



Wearable Eye Technologies

A showcase of some of the latest advances in this space, including the bionic eye, an electronic smart lens, and drug-releasing lenses.

BY THOMAS A. FINLEY, MD; JEFFREY SONSINO, OD, FFAO; AND MARK E. BYRNE, PHD, FAIMBE

Bionic Eye Technology: A Promising Device for Patients With Age-Related Macular Degeneration

THOMAS A. FINLEY, MD

Technological solutions are being applied to challenging eye conditions in hopes of providing better outcomes to patients. Oculenz AR Wear glasses (Ocutrx Technologies; Figure 1) are a perfect example.

Known by some as a *bionic eye*, these augmented reality (AR) glasses address a variety of concerns for patients with age-related macular degeneration (AMD), including blurry or dark/blind spots and distorted shapes and colors that can make the activities of daily living such as reading, writing, and recognizing faces difficult or impossible. A technological solution that addresses the visual side effects of this condition could have a giant impact on the care and quality of life of individuals with AMD.

DESIGN

The Oculenz AR Wear was unveiled at the Mobile World Congress in 2019. The product's lightweight structure (< 200 g) and floating lens design provide a new visual-assistance option for those with AMD. An eye-tracking camera housed in the nosepiece helps direct computer-mediated video to line up with the user's natural gaze. The camera works at a speed of 200 Hz,



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Oculenz™ AR Headset
for Advanced Macular Degeneration and Low Vision



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Figure 1. The Oculenz AR Wear is designed for use by patients with AMD.

which helps keep the image properly stabilized and in line with the scotoma.

The Oculenz AR Wear is the only technology that can address a scotoma without using magnification. Most visual-assistance devices for individuals with AMD magnify or adjust the image around the scotoma, which leaves a defect in the patient's vision. These glasses measure and track the size of the scotoma and use AR technology to fill in the missing visual to display a full field of vision to the retina, giving the patient a more complete picture. This is particularly valuable for reading because words or letters are often left out with magnification, whereas they are visually filled in with the Oculenz AR Wear (Figure 2).

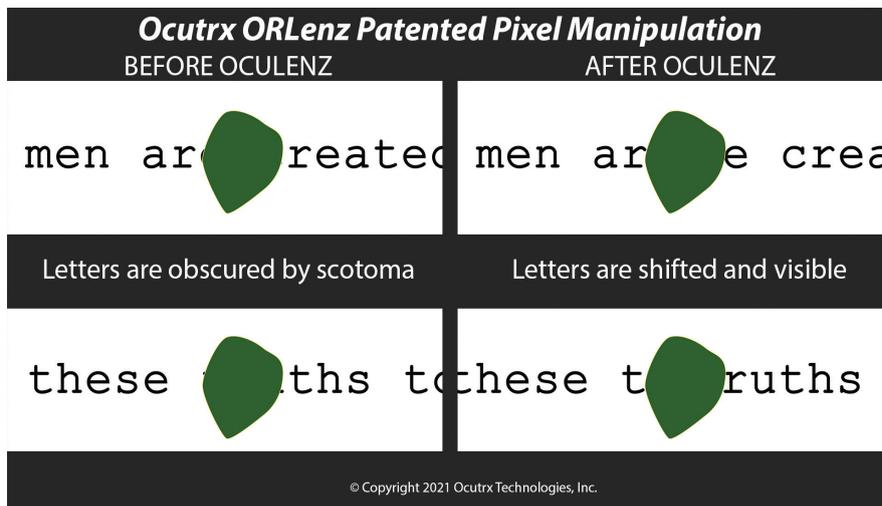


Figure 2. Pixel manipulation improves reading fluidity.

WHY AR?

AR makes sense for holistic patient care. This technology overlays graphics on the natural environment, whereas virtual reality solutions involve wearing a large headset that blocks peripheral vision.

Virtual reality can create immersive experiences, but it also obstructs input from the user's surroundings. With the AR technology of the Oculenz AR Wear, the wearer can walk around and participate in normal activities while receiving visual assistance.

Another notable feature of the Oculenz AR Wear is that it offers a visual field test for at-home patient care. The test takes about 5 minutes

to complete per eye. Patients take the test with the headset on to help identify the location of a defect. This allows the glasses to identify which areas require pixel manipulation.

The Oculenz AR Wear is a connected device, so it can alert the patient's physician if self-directed visual field testing indicates that the size of a scotoma has increased significantly. This facilitates earlier detection of AMD progression and earlier care and treatment.

CONCLUSION

The Oculenz AR Wear has the potential to improve care for individuals with AMD. Patients can benefit from this technology in their real-world environment.

Mojo's Electronic Contact Lens for Patients With Low Vision

JEFFREY SONSINO, OD, FAAO

In early 2020, I visited the Mojo headquarters in Silicon Valley. The team had just finished building a prototype of their electronic smart contact lens, and I was to be the first person from outside the company to wear it. This novel scleral lens projects AR images onto the retina using an image sensor

facing out and a projector facing in. Mojo has an all-star team; one of its founders invented dial-up for early internet access, and a team leader worked on the original iPhone (Apple). At the time of my visit, the company had raised more than \$100 million. Its latest contact lens technology is well positioned for success.

PREPARATIONS

An impression of my ocular surface had been taken a month in advance of my visit using a process developed by scleral lens manufacturer EyePrint Prosthetics. In this painless process, a plastic tray is filled with an amalgam that is similar to dental impression material

Figures 3 and 4 courtesy of Jeffrey Sorsino, OD, FAAO

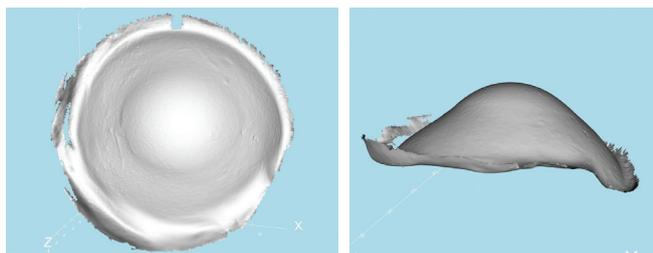


Figure 3. After impressions of the ocular surface are taken in the office, a CAD image is generated using the impressions. A custom scleral lens is built directly from this image, yielding a precise fit every time.

and is placed on the ocular surface (Figure 3). The impression is sent for conversion into a computer-aided design (CAD) image.

Once a CAD image is generated, a custom scleral lens can be manufactured that offers complete rotational stability. The hassle of trial-and-error fitting is avoided. Rotational stability is necessary to ensure the correct orientation of images projected onto the retina.

TECHNOLOGICAL CHALLENGES

The technical hurdles of creating an electronic contact lens were complex. The microelectronic components were novel and therefore had to be custom fabricated. A scleral lens base had never before housed electronics, so a redesign was required. The Mojo team had to devise a way to transmit an adequate amount of oxygen through a lens that had to be thicker than the standard 200 to 400 μm .

They created an air-gap design (Figure 4) that provides ample oxygenation of the cornea and sclera. This was demonstrated in their unpublished studies with Joe Benjamin, OD, PhD.

EXPERIENCE

Wearing the prototype was a life-changing experience that showed me what the future holds for humans. Engineers projected text and images into my central field of view in real time while I viewed the world around me. The purpose of the Mojo lens is to create a true AR experience for the user. My experience with the technology was fun and interesting, but the first application of real clinical benefit (and for FDA clearance) will be to aid people who are visually impaired.

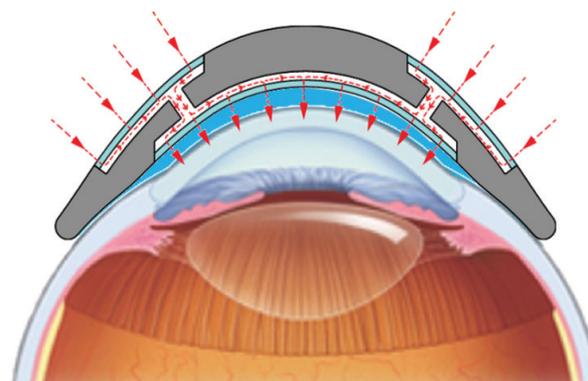


Figure 4. Schematic of the air-gap design of the scleral lens required to deliver oxygen to the cornea and behind the lens tear reservoir of saline.

I have worked with children who are visually impaired for the past 19 years, most recently at the Smokey Powell Center at Georgia Academy for the Blind. Once the Mojo lens has been proven safe and effective for adults, I believe children with visual impairments will readily adopt an AR contact lens designed to assist them with orientation and mobility and enhance contrast; this generation is so accepting of technology. Providers such as myself were once limited to prescribing optical devices for patients. Now, we can use technology to help solve problems such as magnification. The potential for AR contact lenses to increase magnification, enhance contrast, and label borders for orientation and mobility may occur with the next software update.

Technology such as this has the potential to provide significant benefits to patients. The ultimate goal is to create an AR scleral lens that can be used as a mass-market consumer electronic solution. This could attract more patients to eye care providers than ever before.^{1,2} In the process, optometrists and ophthalmologists would have an opportunity to diagnose and treat ocular pathology at an earlier stage, which could dramatically decrease vision loss.

1. Liao Y, Bang D, Cosgrove S, et al. Surveillance of health status in minority communities—racial and ethnic approaches to community health across the U.S. (Reach U.S.) risk factor survey, United States, 2009. *Center for Disease Control. Morbidity and Mortality Weekly Report*. May 20, 2011;60(SS06):1-41.

2. Vision Health Initiative. Fast facts of common eye disorders. Centers for Disease Control and Prevention. Reviewed June 9, 2020. Accessed May 26, 2021. www.cdc.gov/visionhealth/basics/ced/fastfacts.htm

OcuMedic Freedom Lenses: Drug-Releasing Bandage Contact Lenses for Drop-Free Postoperative Treatment

MARK E. BYRNE, PHD, FAIMBE

The topical therapy regimen required after cataract surgery is widely acknowledged to be the biggest negative of what is otherwise a straightforward and elegant procedure. One study found problems with compliance in more than 90% of patients.¹ Even if compliance is perfect (ie, drops are

administered correctly and on schedule), poor bioavailability due to quick tear turnover and barriers to ocular transport can significantly limit the effectiveness of topical eye drops.² A drop-free treatment strategy has the potential to increase the efficacy and convenience of therapy.



Watch It Now

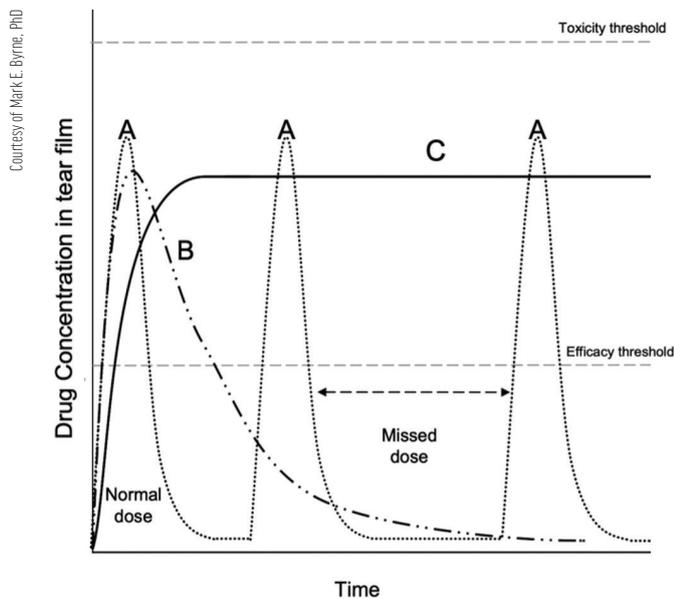


Figure 5. Drug release from Freedom lenses compared to topical eye drops. With a topical eye drop, the tear-drug concentration quickly reaches a maximum directly after administration, and the drug is removed from the tear film with concentrations quickly (approximately 1.0–1.5 hours) dropping below therapeutic levels. Topical drops therefore must be applied multiple times a day (A). Drug release from drug-soaked commercial lenses has been attempted but has not been clinically demonstrated to work because of quick drug release and low drug loading, leading to release durations only slightly longer than with topical drops (B). Freedom lenses are designed to provide controlled and sustained drug release wherein a constant, therapeutic concentration of drug is maintained for an extended period matching the duration of lens wear. The release rate can be titrated via the macromolecular memory of the lens. In other words, the drug concentration reached or the dosage may be increased or decreased depending on the lens used (moving line C up or down in the therapeutic window for various lenses differing in memory for the drug).

Contact lenses are noninvasive and well accepted by patients, and these devices have a strong safety record. It is not surprising, therefore, that the controlled release of drugs from contact lenses has been a subject of investigation for more than 60 years. No such technology has made it to market³ because of poorly controlled drug release and inadequate commercial physiochemical lens properties. Freedom silicone hydrogel lenses (OcuMedic) has overcome these obstacles. (Scan the QR code on pg 72 now to watch a video about this technology.)

DRUG-ELUTING LENS TECHNOLOGY

The drug of choice in OcuMedic’s patented technology is noncovalently linked with the monomer building blocks of the polymer contact lens network during synthesis. This creates a lens polymeric network with small pores or macromolecular memory, unique for each drug, while maintaining all of the lens’ commercial properties. The patented technology enhances the chosen drug’s affinity to the polymer and allows a high payload without preservatives. The rate at which a drug is released from the lens can thus be controlled as the drug moves from one memory site to the next and is released from the lens. The goal is a stable, therapeutic concentration of drug for the duration of lens wear (Figure 5).

In preclinical studies, OcuMedic’s lenses have demonstrated sustained drug release with a constant ocular concentration of drug for the duration of wear, ranging from daily (1 day) to weeklong (7 days), compared to commercial topical drops. Bioavailability was more than 25 times higher than for topical drops currently on the market. Complete ophthalmic examinations and ocular tissue histology performed before and after wear showed that the lenses were safe and well tolerated.

OcuMedic’s lenses can be manufactured in afocal, multifocal, or other vision-correcting models or in plano or bandage models that offer no vision correction. Preclinical studies have shown that these lenses can provide combination therapy by releasing multiple drugs, each at a tailored rate (data on file, OcuMedic). As a platform technology, lenses have been produced for use with certain agents, including steroids, NSAIDs, antibiotics, IOP-lowering drugs, antihistamines, and lubricating agents.

A NEW PARADIGM

Freedom silicone hydrogel bandage lenses are designed to release an NSAID (bromfenac) over the course of 1 week with continuous wear. The constant dosing rate can facilitate compliance, provide more effective therapy, and offer greater convenience compared to therapy with topical drops. After cataract surgery, a new contact lens is placed each week and the amount of drug delivered may be increased or decreased on lens replacement over a 2- to 6-week period. Over 6 weeks, six lenses can replace up to 84 drops. After refractive surgery, one or two lenses can replace seven to 14 drops.

The primary treatment strategy after cataract surgery involves the placement of a Freedom bandage lens that releases a first-line NSAID (bromfenac) and the single-dose injection of a broad-spectrum antibiotic (moxifloxacin) via intracameral irrigation intraoperatively at the conclusion of cataract surgery. Intracameral antibiotics have been found to reduce the risk of endophthalmitis six- to sevenfold compared to topical antibiotic eye drops.⁴ An appropriate dose of moxifloxacin accounts for aqueous turnover. Potential benefits of this drop-free approach utilizing the bromfenac releasing lens and injection for endophthalmitis prophylaxis⁵ include more control of inflammation without compromising corneal endothelial regeneration/function or increasing IOP and the risk of pseudophakic cystoid macular edema.⁶

OcuMedic has met with the FDA and is planning human clinical trials of the technology. This is expected to begin soon. ■

1. An JA, Kasner D, Samek DA, Lévesque V. Evaluation of eyedrop administration by inexperienced patients after cataract surgery. *J Cataract Refract Surg*. 2014;40(10):1857-1861.

2. Agrahari V, Mandal A, Agrahari V, et al. A comprehensive insight on ocular pharmacokinetics. *Drug Deliv Transl Res*. 2016;6(6):735-754.

3. Wuchte LD, DiPasquale SA, Byrne ME. In vivo drug delivery via contact lenses: the current state of the field from origins to present. *J Drug Deliv Sci Technol*. Published online February 18, 2021. doi:10.1016/j.jddst.2021.102413

4. Kessel L, Flesner P, Andresen J, Erngaard D, Tendal B, Hjortdal J. Antibiotic prevention of postcataract endophthalmitis: a systematic review and meta-analysis. *Acta Ophthalmol*. 2015;93(4):303-317.

5. George NK, Stewart MW. The routine use of intracameral antibiotics to prevent endophthalmitis after cataract surgery: how good is the evidence? *Ophthalmol Ther*. 2018;7(2):233-245.

6. Kessel L, Tendal B, Jørgensen KJ, et al. Post-cataract prevention of inflammation and macular edema by steroid and nonsteroidal anti-inflammatory eye drops: a systematic review. *Ophthalmology*. 2014;121(10):1915-24.

A CLOSER LOOK

A nonexhaustive look at other wearable eye technologies in the pipeline.

BY LAURA STRAUB, EDITOR-IN-CHIEF, AND MICHELE CORRY, SENIOR EDITOR

Anzu Smart Glasses

Anzu Smart Glasses (Razer) filter blue light for protection against eye strain and feature built-in speakers with open-ear Bluetooth audio for hands-free communication. The glasses also feature touch controls that allow the wearer to switch between music, calls, a gaming mode, and their smartphone's virtual assistant. They come with 99% UVA/UVB-protected replacement lenses for outdoor use and are compatible with Android and iOS devices.¹

1. Razer Anzu smart glasses-round design-size SM-blue light and sunglass lens bundle. Razer. Accessed June 11, 2021. <https://www.razer.com/mobile-wearables/Razer-Anzu-Smart-Glasses/RZ82-03630800-R3U1>

Artificial Intelligence Kit with Depth

The Artificial Intelligence Kit with Depth (OpenCV, Luxonis) is an Intel AI-powered, voice-activated system designed to help the visually impaired navigate and perceive the world around them. The device detects and alerts the wearer to obstacles such as traffic signs, hanging and moving objects, crosswalks, and changing elevation. The wearer can interact with the system using a Bluetooth-enabled earphone and voice queries and commands to which the system responds with verbal information as the user moves through their environment.¹

1. Intel AI-powered backpack helps visually impaired navigate world. Intel. March 24, 2021. Accessed June 11, 2021. <https://www.intel.com/content/www/us/en/newsroom/news/ai-powered-backpack-visually-impaired-navigate.html#gs.31sfpi>

EssilorLuxottica and Facebook AR and AI Glasses

Through a partnership between EssilorLuxottica and Facebook, Ray-Ban glasses with augmented reality (AR) features and the ability to mirror the display of a connected smartphone are planned for release in 2021.¹

The partnership will also continue development of Facebook's Project Aria, a prototype research device that is worn like glasses and gathers data for machine perception and AI research. When worn, the device captures the wearer's video and audio and tracks their eyes and location, which, when uploaded to back-end storage systems, will aid Facebook with AR software development.²

1. Facebook and EssilorLuxottica announce collaboration for smart glasses. Essilor Luxottica. September 16, 2020. Accessed June 11, 2021. <https://www.essilorluxottica.com/facebook-and-essilorluxottica-announce-collaboration-smart-glasses>
2. Spangler T. Facebook to launch line of smart glasses in 2021, starting with AR-enabled ray-bans. Variety. September 16, 2020. Accessed June 11, 2021. <https://variety.com/2020/digital/news/facebook-smart-glasses-ray-bans-essilorluxottica-1234772183/#>

GenSight Biologics' Optogenetic Vector and Light-Stimulating Goggles

Partial vision was restored in a 58-year-old man with retinitis pigmentosa (RP) and a prior visual acuity of only light perception through a mutation-independent approach to restoring visual function in the last stages of RP.¹ Treatment combines the intravitreal injection of an optogenetic sensor-expressing gene therapy vector (GS030-Drug Product, GenSight Biologics) with light-stimulating goggles (GS030-Medical Device, GenSight Biologics). The optogenetic vector is injected into the worse-seeing eye and targets foveal retinal ganglion cells. The goggles may then be worn to capture images from the outside world. The goggles contain a neuromorphic camera that detects changes in intensity as distinct events, translates them into monochromatic images, and then projects them in real time as light pulses on the retina.

Eleven and a half months after injection and 7 months after the initiation of visual training, the patient reported signs of visual improvement with the light-stimulating goggles. The researchers concluded that the optogenetic vector treatment and light-stimulating goggles induce visual perception that can orient individuals toward objects and allow them to perform visuomotor tasks.

1. Sahef JA, Boulanger-Scemama E, Pagot C, et al. Partial recovery of visual function in a blind patient after optogenetic therapy. *Not Med*. Published online May 24, 2021. doi:10.1038/s41591-021-01351-4

iLens

The iLens (Lenstore) is a silicone hydrogel smart contact lens. According to Lenstore, prescription and nonprescription models of the iLens may be available as early as this year. Both lenses feature an ambient light sensor, a telephoto camera, and a mixed reality display that can provide fitness and air quality alerts and allow wearers to change their eye color, add AR

filters and features, and see in the dark.¹ Wearers can record memories, measure the environment to maintain social distancing, and receive alerts when they have been looking at a digital screen for too long.²

Researchers are also working to incorporate continuous IOP monitoring functionality to the iLens by imbedding a previously designed capacitive pressure sensor, the TonoChip. An external antenna reader connected to the sensor in the lens would allow continuous monitoring of IOP during wear. Additionally, researchers are investigating the iLens as a potential vehicle for the delivery of glaucoma medications via the TonoChip, which could improve the efficacy of medication delivery.³

1. Oakes A. Meet the smart contact lens. *New Digital Age*. Accessed June 11, 2021. <https://newdigitalage.ca/technology/meet-ilens-the-smart-contact-lens>

2. Smart contact lenses have potential to monitor, treat glaucoma. Consult QD. September 9, 2020. Accessed June 11, 2021. <https://consultqd.clevelandclinic.org/smart-contact-lenses-have-potential-to-monitor-treat-glaucoma>

3. New smart glasses offer eye strain relief, hands-free working. *Healio*. March 22, 2021. Accessed June 11, 2021. <https://www.healio.com/news/optometry/20210322/new-smart-glasses-offer-eye-strain-relief-handsfree-working>

Kubota Glass System

The Kubota Glass System (Kubota Vision) is an AR optical system designed to reduce axial length in myopic eyes. The unit contains a battery and a micro-light-emitting diode array. Microlenslets in the Kubota Glass System defocus images by 3.50 D and project them onto the peripheral visual field to actively stimulate the retina. The goal is to slow the progression of myopia by actively stimulating the retina for short periods while maintaining central vision and allowing normal eye movements, reading, and comprehension.

According to the company, the system can vary the parameters of peripheral myopic defocus to maximize retinal stimulation. A proof-of-concept study was completed in August 2020, and the first wearable prototype has been designed. Product design improvements, further clinical studies for regulatory approvals, and the design of smart contact lenses using the Kubota Glass technology are planned.

1. Kubota Glass Technology. Kubota Vision. Accessed June 14, 2021. <https://www.kubotaholdings.co.jp/en/kubota-glass-technology-wearable-device-for-myopia-control-myopia-or/index.html>

SING IMT

The Smaller-Incision New-Generation Implantable Miniature Telescope (SING IMT, Samsara Vision) is designed for patients with late-stage age-related macular degeneration (AMD). The device was successfully implanted in patients at two centers in Germany by Timothy Schultz, MD, and Suphi Taneri, MD, in May, according to a news release. Developed by Isaac Lipshitz, MD, the latest model of the SING IMT incorporates foldable haptic loops to reduce the incision size required for implantation.

The SING IMT is indicated for monocular implantation in patients who meet age requirements and have stable but severe (20/80 distance BCVA) to profound (20/800 distance BCVA) vision impairment caused by bilateral central scotomas associated with late-stage AMD. The device reportedly improves central vision in the implanted eye and enlarges central vision images over a wide area of the retina. The contralateral eye provides peripheral vision for mobility and orientation.

Postoperatively, patients are expected to adapt to their new vision by working with low vision specialists and occupational therapists. Possible side effects from the device include decreased vision and vision-impairing corneal swelling.

Smyle Mouse Head Mouse

The Smyle Mouse Head Mouse (Percept-D) is a downloadable software subscription service that allows individuals who have difficulty using their hands to control computers and/or tablets hands- and voice-free. Apart from a webcam, the software requires no hardware or accessories. Users can operate their computer or tablet device by using their head to move their mouse pointer and smiling to click the mouse or make an adaptive switch selection (eg, selecting between right click and left click or double click).¹ ■

1. Smyle Mouse Head Mouse is a subscription service for hands-free computer control for people with disabilities. Smyle Mouse. June 8, 2020. Accessed June 11, 2021. <https://smylemouse.com/post/smyle-mouse-head-mouse-is-a-subscription-service-for-hands-free-computer-control-for-people-with-disabilities>