



LATEST INNOVATIONS AND FUTURE DIRECTIONS IN OPTOMETRY



From myopia control to IOLs, new technologies keep coming down the pike.

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We are seeing an exponential surge in new trends, technologies, and treatments in optometry and hope to inspire some further research by giving you a high-level introduction to some of the up-and-comers in eye care.

MYOPIA CONTROL

Myopia is an age-old topic, but what is new is the growing prevalence of myopia worldwide. In 2000, the prevalence of myopia in the world population was estimated to be 22.9%, and that figure is projected to rise to 49.8% by 2050.¹ There are multiple theories as to the cause of this growth, including increasing screen time and decreasing time spent outdoors among young people. Luckily, our evidenced-based and validated

treatment options for myopia control are also steadily increasing.

Soft Contact Lenses

In 2020, the FDA approved MiSight 1 day (CooperVision) lenses (Figure 1),

making them the first daily disposable soft contact lenses labeled for slowing the progression of myopia. Clinical studies found that MiSight 1 day lenses provided a 59% reduction in myopia progression in comparison with a

AT A GLANCE

- ▶ New multifocal contact lens and spectacle technologies are additions to the more traditional methods available to address the worldwide growth in the prevalence of myopia.
- ▶ New topical drops, both prescription and over the counter, add to the optometric therapeutic arsenal.
- ▶ A recently approved systemic drug may change management patterns for thyroid eye disease.

Image courtesy of CooperVision.

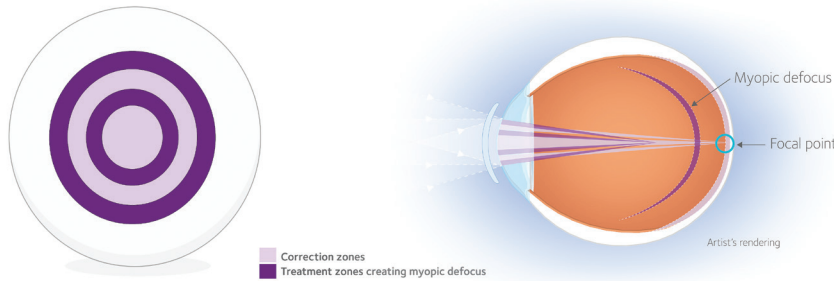


Figure 1. The ActivControl technology in MiSight 1 day lenses uses an optic zone concentric ring design with alternating vision correction zones and treatment zones. Two zones are vision correction zones with the label power of the contact lens, and the alternating two zones are treatment zones with 2.00 D of defocus to slow the progression of myopia.

single-vision 1-day lens, as measured by spherical equivalent, and a 52% reduction in mean axial elongation.²

Gas Permeable Contact Lenses

Orthokeratology (ortho-k) has been used at least since the 1960s in the management of myopia. The first rigid gas permeable lens for ortho-k, Paragon CRT (CooperVision Specialty EyeCare), received FDA approval in 2002,³ and products and options have continued to grow since then. In May of this year, Johnson & Johnson Vision announced FDA approval of its Acuvue Abiliti Overnight Therapeutic Lenses for the management of myopia.⁴ That same month, CooperVision announced that its Procornea DreamLite night lenses for ortho-k had received the CE Mark from European regulators for slowing the progression of myopia in children and young adults.⁵ CooperVision also announced this year that it has begun offering 5-mm customization of the back optic zone diameter for increased efficacy for its Paragon CRT and CRT Dual-Axis lenses in myopia management strategies.⁶

Eye Drops

Many doctors have been prescribing atropine off-label for myopia control. Vyluma, a newly formed subsidiary of Nevakar, announced in May that the phase 3 CHAMP trial of its pharmaceutical atropine eye drop NVK002 is in late stages in the United States and

Europe.⁷ The drop has the potential to be an FDA-approved pharmacologic method for myopia control, the company suggested.

Spectacle Correction

Glasses don't work for myopia control, right? Perhaps it's time to think again.

Essilor announced in May that it has been granted breakthrough device designation by the FDA for its Stellest spectacle lens to correct and slow the progression of myopia.⁸ Data from a pivotal clinical trial presented at this year's Association for Research in Vision and Ophthalmology meeting demonstrated that, at 2 years follow-up, Essilor's highly aspheric lenslet target (HALT) technology, worn at least 12 hours per day, slowed myopia progression by 67% in comparison with single-vision lens wear. After 1 year in the ongoing 3-year trial, eye growth in children wearing the Stellest lenses was similar to or slower than that in nonmyopic children, according to Essilor.⁹

Also in May, researchers at Hoya and the Centre for Myopia Research in Hong Kong published follow-up data on the company's MiyoSmart spectacle lenses with patented defocus incorporated multiple segments (DIMS) technology, showing that wearing the DIMS lens slowed the progression of myopia by 52% and axial length growth by 62%



Figure 2. The Bausch + Lomb Infuse contact lens, a silicone hydrogel daily disposable, helps to address contact lens dryness, according to the company.

at 2 years in comparison with single-vision lens wear.¹⁰

CONTACT LENSES

In addition to the contact lenses for myopia control discussed above, a number of new conventional contact lens models have come to the market recently.

The silicone hydrogel material of the daily disposable Bausch + Lomb Infuse lens (Bausch + Lomb; Figure 2) is *infused* with a proprietary combination of ingredients designed to promote comfort, inspired by the Tear Film and Ocular Surface Society's DEWS II report, according to the company.¹¹ The infused ingredients include osmoprotectants and electrolytes to help maintain ocular surface homeostasis and moisturizers to help retain hydration and maintain tear proteins in a healthy state, the company states.

Alcon added cylinder correction to its Precision1 one-day contact lenses for its toric Precision1 for Astigmatism line (Alcon). The lens settles in less than 60 seconds within 3° of ideal orientation and has a 99% first-fit success rate, according to the company.¹²

Johnson & Johnson Vision introduced an upgrade to its Acuvue Oasys Multifocal Lens, now including a Pupil Optimized Design. The new design optimizes parameters

Image courtesy of Bausch + Lomb.



Image courtesy of Johnson & Johnson Vision.



Figure 3. Acuvue Theravision with Ketotifen is a medication-releasing contact lens for patients in Japan and Canada who need vision correction and itchy eye relief.

for patient age and refraction, according to the company, improving performance and comfort.¹³

We also now have a large selection of options for our astigmatic presbyopic patients, with Biofinity toric and Biofinity XR toric lenses (CooperVision)¹⁴ and Bausch + Lomb Ultra Multifocal for Astigmatism lenses.¹⁵

There are several innovations in the development pipeline aiming to use contact lens technology as a platform to achieve goals such as monitoring IOP,¹⁶ displaying augmented reality,¹⁷ and fostering corneal wound healing.¹⁸

The high-concept contact lens technology that may be closest to reaching the US market is an antiallergy drug-eluting lens being developed by Johnson & Johnson Vision. Acuvue Theravision with Ketotifen (Figure 3) releases an H1 histamine receptor antagonist to reduce itching due to allergies and improve lens comfort. The device has received regulatory approval in Japan and Canada.¹⁹

EYE DROPS

We are lucky to be in a profession where there is continual innovation to allow us to better treat our patients. Let's look at a few new eye drops—in addition to the myopia control drops discussed above—that have expanded our arsenal in the past 2 years.

In June, Santen received FDA approval for its formulation of cyclosporine 0.1% ophthalmic emulsion (Vekazia) for the treatment of vernal keratoconjunctivitis (VKC) in

children and adults.²⁰ The formulation's oil-in-water cationic emulsion provides improved ocular bioavailability of cyclosporine, according to the company. It works by inhibiting T-cell activation, which controls allergic response and inflammation. The drops can be used over a sustained period of time, which means that steroids can be reduced. Recommended dosage is four times daily, and the product is approved for use in children as young as 4 years.

The FDA approved loteprednol etabonate ophthalmic suspension 0.25% (Eysuvis, Kala Pharmaceuticals) for the short-term treatment of the signs and symptoms of dry eye disease in October 2020.²¹ It became the first ocular corticosteroid approved specifically for the treatment of dry eye disease and the first approved specifically for short-term (up to 2 weeks) treatment of the signs and symptoms of dry eye disease. The drop, dosed four times daily, uses the company's proprietary mucus-penetrating particle drug delivery technology (Ampplify) to enhance bioavailability of the active ingredient at the target site, according to Kala.

Also approved last year was oxymetazoline HCl ophthalmic solution 0.1% (Upneeq, RVL Pharmaceuticals), indicated for

patients with acquired blepharoptosis who do not want to pursue surgical repair.²² In two phase 3 trials, patients who received the drug once daily experienced statistically significant improvement in visual field compared to a placebo group (Figure 4). The drop is the only FDA-approved medical treatment for ptosis.

Itching for more over-the-counter (OTC) allergy drops? Alcon's suite of products containing olopatadine is now available OTC: Pataday Once Daily Relief Extra Strength (formerly Pazeo), Pataday Once Daily Relief (formerly Pataday), and Pataday Twice Daily Relief (formerly Patanol).²³ Further expanding the shelf, in September 2020 the FDA approved ketotifen fumarate ophthalmic solution 0.035% antihistamine (Alaway Preservative Free, Bausch + Lomb), which became the first OTC preservative-free eye drop formulation approved to relieve symptoms of allergy.²⁴

Reproxalap ophthalmic solution 0.25% (Aldeyra Therapeutics) is a RASP inhibitor, which could be the next category of antiinflammatory medications in eye care.²⁵⁻²⁷ It targets early, upstream proinflammatory signaling cascades and is showing promise in several ocular conditions such as dry eye, allergic conjunctivitis, and uveitis.



Image courtesy of RVL Pharmaceuticals.

Figure 4. Examples of positive results after a first dose of oxymetazoline for blepharoptosis.



SYSTEMIC DRUG

In January 2020, teprotumumab-trbw (Tepezza, Horizon Therapeutics) became the first drug FDA-approved for the treatment of thyroid eye disease (TED).²⁸ Teprotumumab is a fully human monoclonal antibody and a targeted inhibitor of the insulin-like growth factor-1 receptor. In a phase 3 clinical trial, teprotumumab was shown to improve proptosis, diplopia, and quality of life in patients with TED.²⁹ This finding puts to rest the watch-and-wait mentality traditionally applied to patients with TED.

There may also be applications for this new drug in patients with long-standing, chronic TED.³⁰ This is an excellent example of a situation in which optometry must have an open mind to incorporate new therapeutics. It is crucial that we stay ever-vigilant to detecting ocular conditions early in the disease state, knowing that we are in many cases the gate-keepers and primary care physicians of eye care.

PRESBYOPIA DROPS ... SOON?

The race for an FDA approval of a topical presbyopia treatment is on, and Allergan appears to be in the lead. The company in February submitted a new drug application to the FDA for its investigational eye drop, AGN-190584, for the treatment of presbyopia, and the FDA is expected to act on the application by the end of this year.³¹ The drop is an optimized formulation of pilocarpine 1.25% delivered in a proprietary vehicle. It is administered once daily, and the proposed mechanism of action is through contraction of the iris sphincter muscle to enhance depth of focus and improve near and intermediate visual acuity while maintaining some pupillary response to light. AGN-190584 also contracts the ciliary muscle to facilitate accommodation, according to the company.

But Allergan is not alone. Many

companies are in hot pursuit of their own presbyopia treatment drops. Others rising to the challenge include: Eyenovia, Novartis Pharmaceuticals, Ocuphire Pharma, Orasis Pharmaceuticals, OSRX Pharmaceuticals, Lenz Therapeutics (formerly Presbyopia Therapies), and Visus Therapeutics. For a recent review, see "Answering the Call of Presbyopic Patients" by Selina R. McGee, OD, FAAO, and Melissa Barnett, OD, FAAO, FSLs, FBCLA, on page 57 of the January/February 2021 issue of *Modern Optometry*.

NEW IOLS

Cataract surgery is increasingly becoming an opportunity to enhance patients' vision and treat other ocular pathologies. Multifocal IOL technologies continue to evolve and improve with new options to match the visual demands of patients. The biggest trend seems to be toward lenses that provide improvement at intermediate distances but not enough power for clear vision at the typical near working distance. By giving up the hard near focus of more traditional multifocal IOLs, it appears that these extended range of vision lenses can avoid some of the glare and halos occasionally experienced with full-range multifocal options.

The AcrySof IQ Vivity (Alcon; Figure 5), introduced in January and described by the company not as a multifocal but rather as a "nondiffractive extended depth of focus IOL," is an example of this type of lens option. In clinical trials of the lens, 94% of patients reported having good or very good vision at distance, and 92% reported having good or very good vision at arm's length. Starbursts, halos, and glare were comparable to those experienced with a monofocal lens.³²

A novel implantable technology that may indicate the shape of things to come is the R-TASC smart active IOL (Swiss Advanced Vision; Figure 6).



Figure 5. The AcrySof IQ Vivity IOL uses Alcon's proprietary non-diffractive X-Wave technology to stretch and shift light without splitting it.

If this development program comes to fruition, it could produce the world's first active electronic IOL implant. The company's aim is to develop a smart, real-time autofocus, solar-powered, multifocal IOL. The autofocus system would detect the distance of objects and trigger the transfer of liquid in or out of the lens optic, modifying the power of the IOL. The company's website gives no indication of the phase of development.³³

A PROFESSION RIFE WITH INNOVATION

With the products discussed here and additional releases sure to come in the near future, we have many new treatments and technologies to offer our patients, and we can look forward to more. Look for information in upcoming issues of *Modern Optometry* to help you embrace this bright future. ■

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► COVER FOCUS WILL TODAY'S INNOVATIONS BECOME TOMORROW'S TRENDS?

Image courtesy of Swiss Advanced Vision.

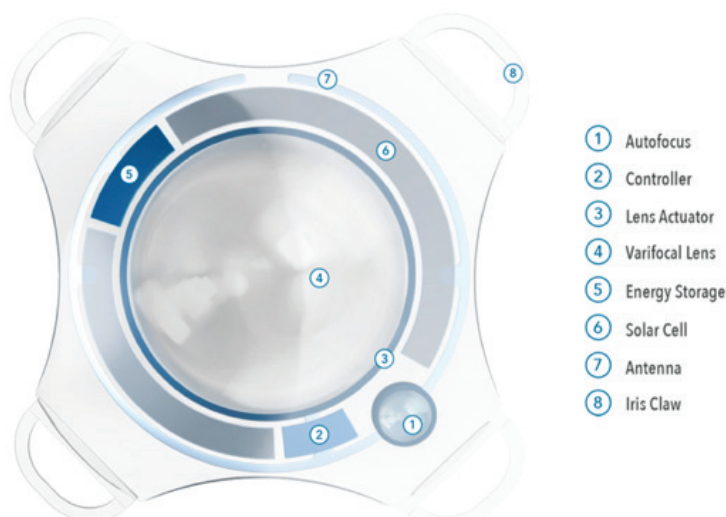


Figure 6. The high-concept R-TASC IOL would be equipped with an autofocus system that detects the distance of objects.

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