White Paper

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The Advantages of Color Optimization For Retinal Surgery

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Key Takeaway Points

- Advancements in analog visualization technology have reached a plateau
- Digital visualization provides several advantages that can be applied to multiple medical specialties that could not be realized with analog technologies
- Several current techniques to aid visualization employ dyes that may have adverse clinical consequences
- Use of digital visualization may minimize the adverse effects of dye use and provide better visualization despite intraocular hemorrhage via digital color optimization

Advances in Color Technology

Color vision is an element of our sense of sight that most of us do not think about; we, proverbially, take it for granted. However, color adds context to what we see in our surroundings and, historically, context on what we see has been an evolutionary advantage.[1] There are many technologies that have, relatively recently, been implemented to aid us in visualizing color to better define and assist us with the activities that we perform.

These technologies work in one of two methods, or a combination of both: by altering the light source that is used to illuminate an object, or by filtering the light returning to our eyes by the use of color filters. When we were younger, many of us may have gone to the amusement park and had a barely-visible, fluorescent stamp placed on the back of our hands, but when the stamp was illuminated by a "black light" (UV-A or ultraviolet) source, the now easily-visible stamp allows us to get back into the park without having to pay for readmission (Figure 1). We have also seen pictures of the Los Angeles skyline in post cards or magazines with a beautiful, blue-skied background; this was only made possible by using a host of different color and polarizing filters to subtract the smog and unusual haze that is characteristic of the Los Angeles atmosphere.[2] Figure 2 provides an example of the use of polarizing and gradient filters.

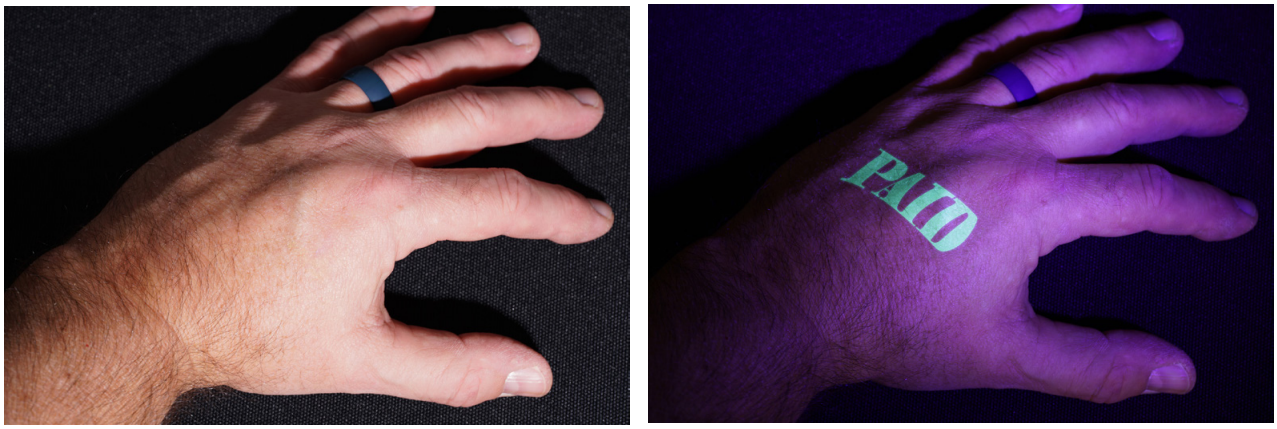

Figure 1: Fluorescent stamp under white and black light, showing enhancement by altering the light source.

Figure 2: Unfiltered photo, and photo using polarizer and gradient filters, showing enhancement by altering light returning to the camera.

Analogous technologies exist in the medical field, as well. For example, Olympus developed narrow band imaging (NBI) technology to enhance the observation of mucosal tissue. NBI enhances visibility by filtering the white light source into specific wavelengths that hemoglobin absorbs and penetrate only into the surface of human tissue. As a result, capillaries on the mucosal surface and veins in the submucosa have a differential color display on the monitor, enhancing differences in benign and malignant tissue.[3] NBI has helped detect neoplasia in colorectal peritoneal metastases,[4] head and neck squamous cell carcinomas[5] and gastric intestinal metaplasia.[6] Similarly, the Pinpoint system by Novadaq evaluates tissue perfusion by utilizing intravenous indocyanine green (ICG) with near-infrared fluorescence imaging. The laparoscope optics are treated with an anti-reflection coating that allows light source transmission in both the visible and the near-infrared spectrum. The camera end of these laparoscopes also employ an excitation light rejection filter, which enhances near-infrared fluorescence imaging. Signal processing allows projection of the white light and ICG fluorescence images into the same image, which provides critical tissue viability information to the surgeon.[7]

The analog operating microscope has played a significant role in allowing the surgical treatment of vitreoretinal disease, however, there has not been any significant change or innovation regarding the basic principles, components and operational experience over the past 60 years.[8] Any visualization updates were limited to enhancements in optics, or to improvements in its light source. The spectral content of a microscope's light source can be a critical factor to optimize tissue visualization, but it can also contribute to phototoxicity. Interestingly, the action spectrum of phototoxicity for the patient is the same as the photopic sensitivity curve of the surgeon. The peak sensitivity of the surgeon and the patient is at 550 nm (green), which happens to be the wavelength with the greatest propensity to cause damage. Green is the most critical part of the visual spectrum followed by red; macular vision is mediated by green and red cones.[9] Vitreous, ILM, retina, and most epiretinal membranes are colorless, and so yellow or green light does not enhance visualization. Macular xanthophyll is yellow and must be visualized in complex retinal detachment and trauma cases, but attempts to visualize using yellow light makes visualization of macular xanthophyll almost impossible. Green light can actually enhance contrast when visualizing blood or blood vessels. Consequently, white light will produce optimal tissue identification with the greatest familiarity to the surgeon. Virtually all slitlamp biomicroscopy, indirect ophthalmoscopy, and fundus photography use white light. Importantly, however, filtering shorter, blue wavelengths can reduce the risk of phototoxicity.[9]

The Use of Dyes in Vitreoretinal Surgery

Performance of some vitreomacular procedures have been made more technically feasible through the use of vital dyes. Procedures such as epiretinal membrane (ERM) peeling and internal limiting membrane (ILM) peeling can be challenging, as surgical planes may be only a few microns thick, and surrounding neuroretinal tissues may be susceptible to mechanical or chemical damage with resulting visual adverse sequelae. As a result, dissection of the proper surgical plane while avoiding injury to the underlying retinal structures becomes critical. There are several commonly used vital dyes or coatings such as indocyanine green (ICG), trypan blue (TB), brilliant blue G (BBG) and triamcinolone acetonide (TA) that have been used to aid in both ERM and ILM peel procedures[10] (Figure 3).

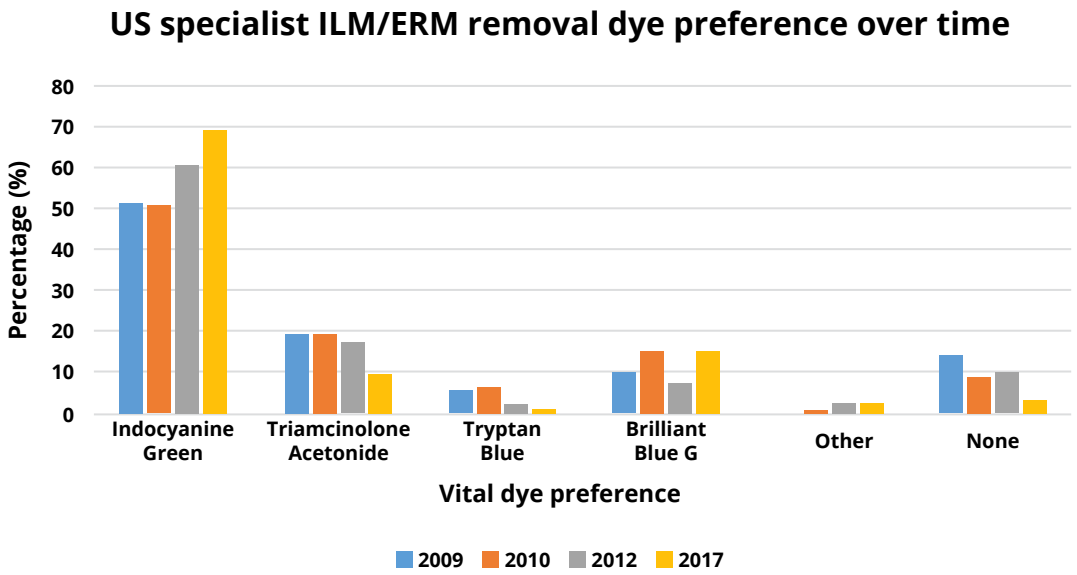

Figure 3: U.S. retina specialist internal limiting membrane (ILM)/epiretinal membrane (ERM) removal dye preference over time. Adapted from Bracha P, Ciulla TA, Baumal CR. Vital Dyes in Vitreomacular Surgery. Ophthalmic Surg Lasers Imaging Retina. 2018 Oct 1;49(10):788-798.

The most used vital dye is ICG, which is a water-soluble, tricarbocyanine dye with infrared absorption properties that is applied directly to the ILM for several minutes and is, then, aspirated. Several studies have indicated inadequate ERM staining with ICG, however, inadequate staining of ERM coupled with good staining of the adjacent ILM may facilitate removal of combined ERM and ILM with ICG. TA is a sterile, corticosteroid suspension that is not a dye but rather a coating that adheres to tissues, allowing for visualization of the membranes to be peeled. Its coating ability can facilitate ERM and preretinal membrane peeling, but it does not highlight the ILM to the extent of the other vital dyes and so it may not enhance visualization to the same degree. BBG is another popular dye that nonselectively binds to most proteins and effectively stains both ERM and ILM, although it may not stain ILM as effectively as ICG. TB dye has demonstrated efficacy in staining the ILM during macular hole surgery, and although numerous studies indicate that TB stains both the ERM and ILM, other studies seem to indicate that TB does not effectively stain the ILM. The historical low use of TB likely may be the result of poorer ILM staining compared to alternative dyes/coatings, or that TB formulations have only recently been approved by the FDA for intraocular use.[10]

Although use of these dyes/coatings can be important, there is concern with some of these dyes with regard to their potential for acute and/or chronic toxicity to the neurosensory retina and retinal pigmented epithelium (RPE). In a study by Morales et al. indocyanine green, infracyanine green, trypan blue, bromophenol blue, patent blue, and brilliant blue G were evaluated in cultured ARPE-19 cells (a well-characterized human retinal pigment epithelial cell line) in vitro for acute and chronic toxicity. Each of the studied dyes showed toxicity after acute exposure at surgical doses, and chronic exposure to the residue of some dyes was associated with reduced proliferation and even cell death.[11] Clinical findings of retinal pigmentary changes and RPE atrophy were observed in some early case reports using ICG, however, RPE changes following pars plana vitrectomy had been reported in up to 1/3 of

patients prior to the use of vital dyes, and so these changes may have been unrelated to the use of ICG.[10] Histopathologic studies evaluating surgically removed ILM specimens utilizing both ICG and TB dyes have shown variable amounts and sizes of attached glial elements; however, ILM specimens dyed with BBG did not contain the large cellular fragments and Müller cell end-feet as were found with ICG-derived ILM specimens. The clinical relevance of these neural elements found on excised ILM specimens is controversial, as functional sequelae have not been consistently demonstrated. Because of these potentially toxic effects to retinal tissue from vital dye use, 3 steps have been taken to decrease vital dye toxicity: 1) minimize vital dye concentration, 2) minimize the exposure time of the dye to the retina, and 3) employ lower levels of both coaxial and focal illumination during surgery.[10]

Benefits of Digital Visualization During Vitreoretinal Surgery

These three strategies to minimize the toxic effects of vital dyes to retinal tissues may be difficult to implement using the standard operating microscope, as reducing dye concentration and/or reducing the illumination may not allow adequate visualization to approach these ultrathin structures. Although there has been a lack of significant change or innovation to the conventional standard operating microscope as stated above, digital video capability has undergone tremendous, rapid advancements in frame rate, pixel count and resolution, dynamic range, and latency over the past 20 years.[8] The use of digital photography in forensic science utilizing software-driven enhancements has served as a viable method to highlight evidence images.[12] In ophthalmology, digital visualization with the NGENUITY Visualization System (Figure 4) has been favorably adopted by many surgeons to perform the delicate maneuvers performed during procedures to include vitreoretinal surgery. Using digital visualization with the NGENUITY platform at maximum system magnification, an aperture setting of 30% open, and a viewing distance of 1.2 meters results in an up to 48% increased magnification, up to 5x extended depth of field and up to 42% finer depth resolution (stereopsis) when compared to analog microscopes.[13] Note the images in Figure 5 to exemplify the significance of an extended depth of field. Another significant advantage is the decreased amount of light required to provide this enhanced visualization to the surgeon. Hamasaki et al. reported the use of NGENUITY for strabismus surgery in which the cases were performed without the use of the microscope's light source with only the room's ambient light being sufficient.[14]

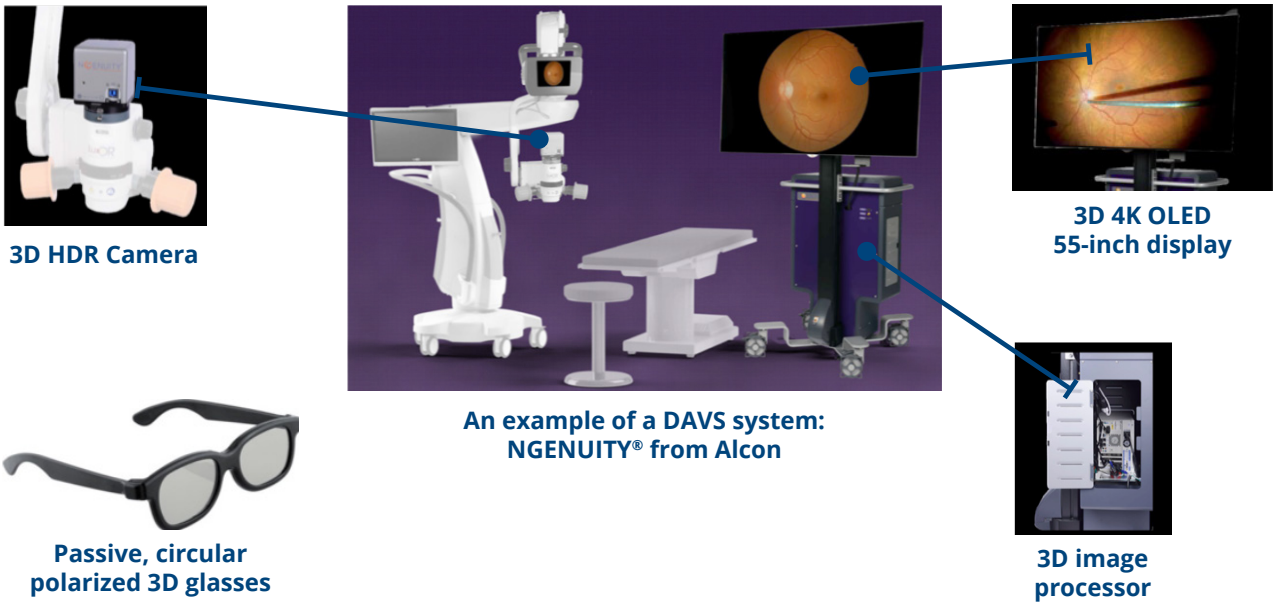

Figure 4: NGENUITY Visualization System – Highlights of the System Component.

Figure 5: A comparison of a photo showing extended depth of field (left) to one with a shallow depth of field (right). Note how the foreground and background are clear in the extended depth of field photograph.

Rather than the need to adjust the color of the light source, digital visualization with NGENUITY can be adjusted by means of digitally applied color channels while the light source intensity can also be minimized. In a recent report by Palácios et al. on the experience of French ophthalmic surgeons using NGENUITY, a black and white filter was applied to aid visualization during some parts of the ILM rhexis procedure in patients with atrophic retinal pigment epithelium.[15] Palácios had also reported earlier on the initial experience of Brazilian ophthalmic surgeons regarding the use of a blue channel for visualization of the peripheral vitreous using NGENUITY.[16] The ability to perform vitreoretinal surgery with minimal illumination levels using NGENUITY was evaluated by Adam et al. in a prospective, observational surgical case series of 10 vitreoretinal surgery patients in which the surgeon felt that they could operate comfortably at an endoillumination level of 10% of maximum output in 9 of 10 cases and at a 3% endoillumination level for the remaining case; this is compared to the approximately 40% endoillumination level routinely used with standard microscopy. They concluded that the 3-D digital platform may permit reduced intraoperative endoillumination levels and a theoretically reduced risk of retinal phototoxicity.[17] A recent report by Rosenberg et al. also discussed the benefits of 3D digital visualization in minimizing coaxial illumination and phototoxic potential in cataract surgery using NGENUITY by including visual recovery measurements. The mean light intensity utilized in the digital group was significantly less (57%) than in the traditional group (18.5% ± 1.5% vs 43.3% ± 3.7%; $p < 0.001$). Furthermore, the digital group achieved a postoperative day 1 visual acuity that was within 2 lines of the postoperative month 1 visual acuity a higher percentage of time than the traditional group (81.5% of eyes vs 54.2%; $p = 0.04$).[18]

Practical Applications of Color Optimization During Vitreoretinal Surgery

Some of the current visualization challenges for vitreoretinal surgeons include not only identifying the ERM and ILM but also the ability to see structures when intraocular hemorrhage occurs, as in cases with removal of fibrous, adherent diabetic membranes. In a similar fashion, the ability to reduce the concentration of vital dyes used for ERM and ILM peeling may actually be achievable by the use of digital color channels to enhance the color change achieved by low-concentration dyes, or possibly eliminate the need for dyes in some cases.

Three common scenarios where better visualization can improve surgical results include: 1) Enhancing the visualization of pre-retinal membranes with minimal use of vital dyes, 2) Enhancing visualization through vitreous opacities such as hemorrhage, and 3) Enhancing visualization of vitreous for more efficient and complete vitreous removal. In conjunction with Alcon scientists, we have provided data to confirm the notion that digital visualization with NGENUITY can both enhance color difference at the border of peeled and unpeeled retina after brief ICG stain, and color difference across retinal landmarks such as vessels or membranes through vitreous hemorrhage.

In order to better understand the description of color, it must be understood that we each may describe a particular color subjectively based on our own experiences. In 1931, CIE (Commission Internationale de l'Eclairage [International Commission on Illumination]), the body responsible for international recommendations for photometry and colorimetry, standardized color order systems by specifying the light source (or illuminants), the observer and the methodology used to derive values for describing color, regardless of the industry involved. CIELAB (L*a*b*) is a well-accepted method to objectively describe both the numerical value of a color as well as numerical differences in color variation. When a color is expressed in CIELAB, L* defines lightness, a* denotes the red/green value and b* denotes the yellow/blue value (Figure 6).[19]

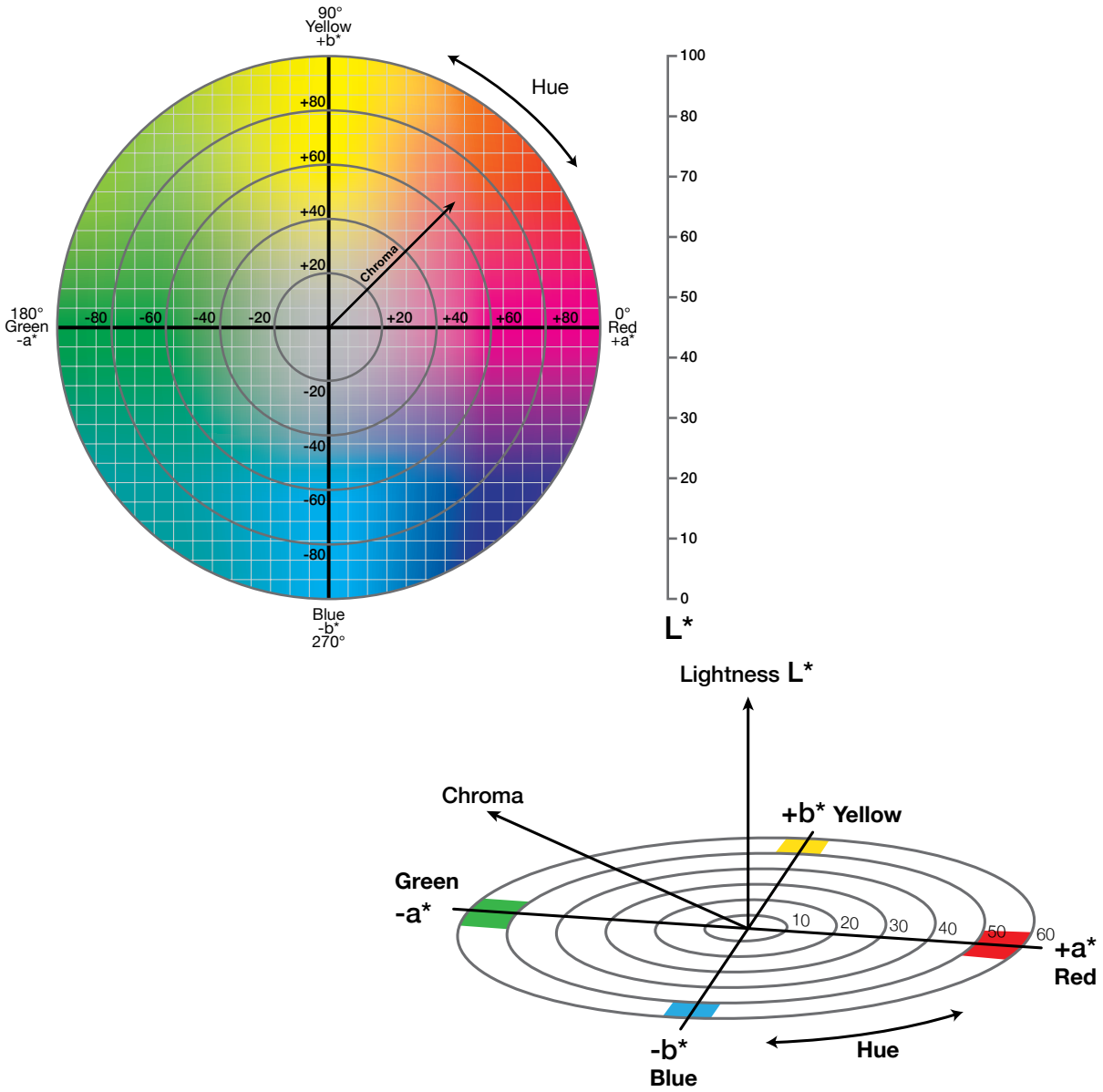

Figure 6: CIELAB color chart; note the L* value is represented on the vertical axis. The a* and b* axes depict the red/green and yellow/blue axes, respectively. Adapted from A Guide to Understanding Color. x-rite PANTONE. L10-001; March 2016.[19]

The difference in color between two stimuli is calculated as the distance between the points representing these stimuli; this is defined as ΔE.

The following table[20] represents the color difference (ΔE) that a standard observer can detect:

0 < ΔE < 1:	observer does not notice the difference
1 < ΔE < 2:	only experienced observer can notice the difference
2 < ΔE < 3.5:	unexperienced observer also notices the difference
3.5 < ΔE < 5:	clear difference in color is noticed
5 < ΔE:	observer notices two different colors

Our experience with NGENUITY for epiretinal membrane delamination has been quite positive. The increased magnification and depth of resolution permits visualization of subtle anatomic changes that are typically not evident with the analogue microscope. The ability to modulate the color palate provides an even greater benefit for digital visualization both by reducing the amount of vital dye used and enhancing visualization of edges of the pre-retinal membranes. Currently, we dilute the standard ICG dye by 50%, and begin to remove the diluted dye by aspiration within 30 seconds of dye injection. The enhancement of the green color channel allows us to see the stain after minimal dye exposure compared to the standard visualization color channel or analogue microscope. Figure 7 shows both the enhancement of the green signal with the green color channel and the contrast of the border between peeled and unpeeled retina. By transforming the standard RGB colors into the CIELAB color space, better quantification of color change between peeled and non-peeled retina is noted. Indeed, there is a small but measurable improvement in the color difference in the visualized color change across the boundary of peeled tissue with the ICG-enhancing color channel as compared to the standard CONSTELLATION color channel (Figure 8).[21]

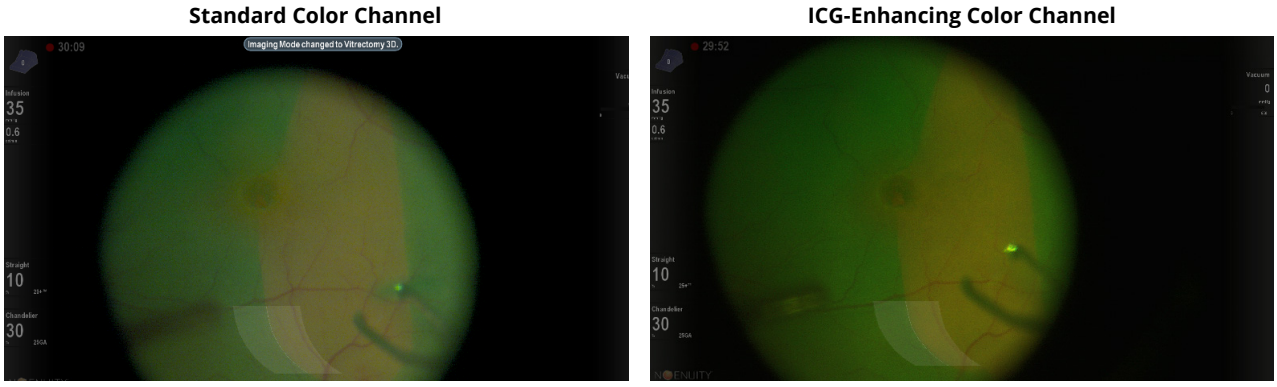

Figure 7: Image captures of Standard and ICG-enhancing color channels. These 2 image captures show the border of peeled and unpeeled retina after dilute ICG staining. Standard CONSTELLATION color channel is on the left, whereas the green dye is highlighted with an enhancing digital color channel on the right. Images provided by Dr. Alan Franklin with permission.

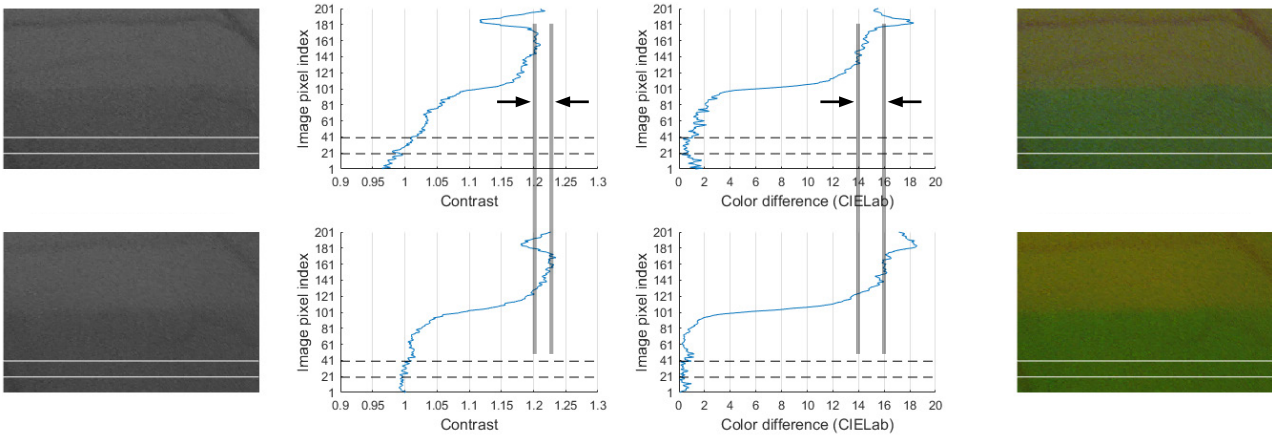

Figure 8: Contrast and color difference analysis of the Standard CONSTELLATION color channel (upper) compared to the ICG-enhancing color channel (lower) in membrane peel captures, above. Note the contrast differences as well as the color differences between these color channels shown by the space between the lines denoted with arrows.[21]

We have enjoyed a similar quite positive experience using digital visualization in the scenario of vitreous hemorrhage during vitrectomy surgery for diabetic eye disease and after trauma. Both the improved depth of field and depth of resolution optimize visualization of pre-retinal membranes both at the point of the active instruments and the tissue adjacent to the instruments which can also be affected by surgical manipulation. With analogue microscopy, during delamination when bleeding is encountered, the active instruments need to be removed and meticulous hemostasis achieved before it is safe to proceed with more delamination. Conversely with digital visualization, the view through mild to moderate vitreous hemorrhage can be enhanced with a vitreous blood suppression color channel so that the surgeon can safely delaminate membranes through mild to moderate blood, which reduces instrument changes, thereby rendering the surgery more efficient. Similar to the ICG-enhancing color channel, we have been able to demonstrate and quantify that the blood suppression color channel enhances visualization of underlying retinal anatomy through vitreous hemorrhage. To demonstrate the enhanced visualization with the vitreous blood suppression color channel mathematically, we chose to analyze the color and gray scale difference of the boundary between a retinal blood vessel and adjacent tissue as a measure of contrast (Figure 9). The vitreous blood suppression color channel leads to a significant higher gray scale contrast of approximately 10%, and color difference of over 5 units compared to visualization through the standard color visualization color channel (Figure 10).[22] The untrained human eye can detect a color change (ΔE) of > 2.0 units,[20] so the color change noted with the blood suppression color channel is quite striking both visually and mathematically.

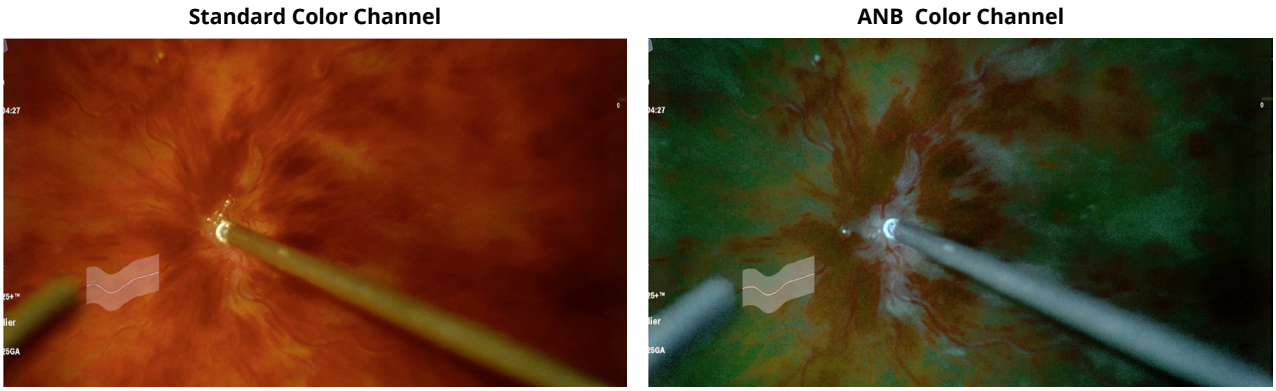

Figure 9: Screen captures with Standard CONSTELLATION color channel on left and ANB color channel on right, with highlighted areas revealing a blood vessel outline for analysis of contrast and color difference (see Figure 10, below). Images provided by Dr. Alan Franklin with permission.

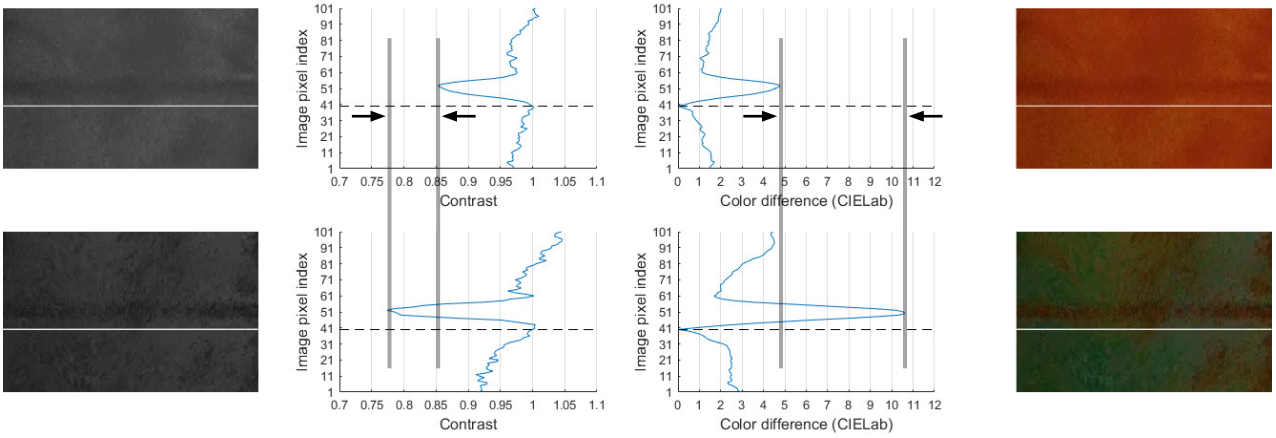

Figure 10: Contrast and color difference analysis of the Standard CONSTELLATION color channel (upper) compared to the Blood Supression color channel (lower) in vitreous hemorrhage during diabetic vitrectomy surgery, above. Note the contrast differences as well as the color differences between these color channels shown by the space between the lines denoted with arrows.[22]

We are also interested in the potential of color channels to enhance visualization of the vitreous. Our initial experience parallels that of Palácios who found that the blue thumbnail qualitatively improves vitreous visualization.[16] Figure 11 shows visualization of vitreous with different thumbnails. NGENUITY Version 1.4 has a customizable thumbnail image mode feature that provides real time image optimization, permitting efficient change of many different color schemes with a friendly user interface.

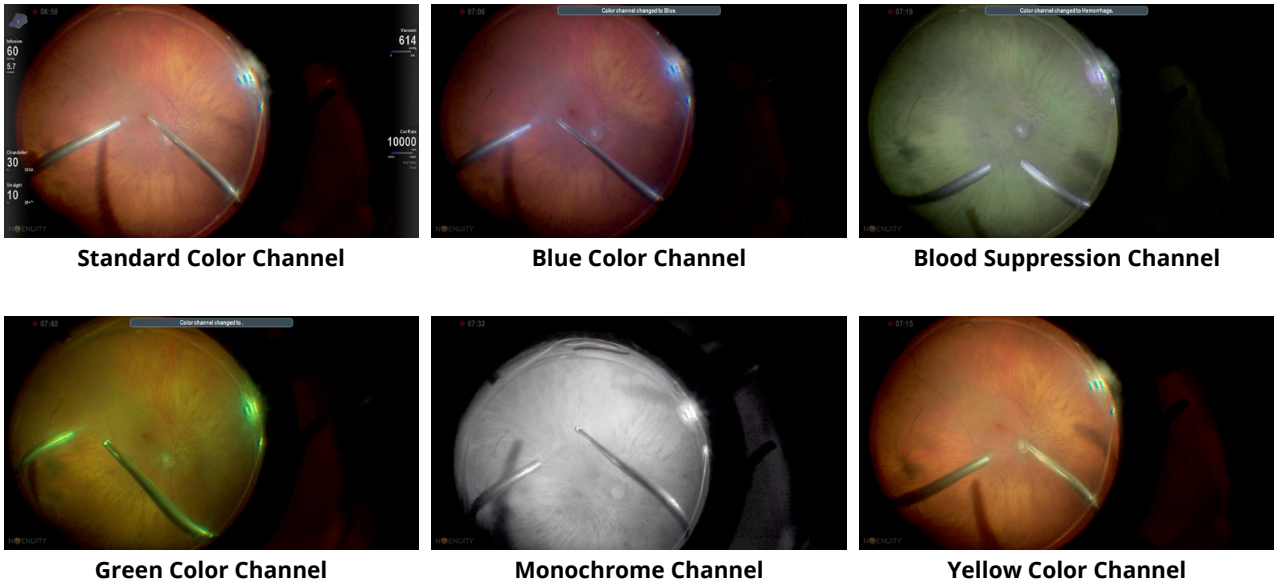

Figure 11: Image captures of different thumbnail color schemes. These 6 image captures show the visualization of retina and vitreous with different customizable color schemes available as thumbnail choices in NGENUITY version 1.4. Images provided by Dr. Alan Franklin with permission.

Conclusion

Digital visualization will revolutionize the way retinal surgeons operate over the next 10 years. The magnification, depth of field, and depth of resolution are all improved with digital visualization.[13] In addition, digital visualization with NGENUITY provides DATAFUSION, or virtual cockpit, that is not available with standard analogue operating microscopy. DATAFUSION integrates a customizable display of CONSTELLATION Vision System parameters onto the display monitor, allowing the surgeon to simultaneously observe these variables while remaining focused on the surgical procedure at hand. Moreover, the ergonomics and educational potential of digital heads up surgery may provide distinct advantages. Compared to standard operating microscopy, digital visualization can also help reduce illumination of the surgical field by 57% to 75%.[17,18] Finally, the ability to modulate the color feed with digital visualization reduces the exposure of potentially toxic vital dyes,[10] enhances the contrast of the boundary of peeled and unpeeled retina[21] as well as the borders of important retinal anatomic landmarks through vitreous hemorrhage,[22] and can potentially enhance visualization of the vitreous to increase efficiency of vitreous removal.[16] As the advantages for digital heads up surgery mount, it becomes increasingly more clear that this modality will represent the new standard of visualization for vitreoretinal surgery.

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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.

Alcon Medical Affairs