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Scleral fixation of fluocinolone acetonide implant☆

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ABSTRACT

Purpose: To report on the technique of scleral fixation of fluocinolone acetonide (FAc) implant in 2 eyes with recalcitrant diabetic macular edema (DME).

Observations: Two eyes of 2 patients with persistent DME, partially responsive to anti-VEGF therapy, underwent intravitreal FAc implant injection. First case had a history of pars plana vitrectomy (PPV) and scleral fixated posterior chamber intraocular lens implant (PCIOL) for retained lens fragments and dislocated IOL. Subsequently, the patient presented with intermittent anterior chamber migration of the FAc implant associated with an increase in DME. The FAc implant was fixated to the sclera, preventing further migrations, and improving the DME. The second case had a history of persistent DME, PCIOL with open capsule, epiretinal membrane (ERM), and a free-floating FAc implant within the vitreous cavity. She underwent PPV, membrane peel, and simultaneous scleral fixation of the free-floating FAc implant. The surgical technique included 23 G PPV, externalization of FAc implant, re-implantation and scleral fixation through the same sclerotomy utilizing a 10/0 prolene suture.

Conclusions and Importance: A surgical technique for scleral fixation of FAc implant is described. The technique is valuable in the management of patients with persistent diabetic macular edema or uveitis who benefit from treatment with fluocinolone acetonide implant but are at risk for anterior chamber migration of the implant.

1. Introduction

Intravitreal corticosteroid therapy is an effective treatment modality in the management of diabetic macular edema (DME) and posterior uveitis. In the setting of DME, dexamethasone intravitreal implant (Dx) (Ozurdex; Allergan Inc, Irvine, CA, USA) and fluocinolone acetonide implant (FAc) (Iluvien; Alimera Sciences Limited, Alpharetta, GA, USA) provide a valuable additional therapeutic option in eyes with suboptimal response to anti-vascular endothelium growth factor (anti-VEGF) therapy. Longer duration of action is an added advantage of corticosteroid implants. Fluocinolone acetonide implant (Yutiq, EyePoint Pharmaceuticals, Inc., Watertown, MA) has recently been approved by the FDA for the treatment of chronic posterior uveitis. Potential side effects of intravitreal steroid implants include elevation of intraocular pressure (IOP), cataract progression, and anterior chamber migration of the implant.

Anterior migration of a dexamethasone implant into the anterior chamber may result in corneal decompensation due to endothelial toxicity and requires prompt removal or repositioning.[1,2] Anterior migration of FAc implant may cause corneal endothelial damage by repetitive mechanical trauma due to eye movements.[3–5] Furthermore, a moving implant is often visually symptomatic giving rise to episodic blurring of vision and floaters. Removal of an intermittently migrating FAc implant has been reported, however, it is desirable to retain the implant when possible. In 2018, Tabandeh described scleral fixation of an intermittently migrating fluocinolone acetonide implant in order to conserve the implant while minimizing risk of future migration.[6] Subsequently, Herold and colleagues reported on scleral fixation of the fluocinolone acetonide implant in 2 eyes with disruption of iris-lens diaphragm.[7]

We report on two patients with DME who underwent scleral fixation of FAc implant.

2. Findings

2.1. Case 1

In July 2017 an 83-year-old man with IDDM and severe non-

☆ The surgical technique for the first case was originally presented at the American Society of Retinal Specialist Annual Meeting, Vancouver, July 2018.

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proliferative diabetic retinopathy (NPDR) underwent injection of FAc implant for the treatment of persistent DME in the right eye. Prior to the injection of FAc implant, the patient had received multiple injections of anti-VEGF drugs including ranibizumab and aflibercept with partial response. Past ocular history included complicated cataract surgery, retained lens fragment, dislocated posterior chamber intraocular lens implant (PCIOL), and corneal edema in the right eye with subsequent pars plana vitrectomy (PPV), removal of retained lens fragments, and scleral fixation of a PCIOL.

At the time of FAc injection, the VA was 20/200, the PCIOL appeared well positioned, and corneal edema, DME, and severe NPDR were present. OCT showed presence of intraretinal fluid and retinal thickening with a CMT of 727 μm (Fig. 1A). Two months after FAc injection the VA improved to 20/100, and CMT decreased significantly to 396 μm (Fig. 1B). The patient presented 4 months after FAc injection with reduced vision and a 3 weeks history of intermittent anterior migration of the implant. On evaluation, VA was 20/200, corneal edema was unchanged, FAc implant was present within the anterior chamber, and DME had increased with OCT showing a CMT of 520 μm (Fig. 1C). In view of multiple prior episodes of anterior migration and history of suboptimal response to anti-VEGF therapy, it was elected to preserve the existing implant but to fixate the implant to sclera in order to prevent further episodes of anterior migration. Once in the operating room, it was noted that the implant had migrated back to the posterior segment. Therefore a 23G PPV approach was used to retrieve and externalize the FAc implant for scleral fixation. Six weeks after scleral fixation of the implant VA was 20/200, and macular edema had improved with a CMT of 458 μm (Fig. 1D).

2.2. Case 2

A 68-year-old woman with longstanding history of NIDDM, severe NPDR, persistent DME, and multiple injections of anti-VEGF drugs including bevacizumab and aflibercept underwent intravitreal injection of FAc implant OU. Past ocular history was notable for PCIOL, posterior capsulotomy, and epiretinal membrane. At baseline, VA was 20/100, and OCT demonstrated a CMT of 537 μm. Two months after the FAc injection the patient described intermittent episodes of bar-like floater and blurring of vision. The VA was 20/80 and CMT had decreased to 480 μm. Funduscopy showed the implant was floating within the inferior vitreous cavity. Five months following the FAc injection, VA was 20/80, persistent DME with CMT of 465 μm, and ERM were present. In view of the persistent DME, presence of ERM, pseudophakia with open capsule, and a free-floating implant, the patient underwent 23G PPV, stripping of ERM, with scleral fixation of the FAc implant. At 2 months follow up, VA was 20/80, ERM had improved, and CMT had improved to 400 μm.

2.3. Surgical technique

A 23G PPV approach, using 25 G MaxGrip forceps (Alcon/Grieshaber, Schaffhausen, Switzerland), was utililized to retrieve and externalize the FAc implant from the posterior segment in both cases (Fig. 2A). In the first case, the option of tying a 10-0 prolene suture around the implant was considered, however, in view of the history of intermittent anterior chamber migrations and high risk of implant migration, the suture was passed through the lining of the implant in order to minimize risk of future migrations (Fig. 2B). In the second case, the suture was tied around the FAc implant by making 2 loops around the central part of the implant followed by 3/2/1 knots. This was repeated once more. In both cases, the supratemporal sclerotomy cannula was removed and the implant was gently inserted through the preexisting sclerotomy while ensuring the integrity of the supporting suture (Fig. 2C and D). Once the implant was completely introduced into the vitreous cavity, the supporting suture was gently pulled back allowing a slack of approximately 1 mm. The suture was subsequently secured to the sclera while closing the sclerotomy at the same time (Fig. 2E). The position and stability of the implant were confirmed by scleral-depressed visualization (Fig. 2F).

3. Discussion

Khurana et al. reported on a series of 15 eyes with anterior chamber

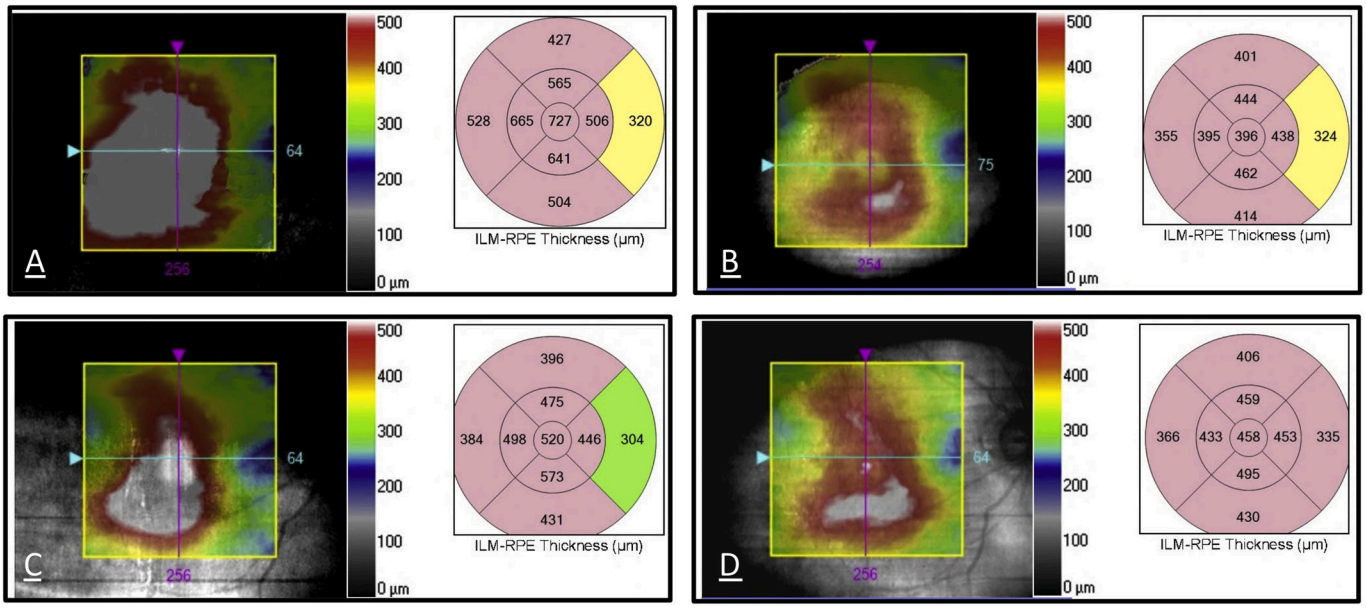

Fig. 1. OCT for case 1 at baseline, 2 months after injection of FAc implant, at the time of anterior migration of the implant, and 6 weeks after scleral fixation of the implant.
A) OCT at baseline showing macular edema with a CMT of 727 μm.
B) OCT 2 months after FAc injection showing decreased CMT to 396 μm.
C) OCT showing increased CMT to 520 μm associated with anterior chamber migration of the FAc implant.
D) Six weeks after repositioning and scleral fixation of the implant the CMT improved to 458 μm.

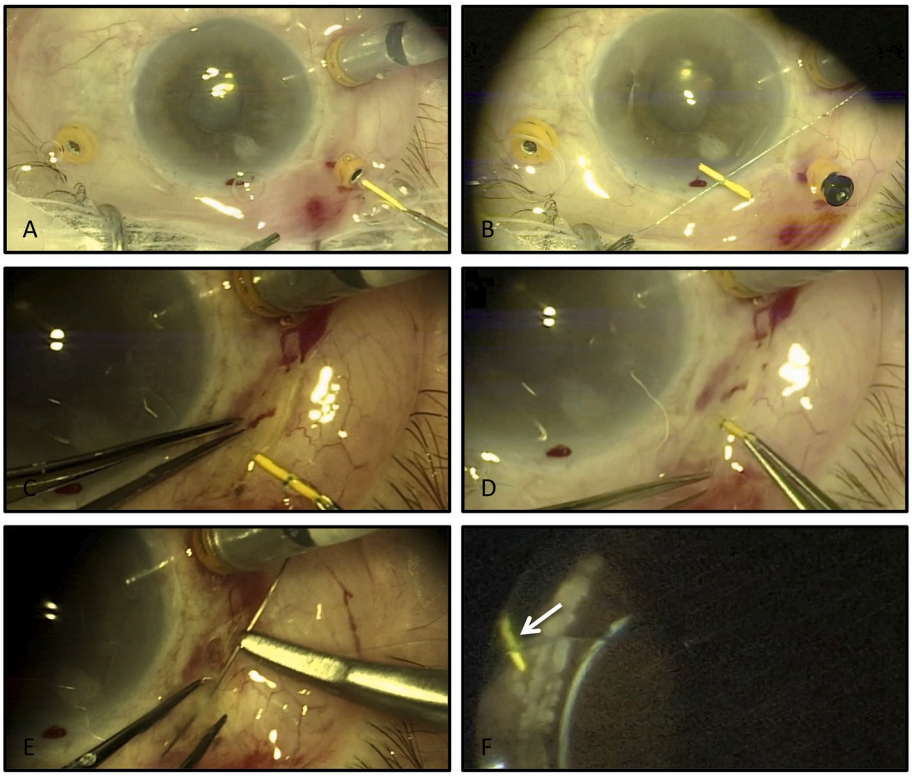

Fig. 2. Intraoperative video grab images.
A) The FAc implant is retrieved from the vitreous cavity and externalized through the 23G sclerotomy cannula.
B) A 10/0 prolene suture is used to secure the implant. The suture is tied around the implant making 2 loops.
C) and D) The supratemporal sclerotomy cannula is removed and the implant is gently inserted through the pre-existing sclerotomy while ensuring the integrity of the supporting suture.
E) The 10/0 prolene suture is secured to the sclera, fixating the FAc implant while closing the sclerotomy at the same time.
F) Intraoperative scleral depressed visualization confirms t he position and stability of the FAc implant (arrow).

migration of Dx implant associated with corneal endothelial toxicity, transient or refractory corneal edema, and steroid-induced glaucoma. The authors suggested early surgical removal in order to limit corneal damage and risk of glaucoma.[1] Aphakia, anterior chamber intraocular lens implant, large defects in the posterior capsule, zonules or iris, and prior vitrectomy are risk factors for anterior migration of intravitreal implants.[1,2]

In 2014, FDA approved use of FAc implant for DME. Subsequently, cases of anterior migration of FAc implant have been reported. In 2015, El-Gharaby et al. reported on anterior chamber migration of a FAc implant in a patient with history of complicated cataract surgery, sulcus fixated PCIOL, and PPV for retained lens material.[3] The implant was repositioned into the posterior segment through the existing capsule defect. IOP was elevated at the time of presentation, however, it returned to normal range after repositioning of the implant. Papastavrou et al. reported on anterior chamber migration of FAc implant in 2 eyes with history of complicated cataract surgery and PPV.[5] In both cases the implant was repositioned into the vitreous cavity, with 1 case developing a recurrent migration resulting in the removal of the implant. Both cases demonstrated corneal edema that improved after repositioning/-removal of the implant. Gunzenhauser et al. reported intermittent anterior migration of a FAc implant in an eye with a history of complicated cataract surgery, capsule defect, and PPV for retained lens fragments.[4] Posterior relocation was accomplished by supine positioning. Mild corneal edema developed 6 months after injection of a second FAc implant. The corneal edema improved after repositioning of the implant and prevention of further migration by topical pilocarpine. In 2018, Tabandeh reported on scleral fixation of a migrating FAc implant utilizing a 10/0 prolene suture in order to minimize risk of recurrent migrations.[6] Subsequently, Herold et al. described a similar technique of scleral fixation of FAc implant in 2 eyes with iris-lens diaphragm disruption at risk for implant migration.[7] The fixation technique is relatively simple and may be combined with other procedures performed for co-existing morbidity. A PPV approach is not needed for primary fixation of the implant or when the implant is present within the anterior chamber at the time of surgery. Placing the suture through the lining of the implant provides additional stability and reduces the risk of recurrent dislocation. However, full thickness penetration of the lining may be associated with increased exposure to the acqueous medium and altered pharmacokinetics. Alternatively, the suture could be tied around the implant, with a slight risk of future migration.

Intravitreal corticosteroid implants are important additional therapeutic option in eyes with suboptimal response to anti-VEGF therapy. However, anterior migration of Dx implant is associated with severe and irreversible corneal endothelial toxicity. Eyes at high risk for anterior migration of an implant present a management challenge. In these eyes treatment options are limited and outcomes are suboptimal. FAc implant is a valuable treatment modality for these cases, knowing that FAc implant is less likely to cause corneal damage short-term and it may be scleral fixated if needed. In our first case, the FAc was scleral fixated because of anterior chamber migration. Anterior migration of the implant was associated with an increase in DME that improved after repositioning of the implant. It is possible that anterior migration of the implant resulted in a lower concentration of drug within the vitreous cavity, restored by repositioning and scleral fixation. The primary reason for surgery in our second case was persistent DME associated with ERM. Additionally, the patient was symptomatic with a floating implant. It was considered that following PPV the implant may become more mobile resulting in increased floater symptoms and higher risk of anterior chamber migration. Therefore, the opportunity was taken to fixate the FAc implant at the time of ERM surgery. A 23G PPV approach was used to retrieve and externalize the FAc implant. Although a smaller gauge PPV platform may be used, a smaller gauge cannula risks compression of the implant by the forceps during transit through the cannula. Use of 25 G or 27 G forceps in conjunction with a 23 G cannula reduces the risk of implant compression.

4. Conclusion

In summary, an anteriorly migrated FAc implant does not appear to

have severe toxic effect on corneal endothelium, however, it may have an adverse effect by physical contact and repetitive trauma associated with eye movements. Presence of FAc implant within the anterior chamber may be associated with higher concentrations of drug at the trabecular meshwork, increasing risk of steroid-induced glaucoma, and a lower concentration of drug within the vitreous cavity diminishing efficacy. Scleral fixation of a FAc implant may be considered in cases with anterior migration of the implant and in eyes with high risk of migration such as lens capsule defect, anterior chamber IOL, scleral fixated PCIOL, aphakia, prior vitrectomy, children, and when later removal may be contemplated.

Patient consent

Consent to publish the report was not obtained. This report does not contain any personal information that could lead to the identification of the patients.

Author contributions

Homayoun Tabandeh: Conceptualization, Methodology, Data curation, Manuscript preparation, reviewing and editing.

Kourous Rezaei: Data curation, Manuscript preparation, reviewing and editing.

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Homayoun Tabandeh: Alimera Sciences Ltd.- stock ownership.

Kourous Rezaei: None.

- All authors attest that they meet the current ICMJE criteria for Authorship.

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