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Fluocinolone acetonide intravitreal implant for diabetic macular edema: a case report of a patient with a therapy resistant diabetic maculopathy.

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Purpose

Evaluation of bilateral implantation of a Fluocinolone acetonide intravitreal implant (Iluvien®) in a patient with a therapy resistant macular edema

Iluvien® Drug Delivery Insert

- nonbiodegradable cylindrical tube with a central drug-polymer matrix (3.5 mm in length, 0.37 mm in diameter)
- injected into the vitreous using a 25-gauge proprietary inserter, which allows for a self-seeling wound
- one implant containing 190 µg fluocinolone acetonide (delivering 0.2 µg/day)
- provides a therapeutic effect up to 36 months

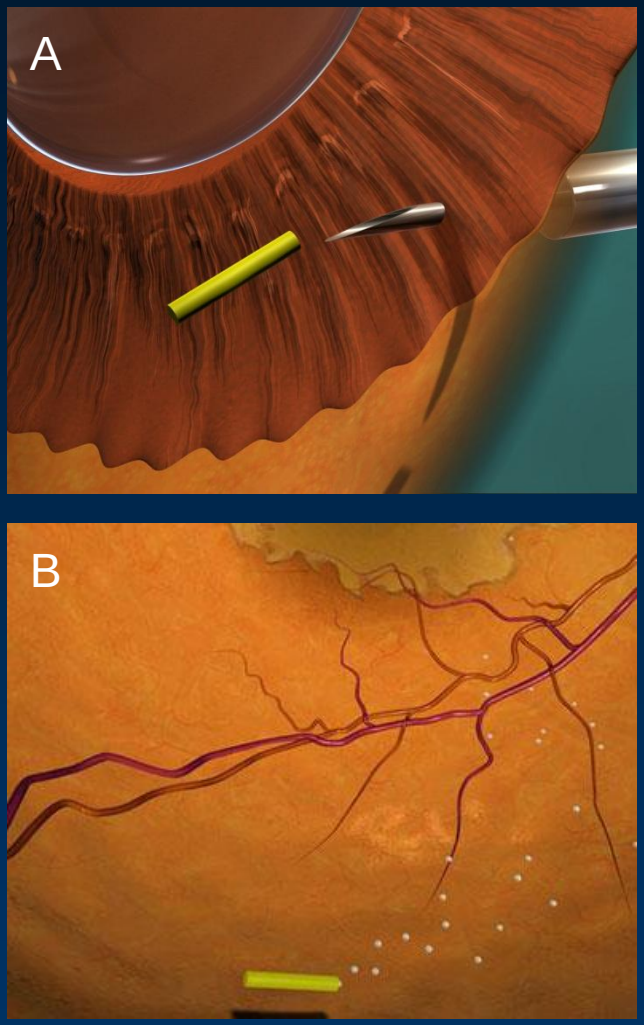

Figure 1A: Insertion into the vitreous body. **B:** Location of the Iluvien implant in inferior vitreous

K. Linz, MD

Patient history

We are reporting of a 87-year-old women with a diabetic Retinopathy who was treated consecutively for diabetic macular edema on both eyes within 5 years in our institution. In-between 2009 and 2013 both eyes were treated with focal laser photocoagulation and multiple intravitreal injections of Anti-VEGF and steroids. The patient almost had to come for follow-up visits and re-treatments monthly, which was very difficult to implement due to her multimorbidity, osteoporosis and hip joint replacement. On August 2013 we decided to inject a long-acting intravitreal fluocinolone acetonide (Iluvien®) implant on both eyes, which obviates the need for repeat procedures during the treatment window.

Patient history

OS:

- 05/27/2009: first consultation presenting a diabetic maculopathy (Fig. 2A)
- treatment with laser focal photocoagulation and multiple intravitreal injections of Anti-VEGF and steroid implants. The following intravitreal injections were performed: Triamcinolon (n=3), Avastin (n=5) and Lucentis (n=4)
- 05/08/2012: Cataract surgery combined with an intravitreal injection of Avastin
- 08/14/2013: Implantation of an intravitreal Iluvien implant

Figure 2A: OCT image of the left eye at the first presentation of the patient with diabetic macular edema

Patient history

OD:

- 11/22/2010: loss of vision due to a diabetic macular edema (Fig. 2B)
- The following intravitreal injections were performed: Triamcinolon (n=2), Avastin (n=3) and Lucentis (n=5). Furthermore focal laser photocoagulation was performed
- 05/18/2012: Cataract surgery combined with an intravitreal injection of Avastin
- 08/12/2013: Implantation of an intravitreal Iluvien implant

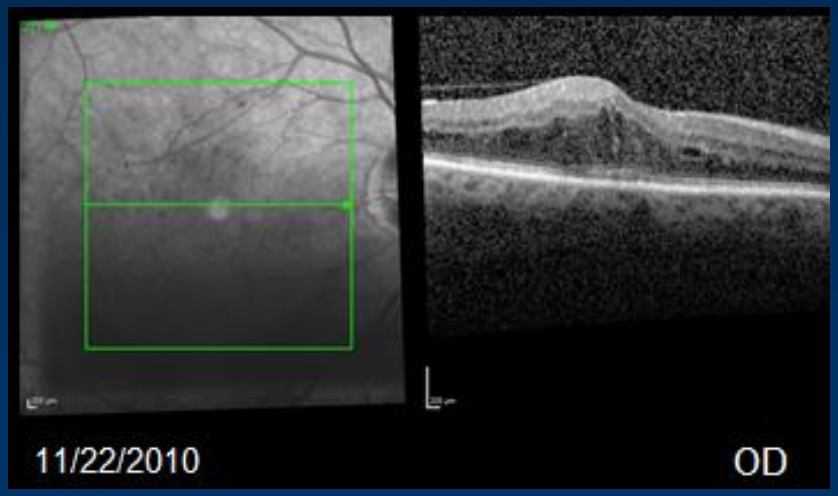

Figure 2B: OCT image of the right eye presenting a diabetic macular edema

Visual acuity over the treatment period of 5 years

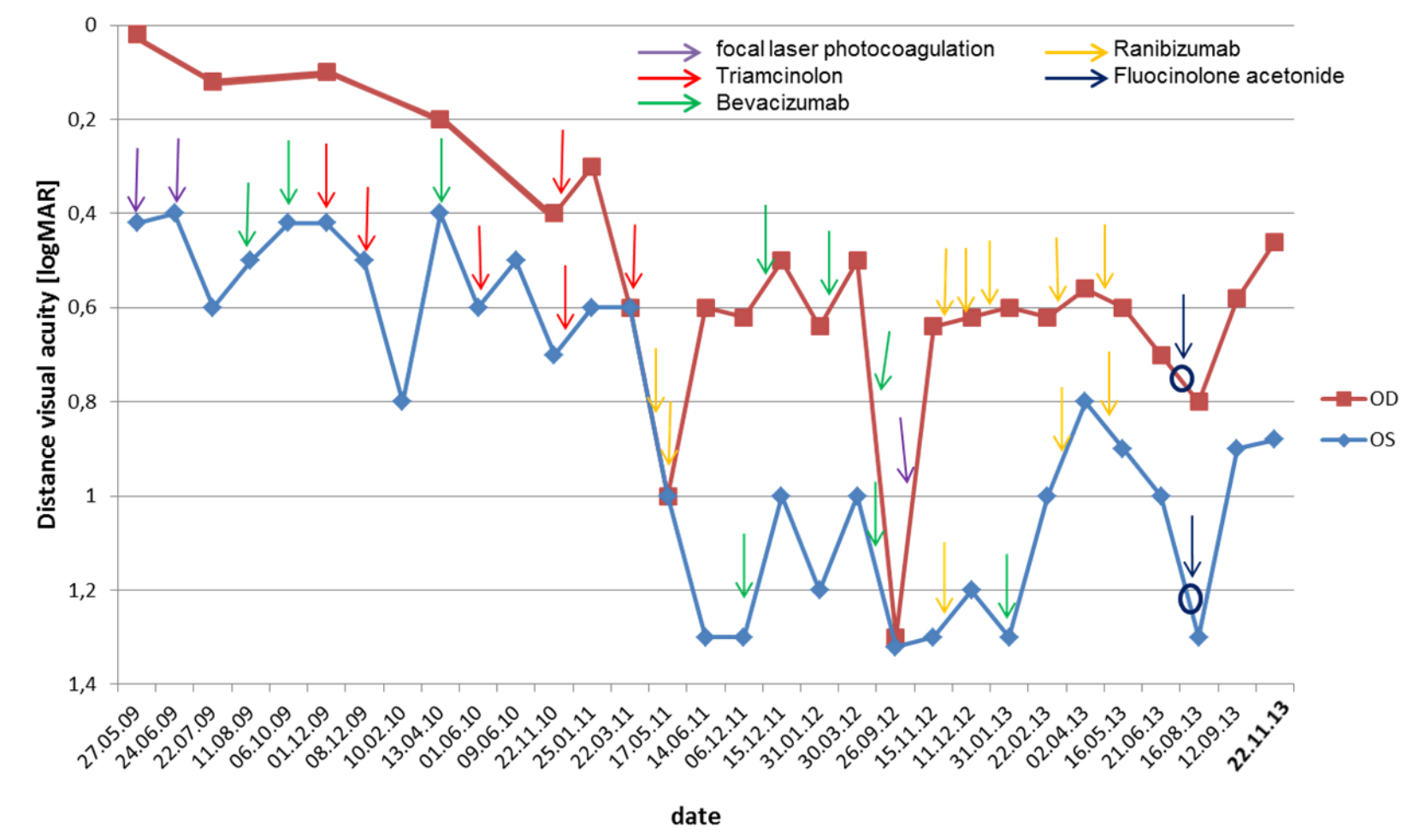

Figure 3: Overview of the uncorrected distance visual acuity (UDVA) in logMAR over a treament period of 5 years. The figure shows no sufficient response under the currently available treatment options

OCT imaging before and after Iluvien implantation

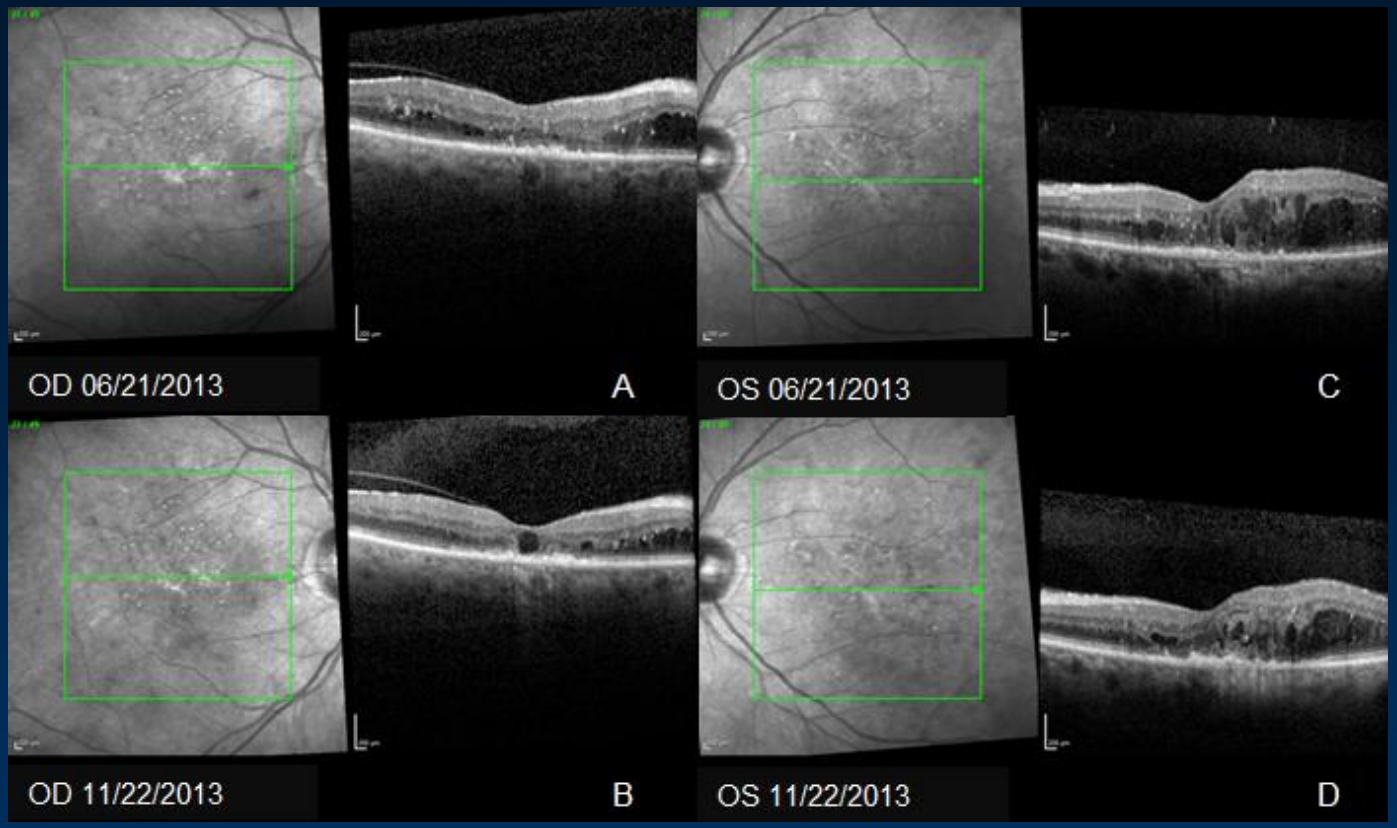

Figure 4A: OCT image of the right eye (OD) before intravitreal injection of Iluvien. The uncorrected distance visual acuity was 0.7 logMAR, central retina thickness 272 µm. (B) OD 3 months after injection. The UDVA improved to 0.46 logMAR, the central retina thickness decresed to 257 µm.

(C) OCT image of the left eye (OS) before intravitreal injection of Iluvien. The UDVA was 1.0 logMAR, the central retinal thickness 312 µm. (D) OS 3 months after injection. Improvement of UDVA to 0.88 logMAR and central retina thickness to 263 µm.

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Intraocular pressure

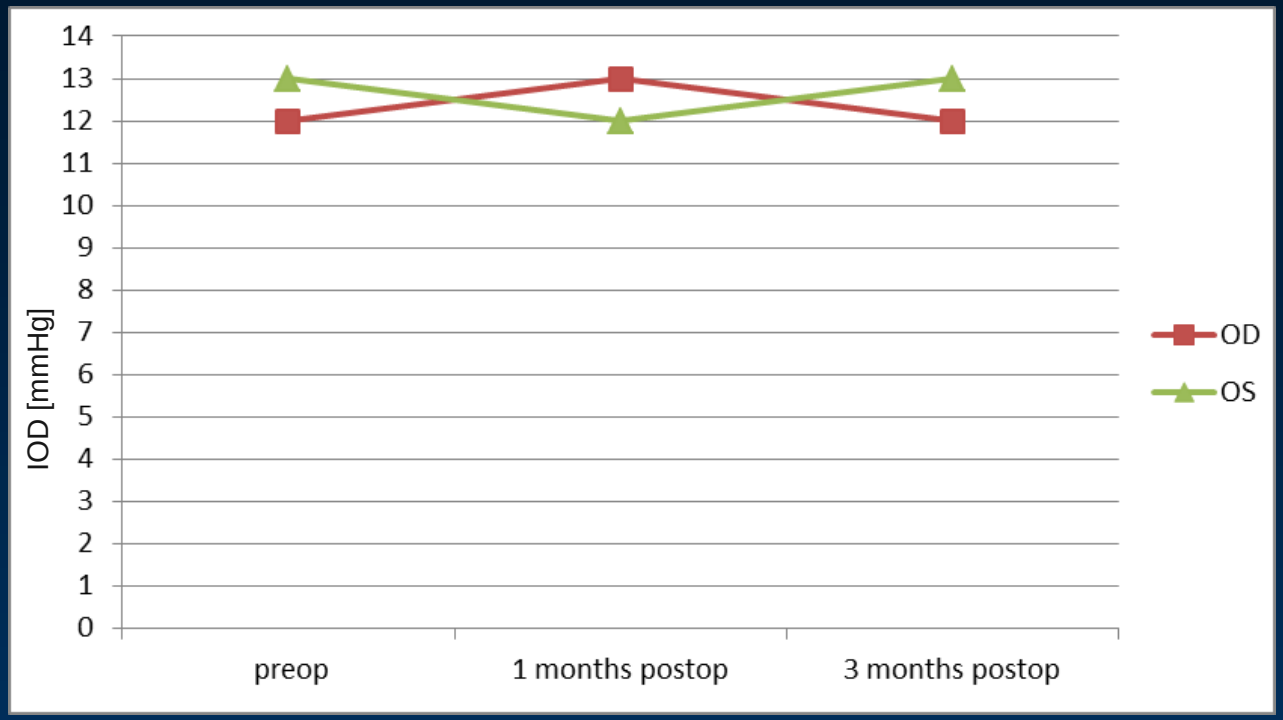

Figure 5: Intraocular pressure (IOP) before, one month and three months after implantation of an intravitreal fluocinolone acetonide implant

The intraocular pressure remained stable on both eyes compared to preoperative measurements

Conclusion

- The implantation of Iluvien offers a sight-saving option for patients with chronic diabetic edema who were previously treated with laser photocoagulation, intravitreal injections of Anti-VEGF or steroids without a sufficient response to the therapy

- The long testing effect also reduces the amount of intravitreal injections and possible risks of complications

- Against the recommendations of the German ophthalmology society and the retina society, bilateral implantation of Iluvien is beneficial for patients with a therapy resistant diabetic macular edema on both eyes

- Based on the safety and efficacy reported by the FAME studies, particularly in patients with chronic DME (≥ 3 years), Iluvien has received its marketing authorization approval in Austria, France, Germany, Portugal, Spain and the United Kingdom for a second-line therapy in chronic diabetic macular edema

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