For many years, optometrists have been saying that it’s an exciting time to be in optometry. An outsider might roll his or her eyes thinking that optometrists can’t possibly continue to say this and mean it for so long. But anyone working in the eye care industry or profession would disagree. Surely some years have seen more change and activity than others, but generally every year in eye care some company or out-of-the box thinker presents an idea that really does spark excitement. Sometimes it’s as simple as a new drug delivery platform, and sometimes it’s mind-blowing, like using artificial intelligence to detect diabetic retinopathy.

With the state of affairs being what it is, it would be easy to chalk 2020 up as a loss, but hang on; there are some promising technologies and innovations in the works. Obviously it’s impossible to include every one in the pipeline here, so this roundup consists of those that we’ve had on our radar. Let’s have a look.

**CONTACT LENSES**

**Progressive-Like Vision**

The Apioc lens, according to developer Lentechs, is a new class of suspended soft contact lens that offers true glasses-like progressive vision for presbyopic patients. Apioc inventors and Lentechs co-founders Joseph T. Barr, OD, FAAO, and Melissa D. Bailey, OD, PhD, came up with the lens design, which anchors the lens in place from the inside of the upper eyelid above the lid wiper, allowing the eye to move freely behind the lens. The company claims that the Apioc lens allows discrete vision correction at far, intermediate, and near distances. The lens received 510(k) clearance from the FDA in July 2019, and is currently in clinical trials.

**GLAUCOMA**

**Laser Treatment**

The External Automatic Glaucoma Laser (EAGLE) device, developed and patented by Belkin Laser, aims to provide accessible first-line treatment for glaucoma. The Belkin Laser’s contact-free direct selective laser trabecuoplasty (DSLT) procedure employs a laser beam with a pulse duration of a few nanoseconds, delivered 120 times...
in about a second, according to the company. The laser beam is delivered to the limbus, targeting the trabecular meshwork, and thus enhancing aqueous drainage.

The Belkin Laser procedure can be used to treat both angle-closure glaucoma and open-angle glaucoma, can be performed by any eye care practitioner, can be used in conjunction with or as an alternative to eye drops, and can be repeated annually as needed, the company states.

The company is currently running the GLAUrious multicenter randomized controlled study, including 124 patients, to assess the noninferiority of the new treatment, DSLT, compared with selective laser trabeculoplasty. Learn more at belkin-laser.com.

Drug Delivery in a Contact Lens

Diopter is using an approved contact lens and approved drugs in combination with its patented drug-eluting process to develop a contact lens drug delivery platform. According to the company, its drug-loaded contact lens can deliver a drug directly to the cornea, increasing bioavailability to at least 20 times that of standard eye drops.

The company has completed phase 1 studies at the University of Florida in which 10 patients with glaucoma were treated initially with vitamin E only. After no adverse events or safety issues were reported in that portion of the trial, two patients then received Diopter’s drug-loaded contact lens. No adverse events, with the exception of slight irritation after a 2-day dosing period, were reported. The company is aiming to achieve once-a-week dosing. Phase 2 glaucoma studies are planned to start in the third quarter of this year.

DRY EYE

Nasal Spray

Varenicline (OC-01, Oyster Point Pharmaceuticals) is a highly selective nicotinic acetylcholine receptor agonist being developed as a preservative-free nasal spray to treat the signs and symptoms of dry eye disease. According to the company, the spray’s mechanism of action activates the trigeminal parasympathetic pathway to stimulate natural tear production.

The multicenter, randomized, double-masked phase 3 ONSET-2 trial evaluated the safety and efficacy of OC-01 for treatment of the signs and symptoms of dry eye disease in 758 patients at 22 centers in the United States. Two doses, 0.6 mg/mL and 1.2 mg/mL, were compared to a control (vehicle) nasal spray. Participants were administered nasal spray twice daily for 4 weeks. For the primary endpoint of ≥ 10 mm improvement on Schirmer test at week 4, both doses of OC-01 performed statistically significantly better than control.

In secondary endpoints, both the 0.6 mg/mL and 1.2 mg/mL doses of OC-01 showed statistical significance in Eye Dryness Score improvement at week 2. OC-01 was well-tolerated, and the adverse event profile was consistent with the ONSET-1 clinical trial.

For more information about this nasal spray, visit oysterpointrx.com/pipeline/oc-01/.

Addressing the Cause

Lacripep (TearSolutions) is a first-in-class topical synthetic peptide treatment that addresses the cause of dry eye disease, according to the company. Lacripep is a synthetic protein fragment of lacritin that heals the corneal surface and restores normal tear quality and sensory neurons at the ocular surface.

Enrollment in a phase 2 clinical trial of Lacripep in primary Sjögren syndrome dry eye disease is complete. The multicenter, double-masked, randomized trial evaluated the efficacy and safety of two strengths of Lacripep ophthalmic solution versus placebo administered three times daily for 4 weeks in 204 patients with a diagnosis of dry eye disease associated with documented primary Sjögren syndrome. Patients were randomly assigned in a 1:1:1 ratio to one of three treatment groups: 0.005% or 0.01% Lacripep or placebo. The primary outcome measure was change in fluorescein corneal staining total score at week 4 from baseline. Results are pending. Find out more about the company and Lacripep at tearsolutions.com.

Killer Instinct

TP-03 (Tarsus Pharmaceuticals) is designed to target the nervous system of Demodex folliculorum mites. The compound has shown rapid, complete, durable efficacy with no serious adverse events in four phase 2 studies including nearly 100 treated patients. The phase 2a Mars study, assessing the efficacy and safety of TP-03 in 15 patients with Demodex blepharitis, showed statistically significant decreases in mean collarette score and mite density beginning at day 14 and continuing throughout the 90-day study period with no reported adverse events.
PRESBYOPIA Drop Treatment

A number of companies are developing presbyopia-correcting eye drops, and Joshua Davidson, OD, FAAO, FLS, and Paul Kimbro, OD, give this growing area their full attention in this issue. Check it out on page 42.

One pipeline product not mentioned in their article is Nyxol Eye Drops (Ocuphire Pharma), a once-daily preservative-free formulation of phentolamine mesylate that has been assessed in more than 150 patients across seven completed phase 1 and 2 trials. This nonselective alpha-1 and alpha-2 adrenergic antagonist is being developed for several indications, including treatment of presbyopia. In the recently completed phase 2b ORION-1 study, Nyxol as a single agent showed statistically significant improvement of 1 or more lines of near visual acuity from baseline, with a trend of 2 or more lines of improvement at multiple time points.2 This was a planned secondary outcome of the trial, the primary outcome of which was reduction of IOP.

Corneal Molding

True Vision Treatment (TVT; Yolia Health) is a noninvasive, self-administered binocular treatment for patients with presbyopia that employs a combination of customized contact lenses and eye drops, which, when used together, safely modifies the sphericity of a patient’s cornea to improve vision. According to the company, after 7 days of treatment with TVT, patients can stop treatment for up to 1 year before needing to resume the treatment. Yolia Health claims that the TVT eye drops increase corneal malleability, making the cornea more adaptable to the contact lenses, which alter the corneal topography into a multifocal optical system by creating varying focal points for all ranges of near vision without compromising distance vision. In many cases, distance vision is also improved by reducing higher-order aberrations through the creation of intentional microtopographic changes.

TVT is available only in Mexico and has been administered to more than 290 presbyopic patients to date. Visit www.yolia.com/true-vision-treatment/ to learn more.

Microdose Treatment

MicroLine (Eyenovia) is a proprietary pilocarpine formulation and drug candidate indicated for the improvement of near vision in patients with presbyopia. The company’s Optejet dispenser provides piezo-print microdosing of the drug to increase precision and reduce waste, according to the company. Additionally, the technology that accompanies the Optejet helps patients manage their therapy with reminders and therapy adherence measures. According to the company, MicroLine provides approximately 3 to 4 hours of near vision with a single microRx spray. Two identical double-masked, placebo-controlled superiority trials (VISION-1 and VISION-2 phase 3 studies) were planned for 2020, examining microdosed pilocarpine 1.0%, 2.0%, and placebo, with a primary endpoint of binocular distance corrected near visual acuity. For more information visit eyenovia.com/presbyopia-2019/.

MYOPIA Microdose Treatment

MicroPine (Eyenovia) is a proprietary microdose array print (MAP) formulation of atropine for the prevention of progressive myopia in children. The company’s Optejet dispenser, described in the preceding section, allows patients to deliver treatment safely, effectively, and reliably to themselves, according to the company.

Eyenovia resumed recruitment for its phase 3 CHAPERONE study for progressive myopia in June following a pause due to the COVID-19 pandemic.8 The company is screening patients between the ages of 5 and 13 years with myopia of between 1.00 D and 6.00 D and is aiming to enroll 501 patients. The primary endpoint is change in refractive error (myopia progression) from baseline through 36 months. For additional details visit eyenovia.com/myopia/.

OPTOMETRY’S THE PROFESION TO BE IN

With so many innovations in the pipeline, how could optometrists not be excited to be a part of such an evolving profession? There are certainly a lot of promising new products and technologies here to keep an eye on, and no doubt many more to come. Let’s keep riding the wave: It continues to be an exciting time to be in optometry—and in eye care in general.