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Evaluation of Plasma Assisted Noninvasive Surgery (PANIS) as a New Approach for the Treating Bullae in Pseudophakic Bullous Keratopathy (PBK); A Clinical Case Report

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Abstract

Purpose: Pseudophakic bullous keratopathy (PBK) is one of the unintended side effects of intraocular surgeries and traumas. This study aims to evaluate plasma as a noninvasive procedure for PBK diseases through drainage of painful and annoying bullae. Methods: Three eyes of three patients with no vision potential were included in this study. Plasma spots are applied on bullae to empty the fluid inside, and also to attach the top of the bullae to the bottom. We evaluated Pain scores, tearing, and burning sensations (scale of 0 to 10) before treatment and one week, one month, and six months after treatment. Results: The results showed that all the annoying bullae entirely eliminated in all patients. No complications and recurrence were observed during the operation and one week, one month, and six months after the procedure. After treatment, there was no tearing and burning sensation. All of the patients scored ten for pain before treatment and zero after treatment. There were no changes in the vision of the patients after treatment. Conclusions: Based on the results, the PANIS method can be used as a safe method for eliminating bullae which are not a good candidate for vision amelioration treatment. This method is safe, quick, office base and inexpensive, which can decrease pain in these patients.

Keywords: Pseudophakic bullous keratopathy; PBK; Plasma; PANIS; Case report.

1. Introduction

Pseudophakic bullous keratopathy (PBK) is one of the unintended side effects of cataract surgery, with 1 to 2% incidence in patients [1]. Other cause of PBK is Trauma, endothelial dystrophies, tumors of the anterior chamber, congenital abnormalities, acute and neovascular glaucoma, herpetic endotheliitis, or surgeries that can lead to endothelial cell loss [1, 2]. This complication causes pain, foreign body sensation, burning, itching, watering irritation, and photophobia [3]. This complication is due to the dysfunction of endothelial cells, and as a result, the cornea becomes edematous and turbid, and bullae will form on the epithelial surface [4]. In addition to the patient's irritation, these blisters reduce patient's vision and, in some cases, cause blindness [5]. In patients with good vision potential, keratoplasty is an appropriate treatment [6]. Keratoplasty is a complex, time-consuming, and expensive surgery which is not practicable in some cases due to the patient's condition, such as a history of other vision problems, old age, or unavailability of good-quality donor corneas for transplantation [3, 7, 8]. Topical hypertonic saline, bandage contact lens, amniotic membrane graft, anterior stromal puncture, and Gunderson flap are other treatments that can help patients [9].

A new method that has been recently considered as a treatment in ophthalmology, called PANIS (Plasma assisted noninvasive surgery) using plasma as the fourth state of matter to treat Conjunctivochalasis, Dry eye disease, Pinguecula, pterygium, Conjunctival Concretions, and Conjunctival Cyst [10-14]. Plasma technology is effective even in Wound healing, infection control, and cancer treatment [15]. Good to be noted that, the safety and effectiveness of applying plasma spots on ocular surface, have been evaluated by Nejat et al. in animal studies [16, 17]. Good history of plasma in medicine reassure us to use PANIS method for the first time for eliminating bullae of PBK patients and define this novel technique as a safe, office base, inexpensive method.

2. Materials and Methods

2.1. Study Design

The study was conducted at the Vision Health Research Center, Tehran, Iran, from 2020 to 2021. All of the processes were considered by the Declaration of Helsinki, and the Semnan University of Medical Sciences approved the study's protocol. The study was registered in the Iranian Registry of Clinical Trials (IRCT20181229042160N1). Patients that were not good candidate for keratoplasty were included in the study. The treatment process, available alternatives, and related risks were entirely described for the patients, and informed consent was obtained. Three patients (1 man and 2 women) participated in this study (Table 1). Case 1 was a 33 years old man whom right eye UCVA was hand motion because of the trauma. Case 2 was a 76 years old woman with Light perception in her left eye. In this case, the PBK occurred after Cataract surgery. A sixty-four-year-old woman was the third case with PBK in the left eye because of Cataract surgery. The UCVA status in this case was no light perception.

2.2. Ocular Examinations

A complete eye examination confirms the disease. One participant had their right eye, and two had their left eye involved. We evaluated the Tearing, Burning sensation, and Pain scores before and one week, one month, and six months after treatment. Patients were asked to answer the severity of Pain sensation questionnaire using a visual analogue scale (0-10). Zero means "no pain," and 10 means "the worst possible pain" [18]. We used slit lamp examination to check corneal edema and Redness. Also, the Cornea/Anterior Segment OCT SS-1000 (CASIA) examination has been used to assess the depth of the bullae before and 6 months after the treatment.

2.3. Surgical Technique

In these cases, we used the PANIS method for eliminating bullae. One surgeon did all these office-based procedures (Dr. Nejat F). Before treatment, we used topical tetracaine 0.5% eye drop (Sina Daro, Tehran, Iran) to numb the eye. This drop has been used three times with 5 minutes intervals. Patients sit behind the slit-lamp and were treated using a white handpiece of the PLEXR PLUS (GMV Srl, Rome, Italy) (Vpp = 500 V, Power = 0.7 W, and Frequency = 75 kHz) (Table 2).

Surgeon started applying plasma spots on the top of the bulla and continued spirally to the surrounding until all the liquid was drained. This process continues separately for each bulla. Plasma spots cause inflammation and scar formation on the surface of bulla which can lead to an attachment of top to bottom of the bulla (See supplemental video). After surgery, the patient was given a medication prescription containing Ciplex (chlobiotic 0.5%, Sina Darou, Tehran, Iran) every six hours a week. Betamethasone 0.1% (Sina Darou, Tehran, Iran) was prescribed every four hours in the first and every six hours in the second week.

3. Results

According to all examinations, the bullae eliminated and were entirely drained in all patients. There was no recurrence one week, one month, and six months after treatments. Also, there were no changes in the patient's vision after treatment.

Before treatment, all patients had a scale of 10 for pain in their eyes; after treatment, this complaint resolved entirely and gave a 0 on the pain scale. Before treatment, the patients complained about excessive tearing; these signs wholly disappeared after treatment. As well as after the procedure burning sensation in all of the patients was removed entirely. Patient's symptoms were sufficiently improved (Table 1).

PANIS method seems to be effective. No complications were observed intraoperative and postoperative (one week, one month, and six months after treatment). CASIA images of patients before and after the procedure mentioned in figure 1 and showed that the depth of the bulla decreased and prove the drainage of the inside fluid. Figure 2 shows the slit-lamp in case 1 before and after treatment. It shows inflammation and redness have disappeared after treatment, and the patient felt comfort in his eyes. Based on the results, treatment was effective in all of the patients.

4. Discussion

Pseudophakic bullous keratopathy (PBK) is a clinical entity caused by the loss of corneal endothelial cells [19]. In PBK, corneal endothelium has been changed and led to excessive corneal hydration, resulting in edema of the corneal epithelial layer. This epithelial bullae finally ruptured and caused severe pain, tearing, and conjunctival hyperemia. This complication leads to major indications for Keratoplasty annually in the world [19]. Keratoplasty is a complicated, relatively expensive surgery that needs expert ophthalmologist and a surgery room with anesthesia, so it is not always executable, especially since the risk of the rejection is not zero [20, 21]. Sometimes, patients prefer symptomatic treatment because of the severe pain and other signs. The palliative treatment modalities include topical hypertonic saline, bandage contact lens, phototherapeutic keratectomy, amniotic membrane graft, anterior stromal puncture, and Gunderson flap [19].

One of the therapies that were recently introduced is plasma therapy. This therapy is almost new, and its safety and efficacy were evaluated by Nejat et al. in animal studies [16, 17]. In these studies, the safety of the plasma on the rabbits' cornea, limbus, and conjunctiva was evaluated and followed up one month and six months after the intervention. According to these studies, plasma can be considered as a novel technique for treating some ocular surface disorders such as Conjunctivochalasis, Dry eye disease, Pinguecula, pterygium, Conjunctival Concretions,

and Conjunctival Cyst [10-14]. In all studies no complications were seen during and after treatment. One week, one month, and six months follow up showed no recurrence in all of the patients. This method introduced as an effective, safe and simple method for treating dry eye disease with occluding punctum, and research showed that plasma could be a temporary practical treatment. This method could control dry eye by retaining tears on the ocular surface [22]. Other researchers used plasma technology for some treatments like blepharoplasty [23, 24]. The Sotiris et al. study showed that plasma could be the better choice for blepharoplasty with less complications such as sutures, cuts and also with less side effects such as ectropion, entropion, slanted eyes, lagophthalmos, in comparison with classical blepharoplasty. Rossi, *et al.* [23] used plasma for blepharoplasty in a pilot study. Based on this study, the treatment was effective, and no severe complications have been seen. Sotiris, *et al.* [24] used this method in dermatology and demonstrated that most patients reported being satisfied with the treatment. Sotiris, *et al.* [25] used the plasma method in 250 patients to remove benign skin lesions (dermal nevi, fibroma, keratosis and xanthelasma), nonsurgical blepharoplasty, wrinkles (perioral, glabellar, neck and preauricular regions), active acne and scarring (post-acneic and posttraumatic). According to this study, the plasma method is reliable and safe, without permanent side effects [26].

In this study, PANIS method used as an office base treatment for eliminating bulla in PBK patients. All annoying symptoms like pain, foreign body sensation, burning, itching, tearing, irritation, and photophobia disappeared. Also, during the follow-up time, there was no recurrence in all three patients. As this method is inexpensive, safe, does not require an operating room, and has a short learning curve, the PANIS method can be a good alternative for patients with no opportunity for Keratoplasty. Vision parameters has not been change in all three patients, although they have not much potential vision. Despite of the novelty of this method, researchers have recently shown that it can be a suitable replacement for some treatments [12, 22] (11, 22). Nevertheless, the present study is a case study, and a clinical trial is needed to compare this method with other treatments. Also, we need longer follow-ups to assess this treatment's effectiveness and possible complications.

5. Conclusion

Based on this study, the PANIS method can effectively eliminate bullae as an easy, economical, fast, and safe method with no recurrence and complications. All annoying symptoms (pain, foreign body sensation, burning, itching, tearing, irritation and photophobia) disappeared. PANIS method is reliable and safe, without side effects for the patients. However, additional studies are needed with more patients and a long-term follow-up.

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Figure-1. CASIA images of patients before and six month after procedure

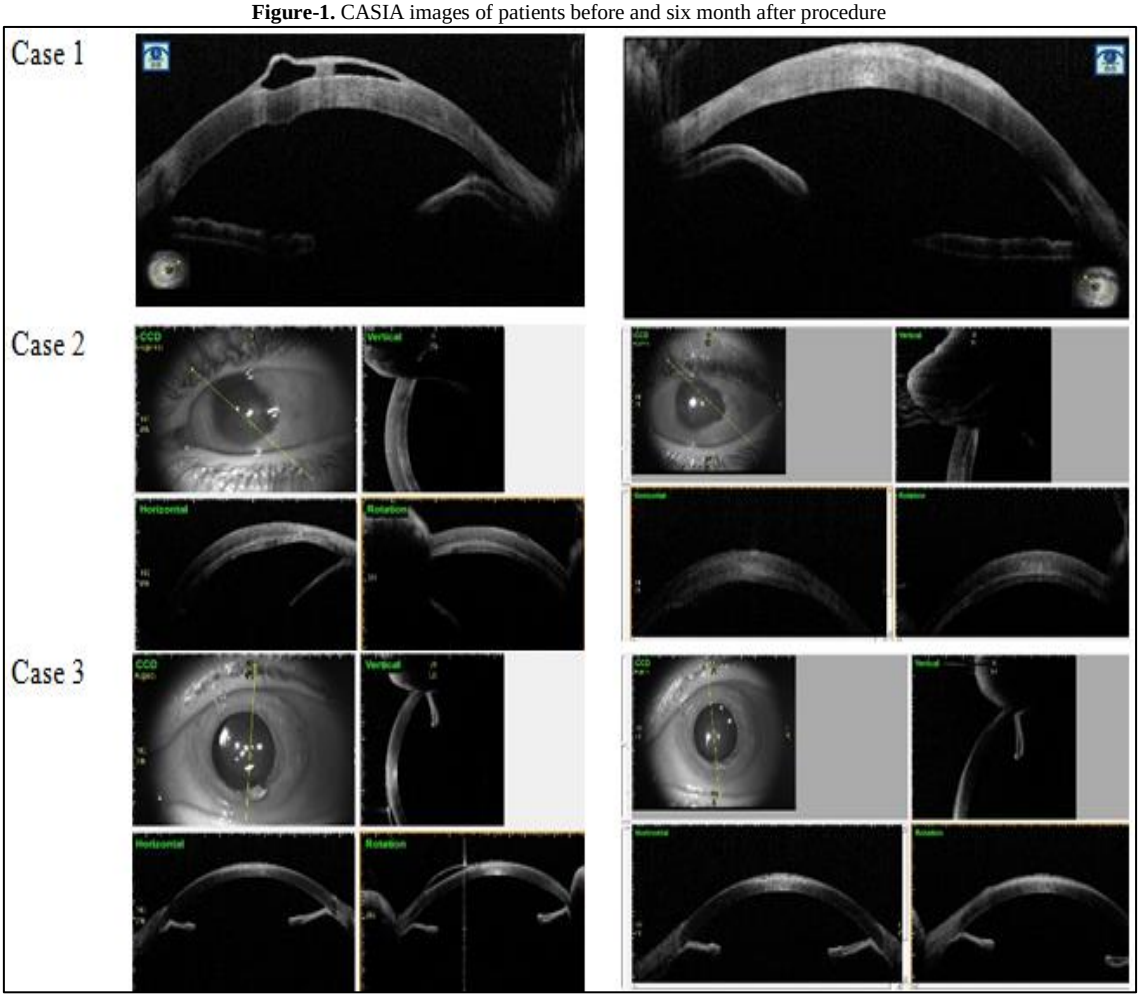

Figure-2. slit-lamp images of case 1 A: before procedure & B: six months after procedure

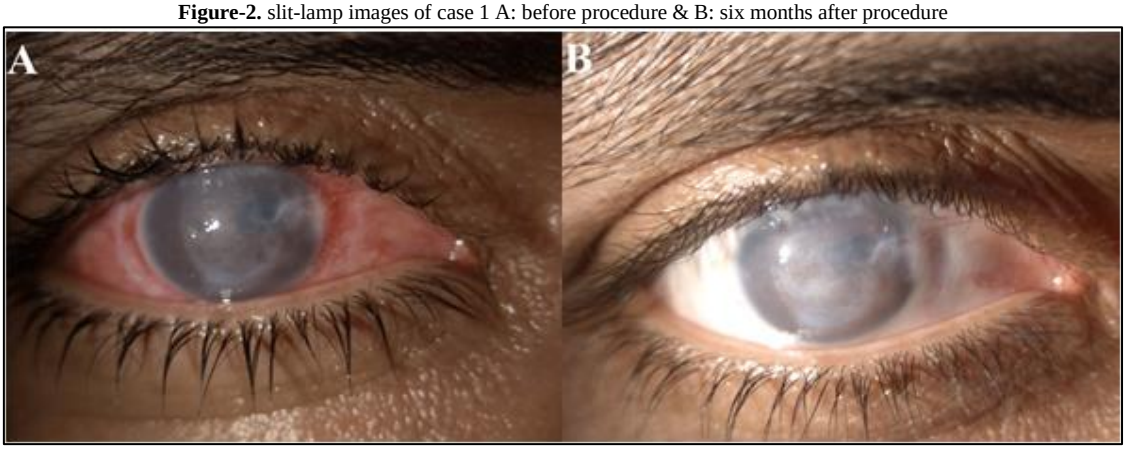

Table-1. Patients symptoms before and one week, one month and six months after procedure

Case PBK	Age (Years old)	Gender	eye	UCVA	Pre tearing	Post tearing			Pre Burning sensation	post Burning sensation			pre Pain score	post Pain score		
						One week	One month	six months		One week	One month	six months		One week	One month	six months
Patient 1	33	Male	OD	HM	YES	No	No	No	YES	No	No	No	10	0	0	0
Patient 2	76	Female	OS	LP	YES	No	No	No	YES	No	No	No	10	0	0	0
Patient 3	64	Female	OS	NLP	YES	No	No	No	YES	No	No	No	10	0	0	0

Table-2. PLEXR PLUS characteristics

Parameters	**Values**
Working gas Air	Air
Power supply	Docking station = 24 V
	Hand pieces: embedded inductive charger = 5 V
Hand pieces:	
Max output	≤ 2 W
Max working voltage	≤ 1.3 kVPP
Output frequency	(70–80) kHz
Hand piece types:	
White*	V peak to peak = 500 V, Power = 0.7 W, Frequency = 75 kHz
Green	V peak to peak = 600 V, Power = 1 W, Frequency = 75 kHz
Red	V peak to peak = 700 V, Power = 2 W, Frequency = 75 kHz
Maximum absorbed power	120 W
(Docking station)	
Applicator electrode	Stainless steel sterile disposable needle
Risk classification of the device	IIb**(Medium-high risk)
*In current study, the white hand piece was used. **This classification relates to the Non-invasive medical devices within the field of dermatology.	