

## **Transcript**

(ISI voiceover)

### **Indication**

Xiidra® (lifitegrast ophthalmic solution) 5% is indicated for the treatment of signs and symptoms of dry eye disease (DED).

[Cunningham]

Hello, everyone, and thank you for joining us. My name is Derek Cunningham and I'm an optometrist in Austin, Texas. I work at Dell Laser Consultants. This is an educational program sponsored by Bausch + Lomb, and compensation was received from Bausch + Lomb to present this program. Please note that this is not an accredited CME program.

I'm going to start talking about a patient that came into my office, and this is a real-life patient. This is a fictional picture, but everything else about this patient is kind of spot-on as far as how they presented.

This was a mortgage lender, a recreational tennis player, a 36-year-old female that came in. She had no significant medical history. She, you know, had mild seasonal allergies. She occasionally used an oral antihistamine, but not on a routine basis. She wore daily disposable contact lenses, and her biggest issue was that she was getting end-of-day discomfort that seemed to be getting worse and worse. She was struggling as the day went on, and ultimately, she couldn't use her contacts when she wanted to do recreational stuff afterwards because her eyes were so discomfort.

She had tried preservative-free artificial tears from other providers as well as recommendations from pharmacists, and she just felt like she was getting diminishing returns. She wasn't getting enough relief from them. And the contact lens intolerance issues seemed to be getting worse despite everything that she could be doing to help.

When I looked at her with the slit lamp, we saw, you know, some significant fluorescein staining. Ah, she had some punctate erosion. She also had, yeah, a fair bit of disruption on her corneal topography. Now, some of that's from the contact lenses, but I like to do the corneal topography on everyone because it's a snapshot of what they were like over the last several days to weeks as far as the dryness goes.

Looking at the slit lamp, not only do we see corneal staining, but, you know, not necessary, but we do lissamine green staining sometimes to look for earlier stage dry eye, which you typically see earlier than the corneal staining. You can see lissamine green staining in the interpalpebral area.

As you're looking at the slit lamp, you notice also with the fluorescein, she has kind of a very significantly reduced tear breakup time. And then along the lids, as is the case, many of these patients also have early or varying stages of meibomian gland disease, so I spent a little time letting her know.

Now, if we look at what the potential options are for a patient like this, she's already failed with artificial tears. They're just not giving her significant relief, and she's felt like she's tried many of them. She had been prescribed things like warm compresses, lid scrubs. So, what's the next step? And you can think to yourself, gosh, you know, there's a multitude of things I can do, but here are three potential options that you could do. And I would say that all these options are really with varying levels or increasing levels of patient involvement.

So, you know, you have the first one, which could be a medication that would address the root of the inflammation. They're just using the drop maybe morning and night. You have an OTC gel, which we know gels theoretically last longer than any of the artificial tears or the aqueous based or solutions that she may have been using. They'll give her longer relief, but that's also going to be very laborious for her to use throughout the workday, which obviously is a problem for most contact lens wearers, as well as just dealing with the blur that can occur from using a gel throughout the day. And then you have the last step here with scleral contact lenses. And we'll touch upon some of these things and really where the pros and cons are of all of them, but these are kind of an escalation of options that you could have in your back pocket, and you'd be thinking about using.

So, let's move on to dry eye and contact lens wear. You know, we know that there's a significant correlation between contact lens wear and patients that experience dry eye.<sup>1</sup> Now, dry eye can also be worsened by contact lens wear and can lead to tissue damage and inflammation.<sup>2</sup>

Now, 1 in 5 contact lens wearers may discontinue the use of their lenses due to symptoms.<sup>3,[Xiidra deck,slide8]</sup>

And I think contact lenses and dry eye can go hand in hand, not only because of the pre-existing patient population, but also simply from disruption of the tear film from the contact lens itself.<sup>4</sup>

Symptoms such as discomfort and dryness were identified as leading contributing factors to dissatisfaction and discontinuation,<sup>5,6</sup> and certainly in a LASIK referral practice like we have here as well, we see that is a very significant issue. As a matter of fact, no one ever comes into my clinic saying, "I love contact lenses," who are going to have LASIK. The vast majority of patients that I see coming in are just kind of fed up with discomfort issues, and that's what leads them to us.

So, let's look at one of the options that's available, and this is the option I ended up choosing simply because it was easiest for the patient's lifestyle, and for me it was important as well because there's a wealth of clinical data on it. There is a safety profile that is well established in clinical studies.

You know, it was studied in the four clinical studies that consisted of over 2,133 people.<sup>7\* [Xiidra deck,slide9]</sup> At two weeks, we saw relief from dry symptoms in two of the four trials.<sup>7,[Xiidra deck,slide9]</sup> That's a big deal for us. At 6 and 12 weeks, relief of eye dryness was achieved in all four studies, and you know, so you have uniformity across those studies.<sup>7,[Xiidra deck,slide9]</sup> And at 12 weeks, improvement in inferior corneal staining was seen in three out of the four trials.<sup>7,[Xiidra deck,slide9]</sup> So that allows you as a clinician to look and say, "yeah, I think I see what's going on here".

\*EDS score was used to assess symptoms in 3 of the 4 clinical trials.

So Xiidra® (lifitegrast ophthalmic solution) 5% is indicated for b.i.d. dosing.<sup>7,[Xiidra deck,slide10]</sup>

That's important for a patient like this because they're on the go, they're wearing contacts during the day, and they don't want to use anything during their day. So, for this patient, using the drop morning and night was important.

It's been nearly a decade since its launch, nine years now, and it's given us a lot of experience with it, and it's a proven dry eye treatment choice, in my clinic at least.<sup>7,[Xiidra deck,slide10]</sup>

It's specifically designed to target dry inflammation, the root of what we think causes dry eye.<sup>2,8,[Xiidra deck,slide10]</sup>

Now, Xiidra has delivered early symptomatic relief as early as two weeks,<sup>7†</sup> not only in studies, but you'll see this in clinical practice sometimes as well, and Xiidra was also well tolerated in clinical studies.<sup>7,[Xiidra deck,slide10]</sup> Some of the common adverse event reactions reported in 5 to 25% of patients were instillation site irritation, altered taste sensation, as well as reduced visual acuity.<sup>7‡ [Xiidra deck,slide10]</sup>

<sup>†</sup>Xiidra significantly reduced symptoms of eye dryness at 2 weeks in 2 of 4 studies, with improvements observed at 6 and 12 weeks in all 4 studies.<sup>7</sup>

<sup>‡</sup>The exact mechanism of Xiidra in dry eye disease are not known.<sup>7</sup>

Now, there was a study that was done after all the FDA studies that looked specifically at contact lens wearers.<sup>9</sup> It aimed to prove that Xiidra could increase comfort levels in contact lens wearers, maybe increase the amount of time that they could wear it, but certainly give them symptomatic relief.<sup>9,[Xiidra deck,slide11]</sup> So it's great to see a real-world example done in this study, which was a single-center prospective open-label study, and it enrolled about 40 patients.<sup>9,[Xiidra deck,slide11]</sup>

And really what this was aiming to do is have these patients use Xiidra before they put their contacts in, 15 minutes before they wear their contact lenses.<sup>7,9,10,[Xiidra deck,slide11]</sup> They were asked to discontinue use of lubricants, just so we get a raw example of how the Xiidra was working, and then they used Xiidra again at the end of the day when they took the contact lenses out.<sup>9</sup> And then evaluation points were at day 14, you know, at day 42, and then you looked all the way out to the 12-week data as well.<sup>9,[Xiidra deck,slide11]</sup> So, let's look at really kind of what this was able to do.

And in this study, Xiidra delivered rapid and sustained dry eye symptom relief that really correlated to end-of-day dryness and discomfort, and that was important for us.<sup>9,[Xiidra deck,slide12]</sup> Patients using Xiidra experienced significant reduction of dry eye symptoms.<sup>[Xiidra deck,slide12]</sup> 90% achieved a clinically meaningful improvement in at least three points on the Contact Lens Dry Eye Questionnaire-8 scores versus baseline at 12 weeks.<sup>9,10,[Xiidra deck,slide12]</sup>

Continued use of Xiidra led to roughly two and a half hours of increased comfortable contact lens wear time,<sup>10</sup> and the safety profile was demonstrated in contact lens wearers, whereas the adverse events that were reported were transient dysgeusia and instillation site irritation, and two primary related events both resolved after treatment was discontinued.<sup>9,10,[Xiidra deck,slide12]</sup>

So that has some background also why we choose Xiidra in a contact lens wearer. It wasn't studied, and to be honest with you, in no FDA study with any drugs due to contact lens wear because it is too much of a variable. But to see a real-world example of us looking at how Xiidra could be beneficial in contact lens wearers was important, and that leads a lot into our experience, but also just having some validity to look at and others having success with this as well.

So, we look[ed] at my patient: Patient reported significant reduction in foreign body sensation and discomfort. They weren't using artificial tears nearly as much as they were before. They had relief at the end of most days, which is a great, great start. They had reduced corneal staining, so when I look, I like to have validation too. The patient's symptoms are paramount for me, but I like to look and make sure it's helping as well. And the topographies of both eyes showed significant improvement, as well as I saw a better tear film between blink, and that was important to me.

(ISI voiceover)

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### **Important Safety Information**

- Xiidra is contraindicated in patients with known hypersensitivity to lifitegrast or to any of the other ingredients.
- In clinical trials, the most common adverse reactions reported in 5-25% of patients were instillation site irritation, dysgeusia, and reduced visual acuity. Other adverse reactions reported in 1% to 5% of the patients were blurred vision, conjunctival hyperemia, eye irritation, headache, increased lacrimation, eye discharge, eye discomfort, eye pruritis, and sinusitis.
- To avoid the potential for eye injury or contamination of the solution, patients should not touch the tip of the single-use container to their eye or to any surface.
- Contact lenses should be removed prior to the administration of Xiidra and may be reinserted 15 minutes following administration.
- Safety and efficacy in pediatric patients below the age of 17 years have not been established.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088

**Please see Full Prescribing Information at [Xiidra-ecp.com](http://Xiidra-ecp.com)**

So, I want to thank you for joining us and having a little glimpse at one of my patients and some success that I had around using Xiidra in a contact lens wearer. Take care.

## References

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