## 11:10 AM

# Intraocular Telescopic System IOL-VIP For Advanced Maculopathies


- Fabio Patelli, MD



**OBJECTIVE** We investigate the telescopic intra-ocular lens for visually impaired people (IOL-VIP) revolution system for patients affected by macular diseases.

**PURPOSE** To investigate the telescopic intra-ocular lens for visually impaired people (IOL-VIP) revolution system for patients affected by macular diseases.

**METHODS** IOL-VIP Revolution system is implanted in patients affected by maculopathy. Inclusion criteria were phakic patients, maculopathy, BCVA < 0.3 decimal, preserved visual field, BCVA improvement at the pre-op simulation test. We considered two groups: group 1 patients with BCVA < 0.1 decimal using electronic video devices (CCTV) for reading; Group 2 patients with BCVA > 0.1 decimal using optical magnifiers for reading. Follow-up was at 1, 3 and 6 months. Primary outcome was BCVA gain at the end of follow-up. Secondary outcome was evaluation of visual system utilization for group 1 and reading distance for group 2 at the end follow-up.

**RESULTS** Eighty-one eyes received the IOL-VIP Revolution system; 58 eyes in group 1 and 23 eyes in group 2. The total mean pre-op BCVA was 0.067 decimal and was 0.181 decimal at 6 months follow-up ($p<0.001$). Of the 58 eyes in group 1, fifty-six (96.5%) reached a final BCVA > 0.1 decimal and could read using optical magnifiers instead electronic CCTV. In group 2 mean reading distance was 10.14 cm pre-op and 21.93 at

the end follow-up. One patient had capsular bag rupture during surgery and could not receive the implant. No post-op complications were present.

**CONCLUSION** IOL-VIP Revolution system is a safe and well-tolerated device for patients affected by maculopathy. Post-op BCVA results are equal or better than expected at simulation test. Patients can at least double their pre-op BCVA with a better quality of life.

**TAKE HOME MESSAGE** Intraocular telescopic IOL-VIP system is a promising technique for improve vision in patients affected by maculopathy.

**HUMAN RESEARCH** This study involves human research.
IRB Approval Status: Approved by institutional review board

## 11:18 AM

# One Year Safety and Visual Function Outcomes in the Argus II Post-Approval Study


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- Hossein Ameri, MD, PhD, FRCSI, MRCOphth
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- Allen C. Ho, MD
- Raymond Iezzi, MD, MS
- Kanishka T. Jayasundera, MD,FRANZCO
- Gregg T. Kokame, MD, MMM
- Jennifer I. Lim, MD
- Naresh Mandava, MD
- Sandra Rocio Montezuma, MD
- Lejla Vajzovic, MD
- Jiong Yan, MD
- Meghan Marino, MS, LGC
- Jessy Dorn, PhD



**OBJECTIVE** The Argus II retinal prosthesis system's safety and effectiveness were evaluated in patients implanted for 1 year or more.

**PURPOSE** The Argus II Retinal Prosthesis System is the only FDA approved treatment in the United States for patients with retinitis pigmentosa and light perception vision. The post-approval study is a prospective observational study evaluating the safety and efficacy of the implant in Argus II recipients.

**METHODS** Data was collected prospectively in this non-randomized, un-masked study of Argus II prosthesis recipients. The current analysis is on patients implanted for 1 year or more. The patient demographics, intraoperative and postoperative serious adverse events (SAEs) and functional outcomes were studied. Visual function testing was

performed at baseline, 3, 6, and 12 months using square localization, direction of motion, and grating visual acuity testing with the device turned ON and OFF.

**RESULTS** Twenty patients with at least one year of follow up were analyzed. Average age at surgery was 61.4 years. There were zero implant failures and explants. Four serious adverse events were device- or procedure-related. Square Localization mean error was significantly less with the System ON than OFF in 45% (3 mos.), 47% (6 mos.), and 56% (12 mos.) of patients. Direction of Motion was better with the System ON than OFF in 43% (3 mos.), 39% (6 mos.), and 29% (12 mos.) of patients. In the implanted eye, 14%-23% of patients had logMAR vision better than 2.9 with the device ON versus 0% with the device OFF at all time points.

**CONCLUSION** In a post-approval setting, the Argus II appeared to be safe and resulted in improved visual function in some patients with advanced retinitis pigmentosa.

**TAKE HOME MESSAGE** In a real world, post-approval setting, the Argus II appeared safe with improved visual function at one year.

**HUMAN RESEARCH** This study involves human research.
IRB Approval Status: Approved by institutional review board

## 11:30 AM

# Augmented Reality Video Microscope (ARVM) Visualization During Retina Surgery


- Adiel Barak, MD
- Anat Loewenstein, MD
- Ron Schneider
- Abraham Zeitouny, PhD
- Amir Manor, MD



**OBJECTIVE** Evaluation of Augmented Reality Video Microscope as platform for retina surgery intra-operative visualization and as a replacement of surgical microscopes.

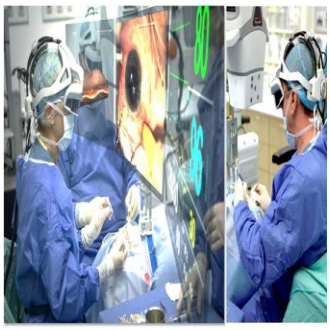
**PURPOSE** Elbit's ARVM is based on state of the art Head Wearable Display (HWD) and imaging technologies currently in use for combat and commercial aviation pilots. As primary purpose, the comfort, quality and value of intra-operative multiple virtual screens projection to the surgeon were tested. In addition, intra-operative surgical assisting applications for improved surgery decision making were tested.

**METHODS** Candidates for extraction of silicone oil from the vitreous cavity and ERM were included in the primary examination. The primary examination was carried out with the use of the ARVM for visualization and the existing vitrectomy system for the surgical procedure itself. During the operation, the surgeon viewed virtual screens using the HWD projection. The main virtual screen was used to project the video microscope image, while other screens were used to visualize clinical data. Related patient OCT data was displayed to the surgeon in real time in correspondence to the retina visualization produced from the ARVM. Different approaches of the OCT visualization during surgery were tested.

**RESULTS** Very good visualization of the posterior chamber was achieved using the ARVM. The HWD did not impose any fatigue or stress on the head, it felt very comfortable to all participants. The use of the HWD created a significant visualization advantage due to the direct video projection to the surgeon eyes continuously during the entire procedure. The virtual screens were orientated in the operating room to maximize comfort while viewing the real time video and data. Using head tracker, each surgeon could navigate with his head between his own customized screens. The availability of the data, viewing comfort and quality of the projection were significant to the operation.

**CONCLUSION** Elbit's ARVM generates high quality detailed visualization for vitreo-retinal surgery. The use of the unique and comfort HWD, the ultra-resolution cameras and computerized processing significantly improves the surgeon's imagery and enables intra-operative supporting information visualization. The improved imaging visualization and efficient information visualization enhances surgical performance.

**TAKE HOME MESSAGE** Elbit's ARVM generates high quality detailed visualization for vitreo-retinal surgery.



**HUMAN RESEARCH** This study involves human research.
IRB Approval Status: Approved by institutional review board

## 11:38 AM

# Digital Assisted Vitreoretinal Surgery Enhances Surgical Management of Retinal Disease


- Marco Mura, MD



**OBJECTIVE** Surgical maneuvers are made safer and easier with digital enhancement in several retinal pathology.

**PURPOSE** To evaluate the feasibility and the clinical relevance of intraoperative digital manipulation of surgical microscopic images aquired with a 3D camera platform.

**METHODS** 120 patients were operated with 3D system and the result compared to 120 patients operated with standard binocular optical microscope. The surgeries were performed by an experienced consultant and 2 second year's retina fellows. Digital filters were tested in different steps of various surgical procedure. Ease of surgery with or without digital manipulation of images, time of surgery, intra and postoperative complications were evaluated.

**RESULTS** All the surgeries in the 2 groups went uncomplicated. The average surgical time with DAVS Ngenuity System was higher than standard optical microscopy but not statistically significant in the fellow group and equivalent to optical microscopy in the consultant cases. The digital system allowed to operate with lower level of light compared to the standard microscope. The use of digital filtering made possible to

simply some steps of the surgery, especially in diabetic delamination and vitreous removal.

**CONCLUSION** Digitally assisted vitreoretinal surgery showed performance comparable to standard optical biomicroscopy and some surgical steps superior to that. The digital system allows to work in lower light intensity. The use of digital filtering allows tissue recognition in difficult surgical maneuvers and highlights the presence of vitreous.

**TAKE HOME MESSAGE** Digital manipulation of surgical image improves ease of surgery.

**HUMAN RESEARCH** This study involves human research.
IRB Approval Status: Approved by institutional review board

## 11:46 AM

# Advances in Endoillumination


- David R. Chow, MD, FRCS(C)



**OBJECTIVE** To present the latest advances in endoillumination using LED light sources and a Digitally asssisted vitrectomy system.

**PURPOSE** To test the safety and brightness of the LED light source (DORC EVA) at the 20 different settings available and to test the changes in the theoretic retinal threshold times using a digitially assisted vitrectomy system (Ngenuoity).

**METHODS** A spectrophotometer (Ocean Optics) and power meter attached to an integrating sphere were used to obtain the brightness and spectal curves of the LED light source on the current DORC EVA system and a new iteration of the LED light source for the DORC EVA. Retinal threshold times were also calculated for the Ngenuity Digitally assisted vitrectomy system being used at modluated levels.

**RESULTS** The brightness of light pipes on the current LED DORC EVA system varied for 25g from 2.9 to 11.58 Lumens, 23g from 4.88 to 15.99 L, and 27g from 1.03 to 5.03 L when tested at a brightness from 20 -100%. A new literation of LED light source for the DORC EVA was also tested which improved brightness for 25g from 3.9 to 15.54 Lumens, 23g from 6.41 to 21.72 L and 27g from 1.43 to 7.82 L. The safety of the LED DORC EVA light source improved dramatically as the color was shifted progressively yellow (0-20). The retinal threshold time at a light color of 0 when used at a brightness of 100% was at a minimum of 285s  increasing to a maximum of 15678s when used at a light color of 20 and brightness of 20%. The Digitally Assisted vitrectomy system

(Ngenuity) is widely reported to be able to be used at a brightness setting down to 10% from the default 34-36% without a compromise in visualization. The increase in retinal threshold time at 10% over the default 35% increased from 6365s to 29194s.

**CONCLUSION** A new iteration of LED light (DORC EVA) features a significant improvement in brightness (25-30%). The Safety of the LED DORC EVA can be improved by up to 55x by changing the color progessively yellow (0-20) and minimzing brightness. The Digitally assisted vitrectomy system (Ngenuity) can be used at lower light levels without sacrificing visualization resulting in up to a 5x increase in safety times.

**TAKE HOME MESSAGE** A new LED source for the DORC EVA features a 30% â‡¡ brightness. The safety of  the LED DORC EVA can be â‡¡ by 55x using color settings. The Ngenuity system allows surgeons to operate at lower light levels resulitng in up to 5x increase in safety.