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Management of Macular Holes in 2015

Report from the Co-developed Accredited Symposia Presented at the 2015 Canadian Retina Society Meeting

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Recent advances in imaging, especially optical coherence tomography (OCT) and enhanced visualization of the vitreomacular interface (VMI), have improved the understanding of the underlying pathophysiology and natural history of VMI-related disorders, including vitreomacular traction and macular holes. This has led to the development of a new OCT-based classification system of macular holes and improvements in both surgical and nonsurgical therapeutic approaches. The latest developments in the management of macular holes were reviewed and further discussed during an accredited satellite symposium that took place during the 2015 Canadian Retina Society Meeting. This issue of *Ophthalmology Scientific Update*, as a companion to the recent review in *Ophthalmology Rounds* by Manusow and Mandell,[1] provides an overview of the salient topics that have an impact on the daily practice of Canadian retina specialists.

A full-thickness macular hole (FTMH) is defined as a foveal lesion with interruption of all retinal layers from the internal limiting membrane (ILM) to the retinal pigment epithelium (RPE).[1] Although macular holes can develop as a result of trauma (secondary macular holes), more than 80% of macular holes are idiopathic in nature (primary macular holes).[2] The overall prevalence of idiopathic macular holes is approximately 3.3 cases per 1000 in people >55 years of age and it is more common in women than men.[3]

Understanding the natural history of macular holes is important in determining patient prognosis, as well as the timing of macular hole repair. While smaller macular holes might regress and resolve spontaneously, larger full-thickness holes rarely do so. Thus, timely intervention is the key in ensuring optimal anatomical and visual outcomes. Currently the gold standard diagnostic test is spectral domain optical coherence tomography (SD-OCT).

Classification of FTMH and Impact on Therapeutic Decisions

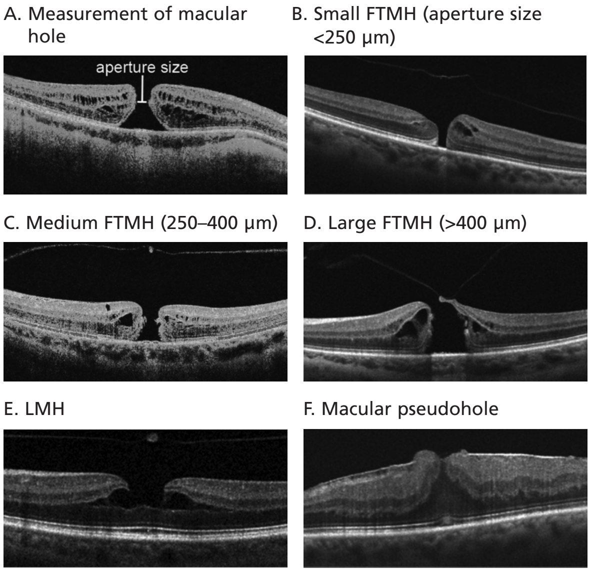
The traditional Gass classification of macular holes divided macular holes into 4 stages based on their appearance on clinical examination.[4] Although this classification is still widely used and referred to, the OCT-based anatomic classification system developed by the International Vitreomacular Traction Study (IVTS) Group includes anatomic data that can be used to support diagnosis and guide therapeutic approaches.[1] The correlation between Gass stages and the IVTS classification system for vitreomacular adhesion (VMA), vitreomacular traction (VMT), and macular holes are as follows:

- Stage 0 is now identified as VMA
- Stage 1 is VMT and denotes an impending macular hole
- Stage 2 is a small/medium FTMH with VMT
- Stage 3 is a medium/large FTMH with VMT
- Stage 4 is an FTMH of any size without VMT

The defining size of a macular hole is measured at the narrowest hole width in the mid retina, using the OCT caliper function, as a line drawn parallel to the RPE (Figure 1A).[1] In the OCT-based anatomical classification system, macular holes are determined to be small (diameter <250 µm), medium (diameter 250–400 µm), and large (diameter >400 µm) (Figures 1B–1D).[1]

The cut-off for small FTMHs at 250 mm is derived from studies indicating a small rate of spontaneous closure, a very high rate of closure with vitrectomy, and high likelihood of responsiveness to pharmacologic vitreolysis for these holes.[1,5,6]

Figure 1: **OCT scans illustrating examples of FTMH, LMH, and macular pseudohole according to the IVTS Classification System**[1]


A. Measurement of macular hole
B. Small FTMH (aperture size <250 µm)
C. Medium FTMH (250–400 µm)
D. Large FTMH (>400 µm)
E. LMH
F. Macular pseudohole

OCT = optical coherence tomography; FTMH = full-thickness macular hole; LMH = lamellar macular hole; IVTS = International Vitreomacular Traction Study

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Medium-size FTMHs have a high rate of postsurgical closure. Pharmacotherapy can also be successful, but the closure rates are lower than for small macular holes. Nearly one-half of FTMHs are large at the time of diagnosis. Vitrectomy is more successful with ILM peel (closure rates 90%–95%) than without (closure ~75%).[7] No anatomic success has been report ed with pharmacologic vitreolysis in eyes with large FTMHs.[5]

FTMHs can be further categorized according to the presence or absence of vitreous attachment. Only holes with coexisting VMT should be considered for pharmacological vitreolysis.

Impending macular holes

The term “impending macular hole” refers to a specific situation where an FTMH is observed in one eye and VMT is observed on OCT in the fellow eye. It has been shown that these fellow eyes are at increased risk for development of FTMHs. According to the traditional Gass classification, the finding of VMA in a fellow eye has been referred to as a stage 0 macular hole (Table 1).

Lamellar macular hole (LMH)

An LMH is a partial-thickness foveal defect (Figure 1E). Anatomic OCT-based features of LMH include an irregular foveal contour, a defect in the inner fovea, intraretinal splitting, and an intact photoreceptor layer. The presence of intact photoreceptors at the base is the key distinguishing feature between LMHs and FTMHs. It is thought that LMHs arise from incomplete FTMH formation, centripetal traction from epiretinal membrane (ERM), or both. A lamellar macular hole usually progresses slowly and is associated with mild or limited central vision loss. Because of progression of associated ERM, reading vision may deteriorate over time. Typically, patients with LMHs have mild metamorphopsia, limited central vision loss, and stable visual acuity. Surgery for LMHs remains controversial and future studies are needed.

Macular pseudohole

A macular pseudohole appears as a discrete, reddish, round or oval lesion in the fovea that is typically 200–400 mm in diameter and similar in appearance to a small or medium FTMH.[1] The most characteristic feature of macular pseudoholes is the presence of a concomitant ERM (Figure 1F), which is often a cause of the pseudohole. Successful removal of the ERM often leads to restoration of the foveal contour and improvement in visual acuity.

Lessons from Recent Clinical Trials

Vitreolysis involving an enzyme that has activity against the molecular components responsible for VMA is a nonsurgical, biologic approach to the treatment of VMI-related disorders. Ocriplasmin is a truncated form of the human serine protease plasmin and cleaves fibronectin and laminin, which are key components of the vitreoretinal interface. Ocriplasmin was approved by Health Canada for the treatment of symptomatic VMA.[8] Efficacy of ocriplasmin in the treatment of FTMHs was assessed in the Phase 3 MIVI-TRUST trial.[5] In this study, overall closure of FTMHs was achieved in 40.6% of ocriplasmin-injected eyes; however, subgroup analysis revealed a success rate of 58.3% if macular holes were £250 m in diameter compared with a rate of 38.6% in holes with a diameter of 250–400 m.[6] Ocriplasmin was unsuccessful in holes >400 mm.

Researchers from the Cole Eye Institute in Cleveland, Ohio, recently published their experience with ocriplasmin in 17 patients with VMT.[9] Following ocriplasmin injection, 4 of the 5 patients with FTMHs at baseline (2 with Stage 2 and 2 with Stage 1 Gass criteria) had hole closure. The patient who did not experience hole closure had a Stage 3 FTMH at baseline and underwent vitrectomy. In another study conducted by Miller et al,[10] 8 patients with stage 2 macular holes received a single injection of 125 g of ocriplasmin. The posterior hyaloid separated from the macula in 6 eyes (75%) and 1 patient (12.5%) demonstrated macular hole closure. All 7 holes that remained open showed enlargement over time and were successfully closed with surgery. Kim et al[11] reported on 19 patients with symptomatic VMA, including 6 patients with macular holes, treated with intravitreal ocriplasmin. Three of the 6 patients experienced macular hole closure. The average size of the holes that closed was 132 mm, and the average time to closure was 28 days. A retrospective interventional case series from Wills Eye Hospital (Philadelphia, Pennsylvania) included 58 eyes of 56 patients.[12] Fifteen eyes had FTMHs: 6 (40%) measured £250 mm, 8 (53%) were 250–400 mm, and 1 (7%) was >400 mm. Four eyes (27%; 2 <250 mm and

2 250 mm–400 mm in size) had complete hole closure following ocriplasmin treatment.

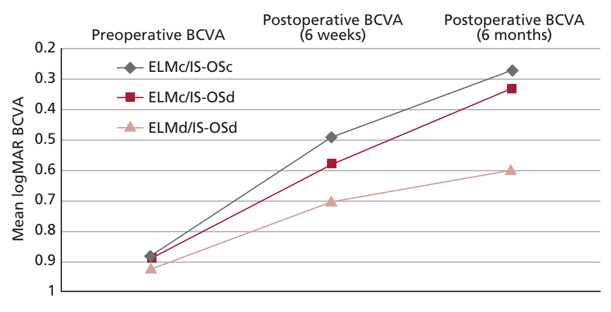
Effect of OCT Scan Pattern and Density on the Detection of FTMH

To evaluate the impact of different scan patterns and scan densities on the detection of small FTMHs, Schneider et al[13] performed a retrospective cross-sectional analysis of 25 eyes. All eyes underwent concurrent imaging with a standard (61-line) raster volume and a 24-line radial pattern. A 6-line radial scan pattern was extrapolated from the higher-density radial pattern. In summary, small full-thickness defects were missed in 5 eyes (20%) with 61-line raster and in 3 eyes (12%) with 6-line radial scanning. These were detected with the 24-line radial scan pattern. Full-thickness detection rates were significantly higher for radial scan patterns when compared to raster scanning ($P<0.001$ for both comparisons). Overall holes that were missed were smaller and often associated with vitreous flaps. As high-density radial scanning demonstrated superior detection rates of small FTMHs compared to standard raster volume scanning, the investigators concluded that failure to use radial scanning in the setting of a suspected macular hole may lead to a delay in treatment, and subsequently worse anatomical and visual outcomes.

Pre- and post-operative OCT findings as predictors of visual outcomes

Recent reports have demonstrated that the postoperative status of the inner segment–outer segment (IS–OS) layer significantly correlates with the visual outcome after macular hole surgery. Landa et al[14] examined the SD-OCT images of repaired macular holes and assessed the relationship between the restoration of the integrity of the external limiting membrane (ELM) and IS–OS junction layers and subsequent visual outcomes. The study included 62 eyes and the primary outcome measures were best-corrected visual acuity (BCVA) and the status of the ELM and IS–OS lines at 6 weeks and 6 months post-operatively. The surgery was successful, resulting in macular hole closure in 56 (90.3%) eyes. At 6 weeks post-surgery, 7 eyes (12.5%) demonstrated continuity of both ELM and IS–OS (ELM^c/IS-OS^c), 29 eyes (51.8%) had continuous ELM with discontinuous IS–OS layers (ELM^c/IS-OS^d), and 20 eyes (35.7%) had discontinuities in both the layers (ELM^d/IS-OS^d). No eye had discontinuation in ELM and continuation in the IS-OS layer. The ELM^d/IS-OS^d group had the lowest visual gain at 6 months post-surgery ($P=0.03$; Figure 2). This demonstrated the importance of the ELM in restoration of visual function following successful surgical macular hole repair. Integrity of the ELM layer appears to be a critical factor for the restoration of the photoreceptor layer and for predicting a successful visual outcome following vitrectomy.

Figure 2: **The mean preoperative and postoperative BCVA according to the integrity of ELM and IS-OS layers**



Comparison of preoperative and postoperative logMAR and BCVA in the 3 groups at 6 weeks and 6 months (Friedman test, $P=0.08$ and 0.03, respectively).

BCVA = best-corrected visual activity; IS-OS = inner segment–outer segment; ELM = external limiting membrane; logMAR = logarithms of the minimum angle of resolution

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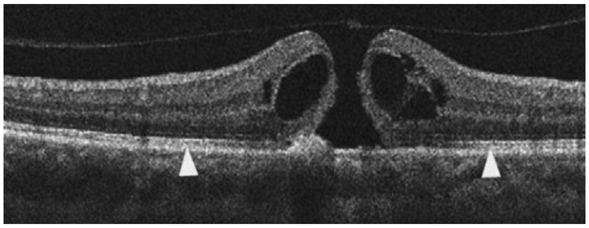
Another study conducted by Itoh et al[15] suggested that the length of the preoperative cone outer segment tips (COST) line defect (Figure 3) may predict BCVA after macular hole surgery. The study included 51 eyes with a surgically closed macular hole. The COST line defect was measured in the images obtained

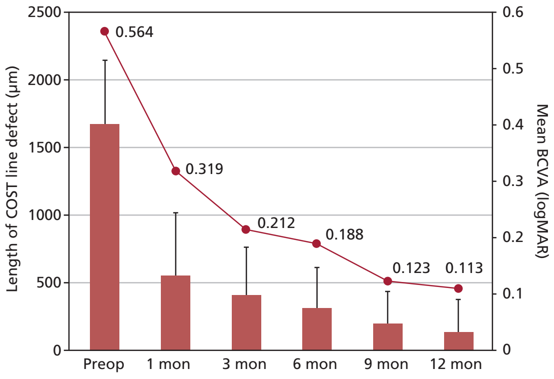
Figure 3: **Length of foveal cone outer segment tips (COST) line defect and its impact on VA after macular hole closure**

A. Preoperative vertical spectral domain (SD)-OCT image of a macular hole with a COST line defect



Arrowheads indicate COST line defect

B. Correlation between VA and mean length of COST line defect



The postoperative mean length of the COST line defect gradually decreased. Postoperative BCVA was correlated with the length of COST line defect at the corresponding period.

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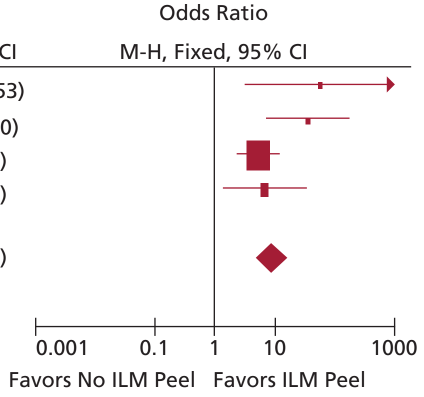
Figure 4: **Macular hole closure rates with ILM peeling versus no peeling**

A. Forest plot of comparison of primary macular hole closure rates between ILM peel and no peel groups

	ILM Peel		No ILM Peel			Odds Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% CI
Christensen 2009[17]	26	26	10	21	2.9%	58.05 (3.13, 1076.53)
Kwok 2005[16]	23	26	4	23	6.6%	36.42 (7.24, 183.20)
Lois 2011[18]	56	67	31	64	70.3%	5.42 (2.41, 12.20)
Tadayoni 2009*	37	39	30	41	20.2%	6.78 (1.39, 32.99)
Total (95% CI)		158		194	100.0%	9.27 (4.98, 17.24)
Total events	142		75			

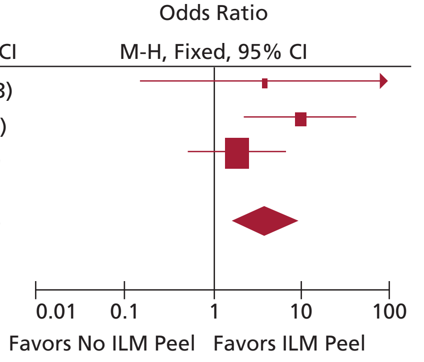


Heterogeneity: Chi^2 = 6.10, df = 3 (P = 0.11); I^2 = 51%

Test for overall effect: Z = 7.03 (P < 0.00001)

B. Forest plot of comparison of primary macular hole closure rates between ILM peel and no peel groups

	ILM Peel		No ILM Peel			Odds Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% CI
Christensen 2009[17]	26	26	20	21	8.1%	3.88 (0.15, 100.23)
Kwok 2005[16]	23	26	10	23	23.8%	9.97 (2.32, 42.85)
Lois 2011[18]	61	65	56	63	70.3%	1.91 (0.53, 6.86)
Total (95% CI)		117		107	100.0%	3.99 (1.63, 9.75)
Total events	110		86			



Heterogeneity: Chi^2 = 2.79, df = 2 (P = 0.25); I^2 = 28%

Test for overall effect: Z = 3.03 (P < 0.002)

ILM = internal limiting membrane; CI = confidence interval

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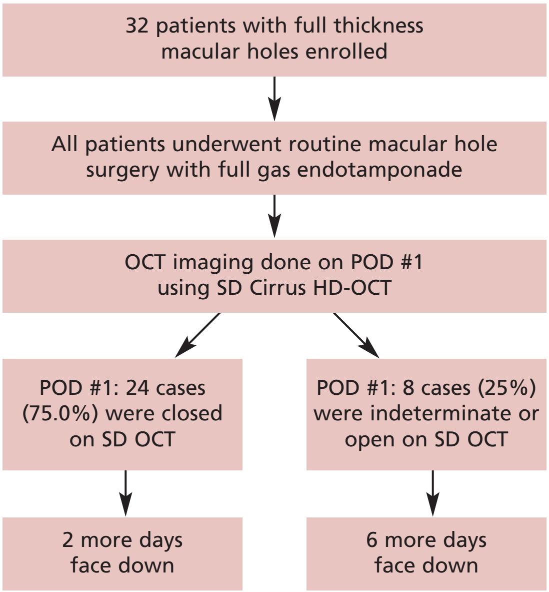
1, 3, 6, 9, and 12 months after macular hole surgery. The preoperative length of the COST line defect was statistically correlated with the BCVA at 1, 3, 6, 9, and 12 months postoperatively (P<0.001 at all times). Based on these findings the investigators concluded that the recovery of the foveal COST line defect is related to visual recovery after macular hole surgery and that the length of the preoperative COST line defect may predict the BCVA after macular hole surgery.

Advances in Surgical Techniques

Technological advances, including the improvement of vitrectomy machines and the utilization of chromovitrectomy, have significantly improved outcomes of vitreoretinal surgery. The two most frequently used chromovitrectomy agents include triamcinolone acetonide to improve visualization of the vitreous and preretinal membranes and indocyanine green (ICG) dye to stain the ILM. These agents are usually injected into the eye through a needle or cannula placed on a syringe, which increases the risk of flow-related trauma or entry into an FTMH. The use of ICG is of particular concern due to potential toxicity. The delivery of the chromovitrectomy agents, as suggested by Hahn,[16] can be improved using a vitrectomy probe that allows for surgeon-controlled reflux. The needle used to draw up the agent is removed from the syringe, and the vitrectomy probe is placed through the syringe tip to aspirate a small amount of the agent. This technique, known as reflux staining, requires the use of a vitrectomy machine that enables reflux of contents through the vitrectomy probe. The technique eliminates the need for an assistant and for additional or specialized cannulas or needles. Furthermore, the same vitreous cutter can be used to immediately detach the posterior hyaloid or remove excess chromovitrectomy agent.

A recent meta-analysis of trials (N=4 large randomized controlled trials) comparing outcomes of ILM peeling versus no peeling[17] supports ILM peeling as the treatment of choice for patients undergoing surgery for idiopathic stage 2, 3, and 4 FTMHs. Although a difference in best-corrected distance visual acuity (BCdVA) at 6 months (primary outcome) was not significant in regard to ILM peeling (mean difference -0.04; 95% confidence interval [CI] -0.12 to 0.03; P=0.27), the difference in BCdVA at 3 months was signifi-

Figure 5: Algorithm to guide duration of face-down positioning



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cantly in favour of ILM peeling (mean difference -0.09; 95% CI -0.17 to -0.02; P=0.02). ILM peeling was superior to no peeling in regard to primary (P<0.00001; Figure 4A) and final macular hole closure (P=0.02; Figure 4B), and less requirement for additional surgeries (P<0.00001). Intraoperative and postoperative complications and patient reported outcomes were similar in patients who had ILM peeling and those without. Finally, the analysis found ILM peeling in all stages of macular holes to be highly cost-effective, as it yielded better closure rates and reduced the need for reoperation. Optic nerve fibre layer issue and potential damage is one of the potential negative consequences associated with ILM peeling.

Recently, higher closure rates for large macular holes were reported with the inverted ILM flap technique.[18] Instead of completely removing the ILM, a remnant attached to the margins of the macular hole is left in place to cover the macular hole during fluid-air exchange. The inverted ILM flap precludes the postoperative flat-open appearance of a macular hole and improves both the functional and anatomic outcomes of vitrectomy for large macular holes. However, the technique resembles packing a macular hole with a folded ILM rather than covering it with a true flap. Shin et al[19] described a modified flap technique with a single-layered flap of the ILM with the assistance of perfluoro-n-octane (PFO). For this technique, a specific order of ILM removal is required to create a flap (Table 2), and a small amount of PFO is used to keep the inverted ILM flap in position during surgery. This modified technique can be beneficial for the management of large macular holes. However, its efficacy should be further assessed in a large-scale case study.

Drawbacks to Surgery

Despite the improvement in macular hole surgery, controversy remains over the duration of face-down positioning, especially since prolonged face-down position presents an inconvenience and significant burden for elderly patients. Although some evidence indicate that 1–3 days of face-down position may be sufficient,[20-22] some surgeons recommend up to 1 week. In order to assess whether the SD-OCT can be used as a guide to monitor the hole closure rates and the need for face-down positioning, Shah et al[23] applied the algorithm depicted in Figure 5. SD-OCT was performed on the first postoperative day. Patients remained face down for 2 additional days if the macular hole was closed or 6 more days if the macular hole was open or if hole closer was undetermined. On postoperative day 1, 24 (75%) holes were closed by SD-OCT, and 23 remained closed during the 3-day postoperative period. Of the 8 remaining macular holes, all of which were >400 μm preoperatively, 6 were closed at subsequent visits over the extended follow-up period. The overall closure rate using this approach was 90.6% (29 of 32).

Chow et al[24] reviewed the medical records of 33 patients who underwent macular hole repair, with a mean hole size of 465 mm. High-risk factors for closure failure included myopic degeneration in 6 patients (17%), chronic holes (³12 months duration) in 13 patients (37%), and large holes (>400 mm) in 19 patients (54%). The post-surgical regimen consisted of face-down positioning at the conclusion of surgery with daily OCT imaging until the hole was confirmed closed. Successful closure of macular holes was achieved in 28 eyes (80%), with closure rates of 92% in the absence of high-risk factors, 85% if 2 factors are present, and 74% with the presence of all 3 factors. Thus, a modified postoperative positioning regimen is suggested based on the presence of risk factors to obtain complete and persistent macular hole closure.

Based on a retrospective analysis of 68 idiopathic FTMHs, Lezzi et al[25] demonstrated that broad ILM peeling, 20% sulphur hexafluoride (SF6) endotamponade, and reading position rather than face-down positioning for 3–5 days is comparable with methods that use longer acting gas endotamponade, face-down positioning, or both.

Conclusions

Recent evidence highlights the importance of patient selection and measurement of macular holes – the smaller the hole, the better the outcome – for successful surgical and pharmacological outcomes. Radial high density scan is more effective than the standard raster volume scan or the historic 6-line radial scan in detecting small macular holes with flap.

Integrity of the postoperative ELM layer and the length of the preoperative COST line defect may be used to predict visual outcomes after macular hole surgery. Reflux staining and a modified flap technique with the assistance of PFO have the potential to reduce surgery-related complications, improve surgeons' efficiency, and yield better patient outcomes. Although ILM peeling may not result in better visual outcomes, it leads to an increase in the rates of hole closure and in a reduction in the need for additional surgeries, resulting in cost savings. Finally, an OCT-guided approach can be used to guide the duration of face-down positioning following FTMH surgery.

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