

Efficacy and Safety of Silicone Punctal Plug Treatment in Moderate to Severe Dry Eye at Thammasat University Hospital

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ปัญหาโรคตาแห้ง โดยเฉพาะในรายที่มีอาการรุนแรง มีผลกับคุณภาพชีวิตของผู้ป่วยเป็นอย่างมาก ในหลากหลายวิธีการรักษา การใช้ซิลิโคนอุดท่อน้ำตา เป็นอีกทางเลือกหนึ่งที่มีประสิทธิภาพดี และมีความปลอดภัยสูง อาจเป็นทางเลือกที่เหมาะสมสำหรับผู้ป่วยโรคตาแห้งที่มีอาการรุนแรงได้

Abstract

- Objective** : To study the clinical efficacy and safety of lacrimal occlusion by silicone punctal plug in moderate to severe dry eye patient at Thammasat University Hospital.
- Methods** : 40 eyes from moderate to severe dry eye patients are included in the study. Dry eye grading is determined by one ophthalmologist. Silicone plug will be inserted in a lower punctum. One, two and four-week follow up are scheduled. We will compare the conjunctival Fluorescein staining before and after a punctal plug insertion. Patient satisfaction will be evaluated before and after a punctal plug insertion. Study designs: Prospective comparative study.
- Results** : Percent of dry eye grading by Oxford Scheme before a punctal plug insertion at one, two and four week in grade A, B, C, D, E and >E was 0, 0, 0, 60, 40, and 0% respectively. Percent of dry eye grading after a punctal plug insertion at one week was 42.5, 50, 2.5, 5, 0, and 0% respectively. Percent of dry eye grading after a punctal plug insertion at two week was 65.8, 34.2, 0, 0, 0, and 0% respectively. Percent of dry eye grading after a punctal plug insertion at four week was 73.7, 26.3, 0, 0, 0, and 0% respectively. The results revealed significant improvement of grading of dry eye after inserted silicone punctal plug in 1st, 2nd and 4th week. Comparing dry eye grading between pre-punctal insertion and 1st, 2nd and 4th week post-punctal insertion has been decreased significantly. Percent of patient satisfaction grade 1, 2 and 3 in four week follow up was 0, 25 and 75% respectively.
- Conclusions** : The silicone punctal plug is safety and effective in treatment of moderate and severe dry eye. In some patients, qualities of life have been improved by treatment of the silicone punctal plug alone without using any tear supplements or other medications.

Key words: Dry eye syndrome, Punctal plug

Introduction

Dry eye syndrome (DES) is characterized by ocular irritation, burning or foreign-body sensation, excess tearing, often exacerbated by smoking, wind, heat, low humidity or prolonged use of the eye resulting from alteration of the tear film. The etiology of DES is idiopathic, collagen-vascular diseases, conjunctival scarring, drugs such as oral contraceptive, antihistamine, phenothiazines, infiltration of lacrimal glands and vitamin A deficiency. The effect of DES can vary from minor inconvenience for most sufferers to rare sight-threatening complications in severe cases. The diagnosis of DES has focused on inadequate secretion or aqueous tear deficiency.

In present, current treatment is to treat the etiology and heavily weighted toward supplementation by preservative or preservative-free tear, lubricating ointment, stimulation, or preservation of aqueous tears and punctal occlusion by collagen or silicone insertion. Silicone punctal plug is used to conserve moisture in tear-deficient eyes. In United States, Japan and Europe have been commonly using silicone punctal plug in dry-eye patient for couple years. There are many researches about the effectiveness and efficacy using silicone plug in those countries.

In Thailand, there are no researches or any reports about using silicone plug even if some ophthalmologists have been using a silicone plug in treatment of dry-eye. We are interested in the efficacy and effectiveness of using silicone plug in moderate to severe dry eye patients at Thammasat university hospital.

Objective

To study the clinical efficacy and safety of lacrimal occlusion by silicone punctal plug in moderate to severe dry eye patient at Thammasat University Hospital.

Materials and Methods

Inclusion criteria

1. Age over 18 year
2. Diagnosed with moderate to severe dry eye according to Oxford Scheme criteria

Exclusion criteria

1. Patients who have allergy to silicone
2. Previous history of nasolacrimal duct obstruction or nasolacrimal duct surgery
3. History or diagnosed with blepharitis

Study designs

Prospective comparative study

Methods

– 40 eyes, 20 patients with moderate to severe dry eye have acknowledgeable and signed informed consent willfully is recruited in the research.

– Dry eye grading is determined by one ophthalmologist using Fluorescein corneal staining.

– Grading dry eye using Oxford Scheme will be evaluated pre and post silicone plug application

– Fluorescein staining

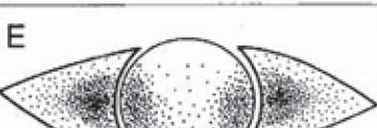
Using Fluorescein staining (sterile strips), a single drop of sterile, and unit-dose saline is instilled onto a fluorescein-impregnated strip. Because fluorescein diffuses rapidly into tissues in the presence of an epithelial defect, the delineation of punctate staining is lost in a short

period of time. It is therefore essential to assess staining rapidly

– Grading ocular surface

Oxford Scheme (Grading of Corneal and Conjunctival Staining in the Context of Other Dry Eye Tests, Cornea. 2003 Oct;22(7):640–50.) as figure 1.

Figure1 Grading of cornea and conjunctival staining Oxford Scheme¹

PANEL	GRADE	VERBAL DESCRIPTOR
	0	Absent
	I	Minimal
	II	Mild
	III	Moderate
	IV	Marked
>E	V	Severe

Main outcome measures

– Lacrimal occlusion by Eaglevision® silicone plug size 0.4 X 1.6 mm will be performed in right and left lower punctum without changing any previous medications.

– The conjunctival fluorescein staining will be compared before and after a punctal plug insertion at one, two and four-week follow up from two ophthalmologists.

– Patient satisfaction will be evaluated after a punctal plug insertion by grading 1, 2, 3, and 4

Grade 1: not satisfied

Grade 2: no change

Grade 3: satisfied

Grade 4: very satisfied

Results

40 eyes of 20 patients diagnosed with moderate to severe dry eyes at department of ophthalmology, Thammasat university hospital (26 females and 14 males) were enrolled. Mean patient age was 65.6 ± 1.07 years (range 57 to 75 years). There were two eyes lost the silicone punctal plug during the experiment and were excluded. No complication in every patient enrolled in research.

Percent of dry eye grading by Oxford Scheme before a punctal plug insertion at one, two and four week in grade A, B, C, D, E and > E was 0, 0, 0, 60, 40 and 0% respectively. Percent of dry eye grading after a punctal plug insertion at one week was 42.5, 50, 2.5, 5, 0, and 0% respectively. Percent of dry eye grading after a punctal plug insertion at two week was 65.8, 34.2, 0, 0, 0 and 0% respectively. Percent of dry eye grading after a punctal plug insertion at four week was 73.7, 26.3, 0, 0, 0 and 0% respectively (table1, diagram 1). The results revealed significant improvement of grading of dry eye after inserted silicone punctal plug in 1st, 2nd and 4th week. Comparing dry eye grading between pre-punctal insertion and 1st, 2nd and 4th week post-punctal insertion have been decreased significantly ($p < 0.05$) using paired t-test (table 2).

Percent of patient satisfaction grade 1, 2, 3 in one week follow up was 2.5, 50 and 47.5% respectively. Percent of patient satisfaction grade1, 2, 3 in two week follow up was 0, 27.5 and 72.5% respectively. Percent of patient satisfaction grade1, 2, 3 in four week follow up was 0, 25 and 75% respectively (table 3).

Table 1 : Comparison of percent of dry eye patients in each group of dry eye grading between pre and post punctal plug insertion.

	Grade A	Grade B	Grade C	Grade D	Grade E	Grade >E	Total
Pre-punctal plug	0.0%	0.0%	0.0%	60.0%	40.0%	0.0%	100%
One week	42.5%	50.0%	2.5%	5%	0.0%	0.0%	100%
Two week	65.8%	34.2%	0.0%	0.0%	0.0%	0.0%	100%
Four week	73.7%	26.3%	0.0%	0.0%	0.0%	0.0%	100%

Diagram 1 : Comparison of percent of dry eye patients in each group of dry eye grading between pre and post-punctal plug insertion.

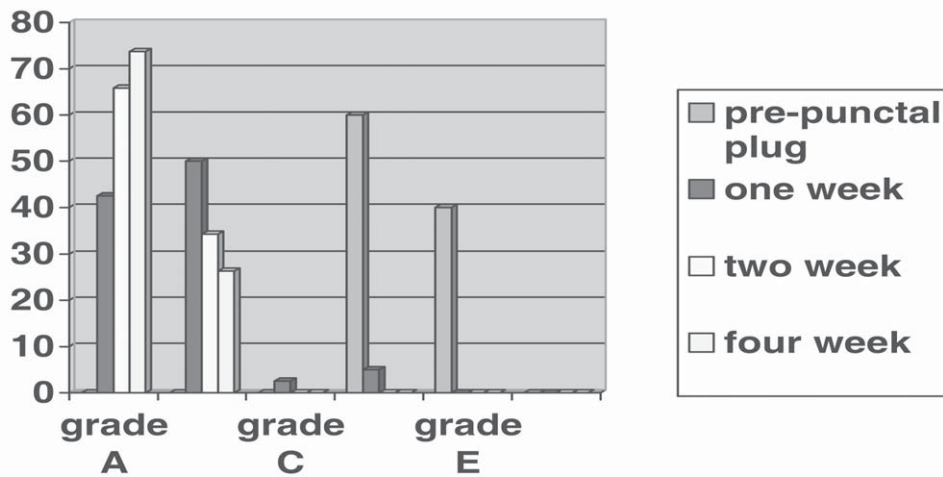


Table 2 : Comparing dry eye grading between pre-punctal insertion and 1st, 2nd and 4th week post-punctal insertion using Paired Samples Test.

	Paired differences					t	df	Sig. (2-tailed)
	Mean	SD	Std. error mean	95% Confidence interval of the difference				
				Lower	Upper			
Pair 1 pre-punctal occlusion dry eye grading – 1 st week post-punctal occlusion dry eye grading	2.70000	0.72324	0.11435	2.46870	2.93130	23.611	39	0.000
Pair 2 pre-punctal occlusion dry eye grading – 2 nd week post-punctal occlusion dry eye grading	3.07500	0.65584	.10370	2.86525	3.28475	29.654	39	0.000
Pair 3 pre-punctal occlusion dry eye grading – 4 th week post-punctal occlusion dry eye grading	3.12500	0.68641	0.10853	2.90548	3.34452	28.794	39	0.000

Table 3 : Comparison of patient satisfaction to punctal plug treatment in one, two and four week post punctal plug insertion.

	Grade 1	Grade 2	Grade 3	Grade 4
One week	2.5%	50.0%	47.5%	0.0%
Two week	0.0%	27.5%	72.5%	0.0%
Four week	0.0%	25.0%	75.0%	0.0%

Discussion

Dry eye grading was much better from moderate to severe level to mild to moderate level after silicone punctal occlusion without changing any topical medication. Two patients have lost one of two punctal plugs during the experiment after discussed with patients they would like to reapply and restart the monitoring. Using the silicone punctal plug in treatment of dry eye is safe and effective.

There were reports of complications form punctal insertion such as spontaneous extrusion, canaliculitis, pyogenic granuloma and recurrent dacrycystitis. In our study, there were no reports of serious complications. However, spontaneous plug loss occurs in two eyes. Careful choosing of the optimal plug size and close follow-up are recommended to ensure the success of the treatment.

However, the silicone punctal plugs that were used in our research are generally used temporarily and for patient sample before using the permanent plug which is very expensive (6,000–8,000 baht). The long term effect of the permanent silicone punctal plug is still need to be monitored.

Conclusions

The silicone punctal plug is safety and effective in treatment of moderate and severe dry eye. In some patients, qualities of life have been improved by treatment of the silicone punctal plug alone without using any tear supplements or other medications.

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ประสิทธิผลและความปลอดภัยจากการอุดท่อน้ำตาด้วยซิลิโคน ในการรักษาผู้ป่วยตาแห้งชนิดรุนแรงปานกลางถึงรุนแรงมาก ในโรงพยาบาลธรรมศาสตร์เฉลิมพระเกียรติ

ผู้ช่วยศาสตราจารย์แพทย์หญิงมัญชิมา มะกรวัฒนะ
ภาควิชาจักษุวิทยา คณะแพทยศาสตร์ มหาวิทยาลัยธรรมศาสตร์

บทคัดย่อ

วัตถุประสงค์ : เพื่อศึกษาประสิทธิผลทางคลินิก และความปลอดภัยของการอุดท่อน้ำตาด้วยซิลิโคน ในการรักษาผู้ป่วยตาแห้งชนิดรุนแรงปานกลางถึงรุนแรงมากในโรงพยาบาลธรรมศาสตร์เฉลิมพระเกียรติ

วิธีการศึกษา : ผู้ป่วยโรคตาแห้งชนิดรุนแรงปานกลางถึงรุนแรงมากในโรงพยาบาลธรรมศาสตร์เฉลิมพระเกียรติ จำนวน 20 คน 40 ตา เข้าร่วมการวิจัยโดยทำการประเมินภาวะตาแห้งโดยจักษุแพทย์ท่านเดียวใช้ซิลิโคนอุดท่อน้ำตาที่รูเปิดน้ำตาด้านล่าง ทำการตรวจประเมินภาวะตาแห้งหลังการรักษา 1, 2 และ 4 อาทิตย์ โดยทำการตรวจประเมินภาวะตาแห้งด้วยการใช้สปีฟูลอเรสเซนส์ย้อมที่กระจกตา และประเมินความพึงพอใจของผู้ป่วยก่อนและหลังการรักษา

ผลการวิจัย : สัดส่วนของผู้ป่วยที่มีภาวะตาแห้งก่อนทำการรักษาโดยใช้ซิลิโคนอุดท่อน้ำตาแบ่งตามความรุนแรงเป็น A, B, C, D, E และ >E คิดเป็นร้อยละ 0, 0, 0, 60, 40 และ 0 ตามลำดับ สัดส่วนของผู้ป่วยที่มีภาวะตาแห้งหลังทำการรักษาโดยใช้ซิลิโคนอุดท่อน้ำตาอาทิตย์ที่ 1 คิดเป็นร้อยละ 42.5, 50, 2.5, 5, 0 และ 0 ตามลำดับ สัดส่วนของผู้ป่วยที่มีภาวะตาแห้งหลังทำการรักษาโดยใช้ซิลิโคนอุดท่อน้ำตาอาทิตย์ที่ 2 คิดเป็นร้อยละ 65.8, 34.2, 0, 0, 0 และ 0 ตามลำดับ สัดส่วนของผู้ป่วยที่มีภาวะตาแห้งหลังทำการรักษาโดยใช้ซิลิโคนอุดท่อน้ำตาอาทิตย์ที่ 4 คิดเป็นร้อยละ 73.7, 26.3, 0, 0, 0 และ 0 ตามลำดับ

จากผลการวิจัยพบมีการเปลี่ยนแปลงของภาวะตาแห้งดีขึ้นอย่างชัดเจนหลังการรักษาโดยใช้ซิลิโคนอุดท่อน้ำตา ผลการเปรียบเทียบความพึงพอใจของผู้ป่วยหลังการรักษาโดยใช้ซิลิโคนอุดท่อน้ำตาหลังรักษาโดยใช้ซิลิโคนอุดท่อน้ำตา 1, 2 และ 4 อาทิตย์ คิดเป็นร้อยละ 0, 25 และ 75 ตามลำดับ

สรุปผลการวิจัย : การใช้ซิลิโคนอุดท่อน้ำตาในการรักษาผู้ป่วยตาแห้งชนิดรุนแรงปานกลางถึงรุนแรงมากมีประสิทธิภาพและความปลอดภัยสูง อีกทั้งยังเป็นการพัฒนาคุณภาพชีวิตให้แก่ผู้ป่วยโรคตาแห้งชนิดรุนแรงปานกลางถึงรุนแรงมากอีกด้วย

นัยามคำศัพท์ : ตาแห้ง, ซิลิโคนอุดท่อน้ำตา