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Fluocinolone Implant Forceps: Instrument Modification for Enhanced Implant Insertion

Samuel Burke, MS, Thomas A. Albini, MD, Juan Silgado, BSBME, Basil K. Williams, MD, and Jean-Marie A. Parel, PhD, FARVO

Bascom Palmer Eye Institute, Department of Ophthalmology, Miller School of Medicine, University of Miami. Miami, FL USA

Introduction

The fluocinolone acetonide intravitreal implant (FAI; Retisert; Bausch & Lomb, Rochester, New York) is a Food and Drug Administration approved treatment for chronic, non-infectious uveitis that works via sustained release of corticosteroids over a period of 2.5 years¹. Several prospective randomized clinical trials including the recent MUST trial have shown the implant to be very effective in controlling inflammation and reducing uveitis recurrence rates^{2,3,4,5,6}. The major adverse effects in implanted eyes are high rates of cataract development and increased intraocular pressures requiring either medication or glaucoma surgery⁷.

A more recently recognized problem with the FAI is implant dissociation and dislocation. The implant is composed of an anchoring suture strut glued to a drug pellet by a silicone-based adhesive. Dissociation occurs when the adhesive fails to bind the suture strut and the drug pellet together and dislocation occurs when the unbound drug pellet separates from the strut and migrates to a different location in the eye. The rate of spontaneous dissociation ranges from 2.6–4.8% at a mean post-implantation time of 65–77 months with a higher rate of surgically-induced dissociation of 14.2–40.7%^{8,9,10,11}. Some patients with dissociated or dislocated implants suffer no visual symptoms while others experience black spots, floaters, or blurred vision. Eyes with these problematic implants may have a decrease in visual acuity, recurrent inflammation, or cystoid macular edema but it is nearly impossible to determine whether this is attributable to the dysfunctional implant or the underlying disease process^{8,9}. Surgical removal of the dissociated or dislocated implants has resulted in complications including retinal tears^{8,11,12}, retinal commotio¹², suprachoroidal hemorrhage¹¹, and corneal endothelial dysfunction and edema^{12,13}.

Due to these possible consequences of implant dissociation, a redesigned FAI became available in March 2013. The new generation of implants incorporates a suture tab made of silicone and an embedded mesh in order to strengthen the connection between the suture strut and drug pellet¹⁴. Given the short time elapsed since its release and the mean time before dissociation, there is no clinical data available yet to determine whether these changes

do in fact decrease the rate of dissociation. The new FAI design, however, presents a technical challenge to the retinal surgeon during implant insertion that was not seen with the older model. The suture strut is now much more flexible and has a tendency to buckle when the surgeon attempts to pass it through the incision site. This increased flexibility may even allow the implant to bend into the suprachoroidal space, because the surgeon cannot ensure that the implant maintains a perpendicular trajectory as it enters the eye. To compensate for this change in the material properties, we modified standard forceps to ensure secure purchase and maintain perpendicular trajectory of the implant as it is inserted into the vitreous cavity.

Methods and Results

The procedures described here were performed at the Bascom Palmer Eye Institute (BPEI). Written consent was obtained from all patients undergoing this procedure.

Fluocinolone implant forceps were created by modifying standard forceps according to the schematic in Figure 1 at the Ophthalmic Biophysics Center, BPEI (concept: Thomas A Albini, MD, sketch: Jean-Marie Parel, PhD, fabrication: Juan Silgado, BSBME). Conceptual representations of the fluocinolone implant forceps and the actual finished product are shown in Figure 2 and Figure 3. The dimensions of the FAI were measured using a laboratory stereo microscope (7–40x, Olympus, Tokyo, Japan) equipped with a micrometric reticle and digital calipers (CD-6" CX Digimatic, Mitutoyo, Tokyo, Japan). Jeweler forceps (#2A, Stainless steel, Rubis SA, Stabio, Switzerland) were modified by cutting 3.70mm of the tip of its upper arm using a grinder and the edges were smoothen using a metal file and fine emery paper and polished with a motorized hand-piece (Dremel tool, Sears, Inc.) equipped with a cotton wheel. One side of the forceps was engraved using a computer-controlled 4-axis milling machine (MDX-2CL 540, Roland DGA Corp., USA).

FAI implants were placed in two patients according to standard protocol. The procedures differed only in the type of forceps used for insertion of the implant – standard forceps for the first patient and Albini forceps for the second patient (see Video 1, demonstrating insertion). When using angled tying forceps, the implant strut exhibited increased flexibility and was difficult to place securely through an opened wound. Using the modified forceps, the elongated bottom member provided a stiff backbone to guide the implant strut and allowed the implant to maintain a perpendicular trajectory throughout implantation.

Discussion

The newest generation of FAI utilizes a re-engineered suture strut so as to lower the rate of implant dissociation. The benefits of this redesign will be assessed in the upcoming years as more data accumulates, but the altered material properties of the implant pose a new difficulty in the meantime. The new implant has increased flexibility, and is more likely to bend along the suture strut as force is applied during insertion of the drug pellet through a 3.75 – 4.00 mm pars plana surgical incision. This results in possible delays in implant insertion, increased force applied to the incision site, and decreased control over the exact intraocular location to which the implant is ultimately placed and anchored. Of particular

concern is the possibility of the strut bending and misguiding the implant into the suprachoroidal space, which has been recognized as a major complication requiring implant removal and replacement.

The fluocinolone implant forceps were designed to compensate for the decreased rigidity of the suture strut. Staggering the length of the two forceps arms allows for increased support of the implant without compromising grasping ability. The lower arm functions as a brace along the entirety of the implant underside eliminating the possibility of buckling; the upper arm grasps the suture tab without physically obstructing the drug pellet during insertion. This simple modification in forceps design helps the surgeon to more swiftly place the FAI with greater ease and control, potentially preventing significant complications.

In conclusion, modification of standard jeweler forceps into a fluocinolone implant forceps improves placement of the newest generation of FAI implants potentially lowering the risk of significant surgical complications.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1.
Design schematic for fluocinolone implant forceps

Figure 2.
Conceptual design of fluocinolone implant forceps from different angles

Figure 3.
Real-life fluocinolone implant forceps grasping a Retisert implant