5-Year real-world efficacy and safety of intravitreal 0.19mg fluocinolone acetonide implant for the treatment of chronic diabetic macular edema

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Introduction

Diabetic macular oedema (DMO) is a leading cause of visual loss in young adults in developed countries. Anti-VEGF agents have become the first line treatment options, but for an estimated 40% of patients, response to anti-VEGF remains sub-optimal. In such cases, intravitreal corticosteroids are a valuable alternative, which works by targeting alternative pathways to VEGF.

ILUVIEN® provides a slow-release preparation of fluocinolone acetonide 0.19mg and is approved by UK regulators for the treatment of chronic DMO that is insufficiently responsive to alternative therapies in eyes with a pseudophakic lens and it offers the advantage of prolonged clinical effects lasting for up to three years. Its effectiveness and safety have been well established in several clinical trials, with the most common adverse effect reported being cataract formation and elevated intraocular pressure (IOP).

Aims of this study

To report on 5-year real-world efficacy and safety data following the treatment of chronic diabetic macular oedema (DMO) with the intravitreal 0.19mg fluocinolone acetonide implant (ILUVIEN).

What this study adds

To our knowledge, this is the first long-term report of real-world safety and efficacy of intravitreal ILUVIEN implant over a 5-year follow-up period in a cohort of 31 eyes at a tertiary ophthalmology centre in the UK.

Methodology

This a retrospective cohort study of patients treated for chronic DMO with an intravitreal ILUVIEN implant (fluocinolone acetonide 0.19mg) from 2014 to 2016 at the Birmingham and Midland Eye Centre (UK).

Inclusion criteria

- Eyes treated with ILUVIEN for chronic DMO between 2014 -2016
- Minimum 5 years follow-up data following treatment with ILUVIEN

Exclusion criteria

- Missing best corrected visual acuity (BCVA) or Optical Coherence Tomography (OCT) data at 5-year follow-up visit

→ 31 eyes from 25 individual patients included in this analysis

Study Endpoints

1) Functional outcome: BCVA at the 5-year visit
2) Anatomical outcome: central retinal thickness (CRT) measured by OCT at the 5-year visit
3) Safety:

- IOP-lowering medication use at 5-year follow-up.
- IOP-lowering interventions (laser or incisional surgery) over 5 years post-ILUVIEN
- Any other serious adverse event

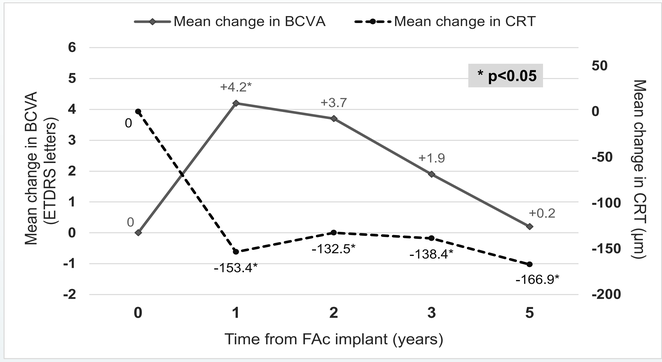
Demographics and baseline characteristics

Mean age was 67 years, and mean DMO duration was 5.9 years. All eyes were pseudophakic and all eyes had received some prior treatment for DMO (97% anti-VEGF, 58% intravitreal corticosteroids, and 68% macular laser).
Five eyes were on IOP-lowering medication at baseline, due to:

- Ocular hypertension (n=3)
- Previous steroid-related IOP elevation (n=2).

Results

1) Functional outcome and 2) anatomical outcome



After 5 years, 13 eyes had improved BCVA >5 letters, 8 eyes had a similar BCVA, and 10 eyes had a worse BCVA with a loss of >5 letters
→ **68% of eyes had a similar or improved BCVA after 5 years**

3) Safety

The rate of treatment-emergent IOP-lowering medication was higher than that reported in other studies.
However, the rate of IOP-lowering interventions (laser trabeculoplasty and incisional surgery) remains low, in keeping with clinical trials results.

IOP-related Outcomes	Eyes (n=31)
On IOP-lowering medication at baseline, n (%)	5 (16%)
On IOP-lowering medication after 5 years, n (%)	22 (70%)
Mean number of IOP-lowering medications after 5 years (±SD)	1.3 (±1.1)
SLT laser, n (%)	2 (6.5%)
Cyclodiode laser, n (%)	1 (3%)
Incisional glaucoma surgery, n (%)	1 (3%)

Other significant adverse events:

Likely related to ILUVIEN :	Likely NOT related to ILUVIEN :
1 case of endophthalmitis (3 days post-ILUVIEN)	1 case of rubeotic glaucoma (>4 years post-ILUVIEN)
1 case of vitreous hemorrhage (6 days post-ILUVIEN)	1 case of rhegmatogenous retinal detachment (20 months post-ILUVIEN)

Treatment burden:

Following treatment with ILUVIEN 42% remained free of intravitreal injections for 5 years. Mean time to first rescue injection was 2 years and 5 months.

→ **69% reduction in treatment burden** following treatment with ILUVIEN implant.

Conclusion

Our real-world results confirm the efficacy of the ILUVIEN implant over 5 years, with two thirds of eyes having improved or stable visual acuity 5 years after ILUVIEN, and an overall sustained improvement in anatomical outcome.

Although the rate of IOP-lowering medications use was higher than previously reported, the rate of incisional IOP-lowering surgery and other complications remained low and suggests the IOP is well controlled using topical medication.

Related Literature

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