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Human amniotic membrane graft with viscodissection and intraoperative OCT for macular hole repair

Shu Yu Qian [a], Marc Saab [b,*]

[a] Faculty of Medicine, University of Sherbrooke, 3001 12 Ave N, Sherbrooke, QC, J1H 5N4, Canada
[b] Department of Ophthalmology, Charles LeMoyne Hospital, 3120 Taschereau Blvd, Greenfield Park, QC, J4V 2H1, Canada

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ABSTRACT

Objective: To present the human amniotic membrane (hAM) graft with the novel addition of viscodissection and usage of intraoperative OCT as a potential approach to treating challenging macular holes and to describe the outcomes.
Design: Retrospective interventional case series.
Participants: 10 patients with large, chronic, or persistent macular holes were included in this study.
Methods: 10 eyes of 10 patients were treated using a hAM graft with viscodissection. Intraoperative OCT was utilized to assist the placement of the graft. Outcomes were monitored through clinical examinations, retinal imaging, and OCT.
Results: Macular holes were closed in all 10 patients and remained so during the entirety of the follow-up periods. 9 out of 10 patients experienced an improvement in visual acuity. Mean best corrected visual acuity increased from 1.68 logMAR (20/1000) preoperative to 0.74 logMAR (20/100) at 6 months postoperative. No adverse events were observed for any of our patients.
Conclusions: The addition of viscodissection to the standard hAM graft surgery is a potential optimization that reduces risks of iatrogenic damage to the retina. Surgeons can consider including this approach as part of their arsenal to treat such macular holes.

1. Introduction

Since its implementation, pars plana vitrectomy (PPV) with internal limiting membrane (ILM) peel and gas tamponade has been the conventional procedure to treat full-thickness macular holes.[1]. Despite these advancements, chronic, large, or persistent macular holes remain challenging to repair and frequently require multiple surgical interventions.[2]. One report suggests that macular holes larger than 500 μm in diameter show a closure rate of just 50 % after one surgery compared to rates greater than 90 % for those smaller than 500 μm.[3]. Another investigation by Steel et al. also concluded that a (minimal linear diameter) MLD of around 500 μm is the threshold where success rates start to diminish.[4]. To overcome this difficulty, surgeons have recently developed a variety of techniques such as ILM flaps, autologous retinal transplants, and subretinal dissections.[5].

Another promising method to treat persistent and large macular holes is the use of human amniotic membrane (hAM) plugs as described by Rizzo et al., in 2018.[6]. This tissue has already been widely used for multiple decades in corneal and conjunctival operations, but only recently have ophthalmologists discovered its potential for retinal surgeries.[7]. Based on empirical observations, the amniotic membrane (AM) is hypothesized to help promote neurosensory retinal regeneration and maintain retinal homeostasis via the secretion of growth factors.[8]. These properties make the hAM transplantation a viable option to treat challenging macular holes with good anatomical and functional outcomes.[9].

Currently, the standard procedure involves using an illuminated pick to elevate the macular hole borders in order to make space for the hAM.[6]. Although generally well tolerated, adverse events have been reported to occur with choroidal neovascularization (CNV) being one of them.[10]. Although the exact cause of CNV post macular hole surgery remains unknown, some experts have identified intra-operative trauma as a possible significant contributing factor.[11]. Hence, it is perhaps preferable to avoid touching macular holes' edges. Other commonly documented complications includes macular edema, atrophy, subretinal silicone oil.[10]. In Qiao and colleagues' cohort of 23 patients, AM translocation occurred in 2 eyes, which needed secondary surgeries to

* Corresponding author.
E-mail address: marcsaab.md@gmail.com (M. Saab).

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readjust the membrane. No other serious adverse events (vitreous hemorrhage, endophthalmitis, and intraocular hypertension) were documented.[12]. Therefore, we propose viscodissection as a potentially easier and less traumatic alternative to the manual elevation of the macular hole border with forceps. In this report, we present a series of 10 patients who underwent hAM graft with viscodissection.

2. Methods

This is a retrospective interventional study containing 10 patients operated on from March 2019 to June 2023 conducted at Charles LeMoyne Hospital. The inclusion criteria for our study are macular holes that are either chronic, persistent, at least X-large, or a combination of these factors. Chronic macular holes were defined by the duration of at least 1 year, and persistent is defined as having already undergone at least 1 unsuccessful operation. In terms of size, the macular holes in our cohort were classified in accordance to the CLOSE Study Group's categories. Based on MLD the categories are large (400–550 μm), X-large (550–800 μm), XX-large (800-1000 μm), or giant (>1000 μm).[13]. All surgeries presented were performed by the same experienced vitreoretinal surgeon (M.S.). Verbal consent was obtained from all patients.

In this study, the preoperative work up included ophthalmic history, best-corrected visual acuity (BCVA) assessment, dilated ophthalmic fundus examination, as well as an optical coherence tomography (OCT) to provide accurate measurements of the macular hole diameters at the aperture and the base. Fig. 1 illustrates the measurement of these parameters. Based on these measurements, the dimensions of the hAM graft were then adjusted accordingly. To best promote closure, the size of the plug should be larger than the hole itself such that its flaps could be secured under the edges of the macular hole.

For the surgery, a standard 3-port PPV with retrobulbar anesthesia was performed for all patients. A 4th port was added to allow for bimanual manipulations if deemed necessary. The choice of gauge, either 25 or 27, was at the surgeon's discretion. A posterior vitreous detachment followed by peripheral vitrectomy is then performed. Afterwards, indocyanine green dye is injected to stain any ILM that needs to be peeled or to confirm its absence in eyes that have already undergone previous surgeries.

For the viscodissection step, a cohesive ophthalmic viscosurgical device (OVD) is fitted through an extrusion cannula. Next, the OVD is slowly injected while moving the cannula in a circular motion around the macular hole, as shown in Fig. 2. This ensures that the OVD spreads out evenly under the retina, elevating all edges of the hole and separating any adhesions it may have with the retinal pigment epithelium (RPE) underneath. Using forceps, the hAM plug is brought into the vitreous cavity and the flaps are gently inserted under the border of the macular hole ensuring a uniform spread. Intraoperative OCT (iOCT) is utilized to ensure adequate positioning of the graft.

Our video demonstrates this viscodissection step.

After the hAM is put in place, an air-fluid exchange is performed. In our cases, the OVD is left in place. An air-gas tamponade with 20 % sulfur hexafluoride (SF6) is inserted for all patients, and the eye is closed. After the surgery, the patients are instructed to maintain a face down position for 5 days. Combined phacoemulsification was performed for all our phakic patients due to the presence of cataracts or other significant lenticular changes. Doing so provides better posterior pole visualization for the surgeon and saves the patient from needing cataract surgery at a later moment.

For all our patients, follow-ups were conducted postoperatively at 1 day, 1 week, 1 month, 3 months, 6 months, and later as needed during which BCVA evaluations, intraocular pressure (IOP) measurements, fundus examinations, and OCTs were performed. Snellen values were converted to logMAR (logarithm of the Minimal Angle of Resolution) for statistical calculations. An increase of 0.3 logMAR units or more on the Early Treatment Diabetic Retinopathy Study (ETDRS) chart was considered the threshold for a clinically important improvement of a patient's visual acuity.[14]

3. Results

10 patients, all female, were included in our study. Prior to this study, patients 1 and 6 had each already undergone one PPV for macular hole. Patient 2 had undergone two prior PPVs. The rest of the patients were operated on for the first time. All macular holes were idiopathic and had flat edges. In this cohort, the mean age was 72.0 ± 10.2 years (range 62–86 years). All patients were diagnosed with a large and chronic macular hole, 6 in the left eye and 4 in the right eye. 5 eyes were phakic and the other 5 were pseudophakic at time of surgery. The mean diameter at the aperture was 697 ± 144 μm (range 401–856 μm). On average, the macular holes have been present for 14.5 ± 12.2 months (range 3–36 months). The mean preoperative BCVA was 1.68 ± 0.70 logMAR (range 0.88–3), approximately 20/1000 on the Snellen chart. All patients completed at least 6 months' worth of follow-ups. Table 1 details these characteristics.

At 6 months postoperative, the mean BCVA increased to 0.74 ± 0.49 logMAR (range 0.4–2) or approximately 20/100. This increase in BCVA was noted for 9 patients out of ten, 8 of whom had a visual improvement of at least 3 logMAR lines. 1 patient improved by less than 3 lines. The remaining patient experienced no change in BCVA. In this cohort, no patient suffered deteriorations of their BCVA. The largest improvement in visual acuity was seen in patient 9, who went from 3 logMAR (20/20 000) to 0.70 logMAR (20/100). The best acuity achieved in our study was 0.4 logMAR (20/50), obtained jointly by 2 patients (patients 4 and 8). Out of these 3 aforementioned cases, it is important to note that patients 4 and 9 underwent simultaneous cataract surgery, which could have contributed to their BCVA improvements. Macular hole closure was observed in all of the patients in our study, even within the first week for certain cases. Fig. 3 demonstrates full closure of the macular hole in one of our patients on the OCT scan. During the following months, the healing process was noticeable on OCT scans, as shown in Fig. 4. Despite the lack of more conclusive tests like microperimetry, we hypothesize that the neurosensory retina progressively regenerates over the plug. Although the exact mechanism of this complex phenomenon has yet to be fully elucidated, researchers speculate that the AM contributes to the upregulation of certain growth factors, thus promoting cell differentiation and proliferation.[15]. Capeáns and colleagues' in vitro

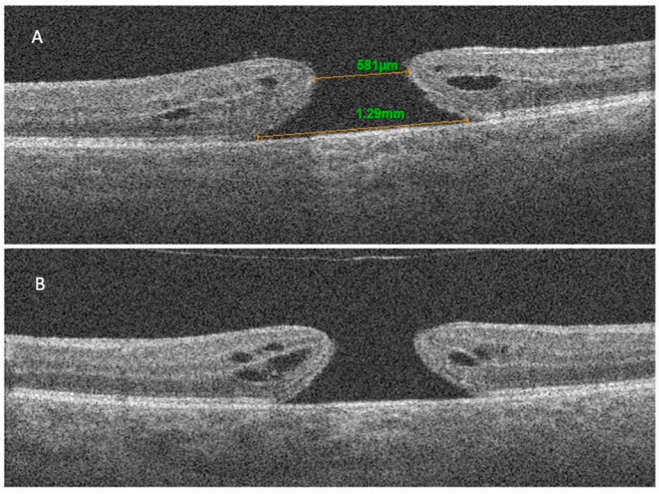

Fig. 1. Preoperative (A) horizontal and (B) vertical OCT images revealing the presence of a full thickness macular hole with a diameter of 581 μm at the aperture and 1290 μm at the base. This 62-year-old female patient had undergone 2 prior PPVs and had a BCVA of 20/200 at this moment. She does not have high myopia. BCVA = best-corrected visual acuity; OCT = optical coherence tomography; PPV = pars plana vitrectomy.

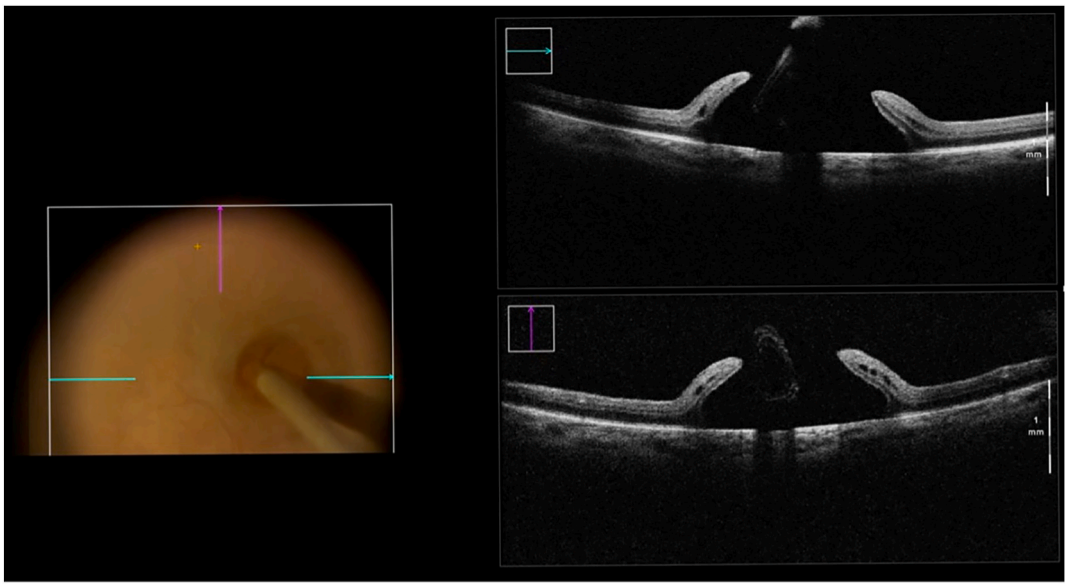

Fig. 2. Image of the viscodissection step with iOCT confirming the elevation of the macular hole borders. iOCT = intraoperative optical coherence tomography.

Table 1
Patient demographics with pre and postoperative clinical data. All macular holes were idiopathic with flat edges. Patients 1 and 6 had previously undergone 1 PPV while patient 2 had undergone 2 PPVs. Other patients were operated on for the first time. All phakic patients at time of surgery underwent concurrent phacoemulsification. 20 % SF6 tamponade was used in all cases. BCVA = best-corrected visual acuity; F = female; logMAR = logarithm of the Minimal Angle of Resolution; MLD = minimal linear diameter; PPV = pars plana vitrectomy; SF6 = sulfur hexafluoride.

Patient number	Sex	Age	Eye	MLD (μm)	Macular hole duration (months)	Preoperative lens status	Preoperative BCVA – Snellen (logMAR)	Postoperative BCVA – Snellen (logMAR)
1	F	66	Left	856	12	Phakic	20/150 (0.88)	20/70 (0.54)
2	F	62	Left	581	18	Phakic	20/200 (1)	20/60 (0.48)
3	F	55	Right	747	6	Pseudophakic	20/2000 (2)	20/2000 (2)
4	F	86	Right	830	3	Phakic	20/2000 (2)	20/50 (0.4)
5	F	82	Right	757	36	Pseudophakic	20/150 (0.88)	20/80 (0.6)
6	F	83	Left	852	4	Phakic	20/2000 (2)	20/70 (0.54)
7	F	72	Left	712	6	Pseudophakic	20/2000 (2)	20/80 (0.6)
8	F	77	Left	621	12	Pseudophakic	20/200 (1)	20/50 (0.4)
9	F	73	Right	616	12	Phakic	20/20 000 (3)	20/100 (0.70)
10	F	64	Left	401	36	Pseudophakic	20/2000 (2)	20/250 (1.1)

experiments demonstrated that RPE cells seeded over a hAM grew in a highly organized manner and possessed well-defined cell-cell and cell-substrate interactions.[16]. Via a series of OCT scans, Rizzo et al. also observed retinal cells regenerating over the hAM and stratifying over time into recognizable layers.[6]. Fundus imaging, examples of which are provided in Fig. 5, revealed the hAM patch remaining in place during follow-up visits. During this time, the hAM maintained its thickness and did not seem to shrink or resorb.

No major adverse events such as endophthalmitis, IOP increase, or CNV occurred in any of our patients during the follow-up period. No cases of hAM implant rejections were reported.

4. Discussion

Even with the advent of modern approaches, successfully treating large, chronic, or persistent macular holes is still challenging for surgeons. Causes of surgical failure may include residual epiretinal traction, high myopia, or insufficient compliance to post-operative positioning instructions.[17]. Many of the currently proposed techniques have potential, but also certain drawbacks. For example, patients suffering from persistent macular holes who have already undergone previous PPVs may not have any remaining ILM to be peeled, rendering certain operations like the inverted ILM flap technique not performable. Autologous neurosensory retinal transplants have also been described as a possible option. However, it nonetheless comes with inherent risks such as choroidal and retinal hemorrhage since it involves cutting off a piece of the retina.[18]. Therefore, a hAM graft is a possibly safer alternative while circumventing certain difficulties encountered in other procedures.[19]. Consisting of a singular layer of epithelium on top of a basement membrane and layers of collagen matrix, it has numerous desirable characteristics making it suitable for ophthalmic surgeries. The hAM has been thought to possess anti-inflammatory, anti-angiogenic, anti-bacterial effects as well as low immunogenicity.[20]. We speculate that these properties help promote the differentiation and proliferation of the RPE cells.

In light of these benefits, increasing numbers of surgeons have attempted to use hAM plugs to treat large and persistent macular holes. Notably, in a series of 36 macular hole patients treated by Caporossi et al., the authors reported 35 holes being closed at the 3-month mark with only 1 patient requiring an additional surgery. 33 of their patients experienced an improvement in BCVA, 1 patient's visual acuity deteriorated, and the remaining 2 patients experienced no change.[9].

Even though good outcomes are achievable, certain optimizations can still be made to the current method. In an interventional study on hAM grafts by Ferreira et al., the researchers described the healing process as more pronounced in patients for whom the transplant was placed directly over the macular hole compared to those for whom the graft was inserted into the subretinal space. To explain this finding, the

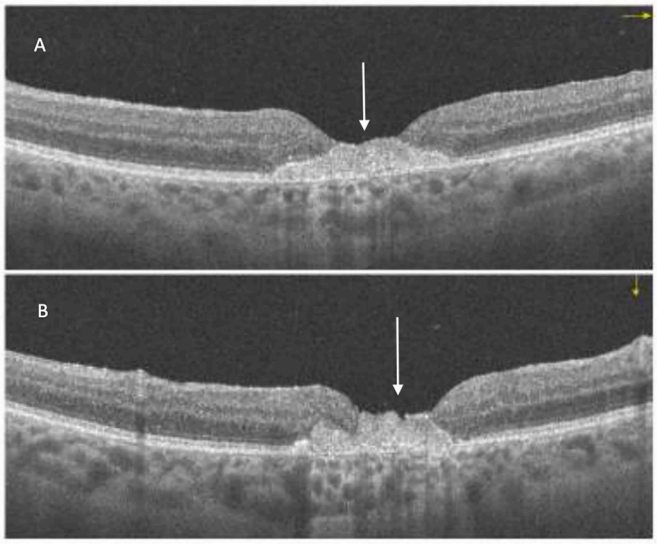

Fig. 3. (A) horizontal and (B) vertical OCT images at 1 week postoperative showing full closure of the macular hole (white arrows). At this follow-up, the 62-year-old patient had a BCVA of counting fingers at 1 foot. BCVA = best-corrected visual acuity; OCT = optical coherence tomography.

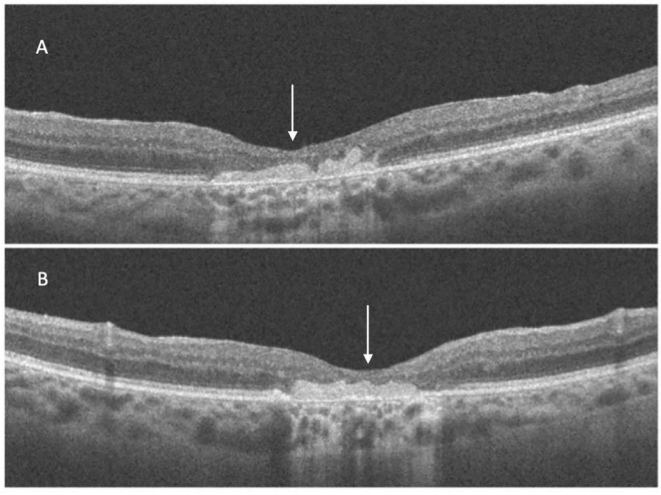

Fig. 4. (A) Horizontal and (B) vertical OCT images of the same patient at 6 months postoperative showing the regenerated retina (white arrows) completely overfilling the hAM patch. Her BCVA at this moment improved to 20/60. BCVA = best-corrected visual acuity; hAM = human amniotic membrane; OCT = optical coherence tomography.

authors hypothesized that manipulating the edges of the macular hole possibly damaged the retina, consequently affecting its regenerative capabilities.[21].

To address this shortcoming, we suggest viscodissection as an equally effective, but less traumatic technique that can be used to raise the borders of the macular hole. Gently injecting the OVD into the macular hole would sufficiently elevate its edges without needing forceps. As such, avoiding contact between the retina and surgical tools diminishes the risk of inducing iatrogenic injuries. On top of having a better safety profile, viscodissection can even be considered, difficulty-wise, as easier to execute compared to the conventional manual technique. In our cases, the OVD did not provide resistance to the insertion of the AM and did not seem to hamper air-gas exchange. Vitreoretinal surgeons can consider incorporating this approach to their toolkit for treating macular hole patients.

We also advocate for the usage of iOCT to assist the surgeon in securing the appropriate positioning the hAM patch. Firstly, it can be used to confirm the successful injection of the OVD. Additionally, experts agree that the membrane should be more than just tucked in the macular hole; it should instead be spread evenly underneath the hole's edges such that it forms a uniform layer. Doing so is theorized to increase proliferation of neurosensory cells and to allow for better stratification of retinal layers.[6]. Furthermore, the borders of the macular hole should cover the graft in all 360° to avoid AM slippage. Hence, iOCT can be employed to verify that the aforementioned steps are performed properly, which allows for a smoother recovery. We believe this technique can be done without the guidance of iOCT. However, its usage is still highly encouraged.

Using the techniques we discussed, we obtained satisfactory results. In our cohort, we achieved a rate of 100 % for anatomical success and 90 % for functional improvement. In our patients with an intact ILM, it is frequently the chronic nature of the macular holes that oriented our decision towards hAM grafts even though simple ILM peeling or flaps could have been viable surgeries. In the first patient to be operated and for whom we have the longest follow-up period, we observed that the AM still remains in place unaltered more than three years after its insertion.

Apart from viscodissection, other variations of macular hole surgeries with hAM transplants have been described in the literature, one of them being hydrodissection. This procedure consists of mobilizing the macular hole by refluxing a liquid solution into the hole with a soft-tipped cannula and passively aspiring it afterwards.[22]. In patients treated using this technique, Felfeli et al. found an 87 % success rate at closing macular holes, while 95 % of their patients experienced an improvement in VA.[23]. In another presentation, Soares and Kuriyan discussed creating balanced salt solution blebs with a 41-gauge cannula to raise the macular hole before bringing in the hAM patch.[24]. Similarly to our approach, both these methods avoid manipulating the retinal layers with metal tools.

Our study has certain limitations such as the small number of patients and the short follow-up periods. Randomized controlled trials containing more patients and longer follow-up durations should be conducted to compare the outcomes of this technique with standard procedures. Another limitation to take into account are the concurrently cataract surgeries in phakic patients being a confounding factor for their BCVA improvements.

To sum, we propose this technique for macular holes that are either chronic, persistent, or wider than 550 μm (X-large or bigger). Such holes will continue to be complex for ophthalmologists to manage, hence the need for the development of new approaches. We thus encourage surgeons to familiarize themselves with this variety of novelties, allowing them to select the most appropriate technique in a given situation.

CRediT authorship contribution statement

Shu Yu Qian: Writing – review & editing, Writing – original draft, Visualization, Data curation, Conceptualization. **Marc Saab:** Writing – review & editing, Supervision, Methodology, Data curation, Conceptualization.

Patient consent

Written consent to publish this case has not been obtained. This report does not contain any personal identifying information.

Authorship

All authors attest that they meet the current ICMJE criteria for Authorship.

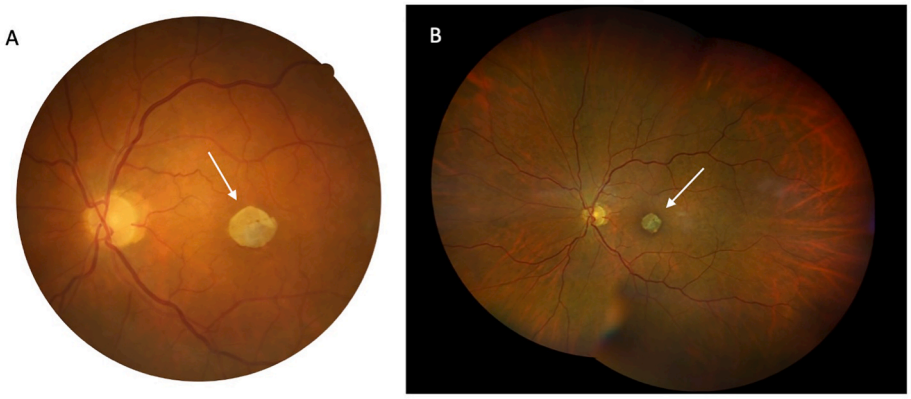

Fig. 5. Retinal photographs of the same patient at (A) 1 week and (B) 6 months postoperative illustrating the AM (white arrows) remaining in place during the entire follow-up period. AM = amniotic membrane.

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.ajoc.2025.102302.

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