ORIGINAL RESEARCH

Expanded Polytetrafluoroethylene Spacer for Nonpenetrating Deep Sclerectomy Combined with Cataract Surgery

Maryam Hajizadeh[1], Aidin Meshksar[2], Kiana Hassanpour[3], Saeed Rahmani[4], Sadid Hooshmandi[5], Azadeh Doozandeh[6], Farideh Sharifipour[7], Shahin Yazdani[8], Mohammad Pakravan[9], Azadeh Samaeili[10]

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Abstract

Purpose: To compare the outcomes of nonpenetrating deep sclerectomy (NPDS) with and without an expanded polytetrafluoroethylene (e-PTFE) implant combined with phacoemulsification (PE).

Design: Interventional case series with concurrent control group.

Materials and methods: Patients with medically uncontrolled glaucoma underwent PE nonpenetrating deep sclerectomy (NPDS) and were consecutively divided into a study group receiving an e-PTFE implant and a control group undergoing PE-NPDS. Intraocular pressure (IOP), corrected distance visual acuity (CDVA), and the number of glaucoma medications at 1 day, 1 week, 1 month, 3 months, and 6 months were recorded.

Results: A total of 22 eyes of 16 patients underwent PE-NPDS, including 11 eyes receiving an e-PTFE implant and another 11 eyes with no implant. NPDS with spacer achieved successful results in all patients, including eight (72.7%) complete and three (27.3%) qualified success, 6 months, postoperatively. The corresponding values in the control group were 10 (90.9%) and 1 (9.1%), respectively. In the spacer group, mean IOP was decreased from 19.3 ± 2.8 at baseline to 12.1 ± 2.0 mm Hg at month 6 ($p < 0.001$). Corresponding values for the control group were 18.6 ± 3.4 and 10.6 ± 1.5 mm Hg, respectively ($p < 0.001$). Mean IOPs were comparable between the study groups at all time points. Implant exposure occurred in one of the patients in the study group. While the implant was extruded, the IOP was medically controlled.

Conclusion: Outcomes of PE-NPDS using an e-PTFE implant were comparable to the same surgery without a spacer in the short term. Larger studies with longer follow-ups are needed to determine the efficacy and safety of this new implant.

Keywords: Expanded polytetrafluoroethylene, Glaucoma, Intraocular pressure, Nonpenetrating deep sclerectomy.

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Introduction

Trabeculectomy remains one of the procedures of choice in glaucoma management; nevertheless, it is associated with several potentially serious complications. Nonpenetrating glaucoma surgery was introduced to reduce complications and enhance the success rate.[1,2] Nonpenetrating deep sclerectomy (NPDS), described in 1982, shares many steps with trabeculectomy. However, the major difference is the lack of complete penetration into the anterior chamber (AC) in NPDS. During the procedure, Schlemm's canal is unroofed by dissecting a deep scleral flap while its inner wall remains intact.[3]

Nonpenetrating deep sclerectomy (NPDS) lowers intraocular pressure (IOP) through various mechanisms, including subconjunctival bleb formation, intrascleral lake formation, supraciliary pathways, and episcleral venous outflow. Multiple implants have been employed as space maintainers that are placed inside the scleral lake to optimize the IOP-lowering effect of NPDS.[4] The Ologen collagen matrix used as a spacer during NPDS has been associated with better IOP control, lower rates of bleb failure, and reduced need for postoperative needling.[1,5,6] In another study, NPDS combined with a collagen implant was as effective as trabeculectomy but with lower complications.[7]

Polytetrafluoroethylene (PTFE) is an inert, hydrophobic, biocompatible material that delays inflammatory reactions, prevents adhesion of plasma components to the surface of the implant, and has been widely used in neurosurgery and cardiovascular. PTFE has also been used for the repair of orbital floor fractures and strabismus surgery and has been durable in the vitreous cavity of rabbits' eyes for 6 months.[8] The PTFE mesh has been applied in vitreoretinal surgery in animal and human eyes and was safely tolerated for up to 1 year with no complications such as extrusion, migration, inflammation, or granuloma formation.[9] Expanded PTFE is a porous plate constructed from

[1,10]Ophthalmic Research Center, Shahid Beheshti University of Medical Sciences, Tehran, Tehran Province; Department of Ophthalmology, School of Medicine, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran

[2]Ophthalmic Research Center, Shahid Beheshti University of Medical Sciences, Tehran; Poostchi Ophthalmology Research Center; School of Medicine, Shiraz University of Medical Sciences, Shiraz, Iran

[3–9]Poostchi Ophthalmology Research Center; School of Medicine, Shiraz University of Medical Sciences, Shiraz, Iran

Corresponding Author: Azadeh Samaeili, Ophthalmic Research Center, Shahid Beheshti University of Medical Sciences, Tehran, Tehran Province; Department of Ophthalmology, School of Medicine, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran Phone: +98 9173159125, e-mail: as100973@gmail.com

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PTFE after expansion treatment, which results in the development of large amounts of 2 μ pores. The high porosity of expanded polytetrafluoroethylene (e-PTFE) enhances the biocompatibility of these polymers for biomedical use.[10]

Leszczynski et al. reported promising results examining the histopathologic results of NPDS with e-PTFE implants in two experimental studies; they concluded that an e-PTFE implant is well tolerated and has an inhibitory effect on fibroblast activity and, therefore, may prevent fistula closure in glaucoma surgery.[11,12]

Herein, we investigated the safety and efficacy of NPDS with an e-PTFE implant in human eyes with glaucoma. We hypothesized that e-PTFE could enhance the IOP-lowering effect of NPDS without inflammatory reactions.

Materials and Methods

In this prospective, interventional comparative case series, 22 eyes of 16 patients underwent NPDS with or without an e-PTFE implant combined with phacoemulsification (PE) from March 2017 to January 2019. The study protocol was approved by the local ethics committee and adhered to the principles of the Declaration of Helsinki. All patients were informed about the surgery, complications, and other alternative treatments, and written informed consent was taken.

The inclusion criteria included patients with uncontrolled primary open-angle or exfoliation glaucoma, despite maximally glaucoma medication or well-documented progression (functional or structural) scheduled for phaco-NPDS. Exclusion criteria were age younger than 18, preexisting ocular surgery or trauma, argon or selective laser trabeculoplasty, angle-closure or secondary causes of glaucoma, posterior segment pathologies, and patient refusal.

A total of 11 eyes in the e-PTFE implant group underwent PE-NPDS with the spacer placed under the scleral flap, while 11 eyes underwent PE-NPDS without any spacer, which served as the control group. Spacer implantation was determined on every other patient basis.

A complete ocular examination including slit-lamp biomicroscopy, determination of corrected distance visual acuity (CDVA), IOP measurement using a Goldmann applanation tonometer, gonioscopy using a Zeiss four-mirror lens, measurement of central corneal thickness (CCT), and dilated fundus examination, visual field examination with automated perimetry (Humphrey 24-2 full-threshold test) was performed in all individuals before surgery.

Follow-up visits were planned for 1 and 7 days and 1, 3, and 6 months after the operation. Postoperative examinations included CDVA, slit-lamp examination, tonometry, and fundoscopy.

Implant Preparation

The implant was a plate of e-PTFE (GORE® PRECLUDE® pericardial WL Gore and Associates Inc., Flagstaff, Arizona, United States of America). The implants were provided as irregular plates with a thickness of 0.6 mm, packed and sterilized before surgery. Before insertion into the eye, they were manually fashioned by the surgeons at the operating table to an approximate size of 3 × 3 mm, proportional to the size of the scleral flaps.

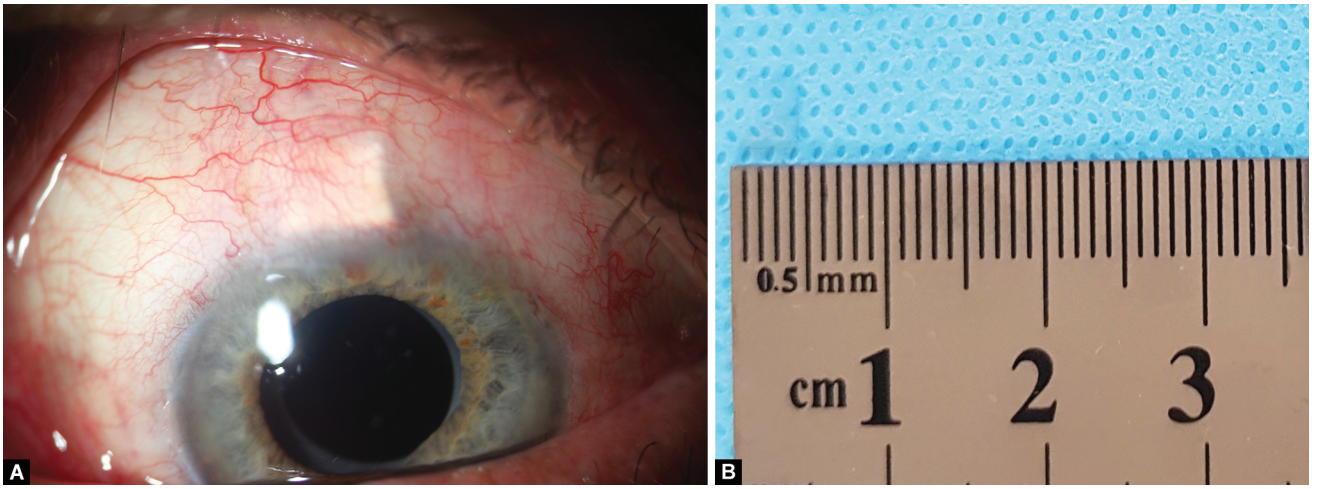
Surgical Technique

One experienced glaucoma surgeon (MH) performed all procedures. After uneventful temporal incision PE with posterior chamber intraocular lens implantation, NPDS was performed. Superior fornix-based conjunctival and tenon dissection was done, hemostasis with light bipolar cautery was performed, and mitomycin C 0.2 mg/mL in soaked sponges was applied under the conjunctival flap for 2 minutes. After removal of the sponges and copious irrigation with normal saline, a 5 × 5 mm one-third thickness square-shaped scleral flap was fashioned and extended anteriorly 2 mm into the clear cornea. A deeper second scleral flap measuring 4 × 4 mm was dissected, and Schlemm's canal was unroofed, creating a thin trabeculo-Descemet membrane (TDM), after which the deeper flap was amputated.

In the e-PTFE group, the implant was placed under the superficial scleral flap with two 10-0 nylon sutures at each posterior corner of the superficial scleral flap (Fig. 1). After burying the sutures; the conjunctiva was repaired with separate nylon 10-0 sutures.

Postoperatively, patients received topical antibiotics (chloramphenicol 0.5%; one drop four times per day) for 5 days and a topical steroid (β-methasone 0.1%; one drop six times per day then tapered based on examination findings) for 3 months.

All patients underwent ocular examinations on days 1, 7, and 14 and months 1, 2, 3, and 6, and every 3 months thereafter.



Figs 1A and B: (A) Nonpenetrating deep sclerectomy (NPDS) with e-PTFE implant as a spacer in the left eye of a patient 1 month after the operation; (B) The e-PTFE implant beside a ruler

Statistical Analysis

The main outcome measure was success rate based on IOP, while secondary outcome measures included CDVA, number of postoperative glaucoma medications, and adverse events. Complete success was considered as an IOP of 21 mm Hg or less without the need for glaucoma medications together with at least 20% IOP reduction from baseline; qualified success was defined as the same as above with the use of glaucoma medication. Failure was defined as a mean IOP greater than 21 mm Hg despite the use of medications, <20% IOP reduction from baseline, further glaucoma surgery, loss of light perception, or phthisis bulbi.

To present data, we used mean values, standard deviations, median, range, frequency, and percentage. To assess changes within the study groups, we used the paired *t*-test. The normality of the data was tested using the Kolmogorov–Smirnov test. To evaluate differences between the groups, we used *t*-test, Chi-squared, and Fisher exact test. Also, whenever necessary, we used generalized estimating equations to compensate for the possible correlation of the results in fellow eyes of the same subject. All statistical analyses were performed using SPSS software (version 25.0 Released 2013. IBM SPSS Statistics for Windows, IBM Corp. Armonk, New York, United States of America. Any *p*-values <0.05 were considered statistically significant.

Results

A total of 22 eyes of 16 patients were enrolled in the present study. A total of 11 eyes with a mean [± standard deviation (SD)] age of 69 ± 4 (range, 62–77) years underwent PE-NPDS with spacer implantation (e-PTFE group). A total of 11 eyes of nine participants underwent PE-NPDS without spacer implantation, and they served as the control group. Nine patients (81.8%) in the e-PTFE group and eight patients (72.7%) in the control group were male. The study groups were comparable in terms of age, sex, laterality, glaucoma diagnosis, logarithm of minimum angle resolution (log MAR) CDVA, CCT, and cup to disk (CD) ratio (Table 1). All patients completed the 6-month follow-up period.

At 6 months, all eyes in both study groups were considered to be a surgical success. In the e-PTFE group, 72.7% of eyes, and in the control group, 90.9% fulfilled complete success criteria. The study groups were comparable in terms of complete and qualified success rates at 6-months ($p = 0.65$) (Table 2).

The mean preoperative IOP was 19.3 ± 2.8 mm Hg in the e-PTFE group and 18.6 ± 3.36 mm Hg in the control group ($p = 0.39$). The e-PTFE group, mean IOP was significantly decreased to 10.4 ± 3.1, 10.8 ± 2.9, 12 ± 2.9, 11.3 ± 1.7, and 12.1 ± 2.0

Table 2: The outcome of cases at 6th month follow-up

	Group		
Status	*DS + spacer*	*Control*	*p-value**
Failure	0 (0%)	0 (0%)	
Success	11 (100%)	11 (100%)	0.654
Qualified success	3 (27.3%)	1 (9.1%)	
Complete success	8 (72.7%)	10 (90.9%)	

*Based on the Chi-squared test

Table 1: Baseline characteristics of study groups

		Group		
		PE-NPDS + e-PTFE, N (%)	*Control, N (%)*	*p-value*
Eye	OD	7 (63.6%)	5 (45.5%)	0.392*
	OS	4 (36.4%)	6 (54.5%)	
Sex	Male	9 (81.8%)	8 (72.7%)	0.611*
	Female	2 (18.2%)	3 (27.3%)	
Diagnosis	XFG	5 (45.5%)	6 (54.5%)	0.67*
	POAG	6 (54.5%)	5 (45.5%)	
Age	Mean ± SD	69 ± 4	73 ± 7	0.158¥
	Median (range)	70 (62, 77)	70 (65, 85)	
Log MAR	Mean ± SD	0.52 ± 0.5	0.58 ± 0.4	0.687¥
	Median (range)	0.22 (0.05, 1.39)	0.52 (0.05, 1)	
CCT	Mean ± SD	534 ± 38	526 ± 26	0.553¥
	Median (range)	529 (468, 583)	531 (480, 565)	
CD Ratio	Mean ± SD	0.86 ± 0.08	0.85 ± 0.08	0.796¥
	Median (range)	0.9 (0.7, 1)	0.9 (0.7, 1)	

*Based on Fisher-exact test; ¥based on independent *t*-test; NPDS, nonpenetrating deep sclerectomy; e-PTFE, expanded polytetrafluoroethylene; log MAR, logarithm of minimum angle resolution; CCT, central corneal thickness; CD ratio, cup to disk ratio; XFG, exfoliation glaucoma; POAG, primary open-angle glaucoma; SD, standard deviation

on the 1st day, and at week 1, and months 1, 3 and 6, respectively (all *p*-values of <0.001, Table 3 and Figs 2 and 3). Corresponding values were 9.3 ± 2.5, 8.7 ± 1.2, 10.6 ± 1.5, 10.6 ± 1.2, and 10.6 ± 1.5 in the control group at the same time intervals, respectively (all *p*-values of <0.001). The two groups were comparable in terms of IOP at all time points (Table 3).

Mean IOP reduction from baseline was 8 ± 3.1 (58.4%) and 7.2 ± 2.9 (62.7%) in the e-PTFE group at months 3 and 6. Corresponding values for the control group were 7.9 ± 3.5 (57.3%) and 7.9 ± 3.6 (57.6%) mm Hg at the same time intervals. The two study groups were comparable in terms of IOP reduction at all time points (Table 3).

Table 3: IOPs and IOP changes within and between study groups

	Group		
IOP at different intervals	*With spacer*	*Control*	*p-value**
Baseline	19.3 ± 2.8	18.6 ± 3.4	0.587
1 day	10.4 ± 3.1	9.3 ± 2.5	0.378
Change 1 day	−8.9 ± 2.9	−9.3 ± 3.6	0.797
p within from baseline	<0.001	<0.001	
7 days	10.8 ± 2.9	8.7 ± 1.2	0.037
Change 7 days	−8.5 ± 2.8	−9.8 ± 3.5	0.322
p within from baseline	<0.001	<0.001	
1 month	12 ± 2.9	10.6 ± 1.5	0.159
Change 1 month	−7.3 ± 2.8	−8 ± 2.8	0.549
p within from baseline	<0.001	<0.001	
3 months	11.3 ± 1.7	10.6 ± 1.2	0.319
Change 3 months	−8 ± 3.1	−7.9 ± 3.5	0.949
p within from baseline	<0.001	<0.001	
6 months	12.1 ± 2.0	10.6 ± 1.5	0.07
Change 6 months	−7.2 ± 2.9	−7.9 ± 3.6	0.61
p within from baseline	<0.001	<0.001	

**p*-values are based on independent *t*-test; ***p*-values are based on paired *t*-test

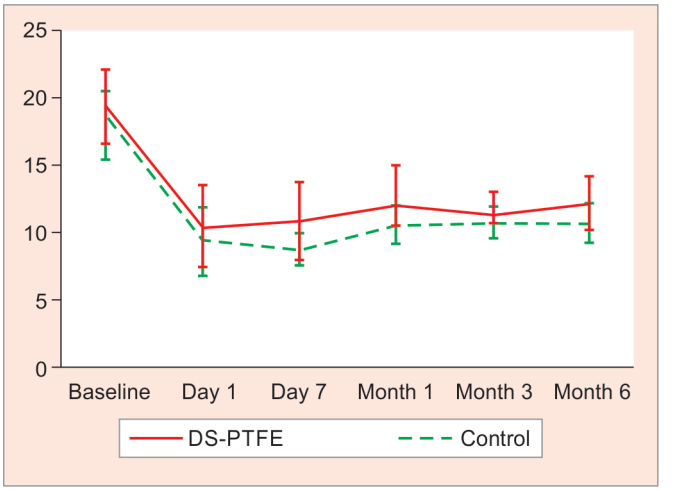
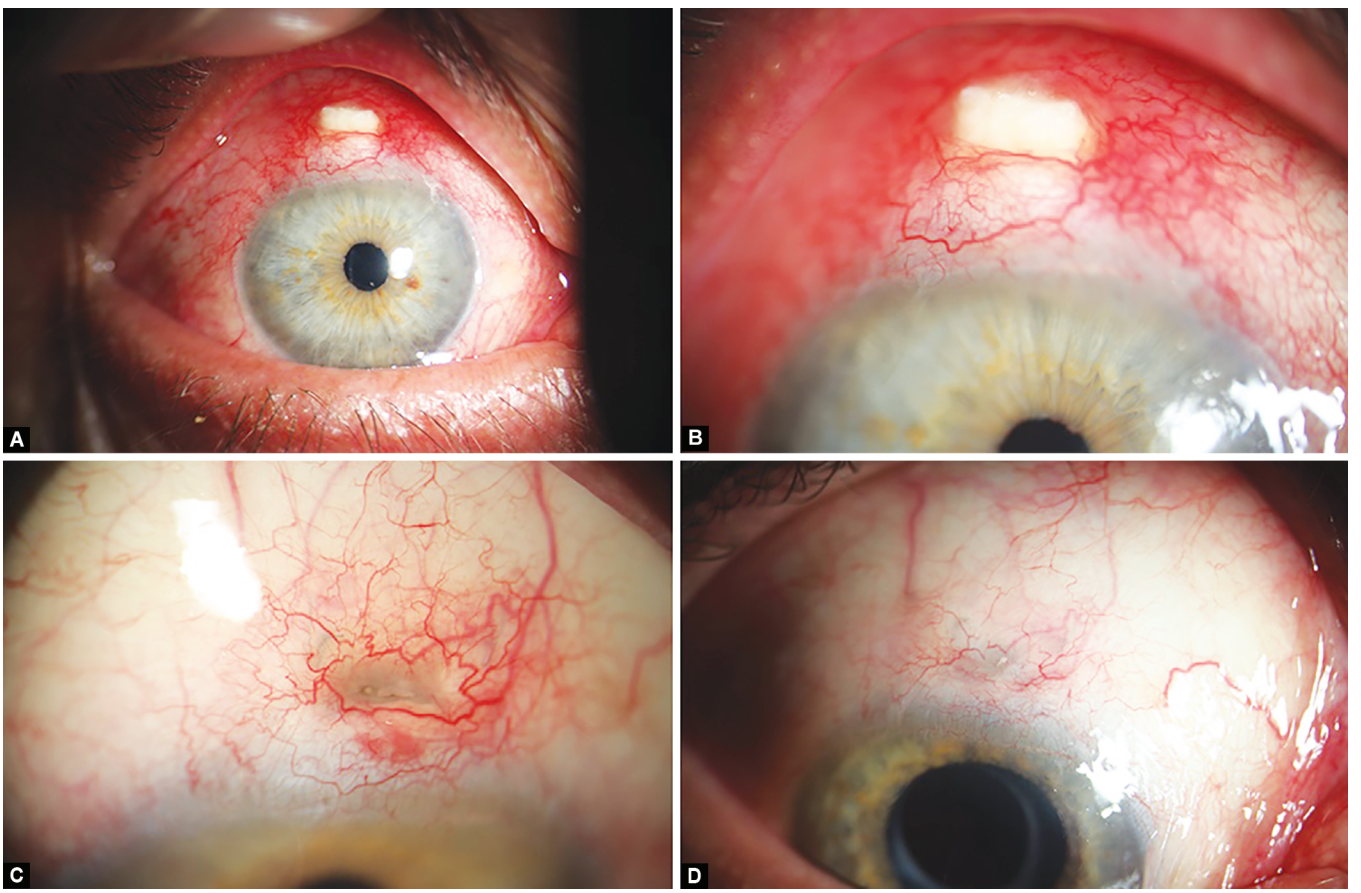


Fig. 2: Intraocular pressure (IOP) changes at different time intervals in study groups



Figs 3A to D: The e-PTFE implant exposure (A) 4 months postoperatively in the right eye of a patient and (B) with higher magnification; (C, D) The same eye after 1 and 2 months of implant extrusion, respectively

The average number of glaucoma medications was 3 ± 1 in both study groups at baseline, which was significantly decreased to 1 ± 1 and 0.1 ± 0.3 in the e-PTFE and control groups at 6 months. The change in the number of medications was not different between the two groups ($p = 0.14$).

No intraoperative complication occurred in the study groups. In the postoperative course, none of the eyes required needling or goniopuncture procedures. One patient in the spacer group developed the implant exposure 4 months postoperatively, leading to extrusion. However, IOP was well controlled with one antiglaucoma drop, and the patient did not meet the failure criteria at 6 months.

Mean log MAR CDVA was 0.52 ± 0.5 in the e-PTFE group and 0.58 ± 0.4 in the control group, preoperatively ($p = 0.68$). At the final follow-up, there was no significant change in CDVA. None of the patients lost more than three Snellen lines of visual acuity in either study group.

Discussion

The current study demonstrated that an e-PTFE implant used as a spacer in PE-NPDS was associated with >50% IOP reduction in eyes with primary open-angle glaucoma (POAG) and exfoliation glaucoma (XFG) with short-term follow-up. The efficacy of surgery with adjunctive use of the implant was comparable to that of surgery without a spacer.

Nonpenetrating glaucoma surgery was introduced to overcome the complications of trabeculectomy, which may predispose surgeons to postpone surgical intervention until the advanced stages of glaucoma. These procedures are considered a favorable alternative to trabeculectomy due to the higher safety profile and can be performed with less risk in early disease.[13]

In NPDS, a thin TDM is created, which allows controlled percolation of aqueous humor from the AC into the created intrascleral lake; therefore, the risk of early postoperative hypotony, a frequent complication of trabeculectomy, is low.[14] To enhance the efficacy of NPDS and to maintain the intrascleral space longer, different types of implants have been employed, resulting in higher success rates than conventional surgery.[7,15,16] Kozlov and Fedorov first used a collagen implant made from porcine scleral tissue as a spacer. Even though the implant was resorbed after 6–9 months, it increased the success rate of NPDS and decreased the number of postoperative antiglaucoma medications. The spacer presumably diminished bleb and scleral flap fibrosis and also helped maintain aqueous humor filtration.[17]

Polytetrafluoroethylene (PTFE) is a biocompatible polymer with hydrophobic and lipophobic properties, making it completely inert to physiologic reactions. These unique properties have led to the use of PTFE (and e-PTFE with extraporous characteristics) in many different fields, such as cardiovascular and gynecological surgery, to decrease the chance of postoperative adhesions.[18–20] In ophthalmology, PTFE has been widely used for orbital reconstruction surgery. In glaucoma, the polymer has been safely incorporated into a membrane-tube implant[19] and had results comparable to that of the Ahmed glaucoma valve.[21] In an experimental study, pieces of PTFE were used as a conduit in glaucoma filtering surgery, resulting in a well-constructed surrounding filtering bleb with no tissue adhesion and minimal inflammatory reaction.[18]

To the best of our knowledge, this is the first human study evaluating the efficacy and safety of an e-PTFE implant used as a spacer during NPDS in human eyes. However, e-PTEF has been safely and successfully used in NPDS in rabbit eyes,[11,12] which showed a thin-walled bleb with minimal inflammatory reaction and no foreign-body reaction around PTFE. These findings support the use of this material for NPDS.[18]

In additional investigations, the efficacy of the e-PTFE implant in glaucoma surgical procedures has been subject to assessment. Bae et al.[18] conducted a study involving 40 eyes from 30 rabbits that underwent glaucoma filtering surgery incorporating an e-PTFE implant, yielding satisfactory outcomes. Furthermore, alternative human and animal models have provided evidence of the utilization of this implant in trabeculectomy surgery, signifying advancements in surgical effectiveness.[22]

The effectiveness of the e-PTFE implant in glaucoma drainage surgeries has also been established in both animal and human trials. In our previous study, we explored using PTFE for glaucoma drainage. It involved two stages: tests on rabbits and six patients. The tube, with a two-layer PTFE membrane (8 × 6 mm, 1.8 mm thick) and silicone, was implanted in the eyes. The evaluation showed fibrovascular infiltration, and patients' IOP reduced (36.6 ± 5.7 to 16.2 ± 8.9 mm Hg).[23] Similar studies display a reduction in inflammatory reactions and the formation of fibrous tissue adjacent to the implant site. Consequently, the functionality of these implants in mitigating intraocular pressure (IOP) is heightened.[19,21,24–26]

Utilizing a spacer to maintain the intrascleral space is believed to enhance the success of NPDS. Shaarawy et al. reported promising results with the implantation of a collagen spacer during NPDS.[13] Different materials have been used for this purpose; however, PTFE has special properties, making it particularly appropriate for NPDS in which minimal postoperative scar formation is desirable. Therefore, it might be an ideal substance to prevent adhesion of the scleral flap and create a permanent conduit for the percolation of aqueous humor into the subconjunctival space. Furthermore, the presence of a spacer may theoretically improve the results of goniopuncture and needling procedures by preventing obliteration of the intrascleral space in the flap area.

In the current study, none of the patients in the spacer group encountered major intraoperative or postoperative complications; only one eye developed extrusion of the spacer 4 months after the operation, and consequently, IOP-lowering medications were needed for IOP control.

The IOP decrease was similar in both study groups. After 6 months, three of the patients in the spacer group required an IOP-lowering medication vs one patient in the control group. In a study by Sharaawy et al., patients who underwent NPDS with a collagen implant had greater long-term success rates than patients without implants, and they also required fewer antiglaucoma medications.[15] Deep sclerectomy utilizing a porous collagen implant (Ologen) as a spacer led to better IOP control and could be helpful in managing inadvertent TDM rupture during surgery without the need for converting to trabeculectomy.[1] Moreover, the use of Ologen as a spacer resulted in lower bleb failure rates, more IOP reduction, and less need for postoperative needling.[6]

Despite limitations, including a small sample size and limited follow-up, our report may be considered a pilot study for future research on e-PTFE implants for NPDS. In summary, the e-PTFE implant used as a spacer in PE-NPDS resulted in IOP control comparable to PE-NPDS without a spacer in the short term with few complications. This warrants future studies with a larger number of patients and longer follow-up times to better elucidate the efficacy and safety of this material for NPDS.

Orcid

Sadid Hooshmandi https://orcid.org/0000-0001-5079-7239

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