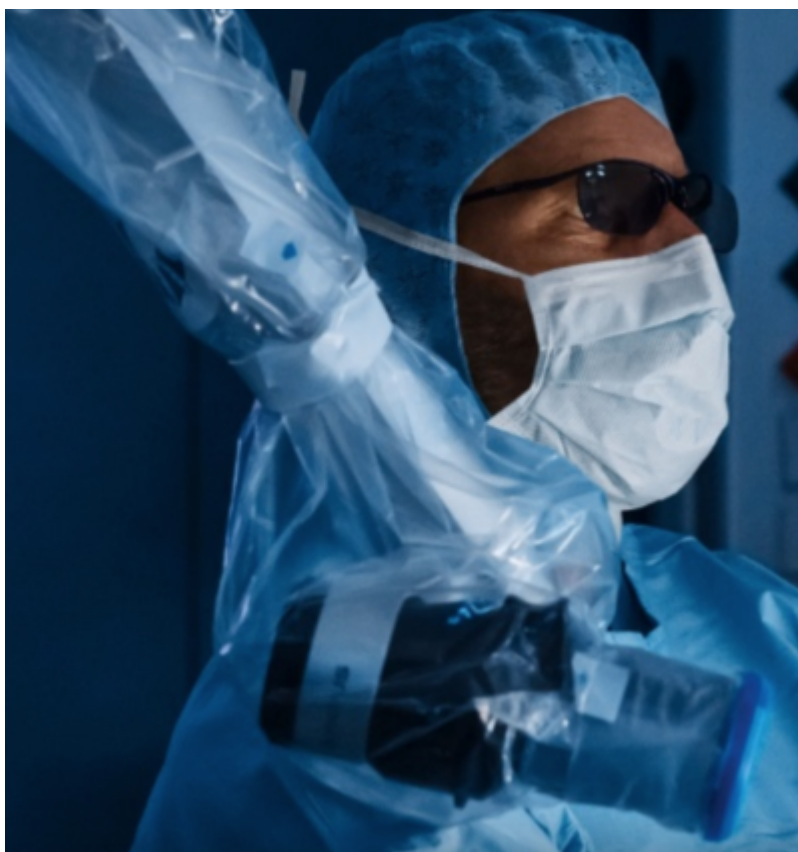


# Orbeye



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This [system](#) offers 4K, three-dimensional magnified and illuminated imaging without the need for eyepieces. Magnification of the field of view facilitates a more precise dissection, preserving the anatomical structure. Currently, the Orbeye™ is regularly used in neurosurgery; however, its potential

in conventional open surgery has not yet been fully exploited <sup>1)</sup>

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By displaying the progress of surgical procedures on a large 55-inch monitor, the new model has the potential to both reduce surgeon fatigue by eliminating the need for extensive viewing via microscope eyepieces and to include the entire surgical team in the view of the procedure. Because the use of digital technology has made the new microscope unit approximately 95 percent smaller in volume above the surgical field than the previous model, it additionally helps free up surgical space and shortens setup times. The microscope unit was also made 50 percent lighter than the previous model to facilitate its transportation between operating rooms. The device will be marketed by Olympus Corporation.

The benefits of ergonomics, improved precision and ease of positioning in the OR are the result of the following features:

**High-resolution 4K-3D digital images supporting precision surgery** – The two Sony 4K ExmorRTM CMOS image sensors deliver high-sensitivity, low-noise images. The system deploys an image processing circuit designed to work across a wide color range as well as with four times the pixel count of the Full High Definition standard to provide high-resolution digital images during surgery. Because it additionally minimizes the delay associated with the large amounts of data that need to be processed by 4K-3D systems, ORBEYE provides zero image latency for smoother viewing and manipulation of the target location.

**Use of 55-inch 4K 3D monitor helps reduce surgeon fatigue and facilitates team surgery** – The new model displays via a monitor and has no eyepiece. This helps reduce surgeon fatigue by allowing a more comfortable working posture without requiring them to spend long periods peering into a microscope lens. Moreover, because the large 55-inch monitor enables the entire surgical team to view the same image, it allows more than one surgeon to operate and improves efficiency by allowing information to be shared with other surgical staff.

**Significant reduction in microscope size (95 percent smaller than previous model) helps free up surgical space and shortens setup times** – The use of digital technology has made the microscope unit much smaller and it therefore provides the surgeon with additional space to perform operations. The unit's reduced size also allows faster setup times by eliminating the need to make often awkward adjustments to the balance of the arm, and by allowing use of a smaller and easier-to-fit surgical drape to keep the microscope clean.

"The ORBEYE [exoscope](#) represents the next generation of operative imaging- a true quantum shift," said Dr. David Langer, MD, Lenox Hill Hospital/Northwell Health. "Its adoption is certain and will impact the use of loupe magnification as well as the current operating microscope. The ease of use, surgeon ergonomics and effects upon the operating team are revolutionary and I look forward to continuing to train and develop new strategies for its adoption."

"We have already received resounding enthusiasm for our 4K and 3D technology for laparoscopy and endoscopy. We are pleased that through the development of ORBEYE, this 4K-3D technology can be offered to more specialties such as neurosurgery, spine, microsurgery, ENT, and cardiac," said Randy Clark, Group Vice President of the Surgical Division at Olympus America Inc. "We understood that with such complex and lengthy surgeries, the technology would have to be innovative and groundbreaking enough to entice surgeons to make a change, and we were pleased to work with SONY through our SOMED joint venture to meet the challenge."

The name ORBEYE, a combination of “orb” and “eye”, expresses the idea of being able to approach things from an angle or direction that was not possible using existing microscopes. It also references the product’s potential for global reach.

ORBEYE launched to the healthcare community at the [Congress of Neurological Surgeons](#) (CNS) in Boston, October 7-11, [2017](#).

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The [operating microscope](#) has been an essential tool in [neurosurgery](#) since the late 1960s and continues to be a critically important tool for neurosurgical [procedures](#). However, it may be accompanied by flaws since the neurosurgeon's position during surgery is limited. A newly developed [surgical microscope](#), ORBEYETM(OLYMPUS, Tokyo, Japan), was launched to overcome the shortcomings of the [surgical microscope](#) and offers 4 K, high-quality, and three-dimensional(3D)imaging. ORBEYETM offers similar visual fidelity but superior ergonomics and educational benefits compared with those of the operating microscope. Exoscopic surgeries maintain the same safety profiles as those using operative microscopes and have the potential to allow neurosurgeons to generalize neurosurgical procedures, which are considered difficult due to the neurosurgeon's awkward positions <sup>2)</sup>.

## Advantages

Compared to microscopes, [exoscopes](#) have advantages in field-depth, ergonomics, and educational value. Exoscopes are especially well-poised for adaptation to [fluorescence-guided surgery](#) (FGS) due to their excitation source, light path, and image processing capabilities. We evaluated the feasibility of near-infrared FGS using a 3-dimensional (3D), 4 K exoscope with nearinfrared fluorescence imaging capability. We then compared it to the most sensitive, commercially-available near-infrared exoscope system (3D and 960 p). In-vitro and intraoperative comparisons were performed.

Methods: Serial dilutions of indocyanine-green (1-2000 µg/mL) were imaged with the 3D, 4 K Olympus Orbeye (system 1) and the 3D, 960 p VisionSense Iridium (system 2). Near-infrared sensitivity was calculated using signal-to-background ratios (SBRs). In addition, three patients with brain tumors were administered indocyanine-green and imaged with system 1, with two also imaged with system 2 for comparison.

Results: Systems 1 and 2 detected near-infrared fluorescence from indocyanine green concentrations of >250 µg/L and >31.3 µg/L, respectively. Intraoperatively, system 1 visualized strong near-infrared fluorescence from two, strongly gadolinium-enhancing meningiomas (SBR=2.4, 1.7). The high-resolution, bright images were sufficient for the surgeon to appreciate the underlying anatomy in the near-infrared mode. However, system 1 was not able to visualize fluorescence from a weakly-enhancing intraparenchymal metastasis. In contrast, system 2 successfully visualized both the meningioma and the metastasis but lacked high-resolution stereopsis.

Conclusion: Three-dimensional exoscope systems provide an alternative visualization platform for both standard microsurgery and near-infrared fluorescent guided surgery. However, when tumor fluorescence is weak (i.e., low fluorophore uptake, deep tumors), highly sensitive near-infrared visualization systems may be required <sup>3)</sup>.

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## Microscope comparison

Murai et al. from [Tokyo](#), reported 22 clinical cases by 5 experienced neurosurgeons and the comparative results of training 10 residents. An observation study with questionnaire survey was conducted on usability. Twelve items including image quality, eyestrain, and function of the arm were evaluated.

The following 22 clinical procedures were conducted: surgery for [intracranial hemorrhage](#) (n = 2) and [brain tumor](#) (n = 8), [laminectomy](#) (n = 3), aneurysm [clipping](#) (n = 3), vascular anastomosis (n = 2), [carotid endarterectomy](#) (n = 2), and nerve decompression (n = 1). No complications were observed. The fluorescent study, including indocyanine-green and 5-aminolevulinic acid, allowed for clear depiction on the 4K monitor. The surgeon could operate in a comfortable posture. Similar to the [microscope](#), it was possible to change the optical and viewing axes with the OE, but the OE was switched to the microscope or endoscope in [hematoma](#) removal and [pituitary surgery](#). Residents judged that eyestrain was strong ( $P = .0096$ ). Experienced neurosurgeons acting as assistants judged that the scope arm's range of movement was narrow ( $P = .0204$ ). Sixty percent of residents judged that the OE was superior to the microscope.

Although based on limited experience, it was not possible to substitute the microscope with the OE in all operations; however, the OE surpasses the microscope in terms of ergonomic features <sup>4)</sup>.

## Learning curve

study aimed to investigate the learning curve, plateau, and rate of novice surgeons using an Olympus ORBEYE exoscope compared to an operating microscope (Carl Zeiss OPMI PENTERO or KINEVO 900).

**Methods:** A preclinical, randomized, crossover, noninferiority trial assessed the performance of seventeen novice and seven expert surgeons completing the microsurgical grape dissection task "Star's the limit." A standardized star was drawn on a grape using a stencil with a 5 mm edge length. Participants cut the star and peeled the star-shaped skin off the grape with microscissors and forceps while minimizing damage to the grape flesh. Participants repeated the task 20 times consecutively for each optical device. Learning was assessed using model functions such as the Weibull function, and the cognitive workload was assessed with the NASA Task Load Index (NASA-TLX).

**Results:** Seventeen novice (male:female 12:5; median years of training 0.4 [0-2.8 years]) and six expert (male:female 4:2; median years of training 10 [8.9-24 years]) surgeons were recruited. "Star's the limit" was validated using a performance score that gave a threshold of expert performance of 70 (0-100). The learning rate (ORBEYE  $-0.94 \pm 0.37$ ; microscope  $-1.30 \pm 0.46$ ) and learning plateau (ORBEYE  $64.89 \pm 8.81$ ; microscope  $65.93 \pm 9.44$ ) of the ORBEYE were significantly noninferior compared to those of the microscope group ( $p = 0.009$ ;  $p = 0.027$ , respectively). The cognitive workload on NASA-TLX was higher for the ORBEYE. Novices preferred the freedom of movement and ergonomics of the ORBEYE but preferred the visualization of the microscope.

**Conclusions:** This is the first study to quantify the ORBEYE learning curve and the first randomized controlled trial to compare the ORBEYE learning curve to that of the microscope. The plateau performance and learning rate of the ORBEYE are significantly noninferior to those of the microscope in a preclinical grape dissection task. This study also supports the ergonomics of the ORBEYE as reported in preliminary observational studies and highlights visualization as a focus for further development <sup>5)</sup>.

## Case series

Twenty-two cases, including 14 requiring microvascular decompression (MVD) and eight requiring tumor removal, were performed by endoscopic-assisted exoscopic surgery. The endoscope could be inserted safely because its relationship with the surrounding structure could be observed under the exoscope, and the operator could observe both screens without moving the head. Fourteen of 22 patients required additional endoscopic treatment. Satisfactory two-handed operation was performed in 13 cases. Symptomatology disappeared in all cases of MVD, and sufficient tumor resection was achieved.

Exoscopic surgery provides excellent surgical view that is not inferior to conventional microsurgery. As a large space can be secured between the scope and the surgical field, it is safer and easier to manipulate the endoscope under the exoscope <sup>6)</sup>.

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ORBEYE™ use in 14 microneurosurgical procedures was retrospectively assessed by nine neurosurgeons after the procedure. A questionnaire comprising 20 questions was designed and used for evaluation.

Compared with the current gold standard, the binocular microscope, ease of setting up the equipment was scored the highest, whereas ease of conducting surgery in a position of an assistant was scored the lowest. Among characteristics of ORBEYE™ itself, the space-saving feature was scored the highest and was followed by the ability to perform procedures in a comfortable position. The only characteristic that was rated below average was ease of operation in a position of an assistant. Neurosurgeons with greater experience (more than five procedures using ORBEYE™) provided significantly higher scores ( $p = 0.0196$ ) for characteristics of ORBEYE™ itself compared with neurosurgeon with fewer ORBEYE™ experience.

The main benefits of the ORBEYETM are its compact size and freedom from focusing through the eye lens of a conventional binocular microscope. However, it appears to be disadvantageous for operating in a position of an assistant because the surgical field has a rotated view on the monitor from a position of an assistant. Nonetheless, because of certain advantages, we believe the ORBEYE™ could be of additional help to use of conventional binocular microscope at the moment and will facilitate microneurosurgery in the future <sup>7)</sup>.

## Case reports

A case of a 46-year-old patient with a [low-grade glioma](#) recurrence of the right gyrus cinguli removed with a contralateral transfalxine approach using an exoscope (ORBEYE 4K-three-dimensional (3D) exoscope, Sony Olympus Medical Solutions Inc., Tokyo, Japan). The operating room setup for this approach is illustrated. During the procedure, the surgeon was seated with head and back in an upright position, while the camera was aligned with the surgical corridor. The exoscope provided detailed, high-quality 4K-3D images of the anatomical structures and optimal depth perception, making surgery accurate and precise. At the end of the resection, an intraoperative MRI scan showed complete removal of the lesion. The patient was discharged on postoperative day 4 with an excellent performance on neuropsychological examination.



In this clinical case the contralateral approach was favorable because the glioma was located close to the midline and because it offered a straight path to the tumor, minimizing retraction on the brain. The exoscope provided the surgeon with important advantages in terms of anatomical visualization and ergonomics during the entire procedure <sup>8)</sup>.

5-ALA-fluorescence-guided resection of low-grade glioma using the ORBEYE was useful for determining the extent of removal <sup>9)</sup>

A 65-year-old woman was admitted for clipping of a right unruptured VA-PICA aneurysm (maximum diameter, 5mm) located medially and ventral to the hypoglossal canal. After induction of general anesthesia, the patient was placed in the prone position with the head tilted slightly downward. A midline suboccipital approach was performed from the rostral end of the patient using ORBEYE. Clipping was safely accomplished in a comfortable posture. No operative complications occurred. Postoperative computed tomography angiography showed complete aneurysmal obstruction.

Conclusion: Exoscopic surgery using ORBEYE is feasible for a midline suboccipital approach to VA-PICA aneurysms from the rostral end of the patient with the patient in the prone with slight head-down position <sup>10)</sup>.

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