

Role of Sub-Silicone Oil Application of Triamcinolone Acetonide (TA) Drops on Outcomes After 360° Relaxing Retinectomy in Extreme Proliferative Vitreoretinopathy Cases- A Pilot Study.

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Keywords: Sub silicone oil Triamcinolone acetonide crystal drops, 360° Relaxing Retinectomy, complex retinal detachment, advanced proliferative vitreoretinopathy (PVR).

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Title Page

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Keywords: Sub silicone oil Triamcinolone acetonide crystal drops, 360° Relaxing Retinectomy, complex retinal detachment, advanced proliferative vitreoretinopathy (PVR).

Summary statement : We evaluated the anatomical and functional outcomes of with or without sub-silicone oil Triamcinolone acetonide (TA) crystal application after 360 degree relaxing retinectomy, required for complex RD with advanced proliferative vitreoretinopathy. Cases where TA was applied showed better visual outcomes, less recurrence of RD and more propensity for silicone oil removal.

ABSTRACT

Purpose: To perform a pilot study to evaluate the role of sub-silicone oil Triamcinolone Acetonide (TA) crystal drops in complex Retinal Detachment (RD) with extreme proliferative vitreoretinopathy (PVR) requiring 360-degree relaxing retinectomy (RR).

Design : It was a retrospective pilot study.

Materials & methods :It was a retrospective, case-control pilot study. TA assisted 23G or 25G vitrectomy was done in 24 complex RDs with extreme PVR where 360 degree RR had to be performed. Group A (n=13) included cases where additional TA crystal drops were applied, after settling the detached retina, over the site of RR under silicone oil (SO 5000 cSt) tamponade. In control arm, group B (n=11), additional TA crystals were not applied.

Main outcomes measured : Mean pre and post operative BCVA, ultra-widefield retinograph by Optos 200Tx, macular OCT and the propensity to remove silicone oil were measured.

Results: Mean preoperative and postoperative BCVA at final follow up were Log MAR 2.69 (20/9795) \pm 0.41 and Log MAR 1.51 (20/647) \pm 0.90 ($p<0.05$) respectively in Group A and Log MAR 2.9 (20/15886) and Log MAR 2.37 (20/4688) \pm 0.86 ($p<0.05$) respectively in group B. Visual improvement in group A was significantly better than group B (two-sample t-test, $p<0.05$) with significantly less recurrence of RD (Fisher's Exact Test, $p=0.002$). Silicone oil removal was done significantly more in group A (Fisher's Exact Test, $p=0.0017$).

Conclusion :Sub-silicone oil TA crystals application over sites of RR after 360-degree relaxing retinectomy leads to improved postoperative visual recovery as well as improved anatomical outcomes with fewer complications.

Full text :

Title : Role of sub-silicone oil application of Triamcinolone acetonide (TA) drops on outcomes after 360° Relaxing Retinectomy in extreme Proliferative Vitreoretinopathy cases- A pilot study.

Introduction: Proliferative vitreoretinopathy (PVR) is one of the major challenges to manage in retinal detachment surgery. It causes formation of epiretinal membranes, intraretinal fibrosis and subretinal bands. [1] Major contributors to the development of PVR are retinal pigment epithelial cells and Muller cells. [2] Rhegmatogenous retinal detachments (RRD) which are more prone to develop PVR are those associated with large retinal breaks, giant retinal tears and chronic RRD. Retinal detachment cases with severe PVR requires meticulous peeling and removal of membranes. However even than in few cases intraoperative retinal reattachment cannot be achieved due to extensive retinal puckering (like in PVR grade D2 or D3), retinal incarceration, severe anterior PVR or intrinsic retinal contraction due to intraretinal fibrosis. Under these circumstances the vitreoretinal surgeon has no other option except relaxing retinectomy to settle the detached retina. The technique of relaxing retinectomy, which was first described in 1986 by Robert Machemer, is used in a variety of clinical settings, including retinal detachment with incarcerated retinas, retinal shrinkage from PVR, proliferative vasculopathy, and to reattach the retina after scleral buckling, in order to remove retinal contractile elements. [3,4]. Sometimes intra-operative large areas of relaxing retinotomies (RR) are often needed in complex retinal detachment cases to remove retinal contractile elements as much as possible. Haut et al described 360-degree retinotomy in 1985. [5,6] But this technique is viewed as last resort, as complications, including postoperative redetachments, [7,8,9] exaggerated PVR [10] and post-vitreotomy hypotony [11] are frequent. Adjuncts known to modify different stages of PVR are intravitreal anti proliferative drugs like Daunorubicin, 5-Fluorouracil, low molecular weight heparin in infusion bottle or intravitreal combined anti-proliferative and anti-inflammatory agents like dexamethasone and triamcinolone acetonide (TA) which modify cellular proliferation and reduce inflammation. Previous studies have shown intravitreal injection of TA (2 mg and 4 mg) to be effective as well as safe in silicone oil-filled eyes as an adjunct in treating PVR(grade C or D). [12,13] But TA crystals that sediment at the lower border of silicone oil bubble, showed pronounced cytotoxic effect to retinal cells. [14] Our previous work on sub-silicone oil application of TA drops showed encouraging result to decrease post-operative PVR formation. [15] In present article we described another innovative approach in the management of complex retinal detachments with extreme PVR which required 360-degree relaxing retinectomy and evaluated the role of sub silicone oil TA crystals on post-operative outcomes in these situations. This novel approach is compared with another group of cases where sub-silicone oil TA was not applied.

Materials and Methods : It was an institutional, retrospective, interventional case control study. The present study strictly adhered to the Declaration of Helsinki, and informed consent was obtained from every patient after being informed about the procedure and its possible complications. Approval of Institutional Ethical Committee [Disha Eye Hospitals Pvt Ltd Ethics Committee, Registration No.ECR/876/Inst/WB/2016/RR-19] was obtained. 23G or 25G vitrectomy was done in 24 consecutive complex retinal detachments with extreme PVR like PVR D2 or more and 360 degree intrinsic retinal contraction from various aetiology where 360-degree circumferential Relaxing Retinectomy (RR) was required to settle the retina with the help of Perfluorocarbon Liquid (PFCL) and 360-degree laser retinopexy along the retinectomy margin since May 2014 to August 2019. A pilot study was performed after retrospectively analysing all the data. In addition to general demographic data, baseline preoperative and post-operative Best Corrected Visual Acuity (BCVA), indication for surgery, PVR status, any post-operative complications, duration of follow up, whether silicone oil removal (SOR) was done or not and post-operative intraocular pressure (IOP) were collected and analysed (Table 1 and 2). Complete ophthalmic evaluation including slit-lamp examination, measurement of IOP, and dilated fundus examination was performed at all pre and postoperative visits. Pre and postoperative ultra-wide field retinograph by Optos 200Tx (Optos, Dunfermline, UK) and OCT for macular status were evaluated. Propensity to remove silicone oil was also assessed for anatomical stability. Follow-up till sixth months were considered for functional and anatomical outcomes.

Surgical technique:

All eyes underwent standard 23 or 25-gauge pars plana vitrectomy using Constellation vitrectomy machine (Alcon Laboratories, Fort Worth, TX). Crystalline lens or intraocular lens was removed whenever it hindered adequate peripheral retinal visualisation or manipulation. Meticulous removal of posterior epiretinal and sub-retinal membranes was performed. 360-degree retinectomy was considered only when meticulous removal of posterior epiretinal and sub-retinal membranes were unsuccessful in relieving the tractions or to settle retina. Endocautery was done at the site of the proposed retinectomy, followed by retinectomy with vitreous cutter. Retina anterior to the retinectomy was removed using cutter. Fluid air exchange was performed till the margin of PFCL followed by endolaser photocoagulation posterior to retinectomy margins done under PFCL. Then silicone oil of 5000cSt viscosity (Howard Instruments II Inc, Langenhagen, Germany) injected as long-term tamponade. Cases were operated by two separate surgeons (SB and AD). In Group A (n=13), one surgeon applied additional Triamcinolone Acetonide (TA) crystal drops (0.1 ml of 40 mg/ml of non-preservative free TA crystals) with the help of silicone tipped flute needle under silicone oil tamponade over the

site of RR at this stage. In Group B (n=11), other surgeon didn't applied Triamcinolone Acetonide (TA) crystal drops, which served as control group.

Statistical analysis: Preoperative and postoperative corrected Snellen visual acuities were converted into logMAR of visual acuity for statistical analysis. Student's paired t-test was used to evaluate change in BCVA and IOP before and after surgery in each group. Two-sample t-test was performed to evaluate the visual improvement in both groups. Fisher's Exact Test was performed to note the recurrence rate of retinal detachment in both groups as well as to note the propensity to remove silicone oil. After preliminary analysis, we performed variable selection for regression. Statistical analysis was performed using SPSS software version 20. P-value less than 0.05 was considered statistically significant.

Results : Present study included 24 eyes of 24 patients, which comprised of 16 males and 8 females. The mean age at presentation was 37.31 ± 24.47 years (Group A) and 43.18 ± 26.47 years (Group B). Indications for 360-degree RR included complex rhegmatogenous retinal detachment with extreme PVR were PVRD2 or D3 (n=9 in each group), and 360-degree intrinsic retinal contraction (n=4 in group A and n=2 in group B). BCVA at presentation was poor in both groups. In Group A, mean preoperative and postoperative BCVA at final follow up (6 months) were Log MAR $2.69 (20/9795) \pm 0.41$ [Log MAR mean (Snellen's equivalent) \pm SD] and Log MAR $1.51 (20/647) \pm 0.90$ ($p < 0.05$) respectively. In Group B, mean preoperative and postoperative BCVA at final follow up (6 months) were Log MAR $2.9 (20/15886)$ and Log MAR $2.37 (20/4688) \pm 0.86$ ($p < 0.05$) respectively. Visual improvement in Group A was significantly better than Group B (two sample t-test, $p < 0.05$). Mean postoperative IOP was 10.31 ± 5.84 mmHg (Group A) vs 11.82 ± 9.35 mm Hg (Group B). Follow-up was 12.46 ± 8.38 months in group A and 13.36 ± 9.23 months in group B. Silicone oil removal done after 6 months of primary surgery in 9/13 cases (Group A) and 1/11 case in Group B, awaiting in 2/13 (Group A) and 1/11 (Group B) and not recommended in 2/13 (Group A) and 9/11 cases (Group B). Recurrence of RD developed in 1/13 cases in Group A and 4/11 cases in Group B. This recurrent RD was found to be statistically more in Group B (Fisher's Exact Test, $p = 0.002$). Silicone oil removal (after 6 months of primary surgery) was done significantly more in Group A than Group B (Fisher's Exact test, $p = 0.0017$). Additional postoperative complications noted were postoperative epiretinal Membrane (ERM) formation (7 vs. 4 cases, Group A/B, respectively), hypotony with IOP < 8 mm Hg (6 vs. 5 cases, Group A/B, respectively), Cystoid Macular Edema (CME) (2 cases, both groups), disc pallor (2 cases, both groups), pre retinal & sub-retinal PFCL bubble (1 case, both groups), posterior pole folds (1 case, Group A) and recurrent retinal detachment due to proliferative vitreoretinopathy (1 vs. 4 cases, Group A/B, respectively). Complications have been highlighted in Table 3.

Discussion: Retinectomies are seldom required, sometimes as extensive as 360-degree retinotomy with complete excision of anterior retinal flap. Study already revealed triamcinolone reduced glial cell proliferation in acute retinal detachment. [16] Shi H et al showed the rate of primary reattachment was not significantly different between the steroid (treated with intravitreal TA during vitrectomy) and control groups, though use of steroids as an adjunct can significant-

ly decrease the incidence rate of postoperative PVR, especially for grade B PVR. [17] So adjunctive steroid treatment had the potential to modify the retinal response to detachment and thus could influence the development of new PVR. In this retrospective interventional study we report the novel approach of sub silicone oil application of triamcinolone acetonide crystal particles over the areas of RR after circumferential peripheral 360-degree retinectomy and compared them with cases where sub silicone oil TA was not applied. We hypothesised that the application of sub-silicone oil TA crystals under the silicone oil during the procedure would lower the rate of postoperative complications seen in cases requiring 360-degree RR. The extent of bare RPE-Choroid area was variable in case to case. But we have used a fixed dosage of TA, i.e. 0.1 ml (4mg) in all of our cases of Group A, irrespective of extent of bare RPE-Choroid area. Rationalities of sub-silicone oil TA crystal application over sites of RR are many. Firstly, triamcinolone acetonide, being a long-acting corticosteroid reduces deposition of fibrin due to its anti-inflammatory effect. It also inhibits RPE proliferation and subsequent PVR changes by its anti-proliferative effect. Its application under silicone oil exerts anti-PVR effect at precise location as trapped TA particles in between bare RPE/ choroid layer and silicone oil act for a long time, especially in initial periods when inflammatory activities are maximum. It can also control further blood oozing which helps in clot formation and thus again have anti-PVR effect. As it remains trapped between bare RPE-Choroid complex and Silicone oil, it doesn't cause IOP rise. Moreover application of TA under the silicone oil circumferentially can prevent targeted cytokines in a more uniform manner to halt new PVR formation from anywhere around the margin of 360-degree RR. A few studies showed that migration of TA crystals into sub-retinal space might cause retinal toxicity, [18,19] however previous studies have shown it to be safe, since it does not cause breakdown of the blood-retinal barrier and have no toxic effect on outer retinal layer in animal models. [20,21] However, it may interfere with laser retinopexy reactions at the break margin, but in our present study, we didn't find any incidence of reopening of break margin during follow-up.

Though there is significant improvement in BCVA post-operatively in both the groups, visual improvement in Group A was significantly better than Group B (two-sample t-test, $p < 0.05$) in our study. Kolomeyer AM et al reported recurrent retinal detachment in 37% of cases after primary surgery which consisted of pars plana vitrectomy with 360-degree retinectomy. [8] Similarly recurrence of RD was noted by Banaee et al in 30% of cases. [9] In the present study, recurrence of RD due to proliferative vitreoretinopathy (PVR) developed in only 7.69% (1/13) cases where sub-silicone oil TA crystal was applied, vis-a-vis 36.36% (4/11) cases in group of patients where sub-silicone oil TA crystal was not applied. This difference was statistically significant (Fisher's Exact Test, $p = 0.002$), highlighting improved anatomical outcome after intra-operative sub silicone oil application of TA crystal drops. However the incidence of post-operative ERM formation was more in Group A than Group B (53.85% vs 36.36%). Epiretinal membrane formation is the milder form of PVR, but more severe form of PVR can lead to recurrent retinal detachment formation. Our previous study showed that sub-silicone oil TA application on limited RR sites can decrease post-operative ERM formation, but can't prevent recurrent RD. [15] However it appeared from our present study, that the anti-proliferative effect

of sub-silicone oil application of TA crystal drops approach on more wide spread 360 degree RR sites may not prevent milder form of new PVR formation, like ERM, but it can prevent severe new PVR formation, which may result in recurrence of RD. Moreover silicone oil removal was also significantly more recommended in Group A. Silicone oil removal after 6 months of primary surgery was done significantly more in group A than group B (Fisher's Exact Test, $p=0.0017$). This fact indirectly highlights that treating surgeon considered cases in group A to be more anatomically stable than group B, thereby advising SOR more frequently in group A. We have seen a single case of RD after SOR only in Group B, though study showed 9.38% (3/32) cases developed retinal detachment after silicone oil removal from eyes treated with retinectomies. [22] Proportion of post-operative hypotony was nearly same in two groups. Out of 6 cases with hypotony in Group A, we removed silicone oil in 3 patients and whereas we could remove silicone oil only in 1/4 patients with hypotony in Group B. We considered anatomical success even in eyes with hypotony in absence of recurrent RD and considering this fact, Group A patients were having better anatomical outcomes. Less recurrence of RD was also the reason for more functional recovery in TA group (Group A).

In this pilot study, we had collected only 24 consecutive cases of complex RDs with extreme grade of PVR like either PVR D2/ PVR D3 or 360 degree circumferential intrinsic retinal contraction where after all kinds of intraoperative surgical manipulations, 360 degree relaxing retinectomy was the only option left to settle the detached retina as a last resort. Although the safety of sub-silicone oil application of TA particles is not a major concern, as we didn't notice any untoward side effect of TA application under silicone oil, but it's efficacy in large scale has to be proved after this pilot study. We faced some preliminary challenges during our statistical analysis. First of all, we have a small sample size comparable to the number of attributes. Another problem that needs consideration is that patients by virtue of their age, the severity of their existing PVR condition or due to other pre-conditions might inherently show better results after a surgery. In such cases, even if the effect of sub-silicone oil TA were insignificant, it's effect getting confounded with the inherent better 'recovery capability' of the patients would lead to misleading conclusions. Although we considered only extreme PVR cases like PVR D2 or more and 360 degree intrinsic retinal contractions and tried to maintain the homogeneity in both groups, the problem of some degree of 'selection Bias' could be there, as we couldn't divide the patients according to a predetermined criteria, which may cause bias in selection of cases. Thus, our problems regarding our analysis consist of : (i) Developing the procedure that would avoid the shortcomings of small sample size and (ii) Testing for the presence of selection bias, and implementing a correction for the same. In such a situation, we propose the following: We had selected variables that best described the the model to construct the regression line, and used a similar methodology to test the significance of sub-silicone oil application of TA (i.e. chose the best possible variable subset omitting TA, and test whether addition of TA was significant in the determined best variable subset). The analysis of the variable 'propensity of SOR' was done separately. We pursued the problem of variable selection for our preliminary regression analysis. Since, our sample size is small, any analysis based on large number of attributes could be potentially misleading. Moreover, as the efficacy of sub-silicone oil TA on outcomes after 360 degree RR was

the major concern in our study, we did two sample t test, although the relevance of other factors like age, pre-operative PVR status, extent of bare RPE-Choroid area after retinectomy etc should also to be considered on final outcomes in further study. In future multi-centric, prospective randomised studies with larger number of cases and long term follow up are needed to reach a consensus. Despite the above mentioned limitations the present study highlights that intra-operative sub-silicone oil application of TA crystal drops over the sites of RR after 360-degree retinectomy can help to improve anatomical and functional outcomes as a last-ditch attempt.

Conclusion: Sub-silicone oil TA crystals application over sites of RR after 360-degree relaxing retinectomy is a viable option as an adjunct in treating complex RD cases with extreme PVR, which lowers the rate of postoperative complications. Trapped TA particles in between silicone oil and bare RPE-Choroid exert localised anti-PVR effect. Functional and anatomical outcomes in group A was significantly better than in group B. Silicone oil removal was significantly more recommended in Group A.

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Legends:

Figure 1 : Intraoperative Sub-silicone oil TA crystal particles over sites of relaxing retinectomy

Figure 2 : A. TA crystal particles under silicone oil over 360-degree RR sites after 2 weeks, B. Attached retina of same patient with resolving sub-silicone oil TA particles at post-operative 1 month and C. Post SOR after 6 months of same patient with attached retina.

Figure 3 : A-D Postoperative ultra-wide field fundus picture after 360-degree relaxing retinectomy in sub-silicone oil TA crystal applied group with attached retina.

Figure 4 : The case of recurrent RD in group A.

Table 1 : Shows clinical and demographic profile of Group A patient of 360-degree RR with sub-silicone oil TA crystal applied

Table 2 : Shows clinical and demographic profile of Group B patient of 360-degree RR without sub-silicone oil TA crystal applied

Table 3 : Shows list of post-operative complications in both groups

Video 1 : Shows surgical technique of sub-silicone oil application of TA crystal drops after 360-degree RR which was applied in Group A and not in Group B.

Figures

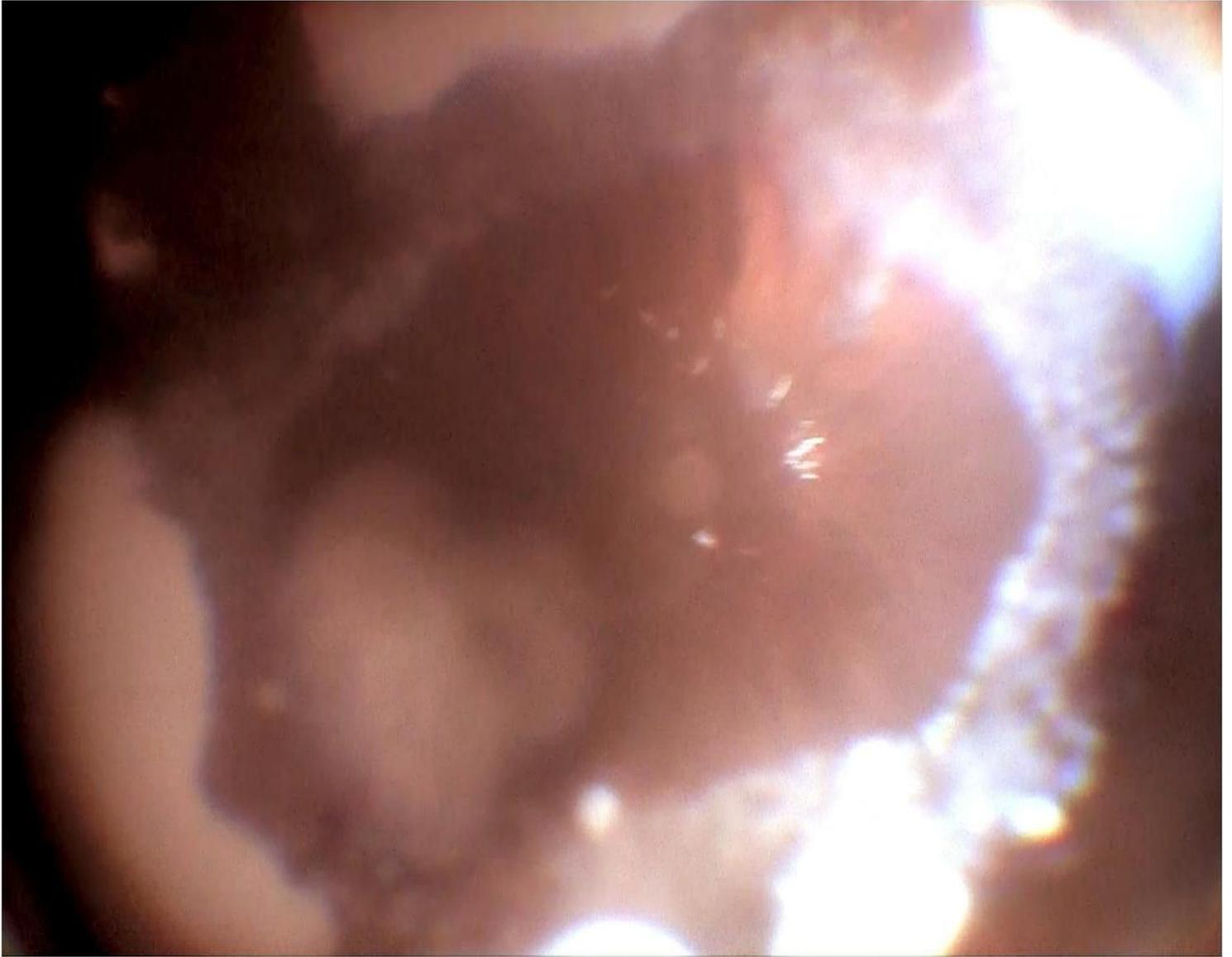


Figure 1

Intraoperative Sub-silicone oil TA crystal particles over sites of relaxing retinectomy

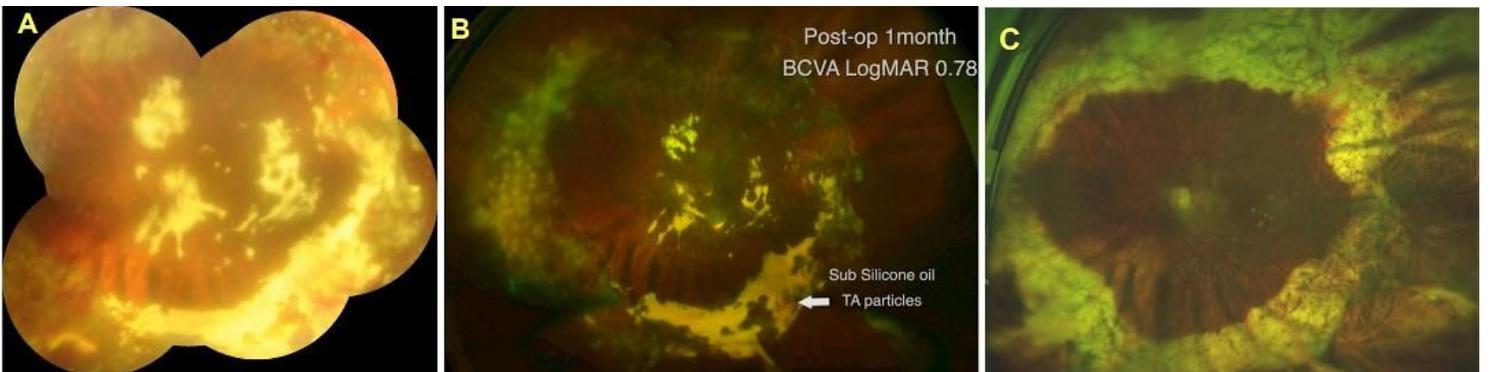


Figure 2

A. TA crystal particles under silicone oil over 360-degree RR sites after 2 weeks, B. Attached retina of same patient with resolving sub-silicone oil TA particles at post-operative 1 month and C. Post SOR after 6 months of same patient with attached retina.

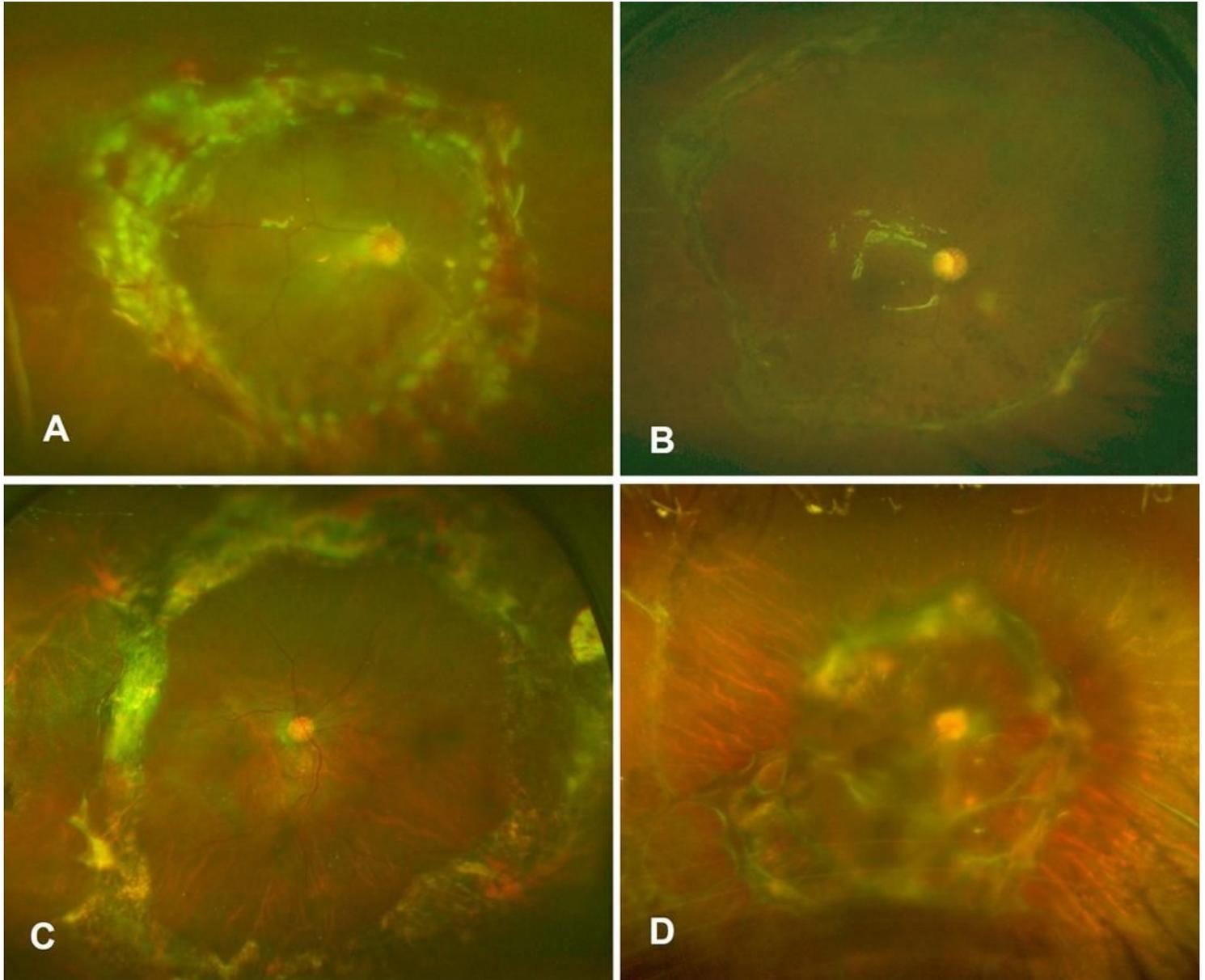


Figure 3

A-D Postoperative ultra-wide field fundus picture after 360-degree relaxing retinectomy in sub-silicone oil TA crystal applied group with attached retina.

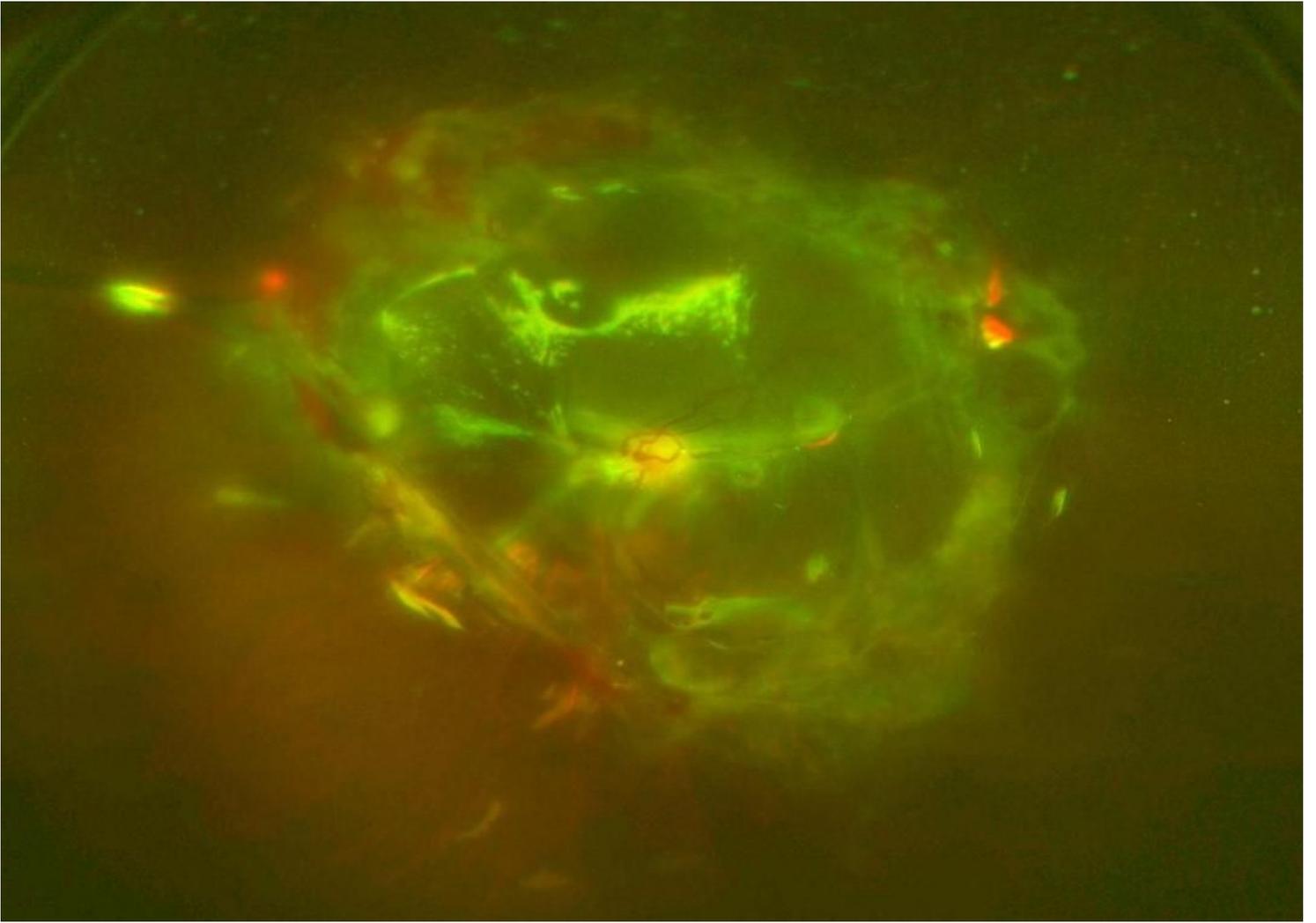


Figure 4

The case of recurrent RD in group A.

Supplementary Files

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