

Original Research Paper

**A clinical study of tear functions in patients with pinguecula and its management**

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**ABSTRACT**

**Introduction:** Pinguecula is a common conjunctival degenerative disorder. Its origin came from the Latin word "pinguis," which means fat or lipid. It is a round, elevated, yellowish fleshy mass located in the interpalpebral fissure at the limbus (usually at 3 o'clock or 9 o'clock position).

**Material and methods:** This interventional and prospective study included 100 patients with pinguecula [random eyes; 39 males and 31 females, 17 to 70 years of age (mean  $\pm$  SD: 46.52  $\pm$  16.31 years) for medical management and 14 males and 16 females, 26 to 69 years of age (mean  $\pm$  SD: 50.9 $\pm$ 12.20 years) for surgical management]. Thereafter they were categorised as grade P (0), P (1) and P (2) by slit lamp bio-microscopy.

**Results:** On the basis of statistical analysis applying unpaired -t test, for each test parameter in P (0) grade of pinguecula patients, the p- values for Schirmer-1 test and Tear film breakup time were 0.93, 0.46, 0.03 and 0.22, 0.002 and <0.0001, For P (1) grade of pinguecula 0.81, 0.08, 0.0002 and 0.31, <0.0001 and <0.0001, Before medical management vs After medical management at 1m, 3m and 6m respectively. These p – values showed that there were no significant changes in ST-1 at 1m and 3m follow-up after medical management. For TFBUT p - values showed there were no significant changes at 1m of follow-up but extremely significant at 3m and 6 m of follow-up. For P (1) grade there were no significant changes in ST-1 and TFBUT at

1m follow-up after medical management, while extremely significant changes at 3m and 6 m of follow-up were found in ST-1 as well as TFBUT both. For surgical management in P (2) grade of pinguecula patients, the p- values for Schirmer-1 test and TFBUT were  $< 0.0001$  for pre-op vs post-op at 1m, 3m and 6m respectively. These p – values showed that there were extremely significant changes in ST-1 as well as TFBUT at 1m, 3m and 6 m follow-up.

**Conclusion:** The alteration in schirmer-1 test and TFBUT after medical management with e/d Carboxy methyl cellulose 0.5% and/or eye drop Fluorometholone 0.1% showed improvement in tear film production and tear film stability after 6 months of follow-up. Vascularised pinguecula excision resulted in both vascular regression and cosmetic improvement without serious or permanent complications. Tear film parameters after 6 months of follow-up improved more in surgical management group (ST-1 by 8.87mm and TFBUT by 5.57 secs) as compared to medical management group (ST-1 by 4.14mm and TFBUT by 2.62 secs).

**Key words:** Grading of Pinguecula, Schirmer 1 test, TFBUT, ST-1

## Introduction:

Pinguecula is a common conjunctival degenerative disorder. Its origin came from the Latin word "pinguis," which means fat or lipid. It is a round, elevated, yellowish fleshy mass located in the interpalpebral fissure at the limbus (usually at 3 o' clock or 9 o'clock position). Usually bilateral in presentation, more often situated at the nasal rather than the temporal limbus. The prevalence of pinguecula in published reports varies widely from 22.5% [1] to 70% [2-4] across different geographical locations [1-4]. The few population-based studies on the prevalence of pinguecula that have been conducted to date show estimate rates  $>50\%$  in the adult population [1, 2, 5]. pinguecula is the common ocular surface disorder, usually contains deposits of protein, fat or calcium [6]. The nodular elastotic degeneration of pinguecula consists of material that stains for elastin but it is not destroyed by elastase. Sometimes it is associated with calcification or fat globules. Histologically pinguecula and pterygium are analogous to each other, except for the lack of corneal involvement and vascularisation [7]. A study was carried out on localized advanced glycation end (AGE) products in the subepithelial amorphous which was deposited in the pinguecula, may denote the severity of exposure to sunlight or the decreased levels of anti-oxidants [8]. The etiology behind nasal predominance could be the actinic damage which occurs in this region because of reflection from the side of the nose [9]. Few studies that graded the pinguecula have reported that the severity of dry eye is correlated with the grade of pinguecula. Reid and Dushku [10] and Dushku and Reid [11] have proposed a new grading system for pinguecula.

**Grading system for pinguecula**

Grade	Pinguecula
P (0)	No pinguecula
P (1)	Mild or moderate pinguecula, yellowish white, and flat or nodular lesion with a maximum diameter <5 mm
P (2)	Sever pinguecula, highly vascularized and nodular lesion or large pinguecula with a diameter ≥5mm

**MATERIAL AND METHODS:**

An interventional and prospective study titled “A clinical study of tear functions in patients with pinguecula and its management” was carried out in the Department of Ophthalmology, Shyam Shah Medical College and associated Gandhi Memorial Hospital, Rewa (M.P.). This study was performed in the interval between December 2019 to December 2020.

**Study design:** - Interventional prospective study

**Data collection and methods:** After enrollment, a written informed consent was obtained from all study participants. The purpose of study was explained to the subjects and confidentiality was also assured. A thorough history was taken which included demographic profile and ophthalmic complaints with special reference to duration of pinguecula and associated symptoms of tear film dysfunction.

**Evaluation:** - A comprehensive ophthalmic examination was conducted in all the study subjects which included:

- 1) Best corrected visual acuity (BCVA)
- 2) Anterior segment examination: -  
Slit lamp bio-microscopy  
Intraocular pressure (IOP)
- 3) Special tests:

The following tests and procedures were successively performed on each patient to investigate the tear film production and tear film stability in patients with pinguecula.

- Schirmer-I test
- Tear film break-up time (TFBUT)

**Schirmer- I test** – This test was performed on random eyes of the patients without using any topical anesthetic agents and standardized test strip maintained between lateral one-third and medial two-third of the lower conjunctival fornix for 5 minutes. The patient was seated in a dim light room and advised to remain open his/her eyes with minimal blinking and measurement of wetted length of the strip was taken in millimeters.

**Tear Film Break-Up Time (TFBUT)-** One hour after the Schirmer I test, TFBUT was assessed. A fluorescein strip was moistened with eye drop moxifloxacin. To distribute the fluorescein evenly, the patient was asked to blink several times and then asked to look ahead without blinking or holding the eyelids. TFBUT was measured by taking time interval of the last blink and the first dry spot on the cornea, by using the

diffuse and cobalt blue illumination of the slit lamp. The average of result of three measurements was taken.

All patients were treated according to their grade of pinguecula by

1) **Medical management:** - We use 0.5% eye drop carboxy methyl cellulose in patients with pinguecula size less than 5mm .In vascularized pinguecula (Pingueculitis) /size more than 5mm we use e/d fluometholone 0.1% in tapering manner for 1 month along with e/d carboxy methyl cellulose 0.5%.

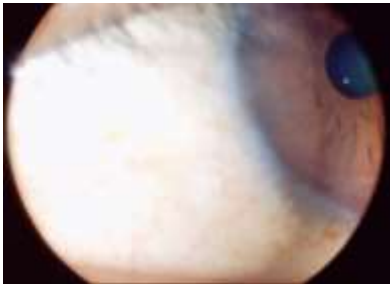
2) **Surgical management:** - Patients with P (2) grade of pinguecula

- a. Those who had not improved with medical management
- b. Which causes severe dry eye symptoms
- c. With cosmetic problems

Managed with surgical excision and conjunctival auto grafting.

The study participants were examined at 1 month, 3 month and 6 months after management, for the assessment of tear function.

**P (0)**



**Figure 1: No pinguecula**

**P (1)**



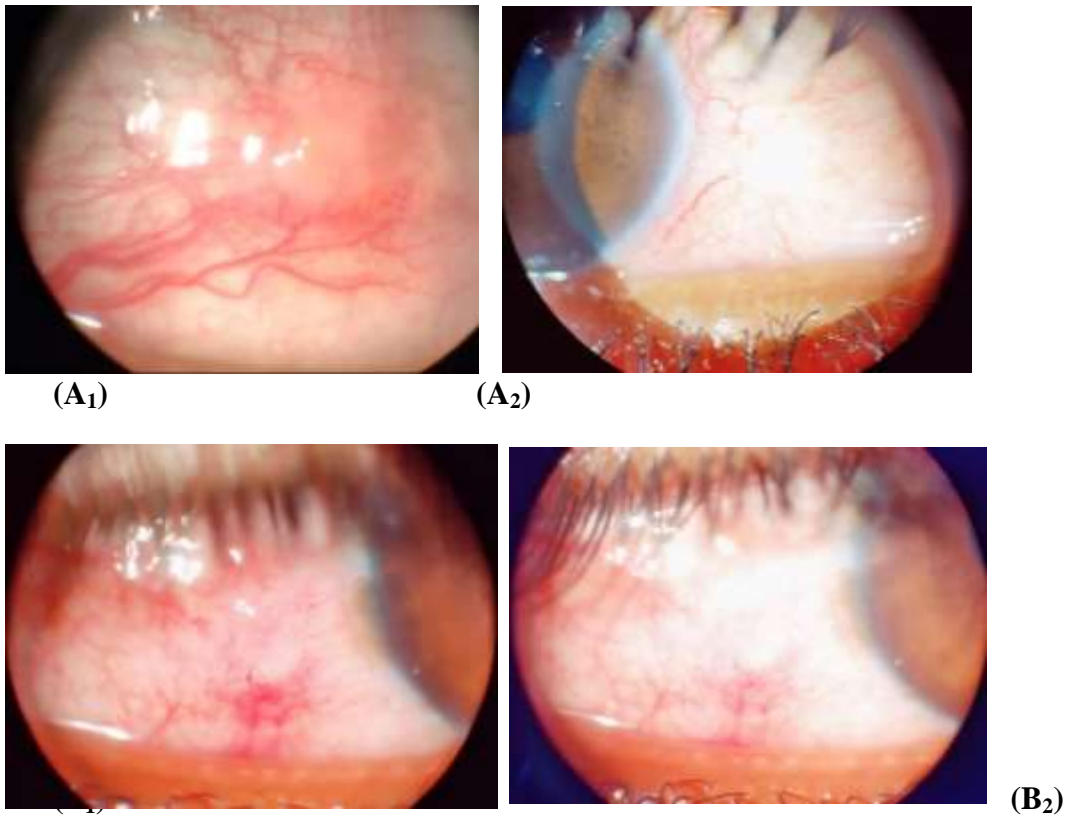
**Figure 2: Yellowish white, flat and slightly elevated lesion with a diameter of <5 mm**

**P (2)**



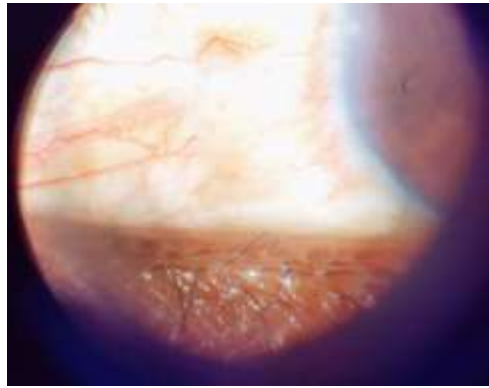
**Figure 3: Highly vascularized and elevated lesion with a diameter of >5 mm**

**SURGICAL MANAGEMENT**

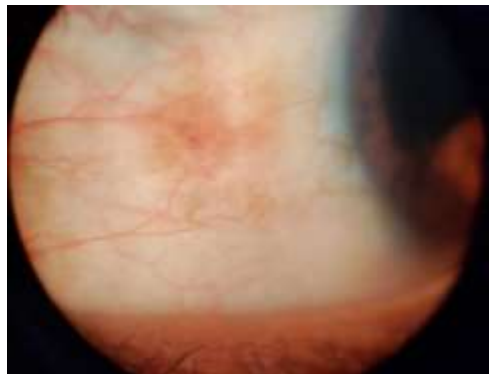
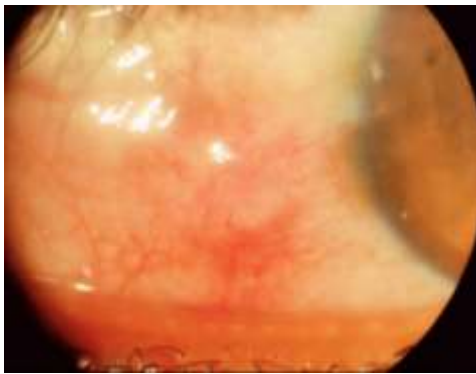


**Figure 4:** Pre and postoperative slit-lamp biomicroscopic photographs of two patients. A 52year old female with protruded temporal pinguecula: P (2) (A<sub>1</sub>) underwent surgery and showed flattening and vascular regression; 6 months after the surgery (A<sub>2</sub>). A 60-year-old male with nasal pinguecula: P (2) (B<sub>1</sub>) showed improvement of conjunctival protrusion and vascularization; 1 months after the surgery (B<sub>2</sub>).

MEDICAL MANAGEMENT



(A)



(B)



(C)

**Figure 5:** Before and after medical management slit-lamp biomicroscopic photographs of three patients. A 30-year-old male with protruded nasal pinguecula: P (1) (A) A 60-year-old male with nasal pinguecula: P (1) (B) A 46-year-old female with nasal pinguecula (C): Pinguiculitis P (2).

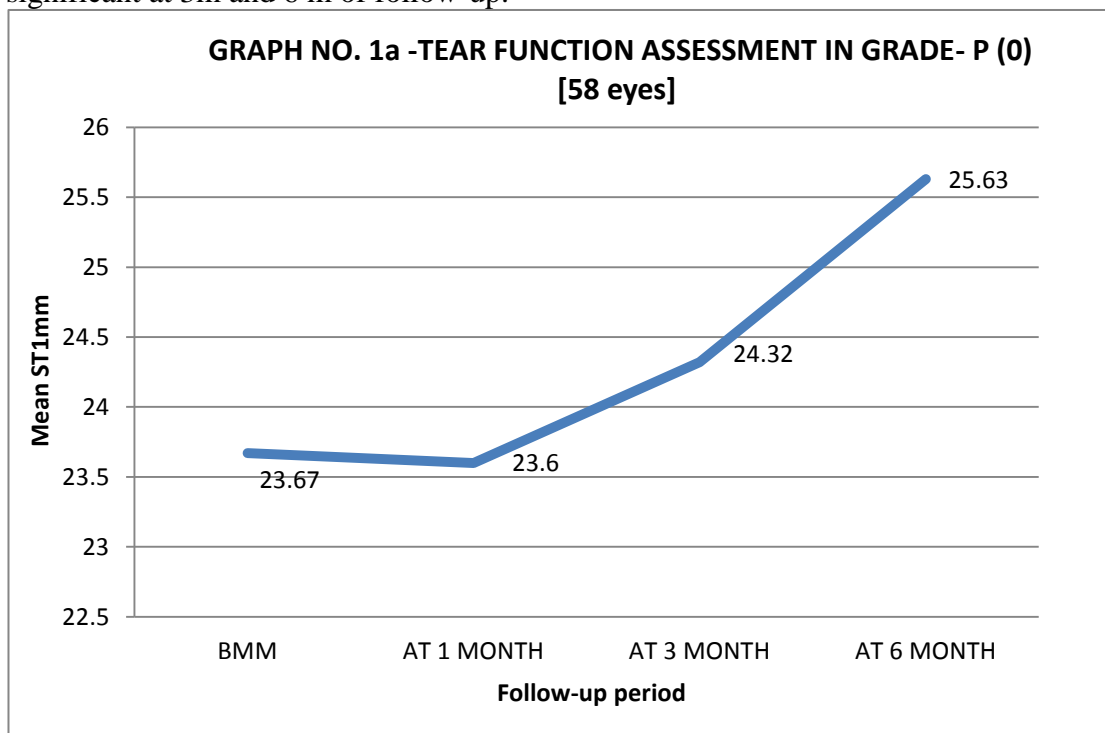
**OBSERVATIONS AND RESULTS:**

Hundred patients with pinguecula [random eyes; 39 males and 31 females, 17 to 70 years of age (mean ± SD: 46.52 ± 16.31 years) for medical management and 14 males and 16 females, 26 to 69 years of age (mean ± SD: 50.9±12.20 years) for surgical management] were enrolled in this study. Thereafter they were categorised as grade P (0), P (1) and P (2) by slit lamp bio-microscopy.

TABLE NO. 1: TEAR FUNCTION ASSESSMENT IN GRADE-P (0) [58 eyes]

TFT	BMM	AMM			p -VALUE		
		AT 1 MONTH	AT 3 MONTH	AT 6 MONTH	BMM vs 1 Month	BMM vs 3Month	BMM vs 6Month
ST-1 (mm)	23.67 ± 4.86	23.60 ± 4.65	24.32 ± 4.79	25.63 ± 4.86	0.93	0.46	0.03
TFBUT (s)	11.29 ± 1.41	11.60 ± 1.33	12.05 ± 1.16	13.06 ± 1.04	0.22	0.002	<0.0001

In P (0) grade of pinguecula patients, the p- values for mean Schirmer-1 test and TFBUT were 0.93,0.46, 0.03 and 0.22, 0.002 and <0.0001 for BMM vs AMM at 1m, 3m and 6m respectively. These p – values showed that there were no significant changes in ST-1 at 1m and 3m follow-up after medical management. For TFBUT p - values showed there were no significant changes at 1m of follow-up but extremely significant at 3m and 6 m of follow-up.



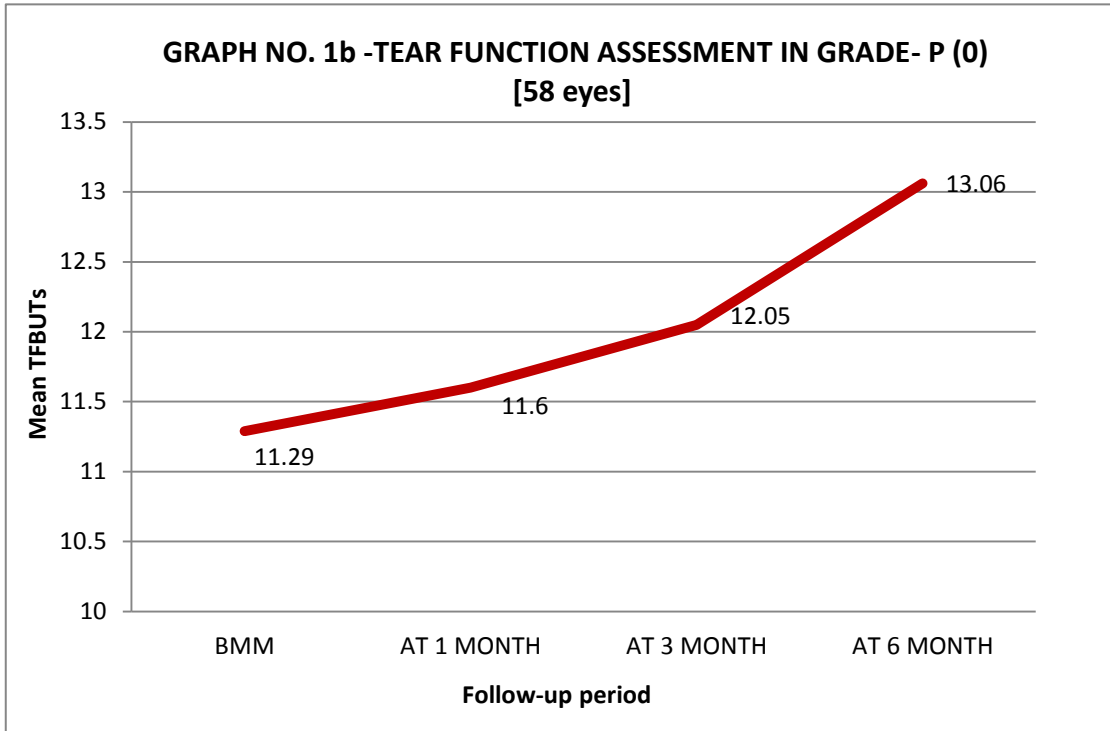
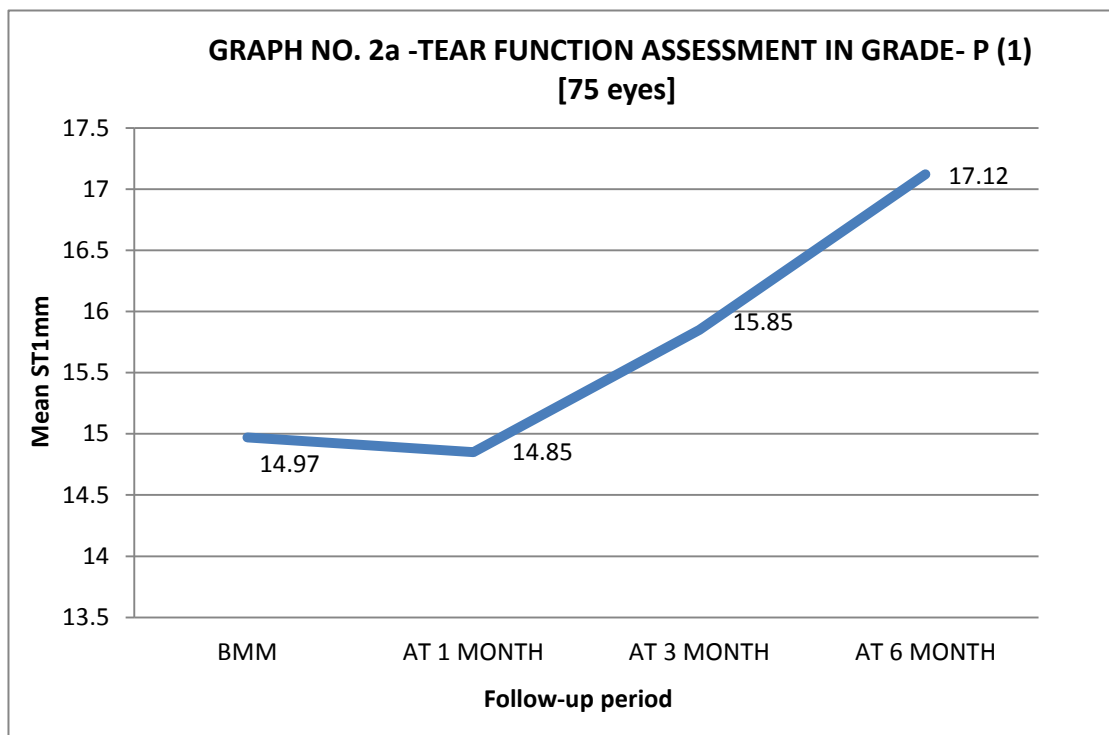


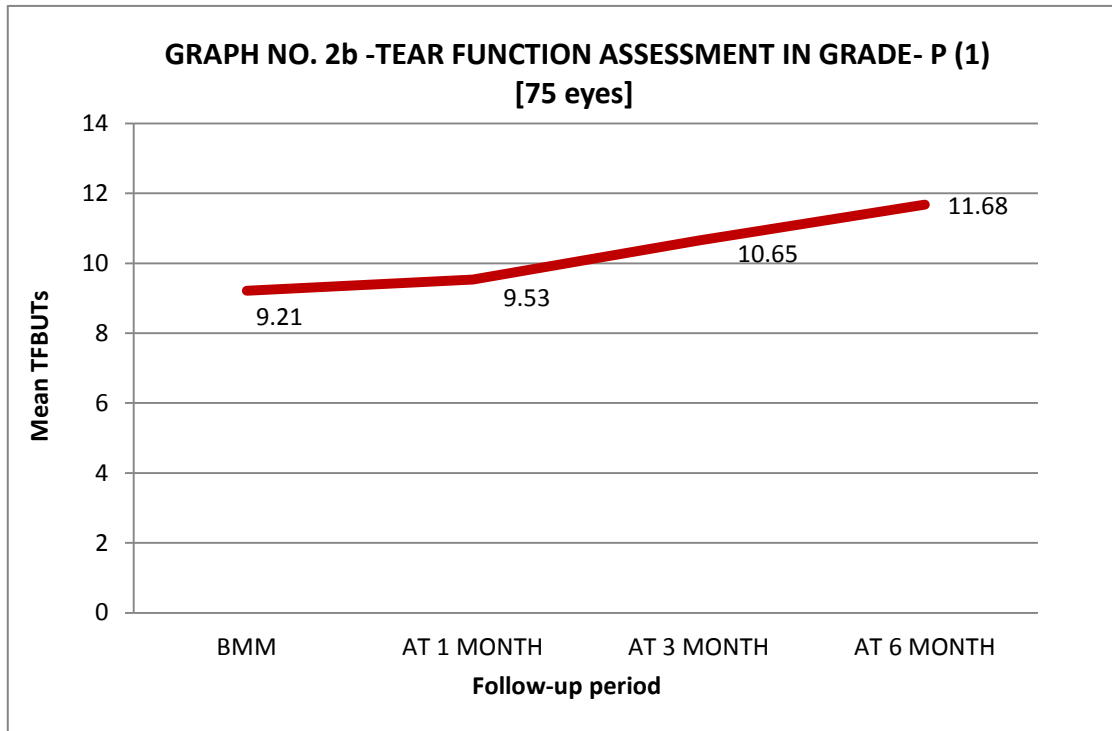


TABLE NO. 2: TEAR FUNCTION ASSESSMENT IN GRADE- P (1) [75 EYES]

TFT	BMM	AMM			p- VALUE		
		AT 1 MONTH	AT 3 MONTH	AT 6 MONTH	BMM vs 1 Month	BMM vs 3Month	BMM vs 6Month
ST-1 (mm)	14.97 ±3.16	14.85 ±3.12	15.85 ±3.12	17.12±3.09	0.81	0.08	0.0002
TFBUT (s)	9.21 ±1.92	9.53 ±1.93	10.65 ±1.72	11.68±1.64	0.31	<0.0001	<0.0001

In P (1) grade of pinguecula patients, the p- values for mean Schirmer-1 test and TFBUT were 0.81, 0.08, 0.0002 and 0.31, <0.0001 and <0.0001 for BMM vs AMM at 1m, 3m and 6m respectively. These p- values showed that there were no significant changes in ST-1 and TFBUT at 1m follow-up after medical management, while extremely significant changes at 3m and 6 m of follow-up were found in ST-1 as well as TFBUT both.

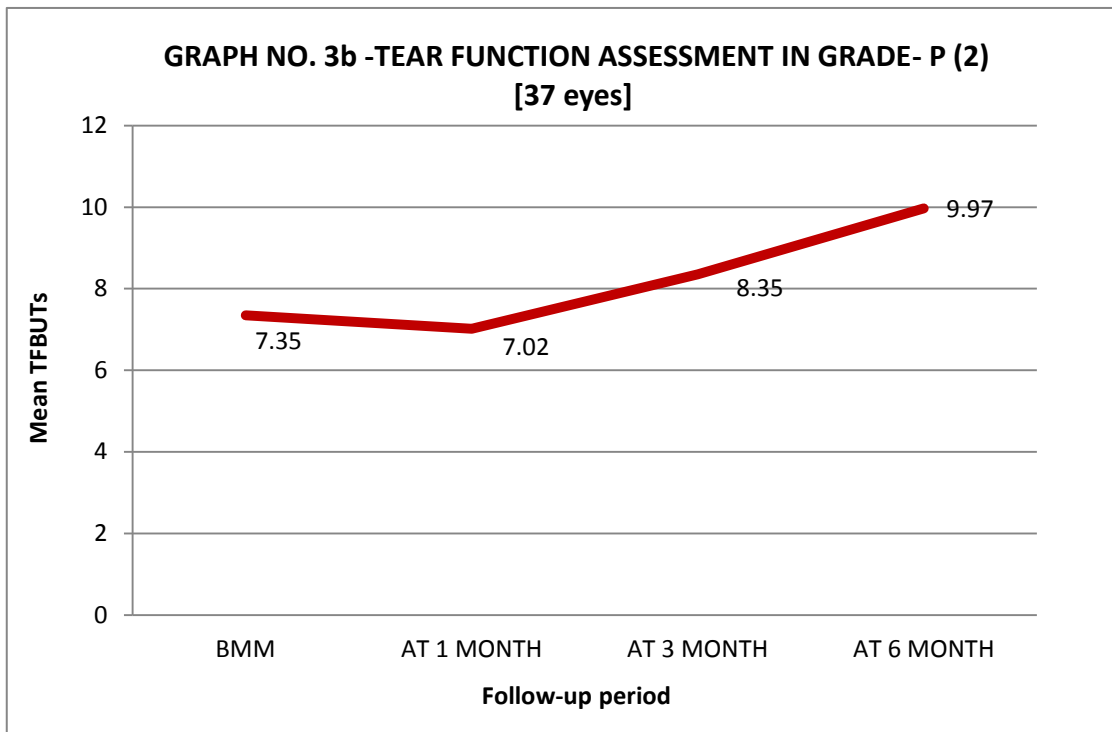
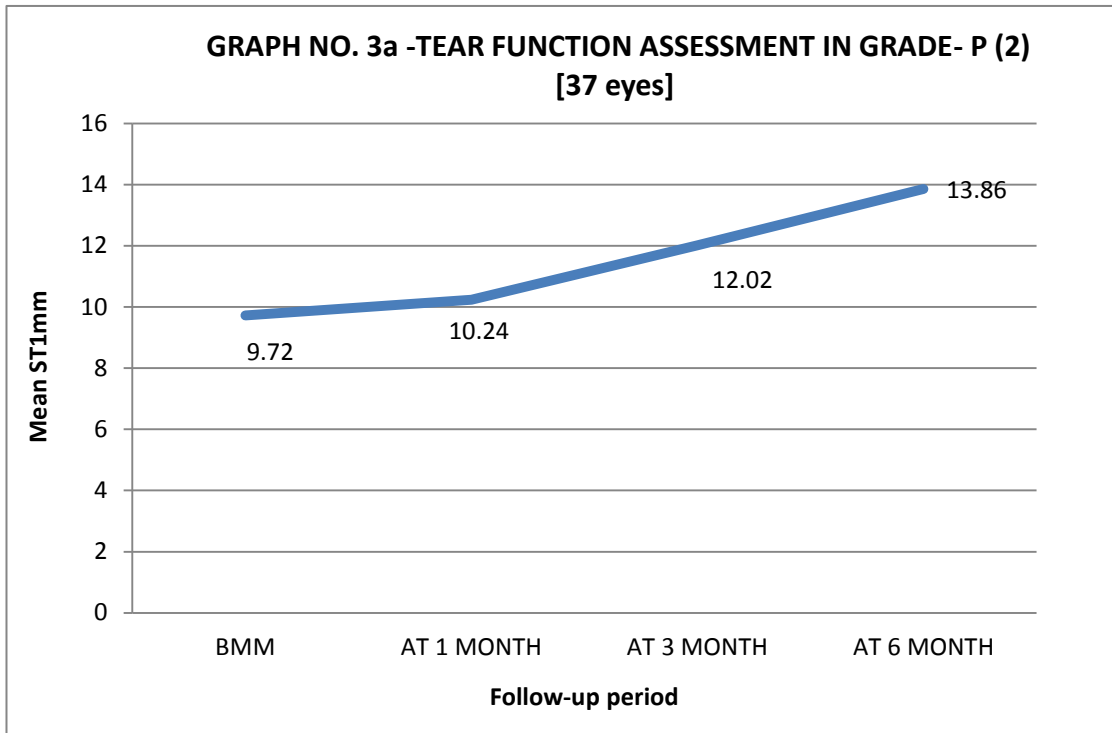




**TABLE NO.3**  
**TEAR FUNCTION ASSESSMENT IN GRADE- P (2) [37 EYES]**

TFT	BMM	AMM			p- VALUE		
		AT 1 MONTH	AT 3 MONTH	AT 6 MONTH	BMM vs 1 Month	BMM vs 3Month	BMM vs 6Month
ST-1 (mm)	9.72 ±2.43	10.24 ±1.86	12..02 ±1.97	13.86 ±1.91	0.30	<0.0001	<0.0001
TFBUT (s)	7.35 ±2.04	7.02 ±1.86	8.35 ±2.01	9.97 ±1.93	0.47	0.03	<0.0001

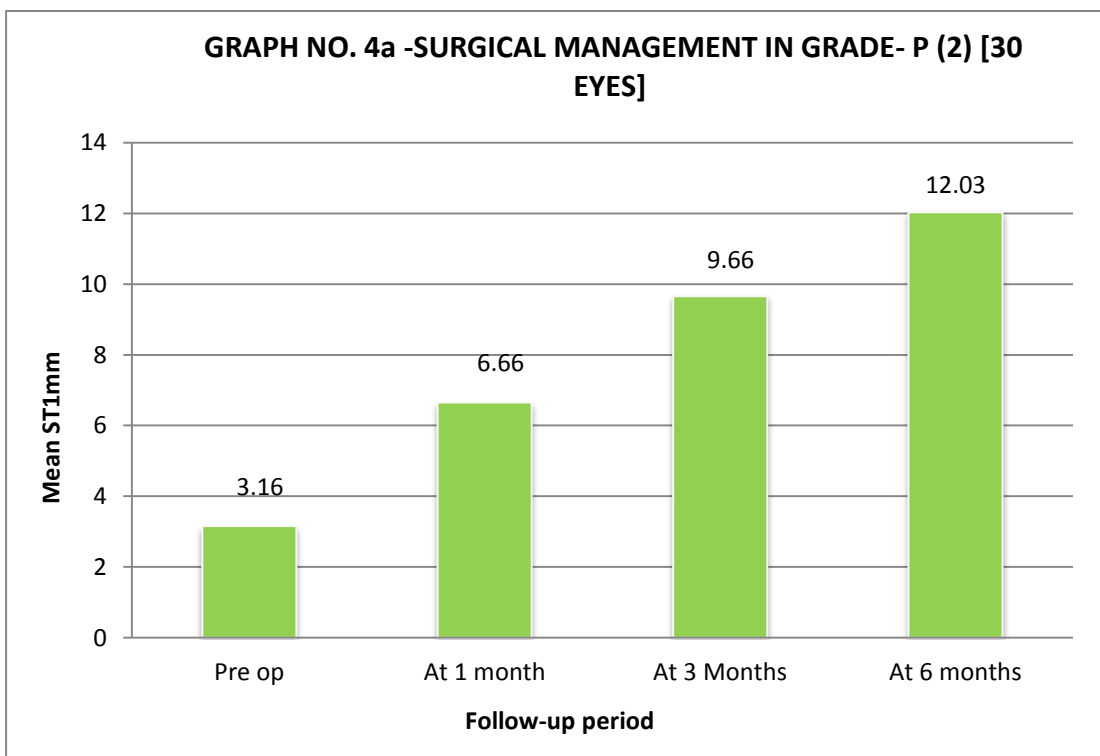
For P (2) grade of pinguecula patients, the p- values for mean ST-1 and TFBUT were 0.30, <0.0001, <0.0001 and 0.47, 0.03 and <0.0001 for BMM vs AMM at 1m, 3m and 6m respectively. These p – values showed that there were no significant changes in ST-1 and TFBUT at 1m follow-up after medical management, while there were extremely significant changes in ST-1 as well as TFBUT both at 3m and 6 m of follow-up.



**TABLE NO. 4**  
**SURGICAL MANAGEMENT IN GRADE- P (2) [30 EYES]**

TFT	PRE-OP	POST-OP			p-VALUE		
		AT 1m	AT 3m	AT 6m	PRE-OP vs 1m	PRE-OP vs 3m	PRE-OP vs 6m
Mean ST-1 (mm)	3.16 ±0.94	6.66 ±1.77	9.66 ±2.08	12.03 ±2.41	<0.0001	<0.0001	<0.0001
Mean TFBUT(s)	3.43 ±1.00	5.8 ±1.56	7.2 ±1.78	9±2.36	<0.0001	<0.0001	<0.0001

After surgical management in P (2) grade of pinguecula patients, the p- values for mean Schirmer-1 test and TFBUT were < 0.0001 for pre-op vs post-op at 1m, 3m and 6m respectively. These p – values showed that there were extremely significant changes in ST-1 as well as TFBUT at 1m, 3m and 6 m follow-up.



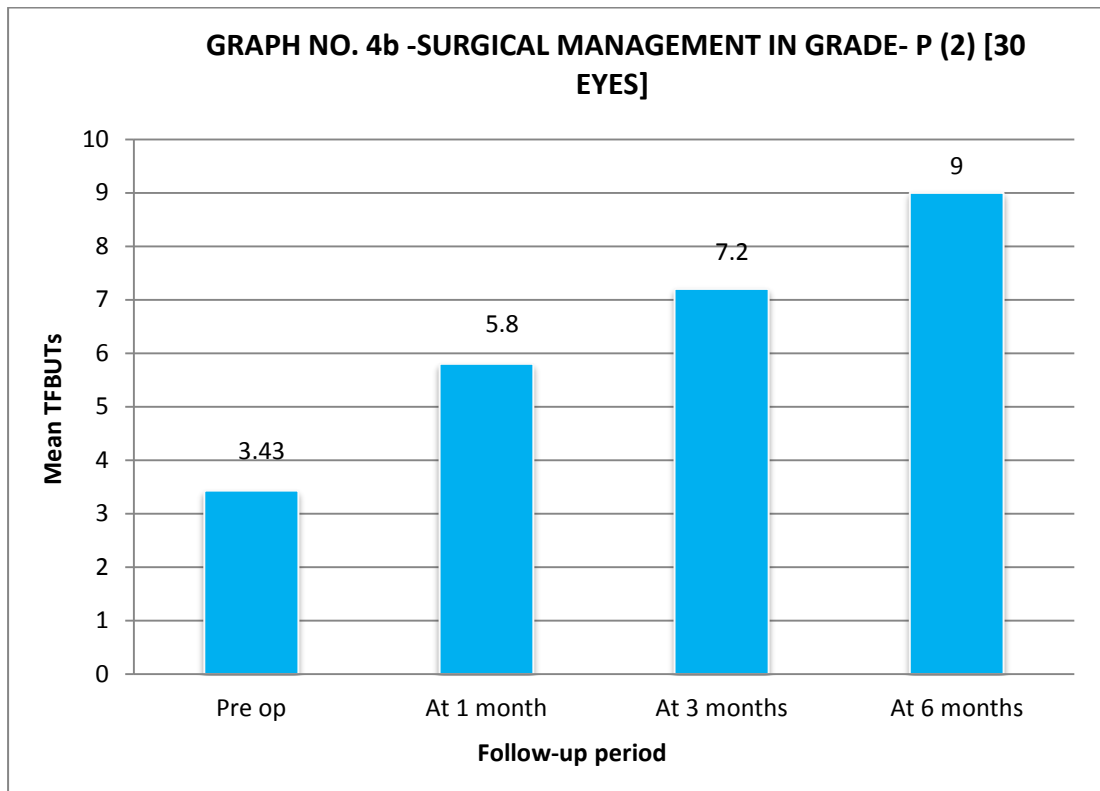
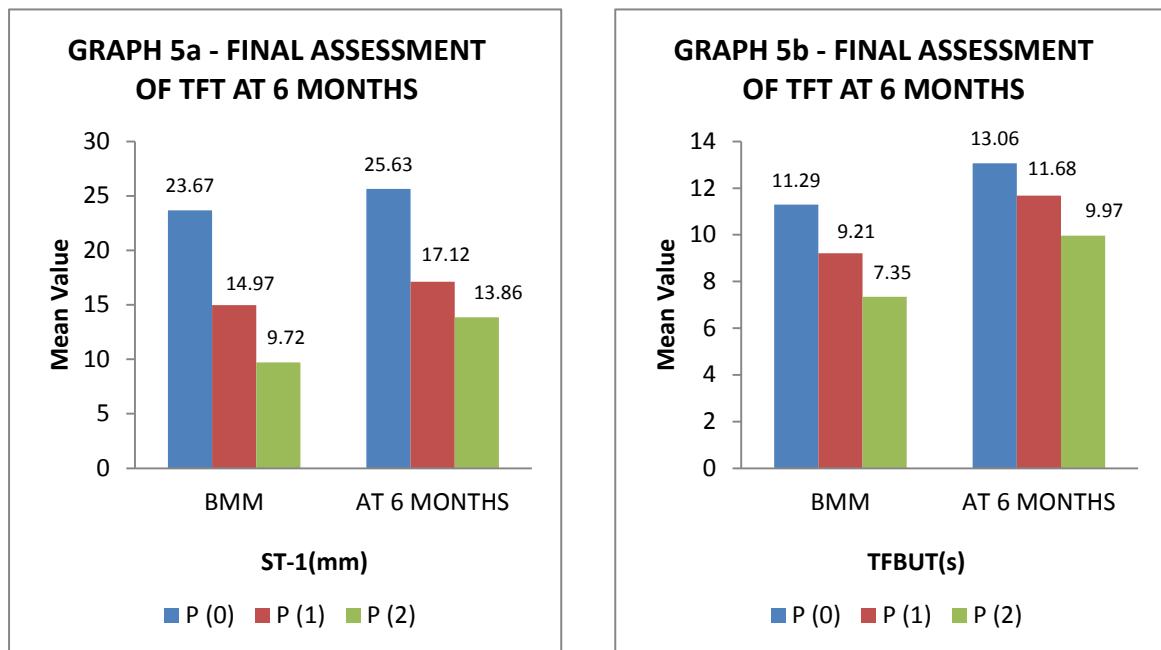


TABLE NO.5: FINAL ASSESSMENT OF TFT AT 6 MONTHS

TFT	MANAGEMENT	P (0)	P (1)	P (2)	p-VALUE		
ST-1(mm)	BMM	23.67 ±4.86	14.97 ±3.16	9.72 ±2.43	P (0) vs P (1)	P (0) vs P (2)	P (1) vs P (2)
	AT 6 MONTH	25.63 ±4.86	17.12 ±3.09	13.86 ±1.91	0.02<0.0002 P (0) LS than P (1)	0.02<0.0001 P (0) LS than P (2)	0.0002<0.0001 P (1) LS than P (2)
TFBUT(s)	BMM	11.29 ±1.41	9.21 ±1.92	7.35 ±2.04	<0.0001 P (0) =P (1)	<0.0001 P (0) =P (2)	<0.0001 P (1) =P (2)
	AT 6 MONTH	13.06±1.04	11.68 ±1.64	9.97 ±1.93			

On final assessment of TFT at 6months on the basis of statistical analysis we found that after 6months of medical management, there were no significant changes in ST-1 of P (0) grade of pinguecula (p=0.02), while extremely significant changes in ST-1and TFBUT of P (1) and P (2) grade of pinguecula (p<0.0001).



## DISCUSSION:

### TEAR FUNCTION ASSESSMENT AFTER MEDICAL MANAGEMENT

There is a significant amount of research on the association of pterygium and dry eye syndrome [25], but very little on the association between pinguecula and dry eye, even though pinguecula is more prevalent and its pathophysiology may be different [2,17,24]. For pinguecula size of less than 5mm, we used eye drop carboxy methyl cellulose 0.5%. In vascularised pinguecula /size more than 5mm we used e/d flurometholone 0.1% QID in tapering manner for 1 month along with e/d carboxy methyl cellulose 0.5%. In this study, we obtained that before and after management comparison of mean Schirmer -1 test and Tear film breakup time between the groups [P (0), P (1) and P (2)] showed statistically not significant difference at 1m ( $p=0.93$ ,  $p=0.22$ ,  $p=0.81$ ,  $p=0.31$ ,  $p=0.30$  and  $p=0.47$ ) respectively.

At the 3<sup>rd</sup> month, the difference in ST-1 was not significant ( $P=0.46$ ,  $P=0.11$ ), but changes in TFBUT were statistically significant ( $P=0.002$ ,  $P<0.0001$ ) in P (0) and P (1) grade, but in P (2) both the parameters changed significantly ( $P<0.0001$ ,  $P=0.03$ ).

At the 6<sup>th</sup> month, changes in both the parameters were extremely significant ( $p<0.0001$ ). There have not been many studies describing medical management of pinguecula, some limited researches on it like *Frucht-Pery J et al* [26] documented that topical indomethacin 0.1% solution was as effective as topical dexamethasone phosphate 0.1% solution for the treatment of inflamed pinguecula and therefore, was suggested as an effective treatment for these conditions. Total signs and total symptoms were significantly lower ( $p=0.001$ ) by day 14 in their study.

*O Halit et al (2001)[12]* found that the mean Schirmer test value was  $22.72\pm 12$  mm in the eyes with pinguecula and  $22.7\pm 8.5$  mm in the control eyes. The difference in results was not statistically significant ( $t=0.01$ ,  $p=0.99$ ) between the comparison groups. The mean TFBUTs were  $11.42\pm 6.89$  s in the eyes with

pinguecula and  $15.46 \pm 5.85$ s in the control eyes. Comparison of TFBUTs between the clusters showed a statistically extremely significant difference ( $t=3.37$ ,  $p=0.0010$ ). They concluded that the modification in the mucin layer was a possible change inducing pinguecula formation. In our study we found that both the parameters (ST-1 and TFBUT), decreased significantly as the grade of pinguecula increased. Mean Schirmer test value and TFBUT were  $14.97 \pm 3.16$ ,  $9.21 \pm 1.92$  and  $9.72 \pm 2.43$ ,  $7.35 \pm 2.04$  for P (1) and P (2) grade of pinguecula respectively.

### **SURGICAL MANAGEMENT**

There were limited studies on pinguecula excision and its clinical outcomes to date. Such procedures are very rarely performed because most of the surgeons considered as pingueculae are benign enough medically and cosmetically that surgical management is not warranted in most cases. However, when a pinguecula causes dry eye symptoms, other cosmetic problems and symptoms are not relieved after medical management then with proper patient selection and consent, pinguecula excision may provide benefit both in ocular health and cosmesis.

We found that TFBUT and Schirmer test improved after surgery. This improvement was extremely significant both clinically as well as statistically ( $p < 0.0001$ ). This result was also supported by *Jinho Jeong et al [22]*. They found that all included measures of dry eye syndrome (TFBUT, Schirmer test, and dry eye symptom score) improved after surgery. They observed postoperative improvement in average TFBUT and Schirmer test scores of 2.7 sec and 1.2 mm, respectively after 3 months of follow-up.

Previous other reports have shown that tear film stability improved after pinguecula and pterygium excision [*16,17,27,28,29*].

On the basis of our observation, we found that tear film stability and tear film production both were improved postoperatively.

**CONCLUSION:** The following conclusions were drawn from our study:

- ✓ The alteration in schirmer-1 test and TFBUT after medical management with e/d Carboxy methyl cellulose 0.5% and/or eye drop Fluorometholone 0.1% showed improvement in tear film production and tear film stability after 6 months of follow-up.
- ✓ Vascularised pinguecula excision resulted in both vascular regression and cosmetic improvement without serious or permanent complications.
- ✓ Tear film parameters after 6 months of follow-up improved more in surgical management group (ST-1 by 8.87mm and TFBUT by 5.57 secs) as compared to medical management group (ST-1 by 4.14mm and TFBUT by 2.62 secs).
- ✓ To our knowledge, this study is the first to systematically determine tear film functions after medical and surgical management in central India. Our study revealed statistically significant improvement in tear functions at 6 months of follow-up after medical or surgical management.

**Conflict of interest:** None declared

**Funding:** Nil

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