Extended real-world experience with ILUVIEN® (fluocinolone acetonide) implant for diabetic macular oedema in the UK: 6-year results from Medisoft® audit study

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Introduction

- The Medisoft audit study was designed to assess the long-term effectiveness and safety of the fluocinolone acetonide (FAc; ILUVIEN) implant in patients with diabetic macular oedema (DMO)
- Following the publication of NICE guidance TA301 in November 2013[1], the Medisoft audit study was designed to assess outcomes with the FAc implant in UK practices
- Real-world outcomes have been reported in patients monitored for ≥3 years[2] and provided evidence of the value of the FAc implant in DMO that persisted or recurred despite treatment
  - *It was well tolerated, with predictable and manageable IOP-related events*
  - *Provided stable or improved best-recorded visual acuity (BRVA) in the majority of patients (≥72%)*

Purpose

- To assess the effectiveness and safety outcomes of ILUVIEN in UK clinical practice over a 6-year period

Methods

- The Medisoft audit tool was used to extract pseudo-anonymised data from electronic medical records (EMRs) across 14 NHS eye units between 2014 and 2022
  - The lead clinician and Caldicott Guardian (responsible nominee for data protection) at each NHS Hospital gave written approval for anonymised data extraction
  - This study was conducted in accordance with the Declaration of Helsinki and the UK's Data Protection Act
- Patients were included if they had DME and had been treated with an FAc implant (Table 1)
  - A total of 256 patients (from 302 eyes) were included
  - Follow-up was ≥3 years
- Clinical effectiveness and safety were analysed EMRs
- Descriptive statistics are reported in the text, Figures and Tables

References

1. NICE Technology Appraisal TA301 published November 2013.
2. Bailey C, *et al. Eye (Lond)*. 2022; 36(5): 1012-1018.

Acknowledgments

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Table 1. Baseline characteristics

Demographics	
Number of eyes / patients	302 / 256
Gender, %	
Male, female	52.0, 48.0
Age, mean (SD), years	64.2 (14.7)
Age at diabetes diagnosis, mean (SD), years	47.2 (15.6)
Type of diabetes, %	
Type I, type II, other / missing	17.9, 77.8, 4.3
HbA1c, mean (SD), mmol/mol	62.3 (19.8)
Pre-FAc history, mean (SD) [range], days	1851.9 (1026.4) [116.0 – 5719.0]
Post-FAc follow-up, mean (SD) [range], months	64.2 (18.4) [36.0 – 123.0]
Ocular characteristics	
Lens status, %	
Pseudophakic, phakic	88.7, 11.3
Mean CRT, mean (SD) [range], microns	441.5 (134.6)[185.0 – 924.0]*
Time since first episode of DME, mean (SD) [range], days	1851.9 (1026.4) [116.0 – 5719.0]
Time since first injection for DME, mean (SD) [range], days	812.1 (617.0) [0.0 – 4129.0]
Time between last treatment and FAc implant, mean (SD) [range], days	188.0 (312.0), [0.0 – 3116.0]
Mean number of FAc implants, injections	1.15 (346 injections)
Mean time to second FAc implant, mean (SD) [range], days	1179.0 (514.0) [14.0-2427.0]

*N=88; SD, standard deviation; FAc, fluocinolone acetonide; BRVA, best-recorded visual acuity; CRT, central retinal thickness; IOP, intraocular pressure

Results

- Long-term improvements in visual acuity were maintained at years 3 and 6.
- Improvements were observed and maintained for all parameters of visual acuity, which included mean BRVA (Figure 1), stable/improved BRVA (Figure 2), the proportion of eyes gaining 6/12 (20/40; Figure 3) vision.
- In terms of safety, mean IOP remained stable and below 21 mmHg throughout (Figure 5).
- IOP-events over the 6 years (Figure 6) were consistent with previously reported findings from Medisoft[2] and confirmed that events were managed with IOP-lowering drops or surgery in a small number of cases.

Author commercial relationship disclosures

BM: Alimera Sciences (R), Alcon (R), Bayer(R), Novartis (R). **CB:** Alcon (F), Alimera Sciences (F), Allergan (F), Allergan (R), Bayer (F), Bayer (R), Novartis (F), Novartis (R), Apellis, Boehringer-Ingelheim, Janssen. **UC:** Apellis (C), Alimera (C), Abbvie (C), Isarna (C), Roche (C), Novartis (C), Unity Biotechnology (C), Deepeye (C), and RetinaAI (C). **AL:** Bayer (C), Bayer (R), Gyroscope Therapeutics (C), Roche (C), Roche (R), Eyebio (C). **GM:** Bayer (R), Novartis (R). **JT:** Alimera (F), Bayer (C), Bayer (F), Bayer (R), BI (F); Roche (C), Roche (F), Roche (R), Novartis (C), Novartis (F).

Figure 1. Mean BRVA

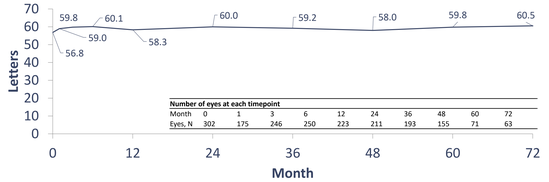


Figure 2. Eyes with stable / improved BRVA



Figure 3. Eyes gaining ≥6/12 vision

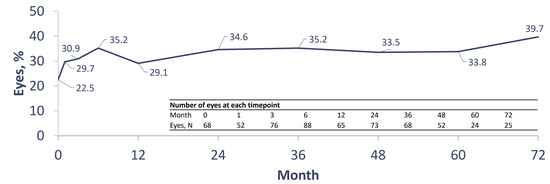


Figure 4. Eyes gaining ≥5, ≥10, ≥15 letters



Figure 5. Mean IOP

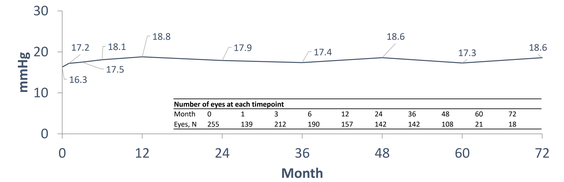


Figure 6. IOP events

N=302	*IOP-lowering medication	**IOP change ≥10mmHg	**IOP ≥25mmHg	**IOP >30mmHg	Laser trabeculoplasty	***IOP-lowering surgery	IOP-trabeculectomy
Eyes, %	23.5	34.4	43.4	21.9	1.70	5.6	4.0
Time to first event, mean (SD), days	633.8 (519.4)	565.4 (602.8)	631.2 (589.4)	766.1 (566.1)	Not calculated		

* Treatment emergent. ** At any time point. IOP, intraocular pressure *** Other procedures included: tube implant for chronic or primary open angle glaucoma; cyclodiode; deep sclerectomy with spacer or insertion of Xen implant laser peripheral iridotomy for primary angle closure bleb resuture/conjunctival suture

Conclusions

- This data was obtained since the first eye was treated in the UK and complement previous findings[2]
- Over the 6-year follow-up, data from real-world practice showed:
  - *Three-out-of-four patients benefited from stable/improved BRVA*
  - *One-in-three patients had a visual acuity of 6/12 or better*
  - *Improvements in BRVA were maintained at years 3 and 6*
  - *IOP events were monitored over a 6-year period*
- The ILUVIEN implant offers an important long-term treatment option for patients where a response to primary DME treatments is sub-optimal
- This is an ongoing audit study that continues to provide clinical insights into the long-term management of DME patients with the FAc implant in UK practices