Evaluating the Level of Endo-illumination Required during Digitally Assisted Vitreo-Retinal Surgery (DAVS) : A Systematic Literature Review

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Introduction

- Traditional microscopy is used in ophthalmic procedures to facilitate the visualization of critical tissues during surgical cases
- While technological or procedural advances have resulted in low complication and re-operation rates, there are limitations of existing technologies — including but not limited to: surgical endo-illumination challenges, need for in-procedure adjustments, and additional information/support provided by other surgical devices — all of which can create challenges for surgeons during procedures[1,2,3]
- Recent developments in digitally assisted vitreo-retinal surgery (DAVS) and heads-up setup were introduced to the global ophthalmic surgical community to enhance visualization with digital signal amplification, higher resolution, and increased depth of field, while addressing some of the endo-illumination challenges associated with conventional microscopes

Objective

- To evaluate the available endo-illumination related evidence for heads-up setup and DAVS compared to conventional microscopy

Methods

Literature Search Approach and Inclusion/Exclusion Criteria

- A systematic search of the PubMed database was performed for studies published between 2009 and 2019 using predefined search terminology focusing on retinal surgery, 3D heads-up visualization, and clinical and economic outcomes
  - An additional search of the Embase database with targeted terms was conducted to supplement the findings of the systematic PubMed search
  - Table 1 presents search terms and combinations used in PubMed and the targeted search terms used in the additional Embase search
- Only studies published in English and conducted in human subjects were included
- Exclusion criteria included: non-original articles, studies not primarily focused on the conditions of interest (oculoplastics, blepharoplasty, and other unrelated surgeries), and technologies that were not of interest (optical coherence tomography (OCT) and other unrelated technologies)
- The final literature pool included clinical trials, retrospective studies, and case reports describing the benefits of DAVS or comparing DAVS to conventional microscopes

Table 1. Search Terms and Combinations Used

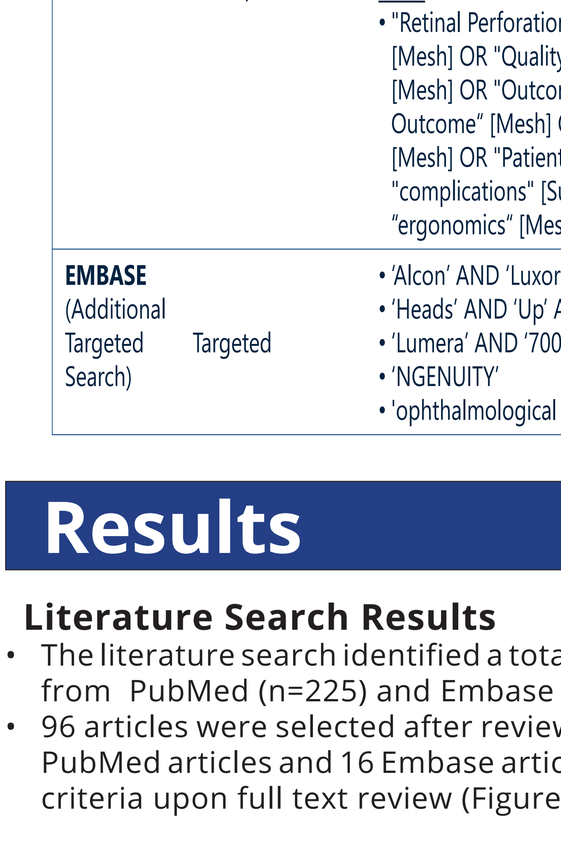
Databases	Topic	Search Terms
PubMed (Primary Search)	Retinal Surgery	"Ophthalmologic Surgical Procedures" [Mesh]
	Treatment	**AND** • "3D Visualization" OR "Ophthalmoscopes" [Mesh] OR "heads up display" OR "heads-up display" OR "heads up surgery"OR • "heads-up surgery" OR "NGENUITY" OR "TrueVision"
	HEOR/Misc.	**AND** • "Retinal Perforation" OR "Economics, Medical" [Mesh] OR "Cost of Illness" [Mesh] OR "Quality of Life" [Mesh] OR "Patient Outcome Assessment" [Mesh] OR "Outcome Assessment (Health Care)" [Mesh] OR "Treatment Outcome" [Mesh] OR "Outcome and Process Assessment (Health Care)" [Mesh] OR "Patient Reported Outcome Measures" [Mesh] OR "complications" [Subheading] OR "Vision Disorders" [Mesh] OR "ergonomics" [Mesh]
EMBASE (Additional Targeted Search)	Targeted	• 'Alcon' AND 'Luxor' • 'Heads' AND 'Up' AND 'Display' • 'Lumera' AND '700' • 'NGENUITY' • 'ophthalmological surgical microscope'

Results

Literature Search Results

- The literature search identified a total of 302 articles after removing duplicates from PubMed (n=225) and Embase (n=87)
- 96 articles were selected after reviewing titles and abstracts (composed of 80 PubMed articles and 16 Embase articles) and 16 articles met the final inclusion criteria upon full text review (Figure 1)

Figure 1. Study Selection Process



Exclusion Criteria	Number of Excluded Records
Unrelated Surgery	150
Unrelated Technology	66
Other (e.g., Animal Study)	40
OCT	21
Drugs or Therapeutics	7
Non-English Language	2

- The focus for this poster was placed on studies which described key components of the DAVS endo-ilumination, as a result, only 3 studies were included in this poster[4,5,6]

The table below (Table 2) summarizes the key evidence for 3 papers, reviewing endo-illumination data for DAVS vs. conventional microscopes

Level of Endo-illumination

- 3 studies evaluated the level of endo-illumination required for DAVS and conventional microscopes; all 3 studies showed that procedures using DAVS were conducted at a lower level of minimum required endo-illumination than procedures leveraging conventional microscopes[4,5,6]

- Talcott et al. recorded minimum levels of required endo-illumination for DAVS and conventional microscopes during surgeries and determined that the minimum required level of endo-illumination was significantly lower with DAVS compared to conventional microscopes while still adequate for visualization[5]
- Adam et al. set endo-illumination to 40% of maximum output and decreased it at set intervals to 0% while measuring via lux meter. In 9 of 10 cases, the surgeon felt that they could operate comfortably at an endo-illumination level 10% of maximum output and in the remaining case, the surgeon felt comfortable at 3% of maximum output[6]
- Zhang et al. recorded the lux of the endo-illumination pipe during surgeries and determined that significantly lower endo-illumination intensity was recorded in DAVS compared to conventional microscopes[4]

Table 2. Literature Review Findings

First Author, Year Sample Size and Type Study Design	Surgery Type	Endpoints	Results Compared to Traditional Microscopes	Favors HUD/DAVS
Talcott, K. E., et al. N=39 eyes Prospective, single-center, unmasked, randomized study	PPV for epiretinal membrane (ERM) or for full-thickness macular hole (MH)	Level of Endo-illumination	Statistically significant improvement for 3D procedures compared to TM. Minimum required endo-illumination was significantly lower with 3D HUD (mean 22.70±15.10%) compared to SOM (mean 39.06±2.72%; p<0.001)	●
Zhang, Z., et al., 2018 N=59 eyes Prospective controlled trial	PPV, silicone oil removal, phacoemulsification with/without intraocular lens implantation, membrane peeling, retinotomy, and silicone oil infusion	Level of Endo-illumination	Statistically significant improvement for 3D procedures compared to TM. Lower endo-illumination intensity was seen in Group Study than that in Group Control (10% vs 35%; 598.7 ± 5.4 vs 1913.0 ± 12.9 lux, P < 0.001)	●
Adam et al. N=10 eyes Prospective, observational surgical case series	Vitreoretinal surgery with surgical indications including vitreous floaters, epiretinal membrane, diabetic vitreous hemorrhage, tractional and rhegmatogenous retinal detachment	Surgeon Comfort at Low Endo-illumination Levels	In 9 of 10 cases, the surgeon felt that they could operate comfortably at an endo-illumination 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% endo-illumination level with corresponding HUD emittance of 15 lux	●
		Level of Endo-illumination	Endo-illumination levels were correlated with luminous emittance from the 3-dimensional HUD (P, 0.01). The average coefficient of variation of HUD luminance was 0.546	●

Abbreviations: HUD = heads-up display; PPV = Pars plana vitrectomy; TM = traditional microscope; VS = vitreoretinal surgery

● = Favors HUD/DAVS with statistical significance ● = Favors HUD/DAVS, but no statistical tests done

Conclusions

- There is a paucity of data investigating the impact of endo-illumination with DAVS. vs. conventional microscopes
- All related studies on DAVS noted that lower levels of endo-illumination were required with DAVS compared to those using conventional microscopes
- With increasing literature on the impact of photo-toxicity on surgical outcomes in eyes at higher risk such as AMD or high myopia, lower endo-illumination with DAVS could reduce macular photo-toxicity compared to conventional microscopes
- Future studies exploring the link between endo-illumination and safety outcomes are warranted

Acknowledgments

The authors were responsible for all content and editorial decisions of this poster. All authors contributed to the research, writing, and reviewing of all drafts of this poster and approved the final version. Editorial support in the preparation of this presentation was provided by Trinity Life Sciences, funded by Alcon, Inc.

Disclosures

V. Sandwick was an employee and C. Lathia, N. Hadker, and K. Hennegan are current employees of Trinity Life Sciences at the time of research. Trinity Life Sciences has conducted this research for Alcon, Inc.; L. Morris, and H. Cheng are employees of Alcon, Inc.

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