

Incidence of epiretinal membrane formation following treatment of diabetic retinopathy with panretinal photocoagulation therapy

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Abstract

• **AIM:** To report the incidence of epiretinal membrane (ERM) formation following panretinal photocoagulation (PRP) as the treatment for diabetic retinopathy (DR).

• **METHODS:** Retrospective cross-sectional study of patient charts between January 1st, 2010 to January 1st, 2017 with at least 1y follow-up data. All 809 patients treated with PRP for DR were evaluated for exclusion criteria and 73 eyes remained after exclusion for confounding variables related to ERM formation such as other procedures or diseases. Outcomes were determined through medical record review and masked review of optical coherence tomography (OCT) images. Cohen's kappa was completed to determine if there was an agreement between masked retinal specialists on OCT evaluations. Univariate logistic regression was used to determine the unadjusted odds ratio for patient and procedural characteristics on the formation of ERMs. Multiple logistic regression was then completed on select variables that met the cutoff of 0.25 for a statistically significant contribution by the Wald test with the sequential addition of clinical variables that contributed positively to the model.

• **RESULTS:** Among the 73 eyes studied, 9.6% formed an ERM with an average time to formation of 1.4y. The minimum power used during PRP was found to be statistically significant between non-ERM formers and ERM formers ($P=0.044$). When adjusting for all selected variables aside from minimum power used, multiple logistic

regression determined that for every 10 mW increase in minimum power used during PRP, there is an increase in log odds of 1.009 (SE: 0.003, $P=0.014$).

• **CONCLUSION:** The incidence of ERM formation in 2y following treatment of DR with PRP is roughly 1 in every 10 eyes treated.

• **KEYWORDS:** diabetic retinopathy; panretinal photocoagulation; epiretinal membranes; proliferative diabetic retinopathy

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INTRODUCTION

An epiretinal membrane (ERM) is a fibrocellular membrane that forms on the surface of the internal limiting membrane and can cause visual distortion, decreased vision, and metamorphopsia^[1-3]. ERM formation in patients with diabetic retinopathy (DR) have been associated with panretinal photocoagulation (PRP), vitreous hemorrhage (VH), intravitreal injections for treatment of diabetic macular edema (DME), and retinal detachment repair^[1,4-11]. Among the various methods of retinal detachment repair studied, the incidence of ERM formation after surgical treatment was reported to be approximately 3% to 13%, and anywhere from 7% to 70% of ERMs requiring subsequent membrane peel^[4,12-16]. The prevalence of ERM occurring following PRP as a treatment for DR has been reported at a rate of 15.8%^[17]. In the ongoing development of DR management, knowledge regarding the incidence of new ERM formation following PRP can help providers stratify risks and benefits, alongside providing insight for further investigation of the underlying mechanism for ERM formation.

However, the incidence of new ERM formation following PRP is unclear and requires further investigation and

characterization. Thus, this study aims to report the incidence of ERM formation following PRP treatment of DR.

PARTICIPANTS AND METHODS

Ethical Approval This study was approved and monitored by the University of North Carolina Institutional Review Board (Reference ID 228008), and the research adhered to the tenets of the Declaration of Helsinki. In this retrospective cross-sectional study, informant consent was waived.

A retrospective cross-sectional review of medical records for patients >18 years old treated with PRP for DR from January 1st, 2010 to January 1st, 2017, in the Department of Ophthalmology at the University of North Carolina at Chapel Hill. Patients were required to have at least 1y of follow-up data and a pre-PRP optical coherence tomography (OCT) completed. A masked review of pre-PRP OCT images was performed to identify and exclude eyes with pre-PRP ERM formation. Furthermore, patients with conditions predisposing to ERM formation prior PRP (history of endophthalmitis, retinal break, juvenile idiopathic arthritis, anterior or intermediate uveitis, sarcoidosis, Von Hippel-Lindau disease, combined hamartoma of the retina and RPE, VH, central retinal vein occlusion, retinal artery microaneurysm, Eales disease, retinitis pigmentosa, or neurofibromatosis type II) or having undergone a retinal procedure associated with increased ERM formation (retinal cryotherapy, pars plana vitrectomy, laser retinopexy, or scleral buckling) before PRP or within the study period were excluded.

Medical records of pre-PRP visits, procedural documentation, and visits at 6mo, 1, and 2y were reviewed for patient demographics, age at the time of treatment, diabetes mellitus diagnosis, post-PRP intravitreal injection, development of DME, development of VH, sessions of PRP, number of laser treatment spots, the power used during PRP, the subsequent need for ERM removal surgery and best-corrected visual acuities (BCVA). Visual acuity was converted to LogMAR values with count finger vision equating to 1.8, hand motion to 2.3, light perception to 2.6, and no light perception to 2.9. Allowance for ± 1 mo from the exact time of required follow-up was allowed during data collection. The PRP protocol implemented in the study was the conventional protocol with pulse duration of 100ms, spot size of 200 μ m, and power titrated for adequate uptake.

Masked Optical Coherence Tomography Image Review

Masked review of pre-PRP and post-PRP OCT images were performed to exclude the presence of pre-PRP ERM formation and to identify the presence of post-PRP ERM formation. OCT images were obtained from the pre-operative, 6mo, 1, and 2y follow-up visits and reviewed by two masked retina specialists (George R and Zhang AY) for the presence or absence of an ERM. A third masked retina specialist's (Landers III

MB) assessment was used when the original two specialists disagreed. Based on Stevenson *et al*^[18], the accepted definition of an ERM on OCT is a hyperreflective white line above the level of the internal limiting membrane that crosses the fovea. Cohen kappa was completed to determine the degree of agreement between masked retinal specialists on OCT evaluations.

Statistical Analysis The primary outcome of interest was the presence of an ERM following treatment. The normality of distributions was assessed by the Shapiro-Wilk test. Medians and interquartile ranges (IQR) were reported when the distribution was non-parametric. Chi-square tests or Fischer's exact test, when sample sizes were small, were used to determine whether categorical variables, such as sex, were statistically significantly different between groups alongside the Cramer's V to calculate correlation when statistical significance was present. Mann-Whitney *U* test was used when comparing continuous variables, such as age at PRP, between ERM formers and non-ERM formers. The Mann-Whitney *U* test results were confirmed to have similar distributions by visual inspection. The Wilcoxon signed-rank test was used to determine whether a statistically significant difference was present between paired or match observations, such as comparing pre-PRP to post-PRP best-corrected visual acuity. The approximate symmetrical distribution of difference scores from the Wilcoxon signed-rank tests was confirmed by a histogram with a superimposed normal curve.

Univariate logistic regression was used to determine the unadjusted odds ratio (OR) for patient and procedural characteristics on the formation of ERMs. Multiple logistic regression was then completed on select variables that met the cutoff of 0.25 for a statistically significant contribution by the Wald test with the sequential addition of clinical variables that contributed positively to the model^[19]. Cohen's kappa was completed to determine if there was an agreement between masked retinal specialists on OCT evaluations. All data were analyzed using the Statistical Package for the Social Sciences (version 26.0; IBM Corporation, Armonk, NY, USA), and *P*-values less than 0.05 were considered statistically significant.

Post-Hoc Analysis Repeat review of patient charts were completed to provide comparison with sole retrospective chart review findings and to assess for the presence of cataract and/or refractive surgery during the study period.

RESULTS

Patient Characteristics During the study period, there were 26 593 patients with diabetes mellitus evaluated by the department of ophthalmology and 809 patients met inclusion criteria. Among them, 54 patients (73 eyes) were analyzed following evaluation of exclusion criteria (363 patients had a disease other than DR associated with ERM formation, 230 patients had other procedures related to ERM formation,

129 had a session of PRP prior to establishing care with the department of ophthalmology, 25 patients did not have sufficient follow-up data, 8 patients had pre-PRP ERM on masked review). All patients were required to have completed 1-year follow-up with OCT imaging, and 69.9% had completed a two-year follow-up visit.

Among 73 eyes from 54 patients studied, 29 (54.7%) eyes were from women. The median age at the time of PRP was 56-years-old (IQR 12.37). Eyes from individuals who identified as White or Caucasian comprised 65.8% of the population, while 27.4% identified as Black or African American, and 0.1% identified as other. Eyes diagnosed with type II diabetes mellitus were the majority at 86.3%. Post-PRP development of DME was present for 30.2% of eyes, while post-PRP development of VH was present for 12.4% of eyes, and post-PRP intravitreal injection treatment was needed for 34.1% of eyes. There was no statistically significant difference between ERM formers and non-ERM formers regarding sex ($P=0.198$), race ($P=0.187$), or diagnosis of diabetes mellitus ($P=0.578$).

Graders were offered the option of present, absent, or insufficient image quality for each OCT image. Both specialists agreed on 450 OCT images out of 484 images. However, specialist 1 diagnosed the presence of an ERM on 17 eyes that specialist 2 did not, and specialist 1 diagnosed the lack of an ERM on 7 eyes that specialist 2 diagnosed as being present. There was moderate agreement between the two masked retinal specialists, $\kappa=0.568$, $P<0.0005$ ^[20]. Masked review of OCT images determined an incidence of 9.6% (7 eyes) within the following two years after PRP, with an average of 1.4y between treatment and ERM diagnosis. Among ERM formers, no eyes underwent subsequent pars plana vitrectomy with membrane peeling due to ERM formation.

Median pre-PRP BCVA for non-ERM formers was logMAR 0.34 (IQR 0.40), while the median pre-PRP BCVA for ERM formers was logMAR 0.27 (IQR 0.29). Post-PRP, at time of 2-year follow-up, BCVA for non-ERM formers was logMAR 0.34 (IQR 0.47) and post-PRP BCVA for ERM formers was logMAR 0.44 (IQR 0.43). A total of 16 eyes (21.9%) experienced a decrease in visual acuity of at least 2 lines on the Snellen chart at 2 years. Pre-laser and post-laser BCVA was not statistically different between membrane formers and non-formers ($P=0.568$ and $P=0.488$, respectively). There was also no statistically significant difference between pre- and post-laser BCVA for ERM-formers ($P=0.307$). Furthermore, no patients underwent cataract or refractive surgery during the study period.

The median minimum power used for non-ERM formers was 200 mW (IQR 110 mW) and 300 mW (IQR 190 mW) for ERM formers. The median maximum power used for non-ERM formers was 300 mW (IQR 170 mW) compared to 355 mW

Table 1 Univariate analysis (unadjusted OR)

Variable of interest	OR	95%CI		P
		Lower	Upper	
Sex	3.318	0.944	11.665	0.053
Race	5.174	1.502	17.819	0.589
Age at PRP	1.033	0.974	1.095	0.258
Diabetes mellitus type	1.495	0.179	12.48	0.697
History of intravitreal injection	0.963	0.273	3.392	0.952
History of DME	0.432	0.09	2.073	0.258
History of VH	0.618	0.074	5.138	0.637
Number of PRP session	1.469	0.897	2.406	0.133
Number of PRP spots	1	1	1.001	0.443
Minimum power during PRP	1.007	1.001	1.012	0.026
Maximum power during PRP	1.002	0.998	1.006	0.258
Visual acuity prior PRP	0.672	0.172	2.625	0.542

OR: Odds ratio; CI: Confidence interval; PRP: Panretinal photocoagulation; DME: Diabetic macular edema; VH: Vitreous hemorrhage.

(IQR 182.5 mW) for ERM formers. The median sessions of PRP were 2 (IQR 2) for both non-ERM formers and ERM formers. The median number of PRP spots for non-ERM formers was 1828 (IQR 1249) and 1983 (IQR 1325) for ERM formers. Most eyes (56.6%) received multiple sessions of PRP. ERMs formed in 10% of eyes that experienced a 2 line Snellen chart decrease in visual acuity, 11% of eyes that had multiple sessions of PRP, and 7.1% of eyes that had a single session of PRP. Among ERM-formers, 66.7% have multiple sessions of PRP. Regarding PRP characteristics, only the minimum power used was found to be statistically significant between non-ERM formers and ERM formers ($P=0.044$). No statistically significant difference was found between ERM formers and non-ERM formers based on the number of PRP sessions ($P=0.337$), maximum power ($P=0.134$), or number of PRP spots (0.898).

Following univariate logistic regression analysis, sex ($P=0.053$), number of PRP sessions ($P=0.133$), and minimum power used during PRP ($P=0.026$) met the threshold for inclusion as adjustments in the multiple logistic regression model (Table 1). When including sex, number of PRP sessions, and minimum power used during PRP, the model area under the receiver operating characteristic (ROC) curve was 0.845 (95%CI 0.739-0.951, $P<0.0005$). The additional inclusion, based on clinical relevance, of the age, post-PRP intravitreal injections, and post-PRP development of VH produced a model with an area under the ROC curve of 0.847 (95%CI 0.742-0.953, $P\leq 0.0005$)^[21-26]. When adjusting for all selected variables aside from minimum power used, multiple logistic regression determined that for every 10 mW increase in minimum power used during PRP, there is an increase in log odds of 1.009 (SE: 0.003, $P=0.014$). Other patient and procedural characteristics were found to not have an association following the addition of model adjustments.

DISCUSSION

There is currently no direct comparison available for our reported incidence rate of ERM formation at 9.6%. Soman *et al*^[17] reported a prevalence for post-PRP ERM formation, lacking pre-PRP OCTs needed to exclude pre-existing ERMs, of 15.8% at three months. When we performed a subsequent analysis of overall prevalence rate of ERM in our study by including eyes with pre-PRP ERMs, our study finds a similar rate of 11% at 6mo.

Demographic Factors The mean age of eyes at the time of PRP studied by Soman *et al* is similar to the median reported within our study, but no analysis on the influence of age is available for comparison^[17]. However, patients who were 30y or older had a higher incidence of ERM formation following retinal detachment repair, with the highest incidence at 50–60 years of age^[13]. Additionally, studies combining primary and secondary ERMs found the prevalence of ERMs to be related to later ages in life^[24-27]. Even so, multiple logistic regression found no difference in the strength of association among different ages when adjusting for model covariates, which suggests variables other than age at PRP are at play when discussing ERM formation following PRP for treatment of DR. Similarly to age at the time of PRP, the ratio of male to female in our study is similar to the population previously studied by Soman *et al*^[17], but no analysis is available for comparison. Investigation of the prevalence of both primary and secondary ERMs among Caucasians and Asians, however, find women to have a higher prevalence^[24-27]. In contrast, ERM-formers were more likely to be male in our study. Regardless, multiple logistic regression determined no difference in the strength of association with ERM formation between men and women. Again, suggesting other variables to be more influential to the association between ERM formation and PRP for the treatment of DR than sex.

Comparison of Retinal Procedures and Surgeries

Compared to other procedures associated with ERM formation, PRP is similar to the incidence of 9.5% found following intravitreal injections for treatment of DME and within the range of 6.1% to 12.8% reported following retinal detachment repair involving pars plana vitrectomy^[4-5,12-13]. Conversely, the incidence of ERM formation following cryoretinopexy and laser retinopexy is significantly lower at 4.3% and 2.9%, respectively^[14]. The larger surface area of retina interacting with the treatment modality seen in PRP in comparison to cryoretinopexy or laser retinopexy may contribute to the difference in incidence. However, in regards to the timing until ERM formation after a procedure, an average of 1.4y is similar to rates following cryoretinopexy and laser retinopexy^[14].

PRP is the gold standard for the treatment of PDR, but carries the potential for vision loss at rates varying between 10% to 43%^[17,28-29]. ERM formation was discovered in 9% of eyes that

experienced vision loss by McDonald and Schatz^[28], defined as a decrease in at least 2 lines on the Snellen chart. Similarly, we found ERMs present in 10% of eyes with 2 lines of visual acuity decline. However, there was no statistical difference in the BCVA between ERM formers and non-ERM formers at 2y. Furthermore, no eyes underwent membrane peel due to visual significance or metamorphopsia compared to after Cryoretinopexy at 7.7%, laser retinopexy at 10.4%, and pars plana vitrectomy retinal detachment repair of 33%-70%^[4,12,14].

Effect of Laser Power Documentation of the power used during PRP is not clearly documented in previous reports investigating the relationship between ERM formation and PRP for treatment of DR^[17,28]. Nevertheless, our study's findings from multiple logistic regression suggest an increase in 50 mW of minimum power used during PRP to increase the odds of an ERM forming in the upcoming two years by 1.57. In the context of the DRS protocol for a standard argon-type laser PRP, selecting the upper bound of power at 250 mW rather than the lower bound of power at 200 mW as a minimum will equate to an increase in odds for ERM formation in the upcoming two years by 1.57^[30].

Study Design and Generalizability The retrospective nature of the study design precludes conclusions of causation. Furthermore, the study was designed to elucidate the incidence of ERM formation, but we present our findings on potential associations for future investigation. Study generalizability should be noted in the context of the study predominance for White or Caucasian eyes and eyes with type 2 diabetes mellitus. Furthermore, findings are limited by the small sample size. However, this is a byproduct of the study design's strength in rigorous inclusion/exclusion criteria needed to best isolate the incidence rate. To illustrate the concern for retrospective analysis of incidence without evaluation of retinal imaging, post-hoc analysis of data based on chart review alone determined a rate for ERM formation following PRP at 21%. Furthermore, the presence of multiple diagnostic criteria for ERM formation and the inherent subjective aspects within those criteria can further confound retrospective chart review study findings. Nevertheless, there also remains a subjective component to our studies agreed upon diagnostic criteria. Even so, our Cohen kappa score showed moderate to borderline good agreement^[20].

In conclusion, studying predominantly white or Caucasian eyes with type 2 diabetes mellitus demonstrates an incidence of ERM formation within two years following treatment of DR with PRP is roughly 1 in every 10 eyes treated.

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