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Extraction of Retinal Tacks from Subjects Implanted with an Epiretinal Visual Prosthesis

Eugene de Juan Jr., MD¹, Rand Spencer, MD², Pierre-Olivier Barale, MD³, Lyndon da Cruz, MD⁴, and Jordan Neysmith⁵

¹Department of Ophthalmology, School of Medicine, University of California, San Francisco (San Francisco, CA)

²Retina Foundation of the Southwest (Dallas, TX)

³Centre Hospitalier National d'Ophthalmologie des Quinze-Vingts (Paris, France)

⁴NIHR Biomedical Research Centre for Ophthalmology, Moorfields Eye Hospital (London, United Kingdom)

⁵Second Sight Medical Products Inc. (Sylmar, CA)

Abstract

Background—Retinal tacks, first developed for the treatment of complex retinal detachments, have more recently been used for the fixation of epiretinal electrode arrays as part of implanted visual prostheses. Here we report on the clinical experience of extracting four such tacks after chronic implantation. The ability to safely extract retinal tacks ensures that epiretinal devices can be repositioned or removed if necessary.

Methods—Custom-built, titanium alloy retinal tacks were mechanically removed from the posterior coats after prolonged implantation (up to 19 months). The resulting wound was characterized by clinical evaluation, fundus photography and fluorescein angiography while being monitored for stability over time. The wounds were also compared to earlier published reports of the healing response around retinal tacks in human subjects.

Results—Tack extraction was accomplished successfully, without complication, in all four subjects. The wound site was readily identified by pale scar tissue. No change in the wound size or appearance was noted over many months of post-operative observation (up to 22 months after explant). No adverse effects on overall ocular health were detected.

Conclusion—Extraction of retinal tacks from subjects implanted with epiretinal prostheses can be performed without significant complication. The long-term healing response appears to be stable and localized in eyes afflicted with retinitis pigmentosa or choroideremia. There was also minimal, if any, impact on the local circulatory system. These cases suggest that the use of retinal tacks for anchoring epiretinal visual prostheses does not preclude safe repositioning or removal of the device more than a year after implant.

Corresponding Author: Jordan Neysmith, Second Sight Medical Products Inc., 12744 San Fernando Rd, Bldg. 3 Sylmar, CA 91342 USA. Tel: 818-833-5028. Fax: 818-833-5067. jordan@2-sight.com.

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Keywords

Retinal tack extraction; posterior coats healing response; visual prosthesis safety; epiretinal electrode array; human case study

Introduction

Retinal tacks were introduced in the 1980's as a treatment option for the repair of complicated retinal detachments [1, 2]. Retinal tacks were fabricated from a variety of materials, primarily titanium and steel alloys but also plastics. Tacks also differed in design -- generally based on either conical or cylindrical profiles. Many retinal tacks have been evaluated in clinical settings. Although mechanical fixation of retinal detachments with such tacks has greatly diminished due to the adoption of laser retinopexy, tacks have found new utility in anchoring epiretinal electrode arrays [3, 4].

Epiretinal electrode arrays are the neural interface component of certain visual prostheses designed to restore visual function in blind subjects suffering from degenerative retinal disorders [5–7]. These arrays are placed against the inner retina and deliver pulses of electrical current to stimulate inner retinal neurons, thereby inducing visual phosphenes [8–10]. Mechanical fixation of such arrays in the area centralis (perifovea) is desirable in order to stimulate central vision. This fixation can be achieved with retinal tacks that fully penetrate the posterior coats.

Here we describe the clinical experience of extracting retinal tacks from four subjects chronically implanted with epiretinal nerve stimulators and compare those results with prior published reports of tack extractions. The ability to safely extract retinal tacks ensures that epiretinal devices can be repositioned or removed if necessary.

Materials & Methods

The Argus® II Retinal Prosthesis is part of the Argus II Retinal Prosthesis System (Second Sight Medical Products Inc., Sylmar USA), a recently commercialized device intended to restore some visual function to the blind [11]. This epiretinal nerve stimulator device includes an electronics case, wireless telemetry coil, scleral band and flexible electrode array. The intraocular electrode array is anchored to the posterior retina with a spring loaded, titanium alloy retinal tack as shown in Figure 1. The tack is compatible with 19ga retinal tack forceps (Alcon Grieshaber AG, Schaffhausen Switzerland) for surgical handling. Extraction of the retinal tack is required prior to removal or repositioning of the electrode array. The general surgical approach for all cases involved conjunctival incisions, infusion line placement and pars plana access to the vitreous chamber using standard vitreoretinal techniques. Where appropriate, device diagnostics were run after tack extraction to confirm that no damage had occurred to the implant.

We describe herein four observational case reports (following subjects up to 22 months after tack extraction) and the results of a literature review on the topic of tack extraction. Follow-up evaluation consisted of clinical examination, fundus photography and fluorescein angiography. Optical coherence tomography was attempted but the severity of acquired nystagmus in these subjects prevented the acquisition of clear scans showing the very small tack extraction sites. Measurement of the extracted tack wound size was performed with the open source analysis software ImageJ (National Institutes of Health, Bethesda USA), calibrated using features of known dimension on the electrode array. Measurement uncertainty was approximately $\pm 0.05\text{mm}$. All subjects were enrolled in an approved clinical trial reviewed by the appropriate ethics committees and performed in accordance with the

ethical standards laid down in the 1964 Declaration of Helsinki. All persons gave their informed consent prior to their inclusion in the study. The cases presented in this article represent the first four instances of retinal tack extraction which occurred during the clinical trial (ID# NCT00407602).

Results

In one case, at the University of California San Francisco, the Argus II device had been implanted for 14 months in a 55 year old female with retinitis pigmentosa. Extraction of the retinal tack was indicated to permit full explant of the device, for reasons unrelated to the electrode array. The retinal tack was slowly pulled out of the posterior coats into the vitreous chamber, under an infusion line pressure of 80mmHg. At this point a fibrotic membrane was detected between the temporal array surface and the retina. After separating the retinal tack from the electrode array and extracting it from the eye through a superonasal sclerotomy, a vitreous cutter was used to peel and remove the membrane. The electrode array was then removed.

The infusion line pressure was maintained at 80mmHg for a total of approximately five minutes. The tack site in the posterior coats was observed for signs of local hemorrhage or detachment, neither of which occurred. The tack site was not treated with laser.

The wound left by the extracted tack was located slightly below the horizontal raphe, approximately three disk diameters temporal of the optic disk, as shown in Figure 2a. The wound site was roughly triangular in shape with a blurred border. The base and altitude of the site were measured at 0.5mm and 0.4mm respectively. Follow-up evaluations showed no signs of detachment at the tack extraction site, which was readily identified by pale white scar tissue. Minimal change in the wound size or appearance was observed over a 12 month period following extraction of the tack, and no additional fibrotic response was detected, as apparent in Figure 2b. An angiogram taken 3 months after explant showed minimal late phase fluorescein staining in the vicinity of the tack site (Figure 3).

In a second case, at the Retina Foundation of the Southwest (Dallas, TX), the Argus II device had been implanted for 19 months in a 77 year old female with retinitis pigmentosa. Extraction of the retinal tack was elected to permit repositioning of the electrode array, which was not in close contact with the retina due to tension in the cable that connects it to the extraocular device components. The tack and array were inspected for the presence of fibrosis or membranes. No such formations were detected so the electrode array itself was grasped by a handling structure near the distal end and gently lifted off the retina to ensure that no traction existed. The retinal tack was then carefully pulled out of the posterior coats into the vitreous cavity, under an infusion line pressure of 60mmHg. At this point the retinal tack was separated from the electrode array and removed from the eye through a superonasal sclerotomy.

After about a minute, the infusion line pressure was gradually lowered to 40mmHg while the tack site in the posterior coats was observed for evidence of hemorrhage or detachment; none was found. The tack site was then treated with laser retinopexy. At this point new tacks were introduced into the vitreous cavity and the array was anchored to the retina in a more peripheral location, necessitated by the available cable length (the array had originally been positioned over the area centralis).

The wound left by the extracted tack was located along the horizontal raphe, approximately four disk diameters temporal of the optic disk, as shown in Figure 4a. The wound site was elliptical in shape with a sharp border. The major and minor diameters of the site were measured at 0.6mm and 0.4mm, respectively. Follow-up evaluations showed no signs of

detachment at the tack extraction site, which was faintly visible as pale scar tissue within a larger area of laser treatment. No significant change in the wound size or appearance was observed over a 16 month period following extraction of the tack, and neither fibrotic response nor atrophic creep was detected, as apparent in Figure 4b. A fluorescein angiogram taken at 16 months post-extraction showed little, if any, evidence of circulatory disturbance in either the retina or choroidal vasculature (beyond those prominent changes associated with the disease). No indication of choroidal neovascularization was seen (Figure 5).

In a third case, at Le Centre Hospitalier National D'Ophthalmologie des Quinze-Vingts (Paris, France), the Argus II device had been implanted for 15 months in a 57 year old male with retinitis pigmentosa. Extraction of the retinal tack was indicated to permit repositioning of the electrode array, which was peripheral to the desired macular location. The tack and array were inspected for the presence of fibrosis or membranes but none were found and it was confirmed that no traction existed. Under an infusion line pressure of 45mmHg the retinal tack was carefully pulled out of the posterior coats into the vitreous chamber, and it separated from the electrode array in the same motion. The tack was then removed from the eye through a nasal sclerotomy.

The tack site in the posterior coats was monitored for signs of local hemorrhage or detachment, neither of which occurred. The tack site was not treated with laser. At this point a new tack was introduced into the vitreous chamber and the array was anchored to the retina in a more central location, achieving the desired macular proximity.

The wound left by the extracted tack was located in the superotemporal periphery, approximately six disk diameters from the optic disk, as shown in Figure 6a. The wound site was elliptical in shape with a blurred border. The major and minor diameters of the site were measured at 0.5mm and 0.4mm, respectively. Follow-up evaluations showed no signs of detachment at the tack extraction site, which was identified by pale white scar tissue. No change in the wound size or appearance was observed over a 22 month period following extraction of the tack, and no fibrotic response was detected, as apparent in Figure 6b. Fluorescein angiograms taken after tack extraction did not capture the peripheral tack site in this subject.

In a fourth case, at Moorfields Eye Hospital (London, England), the Argus II device had been implanted for 15 months in a 60 year old male with choroideremia. Extraction of the retinal tack was elected to permit repositioning of the electrode array which was over the area centralis but not in close contact with the retina (potentially due to incomplete tack penetration of the sclera). The tack and array were inspected for the presence of tractional fibrosis or membranes but none were found. Under an infusion line pressure of 85mmHg the retinal tack was then carefully pulled out of the posterior coats into the vitreous cavity, separating from the electrode array in the same motion. The tack was then removed from the eye through an inferior-nasal sclerotomy.

The infusion line pressure was gradually lowered to 15mmHg, after a few minutes at 85mmHg, while the tack site vicinity in the posterior coats was observed for signs of local hemorrhage or detachment; no such indications were seen. The tack site itself was not immediately visible and no laser treatment was performed. At this point a new tack was introduced into the vitreous cavity and the array was anchored to the retina in a similar position.

The wound left by the extracted tack was located above the horizontal raphe, approximately three disk diameters superotemporal of the optic disk, as shown in Figure 7a. The wound site was round in shape with a sharp border. The diameter of the site was measured at 0.3mm. Follow-up evaluations showed no signs of detachment at the tack extraction site, which was

barely perceptible (little contrast existed with the translucent scar tissue). No change in the wound size or appearance was observed over a 21 month period following extraction of the tack, and no fibrotic response was detected, as apparent in Figure 7b. A fluorescein angiogram taken 21 months post-extraction showed minimal circulatory impact with no obvious vascular dropout or clear neovascularization (Figure 8). There was slight increased late stage fluorescence at the tack site that may have been staining due to a breach of the pigment epithelium rather than a vascular phenomenon.

The characteristics of the wound resulting from extraction of a chronically implanted retinal tack were similar in all cases. No complications resulting from tack extraction were detected. On average the tacks had been implanted for 16 months before removal and follow-up observation continued for 18 months after explant. The results of these four cases are summarized in Table 1.

Discussion

Our clinical experience extracting retinal tacks from subjects implanted long-term with epiretinal nerve stimulators is that the healing response is localized, stable and consistent. The elevated infusion line pressure used briefly during each procedure did not cause any permanent circulatory disturbance or corneal edema, while acting as a tamponade against any tendency for bleeding to occur. All four subjects had marked attenuation of the retinal vessels and atrophy of the choriocapillaris as a result of their disease, contributing factors that would make bleeding at the time of tack insertion, or removal, less likely. Any impact of the tack on local circulatory structures appeared minimal and was clinically insignificant to these subjects with severe retinal degeneration. The appearance of the tack extraction site in all four cases was similar to earlier published interpretations of healing response around retinal tacks in human subjects, which involved localized fibrovascular tissue proliferation [12] and moderate gliosis [13].

Various literature reports of human cases describe the deliberate extraction of at least 79 retinal tacks, where the tacks were used purely for mechanical retinopexy, and in no instance were significant complications observed [14–17]. Occasional bleeding was reported but found to be easily controlled [14,16]. In one report, four grooved, Grade 4 titanium retinal tacks were inserted to achieve fixation of a 200° relaxing retinotomy [14]. When these tacks were deliberately removed at the completion of surgery transient bleeding was noted but “did not cause significant problems” according to Abrams et al. In a second report, one stainless steel retinal tack was extracted, after acute placement, without complication [15]. Lewis et al. deemed that scar tissue had remained at the wound site and not been dislodged by extraction of the tack. In a review of 23 cases where 74 stainless steel alloy tacks were extracted, the most common complication was bleeding into subretinal space, which could be controlled with increased intraocular pressure, diathermy and aspiration [16]. No cases of suprachoroidal bleeding or expulsive hemorrhage were noted, though de Juan et al. recommended that extraction after chronic implantation should be preceded by removal of any fibrous encapsulation. In another report an indeterminate number of tacks were removed from one subject; no complications were mentioned [17].

Historically, the extraction of retinal tacks from subjects without degenerative retinas has been accomplished without significant complications. Our recent clinical experience indicates that extraction of retinal tacks from subjects with retinitis pigmentosa or choroideremia can be performed without complication as well, even after the tack has been in place for prolonged periods (from 14 to 19 months). The wound sites did not change in size or appearance from immediately after tack extraction through the duration of follow-up observation (from 12 to 22 months post-operative). Tack extraction had no adverse effects

on overall ocular health in these cases -- no hemorrhage, no retinal detachment, no fibrous proliferation, no posterior uveitis, and no endophthalmitis was detected. This suggests that the chronic use of retinal tacks for anchoring epiretinal visual prostheses does not preclude safe repositioning or explant of the electrode array even more than a year after implantation, since tacks have been extracted without complications from four Argus II subjects.

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Figure 1.
Argus II Retinal Tack

Figure 2.
Fundus color photograph, post-extraction, Case 1. **(a)** 3 months. **(b)** 12 months.

Figure 3.
Fluorescein angiogram 3 months post-extraction, late phase, Case 1.

Figure 4.
Fundus color photograph, post-extraction, Case 2. (a) 1 month. (b) 16 months.

Figure 5.
Fluorescein angiogram 16 months post-extraction, venous phase, Case 2.

Figure 6.
Fundus color photograph, post-extraction, Case 3. **(a)** 3 months. **(b)** 22 months.

Figure 7.
Fundus color photograph, post-extraction, Case 4. (a) 1 week. (b) 21 months.

Figure 8.
Fluorescein angiogram 21 months post-extraction, late phase, Case 4.

Table 1
Summary of Tack Extraction Results (RP = Retinitis Pigmentosa, C = Choroideremia)

Case	Gender	Age	Disease	Implant Duration [months]	Follow-up Duration [months]	Wound Size [mm ²]	Complications
1	F	55	RP	14	12	0.1	None
2	F	77	RP	19	16	0.2	None
3	M	57	RP	15	22	0.2	None
4	M	60	C	15	21	0.1	None