A comparison of pterygium surgery recurrence rates after amniotic membrane grafting by vicryl versus nylon fixating sutures

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Objective: To examine the recurrence rate after pterygium excision with amniotic membrane grafting surgery comparing between Vicryl 8/0 (fixation group) and Nylon 10/0 (non fixation group).

Design: Prospective randomized study

Methods: A prospective study in pterygium patients undergone surgery randomized into Vicryl 8/10 or Nylon 10/0 suture techniques performed at Thammasat hospital during July 2014 to April 2017. Pterygium grading was classified by modified from Tan's classification. Furthermore, The patient's age, gender and risk factors for recurrence (occupation, history of previous pterygium surgery, size of the pterygium) were recorded in preoperative period and followed up for signs of pterygium recurrence at 1, 3, 6 months and 12 months postoperatively. The results were analysed by paired t-test. Recurrence and complication were observed until April 2017 and analysed by Chi-square test. **Results:** There were 132 eyes of 132 patients included in this study (67 females and 65 males; age range of 21-75 years, mean 56.136). 66 eyes were operated with Vicryl fixed technique and 66 eyes without Vicryl fixed technique. The recurrence rate was 19.69% in Nylon group (without vicryl fixed technique) and 28.78% in the Vicryl group. The vicryl group had a higher recurrence rate than the nylon group. There was a significant difference in pterygium recurrence between the fixation and non-fixation group at 3 months and 12 months follow up P=0.42 and 0.29 respectively. No serious complications were found in either group.

Conclusions: Fixation group (Vicryl technique) showed the recurrence rate of pterygium is significantly different compared with the non fixation group (Nylon technique) at 3 months (P=0.42) and 12 month (P=0.29). Age, gender and outdoor activity were not found to be significant factors affecting the recurrence of pterygium.

Keywords: Pterygium excision, amniotic membrane transplantation, Vicryl suture, Nylon suture, recurrence rate

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Introduction

Pterygium^{1,2} an external eye disease is common worldwide but is particularly prevalent in tropical and subtropical areas. The prevalence rates range from 0.7 to 31% among different populations and are also influenced by age, race and exposure to solar radiation. Pterygium³

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E-mail: twimolwan@gmail.com Received : Febuary 20,2020 Accepted: Febuary 21,2020 Published: June 30,2020 appears as a fleshy vascular mass in interpalpabral area. The typical pterygium is triangular in shape. It is more frequently located nasally rather than temporally. The causes of pterygium mostly were from chronic conjunctival irritation, sunlight or ultraviolet radiation especially UV-A and UV-B (290-400nm) and wind exposure.

Various surgical techniques³ have been described in literature in treating pterygium, which includes bare sclera techniques, beta irradiation, intra and postoperative mitomycin, conjunctival autograft, amniotic membrane transplant and some combination of the above

mentioned procedures. However, the most common problem in all these procedures is recurrence.

The pterygium excision with bare sclera⁴ has a high recurrence rate ranging from 24-89%. Kenyon et al⁹ first described a conjunctival autograft in 1985; They reported a recurrence rate of 5.3% with less complications. The standard technique of pterygium excision^{5,6} with amniotic membrane transplantation uses non-absorbable suture materials to fix the amniotic membrane graft after pterygium and beneath tenon tissue removal. The Vicryl or Polyglyconate lactide suture materials^{7,8} are absorbable sutures which can provoke a heightened inflammatory response.

Material and Methods

A prospective study in pterygium patients who were operated with or without vicryl fixed technique by randomization in Thammasat hospital during July 2014 to April 2017. All procedures were performed by a single experienced ophthalmologist at a tertiary hospital. Patients with primary pterygium was included. Patients with pseudopterygium, history of ocular diseases predisposing to ulceration or poor wound healing such as autoimmune disease, collagen vascular disease, dry eye, ocular trauma and glaucoma were excluded in this study.

Patients were randomized into two groups. Group 1 (Combined Nylon and Vicryl fixed technique) and Group 2 (only Nylon suture technique) 132 eyes of 132 patients were included in the study. There were 65 male and 67 female patients. Age range was 21 to 75 years (mean 56.136) All patients underwent a complete ophthalmic examination. Preoperative data parameters included name, age, sex, visual acuity, extent and location of pterygium. Written informed consent was obtained from each patient. The patients were divided into two groups. The fixed group (n=66) underwent pterygium excision followed by using Vicryl 8-0 fixations 2 points at the excisional border at superior and inferior of conjunctiva. The nylon or non-fixation group (n=66) underwent pterygium excision with amniotic membrane transplantation using nylon 10-0 suture for fixation. Data regarding the influence of the patients's characteristics on the chosen suture techniques are compared for statistical significance using chi-square.All eyes were given topical anesthesia. The surgical

procedure was as follows:

After cleaning the eye with Betadine paint, eyelids were retracted by a self-retaining eyelid retractor. Intralesional was injected by 1% lidocaine with adrenaline 2-3 ml. The head of the pterygium was separated from the cornea and 4-5 mm conjunctiva including the body of the pterygium was excised. Light cautery was applied to bleeding points for hemostasis. The size of the amniotic membrane graft was measured the pterygium and continuous with nylon suture with or without vicryl fixed technique. The vicryl fixed technique is a stitch fixation between the rim edge of conjunctival excisional area at superior and inferior to the sclera below the edge.

At the end of the surgery, eyes of all patients were patched after applying moxifloxacin eyedrops. Patients were asked to return on the first postoperative day and the eye dressings were removed. Post-operative medicine regimen was the same in both groups, consisting of topical antibiotic (Levofloxacin) and steroids drops (Fluorometholone) four times for 1 month postoperatively.

All patients were followed up on the first postoperative day then at 1 week, 1 month, 3 months, 6 months and then 1 year apart. All patients fixated with nylon had sutures removed within 1-2 weeks. On the contrary, vicryl don't. Follow-up examination included visual acuity assessment, intraocular pressure and slit lamp examination.

Signs of recurrent pterygium consisted of visible changes in the conjunctiva such as vascular congestion and thickening, fibrovascular proliferative tissue in the site of previous pterygium, pterygium invadsion of the cornea (modified from Tan's classification). We defined the grading of pterygium recurrence as follows: grade I as fibrovascular tissue at conjunctiva with visible scleral vessels, grade II as thin fibrovascular tissue at conjunctiva without visible scleral vessels, and grade III as thick fibrovascular tissue at conjunctiva with invasion of the cornea (Table 1).

Upon detection of signs of pterygium recurerence, the surgeon considers management options such as intralesional 5-Fluorouracil (5-FU) or corticosteroid injection, using more intensive anti-inflammatory medication with corticosteroids eyedrops and lubricating the

ocular surface. The main outcome is rate of pterygium recurrence between two groups and analysed by paired t-test. Recurrence and complications were observed until April 2017. Other factors of recurrence were analysed by Fisher exact test and Chi-square test.

Results

There were 132 eyes of 132 patients in this study (67 females and 65 males; age range of 21-75 years, mean $56.136 \pm 2(12.13)$ years in the fixation group and $55.106 \pm 2(12.32)$ years in the non-fixation group). 66 eyes were operated with Vicryl fixed technique and 66 eyes belonged in the non-fixation group.

The fixation group had 36 females (53.7%) and 30 males (46.2%) while the non-fixation group had 31 females (46.3%) and 35 males (53.8%) (P=0.384). Age range between both groups were 21-77 years. Of the patients aged between 21 - 30 years were 3(100%) eyes in contrast to the non-fixation has no patient in this

range. Of the patients aged 31-40 years, 6 eyes (33.3%) and 12 eyes (66.7%) belonged in the fixation and non-fixation groups respectively. Of the patients aged 41-50 years, 12 eyes (52.2%) and 11 eyes (47.8%) belonged in the fixation and non-fixation groups respectively. Of the patients aged 51-60 years, 13 eyes (43.3%) and 17 eyes (56.7%) belonged in the fixation and non-fixation groups respectively. Of the patients aged 61 years or older, 32 eyes (52.2%) and 26 eyes (44.8%) belonged in the fixation and non-fixation groups respectively and number of patient loss follow up at 12 month higher in non-fixation group 6 (4.54%) and fixation group 4 (3.03%).

The total recurrence of pterygium in both non-fixation and fixation group was 64 eyes (48.4%). This study showed recurrence in all grades of pterygium (Table 2). For Grade I, 20 eyes (57.14%) and 15 eyes (42.86%) belonged in the fixation and non-fixation groups respectively.

Grade II had 16 eyes (59.25%) and 11 eyes (40.75%) in fixation and non-fixation groups

Table 1: Table define pterygium grading size and clinical feature

Pterygium grading	Characteristics	Extent of invadsion into the cornea (mm)
Grade I	fibrovascular tissue at conjuntiva, scleral vessels can be seen.	< 3.00
Grade II	Thin fibrovascular tissue at conjuntiva, scleral vessels cannot be seen.	3.00-6.00
Grade III	thick fibrovascular tissue at conjuntiva and invasion of the cornea.	>6.00

respectively. In contrast, grade III had recurrence in only 2 eyes in the fixation groups (*P*=0.428).

Regarding occupations, in the fixation group, 35 (50.7%) worked outdoors vs 31 (49.2%) worked indoors whereas in non-fixation group, 32 (50.8%) worked outdoors vs 34 (49.3%) work indoors. Comparing the size and number of pterygium in non fixation groups and vicryl fixed group, for pterygium size less than 3mm, 35 (48.6%) and 37 (51.4%) belonged in the fixation and non-fixation groups respectively. In eyes with pterygium sized between 3.00 - 6.00 mm, 28 (51.9%) and 26 (48.1%) belonged in fixation and non-fixation groups respectively. In pterygium larger than 6.00 mm, 2 (66.7%) and 1

(33.3%) belonged in the fixation and non-fixation groups respectively.

The recurrence rate of pterygium between fixation and non-fixation group is shown in table 3. The number of recurrent pterygium after excision at 1 month was 4 (6.1%) and 9 (13.6%) in the fixation and non-fixation groups respectively (X^2 Chi-square 2.133 : P=0.144) while the number of recurrent pterygium after excision at 3 months showed a significant increase when compared between the fixation group vs non-fixation group, 13 eyes (19.7%) vs 5 eyes (7.6%) respectively (X^2 Chi-square 4.177 : P=0.042). The number of recurrent pterygium after excision at 6 months was 13 eyes (18.2%) and 11 eyes

(16.7%) in the fixation vs non-fixation groups respectively (X^2 Chi-square 0.053 : P=0.819), in contrast to the number of recurrence rate in both groups where the decrease was significant after excision at 12 months (Table 3), with 7 eyes (10.6%) and 3 eyes (1.5%) in the fixation vs non-fixation groups respectively (X^2 Chi-square 4.970 : P=0.029)(figure 1).

The mean astigmatism of both groups at first visit was 2.77 in fixation groups and 2.43 in the non-fixation groups (Figure 2). Mean post operative astigmatism was found to be following during follow up results shown as fixation vs non-fixation groups: At 1 month 0.97 vs 0.82, at 3 month 1.02 vs 0.975, at 6 month 1.25 vs 1.17 and at 12 month 1.33 vs 1.25 respectively.

The recurrence rate of pterygium in fixation and non-fixation group (Figure 3) throughout the follow up period comparing fixation vs non-fixation groups. Recurrent pterygium grade I were; at 1 month, 3 eyes (6%) vs 5 eyes (10%), at 3 months 5 eyes (8%) vs 2 eyes (4%), at 6 months 7 eyes (10%) vs 6 eyes (9%), at 12 months 5 eyes (5%) vs 2 eyes (4%) respectively. Recurrent pterygium grade II were; at 1 month 2 eyes (2%) vs 3 eyes (4%), at 3 months 6 eyes (10%) vs 3 eyes (6%), at 6 months 6 eyes (8%) vs 4 eyes (7%) and at 12 months 2 eyes (4%) vs 1 eye (2%) respectively. Recurrent pterygium grade III was only found at 3 months postoperatively in 2 eyes (4%).

Discussion

Pterygium is a common ocular surface disorder in Thailand. Various surgical techniques for pterygium excision has shown variable rates of pterygium recurrence. In this study, the recurrence rate was 21.9 % in Fixation group (vicryl technique) and 15.09 % in non fixation

Table 2 Demographic and clinical data of patients in fixation group and non-fixation group.

		Suture Techniques		X^2	
Characteristics		Fixation Group (N=66)	Non-fixation Group (N = 66)	Chi- square	<i>P</i> -Value
Gender	Female	36 (53.7%)	31 (46.3%)	.758	.384
	Male	30 (46.2%)	35 (53.8%)		
Age	21-30 years old	3 (100.0%)	0 (0.0%)	6.198	.185
	31-40 years old	6 (33.3%)	12 (66.7%)		
	41-50 years old	12 (52.2%)	11 (47.8%)		
	51-60 years old	13 (43.3%)	17 (56.7%)		
	Older than 61 years old	32 (55.2%)	26 (44.8%)		
	Mean/+-2SD	56.1364 +- 2 (12.13)	55.1061 +- 2 (12.32)		
Grade	Grade I	20 (57.14%)	15 (42.86%)	1.697	.428
	Grade II	16 (59.25%)	11 (40.75%)		
	Grade III	2 (100.0%)	0 (0.0%)		
Occupation	Indoor	35 (50.7%)	34 (49.3%)	.030	.862
	Outdoor	31 (49.2%)	32 (50.8%)	.030	
Size	Less than 3.00 mm	35 (48.6%)	37 (51.4%)		.796
	3.00 - 6.00 mm	28 (51.9%)	26 (48.1%)	.455	
	Greater than 6.00 mm	2 (66.7%)	1 (33.3%)		

group (Nylon technique).

We defined pterygium grading into 3 categories by characteristic as size, thick or thin fibrovascular membrane, degree of scleral vessel obsecure and invade cornea: as Chen et al¹⁷ showed that the severity of inflammation and the preoperative grade of pterygium are associated with pterygium recurrent. Tan et al¹⁸ also explain that the pathophysiologic features and morphology have impact to success rate of

pterygium surgery. In our study, we classified pterygium grading by modified from Tan's classification and base on severity of pterygium such as size less than 3 mm but thick fibrovascular tissue and invade cornea, in this case we will classified as grade III etc. As a result of study, Grade III pterygium have the highest number of people who were treated with fixation technique, 100.0 percent, followed by the patients with Grade I and Grade II pterygium,

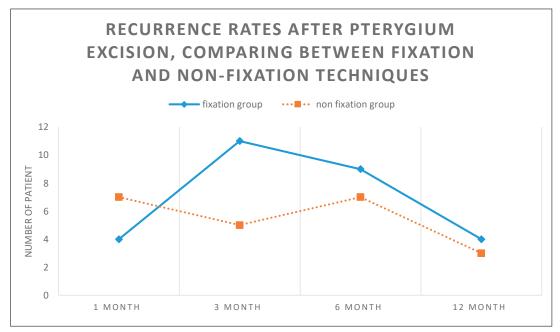


Figure 1: The cumulative frequency of pterygium recurrence

Table 3: comparison of pterygium recurrence in each suture technique in each follow up visit

Time after the pterygium surgery	Recurrence				
	Suture Technique	Number of Recurrent Patients	Number of Non-recurrent Patients	X ² Chi-square	<i>P</i> -value
1 month	Fixation* group	4 (6.1%)	62 (93.9%)	2.133	.144
	Non fixation group**	9 (13.6%)	57 (86.4%)		
3 months	Fixation group	13 (19.7%)	53 (80.3%)	4.117	.042
	Non fixation group	5 (7.6%)	61 (92.4%)		
6 months	Fixation group	13 (18.2%)	54 (81.8%)	0.053	.819
	Non fixation group	10 (16.7%)	55 (83.3%)		
12 months	Fixation group	7 (10.6%)	59 (89.4%)	4.970	.029
	Non fixation group	3 (1.5%)	65 (98.5%)		

^{*} Fixation group (Vicryl fixation technique)

^{**}Non fixation group (Nylon technique)

having the percentage of 57.14 percent and 59.25 percent, respectively. However, the difference in pterygium grading does not lead to a significant difference in suture technique.

For the occupation, we known that sunlight exposure specifically UV-B can cause the progression of pterygium from transformation fibroblast and the working outdoor activity have more radiation expose causes mutations in the p53 tumor suppressor gene¹⁴⁻¹⁶, thus facilitating the abnormal proliferation of limbal epithelium: according to the result found that number of recurrent pterygium higher in fixation

group compaired with non-fixation group but the proportion of indoor activity patient much more than outdoor activity. However, the difference is not statistically significant so we conclude that outdoor activity have effect to recurrent pterygium but should be consider another factor also.

Pterygium size is the risk factor in recurrent pterygium: Nuzzi R et al¹⁹ found that the more size of bigger the more rate of recurrent are higher also but depend on surgeon experience and surgical technique; the higher rate of recurrent found in bare sclera technique more

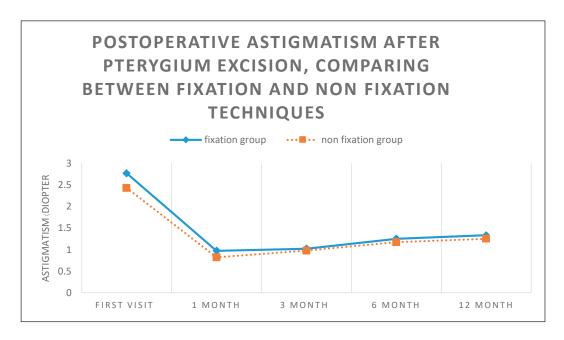


Figure 2: mean astigmatism after pterygium excision and follow up

than amniotic membrane and conjunctival autograft. From our result we found the patients with the pterygium sizes that are larger than 6.00 mm. have the highest percentage of the people who were treated with the fixation technique, comparing to those who have the pterygium sizes that are smaller than 3.00 mm and between 3.00 and 6.00. Even though the percentages are different, the distinction is insignificant.

Even though the there is a higher number of patients with the recurrent rate for the non-fixation group at 1 month after excision, this is insignificant. For the 3-month period after the operation, 19.7 percent of the patients who were

treated with the Vicryl suture technique was found to have recurrent signs while compaired to only 7.6 percent of patients treated with the nylon only technique. For the 6-month period after the operation, 18.2 percent of the patients who were treated with Vicryl suture technique was found to have pterygium recurrence. Similarly, 16.7 percent of patients treated with non-fixation technique using only nylon suture was found to have signs of recurrence. For the 12-month period after the patients are treated, 10.6 percent of the patients who were treated with Vicryl suture technique was found to have pterygium sign. On the contrary, there is only 1.5 percent

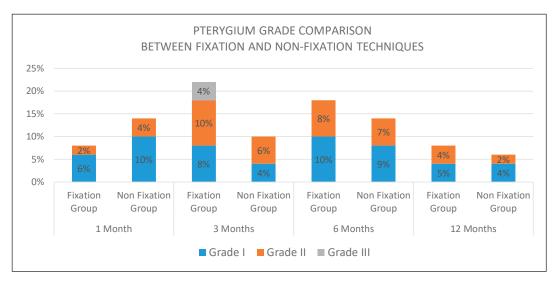


Figure 3: recurrence of pterygium in fixation and non-fixation techniques

of the patients who were treated with only nylon suture was found to have signs of recurrence.

According to vicryl suture material can have more inflammatory response and the mechanism of pterygium recurrence is inflammatory process: as A. Schrier et al. (2003)¹³ reported the incidence of recurrence in patients who used Vicyl material was higher compaired to Nylon sutures for pterygium surgery. Carla et al.12 evaluated the efficacy of pterygium excision with conjunctival autograft by using either nylon, vicryl and fibrin glue for conjunctival autograft suturing: reported a higher incidence of vicryl group more than nylon and fibrin glue respectively. In our results we found that number of recurrent rate was significantly between 2 group at 3 month and 12 month post-operative but complications such as granuloma or cicatricial symblepharon or limitations in ocular motility were not found.

In summary, althrough the nylon and vicryl was effective for suturing pterygium surgery, the recurrence rate in the fixation group (vicryl technique) was more than non-fixation group (nylon technique), especially in the 3 month and 12 month period after pterygium surgery. The fixation technique had higher recurrent rates propositionally due to the inflammatory nature of vicryl sutures left in place, whereas nylon sutures in both groups were removed within the first 2-3 weeks. Furthermore, the recurrence at 12 months in both groups in this study may be

skewed by the unequal number of cases loss to follow up at 12 months. Nylon suture material in pterygium surgery with amniotic membrane autograft results in significantly lower rates of pterygium recurrence compaired with vicryl sutures.

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