Dexamethasone Implant (DEX-I) Delivers on Injection Burden Reduction: Insights From the United Kingdom Medisoft Registry

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OBJECTIVE

To assess the real-world injection burden of anti-vascular endothelial growth factor (anti-VEGF) agents and dexamethasone implant (DEX-I) in treatment-naïve patients with diabetic macular oedema (DMO) during the first year of treatment

CONCLUSIONS

DEX-I maintains a substantially lower injection burden over time versus anti-VEGF therapies in patients with DMO

DEX-I achieved meaningful visual improvements that were comparable to anti-VEGF therapies despite fewer injections

These real-world findings support the use of DEX-I as a durable, efficient treatment strategy for DMO to reduce treatment burden whilst maintaining comparable visual outcomes to anti-VEGF therapies

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INTRODUCTION

- Diabetic macular oedema (DMO) is the leading cause of vision loss in people with diabetes[1]
- Although anti-vascular endothelial growth factor (anti-VEGF) therapies improve vision for many patients, a substantial proportion do not show a complete response despite repeated injections[2–4]
- There is a need to reduce the burden of care for patients with DMO in the real world, with the intensive injection regimen and requirement for multiple hospital visits with anti-VEGF therapies placing a significant practical burden on patients[5]
- Dexamethasone implant (DEX-I) provides sustained delivery of dexamethasone and does not require a loading dose, offering an alternative treatment strategy with a low injection burden for patients with DMO[6]
- The RELIEF study evaluated real-world injection burden and visual acuity outcomes in eyes with DMO treated with DEX-I or anti-VEGF therapies using data from the UK Medisoft registry

METHODS

Study Design

- Two real-world retrospective analyses were conducted using data from the UK Medisoft registry, each evaluating intravitreal therapies for DMO (DEX-I, AFL 2 mg, RBZ, BEV or FAR) (**Figure 1)**

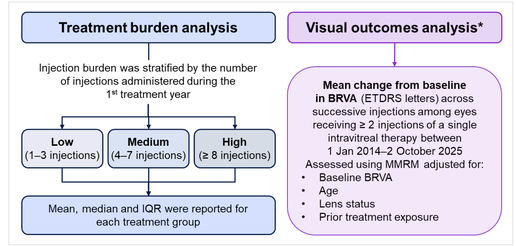
Inclusion Criteria

- ≥ 18 years of age
- Confirmed DMO diagnosis on or after 01 January 2014
- Baseline visual acuity data
- ≥ 3 months of follow-up data

Exclusion Criteria

- Eyes with prior concurrent exposure to alternative intravitreal agents
- Eyes with coexisting ocular pathology (eg, eyes with proliferative diabetic retinopathy and neovascular glaucoma

Figure 1. Study Design



*The analysis accounted for the longer dosing intervals typically observed with DEX-I in clinical practice.
Abbreviations: BCVA, best-corrected visual acuity; DEX-I, dexamethasone implant; DMO, diabetic macular oedema; ETDRS, Early Treatment Diabetic Retinopathy Study; IQR, interquartile range; MMRM, mixed-model for repeated measures.

RESULTS

Baseline characteristics

- Across N = 2883 patients, mean age was 62.4 years (median: 63.0 years)
- Most patients (62.7%) identified as White British and 63.9% were male

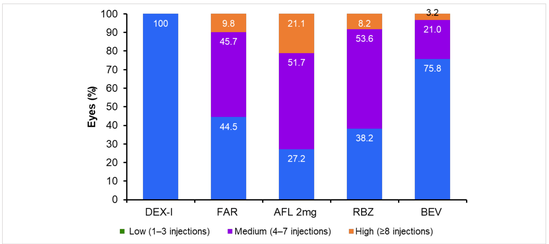
Table 1. Injection Frequency in Year 1

	Mean (SD) Number of Injections	Mean (IQR) Number of Injections
DEX-I (n = 6 eyes)	2.2 (0.4)	2 (0)
FAR (n = 133 eyes)	6.8 (1.5)	7 (2.0)
AFL 2 mg (n = 622 eyes)	7.1 (1.7)	7 (2.0)
RBZ (n = 188 eyes)	6.1 (1.5)	6 (2.0)
BEV (n = 11 eyes)	5.5 (2.4)	5 (3.5)

2019 eyes were included at baseline (DEX-I = 43 eyes, FAR = 407 eyes, AFL = 1093 eyes, RBZ = 414 eyes, BEV = 62 eyes), however not all patients completed the study.
Abbreviations: AFL, aflibercept; BEV, bevacizumab; DEX-I, dexamethasone implant; FAR, faricimab; IQR, interquartile range.

- All anti-VEGF agents show a similar injection burden over 1 year, with AFL 2 mg and FAR requiring the highest number of injections (7.1 and 6.8, respectively)

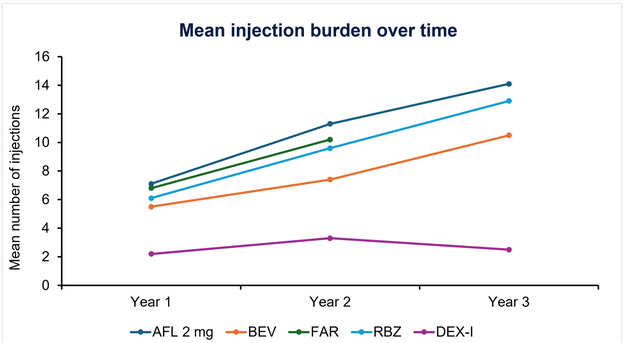
Figure 2. Injection Burden Over Year 1 by Treatment Group



Abbreviations: AFL, aflibercept; BEV, bevacizumab; DEX-I, dexamethasone implant; FAR, faricimab.

- In Year 1, eyes treated with DEX-I fell exclusively in the low-injection category, while anti-VEGF therapies showed distributions spanning all injection categories

Figure 3. Injection Burden Over 3 Years



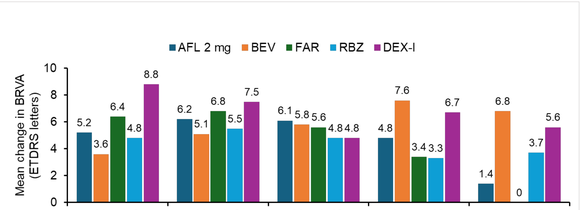
Number of eyes by year, n

	Year 1	Year 2	Year 3
AFL 2 mg	622	307	227
BEV	11	5	2
FAR	133	24	0
RBZ	188	96	69
DEX-I	6	3	2

Abbreviations: AFL, aflibercept; BEV, bevacizumab; DEX-I, dexamethasone implant; FAR, faricimab.

- Mean injection counts increased over 3 years for anti-VEGF therapies, whereas DEX-I maintained a low injection burden throughout the observation period

Figure 4. Mean Change From Baseline in BRVA



Number of eyes, n

AFL 2 mg	1,207	961	807	701	537
BEV	78	48	52	44	45
FAR	320	174	118	59	0
RBZ	618	534	472	437	427
DEX-I	38	25	26	18	12

*A one-way ANOVA based on group means, standard deviations, and sample sizes was used to check for meaningful differences between treatment groups at each time point, estimating the between-group and within-group variance. Significance $P < .05$.
Abbreviations: AFL, aflibercept; BEV, bevacizumab; BRVA, best-reported visual acuity; DEX-I, dexamethasone implant; ETDRS, Early Treatment Diabetic Retinopathy Study; FAR, faricimab.

- No statistically significant differences seen across AFL 2 mg, FAR and DEX-I at any time point up to Month 18*:
  - Month 3: $P = .06007$ → Suggests non-significant trend towards higher efficacy with DEX-I
  - Month 6: $P = .7717$
  - Month 12: $P = .8474$
  - Month 18: $P = .7346$

- Despite the lower injection frequency for DEX-I, the magnitude and durability of vision gain were comparable to anti-VEGF therapies