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Discussion: Bilateral anti-VEGF treatment

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Session aims

- To provide a summary of the Vision Academy's Viewpoint on bilateral anti-VEGF treatment
- To highlight the key barriers to implementing bilateral anti-VEGF treatment in clinical practice in Europe



Background

Intravitreal injection is the most commonly performed ophthalmic procedure, and injection of anti-VEGF agents is the gold standard treatment for many retinal vascular disorders. Clinical risk and real-life experience have demonstrated that single intravitreal injections carry a very low risk of serious complications when proper procedures and precautions are followed.¹⁻⁴ However, many patients present with bilateral disease, meaning that both eyes require treatment.

Treating each eye at separate, staggered visits adds significantly to the burden of anti-VEGF therapy, essentially doubling both clinic time and cost.⁵ There is potential to substantially reduce this burden by treating both eyes concurrently at the same patient visit. Furthermore, several studies have highlighted that patients undergoing treatment in this manner.⁶⁻⁸

Although the potential benefits are clear, the risks of bilateral anti-VEGF treatment have not yet been thoroughly discussed and evaluated. This Viewpoint offers pragmatic, clinical considerations that should help to mitigate any additional risks.

Endorsed by the Vision Academy
in January 2016.
Date of review: January 2016

Full consensus 1 2 3 4 5

Viewpoint

1. It is possible and reasonable to conduct bilateral injections while observing appropriate procedures and precautions

Bilateral treatment can be defined as simultaneous or consecutive administration of anti-VEGF treatment, with both injections administered during the same patient visit. While some fear that this may pose an enhanced risk of local injection-related complications, there is no evidence to date suggesting that there is an increased risk of ocular adverse events with bilateral treatment compared with unilateral treatment.^{9,10} Furthermore, while there may be a theoretical risk of systemic adverse events associated with intravitreal injection of anti-VEGF agents, there is also no evidence that treating both eyes concurrently alters this risk.¹¹⁻¹³ To manage the risks associated with the injection procedure, it is recommended to follow the guidance outlined in points 2-4 below in cases where bilateral treatment is deemed to be appropriate.

2. The second injection should be treated as a separate procedure within the same visit

To minimize the risk of procedure-related complications or cross-contamination between treatments, each injection should be treated as a completely new procedure. After the first injection, the patient should be prepared again, following the recommended procedure for intravitreal injections. In brief, this should include:

- Surgical disinfection of the surgeon's hands and/or application of new sterile gloves
- Application of povidone-iodine* to the conjunctival sac
- Cleaning of the periorbital skin, eyelid margins and eyelashes with povidone-iodine*
- The use of sterile equipment, including masks, eyelid speculum, forceps, and ophthalmic drapes (if used)¹⁴⁻¹⁶

*Or suitable alternative, such as chlorhexidine

An introduction to bilateral anti-VEGF treatment

- Many patients present with bilateral disease that is treatable with anti-VEGF agents
 - 1 in 4 unilateral AMD cases progress to bilateral disease within 5 years¹
 - Up to 1 in 2 unilateral late AMD cases progress to bilateral disease within 5 years¹
- Patients with bilateral neovascular AMD have reported substantially worse QoL²
- Treating each eye at separate visits adds significantly to the patient and clinic burden³
- Bilateral same-day injections are an appropriate and more convenient treatment option⁴

The Vision Academy defines bilateral anti-VEGF treatment as:

“Simultaneous or consecutive administration of anti-VEGF treatment, with both injections administered during the same patient visit”



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What is the Vision Academy's position?



Vision Academy Viewpoint: Bilateral anti-VEGF treatment

“Simultaneous or consecutive administration of anti-VEGF treatment, with both injections administered during the same patient visit”



It is possible and reasonable to conduct bilateral injections while observing appropriate procedures and precautions



The second injection should be treated as a separate procedure within the same visit



Compounded products should not be from the same batch



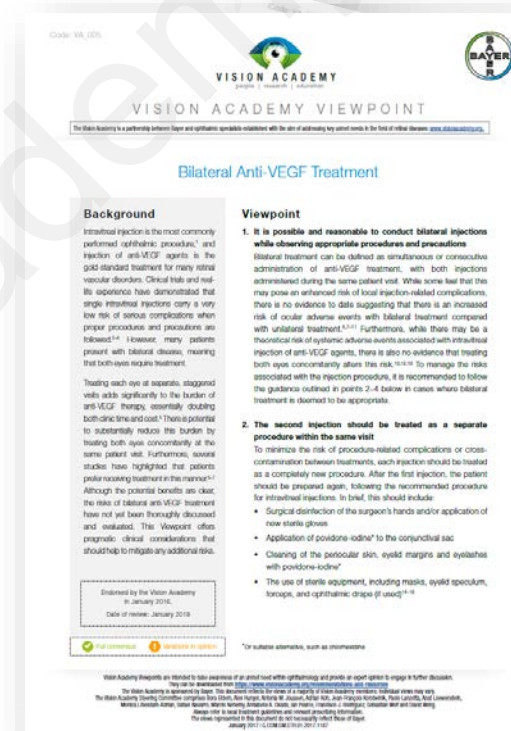
Extra care is required for patients who require bilateral injections at the first visit

Vision Academy Viewpoint: Practical guidance points

It is possible and reasonable to conduct bilateral injections while observing appropriate procedures and precautions



- There is **no evidence** to date to suggest that there is an increased risk of ocular events with bilateral compared with unilateral treatment^{1–5}
- There is **no evidence** that treating both eyes concomitantly alters the risk of systemic adverse events^{1,4,5}



General consensus



Variation in opinion

1. Davis RP *et al. Clin Ophthalmol* 2010; 4: 703–707. 2. Abu-Yaghi NE *et al. Int J Ophthalmol* 2014; 7 (6): 1017–1021. 3. Lima LH *et al. Retina* 2009; 29 (9): 1213–1217. 4. Bayer plc. EYLEA 40 mg/mL solution for injection in a vial – summary of product characteristics; August 2016. 5. Ruão M *et al. Clin Ophthalmol* 2017; 11: 299–302.

Vision Academy Viewpoint: Practical guidance points

The second injection should be treated as a separate procedure within the same visit



- Surgical disinfection of the surgeon's hands and/or application of new sterile gloves
- Application of povidone-iodine* to the conjunctival sac
- Cleaning of the periocular skin, eyelid margins and eyelashes with povidone-iodine*
- Use of sterile equipment, including masks, eyelid speculum, forceps, and ophthalmic drape¹



General consensus



Variation in opinion

*Or a suitable alternative, such as chlorhexidine.

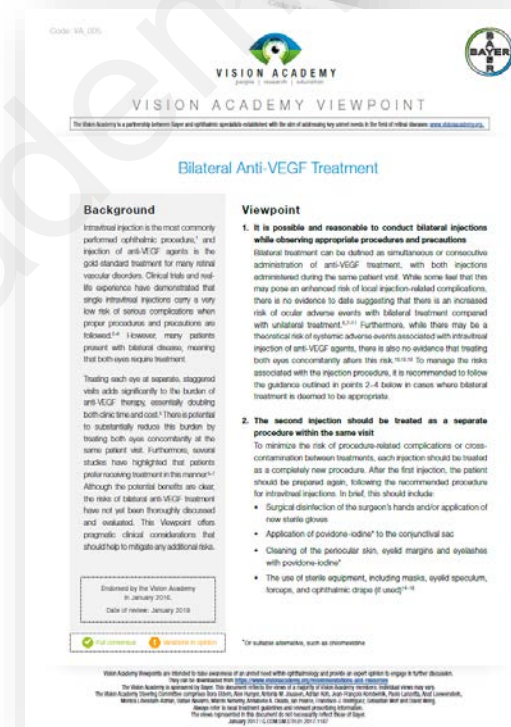
1. McCannel CA *et al.* Updated guidelines for intravitreal injection. Available at: http://www.reviewofophthalmology.com/content/d/retinal_insider/c/55627/. Accessed March 2017.

Vision Academy Viewpoint: Practical guidance points

Compounded products should not be from the same batch



- This is essential to avoid the risks of a contaminated product being administered to both eyes¹



General consensus



Variation in opinion

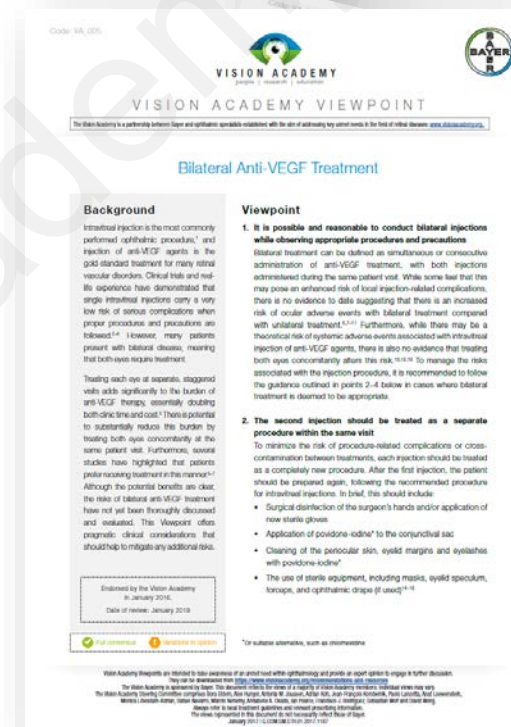
1. McCannel CA *et al.* Updated guidelines for intravitreal injection. Available at: http://www.reviewofophthalmology.com/content/d/retinal_insider/c/55627/. Accessed March 2017.

Vision Academy Viewpoint: Practical guidance points

Extra care is required for patients who require bilateral injections at the first visit



- The preference of the patient should always be taken into account
- There is a small risk that an idiosyncratic hypersensitivity response may occur after the first treatment
- If possible, avoid bilateral injections until the tolerability of the agent has been ascertained
- If bilateral treatment is essential at the first visit, consider separating the injections to allow time for acute hypersensitivity responses to manifest



General consensus



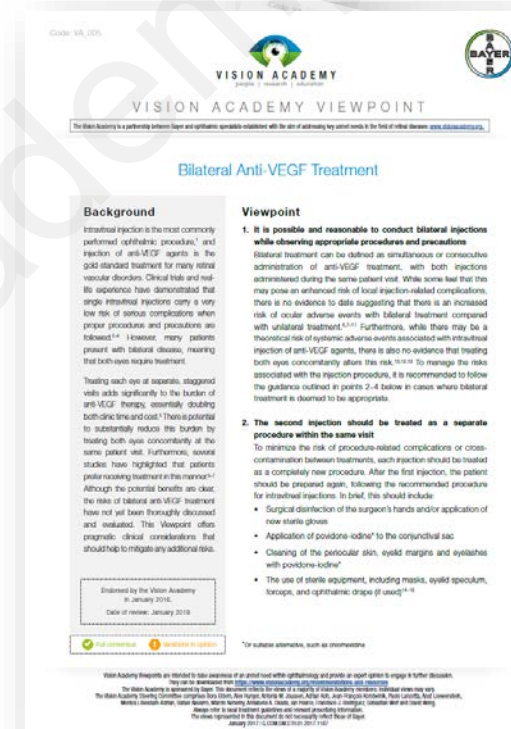
Variation in opinion

Vision Academy Viewpoint: Further considerations

Partial or lack of reimbursement



- Several countries reimburse only partially, or not at all, for bilateral injection procedures
- Physicians have no choice but to treat at separate visits, increasing the burden on patients, clinics, and healthcare systems
- The body of clinical data supporting safety and efficacy of bilateral anti-VEGF therapy must be further developed to enable payors to make informed choices about whether or not to reimburse treatment



General consensus



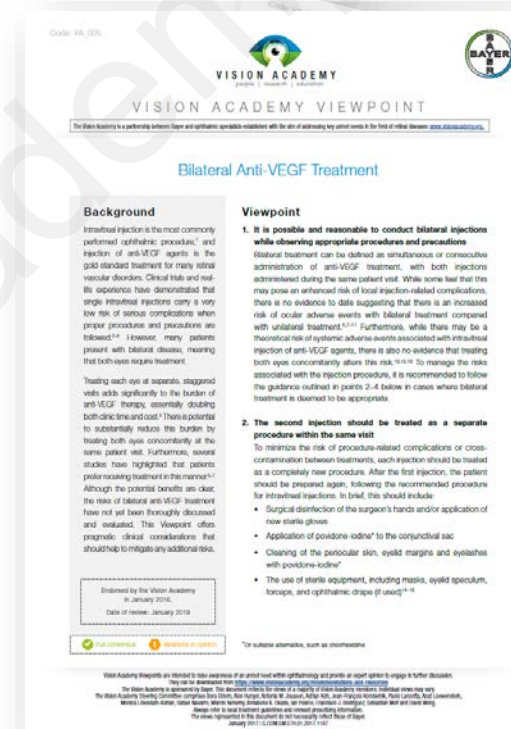
Variation in opinion

Vision Academy Viewpoint: Further considerations

Patients following different treatment regimens



- There is variation in opinion on how to address the needs of patients with bilateral disease who are following a treat-and-extend or PRN regimen
- When extending treatment intervals, the needs of each eye should be considered separately
- It may be preferable to treat both eyes according to the needs of the eye that requires the shortest interval



General consensus



Variation in opinion

Summary



The **Vision Academy Viewpoint** offers practical guidance that should help to mitigate any additional risks associated with bilateral anti-VEGF injections



The body of clinical data supporting safety and efficacy of bilateral anti-VEGF therapy must be further developed to enable payors to make informed choices about whether or not to reimburse treatment



There is variation in opinion on how to address the needs of patients with bilateral disease who are following a **treat-and-extend** or **PRN** regimen



General consensus



Variation in opinion



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Discussion

