Retina Roundup
January 2020

First failed macular hole surgery or reopening of a previously closed hole: Do we gain by reoperating?- A systematic review and meta-analysis.

Retina. 2020 Jan;40(1):1-15. doi: 10.1097/IAE.0000000000002564.

Reid GA, McDonagh N, Wright DM, Yek JTO, Essex RW, Lois N.

ABSTRACT

PURPOSE:

To evaluate repeated surgery for idiopathic full-thickness macular hole that failed to close (FTC) after first surgery or reopened (RO) once originally closed.

METHODS:

Systematic review and meta-analysis. Pubmed.gov and Cochrane Library were searched for studies in English presenting outcomes of idiopathic full-thickness macular hole that FTC or RO (case reports/series of <5 cases excluded).

OUTCOME MEASURES:

Anatomical closure, postoperative best-corrected visual acuity, intraoperative/postoperative complications, and patient-reported outcomes. Meta-analysis was performed on aggregate and available individual participant data sets using the metafor package in R.

RESULTS:

Twenty-eight eligible studies were identified. After reoperation, pooled estimates for anatomical closure were 78% (95% confidence interval 71-84%) and 80% (95% confidence interval 66-89%) for FTC and RO groups, respectively. On average, best-corrected visual acuity improved in both groups. However, only 15% (28 of 189 eyes) of FTC eyes achieved best-corrected visual acuity of ≥6/12. The pooled estimated probability of ≥2-line best-corrected visual acuity improvement was 58% in the FTC group (95% confidence interval 45-71%); meta-analysis was not possible in the RO group. The most common complication was cataract.

CONCLUSION:

Reoperation for FTC or RO idiopathic full-thickness macular hole achieved a clinically meaningful visual acuity improvement in more than half of patients; high levels of vision (≥6/12), however, were uncommon

Understanding biosimilars and its regulatory aspects across the globe: an ophthalmology perspective.

Br J Ophthalmol. 2020 Jan;104(1):2-7. doi: 10.1136/bjophthalmol-2019-314443. Epub 2019 Jul 17.
Sharma A, Kumar N, Kuppermann BD, Bandello F, Loewenstein A.

ABSTRACT

PURPOSE:

This article aims to analyse the key regulatory guidelines across the globe concerning biosimilars.

MATERIALS AND METHODS:

Review of the current literature.

RESULTS:

Biosimilars are well regulated with the majority of regulators having enforced the guidelines for the development and approval, and new biosimilar drugs are appearing on the horizon to provide a therapeutic option to a wider population base because of its cost-effectiveness and proven safety. Due to their extensive analytical data, clinical data and pharmacovigilance studies, their development should not be considered similar to generic drugs.

CONCLUSION:

This review discusses the biosimilars, their regulation globally and their difference from generics from ophthalmic perspective.

.

First-in human clinical study to investigate the effectiveness and safety of pars plana vitrectomy surgery using a new hypersonic technology.

Retina. 2020 Jan;40(1):16-23. doi: 10.1097/IAE.0000000000002365

Stanga PE, Williams JI, Shaarawy SA, Agarwal A, Venkataraman A, Kumar DA, You TT, Hope RS.

ABSTRACT

PURPOSE:

Investigate the effective performance and safety of a new hypersonic vitrector technology.

METHODS:

Postapproval, prospective, single-arm, noncomparative, open-label study at one clinical site in India.

INDICATIONS:

Macular hole (9/20), vitreous hemorrhage (7/20), vitreomacular traction (3/20), and vitreomacular traction with pseudomacular hole (1/20). Safety endpoints included intraoperative and postoperative adverse events. Effective performance endpoints were surgeon-rated effectiveness, range of surgical time, and device settings. Other performance measures were preoperative and postoperative best-corrected visual acuity, slit-lamp and indirect ophthalmoscopy, applanation tonometry, color fundus photography, fundus fluorescein angiography, and spectral domain optical coherence tomography.

RESULTS:

Core vitreous removal (20/20 subjects), peripheral vitreous removal (18/20), and posterior vitreous detachment induction (13/15) surgeries were successfully completed. Total surgical time was 22.5 minutes to 106 minutes. Serious adverse events through 3 months were 2 device-associated retinal tears and detachment (one intraoperative) and one unrelated postoperative enlargement of macular hole with subretinal fluid.

CONCLUSION:

This first-in-human study suggests that this new hypersonic vitrector technology is a promising alternative to commercially available guillotine vitrectors. The hypersonic vitrector was effective in core vitreous removal in all cases. Larger-scale studies are required to expand on our initial findings for induction of a posterior vitreous detachment or peripheral vitrectomy.

Comparison between releasable scleral buckling and vitrectomy in patients with phakic primary rhegmatogenous retinal detachment.

Retina. 2020 Jan;40(1):33-40. doi: 10.1097/IAE.0000000000002348

Zhao X, Huang L, Lyu C, Liu B, Ma W, Deng X, Jiang H, Wang Y, Yu X, Ding X, Luo Y, Ma J, Stewart JM, Liang X, Jin C, Lu L.

ABSTRACT

PURPOSE:

To compare the efficiency of releasable scleral buckling (RSB) and pars plana vitrectomy (PPV) in the treatment of phakic patients with primary rhegmatogenous retinal detachment.

METHODS:

The current study was a prospective randomized clinical trial. One hundred and ten eyes from 110 patients with primary rhegmatogenous retinal detachment and proliferative vitreoretinopathy of Grade B or less were included in this study. The patients were randomly allocated into an RSB group and a PPV group. The functional and anatomical success was compared between groups.

RESULTS:

The primary anatomical success rate (PPV 41/43 [95.35%] and RSB 38/41 [92.68%]) and final anatomical success rate (PPV and RSB 100%) showed a nonsignificant difference. The best-corrected visual acuity, intraocular pressure, and complications were not different between the groups. However, the incidence of cataract progression was higher in the PPV group (26 of 43 [60.47%]) than in the RSB group (4 of 41 [9.76%]) at the 12-month follow-up. The subfoveal choroidal thickness increased significantly in the RSB group 3 months after surgery, but no longer differed at the postoperative 6-month and 12-month follow-ups. The axial length had increased significantly 1 month after surgery, but the difference was no longer significant at 3 months, 6 months, and 12 months.

CONCLUSION:

The RSB and PPV procedures have the same effects on the functional and anatomical success for patients with phakic primary rhegmatogenous retinal detachment. Nevertheless, based on

the few cases of intraocular complications and cataract progression, we believe that the RSB technique should be preferentially recommended.

Incidence and risk factors for hypotony after 25-gauge pars plana vitrectomy with non-expansile endotamponade.

Retina. 2020 Jan;40(1):41-46. doi: 10.1097/IAE.0000000000002336.

Mimouni M, Abualhasan H, Derman L, Feldman A, Mazzawi F, Barak Y

ABSTRACT

PURPOSE:

The purpose of this study was to assess the incidence and risk factors for early postoperative hypotony after 25 gauge pars plana vitrectomy with non-expansile endotamponade.

METHODS:

A retrospective study of consecutive patients who underwent 25-G pars plana vitrectomy. Hypotony was defined as an intraocular pressure of 5 mmHg or less after surgery and ocular hypertension as an intraocular pressure greater than 21 mmHg.

RESULTS:

Overall, 307 eyes of 307 patients with a mean age of 61.7 ± 14.3 of which 56.7% were males were included. Hypotony was identified in 5.2% of cases (n = 16) at Day 1 and 0.7% (n = 2) at Week 1 with no hypotony-related complications. The hypotony group had a higher number of previous vitreoretinal surgeries (1.5 ± 1.1 vs. 0.4 ± 0.7, P < 0.001) and a higher prevalence of preoperative ocular hypertension (22.2% vs. 4.8%, P = 0.02), pseudophakia (77.8% vs. 48.4%, P = 0.01), silicone oil removal (61.1% vs. 8.3%, P < 0.001), and external diathermy performed (55.6% vs. 20.1%, P = 0.001). In stepwise multivariate analysis, significant parameters were silicone oil removal (R = 16.34%, odds ratio 13.45, P < 0.001), pseudophakia (R = 5.69%, odds ratio 3.65, P = 0.03), and younger age (R = 2.68%, odds ratio 0.96, P = 0.04).

CONCLUSIONS:

Silicone oil removal is a significant risk factor for early postoperative hypotony after 25-G pars plana vitrectomy.

Characterizing retinal-choroidal anastomosis in macular telangiectasia type 2 with optical coherence tomography angiography.

Retina. 2020 Jan;40(1):92-98. doi: 10.1097/IAE.0000000000002619.

Breazzano MP, Yannuzzi LA, Spaide RF

ABSTRACT

PURPOSE:

To characterize structural and angiographic findings in macular telangiectasia Type 2 (MacTel 2) and examine associations with visual acuity.

METHODS:

MacTel 2 patients with complete ophthalmologic examination, including fundus photography, autofluorescence, spectral-domain optical coherence tomography, and projection-resolved optical coherence tomography angiography, were retrospectively evaluated.

RESULTS:

There were 43 eyes of 22 patients with a mean age 63.9 (±10.3) years. Six patients had diabetes. Twenty-one eyes (48.8%) had retinal-choroidal anastomoses (RCAs) without any evidence of neovascularization extending laterally in a plane above or below the retinal pigment epithelium. None of the eyes had hemorrhage, lipid, or signs of subretinal exudation. When present, an average of 55 (±33.7) individual RCAs were clustered primarily in temporal juxtafoveal region of involved eyes. Right-angle veins were seen in all 21 eyes with RCAs, and hyperpigmentation was present in 18 ($P < 0.001$ for both). A conical collection of hyperreflective material spanning from Bruch membrane past external limiting membrane of ≥200-μm basal diameter was found in 21 eyes and labeled outer retinal hyperreflective lesion. Retinal-choroidal anastomoses occurred in clusters, often within the outer retinal hyperreflective lesion. This lesion colocalized with focal thinning of the outer nuclear layer and was surrounded by a larger defect in the ellipsoid zone. The presence of diabetes ($P = 0.015$), outer retinal hyperreflective lesion ($P = 0.006$), RCA ($P = 0.005$), and ellipsoid zone defect extent ($P < 0.001$) were associated with decreased visual acuity.

CONCLUSION:

Retinal-choroidal anastomoses occur in eyes with MacTel 2 without signs of exudation. Retinal-choroidal anastomoses occur in numerous clusters particularly in the temporal juxtafoveal macula. Diabetes, ellipsoid zone defect extent, RCAs, and the outer retinal hyperreflective lesion predict poorer vision in MacTel 2.

Characteristics and classification of type 3 neovascularization with B-scan flow overlay and en-face flow images of optical coherence tomography angiography.

Retina. 2020 Jan;40(1):109-120. doi: 10.1097/IAE.0000000000002357.

Kataoka K1, Takeuchi J, Nakano Y, Fujita A, Kaneko H, Ito Y, Terasaki H.

ABSTRACT

PURPOSE:

To study B-scan flow overlay and en face flow optical coherence tomography angiography (OCT-A) images of Type 3neovascularization (NV) and to characterize a staging system for Type 3 NV based on the OCT-A findings.

METHODS:

We retrospectively collected data on consecutive treatment-naive eyes with Type 3 NV. All eyes underwent fluorescein angiography, indocyanine green angiography, structural spectral domain OCT, and OCT-A (AngioPlex). Localization and extension of abnormal flows detected by B-scan flow overlay and en face OCT-A images were assessed.

RESULTS:

Of 24 eyes of 22 patients with Type 3 NV, B-scan flow overlay images showed that 4.2% had telangiectatic flow in the deep retinal layer without outer plexiform layer disruption (Stage 1), 8.3% had downward intraretinal flow and subretinal flow without retinal pigment epithelium disruption (Stage 2), and 87.5% had downward flow and retinal pigment epithelium disruption (Stage 3). Of the Stage 3 eyes, 95.2% showed flow signal penetrating at the site of the retinal pigment epithelium disruption on the B-scan flow overlay images.

CONCLUSION:

We showed the characteristics of Type 3 NV using B-scan flow overlay and en face OCT-A images. B-scan flow overlay OCT-A images seem useful to improve the detection and accurate diagnosis of Type 3 NV.

January 2020 segment compiled by: Dr. Piyush Kohli, Aravind Eye Hospital, Madurai