NGENUITY®
3D Visualization System

Clinical Science Compendium

Summary of
Peer-Reviewed
Clinical Research

Medical Affairs North America

Alcon

INTRODUCTION

At Alcon, our surgical medical device products, such as the NGENUITY® 3D Visualization System for vitreoretinal surgery, are designed, manufactured and marketed with a body of science developed through rigorous bench research and clinical studies. As the body of knowledge behind Alcon's products grows, so does the challenge of making our customers aware of its depth. Our medical affairs organization is thus focused on both high-quality data generation and its communication to the clinical community.

High-quality scientific publications are essential to convey the clinical community's knowledge and experience with new technology. This clinical science compendium provides a consolidated view of peer-reviewed publications for NGENUITY®. The TrueVision® 3D Visualization System was acquired by Alcon and rebranded as NGENUITY® in 2018.

In addition to exploring this compendium, we encourage you to visit Alcon's Medical Affairs website—AlconScience.com—to learn more about how medical science matters to us. Beyond scientific publications relating to Alcon's portfolio, you will find more information on independent medical educational grants, teaching facility equipment placement, and areas of interest for investigator-initiated trials.

METHODOLOGY

The 24 peer-reviewed articles included in this compendium were identified using the PubMed and Google Scholar databases using the search terms such as "NGENUITY," "vitreoretinal surgery," and "digital 3D visualization for vitreoretinal surgery." Articles were included when they were published between January 1, 2016 and January 31, 2020 and contained clinical research involving NGENUITY® to provide high definition, magnified, stereoscopic images during micro-surgery (eg, vitreoretinal surgery, cataract surgery). Only manuscripts published in peer-reviewed journals and available in English were included in this compendium.

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Clinical Studies

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Clinical Literature Review

Heads-Up Surgery for Vitreoretinal Procedures: An Experimental and Clinical Study

System Performance

Surgical Outcomes

Eckardt and Paulo. *Retina.* 2016; 36:137-147

OVERVIEW

STUDY DESIGN

Prospective, experimental study to investigate the feasibility of performing vitrectomies while viewing a three-dimensional (3D) image on a large display in a heads-up position; retrospective analysis of outcomes following vitrectomy for macular holes

STUDY SITE(S)

Single center in Germany

PATIENTS

Prospective experimental study: no patients (20 non-surgeon volunteers aged 26 to 55 years). **Prospective clinical pilot study:** 6 eyes. **Retrospective clinical study:** greater than (>) 400 vitrectomies and phacovitrectomies & 500 phacoemulsification procedures

SURGICAL METHODOLOGY

Prospective experimental: Task based performance evaluation. **Prospective clinical pilot study:** Heads-up 3D surgery on pseudophakic eyes with macular pucker. **Retrospective clinical study:** Vitrectomies, phacovitrectomies and phacoemulsifications; glaucoma surgery (ab interno trabeculotomy) and lamellar keratoplasty (DSAEK)

SURGICAL TECHNOLOGY

Prospective experimental and clinical studies: TrueVision‡ visualization system (Alcon Laboratories, Inc.); Beam splitter (True Vision standard TrueBridge); LED light (Otto-Flex light); DORC EVA phacovitrectomy unit; 27 gauge TwinLight (DORC); stereo inverter (Oculus) and laser filter; vitreoretinal surgery - wide angle viewing system BIOM (Moller-Wedel). **Retrospective clinical study:** M822 surgical microscope (Leica Microsystems); TrueVision visualization system; 3D high dynamic range surgical camera (ICM5); TrueWare software (version 9.5.4); 46" high-definition LCD display (JVC GD463D10UQ); Passive 3D polarized glasses

KEY ENDPOINT(S)

Prospective experimental study: Task performance evaluation; optical quality; endoillumination levels. **Prospective and retrospective clinical studies:** digital image processing; intraoperative complications; ergonomics

ANALYSIS AND CONCLUSIONS

The data indicate that the heads-up method is well suited for routine vitreoretinal procedures with and without combined cataract surgery. The superior ergonomics of the heads-up method, particularly for prolonged vitreoretinal operations, were cited as a major advantage.

The authors suggest that further technical improvements, especially the introduction of ultra-high-definition cameras and displays could result in the heads-up technique becoming a new standard for ophthalmic surgery.

‡ The TrueVision® 3D Visualization System was acquired by Alcon and rebranded as NGENUITY® in 2018

STUDY RESULTS

EXPERIMENTAL STUDY: NON-SURGEON VOLUNTEER EXPERIENCE

- 91.7% of volunteers preferred the ergonomics of the heads-up technique (TrueVision) when performing the fine manipulation tasks
- Heads up and traditional methods showed similar speed, ease of microscopic manipulation and sharpness of image
- Significantly fewer mistakes were made with the heads-up method **(Figure 1)**

EXPERIMENTAL STUDY: SYSTEM PERFOMANCE

- The measured resolution of the eyepieces were roughly twice that of the 3D display, however the depth of field was approximately equal **(Figure 2)**

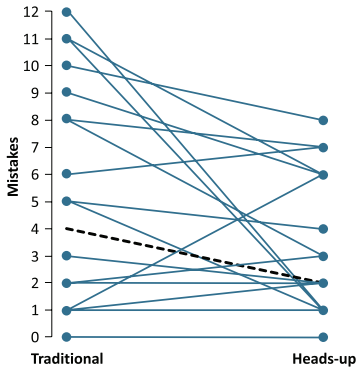
PROSPECTIVE CLINICAL EXPERIENCE

- Electronic amplification of the camera's signal resulted in increased image brightness, allowing use of reduced endoillumination levels

RETROSPECTIVE CLINICAL EXPERIENCE

- None of the procedures resulted in unexpected problems or complications attributable to the heads-up method. In no case was it necessary to switch back to traditional from the heads-up method
- Forty-one (41) of 43 (95.3%) eyes with a full-thickness macular hole had the hole successfully closed by a single operation
- One eye required an additional surgery, where SF6 gas was injected as tamponade rather than air. This success, raised the overall closure rate to 97.7%
- The immense size of macular hole in the final eye, resulted in the decision not to re-operate due to a poor prognosis

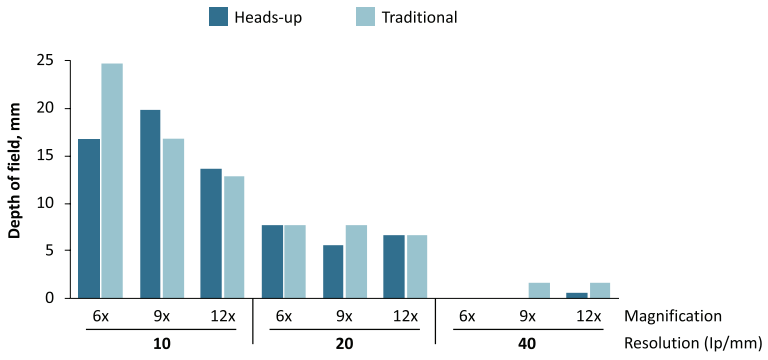
Figure 1. Number of Type B errors* committed by the 20 volunteers in Task 1† using the traditional method and the heads-up technique (TrueVision).



* *Type B error = sequins not correctly placed in alternating concave/c nvex form*

† *Task 1 = black and transparent sequins had to be placed onto 2 needles located on a biconvex polystyrene disk.*

Figure 2. Experimental volunteer experience. Depth of field of the image in heads-up technique (TrueVision) and in traditional method at x6, x9, and x12 magnification in 3 levels of resolution.



Minimal Endoillumination Levels and Display Luminous Emittance During Three-Dimensional (3D) Heads-Up Vitreoretinal Surgery

System Performance

Safety

Adam et al. *Retina.* 2017; 37:1746-1749

OVERVIEW

STUDY DESIGN

Prospective, observational surgical case series to determine minimal endoillumination levels required to perform 3D heads-up vitreoretinal surgery and to correlate endoillumination levels used for measurements of heads-up display (HUD) luminous emittance

STUDY SITE(S)

Single center in United States

PATIENTS

Ten eyes of ten patients

SURGICAL METHODOLOGY

Twenty-three (23-), 25- or 27- gauge three-port vitreoretinal surgery with a commercially available 3D HUD surgery platform. During the operation, the surgeon performing the procedure wore passive 3D polarized glasses and was positioned approximately 1.5 m from the display

SURGICAL TECHNOLOGY

TrueVision Visualization System 3D HUD*; Constellation Vision System (Alcon Laboratories, Inc.); OPMI Lumera 700 surgical microscope (Carl Zeiss); 3D high dynamic range surgical camera (ICM5); TrueWare v. 9.5.4 image processing software; GD-463D10 46" high definition (1980x1024 pixels) liquid crystal display; Dr Meter Model#LX1010BS luxmeter

KEY ENDPOINT(S)

Endoillumination levels during surgery and the corresponding luminous emittance (lux) of the HUD measured by a luxmeter

ANALYSIS AND CONCLUSIONS

Real-time digital processing and automated brightness control associated with 3D HUD platforms may permit reduced intraoperative endoillumination levels and a theoretically reduced risk of retinal phototoxicity during vitreoretinal surgery.

The authors suggest that directly comparing minimum required endoillumination levels and outcomes of surgeries that are at highest risk of phototoxicity using the HUD versus conventional operating microscopes may help confirm the clinical benefits of this emerging technology.

* The TrueVision® 3D Visualization System was acquired by Alcon and rebranded as NGENUITY® in 2018

STUDY RESULTS

SURGICAL RESULTS

- In 9 of 10 cases, the surgeon felt that they could operate comfortably at an endoillumination level of 10% of maximum output with corresponding HUD emittance of 14.3±9.5 lux
- In the remaining case, the surgeon felt comfortable at a 3% endoillumination level with corresponding HUD emittance of 15 lux
- Below this threshold, subjective image dimness and digital noise limited visibility
- Ambient operating room luminous emittance with endoillumination set to 0% and operating room lights off was 4.1±2.77 lux
- Endoillumination levels were positively correlated with luminous emittance from the 3D HUD (P<0.01, 2-tailed Pearson coefficient) (**Figures 1 and 2**)

INTRAOPERATIVE COMPLICATIONS

- There were no intraoperative complications

Figure 1. Correlation between the endoillumination level and the luminous emittance (lux) from the 3D heads-up display (HUD; TrueVision Visualization System), intraoperatively. Error bars indicate standard deviation.

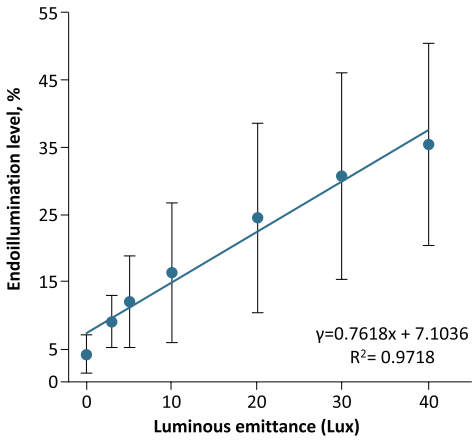
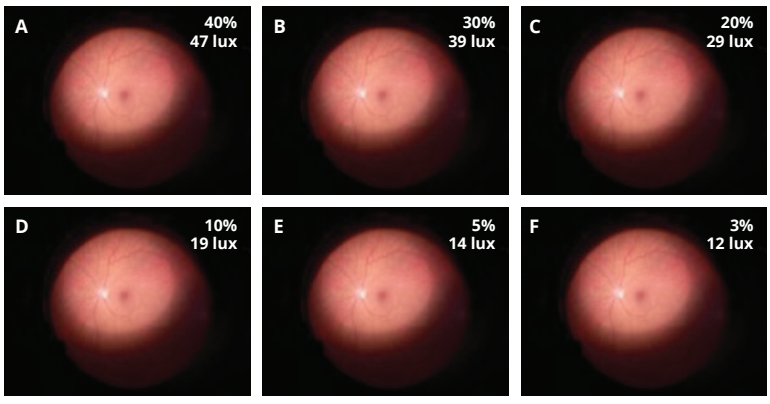


Figure 2. Intraoperative screenshots (A-F) from the 3D heads-up display (HUD; TrueVision Visualization System) of the left eye undergoing 27-gauge vitreoretinal surgery at differing endoillumination levels (%) and the associated luminous emittance (lux) from the HUD.



Heads-Up 3D Vision System for Retinal Detachment Surgery

System Performance

Surgical Outcomes

Coppola et al. *Int J Rein Vitr.* 2017; 3:46

OVERVIEW

STUDY DESIGN
Retrospective study presenting procedural and safety results from initial experience using 3D heads-up vitrectomy for retinal detachment (RD) surgery

STUDY SETTING(S)
Single center in Italy

PATIENTS
Twenty-two (22) cases (eyes); 7 cases in the 3D surgery group (86% primary simple cases, 14% complex-recurrent cases); 15 cases in the traditional surgery group (7% complex-recurrent cases, 93% primary simple cases)

SURGICAL METHODOLOGY
Heads-up 3D system in RD surgery; all cases performed using traditional RD surgical techniques (25-gauge vitrectomy plus endolaser and gas / laser tamponade) by a single surgeon

SURGICAL TECHNOLOGY
NGENUITY® 3D Visualization System (Alcon Laboratories, Inc.); traditional RD surgical system

KEY ENDPOINT(S)
Safety and efficacy; procedural success; post-operative complications; surgery time; mean endoillumination power during procedure

ANALYSIS AND CONCLUSIONS

Data showed that the 3D visualization system (NGENUITY®) was as safe and effective as the traditional RD system, providing all the advantages of digital over an analogic platform (*Table 1*). Further, use of NGENUITY® appeared to help avoid phototoxic risks related to endoillumination.

The authors acknowledge that their findings reflect the initial experience of a single center and require confirmation in larger, multicenter, prospective studies.

STUDY RESULTS

EFFICACY AND SAFETY

- Immediate procedural success (defined as complete reattachment at day 1 after surgery) was achieved in all cases for both groups
- At 30 days post-surgery, there were zero cases of re-detachment in the 3D heads-up (NGENUITY®) group and one case in the traditional surgery control group (p=0.74).
- None of the eyes experienced any major post-operative complications
- 5 eyes in the 3D group and 2 eyes in the control required medications for augmented intraocular pressure at day 1 (p=0.56)

SURGICAL DIFFERENCES AND IMPLICATIONS

- Mean ± standard deviation (SD) surgery time was 55 ± 35 min for the 3D group and 62 ± 28 minutes for the control group (p=0.07)
- Mean endoillumination power during the procedure was 10% and 45% for the 3D heads-up (NGENUITY®) and control groups, respectively (p<0.0001)
- In 60% of cases in the control group, diluted triamcinolone was injected to improve the visualization of vitreous remnants; vitreous staining was not performed in any of the 3D group (p=0.01)
- The 3D system avoided triamcinolone vitreous staining, which may explain the non-significant tendency towards shorter procedure time; surgical time is influenced by the difficulty of each singular case, and the non-randomized retrospective nature of this study cannot guarantee case homogeneity; therefore, differences in operating time between the two systems should be interpreted with caution
- The digital image enhancement enabled the reduction of endoillumination power, significantly reducing the phototoxicity to the retinal pigmented epithelium cells

Table 1. Advantages of three-dimensional (3D) heads-up system (NGENUITY®) for retinal detachment surgery.

Procedure/Indication For Surgery	Number Of Cases
Illumination	Digital enhancement of the image, lower illumination levels and, thus, reduced risk of phototoxicity
Depth of field	Enhance depth of field and amplified stereopsis allows better wider view since multiple planes are contemporary in focus
HDRi	Reduced glare of the instruments and even image brightness
Digital filtering	Filters enable the surgeon to have a better view of intraocular structures (e.g. green filter for vitreous or blood)
Education	Surgical team has the same view of the surgeon
Ergonomics	Surgeon maintains a heads-up position with a less rigid and more comfortable posture
Less asthenopia	Viewing through the eyepiece for a long time may induce asthenopia due to concentration and prolonged accommodation. Since 3D systems does not require near vision, it may reduce asthenopia

3D, three-dimensional; HDRI, high dynamic range imaging

Comparison of Surgical Performance of Internal Limiting Membrane Peeling Using a 3D Visualization System with Conventional Microscope

System Performance

Surgical Outcomes

Safety

Babu et al. *Ophthalmic Surg Lasers Imaging Retina.* 2018; 49:941-945

OVERVIEW

STUDY DESIGN

Prospective, randomized study to compare the surgical performance of internal limiting membrane (ILM) peeling in idiopathic macular hole using a digitally assisted vitreoretinal system (DAVS) and an analog microscope (AM)

STUDY SITE(S)

Single-center in India

PATIENTS

Forty (40) consecutive surgical patients.
Group A: 20 patients undergoing surgery using AM;
Group B: 20 patients undergoing surgery using DAVS

SURGICAL METHODOLOGY

Twenty-five (25)-gauge pars plana vitrectomy and ILM peeling for idiopathic full-thickness macular hole (FTMH); all patients pseudophakic at the time of vitrectomy

SURGICAL TECHNOLOGY

NGENUITY® 3D Visualization System (Alcon Laboratories, Inc.); high-dynamic-range camera; 55-inch LED monitor; passive-polarized 3D glasses; OPMI Lumera T (Carl Zeiss Meditec, Germany); wide-angle viewing system – RESIGHT 500 (Zeiss, Germany); Constellation® Vitreoretinal Surgical System (Alcon Laboratories, Inc.); 25-gauge Grieshaber DSP ILM peeling forceps (Alcon Laboratories, Inc.)

KEY ENDPOINT(S)

Surgical time for ILM peeling; mean number of surgical attempts to create ILM flap, ILM peeling; intraoperative complications (mean number of peeling related hemorrhages, retinal breaks, retinal touch); surgical and visual outcomes (macular hole closure, best-corrected visual acuity)

ANALYSIS AND CONCLUSIONS

DAVS was found to provide almost identical surgical performance as AM; however, surgical performance of some extremely fine maneuvers like the creation of the ILM flap was reported to be more challenging with DAVS compared to AM.

This is the first prospective study to directly compare the use of AM and DAVS in terms of surgical performance of a posterior-segment surgery.

STUDY RESULTS

SURGICAL RESULTS

- The average surgical time to complete ILM peeling was 123.05 ± 42.23 s and 142.35 ± 31.49 s in the AM and DAVS groups, respectively (P=0.109) (**Table 1**)
- There was a significant difference found in the mean number of surgical attempts required to create the ILM flap: 1.05 ± 0.22 in the AM group) and 1.70 ± 1.22 in the DAVS group (P=0.008), however the surgeon did not find this to be a clinically significant disadvantage
- The difference in the mean number of surgical attempts required to complete the ILM peeling was not significant: 22.85 ± 9.95 in the AM group and 27.20 ± 7.16 in the DAVS group (P=0.121)

INTRAOPERATIVE COMPLICATIONS

- The mean number of peeling-related hemorrhages occurring in the AM and the DAVS groups were 3.35 ± 3.75 and 2.20 ± 1.47, respectively (P=0.794) (**Table 1**)
- Intraoperative retinal breaks were not created in any of the patients in either of the groups
- Retinal touch was noted in one patient in the AM group and three patients in the DAVS group (P=0.534)

SURGICAL AND VISUAL OUTCOMES

- All macular holes in both groups closed post-surgery
- Both groups reported similar improvement of best-corrected visual acuity

Figure 1. Comparison of surgical performance of internal limiting membrane (ILM) peeling performed under the analog microscope (AM) and the digitally assisted vitreoretinal surgery system (DAVS; NGENUITY®).

Criterion	Group A (AM)	Group B (DAVS; NGENUITY®)	P Value
Mean surgical time for completing ILM peeling	123.05 ± 42.23 seconds	142.35 ± 31.49 seconds	0.109
Mean number of surgical attempts required to initiate ILM flap	1.05 ± 0.22	1.70 ± 1.22	0.008
Mean number of surgical attempts required to complete ILM peeling	22.85 ± 9.95	27.20 ± 7.16	0.121
Mean number of peeling-related hemorrhages	3.35 ± 3.75	2.20 ± 1.47	0.794
Patients with intraoperative retinal breaks	0	0	
Patients with intraoperative retinal touch	1	3	0.534

AM=analog microscope; DAVS= digitally assisted vitreoretinal surgery system; ILM=internal limiting membrane

The Integrative Surgical Theater: Combining Intraoperative OCT and 3D Digital Visualization for Vitreoretinal Surgery in the DISCOVER Studynd 3D Digital Visualization for Vitreoretinal Surgery in the DISCOVER Study

System Performance

Surgical Outcomes

Safety

Ehlers et al. *Retina.* 2018; 38: S88-S96

OVERVIEW

STUDY DESIGN

Prospective study to evaluate the feasibility of integrating intraoperative optical coherence tomography (OCT) with a digital visualization platform for vitreoretinal surgery

STUDY SETTING(S)

Single center in the United States

PATIENTS

Seven (7) eyes of 7 patients with retinal diseases including epiretinal membranes (n=3), full-thickness macular holes (n=2), symptomatic vitreous opacity (n=1) and traumatic retinal detachment with severe proliferative vitreoretinopathy (PVR, n=1)

SURGICAL METHODOLOGY

Small gauge vitrectomy procedures; vitrectomy with or without membrane peeling and retinectomy; all procedures were completed using the three-dimensional (3D) digital system without reverting to the conventional optical microscope

SURGICAL TECHNOLOGY

Rescan 700® (Zeiss, Germany); NGENUITY® 3D Visualization System (Alcon Laboratories, Inc.); Constellation® vitrectomy system (Alcon Laboratories, Inc.); OLED 55-inch 3D 4K ultra HD monitor; Passive 3D polarized glasses

KEY ENDPOINT(S)

Efficacy and feasibility, safety (intraoperative adverse events)

ANALYSIS AND CONCLUSIONS

Significant advances over the past few years have enabled the use of OCT during surgery and enhanced the potential of digital vitreoretinal surgery. The authors state that in this study these technologies are combined into a seamless integrative surgical theater, enabling the surgeons to view both the OCT and the surgical field simultaneously on a large-screen immersive display.

The authors recommend that further research is required, however note that the merging of these technologies may allow for future unique opportunities for surgeon feedback and display features.

STUDY RESULTS

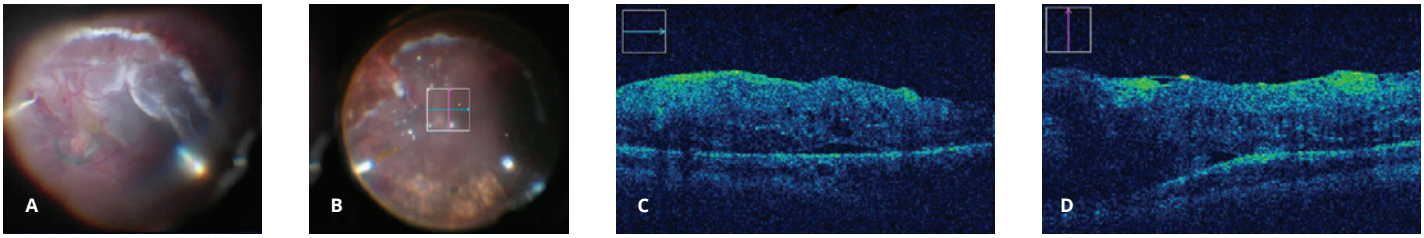
EFFICACY AND SAFETY

- All 7 study participants underwent small-gauge vitrectomy procedures, and all procedures were completed using the 3D digital system without reverting to the conventional optical microscope
- Detailed intraoperative OCT images enabled identification of subtle alterations in retinal microstructure
- Surgeons reported excellent contrast and image visualization while using 4K screen for OCT review, and 100% of cases achieved successful intraoperative OCT image acquisition
- The system was also successfully utilized for a more complex surgical pathology (**Figure 1**)
- OCT datastream details were more easily visualized on the 4K screen with increased contrast setting for the 3D monitor compared to the microscope ocular heads-up display
- Surgeons reported improvements in the operative teaching environment
- No significant subjective increase in operative time was noted
- Surgeons felt the ergonomics and comfort of the surgical environment was good with fewer challenges for a potential accommodative disconnect between the assistant and surgeon during cases

SAFETY

- No intraoperative adverse events were reported
- No adverse events attributed to the visualization system were reported
- Median intraoperative OCT scanning time was 2.2 minutes (range: 1.6-4.2 minutes)

Figure 1. Successful utilization of intraoperative optical coherence tomography (OCT) for complex surgical pathology (**A**) Funduscopic image of retinal detachment with severe proliferative vitreoretinopathy. The existence of the subretinal membrane prevented retinal attachment. The application of peripheral circumferential diathermy is seen. (**B**) Funduscopic view following retinectomy and subretinal membrane removal. Perfluorocarbon liquid is infused to stabilize and flatten the retina. (**C,D**) Horizontal and vertical intraoperative OCT B-scans demonstrate reattachment of the posterior retina with subclinical subretinal fluid. Subtle residual focal membranes and diffuse retinal thickening are also delineated.



Hybrid Wide-Angle Viewing-Endoscopic Vitrectomy Using a Three-Dimensional (3D) Visualization System

System Performance

Surgical Outcomes

Kita et al. *Clin Ophthalmol*. 2018; 12:313-317

OVERVIEW

STUDY DESIGN
Retrospective, consecutive surgical case series to introduce a hybrid wide-angle viewing-endoscopic vitrectomy procedure that uses a 3D visualization system

STUDY SITE(S)
Single center in Japan

PATIENTS
One hundred and thirteen (113) eyes from consecutive surgical cases

SURGICAL METHODOLOGY
Hybrid wide-angle vitrectomy using a 3D visualization system

SURGICAL TECHNOLOGY
Constellation Vision System including 3 valved trocars entrance (Alcon Laboratories, Inc.); NGENUITY® 3D Visualization System (Alcon Laboratories, Inc.); VISU 210 microscope (Carl Zeiss Meditec); twin chandelier light system (Dutch Ophthalmic Res. Center)

KEY ENDPOINT(S)
Surgery completion; retinal reattachment; illumination levels; macular hole closure; intra/postoperative complications

ANALYSIS AND CONCLUSIONS

Hybrid wide-angle viewing-endoscopic vitrectomy using a 3D visualization system (NGENUITY®) appears to be a valuable and promising method that can be used to manage various types of vitreoretinal disease, including complex cases.

System advantages compared to viewing the surgical field through a microscope include: 1) ergonomics of the surgeons due to the heads-up position; 2) educational capability; 3) reduction in phototoxicity risk; 4) real-time color manipulation; 5) integration of several views on a large monitor.

STUDY RESULTS

SURGICAL OUTCOMES

- No cases required conversion of the 3D visualization to a conventional microscopic view
- All surgeries were successfully completed using the 3D visualization system (NGENUITY®) to perform the hybrid vitrectomy, including cases of proliferative vitreoretinopathy and proliferative diabetic retinopathy
- Illuminations of the microscope, chandelier light, and endoscope were reduced by 40%, 60% and 20% respectively, with use of the NGENUITY® 3D Visualization System
- Hole closure was achieved after one operation in all of the macular hole cases (n=11 eyes)
- One eye in a proliferative vitreoretinopathy case had wide subretinal strands requiring a follow-up vitrectomy to reattach the retina
- Retinal reattachment was achieved after first vitrectomy in all other 48 eyes with retinal detachment or proliferative vitreoretinopathy
- There were no other intraoperative or postoperative complications

Comparison of Clinical Outcomes Between "Heads-Up" 3D Viewing System and Conventional Microscope in Macular Hole Surgeries: A Pilot Study

System Performance

Surgical Outcomes

Kumar et al. *Indian J Ophthalmol.* 2018; 66:1816-1819

OVERVIEW

STUDY DESIGN

Prospective, randomized study comparing clinical outcomes of patients undergoing macular hole (MH) surgery with heads-up three-dimensional (3D) viewing system and conventional microscope

STUDY SETTING(S)

Single center in India

PATIENTS

Fifty (50) eyes of 50 patients with a stage 3 or 4 macular hole, randomized into two groups; Group 1: 25 eyes using heads-up digitally assisted vitreoretinal surgery (DAVS); Group 2: 25 eyes using traditional ocular microscopic surgery

SURGICAL METHODOLOGY

Pars plana vitrectomy with multilayered inverted internal limiting membrane (ILM) flap technique and 20% SF6 tamponade used in all cases

SURGICAL TECHNOLOGY

Heads-up (DAVS) or conventional ocular microscopic surgery

KEY ENDPOINT(S)

Postoperative visual acuity; surgical time; internal limiting membrane (ILM) peel time; number of flap initiations; macular hole closure rates; illumination intensity

ANALYSIS AND CONCLUSIONS

The clinical outcomes of MH surgery using 3D viewing system are not inferior to that of conventional microscopes. Additional benefits include: better ergonomics, reduced phototoxicity, peripheral visualization, magnification, less asthenopia and serves as a good educational tool.

This study reflects the initial experience of 3D viewing system in a single center.

STUDY RESULTS

DEMOGRAPHIC PROFILE

- Mean ages were 67.92 ± 7.95 years and 67.96 ± 4.78 in groups 1 (DAVS) and 2 (conventional microscope), respectively; there was no difference with respect to gender and right versus left eye in both groups (**Table 1**)
- Best-corrected visual acuity (BCVA), as measured by logMAR, showed no significant difference at the time of examination (P=0.86) (**Table 1**) and at the end of three months (P=0.92); preoperative macular hole index was also comparable between the two groups (P=0.96)

INTRAOPERATIVE PARAMETERS AND POSTOPERATIVE OUTCOMES

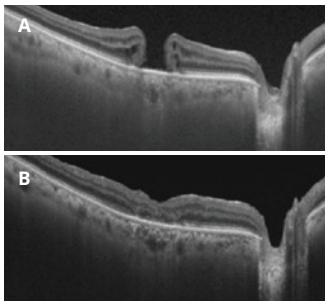
- Mean illumination power was 45% in group 1 and 100% in group 2; the mean endoillumination was 13% and 45% in groups 1 and 2 respectively
- There was no statistically significant difference in the duration of surgery time, time taken for ILM peel, or the number of ILM flap initiations between the two groups
- The duration of Brilliant Blue G (BBG) dye exposure in group 2 was 120 s in all patients, whereas the duration was only 90 s in group 1; despite the longer duration in group 2, two patients needed to be re-stained with BBG, compared to no re-staining in group 1
- Postoperative BCVA were comparable between the two groups (P=0.92); group 1 final BCVA 0.6132±0.26 logMAR ; group 2 final BCVA 0.6212±0.27 logMAR
- Both groups had significant and comparable (P=0.01) improvement of vision from baseline to final vision acuity at 3-month follow-up
- 92% of patients in group 1 had type 1 MH closure, while 8% had type 2 (**Figure 1**); 88% of patients in group 2 had type 1 MH closure, while 12% had type 2; there was no statistically significant difference between groups (P=0.608)

Table 1. Demographic and clinical outcomes, patients undergoing macular hole surgery with heads-up three-dimensional (3D) viewing system or conventional microscope.

Variable	3D viewing system (n=25)	Conventional microscope (n=25)	*P*
Age (years)	67.92 ± 7.95	67.96 ± 4.78	0.98
Gender, *n* (%)			
Male	11 (44)	8 (32)	0.38
Female	14 (56)	17 (68)	
Eye, *n* (%)			
Right	12 (48)	15 (60)	0.39
Left	13 (52)	10 (40)	
Preoperative (logMAR)	1.108 ± 0.35	1.093 ± 0.23	0.86
2 Months (logMAR)	0.6132 ± 0.27	0.621 ± 0.27	0.92
MHI	0.424 ± 0.1	0.422 ± 0.09	0.96
Surgical time	30.32 ± 3.66	29.6 ± 4.92	0.56
ILM peel time	308.48 ± 56.53	298.04 ± 48.36	0.49
Number of flap initiations	15.84 ± 3.37	14.52 ± 2.2	0.11
BBG dye exposure (s)	90	120	0.02
MH closure, *n* (%)			
Type 1	23 (92)	22 (88)	0.61
Type 2	2 (8)	3 (12)	

3D: Three-dimensional, logMAR: Logarithm of the minimum angle of resolution, MHI: Macular hole index, ILM: Internal limiting membrane, BBG: Brilliant Blue G dye, MH: Macular hole.

Figure 1. (A) Preoperative optical coherence tomography (OCT) image of a patient with stage 4 macular hole. **(B)** Postoperative OCT image (Group 1; heads-up digitally assisteted vitreoretinal surgery (DAVS)).



New Instruments – Three-Dimensional (3D) Surgical Viewing System in Ophthalmology: Perceptions of the Surgical Team

System Performance

Surgical Outcomes

Rizzo et al. *Retina.* 2018; 38:857-861

OVERVIEW

STUDY DESIGN

Prospective, observational surgical case series to determine surgical team satisfaction when using NGENUITY® 3D Visualization System

STUDY SITE(S)

Single center in Italy

PATIENTS

Two hundred (200) consecutive surgical patients; 78 males (mean age: 63 years (range: 47-83 years)) and 122 females (mean age: 63 years (range: 22-82 years))

SURGICAL METHODOLOGY

Anterior and posterior segment surgery; 110 vitrectomies (23 or 25 gauge) for retinal detachment; 53 vitrectomies (25 or 27 gauge) for epiretinal membrane or macular hole; 45 other procedures (phacoemulsification, ocular trauma, corneal graft, or squint surgery); 3 Argus two epiretinal implants

SURGICAL TECHNOLOGY

NGENUITY® 3D Visualization System (Alcon Laboratories, Inc.); OPMI Lumera 700 (Carl Zeiss Meditec, Inc); Constellation® Vision System (Alcon) and / or Resight (for retinal detachment); Centurion® Vision System (Alcon) or Stellaris System (Bausch & Lomb) (for cataract surgery)

KEY ENDPOINT(S)

Survey conducted at the end of each surgery (primary surgeon, assistant surgeon, anesthetist, and theater nurse experience and comfort, using a 0-5 rating scale for all questions)

ANALYSIS AND CONCLUSIONS

Based on experiences reported in this study, ophthalmic 3D surgical microscopes appear to be very comfortable for primary surgeons. The assistant surgeons reported issues regarding ergonomics of head position. Anesthetists reported issues reaching patient during general anesthesia.

The authors noted that improvements are needed to improve comfort for every member of the surgical team, and that more studies are required to investigate whether 3D microscopes can reduce total surgical retinal photo stress.

STUDY RESULTS

SURGICAL RESULTS

- Overall, only 0.5% (1/200) of surgeries were converted from the NGENUITY® 3D Visualization System to an operating microscope due to poor visualization

EXPERIENCE SURVEY RESULTS

- None of the other 199 (99.5%) surgeries in this study was converted from NGENUITY® to an operating microscope; a score of 0 was therefore assigned to the question "difficulties declared by the surgeon compared to a standard microscope" for all cases, except for the single case involving a switch to an operating microscope
- Surgeons reported no symptoms (score 0) in response to the question "primary surgeon back and neck ache at the end of surgery" in 185 operations lasting 60 minutes or less, whereas mild pain (score 1 or 2) was recorded for all 14 operations of more than 60 minutes
- Assessment of assistant surgeon dissatisfaction, using the question "second surgeons comfort during surgery," resulted in score 1 or 2 for all procedures, with greater dissatisfaction for general anesthesia (P<0.001)
- Total dissatisfaction by the assistant surgeon was recorded in 19/23 cases for general anesthesia and moderate dissatisfaction in 21 cases for local anesthesia
- Total dissatisfaction on the part of the assistant surgeon was recorded in 54/155 cases for retro-bulbar block (4/81 (5%) surgeries less than 50 minutes in duration, 50/74 (68%) surgeries lasting 50 minutes or more (P<0.001))
- Nurses reported total satisfaction (score 5) in 175/199 (88%) operations
- Anesthetist replies varied, however the reported score was 4 or 5 in 136/199 (68%) of surgeries; their most considerable dissatisfaction was observed during general anesthesia, with a reported score of 1 for 19/19 patients; anesthetist dissatisfaction was greater with more extended operations (odds ratio (OR): 0.35 for each additional 35 minutes; P<0.001) (**Table 1**)

Table 1. Score given by anesthetists during 3-dimensional (3D) ocular surgery using the NGENUITY® 3D Visualization System.

Score assigned	General Anesthesia	Local Anesthesia	Retrobulbar Anesthesia	Total
1	19	0	0	19
2	4	0	8	12
3	0	0	32	32
4	0	0	111	111
5	0	21	4	25
Total	23	21	155	199

Score 1, much worse compared with standard microscope; Score 2, worse compared with standard microscope; Score 3, no difference compared with standard microscope; Score 4, better compared with standard microscope; Score 5, much better compared with standard microscope.

“Heads Up” Digitally Assisted Surgical Viewing for Retinal Detachment Repair in a Patient with Severe Kyphosis

System Performance

Surgical Outcomes

Skinner and Riemann. *Retin Cases Brief Rep.* 2018; 12:257-259

OVERVIEW

STUDY DESIGN
Surgical case report on “heads-up” digital viewing technology to repair a retinal detachment in a severe kyphosis patient

STUDY SETTING(S)
Single center in the United States

PATIENTS
One case – 89-year-old male

SURGICAL METHODOLOGY
Pars plana vitrectomy (25-gauge) and retinal detachment repair; due to severe thoracic kyphosis, surgery was performed with the patient in the Trendelenburg position

SURGICAL TECHNOLOGY
Hi-R NEO 900 microscope (Haag-Streit); NGENUITY® 3D Visualization System (Alcon Laboratories, Inc.); Constellation Vision System (Alcon Laboratories, Inc.); circular polarized “passive” 3D glasses

KEY ENDPOINT(S)
Surgeon and patient report regarding ergonomics; evaluation of anatomical and clinical surgical results

ANALYSIS AND CONCLUSIONS

Severe kyphosis can be very challenging to manage when positioning a patient for vitreoretinal surgery. Past reports have described extreme Trendelenberg positioning (75° angle) resulting in acute discomfort for patient and surgeon, potential cardiac and pulmonary stress, increased intraocular pressure, and decreased cerebral and ocular perfusion.

This case report demonstrates the feasibility of far less extreme patient positioning combined with heads up digitally assisted viewing (NGENUITY® 3D Visualization System) to manage these challenging patients effectively.

STUDY RESULTS

SURGICAL POSITIONING

- Intraoperatively, the patient was supine, with the bed tilted to a Trendelenburg position (30° head down) and surgical towels and pillows used to provide support and comfort
- Surgeon was able to implement the “heads-up” 3D system in a position ideal for the surgical case reported

SURGICAL RESULTS

- The patient reported excellent intraoperative ocular pain control
- Surgeon intraoperative positioning resulted in a report of “superb comfort”
- Neck and back discomfort did not occur intra- or post-operatively for either the surgeon or patient
- The retina was successfully attached and remained attached at 11-week follow-up
- Visual acuity improved to 20/80 at 11-week follow-up

Scleral Transillumination With Digital Heads-Up Display: A Novel Technique for Visualization During Vitrectomy Surgery

Todorich et al. *Ophthalmic Surg Lasers Imaging Retina.* 2018; 49:436-439

System Performance

Surgical Outcomes

Safety

OVERVIEW

STUDY DESIGN
Prospective case series to describe a novel technique of scleral indentation and transillumination for single-surgeon, unassisted vitrectomy and vitreous base shaving enhanced with a digital 3D heads-up display (HUD) system

STUDY SITE(S)
Single center in the United States; surgeries performed by a single surgeon

PATIENTS
Six (6) eyes of 6 patients

SURGICAL METHODOLOGY
Vitrectomy surgery using the direct application of a transscleral illuminated 23-gauge light pipe to provide adequate peripheral vitreous visualization (**Figure 1**)

SURGICAL TECHNOLOGY
NGENUITY® 3D Visualization System (Alcon Laboratories, Inc.); Constellation® Vision System (Alcon Laboratories, Inc.)

KEY ENDPOINT(S)
Efficacy measures (adequacy of surgical view; surgical complications; cases converted to using conventional endo-illumination approach)

ANALYSIS AND CONCLUSIONS

Digitally enhanced scleral transillumination affords surgeons another option for safe and effective simultaneous scleral depression and illumination for unassisted peripheral vitrectomy.

The success of this technique is dependent on the ability of the scleral transilluminator to provide adequate penetration of the necessary amount of light through the sclera. The view was further enhanced using the digital camera and HUD system where endogenous luminance can be significantly amplified.

STUDY RESULTS

INDICATIONS FOR SURGERY

- A list of surgical indications for vitreoretinal surgery in this study include (**Table 1**):
  - Vitreous hemorrhage
  - Retained lens fragments (RLF)
  - Macula on retinal detachment
  - Macular hole
- Vitreoretinal surgery patient lens status, race, fundus pigmentation, and refraction are also provided in **Table 1**

Table 1. Summary of six cases in which vitrectomy was performed with transscleral illumination.

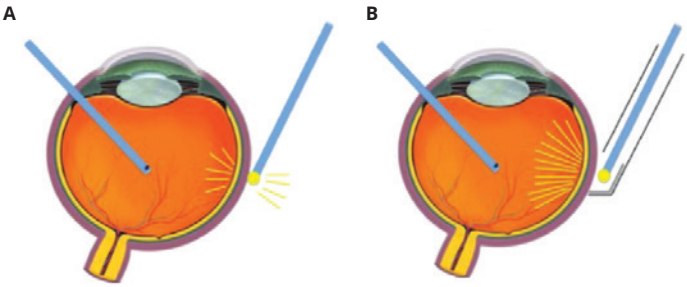
Patient No.	Surgical Indication	Etiology	Phakic status	Race	Fundus pigmentation	Refraction	View adequate for safe VB shaving	Complications
1	Vitreous hemorrhage	RAM	PCIOL	White	Light	Moderate myopia	Yes	None
2	Vitreous hemorrhage	PDR	PCIOL	Black	Dark	Emmetrope	No	None
3	RLF	Complex CE	Sulcus IOL	White	Light	Myopia	Yes	None
4	Vitreous hemorrhage	Hemorrhagic PVD	2 + NSC	White	Light	Myopia	Yes	None
5	Macula or retinal detachment	RD	PCIOL	White	Light	Moderate myopia	Yes	None
6	Macular hole	FTMH	PCIOL	White	Light	Emmetrope	Yes	None

VB= vitreous base; RAM=retinal arterial microaneurysm; PCIOL= posterior chamber intraocular lens; PDR=proliferative diabetic retinopathy; RLF= retained lens fragments; CE= cataract extraction; IOL=intraocular lens; PVD=posterior vitreous detachment; NSC=neural stem cell; RD=retinal detachment; FTMH= full-thickness macular hole.

EFFICACY MEASURES

- In 5 cases, scleral transilluminated depression provided an adequate and safe surgical view for core and/or peripheral vitrectomy (**Table 1**)
- The procedure for one patient, whose fundus pigmentation and density of vitreous hemorrhage precluded the use of the novel scleral transillumination technique, was completed using a conventional endoillumination approach (**Table 1**)
- There were no complications in any of the cases (**Table 1**)

Figure 1. A. The technique of scleral transillumination affords for core and peripheral vitrectomy by placing the light pipe probe on the conjunctiva and sclera and angling the light beam posteriorly and toward the center of the vitreous cavity. **B.** The safety and effectiveness of the scleral transillumination can be enhanced by using a blunt clear adaptor sleeve with a reflective coating that would direct all luminance into the eye.



The Scope of Three-Dimensional Digital Visualization Systems in Vitreoretinal Surgery

Agranat et al. *Clin Ophthalmol.* 2019; 13:2093-2096

OVERVIEW

STUDY DESIGN
A retrospective review of consecutive surgical cases in both the academic and community setting, to report on the variety of indications and surgical efficacy of the NGENUITY® 3D Visualization System in vitreoretinal surgery

STUDY SETTING(S)
Two vitreoretinal centers in the United States (Massachusetts Eye and Ear Infirmary; Florida Retina Institute)

PATIENTS
Two hundred and seventy-two (272) surgical cases

SURGICAL METHODOLOGY
Vitreoretinal surgery for a range of indications (**Table 1**)

SURGICAL TECHNOLOGY
Alcon NGENUITY® 3D Visualization System

KEY ENDPOINT(S)
Efficacy measures (complications attributed to the visualization system; aborted cases; cases converted to an optical microscope)

ANALYSIS AND CONCLUSIONS

The study results show the variety of vitreoretinal surgeries that can be performed using the NGENUITY® 3D Visualization System without compromising surgical viewing or increasing surgical complications. The benefits of the 3D digital visualization systems include improved ergonomics, lower illumination levels, improved depth of field, display filters and digital layout for intraoperative optical coherence tomography (OCT), and excellent trainee and nursing experience/viewing.

The authors indicate that the current 3D digital surgery platform is safe and can be utilized in most surgical cases encountered by a vitreoretinal surgeon.

STUDY RESULTS

INDICATIONS FOR SURGERY
- A comprehensive list of indications for vitreoretinal surgeries and related procedures successfully performed in this study using the NGENUITY® 3D Visualization System provided in **Table 1**

SURGICAL OUTCOMES
- All 272 cases were completed without complications attributed to the visualization system, and no cases were converted to traditional microscope use
- There were no limitations in the type of cases that could be completed, despite the diverse spectrum of vitreoretinal surgical cases examined

Table 1. Indications and total number of surgeries completed using the NGENUITY® 3D Visualization System.

	Number Of Cases	Percentage Of Total Cases (%)	Complications Related To Visualization
Membrane peel for ERM/MH/VMT	77	28.3	0
RRD repair	71	26.1	0
VH/PDR/TRDs	43	15.8	0
IOL procedures	24	8.8	0
Silicone oil removal	23	8.5	0
Floaterectomy	22	8.1	0
tPA injection for AMD-related subretinal hemorrhage	3	1.1	0
IOFB removal	2	0.7	0
Retained lens fragment	2	0.7	0
Choroidal drainage	2	0.7	0
Scleral buckle removal	1	0.4	0
Endophthalmitis	1	0.4	0
Acute retinal necrosis	1	0.4	0

Abbreviations: ERM, epiretinal membrane, MH, macular hole, VMT, vitreomacular traction, RRD, rhegmatogenous retinal detachments, VH, vitreous hemorrhage, PDR, proliferative diabetic retinopathy, TRD, tractional retinal detachment, IOL, intraocular lens, tPA, tissue plasminogen activator, AMD, age-related macular degeneration, IOFB, intraocular foreign body.

Resolution, Depth of Field, and Physician Satisfaction During Digitally Assisted Vitreoretinal Surgery

System Performance

Surgical Outcomes

Freeman et al. *Retina.* 2019; 39:1768-1771

OVERVIEW

STUDY DESIGN

Prospective study to evaluate depth of field, lateral resolution, and image quality of a heads-up three-dimensional (3D) visualization system for vitreoretinal surgery using physician survey and optical measurement outcomes

STUDY SITE(S)

Single center in the United States

PATIENTS

Vitreoretinal surgery cases performed by 6 participating retinal surgeons (number of patients not specified)

SURGICAL METHODOLOGY

Retinal surgeons subjectively graded depth of field and resolution at high and low magnification, contrast, color, and ability to operate through media opacities and small pupils on a 4-point scale (1 = poor; 4 = good) after using the 3D system for 6 weeks; surgeons repeated the survey for the standard optical viewing system using the same microscope but with standard oculars

SURGICAL TECHNOLOGY

Standard ocular viewing setup; TrueVision® 3D Visualization (TrueVision 3D Surgical, CA)†; Leica M844 F40 operating microscope (Leica Microsystems, Germany); 50-inch 4K OLED TV (TrueVision Systems, CA); Passive circular polarizing eyeglasses

KEY ENDPOINT(S)

Depth of field, lateral resolution, surgeon impression of system performance

ANALYSIS AND CONCLUSIONS

Lateral resolution of the digital 3D system was half that of the standard ocular viewing system and there was some improvement in the depth of field with the digital system. Surgeon impression suggested that the digital system was superior when evaluating depth of field at high magnification.

Limitations of the study included the small sample size and recall bias of the survey.

† The TrueVision® 3D Visualization System was acquired by Alcon and rebranded as NGENUITY® in 2018

STUDY RESULTS

SURGICAL SURVEY OUTCOMES

- Physician questionnaire survey scores (subjective impressions) for depth of field at high magnification were significantly better for the digital 3D system (3.6 ± 0.5 vs. 2.8 ± 0.4; P<0.05) and equivalent for all other categories
- Measured lateral resolution was significantly higher in the digital 3D system than the ocular viewing system at all three magnifications tested (x5, x13, x18; all P<0.005) (**Table 1**)
- The depth of field at high magnification (x5) showed a statistically significant, 69% difference in favor of the digital 3D system (6.78 ± 4.49 mm vs. 4.00 ± 0.93 mm; P=0.027); no significant difference was detected at x13 or x18 magnification (**Table 2**)

Table 1. Lateral resolution of eyepiece and digital three-dimensional (3D) system as measured on a 1951 air force resolution target by 6 retinal surgeons.

Microscope magnification	Eyepiece lateral resolution (mm)	Digital 3D lateral resolution (mm)	P Value
x5	16.62 ± 1.58	36.68 ± 4.49	<0.001*
x13	6.43 ± 1.33	14.27 ± 5.27	0.002*
x18	4.16 ± 0.42	9.84 ± 0.00	<0.001*

** Statistically significant difference*

Table 2. Depth of field measurements of eyepiece and digital three-dimensional (3D) system on a millimeter-scale set at a 45-degree angle from 6 retinal surgeons.

Microscope magnification	Eyepiece depth of field (mm)	Digital 3D depth of field (mm)	P Value
x5	4.00 ± 0.93	6.78 ± 1.36	0.027*
x13	0.72 ± 0.43	0.86 ± 0.19	0.311
x18	0.28 ± 0.08	0.40 ± 0.23	0.235

** Statistically significant difference*

Lights-Out Surgery for Strabismus Using a Heads-Up 3D Vision System

Hamasaki et al. *Acta Med Okayama.* 2019; 73:229-233

System Performance

Surgical Outcomes

OVERVIEW

STUDY DESIGN
Case study examining the efficacy of lights-out surgery for strabismus using the NGENUITY® 3D Visualization System

STUDY SITE(S)
Single center in Japan

PATIENTS
Two patients with strabismus

SURGICAL METHODOLOGY
Patient 1: Lateral rectus muscle recession; **patient 2:** Inferior oblique muscle recession. Both surgeries conducted under the illumination of the operating room's general lighting and not using any surgical light or the light source of the microscope

SURGICAL TECHNOLOGY
NGENUITY® 3D Visualization System (Alcon Laboratories, Inc.); high-dynamic range (HDR) camera; film patterned retarder (FPR)-type 4K display; circularly polarized 3-dimensional (3D) glasses

KEY ENDPOINT(S)
Completion of surgery; patient report of photophobia; use of saline for dry eye; difference in illuminance with and without use of the microscopes light-source; intraoperative complications

ANALYSIS AND CONCLUSIONS

Lights-out surgery is a potentially useful modality for strabismus surgery. However, further functional improvements considering the surgery assistant's view is desirable.

Study results confirm that lights-out surgery can be performed with no problems or intraoperative complications.

STUDY RESULTS

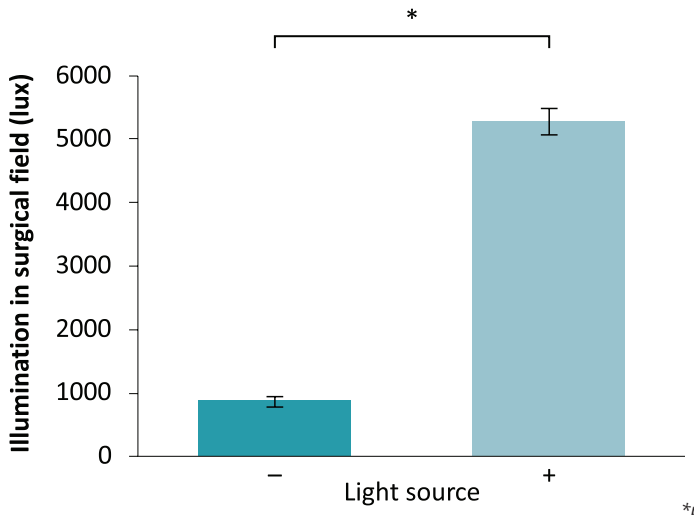
SYSTEM PERFORMANCE

- The two patients' surgeries were performed without problems, despite the fact that the light source of the microscope was not used
- There was a significant difference ($p<0.05$) in illuminance between without the microscope's light source (876± 71 lux) and with the light source (5,270 ± 198 lux), with a mean value of approximately sixfold (**Figure 1**)
- During strabismus surgery using a microscope, the assistant usually sits at a right or left (90° position) to the surgeon; in this study, a limitation of the NGENUITY® system set up was that the assistant could not view the monitor, as it was at a different angle, and had to view the operative field directly from the assistant's scope without digital correction or a light source

SURGICAL OUTCOMES

- There were no patient complaints of photophobia during the surgery
- Saline supply for dry eye was reduced without exposure, compared to with exposure to the microscopes light source
- There were no intraoperative complications

Figure 1. Illumination in the surgical field with or without the microscope's light source. Strabismus surgeries using NGENUITY® for 3D visualization.



**p<0.05, Mann-Whitney U-test.*

Utility of Three-Dimensional (3D) Heads-Up Surgery in Cataract and Minimally Invasive Glaucoma Surgeries

Ohno. *Clin Ophthalmol.* 2019;13: 2071-2073

OVERVIEW

STUDY DESIGN
Feasibility study aimed to assess the utility of the 3D heads-up visualization system for minimal incision cataract surgery (MICS) and minimally invasive glaucoma surgeries (MIGSs)

STUDY SITE(S)
Single center in Japan

PATIENTS
Individuals with cataract and open-angle glaucoma. Number of cases not specified.

SURGICAL METHODOLOGY
Toric intraocular lens (IOL) implantation with phacoemulsification and trabecular microbypass stent implantation

SURGICAL TECHNOLOGY
NGENUITY® 3D Visualization System with VERION Image Guided System (Alcon Laboratories, Inc.); Proveo 8 microscope (Leica); Ocular Hill Surgical Gonioprism (Ocular Instruments, Inc.)

KEY ENDPOINT(S)
Utility of 3D heads-up visualization system measured by surgeon- reported experience

ANALYSIS AND CONCLUSIONS

The feasibility and comfort of the 3D heads up surgery (HUS) system for performing MICS and MIGS was demonstrated.

The authors report the feasibility of MICS and MIGS via 3D platforms that offer good visualization (less need for focusing and emphasized stereoscopic effect by larger display), good compatibility with Verion image guided system and surgeons comfort.

STUDY RESULTS

SURGICAL OUTCOMES

- Compared with the conventional microscopic surgery, cataract surgery and trabecular microbypass stent implantations were compatible with HUS combined with Verion image guided system
- Because of the extended depth of field at high magnification and emphasized stereoscopic effect, which is a direct result of HUS, frequent focus adjustment is not required for trabecular microbypass stent implantation, unlike that required with a conventional microscope
- HUS allows processing of the original image on display, as per surgeons' request, without compromising image quality
- Per surgeon experience, HUS advantages include:
  - Lower intensity of light source
  - Exaggeration of the structure and color of image
  - Ability to overlay images
  - Picture in picture (several images on display simultaneously)
  - Increased comfort for surgeon throughout the procedure

An Experimental and Clinical Study on the Initial Experiences of Brazilian Vitreoretinal Surgeons with Heads-Up Surgery

System Performance

Surgical Outcomes

Palácios et al. ***Graefes Arch Clin Exp Ophthalmol.*** **2019; 257:473-483**

OVERVIEW

STUDY DESIGN

Prospective, experimental and clinical surgical case series to evaluate the initial experiences of several vitreoretinal surgeons in Brazil, both experienced and beginners, with a three-dimensional (3D) visualization system, and to report on the advantages and disadvantages of the technology

STUDY SETTING(S)

Multiple sites in Brazil

PATIENTS

Experimental arm: n/a (porcine eyes). **Clinical arm:** 4 surgeons (1 surgeon= more than 15 years pars plana vitrectomy (PPV) experience, 3 fellows= less than 3 years experience) performed 40 surgeries for macular holes (MH) on 40 patients (24 women; 16 men; age range: 61-85 years)

SURGICAL METHODOLOGY

Experimental arm: vitreoretinal surgery on porcine eyes using the heads-up method. **Clinical arm:** Various types of clinical vitreoretinal surgeries in association with facectomy, Ahmed glaucoma valve implant or minimally invasive glaucoma surgery (MIGS). These surgeries were carried out using either the heads-up method with 3D visualization or traditional microscopy

SURGICAL TECHNOLOGY

Proveo 8 surgical microscope (Leica); NGENUITY® 3D Visualization System (Alcon Laboratories, Inc.) including a 3D high dynamic range (HDR) camera with a complementary metal-oxide-semiconductor (CMOS) image sensor, TrueWare v.9.5.4 software, high definition 55" LCD monitor with a 4-K display (OLED) using passive 3D display technology; DORC EVA phacovitrectomy unit (DORC); BIOM® 5 system; iStent® (Glaukos) fitted with a surgical gonioscopic iprism® lens (Glaukos); endoscope with modified GoPro® 4-K digital camera (GoPro); NGENUITY® 4-K screen (Alcon); Verion™ Image Guided System (Alcon)

KEY ENDPOINT(S)

Advantages and disadvantages of 3D heads-up system; times required for pars plana vitrectomy (PPV) and internal limiting membrane (ILM) rhexis by the 3D system and traditional microscopy; evaluation of anatomical surgical results; surgeons self-report via questionnaire

ANALYSIS AND CONCLUSIONS

In this study, the 3D visualization system (NGENUITY®) was preferred to traditional microscopy. It was favored in particular surgeries and as an educational tool, due to reduced illumination and ability to allow for precise focusing.

In MH surgery, the heads-up method was comparable to traditional microscopy regarding the length of time and anatomical surgical results. The authors suggest that this digital platform may become the new standard for ophthalmic surgery.

STUDY RESULTS

EXPERIMENTAL SURGERY

- Surgeries performed on porcine eyes:
  - Disabling the color channels allowed better visualization of the ILM, either with Brilliant Blue G (BBG), indocyanine green chorioangiography (ICG), or acai dye
  - Transillumination through the sclera was also better without a color channel, however visualization of the peripheral vitreous was better with a blue channel

CLINICAL EXPERIENCE

- The vitreoretinal surgeries included peeling of the internal limiting membrane (ILM) or iris, scleral fixation, rhegmatogenous retinal detachment (RRD), tractional retinal detachment (TRD), vitreous hemorrhage, management of a dropped nucleus, lensectomy and scleral buckle (SB) surgery
- The questionnaire responses showed that the heads-up method was generally favored over traditional microscopy. (**Table 1**)
- Image resolution, ergonomics, depth perception, field of view and educational value were rated as significantly better for the heads-up method
- Despite having a slightly higher average score, technical feasibility was not rated as significantly better with the heads-up method
- Comparing the initial and final (1 year later) questionnaire results, the scores for image resolution, field of view, ergonomics and technical feasibility were higher for 3D; while depth perception and educational value tended to equivalence
- The ability to use a lower amount of illumination, with or without electrical amplification of the signal, without loss of image quality w as universally cited as a significant advantage
- All participants reported difficulties with adaptation time, using the 3D system while performing anterior segment surgeries

FULL THICKNESS IDOPATHIC MACULAR HOLES

- Comparisons between the average time length for a full PPV and ILM rhexis performed by four surgeons using traditional microscopy (p=0.831), and the 3D visualization system (p=0.281) did not reach significance, individually
- Average surgical time for completion of full PPV with traditional microscopy: 35.13 minutes (Surgeon 1); 45.10 minutes (Fellow 1); 53.37 minutes (Fellow 2); 57.17 minutes (Fellow 3)
- Average surgical time for completion of the full PPV with 3D heads up method: 37.21 minutes (Surgeon 1); 48.28 minutes (Fellow 1); 54.07 minutes (Fellow 2); 55.81 minutes (Fellow 3)
- As expected, due to his increased experience, surgeon 1 was significantly more efficient and faster than the fellows performing the procedures by using microscopy and the 3D method
- 90% of eyes with full-thickness MH had the hole successfully closed after one surgery. 5% did not heal using 3D visualization, and 5% did not heal using traditional microscopy

Table 1. Questionnaire rating heads-up 3D system (NGENUITY®) on a 1 to 10 scale relative to traditional microscopy.

	Total (n=14)	*p* values
Image resolution		
Mean (SD[a])	6.71 (2.37)	0.0179
Median	7.5	
Min[b]-Max[c]	3–9	
Depth perception		
Mean (SD)	7.36 (2.21)	0.0015
Median	7	
Min-Max	3–10	
Field of view		
Mean (SD)	7.71 (1.44)	<0.0001
Median	8	
Min-Max	6–10	
Ergonomics		
Mean (SD)	6.64 (2.84)	0.0500
Median	7.5	
Min-Max	2–10	
Technical skills		
Mean (SD)	5.79 (2.08)	0.1814
Median	5.5	
Min-Max	3–9	
Educational value		
Mean (SD)	9.86 (0.36)	<0.0001
Median	10	
Min-Max	9–10	

1=much worse than traditional microscope; 5= equivalent; 10= much better

aSD, standard deviation; b Min, minimum; c Max, maximum

p<0.05=statistically significant

Learning Curve of Three-Dimensional (3D) Heads-Up Vitreoretinal Surgery for Treating Macular Holes: A Prospective Study

System Performance

Surgical Outcomes

Palácios et al. *Int Ophthalmol.* 2019; 39:2353-2359

OVERVIEW

STUDY DESIGN

Prospective study to compare surgeons' opinions of idiopathic full-thickness macular hole (MH) surgery, surgical time for pars plana vitrectomy (PPV) and internal limiting membrane (ILM) rhexis, and anatomical surgical results with traditional microscopy vs use of a 3D visualization system

STUDY SITE(S)

Single center in Brazil

PATIENTS

40 patients (24 women, 16 men; age range: 61-85 years)

SURGICAL METHODOLOGY

Four (4) vitreoretinal surgeons (1 surgeon= more than 15 years vitreoretinal experience, 3 fellows= less than 3 years experience) compared 3D heads-up surgery with traditional microscopy performing either PPV or ILM rhexis

SURGICAL TECHNOLOGY

Proveo 8 surgical microscope (Leica); NGENUITY® 3D Visualization System (Alcon Laboratories, Inc.), including a 3D high dynamic range (HDR) camera with a complementary metal-oxide semiconductor (CMOS) image sensor, TrueWare v.9.5.4 software, high definition 55" LCD monitor with a 4-K display (OLED) using passive 3D display technology; DORC EVA phacovitrectomy unit (DORC); BIOM® 5 system

KEY ENDPOINT(S)

Questionnaire analyzing ergonomics, educational value, image sharpness, depth perception, field of view and technical skill; times required for PPV and ILM rhexis; anatomical surgical results

ANALYSIS AND CONCLUSIONS

The 3D system (NGENUITY®) for MH surgery (PPV or ILM) had a short learning curve and was a refined educational tool when used with reduced illumination and precise focus. The 3D heads up system was comparable to traditional microscopy with respect to total surgical time and anatomical surgical results.

The authors suggest that the 3D heads up system may become a new pattern for ophthalmic surgery as ongoing improvements are applied.

STUDY RESULTS

SURGICAL COMPLETION TIME

- The average time for a full PPV or ILM rhexis procedure, assessed by four surgeons using traditional microscopy and 3D visualization, did not differ significantly in either case (P=0.81 and P=0.281, respectively)
- As expected, surgeon 1, due to greater experience, was significantly more efficient and speedier (P>0.001) than the fellows performing the two procedures via traditional microscopy or 3D visualization (**Figure 1**)

QUESTIONNAIRE & ANATOMICAL SURGICAL OUTCOMES

- Questionnaire responses showed all study physicians rated image resolution and ergonomics in traditional microscopy as 'superior' when compared with the 3D system. (average rating 3.5 and 3.0 of 10, respectively; P=0.014 and P=0.016, respectively) (**Table 1**)
- Technical skills of traditional microscopy tended to be 'strongly superior' (average rating 3.7 of 10; P=0.08) (**Table 1**)
- Field of view and educational values with the 3D system were rated as superior to traditional microscopy (average ratings of 6.7 and 9.7 out of 10 respectively; P=0.035 and P>0.001, respectively) (**Table 1**)
- 90% of eyes with full-thickness MH had the hole successfully closed after one surgery; 5% did not heal using 3D visualization, and 5% did not heal using traditional microscopy

Figure 1. Comparison between the average time to perform internal limiting membrane (ILM) rhexis (minutes) by Surgeon 1, Fellow 1, Fellow 2, and Fellow 3, using traditional microscopy and a three-dimensional (3D) visualization system (NGENUITY®).

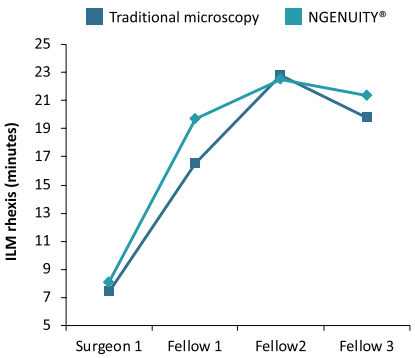


Table 1. Questionnaire rating heads-up three-dimensional (3D) system (NGENUITY®) on a 1-10 scale relative to traditional microscopy.

	Image resolution	Depth perception	Field of view	Ergonomics	Technical skills	Educational value
Surgeon 1	3	7	7	3	3	10
Fellow 1	3	4	8	2	3	10
Fellow 2	4	6	6	3	5	10
Fellow 3	4	3	6	4	4	9
Average rating	3.5	5	6.7	3	3.7	9.7
P	0.014	>0.999	0.035	0.016	0.08	<0.001

Fellows: <3 years of experience in vitreoretinal surgery; Surgeon: > 15 years of experience in vitreoretinal surgery; P<0.05=statistically significant; P>0.999=statistically equivalent
1 = much worse than traditional microscope; 5 = equivalent; 10 = much better

Three-Dimensional (3D) Digital Visualization of Phacoemulsification and Intraocular Lens (IOL) Implantation

System Performance

Surgical Outcomes

Safety

Qian et al. *Indian J Ophthalmol.* 2019; 67:341-343

OVERVIEW

STUDY DESIGN
Prospective, randomized, controlled, clinical trial to evaluate the feasibility and safety of heads-up 3D vision system for phacoemulsification and IOL implantation surgery

STUDY SETTING(S)
Single center in China

PATIENTS
Twenty (20) eyes of 18 patients; mean age 67 ± 5.2 years (range: 62-75 years)

SURGICAL METHODOLOGY
Conventional cataract surgery (phacoemulsification and IOL implantation) performed on patients randomly divided into "heads-up" 3D vision group and conventional surgery group

SURGICAL TECHNOLOGY
OPI Lumera T surgical microscope (Carl Zeiss Surgical GmbH); NGENUITY® 3D Visualization System (Alcon Laboratories, Inc.)

KEY ENDPOINT(S)
Ocular and surgical parameters (surgery time, pre- and postoperative best-corrected visual acuity (BCVA), corneal endothelial cell density); intra- or postoperative surgical complications

ANALYSIS AND CONCLUSIONS

The heads-up 3D vision system (NGENUITY®) is suitable and safe for cataract phacoemulsification and IOL implantation.

The authors recommend further studies with an increased number of surgeries using NGENUITY® 3D system to improve safety and efficacy estimates and evaluate long-term results, and also recommend investigation of the learning curve for this system for different surgeons

STUDY RESULTS

FEASIBILITY & EFFICACY MEASURES

- Mean logMAR BCVA was 0.53±0.37 (pre-surgery) and 0.09±0.14 (post-surgery) in the conventional group, while the mean logMAR BCVA was 0.53±0.30 (pre-surgery) and 0.19±0.25 (post-surgery) in the NGENUITY® 3D group; no difference was found in the pre and post-operative BCVA between patients in the conventional surgery and heads-up 3D (NGENUITY®) groups (P>0.05) (**Table 1**)
- Significant improvement of BCVA after cataract surgery was found in both groups (P<0.05).
- Loss of endothelial cell density (ECD) was observed in both groups; however, there was no significant difference in the pre and postoperative mean ECD between the NGENUITY® 3D group and the conventional group (P>0.05)
- There was no significant difference between the duration of surgery in the two groups (p>0.05)

INTRA- OR POST-OPERATIVE COMPLICATIONS

- There were no significant complications such as posterior capsule rupture, decompensation of the corneal endothelium, or suprachoroidal expulsive hemorrhage during or after surgery in either group

Table 1. Baseline characteristics and postoperative outcomes, patients undergoing phacoemulsification and intraocular lens (IOL) implantation with conventional surgery and surgery with the NGENUITY® 3D Visualization System.

	Conventional group	NGENUITY® 3D Group	*P*
Pre-operative BCVA	0.53 ± 0.37	0.53 ± 0.30	*P*=0.651
Post-operative BCVA	0.09 ± 0.14	0.19 ± 0.25	*P*=0.104
Pre-operative ECD	2733.29 ± 366.40	2521.05 ± 386.69	*P*=0.710
Post-operative ECD	2158.96 ± 402.53	1824.82 ± 497.91	*P*=0.329
Surgery time	542 ± 88.6	498 ± 104	*P*=0.543

BCVA=Best corrected visual acuity (LogMAR), ECD=Endothelial cell density (cells/mm2)

Comparison of a Three-Dimensional (3D) Heads-Up Display Surgical Platform with a Standard Operating Microscope for Macular Surgery

System Performance

Surgical Outcomes

Visual Outcomes

Talcott et al. *Ophthalmol Retina.* 2019; 3:244-251†

OVERVIEW

STUDY DESIGN

Prospective, randomized, single center, unmasked, multi-surgeon, observational pilot study to assess the safety, efficacy and outcomes of vitreoretinal surgery for macular pathology using a 3D heads-up display (HUD) surgical platform compared with a standard operating microscope (SOM)

STUDY SITE(S)

Single center in United States

PATIENTS

Thirty-nine (39) eyes from 29 patients; mean age 67.6 ± 8.2 years

SURGICAL METHODOLOGY

Pars plana vitrectomy (PPV) for epiretinal membrane (ERM) or full-thickness macular hole (MH)

SURGICAL TECHNOLOGY

NGENUITY® 3D Visualization System (Alcon Laboratories, Inc.); Constellation Vision System (Alcon Laboratories, Inc.); OPMI Lumera 700 SOM (Carl Zeiss); 3D high dynamic range surgical camera (ICM5); TrueWare v. 9.5.4 image processing software; GD-463D10 46" high definition (1980x1024 pixels) liquid crystal display; Passive 3D polarized glasses

KEY ENDPOINT(S)

Surgical adverse events; intraoperative parameters; postoperative visual outcomes; visual outcomes by preoperative diagnosis

ANALYSIS AND CONCLUSIONS

Three-dimensional HUD surgical visualization is an evolving technology demonstrating, in this study, comparable efficacy to the SOM for macular surgery. With NGENTUITY® 3D HUD, overall surgical times were similar to SOM, while macular peel times were longer and associated with less ease of use in this study, which may partly be due to a learning curve with new technology.

The authors suggest that considering the relatively small sample size, more extensive studies are needed to compare the surgical platforms.

† This study was financially supported by an Alcon IIT Grant.

STUDY RESULTS

SURGICAL OUTCOMES AND SYSTEM PERFORMANCE

- There was a higher number of preoperative diagnoses of ERM than of MH, however there was no statistically significant difference in surgical indication between the 3D HUD (NGENUITY®) and SOM groups
- For PPV, 25 gauge was the most common gauge chosen (3D HUD: 61% of procedures; SOM: 37.5% of procedures)
- There were no statistically significant differences in lens status, eye, preoperative indication, PPV gauge or follow-up between the 3D HUD and SOM groups (all P>0.065)
- There were no clinically significant intraoperative adverse events reported
- Intraoperative parameters comparing the 3D HUD and SOM groups are shown in **Table 1**
- Minimum endoillumination was significantly lower with 3D HUD (mean 22.7% ± 15.1%) compared with SOM (mean 39.1% ± 2.7%) (P=0.008)
- There was no significant difference in overall operative time between 3HD (mean 32.0 ± 9.1 minutes) and SOM (30.1 ± 12.6 minutes) groups (P=0.004)
- Macular peel time was significantly longer using the 3D HUD (mean 14.8 ± 4.8 minutes) compared with SOM (11.9 ± 8.1 minutes) (P=0.004)
- Surgeon-reported "ease of use" was significantly higher (easier) using SOM (8.3±1.1) compared with 3D HUD (7.0±1.5) (P=0.004)
  - Reported "ease of use" improved and approached significance from the first five 3D HUD cases (6.3 ± 1.6) to the last 5 cases (7.9 ± 1.6) (P=0.0949)
  - In the SOM group, "ease of use" went from 7.3 ± 1.8 in the first 5 cases to 8.1 ± 1.4 in the last 5 cases, indicating more modest improvement (P=0.92)
- There was one case in which an ERM surgery using the 3D HUD was temporarily stopped when the viewing system froze and had to be restarted

VISUAL OUTCOMES

- Patients in the 3D HUD and SOM groups showed improvement in logMAR Visual Acuity (VA) from the preoperative visit (3D HUD: 0.5 ± 0.3; SOM: 0.6 ± 0.3) to postoperative month 3 (POM3; 3D HUD: 0.4 ± 0.2; SOM: 0.4 ± 0.3), and there was no difference between the two groups at POM3 (P=0.724)
- Comparing 3D HUD with SOM, there was no significant difference in logMAR VA or intraocular pressure at any of the visits (P>0.137)

Table 1. Intraoperative parameters comparing 3-dimensional heads-up display (HUD; NGENUITY®) and standard operating microscope (SOM) in vitreoretinal surgery for macular pathology.

	3D HUD, n=23	SOM, n=16	*P* Value
Operative time, min			
Mean ± SD (median, range)			
Surgery time	32.04 ± 9.09 (32, 16-56)	30.12 ± 12.06 (26, 16-63)	0.388*
Peel time	14.76 ± 4.79 (14, 6-23)	11.87 ± 8.07 (10, 4-37)	**0.025**
Ease of use			
Mean ± SD (median, range)	6.95 ± 1.46 (7, 4-9)	8.25 ± 1.12 (9, 5-9)	**0.004***
Minimum endoillumination, percentage			
Mean ± SD (median, range)	22.7 ± 15.10 (20, 5-44)	39.06 ± 2.72 (40, 30-40)	**<0.001***
Indocyanine green aliquots			
0	2 (9)	0 (0)	0.476†
1	14 (61)	11 (69)	
2	7 (30)	5 (31)	
Iatrogenic macular hemorrhage	15 (68)	12 (75)	0.729‡
Iatrogenic macular contusion	2 (9)	0 (0)	0.215‡\
Iatrogenic macular breaks	0 (0)	0 (0)	

*SD = standard deviation; SOM = standard operating microscope; 3D HUD = 3-dimensional heads-up display. Data are n (%) unless otherwise indicated. Bolded values indicate statistically significant. *Mann-Whitney U test. †Chi-square test. ‡Fisher-exact test.*

Heads-Up Cataract Surgery: Complication Rates, Surgical Duration, and Comparison with Traditional Microscopes

Surgical Outcomes

Safety

Weinstock et al. *J Refract Surg.* 2019; 35:318-322

OVERVIEW

STUDY DESIGN

Retrospective case series to compare the complication rates and surgical duration between a three-dimensional (3D) visualization system (heads-up surgery) and traditional binocular microscope in cataract surgery

STUDY SETTING(S)

Single center in United States

PATIENTS

Two thousand three hundred and twenty (2,320) eyes of 1,647 patients (682 men; 965 women; mean age 71.5 ± 9.0 years [range: 32-95 years])

SURGICAL METHODOLOGY

Cataract surgery with visualization via 3D display system or traditional binocular microscope; both groups received either femtosecond laser-assisted cataract surgery (FLACS) or conventional phacoemulsification

SURGICAL TECHNOLOGY

NGENUITY® 3D Visualization System (Alcon Laboratories, Inc.); Stellaris phacoemulsification platform (Bausch & Lomb, Inc.); LenSx (Alcon Laboratories, Inc.); LensAR (LensAR LLC.)

KEY ENDPOINT(S)

Complication rates and surgical duration

ANALYSIS AND CONCLUSIONS

Heads-up 3D visualization for cataract surgery, using NGENUITY®, demonstrated similar safety and efficiency as the traditional binocular microscope.

The authors suggest further prospective studies are required to assess whether the implementation of this technology may overcome work-related disabilities and provide a new educational tool in ophthalmology.

STUDY RESULTS

INTRAOPERATIVE COMPLICATIONS

- There were 12 (0.72%) and 5 (0.77%) complications (all non-significant) in the 3D (NGENUITY®) and traditional microscopy groups respectively (P>0.05) (**Table 1**)
- Complications for both groups included posterior capsular rupture, vitreous prolapse with a need for anterior vitrectomy, and three-piece sulcus IOL implantation; no other type of complication was noted
- There was no statistically significant difference within and between the groups (3D vs traditional) with respect to surgical approach used (FLACS and phacoemulsification) (P>0.05) (**Table 1**)
- There were 6 complications for FLACS and 6 complications for traditional phacoemulsification in the 3D group, and 3 complications for FLACS and 2 complications for traditional phacoemulsification in the traditional group

SURGICAL OUTCOMES

- Mean surgical time overall was 6.48 ± 1.15 minutes (range: 3-28 minutes) for the 3D (NGENUITY®) group and 6.52 ± 1.38 minutes (range: 3-26 minutes) for the traditional microscopy group (**Table 1**)
- There was no statistically significant difference between the two groups in terms of overall surgical duration (P>0.05)
- Mean surgical time, by procedure type:
  - FLACS cases: 3D group: 6.44 ± 1.10 minutes (range: 3-22 minutes); traditional group: 6.49 ± 1.17 minutes (range: 3-25 minutes)
  - Phacoemulsification cases: 3D group: 6.51 ± 1.19 minutes (range: 3-28 minutes); traditional group: 6.54 ± 1.19 minutes (range: 3-26 minutes)

Table 1. Comparative study findings, femtosecond laser-assisted cataract surgery (FLACS) and manual phacoemulsification performed in 3D (NGENUITY®) and traditional microscopy groups.

Parameter	FLACS	Manual phacoemulsification	Total	*P*
Complications				
3D group	6	6	12	> 0.05
Traditional group	3	2	5	> 0.05
P	> 0.05	> 0.05	> 0.05	
Surgical time (min)				
3D group	6.44 ± 1.10	6.52 ± 1.19	6.48 ± 1.15	> 0.05
Traditional group	6.49 ± 1.17	6.54 ± 1.19	6.52 ± 1.38	> 0.05
P	> 0.05	> 0.05	> 0.05	

FLACS=femtosecond laser-assisted cataract surgery; MP=manual phacoemulsification; 3D=three-dimensional visualization system (heads-up surgery); traditional=traditional binocular microscope.

Comparative Analysis of Three-Dimensional (3D) Heads-Up Vitrectomy and Traditional Microscopic (TM) Vitrectomy for Vitreoretinal Diseases

Surgical Outcomes

Safety

Zhang et al. *Curr Eye Res.* 2019; 44:1080-1086

OVERVIEW

STUDY DESIGN

Comparative, retrospective, interventional case series to investigate the visual outcomes and occurrences of perioperative complications after 3D heads up vitrectomy compared with traditional microscopic (TM) surgery for vitreoretinal diseases

STUDY SITE(S)

Single center in China

PATIENTS

Three hundred and twenty-six (326) eyes from 324 patients (mean age, 3D group: 55.89 ± 13.37 years; mean age, TM group: 54.62 ± 15.63 years)

SURGICAL METHODOLOGY

23-gauge pars plana vitrectomy for posterior segment diseases with either traditional microscope or 3D visualization system

SURGICAL TECHNOLOGY

Constellation® Vision System (Alcon Laboratories, Inc.); OPMI Lumera 700 operation microscope, RESIGHT wide-angle viewing operation system (Carl Zeiss Meditec); Alcon NGENUITY® 3D Visualization System (Alcon Laboratories, Inc.); 3D high dynamic range (85 dB) surgical camera (ICM5), 3D compact image processing unit, OLED 3D 4K ultra-high-definition flat panel display

KEY ENDPOINT(S)

Visual outcomes (changes in visual acuity (VA; logMAR scale); anatomical success); operation time; perioperative complication rates

ANALYSIS AND CONCLUSIONS

Comparable visual and anatomical outcomes for treatment of vitreoretinal diseases were found between the 3D and TM vitrectomy surgery groups, without a significant difference in the rate of complications. Therefore, 3D heads-up vitrectomy may be regarded as the treatment of choice for various vitreoretinal disease patients.

The authors indicate these preliminary findings need to be confirmed in further prospective, randomized studies.

STUDY RESULTS

VISUAL OUTCOMES

- There was no significant difference between baseline and postoperative logMAR visual acuity (VA) values in the 3D (NGENUITY®) and TM groups (P=0.595 and 0.821, respectively) (**Table 1**)
- Subgroup analyses of VA between the two groups pre- and post-operation likewise revealed no significant differences
- Significant improvements in mean logMAR VA was shown by both groups at final follow-up (P<0.001)

POSTOPERATIVE OUTCOMES

- Significant improvements in anatomical recoveries were demonstrated in both groups for epiretinal membrane (ERM), vitreous hemorrhage (VH), macular holes (MH), retinal detachment (RRD), and pathological myopic foveoschisis (MF)
- Mean overall operation time was not significantly longer in the 3D group (31.0 ± 17.6 min) than the TM (31.0 ± 15.9) group (P=0.994)
- The postoperative complication incidence rates were similar between the 3D and TM groups (30.6% and 30.2% respectively) during follow-up (P = 0.932)
- No significant differences were found between the 3D and TM groups regarding rates of ocular hypertension, hypotony, VH, recurrent RRD, new-onset RRD, and new-onset MH in early and late postoperative periods, respectively (**Table 2**)

Table 1. Visual acuity outcomes in three-dimensional (3D) heads-up vitrectomy (NGENUITY®) and traditional microscopic vitrectomy groups.

VA Snellen (logMAR ± SD)	Preoperative			Postoperative			*P* (pre vs post)†	
	3D (NGENUITY®)	Traditional	*P**	3D (NGENUITY®)	Traditional	*P**	3D (NGENUITY®)	Traditional
Overall	20/270 (1.13 ± 0.63)	20/266 (1.12 ± 0.68)	0.595	20/112 (0.75 ± 0.43)	20/125 (0.80 ± 0.55)	0.821	< 0.001	< 0.001
Surgical indications								
ERM	20/96 (0.68 ± 0.29)	20/91 (0.66 ± 0.37)	0.933	20/54 (0.43 ± 0.23)	20/56 (0.44 ± 0.36)	0.441	< 0.001	< 0.001
VH	20/1109 (1.74 ± 0.74)	20/836 (1.62 ± 0.69)	0.449	20/202 (1.01 ± 0.54)	20/237 (1.07 ± 0.53)	0.573	< 0.001	< 0.001
MH	20/186 (0.97 ± 0.30)	20/212 (1.03 ± 0.45)	0.662	20/104 (0.72 ± 0.31)	20/94 (0.67 ± 0.44)	0.688	0.001	< 0.001
RRD	20/792 (1.60 ± 0.66)	20/709 (1.55 ± 0.73)	0.802	20/243 (1.09 ± 0.41)	20/303 (1.18 ± 0.59)	0.578	< 0.001	< 0.001
MF	20/109 (0.74 ± 0.24)	20/191 (0.98 ± 0.53)	0.361	20/147 (0.56 ± 0.28)	20/111 (0.74 ± 0.43)	0.282	0.020	0.001
SOR	20/308 (1.19 ± 0.46)	20/200 (1.00 ± 0.47)	0.360	20/147 (0.87 ± 0.42)	20/208 (0.73 ± 0.34)	0.500	0.006	0.063
VO	20/ 115 (0.76 ±0.34)	20/16.67 (-0.08)	N.A.	20/115 (0.76 ± 0.34)	20/20 (0.00)	N.A.	N.A.	N.A.

**Mann-Whitney U test*
†Wilcoxon signed-rank test
NA:statistical analysis not applicable

VA: visual acuity; LogMAR, logarithm of minimum angle of resolution; SD: standard deviation; vs: versus; ERM: epiretinal membrane; MH: macular hole; RRD: rhegmatogenous retinal detachment; VH: vitreous hemorrhage; MF: pathologic myopic foveoschisis; SOR: silicone oil removal; VO: vitreous opacities.

Table 2. Postoperative complications in three-dimensional (3D) heads-up vitrectomy (NGENUITY®) and traditional macroscopic vitrectomy groups.

Complications	No. of eyes (% of total eyes, 0-3 months)			No. of eyes (% of total eyes, ≥3 months)		
	3D (NGENUITY®)	Traditional	P†	3D (NGENUITY®)	Traditional	P†
Ocular hypertension	14 (11.3)	19 (9.4)	0.706	0 (0)	0 (0)	N.A.
Transient	7 (5.7)	12 (5.9)	0.912	0 (0)	0 (0)	N.A.
Medically controlled	6 (4.8)	5 (2.5)	0.251	0 (0)	0 (0)	N.A.
Medically uncontrolled	1 (0.8)	2 (1.0)	0.866	0 (0)	0 (0)	N.A.
Hypotony	5 (4.0)	7 (3.5)	0.792	0 (0)	0 (0)	N.A.
VH	10 (8.1)	14 (6.9)	0.704	0 (0)	3 (1.5)	0.173
Recurrent RRD	2 (1.6)	2 (1.0)	0.620	2 (1.6)	5 (2.5)	0.602
New-onset RRD	1 (0.8)	4 (2.0)	0.402	1 (0.8)	2 (1.0)	0.866
MH	3 (2.4)	5 (2.5)	0.975	0 (0)	0 (0)	N.A.
Total	35 (28.2)	51 (25.2)	0.554	3 (2.4)	10 (5.0)	0.257

†Chi-squared test
NA: statistical analysis not applicable
RRD: rhegmatogenous retinal detachment;
VH: vitreous hemorrhage; MH: macular hole.

The Preliminary Experiences with Three-Dimensional (3D) Heads-Up Display (HUD) Viewing System for Vitreoretinal Surgery Under Various Status.

System Performance

Surgical Outcomes

Zhang et al. *Curr Eye Res.* 2019;44:102-109

OVERVIEW

STUDY DESIGN

Non-randomized case-control study to investigate the preliminary use of 3D heads-up display (HUD) viewing system for vitreoretinal surgery under various status

STUDY SETTING(S)

Single center in China

PATIENTS

Thirty-one (31) eyes of 31 patients in Study Group (18 men, 13 women; mean age 49.2 ± 15.3 years); 28 eyes of 28 patients in the Control Group (16 men, 12 women; mean age 50.1 ± 15.0 years)

SURGICAL METHODOLOGY

25-gauge pars plana vitrectomy (PPV) for all vitreoretinal surgery, including phacoemulsification and silicone oil removal; wide-angle and 3D visualization systems were used for all study group vitreoretinal surgery; operations were performed via the eyepiece, rather than the 3D display in the control group

SURGICAL TECHNOLOGY

Study group: Constellation® Vision System (Alcon Laboratories, Inc.); wide-angle viewing system (Carl Zeiss Meditec); NGENUITY® 3D Visualization System (Alcon Laboratories, Inc.); 3D high dynamic range (85 dB) surgical camera (ICM5); OPMI VISU 200 plus (Carl Zeiss Meditec); 4K ultra-high-definition flat panel display.
Control group: Constellation® Vision System (Alcon Laboratories, Inc.); OPMI VISU 200 plus (Carl Zeiss Meditec)

KEY ENDPOINT(S)

Emittances of the endoillumination pipe in both groups and that of the 3D display in the study group; surgical duration; surgeon/resident preferences; difficulty rating; ergonomics rating; intraoperative and postoperative complications; surgeon and assistant experience of use

ANALYSIS AND CONCLUSIONS

Vitreoretinal surgery under various status can be completed by an experienced vitreoretinal surgeon who is a 3D HUD system novice. Main benefits were found to include lower endoillumination intensity, enhanced user preference, and improved ergonomics. Refinements to the 3D HUD system is expected to provide better users experiences in the future.

The authors indicate that further randomized case-control studies with broader sample-size and more objective parameters should be undertaken.

STUDY RESULTS

SURGICAL POPULATION AND OUTCOMES

- There were no statistically significant differences in terms of age, gender, BCVA, primary diagnosis, surgical duration and difficulty rating between the Study Group and Control Group (all P>0.05)
- The main characteristics of both study and control groups are listed in **Table 1**
- For both surgical groups, there were no severe intraoperative or postoperative complications observed

SYSTEM PERFORMANCE AND SURGEON / ASSISTANT EXPERIENCE

- In the study group, the mean emittance of endoillumination pipe (at 10% intensity) was 598.7 ± 5.4 lux; mean emittance from the display was 62.4 ± 3.9 lux; the correlation between these two figures was not statistically significant (P=0.375)
- In the control group, the minimum endoillumination intensity for the surgeon to see clearly throughout the procedure was 35%
- An overwhelming preference for the 3D HUD surgical system was observed among the surgeon and 10 assistants; improved ergonomics were noted by the surgeon when using the HUD system (P< 0.001)
- Some intraoperative difficulties and discomforts were reported by surgeons and assistants when using the 3D system; main difficulties observed during the surgical procedure included: movement of the patient's head during scleral indentation, opacity of the anterior and/or posterior lens capsule, and nausea and dizziness experienced when performing prolonged laser photocoagulation; surgeon discomfort disappeared after a pause in the manipulation, and there was no need to switch to the microscope eyepiece

Table 1. Main characteristics of patients in the Study Group (n=31) and Control Group (n=28).

	3D (NGENUITY®)	Control Group	*P* value
Gender (male:female)	18:13	16:12	0.943[a]
Age (years)	49.2 ± 15.3	50.1 ± 15.0	0.811[b]
Preoperative logMAR BCVA	2.087 ± 0.591	2.050 ± 0.598	0.710[c]
Main diagnosis			0.718[a]
Recurrent RD with/out SO tamponade	9	10	
SO tamponade with significant cataract	1	2	
Severe PDR with/out tractional RD	8	6	
Idiopathic epimacular membrane with significant cataract	1	0	
Primary RD with various complex conditions	12	10	
Surgical duration (min)	45.0 ± 12.6	47.1 ± 12.8	0.407[c]
Endoillumination (lux)[d]	598.7 ± 5.4	1913.0 ± 12.9	<0.001[b]
Difficulty rating	1.6 ± 0.8	1.6 ± 0.7	0.629[c]
Ergonomics rating	4.4 ± 0.8	3.2 ± 1.0	<0.001[c]

BCVA: best-corrected visual acuity; logMAR: logarithm of minimal angle of resolution; lux: luminous emittance; PDR: proliferative diabetic retinopathy; RD: retinal detachment; SO: silicone oil. Statistical analysis: [a]x2 analysis; [b]unpaired t-test; [c]unpaired Mann-Whitney test. [d]Intensity level: 10% (Study Group); 35% (Control Group). Continuous values presented as mean ± standard deviation.

Comparing Heads-Up Versus Binocular Microscope Visualization Systems in Anterior and Posterior Segment Surgeries: A Retrospective Study

System Performance

Safety

Berquet et al. *Ophthalmologica.* 2020; E-pub ahead of print

OVERVIEW

STUDY DESIGN

Retrospective study to compare efficiency, surgical comfort and safety of a three-dimensional (3D) visualization system to standard binocular microscope (BM) in routine ophthalmologic procedures

STUDY SITE(S)

Single center in France

PATIENTS

One hundred and two (102) surgeon-completed questionnaires corresponding to 102 procedures (73 cataract and 29 vitreoretinal procedures performed with either 3D or BM visualization systems)

SURGICAL METHODOLOGY

Routine procedures were limited to cataract (PK) for anterior segment surgeries; pars plana vitrectomies (PPV) to treat retinal detachment (RD), epiretinal membrane (ERM), macular hole (MH) or vitreous hemorrhage (VH) for posterior segment surgeries

SURGICAL TECHNOLOGY

NGENUITY® 3D Visualization System (Alcon Laboratories, Inc.); Constellation® Vitreoretinal Surgical System and Xenon light sources (Alcon Laboratories, Inc.); OPMI Lumira® 700 surgical microscope (Carl Zeiss)

KEY ENDPOINT(S)

Surgical efficiency and comfort; safety

ANALYSIS AND CONCLUSIONS

The 3D visualization system appears to be at least as safe, efficient, and comfortable, as the standard BM. A significant reduction of PK procedure duration was linked to 3D utilization.

The authors suggest that this emerging technology requires further evaluation in randomized trials for long term phototoxicity evaluation, especially in macular diseases.

STUDY RESULTS

QUESTIONNAIRE REPORTED SURGICAL OUTCOME

- One hundred and two (102) questionnaires corresponded to the following surgical procedures:
  - Seventy-three (73) PK surgeries (25 performed with 3D; 48 performed with BM)
  - Twenty-nine (29) PPV surgeries (15 performed with 3D (8 RD, 5 ERM, 2 VH); 14 performed with BM (7 RD, 3 ERM, 3 TM, 1 VH))
- No statistical differences were found in patient age, gender, preoperative surgical risk estimation, or surgeon visual comfort, backaches, and headaches between the 3D and BM groups
- The 3D system allowed for a decreased PK surgical time (16.44 ± 4.36 minutes vs. 21.44 ± 7.50 minutes; P=0.007) (**Table 1**) and slightly enhanced operative fluency, which was judged as excellent in 80% of 3D-assisted surgeries, and only 60.4% of BM-assisted surgeries (P=0.09)
- In vitreoretinal surgeries (3D, n=14 vs. BM, n=15), no obvious differences between the two visualization systems were observed, however, the 3D system was found to slightly decrease operative fluency (20% "Excellent"; 80% "Normal" vs. 57.1% "Excellent"; 42.9% "Normal"; P=0.04) (**Table 2**)
- Parameters independently associated with PK surgery duration were 3D visualization, high preoperative surgical risk, intraoperative complications, and surgeon status in univariate and multivariate analysis

Table 1. Comparison of clinical and surgical parameters in three-dimensional (3D) and binocular microscope (BM) groups in cataract (PK) surgeries.

	NGENUITY®, n=25 [n (%) or mean ± SD]	BM, n=48 [n (%) or mean ± SD]	P Value
Gender Female Male	 12 (48) 13 (52)	 22 (46) 26 (54)	 0.86†
Age (years)	**72.2 ± 8.6**	**71.2 ± 7.7**	**0.40‡**
Surgical risk Low Intermediate High	 19 (76) 4 (16) 2 (8)	 29 (60.4) 15 (31.3) 4 (8.3)	 0.38‖
Surgeon status Senior only Resident only Resident with help of the senior	 14 (56) 2 (8) 9 (36)	 25 (52.1) 14 (29.2) 9 (18.7)	 0.07*†
Operating time (min)	**16.44 ± 4.36**	**21.44 ± 7.60**	**0.007*§**
Complications Yes No	 1 (4) 24 (96)	 4 (8.3) 44 (91.7)	 0.65‡
Visual comfort Low Normal Excellent	 0 (0) 5 (20) 20 (80)	 2 (4.2) 18 (37.5) 28 (58.3)	 0.21‡
Operative fluency Low Normal Excellent	 0 (0) 5 (20) 20 (80)	 0 (0) 19 (39.6) 29 (60.4)	 0.09†
Backaches None Low Moderate Important	 22 (88) 3 (12) 0 (0) 0 (0)	 40 (83.3) 5 (10.4) 3 (6.3) 0 (0)	 0.66†
Headache Yes No If present, mean intensity (/10)	 3 (12) 22 (88) 1 ± 0	 4 (8.3) 44 (91.7) 4.5 ± 1.73	 0.68†

** Statistically significant P value; † Khi-2 tests; ‡ Fisher tests; § Wilcoxon tests*

Table 2. Comparison of clinical and surgical parameters in three-dimensional (3D) and binocular microscope (BM) groups in pars plana vitrectomy (PPV) surgeries.

	NGENUITY®, n=15 [n (%) or mean ± SD]	BM, n=14 [n (%) or mean ± SD]	P Value
Gender Female Male	 8 (53.3) 7 (46.7)	 9 (64.3) 5 (35.7)	 0.55†
Age (years)	**70.1 ± 10.3**	**66 ± 8.5**	**0.30‡**
Type of surgery RD ERM MH VH	 8 (53.3) 5 (33.3) 0 (0) 2 (13.3)	 7 (50) 3 (21.4) 3 (21.4) 1 (7.2)	 0.41‡
Surgical risk Low Intermediate High	 5 (33.3) 6 (40) 4 (26.7)	 7 (50) 6 (42.9) 1 (7.1)	 0.44‡
Endoillumination intensity %	**29.87 ± 8.50**	**24.35 ± 7.57**	**0.13§**
Operating time (min)	**51.33 ± 24.24**	**46.14 ± 21.72**	**0.63§**
Complications Yes No	 3 (20) 12 (80)	 3 (21.4) 11 (78.6)	 0.92‡
Visual comfort Low Normal Excellent	 1 (6.7) 9 (60) 5 (33.3)	 0 (0) 7 (50) 7 (50)	 0.58‡
Operative fluency Low Normal Excellent	 0 (0) 12 (80) 3 (20)	 0 (0) 6 (42.9) 8 (57.1)	 0.04*‡
Backaches None Low Moderate Important	 8 (53.3) 3 (20) 2 (13.3) 2 (13.3)	 9 (64.3) 3 (21.4) 2 (14.3) 0 (0)	 0.73‡
Headache Yes No If present, mean intensity (/10)	 4 (26.7) 11 (73.3) 4.25 ± 3.20	 5 (35.7) 9 (64.3) 2.80 ± 1.09	 0.70‡

RD=retinal detachment; ERM=epiretinal membrane; MH=macular hole; VH=vitreous hemorrhage
** Statistically significant P value; † Khi-2 tests; ‡ Fisher tests; § Wilcoxon tests*

Clinical Study on the Initial Experiences of French Vitreoretinal Surgeons with Heads-up Surgery

System Performance

Surgical Outcomes

Palácios et al. *Curr Eye Res.* 2020; E-pub ahead of print

OVERVIEW

STUDY DESIGN

Prospective, randomized study to evaluate, via questionnaire, the initial experience with a three-dimensional (3D) visualization surgical system; anatomical surgical outcomes of full-thickness idiopathic macular holes (MH) and primary rhegmatogenous retinal detachment (RRD) by using traditional microscopy (TM) and the three-dimensional (3D) heads-up method

STUDY SETTING(S)

Single center in France

PATIENTS

One hundred and eighty-eight (188) surgical patients; 88 MH (44 TM, 44 3D) — inclusion criteria age >18 years; 100 RRD (50 TM, 50 3D) — inclusion criteria age >18 years and a history of visual complaints of <15 days

SURGICAL METHODOLOGY

Vitreoretinal surgery, both with and without cataract surgery via the heads-up method, including peeling of ILM or epiretinal membrane (ERM), scleral or iris fixation, RRD, tractional retinal detachment (TRD), vitreous hemorrhage, management of a dropped nucleus or intraocular lens (IOL), lensectomy, and scleral buckle (SB) surgery; iOCT used in macula surgeries; Full-thickness idiopathic MHs; Pars plana vitrectomy for treating RRDs

SURGICAL TECHNOLOGY

OPMI LUMERA® 700 & RESCAN®700 intraoperative OCT (iOCT)(Carl Zeiss Meditec, Germany); NGENUITY® 3D Visualization System (Alcon Laboratories, Inc.); 3D high-dynamic-range (HDR) camera with metal oxide semiconductor image sensor; TrueWare, version 9.5.4; (TrueVision Systems); high-definition 55" LCD monitor with 4K OLED display; 25-gauge Constellation® Vision System phacovitrectomy unit (Alcon Laboratories, Inc.); ERBOKRYO® AE cryosurgical system (Erbe Elekromedizin, Germany); DATAFUSION™ software (Alcon Laboratories, Inc.); MiniQuad®; Volk Optical); direct imaging plano-concave vitrectomy lens (France Chirurgie Instrumentation); Chandelier Lighting System (Alcon Laboratories, Inc.); Membrane Blue-Dual or ILM-Blue (DORC, Netherlands); CALLISTO eye™ (Zeiss, Germany)

KEY ENDPOINT(S)

Surgeon preference; ergonomics, educational value, image sharpness, depth perception, field of view, technical feasibility, advantages and disadvantages and expectations for the future; anatomical success

ANALYSIS AND CONCLUSIONS

The participating surgeons preferred 3D visualization to ocular viewing. Vitrectomy surgery to treat both MHs and RRD can be performed using the 3D method with the same efficiency as TM. The digital integration of 3D and other digital platforms, such as iOCT, can be useful in certain cases.

The authors suggest that with continuous refinement to improve the ability to visualize inside of the eye, the promise of 3D technology may enhance surgeon abilities.

STUDY RESULTS

SURGEON QUESTIONNAIRE OUTCOMES

- French surgeon questionnaire reporting showed that 3D was preferred over TM, except in technical feasibility
- Brazilian surgeon responses mirrored the French, however the average ratings for all parameters were higher in the Brazilian group (**Table 1**)
- All surgeons reported that surgery to address the peeling of the ILM or ERM benefitted most from the 3D method (P<0.001)
- Two surgeons reported feeling more comfortable with the 3D system for dissection, such as proliferative vitreoretinopathy (PVR) or TRD
- All participants reported a major advantage of the 3D system was better focus under high magnification and the ability of the light pipe to be held remote from the retina
- Anterior segment surgeries, such as SB and secondary IOL fixation, were reported by all participants to have the least benefit from using the 3D system (P<0.001)
- All surgeons reported using the black and white filter in patients with atrophic RPE during ILM peeling
- Limitations included the following:
  - Factors relating to both patients and surgeons may have influenced outcomes, despite the authors' aim to use precise inclusion criteria
  - Questionnaire reported surgeon preference clearly showed 3D over TM, in all categories, however the article was not powered to detect statistical significance

SURGICAL OUTCOMES

- Unilateral full-thickness idiopathic MH – 88 patients (3D, n=44; TM, n=44); 49 (55.6%) females and 39 (44.4%) males; age range: 55-87 years
  - 92.1% (81) MHs were successfully closed with one surgery
  - The closure failure rate was not significantly different between 3D and TM methods (P=1.000)
- Primary RRD – 100 patients (3D, n=50; TM, n=50); 58 (58%) females and 42 (42%) males; age range 41-84 years
- 91% reported post-surgical anatomical success after 3 months follow-up in eyes with a primary RRD – no statistical significance between 3D and ocular viewing
- General characteristics were not significantly different between the 3D and TM subgroups (P>0.05)

Table 1. Questionnaire rating heads-up three-dimensional (3D) NGENUITY® system on a 1 to 10 Scale relative to traditional microscopy (TM), comparing Brazilian and French experienced vitreoretinal surgeons. 1 = much worse than traditional microscope; 5 = equivalent; 10 = much better than traditional microscope.

	Brazilian n=6	French n=4	Total (n=10)	P Value
Image resolution Mean (SD) Median Min-Max	7.17 (2.4) 8 3-9	6.75 (2.06) 6.5 5-9	7 (2.16) 7.5 3-9	0.7843
Depth perception Mean (SD) Median Min-Max	8.67 (1.51) 9 7-10	6.75 (2.63) 7.5 3-9	7.9 (2.13) 8 3-10	0.1764
Field of view Mean (SD) Median Min-Max	8.33 (1.63) 8.5 6-10	8 (1.83) 8 6-10	8.2 (1.62) 8.5 6-10	0.7701
Ergonomics Mean (SD) Median Min-Max	8 (2.68) 9 3-10	7 (2.58) 7 4-10	7.6 (2.55) 8.5 3-10	0.5743
Technical feasibility Mean (SD) Median Min-Max	6.33 (2.34) 7 3-9	4.75 (0.96) 4.5 4-6	5.7 (2) 5.5 3-9	0.2415
Educational value Mean (SD) Median Min-Max	9.83 (0.41) 10 9-10	9 (0) 9 9-9	9.5 (0.53) 9.5 9-10	0.0143*

**P<0.05 statistically significant SD, standard deviation*

Three-Dimensional (3D) Display Systems in Ophthalmic Surgery – A Review

Moura-Coelho et al. *European Ophthalmic Review*. 2019; 13: 31-6.

OVERVIEW

STUDY DESIGN

Clinical literature review of the applications of 3D display systems in ophthalmic surgery. The authors searched PubMed database, Google Scholar, and Research Gate for published papers, as well as relevant abstracts of personal communications held at meetings of ophthalmology, up to 14 June 2019. A manual search of the reference lists of most primary articles was undertaken

ANALYSIS AND CONCLUSIONS

Three-dimensional (3D) display systems are increasingly demonstrating good results in ophthalmology, both for anterior segment and vitreoretinal surgeons. Heads-up 3D display technology has been gaining acceptance with increased experience.

Head-mounted display systems (HMS) in vitreoretinal surgery have a short learning curve, provide excellent visual experience with greater ergonomics compared with traditional surgery. Heads-Up and HMS 3D technology allow for less light delivery to the retina, potentially allowing for less phototoxicity during vitreoretinal procedures.

Limitations of the current 3D visualization systems (assistant discomfort, operating theater logistics, visual disturbance by media opacities, surgeon headache/nausea after prolonged laser photocoagulation) are being investigated and worth overcoming. Some HMS devices will require wireless capability for widespread adoption of the technology. Technical intraoperative errors pose a significant risk, due to early and insufficient training, therefore more ophthalmology experience is required.

3D heads-up display and HMS technologies have excellent immediate potential for live surgery teaching and training. 3D systems allow the entire surgical teams well as larger audiences, access to the surgeons view with increased depth perception and clarity. Surgery recordings can further be analyzed and used to teach trainees.

* The TrueVision® 3D Visualization System was acquired by Alcon and rebranded as NGENUITY® in 2018

STUDY RESULTS

CATARACT AND ANTERIOR SEGMENT SURGERY

- Cataract and anterior segment surgery in human eyes using heads-up surgery was first reported in a retrospective analysis comparing cataract surgery using a standard binocular microscope with a microscope equipped with NGENUITY® (TrueVision) 3D Visualization System*. Excellent outcomes were reported with minimal procedure time difference between groups. The rate of unplanned vitrectomy was 3x higher in the standard microscope group
- Toric IOL implantation using TrueGuide® resulted in 83.3% of eyes corrected to <0.50 D of cylinder, and 100% of eyes corrected to <1.00 D cylinder. 80% of the eyes had final vision 20/20, and 100% of the eyes achieved 20/25 or better
- Non-Descemet stripping automated endothelial keratoplasty (nDSAEK) for post-traumatic bullous keratopathy, and Descemet membrane endothelial keratoplasty (DMEK) have also been performed using heads-up surgery. Interestingly, although visual experience for DMEK was reported as superior using the 3D heads-up display system, frequent focus changing to detect the graft in the anterior chamber was reported with nDSAEK
- A small case series of strabismus surgery using the NGENUITY® system reported good feasibility and reduced need for illumination but associated with assistant discomfort

VITREORETINAL PROCEDURES

- The first published study assessing whether vitreoretinal surgery could be performed with 3D heads-up display system, using the NGENUITY® (TrueVision) Visualization System found superior ergonomics, superior brightness of the surgical field without exposing the retina to additional light and without loss of image definition and quality. These findings have been corroborated in later studies using the 3D heads-up display systems
- A large-scale prospective study demonstrated the feasibility and utility of integrating intraoperative optical coherence tomography (OCT) with the 3D heads-up display system for ophthalmic surgeries
- There is evidence of good surgical experience using 3D heads-up display systems for retinal detachment surgery and for macular surgery
- The 80-ms latency time (vs. a standard microscope) with 3D heads-up display systems is not noticeable during intraocular procedures. 3D systems may reduce copiopia and asthenopia. Most of the evidence suggests that 3D heads-up display provides similar surgical times, visual outcomes, and complication rates compared to conventional surgery
- The rapid learning curve of the NGENUITY® system has been confirmed in a recent prospective study assessing the learning curve in macular hole surgery
- Limitations of the 3D heads-up surgery include surgeon and assistant headache, nausea and visual disturbances, which may be exacerbated after prolonged laser photocoagulation owing to the flickering green light stimulation, and the greater disturbance caused by media opacities. Operating theatre logistics may cause assistant discomfort owing to the positioning to visualize the monitor, and the anesthesiologist's access to the patient may be more difficult

HEAD MOUNTED SYSTEMS (HMS)

- The HMS is an active system, in which the 3D, stereoscopic image is obtained by showing high-speed consecutive images for the right and left eyes alternately
- Research using the Sony HMS-3000MT helmet in ophthalmic surgeries shows the device is well-fitted and not uncomfortable, with superior ergonomics, excellent image quality, depth perception and spatial orientation, 45° diagonal field of view, and short adaptation time and learning curve
- HMS allows the user to suppress the physical distance inherent to the heads-up display with the consequent loss of image definition and stereopsis, improving and optimizing the surgeon's technical capacity

AVEGANT GLYPH HEAD-MOUNTED VIRTUAL RETINAL PROJECTION DISPLAY

- The Avegant Glyph retinal projection system employs a virtual retinal display technology, in which the image is directly projected onto the user's retina
- Pilot experience using vitrectomy eye models suggests vitreoretinal surgery is feasible using this device, providing a high depth of field. It may have a superior ergonomics profile compared with 3D heads-up surgery and appears to provide an enhanced view for procedures requiring simultaneous intra- and extraocular visualization, such as scleral depression

CLARITY™ HEAD-MOUNTED DISPLAY SYSTEM

- The Clarity™ platform provides an augmented-reality view of the surgery. A pilot study using the platform for vitreoretinal surgeries showed image quality comparable to that of standard microscope, and the HMS provided superior maximum magnification, with half the light level requirements. Surgeon experience was positive, without reported fatigue, comfortable posture, and intuitive head motions

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Important Product Information

Caution: Federal (USA) law restricts this device to sale by, or on the order of, a physician.

Indication: The NGENUITY® 3D Visualization System consists of a 3D stereoscopic, high-definition digital video camera and workstation to provide magnified stereoscopic images of objects during micro-surgery. It acts as an adjunct to the surgical microscope during surgery, displaying real-time images or images from recordings.

Warnings: The system is not suitable for use in the presence of flammable anesthetics mixture with air or oxygen. There are no known contraindications for use of this device.

Precautions: Do not touch any system component and the patient at the same time during a procedure to prevent electric shock. When operating in 3D, to ensure optimal image quality, use only approved passive-polarized glasses. Use of polarized prescription glasses will cause the 3D effect to be distorted. In case of emergency, keep the microscope oculars and mounting accessories in the cart top drawer. If there are any concerns regarding the continued safe use of the NGENUITY® 3D Visualization System, consider returning to using the microscope oculars.

Attention: Refer to the User Manual for a complete list of appropriate uses, warnings and precautions.

The CONSTELLATION® Vision System can be connected to the NGENUITY® 3D Digital Visualization System. Please refer to the CONSTELLATION® Vision System user manual for complete instructions, warnings and precautions.

Alcon