A retrospective audit to show the impact of introducing a long acting steroid into the DMO treatment pathway in the Eye Department of a District General Infirmary

(Real-World Outcomes of 0.19 mg Fluocinolone Acetonide Intravitreal Implant in Diabetic Macular Oedema: A Clinical and Service Evaluation from NHS Dumfries & Galloway, 2019 to 2025)

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Purpose

- In this study, we present an analysis of 19 eyes from 15 patients treated with 0.19 mg Fluocinolone Acetonide Intravitreal Implant [1] (0.19 mg FAc IVI) for diabetic macular oedema (DMO) at NHS Dumfries & Galloway Hospital between ~2019 and 2025. The aim is to evaluate the real-world effectiveness and safety of 0.19mg FAc IVI and to support the implementation of a new treatment pathway designed to optimise clinical outcomes and reduce burden on healthcare resource use.
- At NHS Dumfries & Galloway, increasing patient numbers and clinical workload have posed significant capacity challenges for the macular service. To address this, several service improvements have been implemented, including the introduction of virtual clinics, the utilisation of nurse injectors, and the adoption of new therapies requiring less frequent administration, such as 0.19 mg FAc IVI. The 0.19 mg FAc IVI provides continuous microdosing of fluocinolone acetonide for up to three years, offering a sustained treatment option[2] with reduced injection visits for DMO.
- A new treatment pathway for DMO incorporating 0.19 mg FAc IVI was implemented in 2022, following approval by the Medicines Scrutiny Committee, who also requested a follow-up audit to evaluate its safety, effectiveness, IVT therapy costs, and impact on service capacity. The aim was to determine whether 0.19 mg FAc IVI could contribute to managing the growing demand within the Macular Service by reducing treatment burden and clinic visits for patients with DMO.

Methods

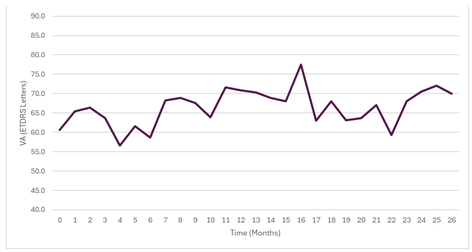
- Data was collected and analysed on all patients who received0.19 mg FAc IVI for chronic DMO and it is part of an on-going retrospective review. Patients were evaluated from time of first Intravitreal Treatment (IVT) to date (n=15). Electronic & paper based medical records were used.
- Data was analysed to determine the effect on best corrected visual acuity (BCVA) by LogMAR chart test, as well as on the central macular thickness on OCT scan over the extended period. The incidence of adverse events including patients showing a significant increase in intraocular pressure as well as those requiring additional treatment were recorded. Cost and resource use were analysed and described.

Demographics

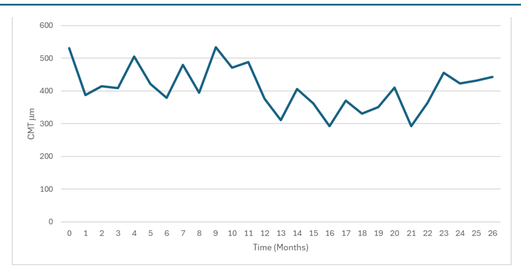
- 100% of the patients in the study were pseudophakic.
- 26.67% of the patients in the study were treated bilaterally with 0.19 mg FAc IVI.
- Average duration of DMO was 6 years from first diagnosis.
- Average time to 0.19 mg FAc IVI was 4 years.
- 46.6% of patients had anti-VEGF supplementary therapy post 0.19 mg FAc IVI (9 anti-VEGF IVT's across 7 patients).

Results

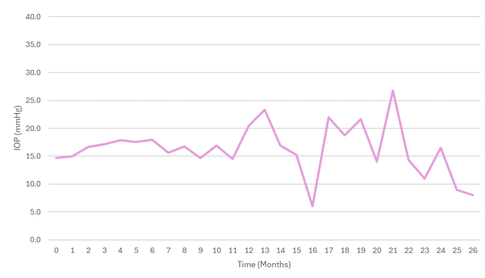
- A total of **19 eyes** of **15** patients were evaluated. Mean VA at baseline, prior to 0.19 mg FAc IVI was (0.49 LogMar) **61 letters** ETDRS (+/-11.2). Baseline IOP prior to 0.19 mg FAc IVI was **14.7**mmHg (+/-3.1) & Baseline CMT prior to 0.19 mg FAc IVI was **530.5**µm (+/-159.9).
- Immediately prior to 0.19 mg FAc IVI **36.7**% of patients had ≥ 70 letters ETDRS (LogMar <0.30).
- Mean BCVA improved from **60.6l** to **65.2l letters** (ETDRS) after first 0.19 mg FAc IVI, an increase of **4.6l letters** with a concurrent reduction in CMT of **530**µm to **383**µm, a 27.7% reduction at 47 Days (mean time to first FU).
- By the final FU (Mean 560 days), BCVA improvement had increased from a mean of **60.6l** to **65.9l letters** (ETDRS), an increase of **5.3l letters** with a reduction of 189µm in CMT from **530**µm to **341**µm, a 35.5% reduction.



Graph 1. Changes in mean VA over time.



Graph 2. Changes in mean CMT over time.



Graph 3. Mean IOP over time.

Maintenance of Functional Vision

- Prior to 0.19 mg FAc IVI **36.7**% of patients had BCVA ≥ 70 letters, at the final recorded follow up visit this had increased to **63.2**%.

Safety

- **16**% of patients were recorded as having an IOP over **25mmHg** during the study with most successfully managed with IOP lowering drops.
- **16**% of patients were recorded as having an IOP over **35mmHg** during the study with most successfully managed with IOP lowering drops. 1 patient required additional surgical or laser procedures and was referred to a Glaucoma specialist for further management.
- The safety outcomes demonstrate that 0.19 mg FAc IVI can be an effective long-term treatment strategy to effectively manage DMO in these patients.

Cost and Resource Evaluation

- Table 1 provides an outlay of all visit and injection frequencies and associated IVT costs over a 6 year period. Direct comparison between pre & post 0.19 mg FAc IVI could not be done as this population, was a single cohort, who were evaluated in a sequential continuum of time.
- In the pre - 0.19 mg FAc IVI phase (4-year duration) patients had an average of ~13.2 IVT injections. This represents suboptimal dosing for a DMO cohort on anti-VEGF therapy. This can be explained as their treatment period coincided with the COVID-19 pandemic.

Table 1 – Audit Data Actuals

Table 1	Pre-FAc Phase	Post – FAc Phase
Patients (n), eyes (n)	15, 19	15, 19
Duration of phase (Years)	4	2
IVT injections (n)	251	19 (FAc)
Supplementary IVTs (n)	N/A	9 (anti-VEGF)
Per Patient injections average (n)	13.2	1.2
Number of clinic visits (n)	251	174
When scaling the 0.19mg FAc IVI phase to a 4-year timeline to match the pre-FAc phase timeline there was a substantial cost-saving favouring use of FAc. When the FAc PAS prices was applied there were further savings. This was derived from a head-to-head comparison of costs on the whole population. In clinical practice corticosteroid therapy is not first line. As per the literature 40% of the population would be more applicable. See Table 2. Note: Scale factor to 4 years and weighting for FAc retreatment (1.14) were applied and supplementary therapies included.		
The list price for all IVTs was applied.		

- As per the literature up to 40% of patients[3] have a sub-optimal response to anti-VEGF therapy and, as per the NICE DR guidelines[4], should be evaluated after 1 year to consider a switch to corticosteroid therapy. Applying a scenario to the actual data; 40% of eyes with sub-optimal response and a switch to corticosteroid therapy after 12 months, the analysis reveals both cost and visit savings that are likely to be generalizable to routine clinical practice. (see Table 2)

Table 2 – Scenario Analysis Applied*

Total population of patients (n), eyes (n)	15, 19	
	1st Line Therapy	2nd Line Therapy
Patients (n), eyes (n)**	9,11	6,8
Duration of phase (years)	4	4
IVT injections (n)	189***	115****
Number of clinic visits (n)	150.6	170
The IVT costs comparison between first line (60% of population) and second line switch (40%) was cost neutral. When the 0.19 mg FAc IVI PAS price was applied the implant was cost saving.		
***Scenario analysis where 40% sub-optimal responders from total population are evaluated separately with introduction of corticosteroid therapy after 1-year (second line therapy).**60% of population evaluated for ongoing 1st line Therapy and 40% of the population evaluated for 1 yr 1st line and 3 yrs second line therapy. ***anti-VEGF therapy only. ****Anti-VEGF + 1 Dex Primer + 0.19 mg FAc IVI (= weighting for additional FAc implant ®) + Supplementary Tx (anti-VEGF IVTs)**		

- As per Table 2 scenario outcomes, where actual IVT and visit frequencies observed during the audit were applied, early transition to corticosteroids as per the NICE DR Guidelines would likely yield a 12.96% reduction in IVT costs. For visit frequencies associated with the 1st line therapy scenario, caution must be exercised when interpreting these, as they are COVID-19 frequencies and are likely to be highly conservative.

Conclusions

- The audit outcomes for 0.19 mg FAc IVI demonstrate long term maintenance of vision along with significant reductions in CMT in patients that have been previously treated and found to be insufficiently responsive to available therapies.
- Patients showed a 4.6l letter gain in VA which was maintained for the period of the study (560 days) and maintained a reduction in CMT. The proportion of patients with driving vision significantly increased. Clinical and safety outcomes are in line with expectations from published real world studies.[5,6]
- Earlier clinical evaluation to consider the transition of treatment to a long-acting corticosteroid therapy, can reduce pharmacological therapy costs and visit burden on both the NHS and patients.
- In the analysis it was found that early switch patients have better visual outcomes.

References

1. 0.19 mg Fluocinolone Acetonide IVI , Summary of Product Characteristics.
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Disclosures

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