White Paper

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Digitally Assisted Anterior Segment Surgery

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Key Take-Aways:

- The NGENUITY® 3D visualization system with DATAFUSION™ allows for similar surgical efficiency to using standard microscopes even in high volume surgical centers performing anterior segment procedures like cataract surgery
- Advanced image processing and lighting can provide for a more comfortable patient experience while providing the surgeon an uncompromised surgical view
- The NGENUITY® 3D visualization system provides the flexibility to use personal protective equipment such as N95 respirators without some of the challenges experienced with oculars on a traditional microscope

Intra-operative Anterior Segment Visualization

Anterior segment surgical procedures address eye disorders from the cornea, conjunctiva, iridocorneal angle, iris, and lens. Visualization is paramount for surgical success in any operation including pterygium excision, penetrating keratoplasty, cataract removal, placement of minimally invasive glaucoma devices, iris repair, or combined specialty cases.

Supplemented with coaxial illumination and extended depth of focus, the modern-day microscope evolved into an irreplaceable commodity for visualization. However, in recent years the improvements in optical quality, illumination, and depth of field have begun to plateau. Concurrently, significant limitations continue to exist such as prolonged exposure of the retina to excess illumination, linear dependency on visible light for visualization, limited performance in high-magnification, and potential for surgeon fatigue due to operating room ergonomic conditions. [Table 1].

While digital visualization was quickly adopted by the posterior segment surgeons given the increased depth of focus, greater magnification, and precise focus, augmenting measured and delicate maneuvers, the anterior segment surgeons are beginning to appreciate the conferred benefits to their respective surgeries. In addition to an improved binocular disparity, reserved almost exclusively for digital platforms, one can expect an improved light intensity profile, better data integration to heads-up-display (HUD) from surgical suite, less dependence on stains to highlight structures, and an equivocal high-volume efficiency setup.

CHALLENGES WITH ANALOGUE MICROSCOPE

- **Dependence on the oculars**
- **Potential for prolonged exposure of the retina to excessive illumination beyond that of manufacturers recommendations**
- **Potential for surgeon fatigue due to less than ideal ergonomic conditions**
- **Lack of data integration into a HUD display, requiring surgeon to pull back from oculars in order to appreciate additional surgical data (e.g. phaco metrics)**
- **Limited performance in high magnification**

Table 1: Existing Challenges with Analogue Microscope

About the NGENUITY®

The NGENUITY® 3D Visualization System features four primary components: a 3D high dynamic range (HDR) camera, a 3D ultra-high definition (UHD) 55-inch 4K OLED surgical display, an ultra-high-speed image processor, and passive, polarized 3D glasses [Figure 1a,b]. The NGENUITY® HDR camera uniquely offers true stereoscopic 3D imaging with two full HD 1920 x 1080 complementary

metal-oxide-semiconductor (CMOS) sensors that do not require alignment, focus, or synchronization [Figure 1c]. Additionally, CMOS sensors provide low-noise and high-sensitivity and captures 60fps per eye (combined 120 fps) with a governable stereoscopic aperture. To recreate binocular disparity, the NGENUITY® 3D Visualization System employs an advanced stereoscopic display, which then separates the delivery of visual information to the right and left eyes. Therefore, when combined with passive, polarized 3D glasses, this creates a dynamic and immersive 3D visualization experience for not just the surgeon, but everyone in the operating room (co-surgeons, staff, fellows, residents, and medical students) [Figure 2].

a)

b)

c)

Figure 1: (a) NGENUITY® 3D Visualization System setup with (b) passive, polarized 3D glasses. (c) The NGENUITY® HDR camera affixed to a microscope system.

Figure 2: Immersive 3D visualization experience for the surgeon, instructors, team members, OR staff, fellows, and residents. [Note: enhanced color profile, improved glare profile, and anatomic detail when compared to the wall mounted monitors]

Data Driven Benefits and Advantages

First and foremost, the implementation of a 3D visualization system for cataract surgery has been shown to offer a similar efficiency and complication rate profile to traditional binocular microscopy in a high volume practice (0.72% vs 0.77%, $p > 0.05$).[1] Additionally, the retrospective study of 2330 eyes from August 2016 to July of 2017 showed a mean surgical time for 3D group and traditional group of 6.48±1.15 minutes and 6.52±1.38 minutes respectively ($p>0.05$).

The second advantage worth noting is the proprietary image processing technology which optimizes 3D HDR surgical images in real-time. This type of processing brings up the intensity of the imagery, providing unparalleled level of contrast, sharpness, and color. The NGENUITY® imaging process system performs this task in real-time, allowing the viewers to appreciate the subtleties, conferring many advantages to the surgeon: (1) no light saturation with automatic gain, (2) elevating the intensity of the imagery, and (3) allowing fine details to become visible in very dim light. Ultimately, this can equate to a much more comfortable patient, and less potential for light induced macular toxicity [Figure 3].[2]

Lastly, the smart 3D platform enables future applications and open architecture for multiple digital inputs. With digitalization and open architecture, NGENUITY® offers a modular platform that can change with the evolving nature of ophthalmic surgery.

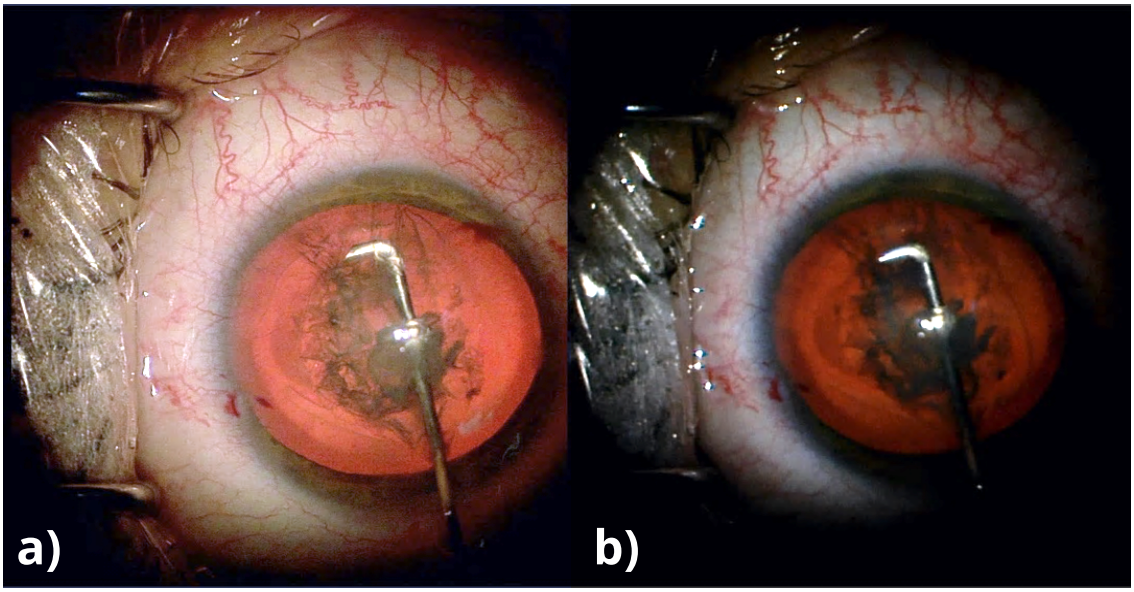

Figure 3: Surgeon view at the time of cataract extraction with 5% coaxial illumination on the (a) NGENUITY® 3D Digital visualization system versus (b) traditional binoculars.

Digitally Assisted Cataract Surgery (DACS) and Practical Applications in Anterior Segment Surgery

Historically, technological advancements have enabled surgeons to optimize workflow and outcomes. The shift to digital visualization platforms is predictable, much like the conversion from typewriter to computer. With the improved ergonomics, progressive teaching capabilities, and the potential for lower light intensity, color channel optimization, digitally displayed alignment or target markings, fluidics overlays, digital marking anatomic overlays, aberrometry overlays, and improved efficiency, it would seem to be the next evolutionary step in improved outcome measures for most anterior segment surgeries.

Digitally Assisted Cataract Surgery (DACS)

Digitally Assisted Cataract Surgery or DACS refers to real-time digital image guidance of cataract surgery, and in this case, captured by two matching CMOS sensors, subsequently directed to a proprietary ultra-high-speed 3D image processor, and displayed on an UHD 3D flat-panel display. The advanced 3D 4K OLED 55-inch display, translates to 3840 x 2160p resolution or 8.3 million pixels, while the OLED technology yields an output in more natural colors, a high contrast ratio, and eliminates image saturating backlight [Figure 4].

Cataracts can vary with changes from minimal nuclear sclerotic to dense brunescent. In the most challenging of cases, surgeons encounter dampened retroillumination, also known as a “blunted red-reflex” with traditional microscope oculars, decreasing visualization and increasing risk of intra- or perioperative complications. To compensate, the philosophy has been to increase coaxial illumination intensity with the hope of an improved red-reflex. While this approach can work, it was not withstanding consequences, such as disabling glare or worsening shadow effects impacting the view of the surgical field. Through the combined effects of all the technologies presented above, digital visualization offers the first known alternative to attempting to increase coaxial illumination intensity in order to improve visualization and the red-reflex. Additionally, in routine cases, the light intensity with DACS can be dialed down thereby reducing corneal glare, improving patient comfort and compliance, and decreasing the risk of potential phototoxic effects on the macula, retina, and ocular surface [Figure 5].[3,4]

The depth of field with DACS can exceed that of a traditional analog operating microscope by up to 2 to 3 times when the camera aperture is set to 30%. This feature allows the surgeon to simultaneously focus on anterior segment maneuvering while keeping an eye on the posterior capsule without the need to refocus. Coupled with binocular disparity, a method employed exclusively by digital visualization that splits the delivery of visual information to each eye separately, the NGENUITY® supports the surgeon by achieving real depth and dimension for a more complete visualization experience. Lastly, use of 3D High Dynamic Range technology leads to optimization of the 3D image exposure and contrast in real-time, further enabling the surgeon to better visualize transparent media such as viscoelastic in the anterior chamber or vitreous if one experiences a capsule rent or zonular dehiscence.

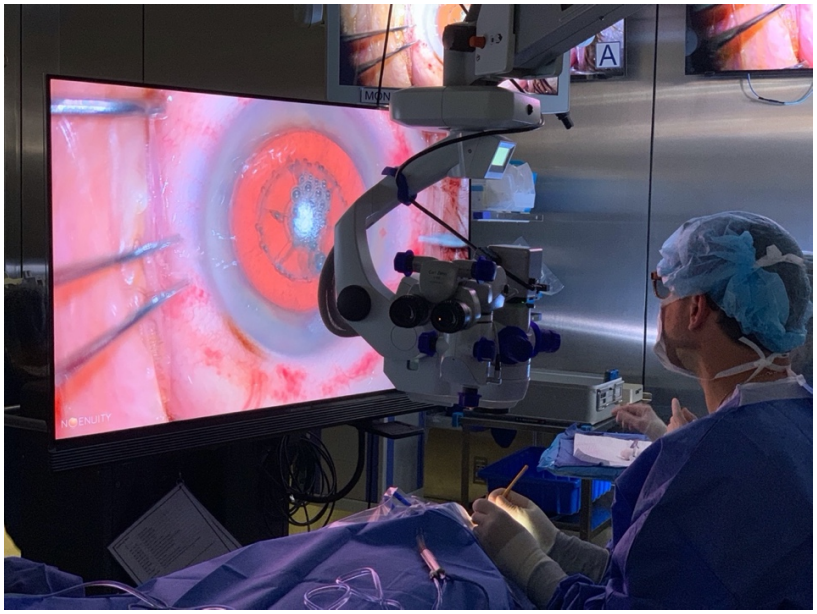

Figure 4: The advanced 3D 4K OLED 55-inch display outputs in more natural colors, a high contrast ratio, and eliminates image saturating backlight

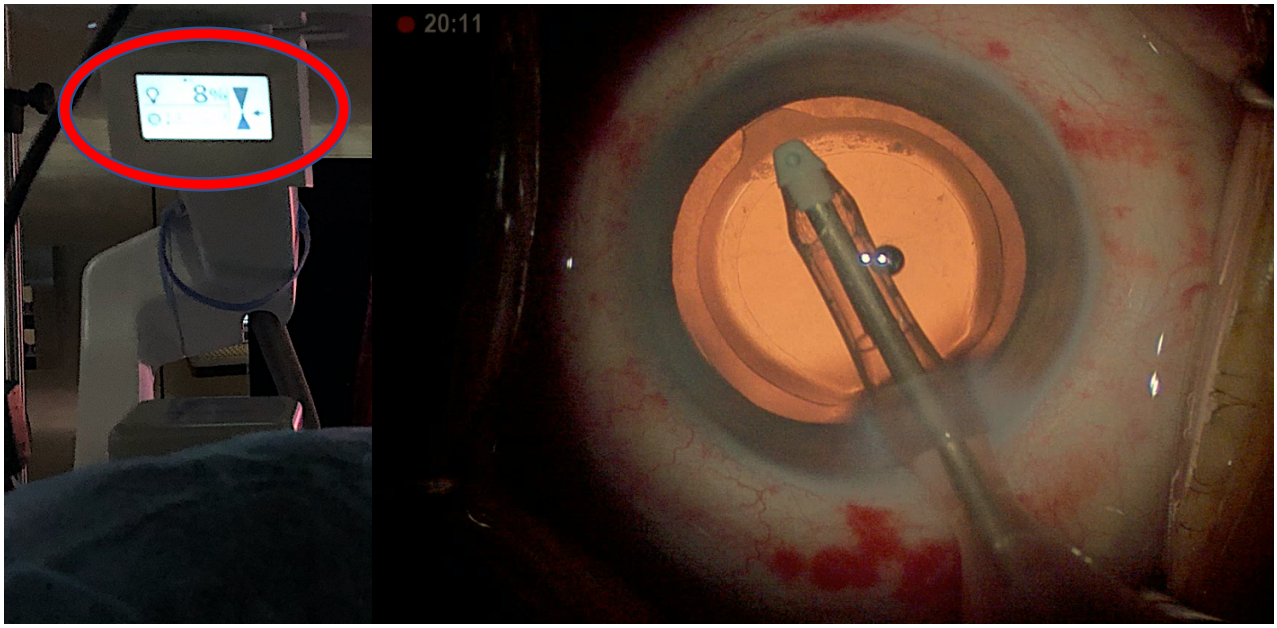

Figure 5: By turning off the surrounding field illumination and room lights, opening the aperture, the computer up-gained the red-reflex to a traditional 40% illumination intensity equivalency

Digitally Assisted Minimally Invasive Glaucoma Surgery

Minimally invasive glaucoma surgery (MIGS) is a rapidly and continually evolving sector within anterior segment ophthalmology. Filling the gap between medical management and large incisional surgical therapies, MIGS relies heavily on intraoperative visualization to identify small anatomic features to either place devices or make targeted cuts for successful outcomes. To obtain adequate visualization using a traditional microscope, most MIGS setups requires the surgeon to rotate the microscope 35 degrees towards the operator, rotate the patients head 35 degrees away, and the surgeons chair will need to be lowered and shifted away from the patient, ultimately requiring the surgeon to extend her/his arms to reach the operative field. When coupled with a handheld gonioscopy lens, the surgeon is able to overcome the total internal reflection optics induced by the cornea, in order to visualize the angle.

Applying the NGENUITY® 3D visualization system to MIGS confers many of the same advantages as outlined above for DACS, such as an extended depth of field at high magnification and an improved binocular disparity, ultimately enhancing stereoscopic effects at the time of surgery [Figure 6]. Improved depth of focus attenuates some of the continuous fine focus adjustments required by the operator during these procedures.[2] Furthermore, by implementing digital visualization, one is able to decouple the surgeon from the microscope eliminating the requirement to be further away from the surgical field, and thereby improving ergonomics and maneuverability. Color channel optimization can be particularly useful in angle feature identification especially in difficult cases where corneal edema or faint features are present.

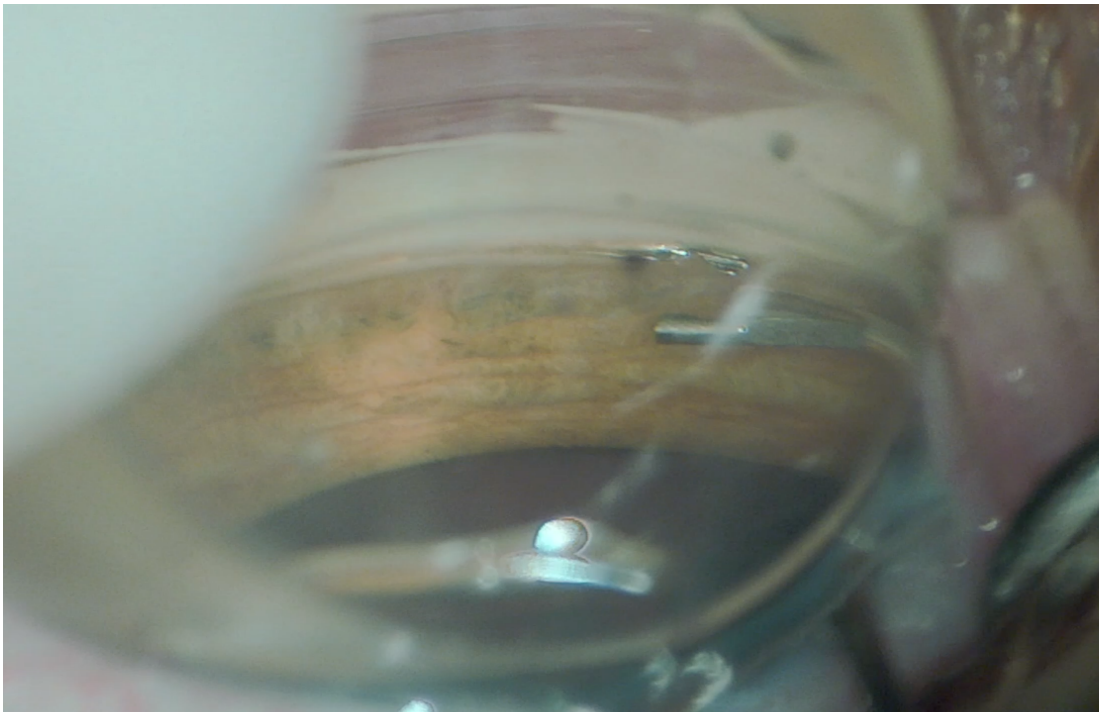

Figure 6: High resolution image of enhanced stereoscopic view during a glaucoma stent injection captured using NGENUITY®

Advanced Anterior Segment Procedures

Complex anterior segment surgery presents unique challenges to even the most experienced surgeons. The margin for error in these cases is frequently small and maintaining or augmenting visualization becomes the key to success. These challenging cases may range from difficult cataracts to combined sub-specialty cases, and implementing digital visualization confers several added benefits.

Enhancing binocular disparity and stereopsis has clear observable utility when employing iris rings/ hooks in small pupil conditions [Figure 7], capsular tension rings in capsular bag instability, and anterior

chamber suturing techniques (e.g. pupilloplasty and iridodialysis repair). In cornea transplantation, the greater zoom and fine detail assists with approximation of the donor to host apposition. Improved depth of focus and dynamic visualization in these settings effectively turns a 2-dimensional floor plan into a 3-D environment.

When the surgical case demands both posterior and anterior segment surgeons, all participants maintain primary surgeon point-of-view, supporting a collaborative approach. Furthermore, the DATAFUSION™ overlays on the NGENUITY® 3D visualization system helps the operator to ensure a closed system by monitoring flow rate even while performing the anterior segment portion of the case [Figure 8]. Lastly, by applying digital filters and color optimization, various steps from identifying sclerostomy port placement indentations to wound incisions become effortless.

While not all difficult cases are the result of a complex eye, some challenges may still surface intraoperatively; for instance, when a patient cannot tolerate the microscope light. In lieu of deepening anesthesia, comfort can now be achieved by lowering the light intensity setting without compromising visualization.

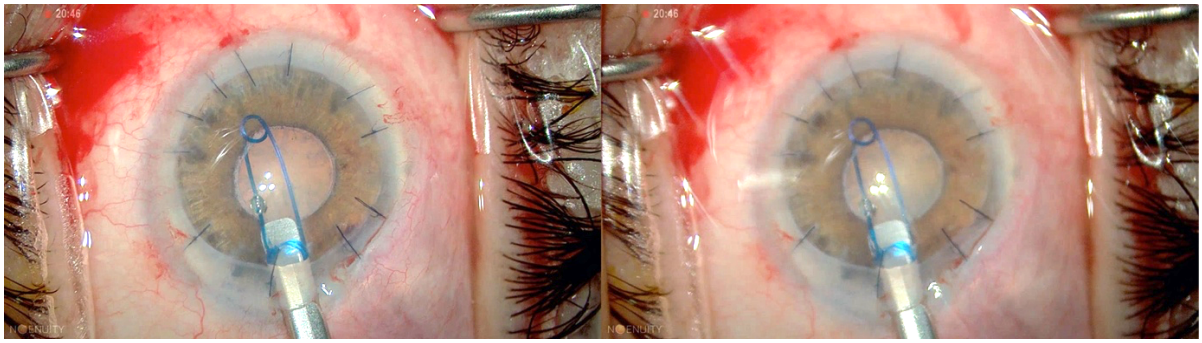

Figure 7: Intraoperative picture taken at the time of cataract surgery. Depicted here the surgeon is utilizing 3-D digital visualization to help deploy an iris ring in a post-penetrating keratoplasty patient. Extreme care was taken not to disrupt corneal endothelium, and atraumatically engage the iris margin.

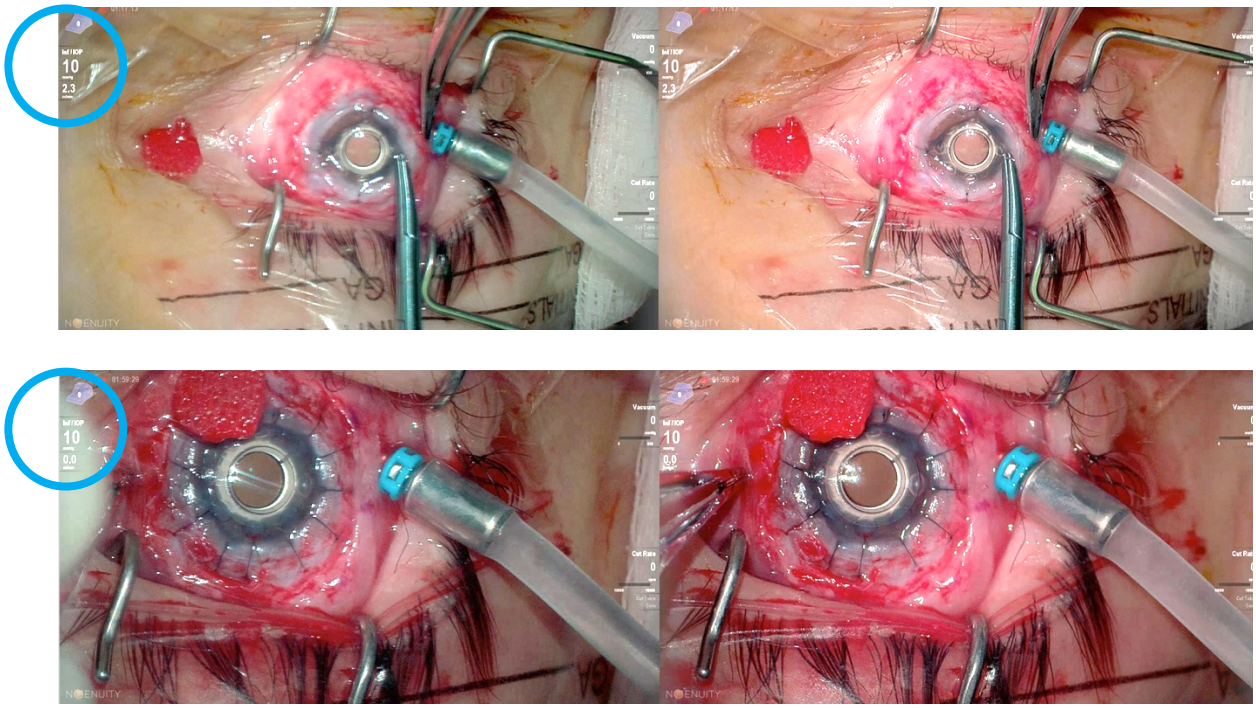

Figure 8: Intraoperative pictures taken at the time of keratoprosthesis surgery. With placement of the initial cardinal sutures, a flow rate of 2.3 cc/min is appreciated, whereas towards the end of suturing a watertight system is noted with a flow rate of 0.0cc/min at an infusion intraocular pressure (IOP) of 10.

COVID-19 Considerations

The American Academy of Ophthalmology (AAO), the American Society of Cataract and Refractive Surgery (ASCRS), and the Outpatient Ophthalmic Surgical Society (OOS) jointly developed a checklist for reopening of ambulatory surgery centers.[5] Line items include comprehensive screening protocols for COVID-19, infection prevention control (e.g. wiping down all surfaces), and proper inventory of personal protective equipment (PPE) (e.g. gloves, masks, respirators and gowns). Collectively established recognized protocols include accounting for rare scenarios that may pose risk of aerosolized virus transmission including at time of intubation, which would entail the provider to don a N95 respirator or other PPE.

While most cataract and anterior segment surgery is performed under local anesthesia, a handful of procedures will still need to take place under general anesthesia. Additionally, the risk of potential aerosolization during phacoemulsification is unknown with respect to infection transmission. Implementing adequate and recommended PPE in these scenarios, while operating with the traditional microscope oculars, will likely pose a challenge such as when using respirators (e.g. an N95 mask) for many surgeons. Given the unique capacity of the NGENUITY® 3D Visualization System to decouple the surgeon from the microscope oculars, this modality may prove useful in the current situation and in years to come. The NGENUITY® 3D visualization system provides flexibility to adapt the use of 3D glasses with respirators, helping to ensure that surgeons continue to be protected without compromising visualization.

Summary and Conclusions

Over a 15-year development period, stereoscopic high-definition visualization systems are now available for use in routine ophthalmic surgeries. The unique technological advancements provided by the NGENUITY® 3D visualization system offer anterior segment surgeons a novel alternative to the conventional analogue microscope. Digitally assisted cataract (DACS) and digitally assisted minimally invasive glaucoma (MIGS) surgery provide the surgeon with improved images under high-magnification, extended depth of field, and numerous options for digitally enhancing images. Providing surgeons an unparalleled level of contrast, sharpness, and color, coupled with a proprietary imaging processing technology results in a viewing experience that is highly optimized when compared to traditional viewing platforms.

With a proven equivalency in operative time and complication rate, digital visualization brings additional features never before available to the surgeon in real-time.[1] Furthermore, light intensity can be grossly reduced without compromising red-reflex or operability, thereby decreasing risk of microscope induced maculopathy. NGENUITY® offers a modular platform enabling future applications and open architecture for digitally displayed alignment or target markings, fluidics, anatomic, and aberrometry overlays on a head-up-display, thereby keeping the surgeons' attention where it belongs – on the case.

References

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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.

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