

Incorporating New Technologies Into Practice: The Big Picture

When it comes to managing patients with diabetic macular edema, embracing new treatments requires planning.

BY SZILÁRD KISS, MD

Evaluating a new technology or product primarily involves weighing risks and benefits, with cost as a secondary consideration. Unfortunately, insurers often dictate what we can and cannot use to manage and treat patients. In an effort to provide the best care to my patients, I ignore insurer factors as much as possible in my initial assessments. That is why it is important to stay ahead of the curve with advances in technology. This article explains how I try to do just that.

DO NOT GET LEFT BEHIND

The pace of innovation in the retina field is dramatic. Luckily, for physicians, learning continues in perpetuity. Remaining inquisitive and driven to understand newly available technologies is imperative to providing patients with optimum care. We can keep up to date on treatments and technologies on the way to market and newly available by attending conferences and reading published literature and literature reviews.

When we integrate new technologies into a practice, there is a balance between reasonable financial risk and potential revenue loss due to insurers denying coverage of your expenses. Your benefits manager and the person running your revenue cycle are important allies in determining the expenses your practice can manage while implementing new technologies.

Sometimes there is hesitancy to embrace the reimbursement assistance and support programs that pharmaceutical companies have available for physicians and patients. There may also be reluctance to let drug company representatives into the office to discuss new products; however, they can serve as valuable resources in determining which technologies and products can be integrated into your practice. For example, their insights into which payers cover certain products, how inventory control works, and how often you can expect to be paid

can be beneficial to consider in determining the best course of implementation in your practice.

FILLING UNMET NEEDS

For a new product or technology to be successful, it must fill an unmet need. For example, consider the case of diabetic macular edema (DME), a disease affecting an estimated 746 000 Americans with diabetes.¹ There has been a revolution in the past decade with the introduction of anti-VEGF medications, yet there has remained an unmet need for a therapy that can reduce the frequency of treatment. Anti-VEGF therapy works well, and many patients with DME have benefited from intravitreal injections of ranibizumab (Lucentis, Genentech), aflibercept (Eylea, Regeneron), and off-label compounded bevacizumab (Avastin, Genentech). However, use of these products comes at a cost. For example, it is not unusual for a patient to require up to 10 anti-VEGF injections in the first year of treatment, which presents a significant burden to the patient and his or her family, not to mention the retina practitioner. Additionally, some insurers cover only bevacizumab, or insist on tiered

At a Glance

- It is important to weigh the visual benefits and potential risks of a new drug or technology before deciding to offer it in your practice.
- Pharmaceutical companies' representatives can be helpful in determining which technologies and products to integrate into your practice.
- New products or technologies may be successful if they fill an unmet need.

Fail-Proof Intravitreal Injection Technique

These simple steps may improve your success rate.

By Alexander M. Eaton, MD

Having performed many intraocular injections, I have discovered a few techniques specific to fluocinolone acetonide intravitreal implant 0.19 mg (Iluvien, Alimera Sciences) injections that make the delivery fail-proof every time.

After I have determined that the fluocinolone implant is indeed the best course of treatment, I typically administer 0.5% proparacaine HCl and 4% lidocaine gel. I then perform a subconjunctival injection of 2.0% lidocaine HCl. Approximately 5 minutes after the injection, I take the inserter out of the package, make sure the implant is visible in the window, and load the device by pressing firmly with my thumb on the activator (Figure). It is important to apply a fair amount of pressure so that the implant advances to the correct position in one step. (The cap remains on throughout this step.) In the event there is significant resistance while advancing the activator to load the implant, I replace the device prior to injection.

Next, I administer additional topical proparacaine to the eye, followed by povidone-iodine 5%. After a 20-second pause, I put the lid speculum in, displace the conjunctiva, and insert the injector into the eye, entering perpendicular to the sclera while holding the sides of the injector. Once the injector is inside the eye, I rotate it so that my forefinger is ready to press



Figure. After removing the inserter from the package, make sure the implant is visible in the window, as shown here.

the activator. When it is in place, I press the rear third portion of the applicator button with moderate force using my index finger to move the button all the way forward until it stops to deliver the implant into the eye.

I prefer the patient's eyes to be dilated so that I can confirm delivery of the device by watching carefully as it leaves the inserter. In my experience, this is an optimal time to visualize the implant, as it quickly becomes difficult to do so after injection. If I have not visualized the device leaving the inserter, I confirm that it is within the eye using a 20-D lens. The device is tiny, and it tends to position itself anteriorly, so if there is lens fibrosis around the implant it can be difficult to see. Gonioscopy can also be useful for locating it, as can ultrasound. Finally, I remove the inserter and thoroughly rinse the eye with sterile saline solution.

treatment decisions, despite the fact that ranibizumab or aflibercept may potentially be more efficacious in certain patients (especially in light of the recently published DRCR.net Protocol T results).²

The fluocinolone acetonide intravitreal implant 0.19 mg (Iluvien, Alimera Sciences) is an option that fulfills an unmet need in the current DME treatment paradigm. As a low-dose corticosteroid therapy that delivers 36 months of continuous treatment with a single injection, it provides both an alternative treatment mechanism and relief from the burden of frequent anti-VEGF injections (see "Fail-Proof Intravitreal Injection Technique" above). This corticosteroid implant can provide a substantial visual benefit in patients with DME (see "Case Studies" on the next page), although patients must first be treated with a course of corticosteroids to screen for any clinically significant rise in intraocular pressure (IOP).^{3,4} In the pivotal phase 3 clinical study of the implant, in the population that did not require IOP-lowering surgery, the benefit of treatment with the implant clearly outweighed the risk.

THE BUSINESS OF RETINA

Once the visual benefits and potential risks of a new drug or technology have been weighed, the more commercial—and less medical—aspects must be considered prior to bringing it into your practice.

Although most physicians (myself included) would prefer to analyze only the health risks and benefits of care for patients, our treatment decisions are often affected by economics. Retina practices are a small business. We do not solely care for our patients' health; we must also conduct benefits investigations with insurance companies to ensure that any new drug will be paid for, and we must manage the mechanics of ordering drugs and maintaining inventory.

Insurers generally catch up with technology at some point, but there are times when insurers have yet to accept a product that is available, or they may mandate the use of an off-label product. That being said, many pharmaceutical companies provide programs to assist with patients' out-of-pocket expenses if a prescribed or recommended product is not covered or, as is often

Case Studies

Intravitreal implant improved visual acuity and decreased macular edema in two patient cases.

By Alexander M. Eaton, MD

Identifying patients who will benefit from the 0.19-mg fluocinolone acetonide intravitreal implant (Iluvien, Alimera Sciences) is the first step in its successful use. Patients who do not experience a reduction in edema after one to three regularly spaced injections of an anti-VEGF agent are not likely to show a sufficient response to this treatment option. These patients need an alternative therapy, usually with a corticosteroid. There is also a significant group of patients who are highly inconvenienced by and/or tired of getting frequent ocular injections. Among these, younger patients are still working, and older patients need someone to drive them to their appointments. These patients can benefit from the convenience of the implant.

The US Food and Drug Administration approval for the 0.19-mg fluocinolone acetonide implant states that a patient must have had prior exposure to a corticosteroid without a significant increase in intraocular pressure (IOP). If the patient has previously received steroid injections, you already have this information, but for those with no previous periocular or intraocular corticosteroid exposure, I perform a steroid challenge with prednisolone acetate 1% (Pred Forte, Allergan). I prescribe one drop four times per day and check IOP at 2 and 6 weeks. I have found that patients who make it through this time period without issue are less likely to have pressure spikes with the steroid implant.

Below are two case examples of patients I deemed to be candidates for the implant.

PATIENT 1

An 80-year-old man with a 20-year history of type 2 diabetes and a 12-year history of diabetic macular edema (DME) has been followed by me for a number of years. He has received multiple laser treatments, intravitreal triamcinolone injections, and ranibizumab (Lucentis, Genentech) injections. He has not had a clinically significant increase in IOP with steroids, and his most recent HbA1c was 6.0.

On the day he received the implant, his visual acuity was 20/200 and IOP was 15 mm Hg. Significant DME was visualized via optical coherence tomography (OCT, Figure 1). Approximately 10 weeks after receiving the implant, his visual acuity had improved to 20/80, and the DME had decreased. His IOP has remained in the normal range (12-16 mm Hg), and we continue to monitor him every 3 months.

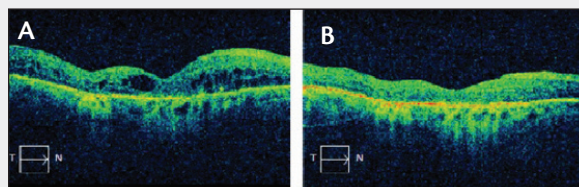


Figure 1. OCT imaging at 2 weeks before insertion of a 0.19-mg fluocinolone acetonide intravitreal implant (A) and 10 weeks after (B).

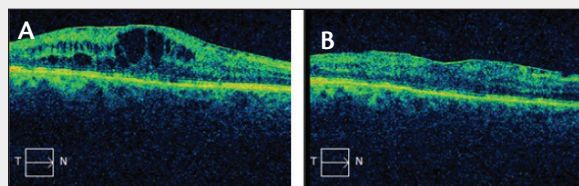


Figure 2. OCT imaging on the day of 0.19-mg fluocinolone acetonide intravitreal implant insertion (A) and the same eye 6 weeks later (B).

PATIENT 2

A 68-year-old man with a 26-year history of type 1 diabetes complicated by a stroke and a 5-year history of DME has been followed by our office for many years. He has received multiple laser treatments and intravitreal triamcinolone, bevacizumab (Avastin, Genentech), and ranibizumab injections. He has not had a clinically significant increase in IOP with steroids, and his most recent HbA1c was 7.0.

Prior to receiving the intravitreal implant, the patient's visual acuity was 20/100, IOP was 14 mm Hg, and significant DME was evident on OCT (Figure 2). At 6-week follow-up, his visual acuity had improved to 20/60, and his DME had improved. IOP has been in the normal range (15-17 mm Hg), and we are monitoring the patient's IOP and DME every 3 months.

Both of these patients are examples of the potential of this implant in our diabetic patients. The FAME study of long-term efficacy and safety of the fluocinolone implant 0.19 mg showed substantial visual benefit for at least 3 years,¹ and we anticipate that these patients will do just as well. These patients who had previous exposure to corticosteroids without a significant increase in IOP have not had any pressure issues since receiving their implants. ■

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“Deciding which new technologies to implement into a practice involves knowing which patient needs are going unmet by current treatment paradigms”

the case, is insufficiently covered. Some income restrictions apply, but most patients qualify for assistance. In addition, most insurers have prior approval and appeal processes, whereby a noncovered treatment can be considered for payment.

Once the determination has been made that a patient is eligible to receive a particular drug or technology, the retina specialist can begin the process of acquiring that product. This includes carrying out a benefits investigation, potentially getting the patient on an assistance program, and performing an inventory management evaluation. Fortunately, most companies have made the process fairly straightforward and expeditious, and often a product will even ship to the practice overnight.

KEEP IT CURRENT

Deciding which new technologies to implement into a practice involves knowing which patient needs are going unmet by current treatment paradigms and which technologies will work best for a particular practice. Using all available resources to stay current on what the best new products are and how they can work for your practice is of utmost importance. Remember to weigh the risks and benefits against the costs, always with the underlying consideration of what is best for your patient. ■

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