INSIDE THE INNOVATOR'S MIND

What does it take to be a game-changer in optometry? Hear from four innovators who've run the gamut.

A ROUNDTABLE DISCUSSION WITH KATHERINE MASTROTA, OD, EMBA, FAAO, DIPL ABO; TIM TRINH, OD, FAAO; JEFFREY KRALL, OD; AND FAYIZ MAHGOUB, OD

Innovation drives the field of optometry forward and shapes everyday practice. But how do you take a great idea to the next level? Let's get inside the minds of Katherine Mastrota, OD, EMBA, FAAO, Dipl ABO; Tim Trinh, OD, FAAO; Jeffrey Krall, OD; and Fayiz Mahgoub, OD—four innovators who have been through it all—to learn about their experiences, challenges, and hard-won advice. Who knows, you might someday find yourself among their ranks—or in the company of an optometry giant like Donald R. Korb, OD, FAAO (see One of the Greats*).*

– Alex Brodin, Associate Editor

WHEN INSPIRATION STRIKES

The passion these game-changers have for innovation in optometry is evident (see *What Excites the Innovators?*). Where did it come from? The innovators share their individual paths to developing their inventions and provide advice to help others along their way (see *Protect Your IP*).

Katherine Mastrota, OD, EMBA, FAAO, Dipl ABO: In the 1980s through the 1990s, I was working with a skilled cataract surgeon and forward-thinker in the field, Mark Jofe, MD, who realized that many of the practice's post-cataract surgery patients were unhappy due to eye discomfort, despite achieving excellent pseudophakic vision. He understood that many patients who were at higher risk for cataract often experienced some form of ocular surface disease, which cataract surgery can aggravate. In an effort to obviate or counter these related disease symptoms, he established a blepharitis and dry eye clinic and appointed me to direct the service. I was determined to make the best of this unique opportunity to explore and experiment in this niche practice. I invented what is now known as the Mastrota Meibomian Paddle (Ocusoft) to diagnostically express meibomian glands without compressing the

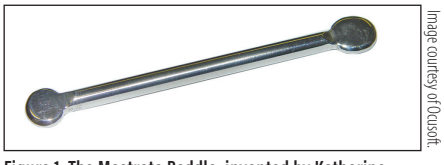

Image courtesy of Ocusoft.

Figure 1. The Mastrota Paddle, invented by Katherine Mastrota, OD, EMBA, FAAO, Dipl ABO, is used to diagnostically express meibomian glands in-office.

Image courtesy of Box Medical Solutions.

Figure 2. Meibox is an option for cloud-based meibography, designed by Tim Trinh, OD, FAAO.

globe at the same time (Figure 1). (I'd had one too many vasovagal responses to digital pressure on the globe.)

Tim Trinh, OD, FAAO: In 2016, there were few choices available for optometrists looking to add diagnostics for dry eye disease to their practices. The only imaging devices available cost upwards of $50,000, which was inaccessible for many offices. Like any good product, Meibox (Box Medical Solutions) was born out of necessity (Figure 2). My partner was one of the original engineers of the Ring video doorbell, and had married a schoolmate of mine from optometry school. During a dinner together, I mentioned the exorbitant cost of a technology that should be more readily accessible and discussed with him the potential of creating a more affordable dry eye diagnostic system.

Pairing his expertise in the tech field and my experiences with real-world clinical challenges, we started discussing, brainstorming, and creating prototypes focused on addressing the pain points surrounding capital equipment in a doctor's office. Until the creation of our device, most available equipment was bulky, leading to poor clinical efficiencies, high capital equipment costs, and risk of becoming obsolete due to the inability to upgrade software.

ONE OF THE GREATS

Inventor. Researcher. Clinician. Lecturer. It's impossible to talk about innovators in optometry without acknowledging the tremendous influence of Donald R. Korb, OD, FAAO, especially in dry eye disease (DED) treatment and contact lens technology. Dr. Korb's work in developing the first membrane hydrophilic (soft) contact lens, known as the CSI lens, helped to resolve complications of corneal swelling and lens discomfort and created the blueprint for nearly all contact lens designs that came after. He is also credited with describing and naming both giant papillary conjunctivitis and meibomian gland dysfunction. Dr. Korb has co-founded several companies, including Corneal Sciences, which developed the CSI lens; Ocular Research of Boston, which produced the first lipid-based eye drop for DED; and TearScience, which is now a part of Johnson & Johnson Vision Care. Add to this robust list of innovations his work on engineering the LipiFlow Thermal Pulsation System (TearScience) for treating dry eye through thermal compression of the meibomian glands.

In contrast, the device we created needed to be affordable, with a rapid return on investment, and portable to remove choke points in an office, as well as have the capacity for software updates.

Jeffrey Krall, OD: I'm a fourth-generation optometrist, and I joined my family's practice in the small town of Mitchell, South Dakota, right out of optometry school. My father was nearing the end of his career while I was just beginning mine, so I started seeing many of his patients by natural attrition. One day, a disgruntled farmer came into the office, complaining loudly to the front desk that the glasses he received were giving him headaches. He made it abundantly clear that he did not want to see that "young doc" again. He wanted to see my father, Charles Krall, OD, "the one who knew what

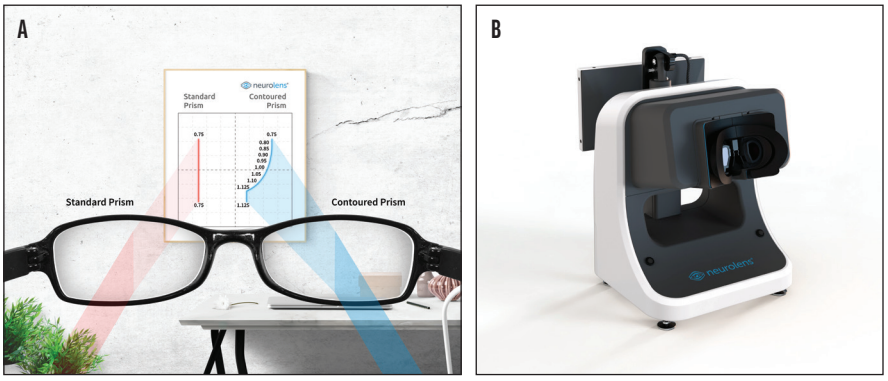

Figure 3. A pair of Neurolenses (A) and the Neurolens Measurement Device (B), designed and patented by Jeffrey P. Krall, OD, and his brother Joseph Krall, OD, to help patients with headaches and eye strain.

he was doing." Everyone in the waiting room and all the staff heard his complaints–not how I wanted to start the day!

After sorting out the problem, my father, who was a world-class clinician and great teacher, said, "Jeff, you did everything right, but missed the key issue causing the symptoms." Not to leave me in suspense, he continued, "If you would have used the Turville, you would have caught the alignment issue causing the problems." The Turville Infinity Balance technique that my father referred to was designed in the 1940s by English optometrist A. E. Turville, FBOA, FSAO, D.ORTH. Dr. Turville suggested that there was a balance between our central vision and our peripheral vision. I must admit, this concept was something I had never thought much about, but it started me on my journey develop the Neurolens measurement device and lenses (Figure 3).

Fayiz Mahgoub, OD: I was responsible for performing lens insertion and removal training during the fourth year of my optometry externship at University Hospitals in Cleveland, Ohio. I noticed that many patients had a hard time inserting their scleral and hybrid lenses. These struggles were temporary for most patients, who got better with practice, but for some, these problems persisted indefinitely due to having a strong blink reflex or conditions such as arthritis, stroke, or muscular tremors. This issue clearly affected these patients' quality of life, and I felt the need to do something about it. That's what motivated me to found my company, Augmented Vision Labs, and undertake the development of the S5 Lens Insertion System to help patients who

WHAT EXCITES THE INNOVATORS?

The panel of innovators share what recent or upcoming technological innovations they are most excited about.

Dr. Mastrota: I find scleral lens materials/designs/solutions/gadgets/technology exciting. So many patients can benefit from expert lens design and fitting. I honor my colleagues who step up to this challenge in our patients with complex diseases. We've also made so much progress in imaging meibomian glands. In the future, I would love to see special technology for evaluating the health of the conjunctiva.

Dr. Trinh: I am excited about the portable devices. Virtual visual field devices and developments in wearable diagnostics will greatly improve the efficiency of clinics and reduce office footprints. The increased portability will also allow doctors a greater reach to deliver high-quality care to a larger audience.

Dr. Krall: I'm still most excited about what we're learning at Neurolens. Aric Plumley, our chief engineer, will never get enough credit for the technology that he has refined with his team. For example, the measuring device he developed takes 10,000 measurements on every patient. The analysis of these data generates a wealth of understanding that will be a great benefit to patients.

Dr. Mahgoub: The application of spatial computing (ie, virtual reality [VR] and augmented reality [AR]) technologies to eye care. The combination of eye tracking and environment tracking sensors with screens (in VR headsets) and holograms (in AR headsets) creates a unique platform for visual diagnostics and treatments. We can potentially use these technologies to assess and enhance patients' visual motor abilities (eg, stereopsis, vergence, accommodation oculomotor skills) and visual information processing abilities.

Artificial intelligence (AI) is another exciting technology being applied to eye care. We will be able to use AI algorithms to expand access to eye care to billions of people around the world who don't currently receive it. There are exciting developments in autonomous AI (eg, operating independently of a clinician), as well as assistive AI (eg, operating in conjunction with a clinician) around the corner, which have potential to be game-changers.

Image courtesy of Augmented Vision Labs.

Figure 4. The S5 Lens Insertion System, invented by Fayiz Mahgoub, OD, helps patients with difficult-to-insert specialty lenses.

experience difficulty with inserting specialty lenses (Figure 4).

Modern Optometry (MOD): What steps did you take when first envisioning your device?

Dr. Mahgoub: I took time to properly research the scope and severity of patient difficulties with lens insertion beyond my personal experiences. I discovered that it was not uncommon for patients to spend 30 minutes to an hour inserting their lenses daily. Some patients are not able to insert their lenses at all, and need to rely on family members or caregivers for help, which compromises their independence. I also learned that patients who struggle with lens insertion incur a larger financial burden, due to consuming larger quantities of nonpreserved saline.

Given these factors, it was not surprising to learn that some patients chose to discontinue lens wear. This was disheartening, because I knew that those patients would be left to choose between poor vision with glasses or invasive options, such as corneal transplantation surgery. A 2019 study by Macedo-de-Araújo et al confirmed and quantified these phenomena, finding that 13% of participants took 60 minutes or longer to insert their lenses, and 27% discontinued lens wear within the first 12 months, with lens handling issues as the top reason (35%).[1]

Dr. Trinh: With a shoestring budget and a lot of creativity, our first goal was simply to create a functioning prototype. Everything we did took longer because it had to be thought out and created in a way to minimize costs. After a dozen prototypes, we came up with a device that became our minimally viable product. Our first Meibox prototype worked, but it was ugly. We created the device, took a few photos of patients, and posted them on social media. Doctors were impressed with the image quality, and their enthusiasm ultimately gave us the confidence that we were on the right track. The rest, as they say, is history.

Dr. Mastrota: Designing the instrument was the first challenge, followed by material choice. The prototype was the next hurdle. Many may remember that the first Mastrota Meibomian Paddle was made with hand-blown glass. Purposely, the "paddle" and the iLidClean (Optego) (Figure 5) each have a simple design, so that the investment to production is nominal, enhancing the chance of a company picking up the idea and bringing it to market. Market selection drives regulatory issues and how the device can be distributed (or not).

Dr. Krall: The first step in creating the Neurolens was developing a device to isolate peripheral vision from central vision. I did this using a shutter lens in conjunction with 3D screens. I spent a great deal of time measuring patients with traditional methods, then seeing what would change when I disassociated the central and peripheral vision and remeasured. Fascinating trends started to emerge.

I have found that the magnitude of misalignment has little correlation with the extent of symptoms. In other words, a patient who is 1.00 D exophoric in the distance and 5.00 D at near can still be much more symptomatic than a patient who is 5.00 D at distance and 20.00 D at near. I found that measuring the balance between these two systems that operate in tandem and adding prism to their lenses significantly reduced their headaches, neck tension, and some digital vision symptoms, such as dry eye.

I started using standard prism correction and testing its utility. I fitted patients with two pairs of glasses that were identical in every way, except one pair had prism correction lenses and the other did not. Patients who spent less time performing near tasks reported a significant decrease in their symptoms. But others working more often at near did not have the same results.

One day, I heard my father tell a patient, "You don't wear the same pair of shoes to church as to the beach, do you?" He was trying to illustrate how two pairs of glasses with different prism corrections were often needed to resolve the difference in alignment at distance versus near. That's how the idea of Neurolenses with contoured prism lenses came to me. Contoured prism describes an increase in the amount of base-in prism at near distance, a practical but elegant solution to the increased misalignment that occurs when we use near vision.

MOD: What has been your biggest challenge?

Dr. Trinh: What hasn't been a challenge in this process is a better question. From product development of the Meibox to navigating device regulations, marketing, pricing strategies, sales, and infrastructure development, obstacles would continuously pop up that we were not anticipating. Just when you

PROTECT YOUR IP

Have an innovation of your own you want to pursue? Here's some advice on how to safeguard your intellectual property (IP).

By Fayiz Mahgoub, OD

Understanding how to protect your IP is very important because without it, you may not be able to fully enjoy the fruits of your labor. It can be a costly process, however, both in terms of time and money, which is why you must be sure you've identified a suitable solution to an important problem before embarking on this path.

Ideally, the problem you're solving is persistent and severe. Ask yourself, is this problem a pain point in someone's life? Would a solution to this problem be a "nice to have" or a "need to have" for the people experiencing this problem? Answers to these questions will help you ensure that your solution provides enough value to the end user to justify adopting it.

Next, decide whether you want to dedicate yourself to solving the identified problem. Ask the following questions:

- Do I have the necessary skills and experience?
- If not, am I passionate enough about it to spend the time and effort to gain what is needed?
- What does success look like? Does success require creating a product that is commercially successful? Or ,is helping people even without financial reward enough?

Once you've decided to embark on your journey, keep in mind that you're traveling in uncharted territory. Success is not guaranteed and may be affected by factors outside of your control. For example, you may fail to achieve commercial success, even if you create an effective solution, due to simple bad timing. If you're not deterred by the possibility of failure, you're probably ready to take on the challenge.

Understanding how to protect your IP is important. I recommend seeking legal advice from an attorney. There will likely be nuances that are applicable to your specific situation and are not obvious to someone without a legal background. The following suggestions are not legal advice, but they may allow you to get more out of your discussion with an attorney by familiarizing you with the fundamental concepts of IP protection. I suggest researching the different types of IP protections available (ie, copyright, trademarks, design patents, utility patents) to see what the right fit could be.

In addition, take time to learn about the process of filing for the IP protections that seem relevant to your project. If you're interested in gaining IP protection in more than one country, familiarize yourself with the available protections and filing processes for each of those countries, because they may vary. At that point, you should have enough information to identify a legal professional who specializes in the services you need. I suggest reaching out to request a consultation to obtain an accurate understanding of the types of protections available, as well as an estimate of the time and expense necessary to pursue them.

think things are going well, bam! There's a new problem to deal with.

With that said, one of the biggest hurdles was figuring out how to market the product. Everyone who has created a product thinks their customers will love it as much as they do. In our case, the Meibox unit was $40,000 less than the next closest competitor and offered amazing quality. However, despite the pricing and the freeform factor, many

doctors just couldn't understand the technology—from its implementation in a dry eye clinic to why it was so different from other capital equipment they'd used in the past.

To overcome this issue, we had to change the way doctors thought about their clinic flow and how they use meibography. With newer technologies, especially in the early days of dry eye treatments, doctors didn't really know what they did or didn't need. The beauty of being a clinician and working with an engineer is that we can tackle the doctors' pain points from a practical and technological perspective. This proved to be our greatest advantage over many of our competitors.

Dr. Krall: For me, the biggest challenge was finding a partner who had the business savvy, determination, and vision to take on a project like this. The founder of Neurolens was on the ground floor to bring LASIK and premium IOLs to the market. He was eager to pursue an opportunity to resolve a problem that had not yet been significantly addressed. He saw that opportunity in Neurolens. I believe that the vision to transform patient's lives, and even the profession, is coming to fruition.

Dr. Mastrota: As you might expect, and as Dr. Krall notes, generating excitement for an idea and finding the correct partner takes effort. Translating the vision of the design to the manufacturer and understanding the limitations of the actual production can be challenging. The Mastrota Meibomian Paddle, for example, was relatively easy. The value of the paddle was that it provided an inexpensive, comfortable tool to act as a backstop for digital pressure to the eyelids. Ocusoft, who manufactures the Mastrota Meibomian Paddle, has been an innovator in eyelid hygiene for more than 35 years. The company saw that the paddle would fill an unmet need in dry eye diagnosis at the time.

Image courtesy of Optego.

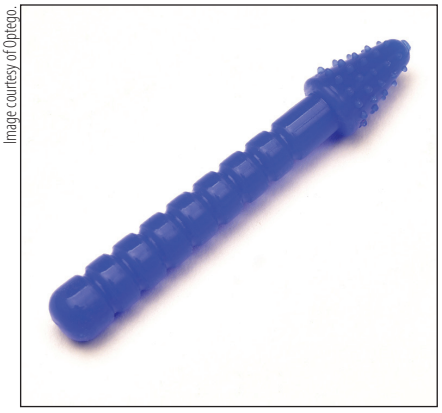

Figure 5. iLidClean, another innovation of Dr. Mastrota's, helps to remove debris from the eyelids, such as mascara residue and bacterial biofilm.

Manufacturing the iLidClean (Optego), however, was a different story. Because it is made of silicone, multiple parameters needed to be evaluated before production. Silicone is gauged in durometers, which defines how stiff or flexible the product feels. To be safe to use, the iLidClean couldn't be too rigid, whereas to be effective, the iLidClean couldn't be too bendable. Then we had to consider the "micro" nubs on the cleaning tip: what size would be most effective, and what was the smallest size that the tooling of the mold could deliver? Optego has expertise in the ophthalmic market and silicone product manufacturing, and so was the perfect partner for this product.

Dr. Mahgoub: My biggest challenge in developing the S5 Lens Insertion System has been efficiently splitting time and resources between the various processes involved with bringing a new product to market, including research and development, manufacturing, supply chain management, customer support, professional education, social media marketing, and business development. The demands of each vary over time, so it's necessary to continuously reassess how much focus each area requires.

MOD: What advice would you give to someone who wants to bring their own idea to market?

Dr. Krall: I've found that the most significant challenge is simply getting started. Once you get rolling with your idea, you can test your results to see if the solution really works. Then, you just have to evaluate if there's a market for the concept and if there is, run hard!

Dr. Trinh: Just do it. There are millions of people who have come up with great ideas, but only a handful who have acted on it. The willingness to act leads to two outcomes: success, or a great lesson. (Notice how I did not say failure, because failure is simply a temporary roadblock in the path to success.) You will not know the way around every obstacle or challenge that presents itself, but if you're willing to put in the effort and resources to try to solve it, you will succeed.

Dr. Mastrota: Don't give up on an idea you believe in. First, decide whether you want to shoulder the financial investment of product development by yourself, or if you're comfortable sharing or selling the idea to a company—and whether you're interested in the royalties on a product, or simply satisfied that it exists. Be clear with any collaborator on your intended role in product development and distribution. These decisions will shift your individual risk/reward equation. It's a personal, lifestyle, fiscal, and time-of-life kind of decision and should be treated as such.

Dr. Mahgoub: Reach out to a diverse group of stakeholders in the space in which you would like to enter and seek their input early and often. For me, this involved consulting with colleagues and patients during the research and prototyping stages, as well as after launching the lens insertion system.

I was able to gain valuable insights that helped shape the development process for the product before launch and helped me further refine it after launch to incorporate user feedback.

MOD: Do you have any other inventions or innovations in the works?

Dr. Trinh: We've expanded our company into data management. Building on the original Meibox software, we created an entire ecosystem called MedBase that connects doctors and patients. MedBase is a HIPAA-compliant, cloud-based data management system that allows doctors to capture images via an iOS app and share images via a secure patient portal.

COVID-19 sped up technology adoption, especially in the medical clinic. With increased labor costs, inflation, and reduced insurance reimbursements, it is important to find low-cost methods to help drive clinic revenue. By providing patients with a portal to view their health data, doctors can help drive out-of-pocket procedures more efficiently by automating the patient education process. Patients downloading their images will likely share their experiences with friends and family via social media, helping practices market their services.

Dr. Mahgoub: I'm developing technology solutions to help make anterior segment photography as ubiquitous as fundus photography. I believe that greater access to this technology will significantly enhance our ability to manage anterior segment disease, as well as educate colleagues and patients. The first product that I created to help address this need is called iSLA (short for iPhone Slit Lamp Adapter). As the name suggests, the device enables providers to connect their iPhone to the slit lamp and capture high-definition photography and 4K video. I will be building on this system in the future by introducing solutions that will further enhance image quality and improve the efficiency of the photography workflow.

Dr. Mastrota: I'm thinking about a nonsurgical, temporary way to help patients with scleral show. The increased exposed ocular surface area predisposes them to dry eye and nocturnal lagophthalmos. ■

1. Macedo-de-Araújo RJ, van der Worp E, González-Méijome JM. A one-year prospective study on scleral lens wear success. *Cont Lens Anterior Eye*. 2020;43(6):553-561.

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