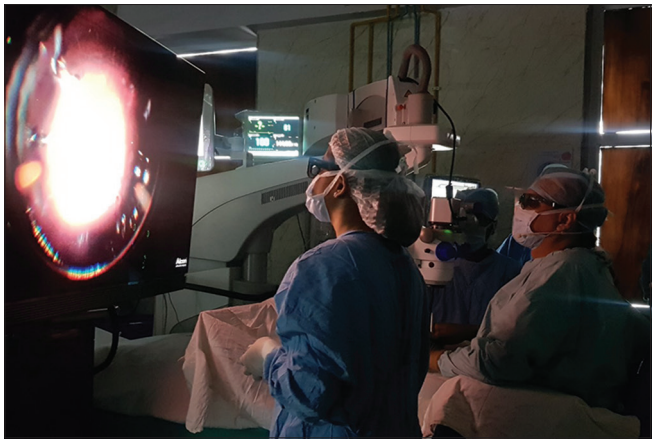


Figure 1: Surgeon operating on 3D DAVS with the 55-inch 4 K display at the distance of 1 meter from the surgeon. The surgeon is wearing 3D polaroid glasses and is operating with the "Heads- Up" position

Intraoperative parameters

In primary RRD, the mean duration of surgery was 61.8 (±22.07) and 58.04 (±12.33) minutes in 3D DAVS and CAM, respectively. Mean duration was lower in recurrent RRD group being 37.22 (±10.27) and 36.55 (±5.92) minutes, respectively. The duration of surgeries in both groups was comparable. ($P = 0.71$ for primary RRD group and $P = 0.69$ in recurrent RRD group).

In our study, mean endo-illumination level in both primary RRD and recurrent RRD group was 14.28 (±1.43) and 14.66 (±0.5) %, respectively, in patients operated on 3D DAVS. This was significantly lower ($P < 0.001$) than endoillumination levels used on CAM, which was 34.24 (±0.52) and 34.11 (±0.33) %, respectively, in primary and recurrent RRD group. Illumination of the microscope was kept at 42% for 3D DAVS and 80% for CAM.

Postoperative parameters

The primary outcome of our study was the anatomical success. In all 68 cases, retina was attached on the first postoperative day and at one week. Redetachment was seen in one eye each in both subgroups of primary RRD at 1-month postop. By the end of 3 months, in the primary RRD group detachment was seen in two eyes that had been operated on 3D DAVS and three eyes operated on CAM group. In recurrent RRD group, none of the eyes operated on 3D DAVS

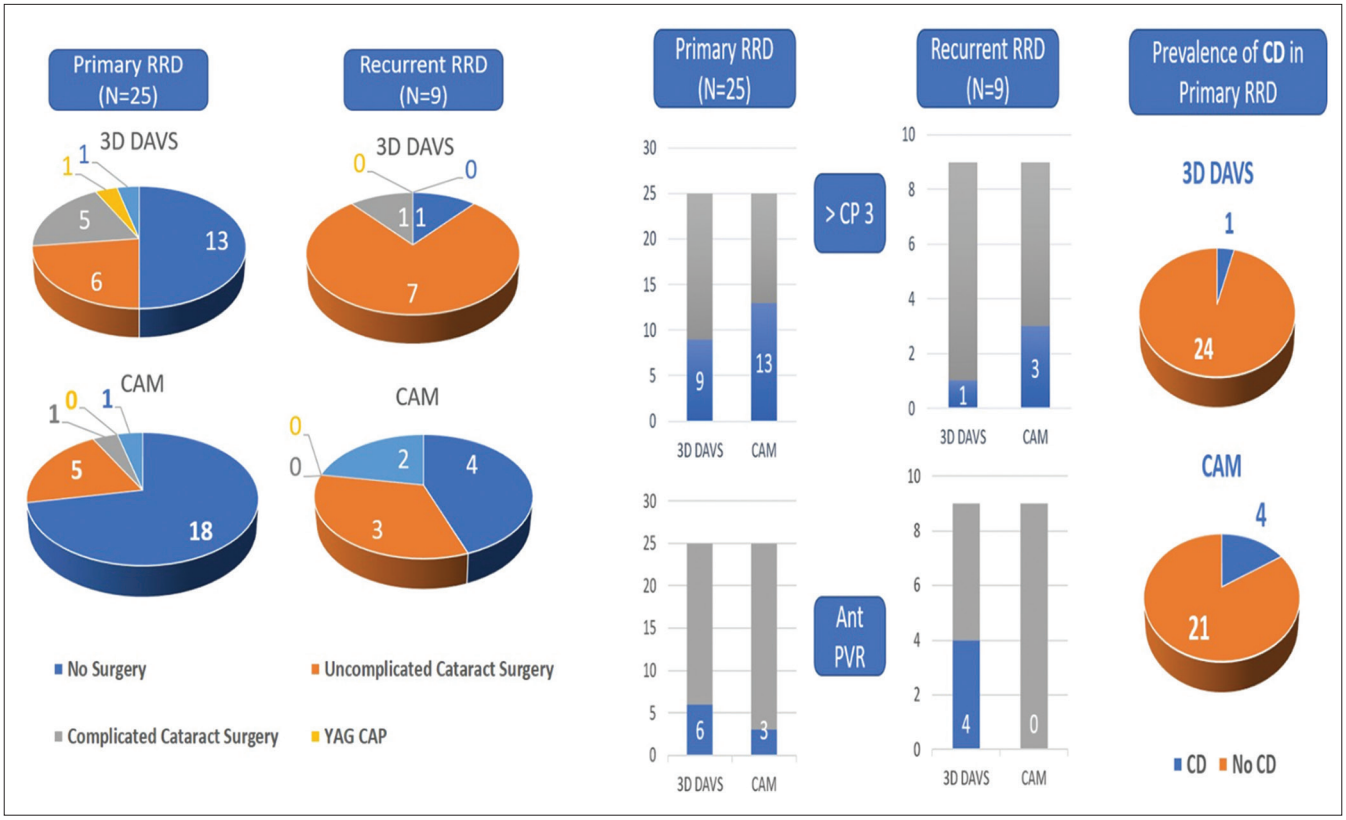


Figure 2: Graphical representation of past surgical history and characteristics of RRD in patients of primary and recurrent RRD with PVR > C1 that underwent VR surgery on 3D DAVS and CAM

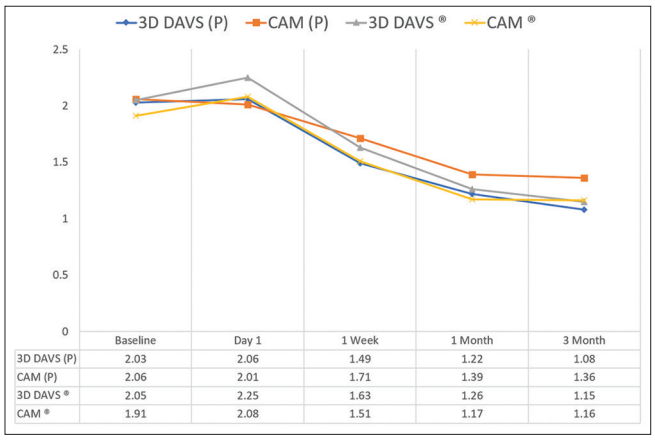
had detached in contrast to two eyes in the CAM group. The outcomes in both groups were comparable with $P > 0.99$ for primary RRD group and $P = 0.21$ for recurrent RRD group. These results establish the safety of 3D DAVS in the practice of VR surgery for RRD.

In the primary RRD group, BCVA improved from a baseline of 2.03 log units to 1.08 log units at the end of three months in 3D DAVS group ($P = 0.0003$). Improvement was similar and comparable to that seen in the CAM group. [2.06 log units to 1.36 log units ($P = 0.0007$)].

In the recurrent RRD group, BCVA at baseline was 2.05 log units in 3D DAVS group and 1.91 log units in the CAM group. At the end of three months, it had improved to 1.15 log units in 3D DAVS group ($P = 0.03$) and 1.16 log units in the CAM group. ($P = 0.02$) [Fig. 3].

Complications

In the primary RRD group, iatrogenic breaks were seen in 16% cases operated on 3D DAVS and 28% cases operated on CAM ($P = 0.49$). Majority of these breaks occurred during peripheral vitreous shaving. One patient in 3D DAVS group had subretinal PFCL and one patient in the CAM group had subretinal oil. Both cases were managed conservatively.



	Baseline	Day 1	1 Week	1 Month	3 Month
3D DAVS (P)	2.03	2.06	1.49	1.22	1.08
CAM (P)	2.06	2.01	1.71	1.39	1.36
3D DAVS ®	2.05	2.25	1.63	1.26	1.15
CAM ®	1.91	2.08	1.51	1.17	1.16

Figure 3: Line diagram showing postoperative best corrected visual acuity (BCVA) at baseline, post-op day 1, 1 week, 1 month, and 3 months in patients with primary and recurrent RRD with PVR > C1 who underwent VR surgery on 3D DAVS and CAM

Prevalence of other complications was also low and comparable.

Satisfaction scores

The comparative evaluation of the surgeon and observer satisfaction score revealed the superiority of 3D DAVS in all fronts except few where it was found to be as good as CAM. The later include quality of Mi-OCT, absence of back pain, neck pain, and eye fatigue. The overall surgeon satisfaction score was 4 (±0.67) for 3D DAVS and 1.9 (±0.57) for CAM. The observer satisfaction score was 4.7 (±0.48) for 3D DAVS and 2.6 (±0.52) for 3D DAVS and CAM, respectively. Table 2 represents the surgeon and observer satisfaction score sheets.

Discussion

3D DAVS has been established to be associated with improved visibility, easy manoeuvrability, superior surgeon ergonomics, and comparable outcomes in various surgeries.

Rhegmatogenous retinal detachment imposes a specific challenge to a vitreoretinal surgeon in terms of the need for improved visualization, better contrast, and improved magnification so that even minute breaks can be detected and lasered appropriately.

The results of our study reveal a similar detachment rate and similar improvement in BCVA in both groups. The rate of intraoperative complications with 3D DAVS was also comparable to CAM. In the primary RRD group, iatrogenic breaks were seen in 16% cases operated on 3D DAVS and 28% cases operated on CAM. The majority of these breaks occurred during peripheral vitreous shaving. The prevalence of iatrogenic breaks was slightly lower on 3D DAVS as compared to CAM. This could be contributed to better peripheral visualization and higher magnification with 3D DAVS. However, the results were not statistically significant to make this comment ($P = 0.49$).

Most VR surgeries for RRD are often of long duration and the surgeon has to perform the surgeries in an uncomfortable position looking inside the eyepieces of a binocular conventional analogue microscope. This has been associated with a higher prevalence of back pain, neck pain, and eye fatigue in VR surgeons.[23]

In our study, mean surgical duration with 3D DAVS was comparable to CAM. This result is supported by works of

Table 1: Baseline clinical characteristics of participants with primary and recurrent rhegmatogenous retinal detachment (RRD) with proliferative vitreoretinopathy (PVR) > C1 undergoing vitreoretinal surgery (VR) on 3D-digitally assisted visualization system (3D DAVS) and conventional analog microscope (CAM)

Parameters	Primary RRD			Recurrent RRD		
	3D DAVS	CAM	*P*	3D DAVS	CAM	*P*
Age in years Median (Range)	58 (24-68)	50 (18-67)	0.34*t*	43 (22-62)	45 (23-64)	0.96*t*
Gender Distribution (M:F)	16:9	18:7	0.54χ^2	5:4	6:3	>0.99∫
Laterality (R:L)	13:12	12:13	0.78χ^2	4:5	6:3	0.32χ^2
Lens Status						
Phakic	10	15	0.16χ^2	1	5	0.06χ^2
Pseudophakic	15	10		8	4	
Axial Length in mm Mean (±SD)	25 (±1.44)	23 (±2.16)	0.94*t*	23.28 (±1.27)	23.72 (±2.61)	0.67*t*
Duration of RD in months Median (Range)	2 (1-24)	2 (1-36)	0.61Φ	4 (1-6)	2 (1-8)	0.34Φ

SD: Standard Deviation; t: Student's *t*-test; χ^2: Chi-Square test; ∫: Fischer's Exact; Φ: Mann Whitney Test

Table 2: Comparison of Surgeon and Observer Satisfaction Score while operating on 3D DAVS and CAM

S. No	Parameter (Surgeon)	3D DAVS: Mean (±SD)	CAM: Mean (±SD)	*P* (*t*)
1	Comfort	4.3 (±0.48)	2.1 (±0.57)	<0.001
2	Visibility	4.1 (±0.57)	2.7 (±0.48)	<0.001
3	Peripheral visualization	4.9 (±0.32)	1.9 (±0.57)	<0.001
4	Image quality	4.7 (±0.48)	3 (±0.47)	<0.001
5	Mi-OCT quality	4.6 (±0.69)	4.4 (±0.52)	0.48
6	Magnification	5 (±0)	2.7 (±0.48)	<0.001
7	Depth perception	4.8 (±0.42)	3.4 (±0.52)	<0.001
8	Simplicity to use	4.7 (±0.48)	2.8 (±0.42)	<0.001
9	Teaching	5 (±0)	2.5 (±0.53)	<0.001
10	Maneuverability	4.9 (±0.32)	3.3 (±0.48)	<0.001
11	Absence of eye fatigue	4.8 (±0.42)	4.6 (±0.52)	0.35
12	Absence of back pain	4.2 (±0.42)	4.4 (±0.52)	0.35
13	Absence of neck pain	4.1 (±0.57)	4.6 (±0.52)	0.05
14	Overall satisfaction score	4 (±0.67)	1.9 (±0.57)	<0.001
	Parameter (observer)			
1.	Visibility	4.4 (0.52)	2.1 (0.32)	<0.001
2.	Depth perception	4.7 (0.48)	2 (0.82)	<0.001
3.	Understanding of anatomy	4.5 (0.53)	2 (0.82)	<0.001
4.	Understanding of step being performed	4.4 (0.52)	1.9 (0.74)	<0.001
5.	Understanding of Mi-OCT	4.6 (0.52)	4.3 (0.95)	0.39
6.	Overall Satisfaction	4.7 (0.48)	2.6 (0.52)	<0.001

SD: Standard Deviation; t: Student's *t*-test

Coppola *et al.* in 2017, Romano *et al.* in 2018, Kumar *et al.* in 2018, Palacois *et al.* in 2019, Babu *et al.* in 2020 and Berquet *et al.*[4,10,11,13,17,22] Few studies have reported longer surgical duration but this can be attributed to learning curve of the surgeon.[12]

Retinal phototoxicity has been described as a function of the amount of light absorbed by retina.[6] This becomes specifically important for the light emitted by endoilluminator used during VR surgery. An endoilluminator when held close to the retina, the entire intensity of light gets focused on a small demarcated area of the retina. Phototoxicity is often augmented by prolonged duration of VR surgeries.

Digital amplification tool of 3D DAVS obviates the need for high endo-illumination. Sharper, clearer images of high resolution can be produced even with endo-illuminator levels set at as low as 10% of the maximum.[19]

In our study, the intensity of endo-illumination required to perform VR surgery was 14.5%. This value is almost half of what is required to operate on CAM. Microscope illumination required for 3D DAVS was also 5 per cent lower than that needed on CAM. This goes in hand with works of Adam *et al*., Romano *et al*. and Zhang *et al.* who also reported endo-illumination levels to be as low as 10%–13% in the sets of surgeries that they performed. A similar study based on macular hole surgeries performed by the same surgeon also reports similar endo-illumination levels with 3D DAVS.[13] The victory of 3D DAVS in this field hence remains unchallenged. Berquet *et al.* in 2020, however, reported endo-illumination levels in 3D DAVS as equivalent to CAM. They attributed this to the learning curve of the surgeon. Lowering endo-illumination mandates an appropriate camera aperture size to balance the illumination level and depth of field. Finding this subtle balance between the two has a significant learning curve.[8,9,13,19,24]

The digital image enhancement feature allows improved magnification, improved depth perception, and higher resolution as compared to the conventional microscope. This helps the surgeon to perform meticulous surgical steps easily. 3D DAVS also allows the surgeon to maintain a comfortable posture so that long surgeries can be performed comfortably. The comfort of the surgeon with 3D DAVS was assessed using the "surgeon satisfaction score". The surgeon found operating on 3D DAVS to be more satisfying and chose it over CAM when given an option. The surgeon has a vast experience of operating on both CAM and 3D DAVS and has been operating on 3D DAVS for the last 4 years. No back pain or neck pain as compared to conventional microscopes was noted. Similar results have been obtained in previous studies.[13] There were no cases that needed to be aborted or converted to CAM. Operating on 3D DAVS was associated with 5 to 10 degrees of face turn to visualize the screen. However, this did not lead to any significant discomfort to the surgeon. No head tilt was noted. Figueiredo *et al*. also reported better ergonomics with the 3D system when compared to CAM in terms of back pain and neck pain.[25] Similar results leading to the superior surgeon's ergonomics have also been reported by many other workers.[4,5,8-12,19-22,25,18] 3D DAVS has also been described to perform surgery in patients with disabling musculoskeletal deformities (e.g., Kyphosis) when operating on a CAM is quite challenging.[16]

Vitreoretinal surgeries involve fine manipulations that require good fusion and a good binocular single vision (BSV). Good BSV is hence a prerequisite for 3D DAVS. Better depth of resolution and dynamic focussing helps surgeon in doing finer manipulations. Viewing surgeries on 3D DAVS wearing polaroid

glasses led to a better understanding of anatomy and surgical steps being performed by the observer. Thus, this new modality can act as a superior teaching tool in the modern practice of ophthalmic surgery. Similar results have also been reported by Chhaya *et al*.[5]

Limitations of the study

Our study had various limitations. The first was the small sample size, which was not sufficient to identify small changes in visual acuity and other surgical and ergonomic outcomes. However, the surgeon has a huge experience in performing the surgeries on both platforms and found 3D DAVS to be ergonomically superior to the other. The follow-up duration was also short and was not enough to comment upon the difference between the long-term outcomes in the two groups. Silicon oil removal (SOR) was not done in any of the cases included and hence our study does not comment on any difference between post SOR detachments in the two groups.

Conclusion

To conclude, it can be said that replacing CAM with 3D DAVS in modern vitreoretinal surgical practice can provide an excellent operating experience with results equivalent to the conventional means. Surgical duration, outcomes, rate of complications is similar to CAM, thus establishing the safety of 3D DAVS. Surgeries can be performed at half of the conventional illumination levels. The surgeon and observer satisfaction rate is significantly higher for 3D DAVS. 3D DAVS has been proved to provide superior ergonomics to the surgeon and enhanced learning experience to residents and trainees. The introduction of 3D DAVS in medical colleges and fellow training institutes must be considered provided it is economically and logistically feasible.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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