

Treating large submacular hemorrhage through tenecteplase delivery without puncturing the retinal surface: Case series

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Case Report

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Abstract

Purpose

To introduce a modified subretinal injection method without retinal puncture for the treatment of large retinal submacular hemorrhage (SMH).

Methods

Fourteen patients with polypoidal choroidal neovascularization (PCV) complicated with SMH were included in this study. Patients received the non-puncturing subretinal injection of the tissue plasminogen activator tenecteplase (TNK) to dissolve subretinal hemorrhage during pars plana vitrectomy (PPV).

Results

The injection was successful in all patients without retinal breaks or additional trauma. After the operation, the subretinal hemorrhage in the macular area was absorbed well in 14 patients, which was manifested as the thinning of the central macular thickness and the decrease of the hemorrhage area. During the follow-up period, rhegmatogenous retinal detachment occurred in two patients at one to two months after surgery, which may be due to the formation of holes in the peripheral degeneration area rather than the holes at the injection site; the complicated cataract was developed in three patients at three to six months after surgery, which were improved after phacoemulsification and intraocular lens (Phaco + IOL) implantation. Four patients received intravitreal injections of anti-vascular endothelial growth factor (anti-VEGF) after surgery. And two patients experienced recurrent vitreous hemorrhage after surgery. Following vitreous cavity irrigation, the subretinal hemorrhage was reduced compared to its preoperative level, and they are currently recovering well.

Conclusions

The surgical method of vitrectomy combined with subretinal injection of TNK without retinal puncture can bring benefits to the anatomical and visual outcomes of patients with large SMH and can be considered for further use in patients with large SMH caused by various diseases.

Introduction

Large retinal submacular hemorrhage (SMH) is a subretinal macular hemorrhage involving the central fovea and is recognized as one of the common retinal diseases in clinical practice. SMH impairs retinal function through several mechanisms, including the shear of photoreceptors by fibrin clots, the physical separation of photoreceptors from the retinal pigment epithelium (RPE) and choroid, and the direct toxic effects of iron^{1,2}. SMH is more common in a variety of eye diseases, including polypoidal choroidal vasculopathy (PCV), neovascular age-related macular degeneration (n-AMD), retinal artery macroaneurysm (RAMA), high myopia, etc. Delayed removal of hemorrhage may lead to poor visual prognosis [3].

A variety of approaches have been used alone or in combination to treat SMH, such as intravitreal gas administration, intravitreal or subretinal application of tissue plasminogen activator (t-PA), intravitreal injection of anti-vascular endothelial growth factor material (anti-VEGF), and subretinal clot removal, photodynamic therapy (PDT), and pars plana vitrectomy (PPV) [4]. However, it is easy to damage the retinal nerve sensory layer and RPE after surgery and cause serious complications, such as retinal detachment, vitreous proliferative lesions, macular hole, and epiretinal membrane formation. Therefore, for patients with SMH, choosing the appropriate treatment plan has an important impact on their prognosis and reducing complications.

At present, patients with PCV involving large SMH (equal to or more than 4 optic nerve head diameters) are recommended to undergo subretinal injections of thrombolytic drugs combined with surgery [5]. Subretinal injection of tPA combined with PPV is used by most doctors for the treatment of SMH. Usually, 38G and 41G subretinal injection needles are used to inject t-PA liquid into

the subretinal space through the vitreous body and the opposite retina to promote the dissolution of hemorrhage. However, the resistance of the retina to the needle tip makes it difficult for the needle tip to penetrate the retina [6]. If high-pressure stimulation of the retina is produced at the time of injection, it will cause injury to the retina, pigment epithelium, and blood vessels, resulting in subretinal hemorrhage, RPE rupture, or choroidal neovascularization [7, 8]. Given the highly invasive nature of retinal puncture and the drawbacks of retinal damage, we propose a modified subretinal injection method without retinal puncture to deliver tenecteplase (TNK), a multi-point variant of t-PA, at the hemorrhage site for subretinal drug delivery during PPV.

Methods

Surgery procedures

(1) Three vitreous microincisions were made in the pars plana of the ciliary body with a 23G needle, and vitrectomy was performed with a 23G vitrectomy head. The posterior pole and equatorial vitreous were cleared. If the internal limiting membrane (ILM) had traction on the posterior pole of the retina, partial ILM peeling was performed to prevent tractional retinal detachment.

(2) Tenecteplase injection was prepared at a concentration of 10 ug/mL. A 2 mL diluted TNK injection was aspirated with a 10 mL sterile syringe and set aside.

(3) A retractable 41G subretinal injection needle was connected to the port (Fig. 1b) of a homemade bolus device (Fig. 1a) equipped with TNK injection. The surgeon held a 41G needle in his right hand and a PPV light source in his left hand. The needle passed through the sclera, from the pars plana of the ciliary body, through the vitreous body and oblique down to the subretinal hemorrhage site, and placed the 41G needle on the slope side of the hemorrhage focus (Fig. 2). The tip of the needle did not puncture the retina.

(4) The assistant pushes the piston of the syringe at a constant speed to disperse the TNK injection into the layer of blood between the subretina and the RPE layer. Subretinal bubbles and retinal breaks should be avoided.

(5) The 41G needle quickly left the retina. If there is bleeding or exudation at the injection site, the exudate should be removed with a vitrectomy head or a flute needle. If not, the 41G needle should be removed.

(6) The retina and subretinal hemorrhage were re-examined, and if there was no hemorrhage or exudation, fluid-air exchange was performed.

(7) If a large number of peripheral retinal breaks were found during the operation, the vitreous body was removed and retinal laser photocoagulation was performed. If the retina is still poorly reattached, SF6 inert gas or silicone oil should be inserted into the vitreous cavity.

(8) Patients were maintained in the face down or lateral decubitus position for seven days after surgery.

All patients were operated by the same surgeon. The preoperative and postoperative visual acuity, subretinal hemorrhage, and postoperative complications of the fourteen patients are listed in Table 1 and Table 2.

Case reports

A 65-year-old man complained of visual loss in the right eye for more than two years, which worsened with dark shadow for seven days. The uncorrected BVCA in the right eye was index/anterior (1/1000), and the intraocular pressure in the right eye was 13 mmHg. Fundus examination showed bloody vitreous opacity, hazy optic disc boundary, yellow-white exudation in the macular area, flat peripheral retina, and unclear details of the remaining retina. Intraoperative pictures showed that the 41G retinal injection needle was applied above the macular area, injection point 1 was applied at the old yellow-white scar lesion of the superior temporal vessel branch (Fig. 3a), and injection point 2 was applied at the dark red lesion of the inferior temporal vessel branch below the macular area (Fig. 3b). Because of his long course and the large area of SMH, the subretinal scar in the macular area was formed, and the best one-time visual acuity was 0.01 (1/100). This patient had a long course of disease and was found to have organized scar lesions during surgery. Multiple subretinal TNK injections did not cause complications, the BVCA was improved and the accumulation of blood was also markedly absorbed (Fig. 3c).

Discussion

As a more accurate and efficient route of ocular drug delivery, subretinal space administration has been widely used in the treatment of a variety of degenerative vitreoretinal diseases such as retinitis pigmentosa; however, there is no unified retinal injection method [9]. In the present study, a self-made 41G subretinal needle containing TNK injection was used to inject TNK into the subretinal space of 14 large SMH without puncturing the retina. This injection method achieves the effect of safe TNK subretinal space injection, and achieves the effect of eliminating hemorrhage, without damage to the retina.

As early as 1999, Hassan et al. (1999) found that injection of t-PA into the subretina to dissolve thrombi was an effective means of treating patients with large SMH (bleeding area > 4PD) [10]. Tranos et al. (2021) showed that t-PA combined with bevacizumab was a safe and effective treatment for age-related macular degeneration with SMH [11]. Jackson et al. (2022) performed PPV and subretinal injection of t-PA in a group of patients with SMH due to various causes and found a good therapeutic effect [12]. In recent years, PPV combined with t-PA subretinal injection has been considered to be superior to anti-VEGF monotherapy for patients with PCV and SMH [13]. In animal experiments, McAllister et al. (2013) found the ability of TNK to penetrate the retina by intravitreal injection in a pig model of branch retinal vein occlusion (BRVO) and speculated that this characteristic of TNK could affect the outcome of thrombolysis [14]. The potentially toxic L-arginine content of the TNK vector is less than one-third of that of t-PA, and it is more penetrating, allowing a reduction in the dose of TNK used, compared with the equivalent dose of t-PA. In clinical studies, TNK has a relatively low plasma clearance rate, a longer half-life, 14 times greater specificity for fibrin than the conventional plasmin t-PA, and 80 times greater anti-inactivation capacity against plasminogen activator inhibitors [15, 16]. Kwan et al. (2006) found that TNK could penetrate the porcine retina in the pig eye model, which had a structure very similar to that of humans, indicating the ability of TNK to penetrate the human retina [17]. In addition, the advantage of TNK is that it can quickly dissolve the subretinal hemorrhage, thereby promoting the recovery of the anatomical structure of the retina and reducing the damage to retinal function. Therefore, some researchers began to consider subretinal injection of TNK for the treatment of SMH. In 2012, Kwon et al. (2012) first reported a case of subretinal injection of TNK 50 µg for the treatment of SMH caused by PCV in a 63-year-old patient and found that SMH was completely absorbed after 1 month, and visual acuity recovered to 20/20 after 2 months during follow-up, which proved that TNK had sufficient hemolytic function [18]. In 2023, Wang et al. (2023) reported the first report of TNK used in the treatment of subretinal hemorrhage in China. The results showed that the treatment method of subretinal injection of TNK combined with gas-fluid exchange could promote the early metastasis of subretinal hemorrhage disease, shorten the dissolution and absorption time of SMH, improve the visual acuity of patients, and improve the recovery of retinal structure and function [19]. Therefore, although the evidence is relatively small, it can also be seen that TNK has the potential to be used for the treatment of subretinal hemorrhage. In this study, a combination of subretinal injection of TNK and PPV was used to achieve resolution of subretinal hemorrhage in 14 patients with PCV and SMH. Our results further support that TNK is safe and effective in thrombolytic therapy in fundus hemorrhage.

Subretinal injection is a recognized strategy for the treatment of SMH; however, the injection methods are diverse, and each has its advantages and disadvantages [8]. In the method of PPV combined with subretinal injection of t-PA for the treatment of large SMH, the subretinal injection needle size from 38G to 41G has been a great breakthrough, but it will still cause microholes when puncturing the retina, and the postoperative healing takes a certain time [20]. Local removal of the ILM for subretinal injection is a special and useful technique that may reduce complications such as retinal thinning and decreased retinal sensitivity, as well as retinal breaks in the presence of subretinal fluid [6]. The above two methods will more or less cause damage to the retina, and the occurrence of complications is uncontrollable. Hartman et al. (2018) found that in the future, a small diameter needle close to the nano size can be used to penetrate the retina and inject drug preparations under the retina, its less invasive characteristics are expected to reduce the damage to the retina, which is also a test for materials and technologies [21]. In recent months, we have found a new way of subretinal injection, which is different from the above retinal puncture, that is, the drug can be injected into the retina when the needle is close to the retina instead of puncturing the surface of the retina. We have successfully used this technique in fourteen patients with PCV combined with SMH, and all the patients were injected smoothly without retinal tears and additional trauma. After surgery, fourteen patients had good SMH absorption, and the central macular thickness became thinner and the bleeding area decreased. The key point of this method is that the 41-gauge needle is close to the slope of the subretinal hemorrhage, so that the bevel of the needle is parallel to the slope of the hemorrhage, and gently close to the retina. Because the needle tip does not puncture the retina, the formation of iatrogenic tears can be effectively avoided, so as to reduce complications. Finally, it is worth mentioning that our injection method does not require special equipment, and uses a common 41G subretinal

injection needle and a common 10mL syringe to make the injection device, which reduces the cost and the difficulty of operation, and is easy to promote among young doctors.

PPV combined with some common subretinal injection methods can cause various complications, such as retinal breaks and retinal detachment, which greatly reduces the patient's satisfaction with the treatment prognosis. In this study, drug injection was performed without penetrating the retina, and some complications related to retinal injury, such as recurrent submacular hemorrhage, permanent RPE damage, and formation or aggravation of retinal structure damage [7, 8], did not occur in the fourteen patients counted. OCT showed that the exudate between the macular retinal nerve and pigment epithelium dissolved and absorbed to a certain extent, and the different degrees of subretinal finger processes were improved, which were the key factors affecting the recovery of visual acuity. In this study, patients who experienced postoperative complications, including rhegmatogenous retinal detachment, vitreous hemorrhage, and complicated cataract, all did so within two months after surgery. Therefore, it is suggested that the period of high incidence of postoperative complications is within three months after operation. During this period, timely reexamination and treatment of complications should be carried out.

The number of subjects in our study was small, and the follow-up time after surgery was short, so it is inevitable that the possible factors causing the later visual loss were not observed, which is also our further work. The significance of this paper is that this new subretinal injection method accompanied by PPV, which takes into consideration the choice of surgical method and drug, is simple and feasible, and is more suitable for young doctors and doctors who are not skilled in subretinal injection. We believe that its simplicity and safety can make it an important procedure for other vitreoretinal surgeons to understand.

In conclusion, vitrectomy combined with subretinal injection of TNK without retinal puncture can bring benefits to the anatomical and visual outcomes of patients with large SMH. It can be considered one of the effective treatment methods and can be considered for further promotion in patients with large SMH caused by various diseases.

Declarations

Ethics approval and consent to participate

This study was conducted in accordance with the ethical principles stated in the Measures for the Ethical Review of Life Science and Medical Research Involving Human Subjects (2023) issued by the National Health Commission of the People's Republic of China, the Good Clinical Practice for Drug Trials (2020), the Guiding Principles for Ethical Review of Drug Clinical Trials (2010), the Good Clinical Practice for Medical Device Clinical Trials (2022), the Interim Measures for the Administration of Human Genetic Resources (1998), the Service Guide for the Administrative Approval of Collection, Gathering, Trading, Export, and Exit of Human Genetic Resources (2015), the Declaration of Helsinki, and the International Ethical Guidelines for Biomedical Research Involving Human Subjects. Ethical approval was obtained from the Clinical Research Ethics Committee of the Affiliated Hospital of Guangdong Medical University (Ethics No.: PJKT2024-068). Written informed consent was obtained from all patients before participation, and the use of informed consent forms was included in the ethics approval document.

Consent for publication

Written informed consent was obtained from all individual participants included in the study.

Data availability statement

All data supporting the findings of this study are available within the paper and its Supplementary Information.

Declaration of competing interest

All authors declare that they have no conflicts of interest.

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Tables

Table 1 Patients' preoperative condition

Case	Age	Gender	Eye Laterality	Preoperative			Subretinal hemorrhage	
				BCVA (logMAR)	Retinal condition	Diagnose	Duration (day)	Extent (PD)
1	65	Male	Left	1.00	SMH	VH	4	20
2	65	Male	Right	2.77	SMH	VH	7	9
3	59	Female	Left	3.77	SMH	VH	30	18
4	88	Male	Left	3.77	SMH	VH	20	15
5	59	Male	Left	LP	SMH	VH	30	12
6	58	Male	Left	2.30	SMH	PCV + SMH	6	12
7	54	Male	Left	1.00	SMH	PCV + SMH	1	4
8	68	Female	Right	1.70	SMH	PCV + SMH	4	8
9	72	Female	Left	LP	SMH	VH	30	16
10	68	Female	Right	1.00	SMH	PCV + SMH	2	10
11	68	Female	Right	2.30	SMH	VH	30	10
12	62	Male	Right	LP	SMH	VH	10	18
13	69	Male	Right	0.52	SMH	PCV + SMH	4	4
14	52	Male	Right	2.30	SMH	PCV + SMH	3	6

Abbreviations: BCVA (best-corrected visual acuity), LP (light perception), SMH (submacular hemorrhage), VH (vitreous hemorrhage), PCV (polypoidal choroidal vasculopathy), and PD (papillary diameter).

Note: All cases underwent pars plana vitrectomy (PPV) combined with a subretinal injection of Tenecteplase (TNK) without retinal surface puncture (PPV+TNK).

Table 2 Patients' postoperative condition

Case	Age	Gender	Eye Laterality	Postoperative			Subretinal hemorrhage		Complications	
				BCVA (logMAR)	Retinal condition	Diagnose	Duration (month)	Extent (PD)	Disease	Duration (month)
1	65	Male	Left	0.82	Flat retina	PCV + SMH	6	0	Fibrosis	3
2	65	Male	Right	2.00	Reduced subretinal hemorrhage area and height	PCV + SMH	2	3	/	/
3	59	Female	Left	1.30	Flat retina	PCV + SMH	2	1	Fibrosis	4
4	88	Male	Left	2.30	Flat retina, reduced subretinal hemorrhage area and height	PCV + SMH	4	4	/	/
5	59	Male	Left	1.30	Reduced subretinal hemorrhage area, partial peripheral retinal detachment	PCV + SMH	2	3	Retinal detachment	2
6	58	Male	Left	2.77	Extensive peripheral retinal detachment	PCV + SMH	6	/	Retinal detachment, Fibrosis	2
7	54	Male	Left	0.82	Flat retina	PCV + SMH	1	0	/	/
8	68	Female	Right	1.00	Reduced subretinal hemorrhage area and height	PCV + SMH	5	1	/	/
9	72	Female	Left	2.77	Illegibility of fundus	PCV + SMH	0.6	/	Reoccurrence of VH	0.25
10	68	Female	Right	1.00	Reduced subretinal hemorrhage area and height	PCV + SMH	1.5	4	/	/
11	68	Female	Right	2.77	Reduced subretinal hemorrhage area and height	PCV + SMH	2	6	/	/
12	62	Male	Right	1.70	Illegibility of fundus	PCV + SMH	1	/	Reoccurrence of VH	0.25
13	69	Male	Right	0.52	Flat retina	PCV + SMH	0.9	0	/	/
14	52	Male	Right	0.70	Flat retina	PCV + SMH	0.5	0	/	/

Figures

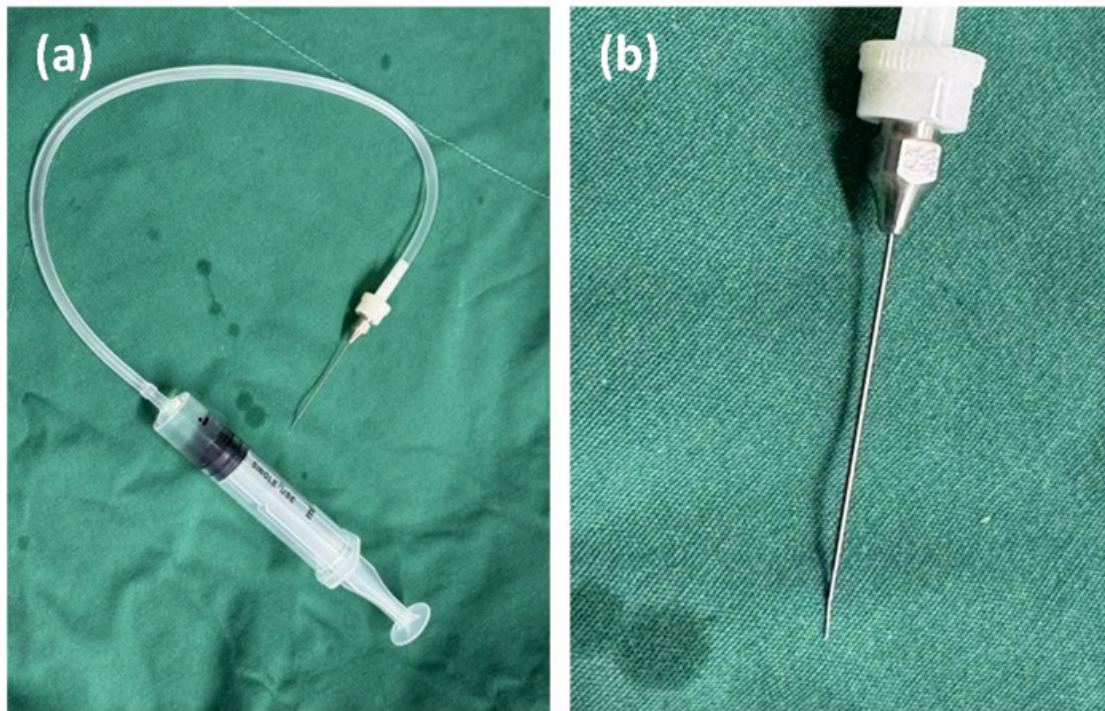


Figure 1

A self-made bolus device connected to a 41G subretinal injection needle. (a) Syringe and high-pressure extension tube. And (b) local magnification of the needle.

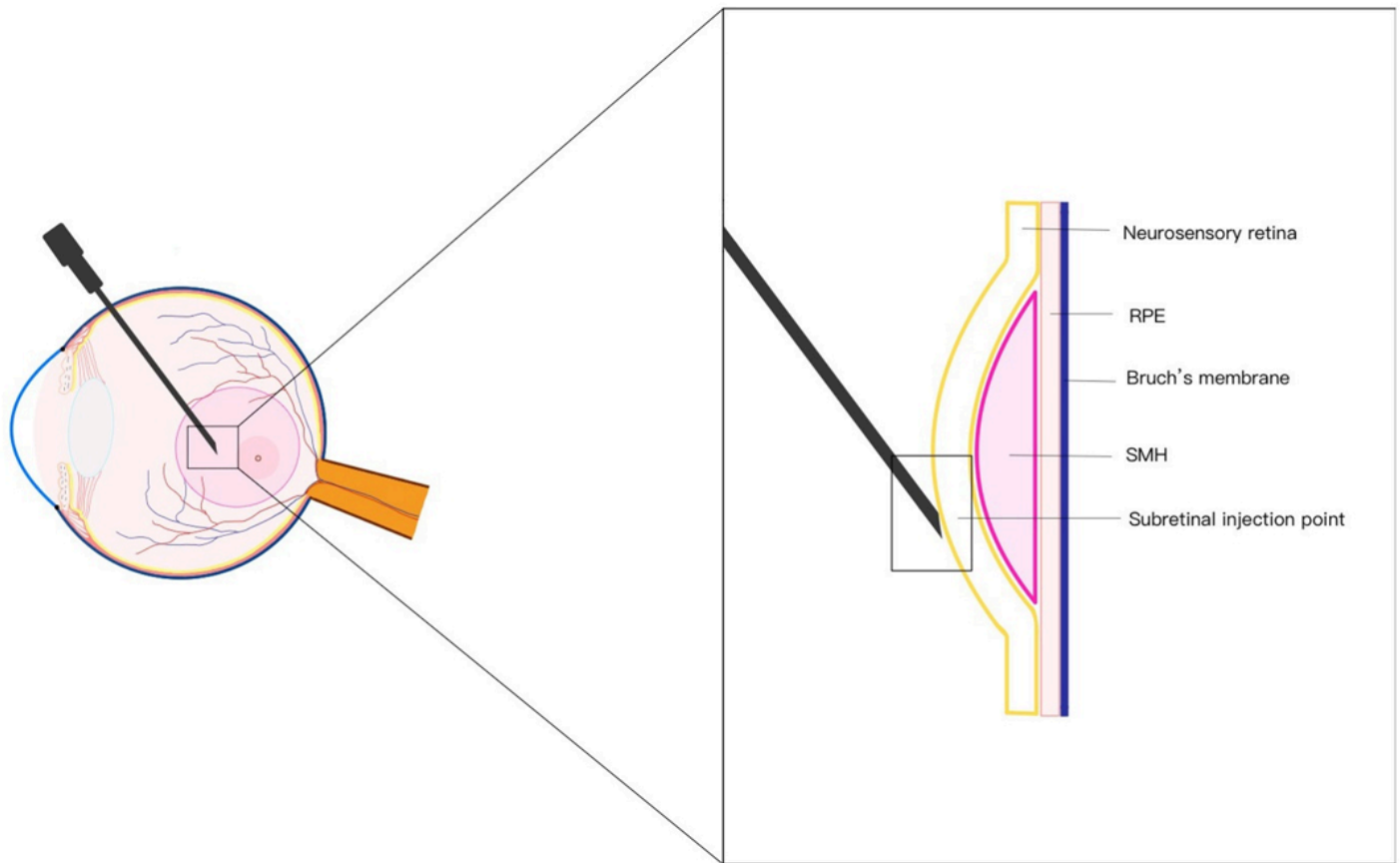


Figure 2

Schematic of the subretinal injection. The needle entered the vitreous cavity through a microincision in the pars plana of the ciliary body, and then slowly approached the retinal lesion. The bevel of the needle was parallel to the retinal bevel, and the needle was close to the retina without puncturing the retina. Subretinal injections are delivered by the tension of the drug into the layer of blood above the RPE.

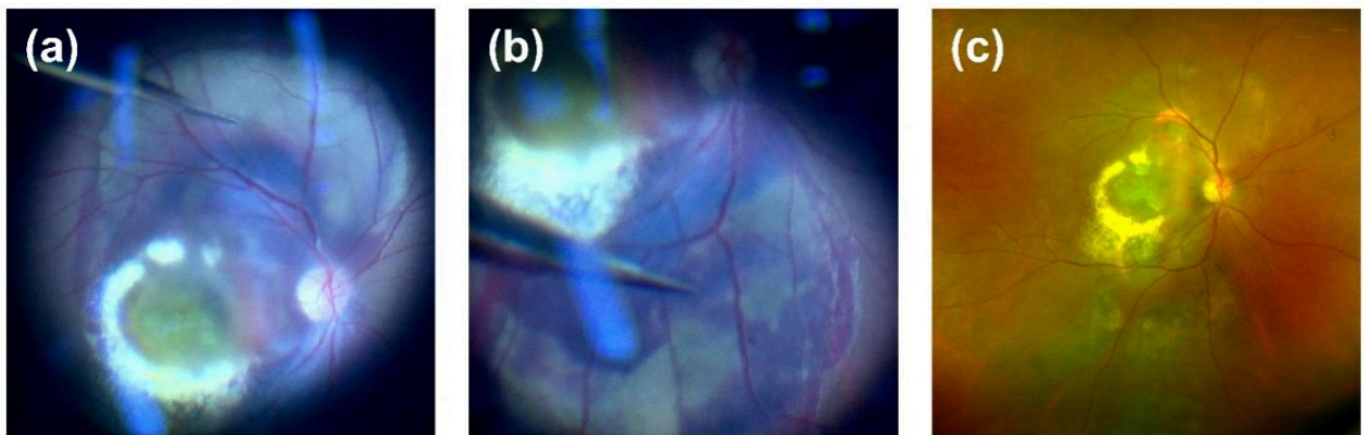


Figure 3

Screenshots of two different TNK injection sites during the operation and postoperative SLO of the patient. (a) The injection site at the old yellow-white lesion. (b) The injection site at the dark red lesion. And (c) SLO 2 months after surgery.