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Authors

Knight, Darren K Wang, Angeline L Tsao, Sean W et al.

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1	Small Gauge Techniques for Removing a Fluocinolone Acetonide Implant
2	Darren K Knight, MD ¹ , Angeline L Wang, MD ² , Sean W Tsao, MD ³ , Steven L Carter, MD ⁴ ,
3	Mitul C Mehta, MD, MS ⁴
4	1. Shiley Eye Institute, University of California, San Diego, CA, USA
5	2. Department of Ophthalmology, UT Southwestern Medical Center, Dallas, TX, USA
6	3. Department of Ophthalmology, Southern California Permanente Medical Group, Orange County, CA, USA
7	4. Gavin Herbert Eye Institute, University of California, Irvine, CA, USA
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16	Corresponding Author/Address:
17	Mitul Mehta, MD MS
18	University of California, Irvine
19	850 Health Sciences Road
20	Irvine, CA, USA 92697
21	mcmehta@hs.uci.edu

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23	Key Words:
24	Fluocinolone Implant, Explantation, foreign body, Illuvien, Vitrectomy, Vitreous
25	Explanting Fluocinolone Implant
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27	Brief Summary Statement:
28	This article describes surgical techniques that may be used for removal of a non-dissolvable,
29	long-acting fluocinolone acetonide implant without causing damage to the vitrectomy system.
30	The implant can be safely vitrectomized or removed en bloc using commonly available surgical
31	instruments.
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44 Abstract

45 **PURPOSE:** Long-acting injectable fluocinolone releasing implants are used in clinical practice. 46 We set out to describe possible explantation techniques and to determine whether these implants 47 can be safely removed from a standard sclerotomy or eliminated using a vitrectomy system. 48 METHODS: A vitreoretinal surgery system was designed using a porcine eye model. A 49 fluocinolone implant was injected into the vitreous cavity. Pars plana vitrectomy was performed 50 and the vitreous cavity was infused with balanced salt solution. The injected implants were 51 removed from 23-Gauge (G) and 25-Gauge (G) vitrectomy cannulas with 27-G forceps. The 52 implants were examined under the microscope for induced defects. The implants were reinjected 53 into the eye model and eliminated using a 23-G and 25-G vitrector system. 54 **RESULTS:** The implant was removed from both the 23-G and 25-G vitrectomy cannulas 55 without causing structural damage to the implant. During implant extraction through the 25-G 56 sclerotomy, the cannula was dislodged from the incision along with the implant. The most 57 technically challenging portion involved aligning the implant coaxially to allow for removal en 58 bloc through the sclerotomy site. Implants could be completely eliminated using both the 23-G 59 and 25-G vitrector using a low cut rate. 60 Conclusion: The fluocinolone implant was removed safely via standard 23-G or 25-G

61 vitrectomy systems. It is unknown whether intraocular manipulation will affect pharmacokinetics

62 of drug delivery if the implant is not explanted.

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66 Introduction

67 Long acting intraocular corticosteroid implants are used in the treatment of a number of ocular conditions, including diabetic macular edema and uveitic macular edema.¹⁻³ A number of new 68 69 devices offer extended dosing of the medication with a single in-office application. The 0.2 70 µg/day fluocinolone acetonide intravitreal implant (FAHFAc, Illuvien, Alimera Sciences) is 71 currently approved for long term, sustained release of drug over the course of 36 months.⁴ The 72 most commonly encountered side effects are directly related to use of corticosteroids including 73 elevated intraocular pressure and formation of cataracts. Even with extremely selective criteria 74 of candidates for this treatment, situations may arise where removal of the implant is indicated 75 and must be addressed surgically. This can include migration of the implant directly into the anterior chamber or intraocular pressure related adverse events.^{5,6} To our knowledge, a consensus 76 77 approach to explantation of the non-dissolving, extended use implant has not been delineated. 78 Multiple approaches to removal of foreign material are conventionally taken, including direct 79 removal with forceps and elimination using a vitrectomy instrument. We set out to describe 80 explantation techniques for the FAII-FAc using commonly available vitrectomy instruments. 81 These include direct removal via small gauge sclerotomy wounds with forceps or via elimination 82 with the vitreous cutter.

83 Surgical Technique

A vitreoretinal surgery system (Dutch Ophthalmic Research Corporation Eva with TDC cutter)
was designed using a porcine eye model and conventional vitrectomy equipment for both 23-

86 Gauge (G) and 25-Gauge (G) surgery. We performed a conventional pars plana vitrectomy of 87 the vitreous cavity with a balanced salt solution infusion. An FAII-FAc implant was injected 88 into the vitreous cavity through the standard 25-G needle injector. The implant was then 89 identified under the surgical microscope within the vitreous cavity. The implant was aligned 90 coaxially using 27-G forceps, then removed en bloc through the 23-G cannula without removal 91 of the cannula (Figure 1). The implant was then reinserted and removed through a 25-G cannula 92 using 27-G forceps (DORC asymmetrical forceps) (Figure 2). During removal from the 25-G 93 port, the cannula was dislodged from the globe along with the implant due to size limitations of 94 the implant within the 25-G cannula. The implant was then examined under the microscope for 95 induced defects after removal (Figure 3). No significant structural damage to the body of the 96 implant and no loss of fragments within the vitreous cavity were noted.

97 Additional implants were injected into the globe using the standard injection technique. These 98 implants were completely eliminated using both the 23-G and 25-G standard vitrectomy cutter 99 under low-cut rate settings (650mmHg vacuum, 1000 cuts per minute, under the core vitrectomy 100 pump settings) (See Video, Supplemental Digital Content 1, which demonstrates removal of an 101 implant using the 25-G vitrectomy system).

102 Discussion

103 Several well-established techniques exist for removal of foreign material from the vitreous cavity 104 during traumatic etiologies. This includes use of magnets, aspiration, and basket devices with 105 occasional creation of larger sized scleral incisions.^{7,8} Long acting injectable implants are an 106 emerging technology that also introduces the risk of iatrogenic need for explantation. The 107 methods described are based on standard vitrectomy techniques and the most technically 108 challenging portion of the removal was aligning the implant coaxially to allow for removal en

109	bloc through the sclerotomy site. The implants were removed without any implant fragments
110	being freed into the vitreous cavity or putting the patient at risk of ongoing exposure to
111	medication. To the best of our knowledge, this is the first report describing removal of the FAII-
112	FAc implant using conventional vitrectomy instruments. This is an inexpensive, effective, and
113	efficient technique to assist in rare occasions when explantation is indicated for an emerging long
114	acting drug delivery system.
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Figure 1: Alignment of the implant coaxially, 27-G forceps through 23-G cannula

Figure 2: Implant removed with 27-G forceps through 25-G cannula, cannula dislodged from

184 sclerotomy

- **Figure 3:** Implant under microscope after removal through the 23-G cannula and manipulation
- 187 with 27-G forceps

- 189 Supplemental Digital Content 1. Video demonstrating alignment of the implant and removal of
- 190 the implant using a 25-G vitrectomy system. mp4