# **Original Article**

# Punctal Occlusion with Prolene Suture Material in the Patients with Dry Eye

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# **Abstract**

**Aim:** To analyze the efficacy and outcomes of punctal occlusion with 5-0 Prolene suture material for the treatment of dry eye. **Materials and Methods:** A total of 20 patients with moderate and severe dry eyes, recalcitrant to maximal medical therapy, underwent temporary punctal occlusion with 5-0 Prolene suture material. The lower punctum was dilated with a punctum dilator. Prolene suture pieces with sizes ranging from 1.5 to 2 mm were made. A total of 8–10 such pieces were inserted into the lower punctum. The patients were followed up on the 1<sup>st</sup>, 3<sup>rd</sup> and 6<sup>th</sup> months, and their values of Schirmer's test, Teat film break up time and ocular surface staining were compared with the baseline values, which were taken as control. **Results:** Punctal occlusion has been shown to improve the objective and subjective measures of dry eye. The patients obtained significant relief from the symptoms of dry eye by the end of 2 months. Recurrence of symptoms was noted at 6 months. Statistically significant difference was noted in the Schirmer's and TBUT values between the baseline and at the end of the 3<sup>rd</sup> and 6<sup>th</sup> months. However, this difference was less than that at the end of the 1<sup>st</sup> month. The corneal surface staining was improved at the end of the 1<sup>st</sup> month, but it again began to deteriorate by the end of the 6<sup>th</sup> month. **Conclusion:** Prolene is a biologically inert, efficacious and cheaper alternative to collagen punctal plug. Occlusion of the puctum with a temporary punctal plug such as a Prolene suture material helps an ophthalmologist to plan for permanent punctal occlusion. Improvement in the eye condition after the use of temporary punctal occlusion suggests that the patient may benefit from permanent punctal occlusion.

**Keywords:** Dry eyes, prolene suture, punctal occlusion, punctal plug

# INTRODUCTION

Dry eye disease was earlier defined as the reduction of the aqueous phase of the tear film. In 1995, the definition was modified to include medical and ocular diseases that reduce tear production and/or increase tear evaporation. [1] It causes damage to the interpalpebral ocular surface giving rise to the symptoms of ocular discomfort.

The management of dry eyes continues to challenge clinicians. Usually, the treatment is aimed at providing a symptomatic relief. Literatures have recognized various risk factors for the development of dry eye. These include the following: female gender, hormonal changes, systemic autoimmune disease (most prominently Sjogren's syndrome), decreased corneal sensation, refractive surgery, blinking abnormalities, drug effects, viral infections such as human immunodeficiency virus, diabetes mellitus, vitamin A deficiency and graft-versus-host disease. In addition to the

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risk factors listed above, environmental, workplace stress (arid atmosphere, constant wind currents) or recreational stress (prolonged use of video display screens), presence of contact lens also add to the development of dry eye disease. [2]

Treatments include the use of artificial tear eye drops, in which effectiveness is limited by patient compliance. In the patients who do not find symptomatic relief despite medical therapy, temporary or permanent punctal occlusion and ocular surface reconstruction are often considered. The punctum can be plugged irreversibly by cautery or laser treatment, or reversibly by a device called a punctum plug. Punctal plugs were first reported as a reversible, effective and physiologic treatment for a variety of dry eye disorders

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**How to cite this article:** Patkar P, Shrivastava S, Ramakrishnan R, Gajera S. Punctal occlusion with Prolene suture material in the patients with dry eye. Niger J Ophthalmol 2017;25:28-35.

Quick Response Code:



Website:

www.nigerianjournalofophthalmology.com

DOI

10.4103/njo.njo\_36\_16

by Freeman<sup>[3]</sup> in 1975. Punctal occlusion helps to preserve any remaining natural tear fluid, which has by far the best wetting and nutrient capacity for the ocular surface. Preserving the patient's own natural tears by blocking the lacrimal drainage system, thereby increasing tear volume and decreasing tear osmolarity, can successfully maintain the integrity of the ocular surface, corneal transparency and visual acuity. In the patients with moderate or severe dry eye, it is capable of improving the quality of life and preventing vision loss. Our study was conducted to analyze the efficacy and outcomes of punctal occlusion with 5-0 Prolene suture material for the treatment of dry eye.

# MATERIALS AND METHODS

A prospective study was conducted. Twenty patients were included in this study. The inclusion criteria comprised the patients having subjective symptoms of dry eye, Schirmer's test value (without the instillation of topical anaesthetics) of <10 and corneal surface damage as evident by fluorescein staining. These patients were asked to fill the dry eye symptom questionnaire, which was developed by Schein et al. [4] It comprised six questions based on six symptoms (dryness, gritty or sandy sensation, burning sensation, redness, crusting or discharge on the lashes and having eyelids stuck shut in the morning). The patients were asked to grade the symptoms under the categories of mild moderate and severe (Supplementary Annexure 1). In addition, the frequency of instillation of artificial teardrops was recorded. We performed Schirmer's I test, tear film breakup time (TBUT) and corneal surface staining on all the patients at the end of the 1st, 3rd and 6th months, and the obtained values were compared with the baseline values, which were taken as control.

Exclusion criteria were the following:

- (1) any prior ocular surgery other than cataract surgery,
- (2) concurrent use of any other topical ocular medications,
- (3) previous use of either punctal plugs or topical cyclosporine,
- (4) an obstructed lacrimal system found during probing and irrigation,
- (5) punctal ectropion,
- (6) the patients who failed to attend follow-up appointment after the procedure and
- (7) the patients with no or mild symptoms according to Schein questionnaire.

Written informed consent was signed by all the patients before the procedure. Approval from the ethical committee was also obtained.

The patients underwent a routine ophthalmological examination, which included visual acuity, slit lamp examination, Schirmer's I test, TBUT and corneal surface staining with fluorescein dye. Tear film stability was

estimated based on TBUT. A fluorescein-impregnated strip (Bell Pharma Pvt. Ltd., Mumbai, India) wetted with non-preservative saline solution was placed in the lower conjunctival sac. The examination was performed under a slit lamp with the use of a cobalt blue filter. The time between the last blink and the first appearance of a black spot on the stained tear film was noted. TBUT values of <7 s suggest an unstable tear film [Figure 1].

The ocular surface was examined by fluorescein staining of the cornea. A fluorescein-impregnated strip wetted with non-preservative saline solution was placed in the lower conjunctival sac. Corneal fluorescein staining was recorded in the upper, middle and lower areas of the cornea, each graded on a scale of 0–3 points, with 0 being no stain and 3 the most intense stain. The total score was from 0 to 9 points.<sup>[5]</sup>

Tear production was measured by the Schirmer's I test. A Schirmer's test strip was placed over the lower lid margin into the tear lake at the junction of the middle and lateral one-third of the eyelid for 5 min. The strip was then removed, and the amount of wetting in millimetres was recorded as the Schirmer's I test score [Figure 2].

The lacrimal sac patency was checked by sac syringing.

# Surgical method

A topical anaesthetic (4% lignocaine) was instilled into the conjunctival sac. The eyelid was then cleaned

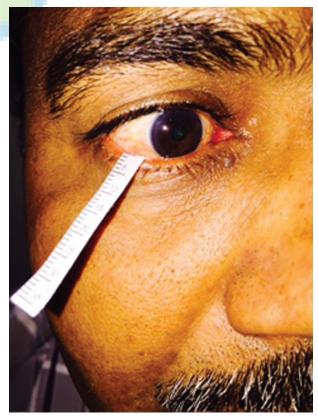


Figure 1: TBUT of the right eye with value of 3 s

with 5% povidone iodine solution and draped. The punctum was sufficiently dilated with a Nettleship punctal dialator. A 5-0 Prolene suture material was cut into 1.5-2 mm sized pieces. A total of 8-10 such small pieces were gently inserted one by one into the lower punctum with the help of plain forceps until the canaliculus was considered to be filled. This end point was determined when no further Prolene suture could easily be inserted into the punctum. An antibiotic eye drop was instilled at the end of the procedure. Postoperatively, lubricating eye drop and antibiotic eye drop were given. After the hands were properly washed, the dropper cap was removed without touching the tip. The patient was asked to tilt the head back, and look up and concentrate at a point on the ceiling with eyes wide open. One or two fingers were placed on the patients' face about an inch below his eye and the lid was gently pulled down. The eye drop bottle was held close to the eye (about an inch away). Care was taken not to let the dropper touch the eye or eyelashes, since this can introduce bacteria and other organisms into the eye drops in the bottle. One drop was instilled inside the lower lid. The patient was then asked to gently close his eyes and tilt his head down for a few seconds or to press lightly on the inner corner of the eyelid, next to the nose for 3 min.

The patients were followed up on day 1, 1<sup>st</sup> week, 1<sup>st</sup> month, 3<sup>rd</sup> month and 6<sup>th</sup> month following the procedure. In the subsequent visits, the patients were asked to fill up the Schein questionnaire.

# RESULTS

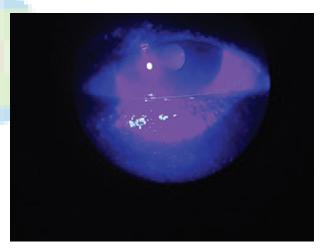
A total of 20 patients of all age groups were enrolled in this study. The baseline values of these 20 patients who were recalcitrant to maximal medical therapy were considered as the control.

The mean age  $\pm$  standard deviation (SD) was  $64.2 \pm 2.4$  years.

Prior to occlusion, seven patients (35.0%) had moderate symptoms, and 13 patients (65.0%) had severe symptoms.

At the end of the  $1^{\rm st}$  month, four patients (20.0%) had no symptoms, eight patients (40.0 %) had mild symptoms, seven patients (35.0%) had moderate symptoms, and one patient (5.0%) had severe symptom. At the  $3^{\rm rd}$  month, two patients (10.0%) had no symptoms, 12 patients (60.0%) had mild symptoms, five patients (25.0%) had moderate symptoms, and one patient (5.0%) had severe symptom. At the end of the  $6^{\rm th}$  month, one patient (5.0%) had mild symptoms, 13 patients (65.0%) had moderate symptoms and six patients (30.0%) had severe symptoms [Table 1; Figure 3].

In multiple comparisons [Table 2; Figure 4], Schirmer's test and TBUT showed statistically significant difference (0.000) between baseline and at the end of the 1<sup>st</sup> month. In addition, it showed a statistically significant difference (0.000) between baseline and at the end of the 3<sup>rd</sup> month, but this difference was, however, less than that at the end of the 1<sup>st</sup> month. There was no statistically significant difference between the 3<sup>rd</sup> month and the 6<sup>th</sup> month. It indicates that the efficacy of Prolene slowly reduced after 3 months. In Schirmer's test, the mean value prior to punctal occlusion was 5.1 mm [Table 3; Figure 5]. At the end of the 1<sup>st</sup> month, the mean value

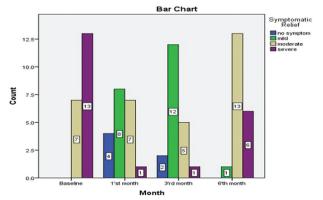


**Figure 2:** Schirmer's test reading of the right eye with 4 mm wetting of the Schirmer's strip

Table 1: Month × symptomatic relief cross-tabulation								
		Symptomatic relief						
		No symptom	Mild	Moderate	Severe			
Baseline	Count	0	0	7	13	20		
	%	0.0%	0.0%	35.0%	65.0%	100.0%		
1 <sup>st</sup> month	Count	4	8	7	1	20		
	%	20.0%	40.0%	35.0%	5.0%	100.0%		
3 <sup>rd</sup> month	Count	2	12	5	1	20		
	%	10.0%	60.0%	25.0%	5.0%	100.0%		
6 <sup>th</sup> month	Count	0	1	13	6	20		
	%	0.0%	5.0%	65.0%	30.0%	100.0%		

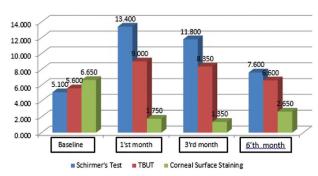
Chi-square = 49.071. df = 9. P < 0.001, significant.

was 13.4 mm and at the end of the 6<sup>th</sup> month, it was 7.6 mm. In TBUT test, the mean value prior to punctal occlusion was 5.6 s [Table 3; Figure 6]. At the end of the 1<sup>st</sup> month, the mean value was 9.0 s and at the end of the 6<sup>th</sup> month, it was 6.6 s.

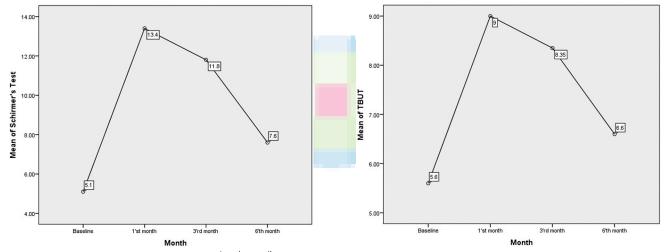


**Figure 3:** Bar diagram showing symptomatic relief in the patients of dry eye after 1<sup>st</sup>, 2<sup>nd</sup> and 3<sup>rd</sup> months as compared to that of the baseline

At the end of 1<sup>st</sup> month and 3<sup>rd</sup> month, corneal surface staining also showed statistically significant difference (0.000) between the values of baseline and that at the end of the 1<sup>st</sup> month. In addition, there was statistically significant difference between the values of the 3<sup>rd</sup> month and the 6<sup>th</sup> month. In corneal surface staining, the mean value prior to



**Figure 4:** Bar diagram of comparison of Schirmer's value, TBUT and corneal staining at the end of 1<sup>st</sup>, 2<sup>nd</sup> and 3<sup>rd</sup> months with the baseline values



**Figure 5:** Mean value of the Schirmer's test at 1<sup>st</sup>, 3<sup>rd</sup> and 6<sup>th</sup> months as compared to that of the baseline

**Figure 6:** Mean value of TBUT at 1<sup>st</sup>, 3<sup>rd</sup> and 6<sup>th</sup> months as compared to that of the baseline

Table 2: Multiple comparisons between the values of Schirmer's test, TBUT and corneal staining							
Dependent variable			Difference	Standard error	Significance		
Schirmer's test	Baseline	1 <sup>st</sup> month	-8.30000 <sup>*</sup>	1.10656	0.000		
		3 <sup>rd</sup> month	-6.70000*	1.10656	0.000		
		6 <sup>th</sup> month	$-2.50000^*$	1.10656	0.027		
	3 <sup>rd</sup> month	6 <sup>th</sup> month	4.20000*	1.10656	0.000		
TBUT	Baseline	1st month	-3.40000 <sup>*</sup>	0.62424	0.000		
		3 <sup>rd</sup> month	$-2.75000^*$	0.62424	0.000		
		6 <sup>th</sup> month	-1.00000	0.62424	0.113		
	3 <sup>rd</sup> month	6 <sup>th</sup> month	1.75000*	0.62424	0.006		
Corneal surface staining	Baseline	1st month	$4.90000^*$	0.42828	0.000		
		3 <sup>rd</sup> month	5.30000*	0.42828	0.000		
		6 <sup>th</sup> month	$4.00000^*$	0.42828	0.000		
	3 <sup>rd</sup> month	6 <sup>th</sup> month	$-1.30000^*$	0.42828	0.003		

<sup>\*</sup>The mean difference is significant at the 0.05 level.

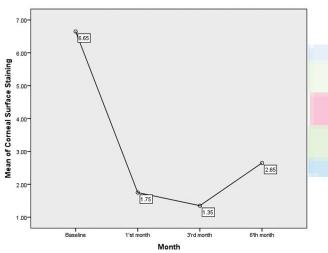
punctal occlusion was 6.650 [Table 3; Figure 7]. At the end of the 1<sup>st</sup> month, the mean value was 1.750, and at the end of the 6<sup>th</sup> month, it was 2.650.

# DISCUSSION

In 2007, the International Dry Eye Workshop updated the original definition and classified dry eye as, 'a multifactorial disease of the tears and ocular surface that results in symptoms of discomfort, visual disturbance and tear film instability with potential damage of the ocular surface. It is accompanied by an increased osmolarity of the tear film and inflammation of the ocular surface'. [6]

Two mutually reinforcing global mechanisms [Figure 8] leading to dry eye formation are tear hyperosmolarity and tear film instability.<sup>[6]</sup>

Tear hyperosmolarity arising from either low aqueous flow or excessive tear film evaporation activates an inflammatory cascade, with the release of inflammatory



**Figure 7:** Mean value of the corneal staining at 1<sup>st</sup>, 3<sup>rd</sup> and 6<sup>th</sup> months as compared to that of the baseline

mediators into the tears that damage the ocular surface. Inflammation can also result in goblet cell loss and decreased mucin production, which further contributes to tear film instability. [6]

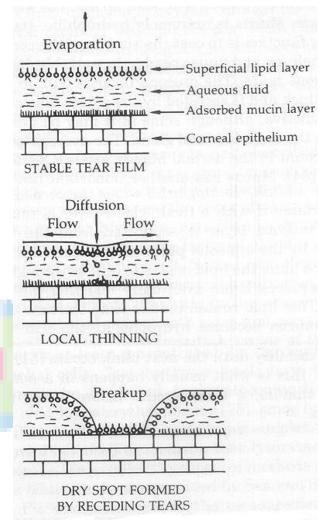


Figure 8: Diagrammatic representation of the pathogenesis of dry eye

		N	Mean	SD	SEM	f-Stat	df	<i>P</i> -value
Schirmer's test	Baseline	20	5.100	1.774	0.397	23.666	3.76	<0.001**
	1st month	20	13.400	4.838	1.082			
	3 <sup>rd</sup> month	20	11.800	4.175	0.934			
	6 <sup>th</sup> month	20	7.600	2.234	0.499			
TBUT	Baseline	20	5.600	2.280	0.510	12.561	3.76	< 0.001**
	1st month	20	9.000	2.026	0.453			
	3 <sup>rd</sup> month	20	8.350	1.755	0.393			
	6 <sup>th</sup> month	20	6.600	1.789	0.400			
Corneal surface staining	Baseline	20	6.650	1.663	0.372	64.297	3.76	< 0.001**
	1st month	20	1.750	1.618	0.362			
	3 <sup>rd</sup> month	20	1.350	1.040	0.233			
	6 <sup>th</sup> month	20	2.650	0.933	0.209			

<sup>\*\*</sup>Significant at 1% level of significance.

Tear film instability can arise secondary to hyperosmolarity, or can be the initiating event (e.g. lipid layer abnormalities in meibomian gland dysfunction disease). Tear film instability results in increased evaporation, which contributes to tear hyperosmolarity.<sup>[6]</sup>

Currently, the choice of therapy for dry eye disease may be determined by the severity of the condition. In mild cases, artificial tears may be applied. In moderate cases, more frequent treatment will be required. In cases of severe dry eye, in addition to frequent instillation of preservative free artificial tears, other treatment strategies such as tear-conserving therapies are often required.

Tear conservation methods include the occlusion of punctum and prevention of the evaporation of moisture from the eye. [7] Room humidifiers are a simple, non-invasive way of reducing the evaporation of tears. Wearing tight fitting goggles, moisture chamber spectacles or tear feeding spectacles are also effective, but are sometimes inconvenient for the patient. [7,8] Hydrophilic bandage contact lenses are often used in the cases of corneal ulceration or following corneal surgery. [8-10] In cases of exposure keratopathy, tarsorrhaphy can substantially reduce the exposed area of the cornea, thus, reducing the evaporation of tears.

Cyclosporine A is another agent used nowadays in the treatment of dry eyes. With its anti-inflammatory effect, it is considered as the first agent that focused on the pathogenesis of the disease. In addition, it can be used for a long term without the presentation of the adverse effects.

Furthermore, autologous serum has been used in the form of eye drops for the treatment of severe ocular surface disorders. Apart from their role in providing lubrication to the eye, they also have a tear-like biochemical character and supply nutritional components.

Occlusion of the lacrimal puncta or canaliculi prevents the drainage of natural and artificial tears and is currently the most common non-pharmacological therapy for dry eye disease. [8,11] It helps by improving the quantity and the quality of the aqueous component of the tear film. There are two main types of punctal occlusion: punctal plugs and punctal cautery. Punctal plugs are the more common type of punctal occlusion. Punctal plugs are plugs used to close up any of the person's four puncta so that the tears do not escape as quickly. In the other method, the patients' tear ducts are permanently cauterized. This is more invasive than punctal plugs.

Two general types of tear duct plugs are:

- (1) Semi-permanent, typically made of long-lasting materials such as silicone, hydroxyethylmethacrylate and Teflon.
- (2) Dissolvable (temporary), made of materials such as collagen or hydroxypropyl cellulose that dissolve slowly at body temperature.

The dissolvable plugs are inserted into the vertical or the horizontal canaliculus. The hydroxypropyl cellulose inserts

last up to 18 h and the collagen inserts up to 2 weeks, although collagen degradation time is quite unpredictable. [12,13] 5-0 Prolene plain catgut suture material has also been used for temporary punctal occlusion for about 1–2 weeks. By testing with the dissolvable plugs first, ophthalmologists are able to make sure that the plugs will help solve the person's dry eye problems before they try more invasive methods. If the temporary punctal plugs treatment works for dry eye, then semi-permanent punctal plugs might be considered. When the semi-permanent plugs are inserted, the head of the plug is left protruding from the punctum.<sup>[3]</sup> Rarely, these plugs fall out, particularly if the punctum has been over-dilated on insertion, but the head of the plug can irritate the conjunctiva and cornea, resulting in reflex epiphora.<sup>[14]</sup> A recent study has found that a bacterial biofilm can form in the holes of punctal plugs, and advises their immediate removal if the accumulation of material is observed in the heads of punctal plugs.<sup>[15]</sup> Intracanalicular plugs, made up of silicone, are also available. They are inserted past the punctum into the horizontal portion of the canaliculus, until it becomes lodged just in front of the common canaliculus. The plug does not stick out of the punctum, and it does not scratch the cornea.<sup>[11]</sup>

The collagen and the silicone punctal plugs are, however, very costly, so an alternative method of punctal occlusion can be tried. It involves the insertion of Prolene suture material through the punctum into the canaliculus. Prolene is composed of an isotactic crystalline steroisomer of polypropene, a synthetic linear polyolefin. This suture is pigment blue to enhance visibility. Prolene is neither absorbable nor elastic [Figure 9].

The size (such as the diameter of the cross-section and the thickness) of the Prolene material as measured with an optical microscope (Nikon Eclipse Me600) and a digital calliper (Mitutoyo) was  $201 \pm 2 \,\mu m$  diameter [Figure 10]. Prolene® was shown to be a monofilament with a smooth surface as reported by Karaca and Hockenberger, [16] although a few scratch marks and some impurities were observed.

In our study, on the occlusion of punctum using Prolene suture material, we observed that the efficacy was found to decrease nearly after 2 months. The commonly observed reason for this was due to the extrusion of the pieces of Prolene suture. When it is performed in the presence of inflammation due to dry eye, aggravation of symptoms occurs, because it allowed inflamed tear to have a prolonged contact with the surface of eye. Some patients experienced infections such as canaliculitis and dacryocystitis. Some patients did not improve. The reason can be attributed to the accumulation of preservatives from the eye drops on the ocular surface leading to toxic epitheliopathy. In addition, an over-dilatation of the punctum during the insertion of the plug can lead to trauma to the punctal annulus, thereby, leading to a poor retention of the suture pieces. An ocular irritation was also observed in some cases due to rubbing of the protruded

fragments to the conjunctival surface. Punctal occlusion can decrease tear production, clearance and ocular surface sensation.<sup>[17]</sup> It is believed that many of the problems that can be caused by occlusion of tear film drainage are derived from delayed tear clearance and turnover.<sup>[18]</sup> A delayed tear clearance can result in an increased concentration of pro-inflammatory cytokines in the tear film, causing



**Figure 9:** Prolene, 5-0 blue monofilament polypropylene, non-absorbable suture material

desensitization of the corneal surface and promoting inflammation. [17-19] As a consequence of all the above-mentioned factors, some patients may experience little, only temporary or no relief at all from therapeutic occlusion of the tear drainage system. In addition, epiphora can occur after occlusion, causing a great deal of discomfort to the patient. To minimize this risk, most authorities advise assessing the result of temporary occlusion with absorbable or removable plugs or inserts before proceeding with permanent occlusion. [11] Rarely reported complications include the rupture of the punctal annulus, pruritus and discomfort, supurative canaliculitis and canalicular stenosis. [11]

Lacrimal punctal occlusion has been reported to be a simple, safe and effective procedure to treat aqueous tear deficiency and ocular surface epitheliopathies associated with Steven–Johnson syndrome, penetrating keratoplasty, superior limbic keratoconjunctivitis, neurotrophic keratopathy, recurrent corneal

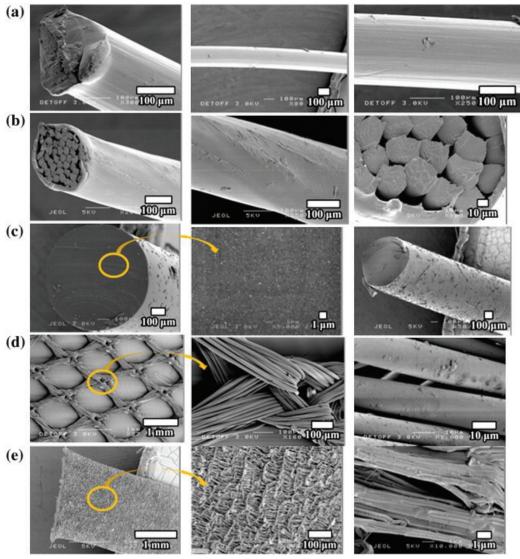


Figure 10: Cross-section of the Prolene material as measured with an optical microscope (Nikon Eclipse Me600). Compared to the other sutures. (a) Prolene; (b) Suprmid Extra II; (c) Visitec Seiff frontalis suspension set; (d) Mersilene mesh; (e) Ptose-Up

erosions and toxic epitheliopathy. Hill *et al.*<sup>[20]</sup> reported that the average time before complications developed with the silicone plug was 3 years. In addition, migration is very common with the punctal plugs. Mukherji *et al.*<sup>[21]</sup> reported a case of a plug that reverse migrated through the lid tissue by pressure necrosis due to its large size, causing a sterile ulcer.

In addition, the dissolution rate of collagen within the canaliculus is around 1–2 weeks. Contrarily, Prolene is non-absorbable and can stay in the body for a very long duration of time if placed properly. Furthermore, accumulation of tears and other debris in or on collagen punctal plug may contain bacteria and may form a bacterial biofilm, which will warrant removal of the punctal plug. Permanent punctal plugs such as silicone punctal plugs have sometimes been associated with the formation of pyogenic granulomas, [22,23] which is a rare occurrence with the Prolene suture material. [22,23]

### CONCLUSION

We, therefore, believe that the use of Prolene suture material in properly selected patients as an alternative method of punctual occlusion is financially beneficial in a developing economy such as ours.

The use of Prolene plugs both resulted in a significant improvement in aqueous tear volume for a short duration after the procedure. Prolene is biologically inert and efficacious. It is also a cheaper alternative to collagen punctal plug. Occlusion of the punctum with a temporary punctal plug, for example, a Prolene suture material helps an ophthalmologist to plan for a permanent punctal occlusion. Improvement after the use of temporary punctal occlusion suggests that the patient may benefit from permanent punctal occlusion.

#### **Declaration of patient consent**

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

# Financial support and sponsorship

Nil.

#### **Conflicts of interest**

There are no conflicts of interest.

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