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Intravitreal dexamethasone implant for recurrent cystoid macular edema due to Irvine–Gass syndrome: a prospective case series

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Learning objectives

Upon completion of this activity, participants will be able to:

1. Assess the pathophysiology and clinical presentation of pseudophakic cystoid macular edema (PCME).
2. Evaluate the effectiveness of the dexamethasone implant among patients with PCME in the current study.
3. Analyze the safety of the dexamethasone implant among patients with PCME in the current study.

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Intravitreal dexamethasone implant for recurrent cystoid macular edema due to Irvine–Gass syndrome: a prospective case series

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Abstract

Purpose To determine the preliminary efficacy and safety of off-label dexamethasone implant for treatment of recurrent cystoid macular edema (CME) secondary to Irvine–Gass syndrome (IGS).

Patients and methods This study was set in Raghudeep Eye Clinic, Ahmedabad and LV Prasad Eye Institute, Hyderabad (India). It is a Prospective Case Series. Prospective case series comprising of patients with uncomplicated pseudophakia and CME due to IGS who recurred after one course of topical steroids with NSAIDs and a sub-Tenon corticosteroid injection. A complete ocular and systemic exam, fluorescein angiography, and central subfield thickness (CST) on optical coherence tomography scans were performed. Follow-up visits were on days 1, 15, and 30 and then monthly for a year. Appropriate statistical analysis was done. The primary outcome measure was the change in CDVA at months 1, 6, and 12. Secondary outcome measures were recurrence of CME and complications if any as noted at months 1, 2, 6, and 12.

Results About 27 patients (27 eyes) with 16 males were included. Median age: 63.24 ± 5.62 years. At 1 month, the CDVA improved to 0.04 ± 0.02 (20/25) logMAR from 0.52 ± 0.12 logMAR (20/70) ($P=0.001$) with a reduction in CST from 454.2 ± 45.3 to 218.32 ± 38.15 microns ($P=0.013$). The CDVA was 0.04 ± 0.03 logMAR ($P<0.001$) at month 6 and 0.05 ± 0.02 logMAR ($P<0.001$) at month 12. The CST was 221 ± 35.2 microns ($P=0.013$) at month 6 and 214 ± 43.34 microns ($P=0.0124$) at month 12. All improvements were maintained for a year.

Only one patient required a second injection. No complications were noted.

Conclusion The implant is safe and effective for the treatment of recurrent CME due to IGS.

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Introduction

Pseudophakic cystoid macular edema due to Irvine–Gass syndrome^{1–5} remains an important cause of decreased vision following uncomplicated cataract surgery and intraocular lens (IOL) implantation. The most accepted patho-physiologic mechanism for PCME is increased inflammation,^{1–5} although vitreous disturbance⁶ and hypotony^{1,2} may account for a sizeable proportion of cases. It typically presents 4–12 weeks after cataract surgery, and often resolves spontaneously.⁴ PCME or Irvine–Gass syndrome develops independently of comorbidities such as diabetes mellitus, vein occlusion, or uveitis.^{1–5}

Prophylaxis is suggested for in situations where patients who are prone to develop cystoid macular edema following cataract surgery, such as patients with uveitic cataract⁷ and those with diabetes.^{8,9} In cases that do not resolve spontaneously, a course of topical steroids and non-steroidal anti-inflammatory agents (NSAIDs) helps in the resolution of a large proportion of cases.¹⁰ A certain subset of patients, however, does not respond to topical therapy alone. A step ladder approach for the management of these patients is proposed and

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includes oral carbonic anhydrase inhibitor therapy,¹¹ peribulbar¹² or intravitreal steroids,¹³ anti-VEGF agents,¹⁴ immunomodulators^{15,16} and, in cases secondary to vitreous traction, Nd: Yag laser vitreolysis,¹⁷ vitrectomy,¹⁸ or other surgical approaches. There is, however, no standardized protocol prescribed for its management, probably because of a lack of randomized trials.

A dexamethasone implant^{19,20} (Ozurdex, Allergan Inc., New Jersey, CA, USA) has been recently approved for the treatment of intermediate and posterior uveitis, as well as macular edema secondary to diabetes mellitus or branch vein occlusions. It appears to have a better safety profile when compared with other corticosteroids used locally^{19–21} and it has been found to be safe and effective in the treatment of the aforementioned conditions. There is published literature available on the use of this implant in recalcitrant cystoid macular edema secondary to the Irvine–Gass syndrome mainly in the form of case reports and retrospective case series.^{22–25} However, there is no prospective study on the use of this implant in either recalcitrant or recurrent cystoid macular edema secondary to Irvine–Gass syndrome in patients with uncomplicated pseudophakia.

We aimed to obtain data on the efficacy and safety of the dexamethasone implant (0.7 mg) in the treatment of recurrent cystoid macular edema due to Irvine–Gass syndrome in patients with uncomplicated pseudophakia (off-label use).

Materials and methods

This prospective case series included adult patients, with senile cataract (age >40 years), who underwent uncomplicated phacoemulsification with posterior chamber IOL implantation.

Study population

For inclusion, patients were required to have: Symptomatic PCME consistent with the diagnosis of Irvine–Gass syndrome that had recurred after at least one course of topical steroids with NSAIDs and one sub-Tenon triamcinolone acetate injection. Additional therapy prior to inclusion was permissible and could consist of any of the following: (1) a repeat course of topical steroids combined with NSAIDs (2) posterior sub-tenon or intravitreal triamcinolone acetate (3) A course of oral carbonic anhydrase inhibitors. The patients could only be included once at least 3 months had elapsed after the last corticosteroid injection.

Resolution and recurrence of CME

Resolution of cystoid macular edema was defined as the complete disappearance of retinal cysts, retinal thickening, and subretinal fluid (if present) along with a restoration of the normal foveal contour and a reduction of central subfield thickness (CST) to 250 microns or less as seen on OCT and clinical examination, and associated with an improvement in CDVA to 20/25 (0.1 logMAR) or better. Recurrence was defined as the re-appearance of retinal thickening, cysts and/or subretinal fluid after complete resolution of the CME with therapy associated with a drop in CDVA to 20/40 (0.3 logMAR) or worse, with or without metamorphopsia.

Exclusion criteria

Patients excluded were patients (1) who were known steroid responders (2) who had PCME secondary to obvious causes such as persistent vitreomacular traction or ocular hypotony (3) confounding co-morbidities such as uveitis, diabetes retinopathy, and/or vein occlusions (4) patients who had already received an intravitreal dexamethasone implant for CME secondary to Irvine–Gass syndrome, and (5) a baseline VA worse than 20/200 (1 logMAR). Informed consent for the procedure was obtained from patients prior to intervention. The study was approved by the institutional review board and adhered to the tenets of Helsinki.

Examination procedure

A thorough history was obtained from all patients and a comprehensive ocular and systemic examination performed. Data noted included demographics, the corrected distance visual acuity (CDVA) measured on an ETDRS chart, details of the anterior and posterior segment examination including the intraocular pressure measured using applanation tonometry. The diagnosis was based on clinical examination, fundus fluorescein angiography, and optical coherence tomography scans.

Fundus fluorescein angiography was performed using the Zeiss Fundus Camera (Visucam 500, Jena, Germany) with informed consent. Cystoid macular edema was identified by the typical ‘flower-petal’ appearance observed in the late phase. Care was taken to rule out other disorders.

The OCT scan was used to document retinal thickening, cysts, and subretinal fluid in these patients and was a part of the diagnostic criteria. The CST was measured using a standardized technique using a spectral domain ocular coherence tomography scan and volume scans were performed (OCT, Zeiss Meditec, Erlangen, Germany) in accordance with past literature.^{19,20,22,23}

Off-label intravitreal dexamethasone implant injection

The conjunctival cul-de-sac was anesthetized using proparacaine hydrochloride (0.5%) eye drops thrice, 10 min apart. A drop of povidone iodine (5%) was instilled in the cul-de-sac 10 min prior to the procedure. The injection was carried out in the operating room using aseptic measures and a standardized surgical technique. The implant (0.7 mg) was injected in the infero-temporal quadrant 3.5 mm from the limbus. The site was massaged using a sterile scleral indenter and a drop of povidone iodine (5%) instilled in the conjunctival cul-de-sac at the end of the procedure. Post operatively the patient was given antibiotic eye drops (ofloxacin 0.3%) four times a day for a week.

Postoperative clinical examination was done on days 1, 15, and 30 and then monthly for a year, unless complications necessitated a more frequent follow-up. The CDVA, IOP, and a complete ocular examination along with the OCT raster scan was performed at each visit. The central foveal thickness was measured at each visit, and the change in thickness, if any was noted. An IOP rise of 6 mm Hg or more from baseline and/or an absolute IOP value of 24 mm Hg or more was defined as an IOP spike.

Outcome measures

The change in CDVA at the 1-month, 6-month, and 1-year follow-up was the primary outcome measure. The change in central foveal thickness at 1 month, 6 months and 1 year, recurrence rate and complications, if any were noted as the secondary outcome measures. Analyses were performed at months 1, 6, and 12. IOP measurements were additionally analyzed at month 2. Thus visits at months 1, 6, and 12 (and IOP measurements at month 2) were analyzed, but patients were followed up at least every month, and monitored both for improvement (or deterioration as the case may be) and to look for complications.

Statistical analysis

The repeated measures ANOVA test was used to assess the significance of the change in CDVA, the IOP, and CST over months 1, 6, and 12. Change in IOP from baseline, if any was also noted, at month 2. Analyses were performed using the Statistical Package for Social Sciences (Version 20.0, Chicago, IL, USA). Statistical significance was set at $P < 0.05$.

Results

A total of 33 patients (33 eyes) were found to be eligible for the study in the stated period of which 27 patients

completed the 1-year follow-up, and these 27 patients (27 eyes) form the basis for our analysis.

Demographics

About 16 of these 27 patients were males. The median age range was 63.24 ± 5.62 years with a range of 50–74 years. None of the patients had co-existent systemic disease that could confound the diagnosis or the response to therapy. None of the patients had any other ocular and/or systemic disease that could confound the results.

All patients had undergone uneventful phacoemulsification with posterior chamber IOL implantation (in the bag). The median duration from cataract surgery to first episode of CME was 6.12 ± 2.72 weeks. All patients had one course of topical therapy with prednisolone acetate and ketorolac eye drops for the treatment of symptomatic CME due to IGS and had responded to it, but had a recurrence following cessation of therapy. Following the course of topical therapy, all patients had at least one sub-Tenon injection of triamcinolone acetonide (dose 40 mg), and responded favorably to it, but had a recurrence once the effect had worn off. Five patients had received a second posterior sub-Tenon injection of 40 mg triamcinolone acetonide prior to inclusion. None of the patients had an IOP spike noted prior to inclusion. The median duration of CME after the last recurrence was 7.25 ± 1.2 weeks (range 4–12 weeks) prior to inclusion. All patients received the intravitreal dexamethasone implant as stated earlier.

The change in CDVA (including the approximate Snellen's equivalent), CST, and IOP over the course of follow-up is outlined in Table 1. Significant improvements were seen in CDVA and CST, with no significant change in IOP. Only one patient had a recurrence of CME, 3 months after the dexamethasone implant injection; he required a second dexamethasone implant injection for recurrent PCME. He experienced no further recurrences, and maintained a vision of 0.04 logMAR (approximately Snellens equivalent of 20/25) till the end of follow-up. Subset analysis of patients who had received a second sub-Tenon injection showed that they responded equally well to therapy, and that none of them had a recurrence till the end of follow-up.

None of the patients developed an IOP spike till the end of the follow-up. None of the patients had any adverse event till the end of the follow-up period. None of the patients required additional therapy till the end of the follow-up period (except for the one patient mentioned earlier). Eventually, at the 1-year follow-up, all patients had a final visual acuity of 20/25 or better (Figure 1).

Table 1 Assessment of change in CDVA, CST, and IOP from baseline at months 1, 6, and 12 after injection of dexamethasone implant

Parameter	Baseline values (range) (Snellen ^a)	Month 1 P-value from baseline	Month 6 P-value from baseline	Month 12 P-value from baseline
CDVA (logMAR)	0.52 ± 0.12 (0.2–0.78) (20/70)	0.04 ± 0.02 (20/25) P < 0.001	0.04 ± 0.03 (20/25) P < 0.001	0.05 ± 0.02 (20/25) P < 0.001
CST thickness (microns)	454.2 ± 45.3 (358–587)	218.32 ± 38.15 P = 0.013	221 ± 35.2 P = 0.013	214 ± 43.34 P = 0.0124
IOP ^b (mm Hg)	14.4 ± 4.32 (8–19)	16.4 ± 4.4 P = 0.56	14.8 ± 5 P = 0.48	13.54 ± 4.2 P = 0.6

Abbreviations: CDVA, corrected distance visual acuity; CST, central subfield thickness; IOP, intraocular pressure. ^aSnellen's equivalent is for mean logMAR. ^bThe median IOP at 2 months was 15.2 ± 3.72 mm Hg (P = 0.59).

Discussion

Our study shows good results through the use of the intravitreal dexamethasone implant (Ozurdex, Allergan Inc.) in patients who have had an otherwise uncomplicated postoperative course following cataract surgery in terms of resolution of CME due to IGS as well as prevention of its recurrence. All patients had at least two episodes of recurrence but demonstrated a subjective and objective improvement without complications after the injection both in terms of visual gain and resolution of the cystoid macular edema on clinical examination, as well as OCT scans. Only one patient required a second injection.

The Irvine–Gass syndrome^{1–5} is a poorly understood entity, and spontaneous resolution (which is a common end point) can take from 2 months to a year. Observation or repeat courses of topical therapy may be troublesome for professionally active individuals.

There have been numerous retrospective reports^{22–25} on the use of the intravitreal dexamethasone implant for recalcitrant or refractory cystoid macular edema. Refractory CME is defined in these studies as persistent CME with foveal thickness more than 250 μm and intraretinal cystic changes revealed by spectral domain optical coherence tomography, lasting for at least 90 days after the initiation of treatment.²³ Subset analysis in one of largest trials on this implant²⁶ found it to be effective in the treatment of Irvine–Gass syndrome with an acceptable safety profile. Two retrospective series^{22,23} comprising 9 and 11 eyes, respectively, reported good results in patients who had several attempts at treatment. Treatment administered in this series prior to treatment with the implant included topical steroids and NSAIDs, triamcinolone acetonide intravitreally or sub-Tenon's, bevacizumab, and oral carbonic anhydrase inhibitors. The CME had persisted in both for more than 6 months. The results were favorable both in terms of safety and efficacy till the end of the follow-up period, which in both series was 6 months. The duration of refractory CME in these studies is comparable to the median time lapse

between cataract surgery and first dexamethasone implant injection.

Corticosteroids other than this implant have been used in the past, with the optimal route of corticosteroids delivery a matter of debate. The sub-Tenon route is considered equal to the retrobulbar route in terms of efficacy and safety too²⁷ in patients with pseudophakic CME. Also, the sub-Tenon route is generally considered safe with respect to IOP.²⁸ A study²⁹ that looked at IOP elevation following administration of triamcinolone acetonide through various routes found that the intravitreal group had a higher incidence of IOP rise beyond 30 mm Hg. Other studies,^{27,28} as already mentioned did not find a significant IOP rise with the use of triamcinolone acetonide irrespective of the route used. There is in general, a concern over a higher incidence of IOP elevation following intravitreal use of triamcinolone acetonide.³⁰ The implant is considered safer than other corticosteroids for ocular use.²¹ Also, a retrospective comparative case series³¹ found the dexamethasone implant superior to sub-tenon corticosteroids in the treatment of inflammatory cystoid macular edema, including CME, due to Irvine–Gass syndrome both in terms of efficacy and safety. Most studies on the role of corticosteroids in refractory CME due to IGS provide a follow-up of 6 months. The intravitreal dexamethasone implant (Ozurdex, Allergan Inc.) remains to date the only steroid preparation approved for intraocular use albeit for diseases other than the IGS. Our study underscores the safety and efficacy of the dexamethasone implant as noticed in the aforementioned study;³¹ however, we cannot comment on its superiority to other corticosteroid preparations as we had no comparative arm.

Our study is limited by the lack of a comparative arm and the relatively small number of patients. The sample size is probably too small to find out any adverse effects such as endophthalmitis, retinal detachment, and vitreous hemorrhage. It deals with an important problem and one that can be frustrating for the cataract surgeon who might feel robbed of success after a perfectly executed cataract

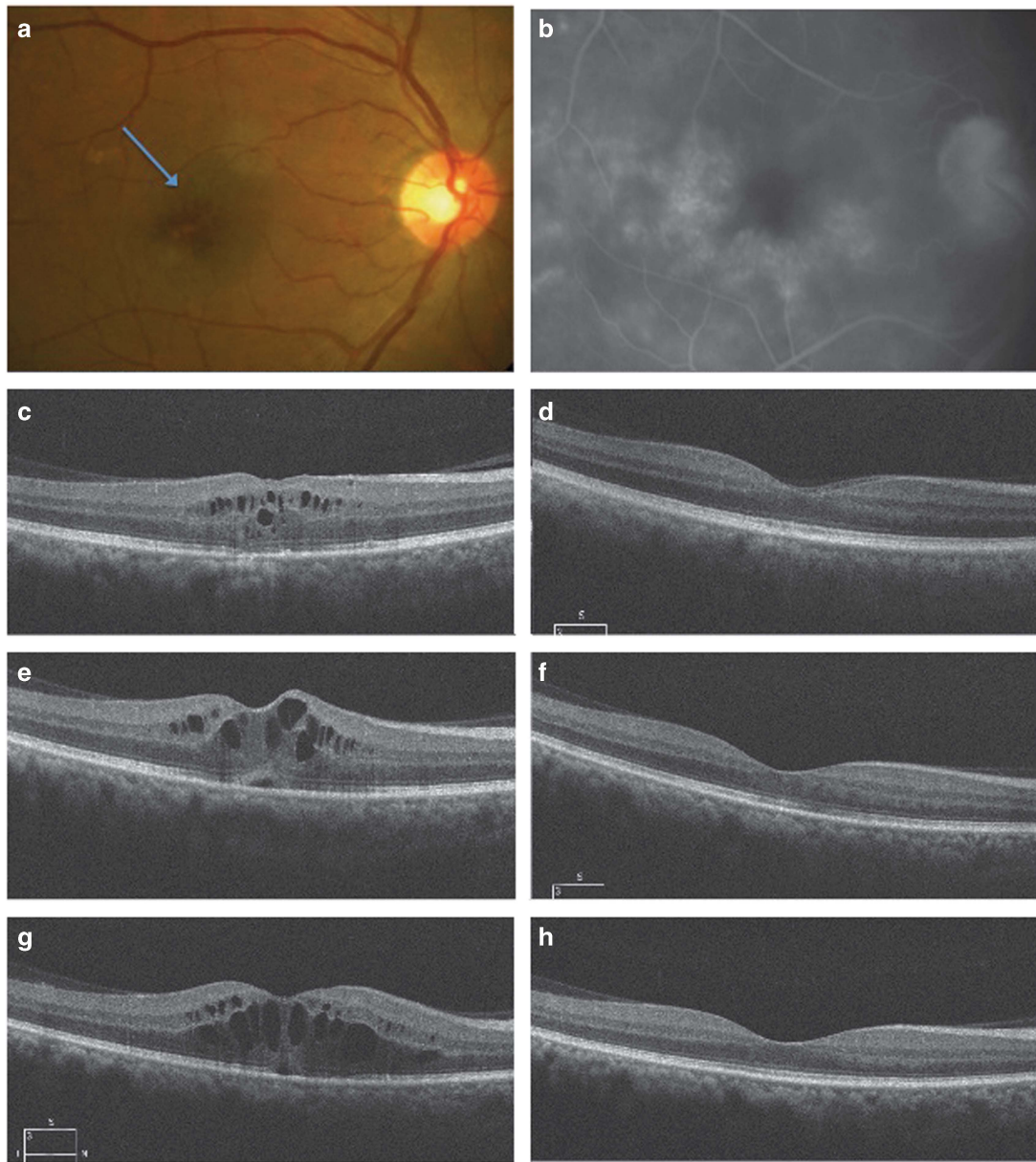


Figure 1 (a) The clinical fundus photograph and (b) the late phase of fluorescein angiogram of a 64-year-old male who underwent uneventful phacoemulsification and developed CME (blue arrow, a) due to IGS 5 weeks postoperatively. His vision was 20/40 and had associated metamorphopsia. OCT (c) showed retinal thickening and cysts with some loss of foveal contour. A course of topical steroids and NSAIDs helped resolve the edema (d) with CDVA improving to 20/20. One month later, he came back with a drop in CDVA(6/18) and metamorphopsia. The OCT (e) shows retinal thickening, cystic changes, and subretinal fluid. A sub-tenon injection was administered and it helped resolve the CME (f) with vision restored to 20/20, but it recurred 2.5 months after the injection. (g) The patient received an intravitreal dexamethasone implant 5 weeks after the recurrence, and the CME had resolved at the 1-month follow-up (h) with no recurrence till the end of follow-up.

surgery. Often, it resolves spontaneously but there are situations wherein it may be vital to the patient's interests to have the CME resolve expeditiously. The intravitreal dexamethasone implant may help achieve rapid resolution of the CME without recurrence, and given its relatively better safety profile, reduce complications. Overall, to the best of our knowledge, this is the first

study that explores the outcome of recurrent CME due to IGS prospectively and for a follow-up period of 1 year.

In conclusion, the intravitreal dexamethasone implant is a valid treatment option for patients with recurrent pseudophakic CME secondary to Irvine-Gass syndrome who have been treated with topical therapy and a posterior sub-Tenon triamcinolone acetonide injection.

It seems to improve visual acuity, reduces CST and is effective in preventing recurrences with a good safety profile upto a year. Further randomized trials can look at its efficacy and safety vis-à-vis triamcinolone acetonide and/or other treatment modalities such as anti-VEGF agents or oral carbonic anhydrase inhibitors.

Summary

What was known before

- The intravitreal dexamethasone implant has been found to be effective in the treatment of recalcitrant CME due to Irvine–Gass syndrome in several retrospective case reports and case series in patients who have been treated with topical steroids, NSAIDS intravitreal steroid, and anti-VEGF injections.

What this study adds

- This, to the best of our knowledge, is one of the first prospective studies on intravitreal dexamethasone implant for CME due to IGS and the first that looks at its utility and safety in the treatment of recurrent (as opposed to recalcitrant) CME due to IGS, and provides a follow-up of for 1 year. The implant is effective in eliminating recurrences with a good safety profile in patients who have had at least two recurrences using current treatment options.

Conflict of interest

The authors declare no conflict of interest.

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1. You are seeing a 63-year-old man for a routine postoperative visit after he has undergone cataract surgery and intraocular lens placement in the left eye. He complains of blurry vision on the left, and you suspect pseudophakic cystoid macular edema (PCME). What should you consider regarding the pathophysiology and clinical presentation of PCME secondary to Irvine Gass syndrome?
 - A The sole root cause of PCME is inflammation
 - B It usually develops 1–2 weeks after cataract surgery
 - C It usually resolves spontaneously
 - D It nearly always occurs among patients with comorbid diabetes or vein occlusion

2. The patient's condition fails to respond to topical therapy and an injection of intravitreal steroids. Which of the following outcomes were noted in the current trial of a dexamethasone implant in cases such as this one?
 - A No change in mean corrected distance visual acuity (CDVA) at month 1
 - B Improved mean CDVA at month 12
 - C No change in mean central subfield thickness at any time point
 - D No recurrences of cystoid macular edema

3. What should you consider regarding the safety of the dexamethasone implant in the current study?
 - A Increased intraocular pressure was noted in approximately one-quarter of patients
 - B Increased intraocular pressure was noted in roughly 40% of patients
 - C Approximately half of patients required additional therapy or surgery by 12 months of follow-up
 - D No adverse events were associated with the implant

Activity evaluation				
1. The activity supported the learning objectives.				
Strongly disagree				Strongly agree
1	2	3	4	5
2. The material was organized clearly for learning to occur.				
Strongly disagree				Strongly agree
1	2	3	4	5
3. The content learned from this activity will impact my practice.				
Strongly disagree				Strongly agree
1	2	3	4	5
4. The activity was presented objectively and free of commercial bias.				
Strongly disagree				Strongly agree
1	2	3	4	5