1:10 PM

Multilayered Inverse Internal Limiting

Membrane Peeling – Is ILM the Culprit or

Savior in the Treatment of Large Macular

Holes and Macular Hole R.D.?



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OBJECTIVE To study the anatomical and visual outcomes of Multilayered inverse ILM peeling in patients with large Macular hole(MH)(>400 microns) and Macular hole associated Retinal detachments (MH-RD)

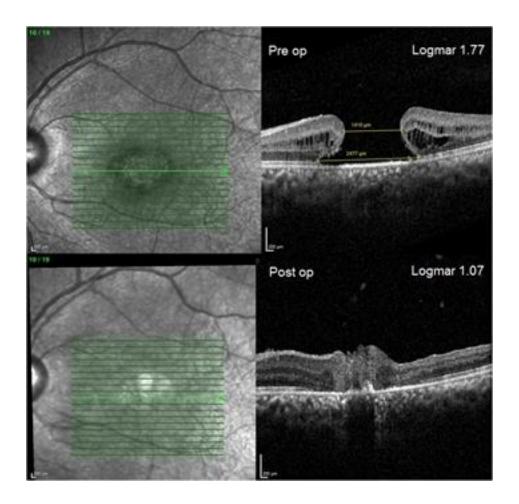
PURPOSE The ILM is believed to be the culprit in MH and conventional ILM peeling has been done till date. Multilayered ILM peeling utilizes autologous tissue to bridge the defect in large MH(>400 microns) and MH-RD and is believed to be a savior rather than culprit. This study aims to analyse the visual and anatomical outcomes of Multilayered Inverse Peeling in both large MH and MH –RD.

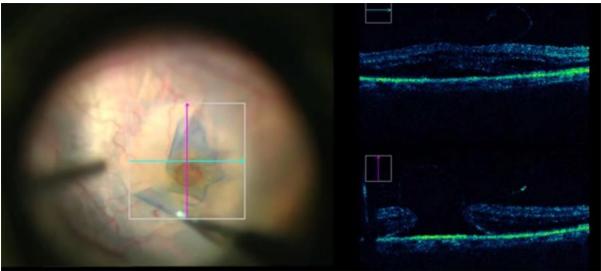
METHODS A prospective, randomized, interventional study of 45 eyes of 44 patients with MH and MH-RD. Pre-op Minimum Linear Diameter, Basal Diameter and Macular hole index were noted in all cases with large MH. All eyes underwent 25 gauge pars plana vitrectomy with induction of PVD.ILM flaps were peeled and placed one over the other

in a multilayered fashion in the macular hole (Intra-op OCT guided). The same technique was done in MH-RD under PFCL. Non-expansile C3F8 gas injected after fluid air exchange. Prone position was advised for 1 week ,patients were followed up 3 months post surgery. BCVA, IOP, type of closure on OCT were noted at post-op visits. Functional and anatomical outcomes were analyzed.

RESULTS 7/45 eyes had MH-RD. Mean age was 55.6 \pm 16.7 years.14(31.1%) were males and 31(68.9%) were females.40(88.9%) had idiopathic macular hole,4(8.9%) had traumatic macular hole and 1(2.2%) had post surgery macular hole. Mean Minimum Linear Diameter was 761.2 \pm 400.8 μ m,Basal diameter was 1392 \pm 427.2 μ m and mean MHI was 0.5 \pm 0.8.Mean Logmar BCVA at Pre-op period was 1.4 \pm 0.5 and at 3rd month was 1.1 \pm 0.5. There was significant improvement in BCVA at 3 months compared to Pre op. 41 (91.1%) achieved type 1 macular hole closure,3(6.6%) achieved type 2 closure and 1(2.2%) did not achieve closure.2/3 eyes showed good visual outcome despite having type 2 closure of MH. Patients with type 1 closure showed a significant improvement in vision at 3 months(p<0.001),while those with type 2 closure did not show a significant change in BCVA.

CONCLUSION Multilayered inverted ILM flap technique improves anatomical and visual outcomes in treatment of MH and MH-RD. It provides a promising method in preserving ILM flaps without causing flap dislodgment. Patients with type 1 closure showed a significant improvement in visual acuity, hence compelling us to attempt closure in large macular holes to achieve better visual outcomes.





HUMAN RESEARCH This study involves human research. IRB Approval Status: Approved by institutional review board

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Structural Outcomes of Autologous Neurosensory Retinal Flap for Large and Refractory Macular Holes: International Collaborative Study Group



- Dilraj S Grewal, MD
- Kazuaki Kadonosono, MD
- · Barbara Parolini, MD
- Steve T. Charles, MD
- Tamer H. Mahmoud, MD, PhD

OBJECTIVE To report the structural outcomes of the autologous neurosensory retinal free flap technique for closure of refractory large macular holes

PURPOSE To report the OCT structural outcomes of the autologous neurosensory retinal free flap technique for closure of large and refractory macular holes (MH).

METHODS IRB approved retrospective, interventional, consecutive case series from four centers. Forty-nine eyes of 49 participants with large full thickness macular holes underwent pars plana vitrectomy with an autologous neurosensory retinal free flap. Surgical technique consisted of harvest of a neurosensory retinal flap from the midperiphery, transfer of the transplant over the macular hole which was covered with perfluorcarbon, and then exchanged for silicone oil (n=27) or gas tamponade (n=14) or the perfluorocarbon was used for short duration tamponade (n=8). Preoperative and postoperative registered OCT images were analyzed at single reading center to compare various macular hole parameters.

RESULTS Forty-nine eyes underwent the autologous neurosensory retinal flap. Mean follow up was 9.05 ± 6.7 months. Among patients with good quality OCT images available, mean preoperative largest basal diameter was 1529 ± 656.4 microns and mean inner opening diameter was 848.8 ± 422.5 microns. Complete anatomic closure of MH by OCT was obtained in 44/49 eyes (89.8%). Mean size of residual MH in the 5 eyes not closed was 1069 microns. Mean preoperative ellipsoid zone defect was 1777.3 ± 513.8 microns which reduced to 1370 ± 556.9 microns at final follow up (p=0.007). Mean preoperative external limiting defect was 1681.5 ± 429 microns which reduced to 1408.5 ± 571.2 microns at final follow up (p=0.017). Mean choroidal thickness was 75.8 ± 86.24 microns consistent with majority of eyes being high myopes. Mean corrected visual acuity (\log MAR) improved from 1.07 ± 0.62 (range 0.3 to 3) to 0.96 ± 0.51 (range 0.1 to 2) at last post-operative visit ((p=0.01, two tailed t test).

CONCLUSION Autologous neurosensory retinal flap for macular holes resulted in complete anatomic closure in 90% of eyes with improved restoration of ellipsoid zone and external limiting membrane.

HUMAN RESEARCH This study involves human research.

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Functional Outcome of Autologous Neurosensory Retinal Flap for Large and Refractory Macular Holes: Multicenter International Collaborative Study Group

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- Tamer H. Mahmoud, MD, PhD
- Steve T. Charles, MD
- Barbara Parolini, MD

OBJECTIVE To report the functional outcomes of the autologous neurosensory retinal free flap technique for closure of large and refractory large macular holes.

PURPOSE To report the functional outcomes of the autologous neurosensory retinal free flap technique for closure of large macular holes (MH).

METHODS IRB approved retrospective, interventional case series from four centers. Forty-nine eyes of 49 participants with large full thickness macular holes underwent pars plana vitrectomy with an autologous neurosensory retinal free flap. Surgical technique consisted of harvest of a neurosensory retinal flap from the mid-periphery, transfer of the transplant over the macular hole which was covered with perfluorcarbon, and then exchanged for silicone oil or gas tamponade or the perfluorocarbon was used for short duration tamponade.

RESULTS Forty-nine eyes underwent the autologous neurosensory retinal flap. Forty-one eyes had refractory macular holes following prior surgery, Intraocular tamponade used was silicone oil (n=27) or C3F8 gas (n=14) or Perfluorocarbon (n=8). Mean age was 61 \pm 14.9 years. Mean follow up was 9.05 \pm 6.7 months. Complete anatomic closure of MH by

OCT was obtained in 44/49 eyes (89.8%). Mean preoperative corrected visual acuity (logMAR) was 1.07 ± 0.62 (range 0.3 to 3) which showed a statistically significant improvement (p=0.01, two tailed t test) to 0.96 ± 0.51 (range 0.1 to 2) at the last post-operative visit. Overall, vision improved 1 or more lines in 21 eyes (42.8%), stayed the same in 20 eyes (40.8%) and worsened in 8 eyes (16.3%). Post-operative complications encountered were retinal detachment (n=1) and vitreous hemorrhage (n=1) both of which required a single additional surgery.

CONCLUSION Autologous neurosensory retinal flap for large macular holes is a safe technique and resulted in anatomic closure in 90% of eyes visual improvement in over 40% of eyes.

HUMAN RESEARCH This study involves human research.

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Comparative Study of Inverted ILM Flap and PRP as an Adjunct in Large Macular Holes



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OBJECTIVE To compare the anatomical and visual outcome of inverted internal limiting membrane (ILM) flap and platelet rich plasma (PRP) as an adjunct in idiopathic large macular holes.

PURPOSE Immense technological refinements have has ameliorated the anatomical success rates of macular hole surgery to as high as 93-98%. But poor prognosis for large macular holes i.e. anatomical success rate of mere 40 to 80%, has demoralized most surgeons from operating upon these patients. The high concentration of platelets present in PRP, due to the presence of their growth factors, is now extensively being used extensively for hair growth, diabetic foot treatment and other cosmetic surgeries.

METHODS Prospective, randomized trial. Patients undergoing 25G pars plana vitrectomy (PPV) for idiopathic full thickness macular hole (FTMH) with minimum diameter (MD) range 600-1500μm. Procedure: Group A- Inverted ILM flap, Group B-PRP as an adjunct. 18mL of blood is mixed with 2mL of anticoagulant citrate dextrose solution A in FDA-approved PRP Kit and centrifuged to separate the plasma layer. After Fluid-air exchange is done, few drops of PRP are injected over the macular hole. The

patients in Group A were advised prone posture while patients in group B were advised supine posture, as platelets being heavier are likely to settle on the maFula.FTMH evaluated with Optical Coherence Tomography. Snellen visual acuity converted to logMAR used for statistical analysis

RESULTS There were 25 patients in each group. Mean MD in Group A and B were 809.93±122.27μm and 757.46±87.54μm (p value, 0.070). Median best corrected visual acuity (BCVA) were logMAR 0.78 and 0.69 respectively (p value, 0.266). Till now we have seen first post-operative follow-up at 15 days of 10 patients only. In Group A, 83.3% (n=10/12) patients attained Type1 Closure while 16.7% (n=2/12) remained open. In Group B, 90.0% patients attained Type1 Closure (n=9/10) while 10.0% (n=1/10) remained open (p value, 0.353). Median BCVA after 15 days were logMAR 0.60 and 0.62 (p value, 0.327). In general, the patients in Group B were happier with the quality of vision attained after the surgery. Also, these patients did not have the pains experienced with prone posture. None of the patients in Group B had any complications like endophthalmitis or any other adverse reaction.

CONCLUSION Although long term results are awaited, PRP seems to be a non-inferior technique compared to Inverted ILM flap is better technique for idiopathic large FTMH. However, PRP does not involve difficult maneuvers as involved in placing the inverted flap. Due to the presence of growth factors, we expect a better visual outcome.

HUMAN RESEARCH This study involves human research. IRB Approval Status: Approved by institutional review board

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Surgical Repair of Chronic Macular Holes: Functional and Anatomic Outcomes Using No Facedown Positioning



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OBJECTIVE To report outcomes for patients who underwent surgery for repair of their chronic macular holes of greater than 1-year duration.

PURPOSE To report visual and anatomical outcomes following the repair of chronic idiopathic macular holes (MH) with no face-down positioning.

METHODS We conducted a retrospective consecutive case-series of MH repair cases that underwent pars plana vitrectomy (PPV) with broad internal limiting membrane (ILM) peeling, 20% SF₆ or 14% C₃F₈ gas and no face-down positioning between March 2009 and December 2017. Cases with MH duration of less than 1 year were excluded. Patients with MH duration >1 year and less than one month of post-operative follow up were also excluded. There were no other exclusion criteria. Hole staging and measurements were performed with spectral domain optical coherence tomography (SD-OCT). Snellen visual acuity was converted to LogMAR for quantitative analysis using the Shapiro-Wilk Normality and Student t-tests.

RESULTS Eighteen eyes of 18 patients were included in this case series. Fifteen eyes had stage 4 MH and 3 eyes had stage 3 MH. Mean MH duration was 5.0 \pm 6.8 years [range 1yr 2days to 21.7 yrs], median 1.8 years (25th quartile 1.2 yrs, 75th 4.6 yrs). Roughly two thirds of MHs had a basal diameter of more than 1000 μ m. Mean preoperative Snellen visual acuity (VA) was 20/275. Single-surgery anatomical success was achieved in 15/18 eyes. Two of the three eyes that did not achieve successful closure with the initial surgery achieved closure with a second surgery. Mean postoperative Snellen VA was 20/102 (p=0.004). Visual acuity improved in all patients who achieved anatomic MH closure. When analyzed by lens status, both phakic and pseudophakic patients demonstrated a significant improvement in visual acuity after MH repair and subsequent cataract surgery in pre-op phakic patients (p = 0.02 and 0.046, respectively). Use of C_3F_8 gas was associated with greater efficacy in the most chronic MHs.

CONCLUSION All patients who had successful repair of their chronic macular hole (94%) in this series experienced improved post-operative visual acuity. Successful closure of chronic MHs is feasible using no-face-down macular hole repair.

HUMAN RESEARCH This study involves human research.

IRB Approval Status: Approved by institutional review board

1:47 PM

Radial Retinal Incisions for the Treatment of Persistent Macula Holes

• Christian Pruente, MD

OBJECTIVE Radial retinal incisions may increase the success rate for macula hole closure in persistent macula holes after initial vitrectomy with ILM peeling.

PURPOSE Various surgical techniques have been described for managing persistent macula holes after vitrectomy with ILM peeling. However the closure rate after these procedures is limited. Therefore, a new technique, performing radial retinal incisions (retinotomies) was performed in eyes with large persistent macula holes despite previous vitrectomy with ILM peeling.

METHODS In a retrospective case series the closure rate and Snellen visual acuity was evaluated in eyes with persistent macular hole after vitrectomy with detachment of the posterior vitreous and ILM peeling. Small incision re-vitrectomy with radial retinal incisions (retinotomies) and air-tamponade was performed in 15 eyes of 15 patients. For all eyes Snellen BCVA, biomicroscopic fundus evaluation and OCT examination were performed 6 to 24 month after re-vitrectomy.

RESULTS At baseline the mean macula hole diameter was $683\pm99~\mu m$. At the final examination 12 of 15 macula holes (80%) were closed. Visual acuity increased in 11 eyes, was stable in 2 eyes (1 without macula hole closure and declined in 2 eyes, both without macular hole closure. Mean BCVA increased from Snellen 0.10 ± 0.05 at baseline to 0.30 ± 0.14 (logMar 1.03 ± 0.19 to 0.60 ± 0.29). In all successful cases the macula hole closure was observed after 3 days and no eye demonstrated recurrence oft a macula hole was observed.

CONCLUSION These results in a limited case serious suggest that radial retinal incisions in persistent macula holes after initial surgery with ILM peeling increases the success-rate

for macula hole closure and results in relevant increase of BCVA. However, as the number of eyes in this series is limited the result has to be confirmed in a larger population.

HUMAN RESEARCH This study involves human research.

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Retinal Function Assessment by Microperimetry-3 After Internal Limiting Membrane Peeling in Macular Hole Patients



Wu Liu, MD

OBJECTIVE To evaluate the retinal sensitivity after internal limiting membrane peeling in macular hole patients by microperimetry-3.

PURPOSE Removal of internal limiting membrane (ILM) may cause mechanical trauma to retinal nerve fiber layer, but its effect on retinal function still needs further clarified. Herein the authors use microperimetry-3 (MP-3) to evaluate the retinal sensitivity changes in areas of ILM peeling in patients with idiopathic macular hole before and after vitrectomy.

METHODS This is a prospective, cohort study on 42 eyes of 42 patients with idiopathic macular holes (MH) who were treated by 23-gauge vitrectomy and ILM peeling with air tamponade. Patients with glaucoma, myopia<-3.0 diopters (D), severe cataract, or other ocular diseases that could interfere with the measurements were excluded. Colour fundus photography, OCT and MP-3 were performed 1 week before and 1 month after surgery. In MP-3 examination, a customized pattern with a visual field of 8° and 45 test

spots was used, which centered on the MH. The spots in the outer rings which are within the ILM peeling area and at least 0.5° off the margin of MH were selected for calculating retinal sensitivity. A follow-up pattern was used to ensure the selected spots were in accord with the initial location.

RESULTS All eyes had achieved an anatomical success within 1 month.

Phacoemulsification and IOL implantation was performed in 33 eyes. BCVA (logMAR) was significantly increased after surgery: 1.06±0.35 versus 0.53±0.29 (t=-3.374, P=0.006). The number of selected spots ranged from 22 to 28 (mean:26.33±1.78). The mean retinal sensitivity (MRS) (in dB) within the selected area was significantly increased after ILM peeling: 22.92±3.71 dB pre-operation versus 25.70±2.45 dB post-operation (u=3.834, P=0.000). The post-operative MRS in the selected area was increased in 36 patients and deceased in 6 patients. Patients with increased MRS are significantly younger than patients with deceased MRS: 61.74±4.99 years versus 70.67±7.53 years (t=-2.677, P=0.038). After ILM peeling, the increasing extent of MRS was significantly higher in inferior retina than that in superior retina (u=3.511, P=0.000), and was significantly higher in nasal retina than that in temporal retina (u=3.937, P=0.000).

CONCLUSION ILM peeling in normal retina will not decreased the retinal function, except in some patients with advanced age. In patients with MHs, the changes of MRS followed by ILM peeling may result from the procedure or the retinal structure itself. Since dye was not used in this study, its potential influence on retinal sensitivity needs further evaluation.

HUMAN RESEARCH This study involves human research.

2:02 PM

Effect of Baseline Ocular Characteristics on Vitreomacular Adhesion/Vitreomacular Traction Resolution With Ocriplasmin: ORBIT Study Subanalysis

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- Jay S. Duker, MD
- Jeffrey S. Heier, MD
- · Peter K. Kaiser, MD
- Daniel F. Rosberger, MD, PhD, MPH
- Mathew W. MacCumber, MD, PhD
- Dante Joseph Pieramici, MD
- · Arshad M. Khanani, MD

OBJECTIVE To assess the effect of baseline ocular patient characteristics on resolution of vitreomacular adhesion (VMA)/vitreomacular traction (VMT) in patients receiving ocriplasmin.

PURPOSE The phase 4 Ocriplasmin Research to Better Inform Treatment (ORBIT, NCT02079883) study evaluated clinical outcomes and safety of patients receiving ocriplasmin for the treatment of symptomatic VMA/VMT in a real-world setting. This sub-analysis of the ORBIT study assessed the effect of baseline ocular patient characteristics on resolution of VMA/VMT. Primary data have been previously reported.

METHODS This multicenter, prospective, observational study included patients (≥18 years) treated with a single intravitreal injection of ocriplasmin 0.125 mg. The presence of VMA was assessed by spectral domain optical coherence tomography (SD-OCT) images analyzed by an independent central reading center (CRC). Clinical measures were assessed at baseline and up to 12 months post-injection. Pre-specified sub-analyses

examined the effect of baseline demographics and ocular parameters on VMA resolution, including patient age, lens status, presence/absence of full-thickness macular hole (FTMH), epiretinal membrane (ERM), and subretinal fluid (SRF). Local IRB/ethics committees approved the protocol.

RESULTS ORBIT enrolled 539 patients; 480 patients had CRC-analyzed SD-OCT confirmed VMA/VMT at baseline and were included in the efficacy analyses. A smaller VMA diameter at baseline was associated with a higher VMA resolution rate at Month 12 (\leq 500 µm: 65.0% [95% CI: 59.6–70.1]; >500– \leq 1500 µm: 41.2% [32.1–50.8]). VMA resolution rate at Month 12 was higher in patients with FTMH at baseline (72.0% [63.0–79.9]) than in patients without FTMH (54.7% [49.4–59.9]). Phakic patients had a higher rate of VMA resolution than pseudophakic patients (65.9% [60.4–71.1] vs 45.1% [37.2–53.1], respectively). The presence of ERM at baseline resulted in a lower VMA resolution rate (43.2% [34.1–52.7]) compared with the absence of ERM (64.1% [58.9–69.0]). The presence of SRF at baseline did not affect VMA resolution (SRF present: 61.6% [51.9–70.6]; SRF absent: 58.2% [52.9–63.2]). The rate of VMA resolution at Month 12 was higher in patients <65 years (80.9% [71.2–88.5]) than in those \geq 65 years (54.0% [48.9–59.0]).

CONCLUSION Patient selection based on baseline ocular characteristics can help identify patients more likely to have resolution of VMA/VMT following ocriplasmin treatment. Patients aged <65 years and those with FTMH, smaller area of focal adhesion, absence of ERM, and phakic lens status have a greater chance of success. These results confirm the findings of previous prospective, randomized studies.

HUMAN RESEARCH This study involves human research. IRB Approval Status: Approved by institutional review board

2:07 PM

Visual Outcomes of Primary Versus Secondary Epiretinal Membrane Following Vitrectomy and Cataract Surgery

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- Sami H. Uwaydat, MD

OBJECTIVE Is the outcome of cataract extraction and pars plana vitrectomy in eyes with secondary epiretinal membranes (ERM) inferior to surgery for primary ERM?

PURPOSE While several studies reported on the visual outcome of cataract extraction and pars plana vitrectomy in eyes with primary ERM, there is paucity of data on the outcome of secondary ERM. We aimed to analyze the visual outcome and cystoid macular edema (CME) risk with following sequential or combined vitrectomy and cataract surgery in eyes with primary and secondary epiretinal membranes (ERM)

METHODS Retrospective review of cataract procedures performed in 8 UK Hospitals was conducted. Subjects who had ERM peel combined with or prior to cataract extraction were included in the analysis. Eyes were classified into primary and secondary ERM groups, the latter was sub-classified into proliferative diabetic retinopathy (PDR), retinal vein occlusion (RVO), retinal detachment (RD) and uveitis. Subjects who had an associated copathologies including age related macular degeneration, glaucoma and multiple copathologies and prior intraocular procedure other than ERM peel were excluded. Change in vision and incidence of cystoid macular edema (CME) after cataract extraction were analyzed.

RESULTS Electronic records of 217,557 eyes undergone cataract surgery between 2005-2015 were extracted. Of these, 2,721 eyes had ERM peel prior to or combined with cataract extraction. After exclusion of 1, 926 ineligible eyes, 554 eyes with primary ERM

and 241 eyes with secondary ERM were included in the study. At 4-12 weeks postoperative visit, the mean visual gain was 0.2 ± 0.5 , 0.4 ± 0.5 and 0.2 ± 0.5 LogMAR in the primary ERM group, RD (n=112) and RVO (n=64) subgroups, respectively (P<0.05). However, the mean visual gain of 0.1 ± 0.2 and 0.2 ± 0.5 in the PDR (n=42) and uveitis (n=23) subgroups, respectively, was not significant (P>0.05). The proportion of eyes achieving 0.3 LogMAR (~20/40) vision were 49.8% in the primary ERM group and 31.2% in the secondary ERM group (P<0.05), respectively. Cystoid macular edema developed in 8.8% of primary ERM group and in 9.9% in the secondary ERM group (P>0.05); 19.0%, 6.2%, 7.8% and 17.4% in the PDR, RD, RVO and uveitis subgroups, respectively (P<0.05).

CONCLUSION Cataract extraction preceded or combined with pars plana vitrectomy for ERM peel is associated with improvement of vision in primary ERM and those secondary to RD and RVO. Postoperative CME rate may vary depending on the aetiology of the ERM

HUMAN RESEARCH This study involves human research.

IRB Approval Status: Exempt from approval

2:15 PM

Treatment of Focal Vitreomacular Traction With Pneumatic Vitreolysis, an Emerging Surgical Technique



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- Richard Gary Lane, MD
- Moises Alexander Chica, MD
- Martha Henao, MD

OBJECTIVE Is pneumatic vitreolysis (PVL) effective for treatment of vitreomacular traction (VMT) with or without stage-2 macular holes (MH)?

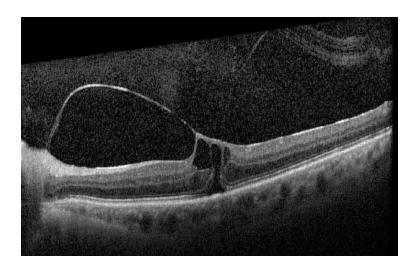
PURPOSE To assess the benefits and risk of pneumatic vitreolysis (PVL) for treating vitreomacular traction (VMT) with or without stage-2 macular holes (MH).

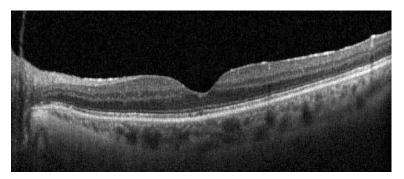
METHODS We performed a retrospective study on patients with focal VMT who underwent PVL in 2 centers from 2010 to 2017. All patients were required to avoid supine position after receiving 0.3 mL C3F8 gas injection until gas resolution. Patients with MH were asked to maintain face-down for at least 4 days. Best-spectacle corrected visual acuity (BSCVA) was performed at baseline and at each follow-up visit.

RESULTS Sixty-nine consecutive eyes in 68 patients with VMT (47 women; mean age of 70.7 [range: 48-85]) underwent PVL. Overall VMT release was achieved in 59 eyes (85.5%) within a mean of 2.9 weeks. Subgroup analysis showed VMT release in 79.2% of VMT-only eyes, but up to 95% of eyes with MH. 61.9% of MH closed. Subsequent vitrectomy closed all failed MH. Median baseline and final BSCVA was 0.3979 ±0.213

and 0.24 ± 0.173 (20/50 and 20/35), respectively (p<0.0001). Younger age and lack of diabetes were strongest predictors for success. Complications (7.2%) included retinal tears in 2 eyes, retinal detachment in 2 eyes, and VMT progressing to MH in 1 eye; all responded to treatment. One eye developed unusual persistent loculated submacular fluid.

CONCLUSION VMT with PVL and limited face-down positioning is a highly effective emerging technique for achieving VMT release (86%) for focal VMT, with a respectable MH closure rate of 62%. The overall BSCVA was significantly better at final visit than baseline. One eye developed atypical post-gas injection eccentric loculated subretinal fluid.





HUMAN RESEARCH This study involves human research. IRB Approval Status: Exempt from approval