

Efficacy of Punctal Plugs in the Management of Ocular Surface Diseases

Oscar Chen*, Sera Choi, Anjali Tannan

Department of Ophthalmology, Rush University Medical Center, Chicago, United States

ABSTRACT

Purpose: To evaluate the clinical efficacy of punctal plugs in the management of various ocular surface diseases.

Methods: A retrospective chart review was conducted in an academic teaching center and private clinic between January 2015 and May 2020. Patients who underwent punctal occlusion with punctal plugs were reviewed. Clinical data such as sex and age of the patient, symptoms, plug location, visual acuity, subjective improvement, tear break-up time, corneal stain and complications were obtained. These parameters were evaluated during the initial follow-up (within 60 days of the procedure) and the final follow-up (180-365 days after the procedure). These data were then compared to the patient's baseline presentation *via* odds ratio analysis.

Results: A total of 572 patients were included in this study. 385 patients were identified from a private clinic, while 187 were identified from a resident continuity clinic. Dry eye syndrome was the most common indication (440, 79.5%), followed by exposure keratopathy (32, 5.6%), meibomian gland dysfunction (29, 5.0%), sjogren's syndrome (26, 4.5%), and neurotrophic keratopathy (19, 3.3%). There was a statistically significant improvement in two key symptoms during the first follow-up; eye pain (0.64, $p=0.02$) and blurry vision (0.70, $p=0.04$). Visual acuity also showed a statistically significant improvement during the first follow-up (-0.03, $p=0.01$). The only parameter that continued to show a statistically significant improvement at the final follow-up was eye pain (0.57, $p=0.03$). None of the clinical findings correlated with dryness, such as tear break-up time or corneal staining showed significant improvement. The most common complications associated with punctal plugs were punctal plug extrusion (168, 29.3%) and epiphora (86, 15%), followed by eye irritation (82, 14.3%).

Conclusion: Punctal plugs offer a simple and effective treatment for improving blurry vision and eye pain associated with various ocular surface diseases. Punctal plugs were shown to improve two key symptoms related to various ocular surface diseases as early as 60 days after installation. Although punctal plugs offer a fast, reversible, and easily implementable treatment for some of the key symptoms of ocular surface diseases, plugs alone do not effectively treat all associated symptoms of these complex ocular surface diseases. Thus, patients would benefit from supplemental and/or adjunctive therapy for a more comprehensive ocular surface disease management.

Keywords: Punctal plugs; Punctal occlusion; Ocular surface diseases; Dry eyes

INTRODUCTION

Ocular surface diseases are a spectrum of diseases that affect the superficial layers of the eye. From dryness to systemic autoimmune disease, a wide range of etiologies can cause damage to the ocular surface [1]. The ocular surface is composed of the tear film, cornea, conjunctiva, eyelids, eyelashes, periocular skin, and the lacrimal system [2,3]. Breakdown or abnormalities of one or more of these structures impacts the integrity, function, and

protective capability of the eye. Furthermore, underlying ocular surface diseases serve as risk factors and can perpetuate other conditions that cause damage to the ocular system [1-3]. Damage to the ocular surface can cause pain, decrease visual acuity, and interfere with daily activities [4]. Effective management of this condition can minimize further injury and improve the patient's overall quality of life.

Punctal plugs are small medical devices that mechanically occlude the puncta of the upper or lower eyelids to prevent the drainage

Correspondence to: Oscar Chen, Department of Ophthalmology, Rush University Medical Center, Chicago, United States, Tel: 310-866-2776; E-mail: oscar_chen@rush.edu

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of tears into the nasolacrimal duct system. This helps to preserve the natural tear film on the ocular surface [5-11]. Punctal plugs can be temporarily or permanently inserted into the lower or upper puncta, unilaterally or bilaterally. This easy-to-implement and readily reversible treatment has been proposed as a relatively safe option for conditions such as dry eyes [12]. Punctal plugs can also prolong the effects of topical pharmacological therapy or when these treatment options are insufficient at improving ocular surface diseases [13].

Although there is increasing literature supporting the efficacy of punctal plugs, there is still debate as to whether punctal plugs conclusively improve ocular surface diseases in the long term [14]. This can be associated with the heterogeneity in the methodology used to study punctal plugs and the clinical outcomes defining successful therapeutic response. Furthermore, few studies have investigated how various ocular surface conditions respond to punctal plugs. This study aims to assess the clinical effectiveness of punctal plugs in the management of various ocular surface diseases.

MATERIALS AND METHODS

A retrospective chart review was conducted to determine the efficacy of punctal plugs in the management of ocular surface diseases. Patients who underwent punctal occlusion *via* punctal plugs for treatment of ocular surface diseases at the Rush University Eye Center Physician (RUECP) resident continuity clinic and University Ophthalmology Associates (UOA) private clinic were included in this study. Patients aged 18 years and older who underwent punctal occlusion with permanent silicone punctal plugs between January 2015 and May 2020, were included in the study. The baseline information included demographic data such as age and sex, as well as the clinic in which they were seen, provider implementing the plugs, indications for the plugs, and symptoms prior to the procedure. Providers range from residents in the academic continuity clinic to attending physicians in the private clinic. All of the implemented punctal plugs were the Oasis Soft Plug® (OSP) silicone plugs.

Clinical signs and symptoms were obtained by reviewing the medical charts during the first and final follow-up periods. The first follow-up was defined as visits within 60 days of punctal plug implementation. The final follow-up included visits between 180-365 days after punctal plug implementation. Patients were excluded if they were lost to follow-up within one year of the procedure. Symptoms assessed included eye pain, blurry vision, and dryness. The patient's perception of the overall improvement with punctal plugs was documented as subjective improvement. Clinical findings included Visual Acuity (VA) calculated as LogMar, Tear Break-up Time (TBUT), and Corneal Stain (CS). The location where punctal plugs were implemented was also recorded. The retention rates of punctal plugs during the first and final follow-ups were calculated. Complications associated with punctal plugs were recorded for each patient. Statistical analysis was performed using odds ratio analysis to determine the significance of the study parameters at the follow-up visits when compared to baseline. Of note, all patients were instructed

to continue using some form of artificial lubricant after the implementation of the punctal plugs.

RESULTS

Patient demographics and clinical indications for punctal plugs are shown in Table 1. Of the 754 patients eligible for the study, only 572 were included. Of the 572 patients, 385(67.3%) were from UOA, and 187(32.7%) were from ECP. The mean age was 62.2 ±16.2 years (range of 18-100 years). The most common indication for punctal plugs was dry eye syndrome (440, 79.5%), followed by exposure keratopathy (32, 5.6%), meibomian gland dysfunction (29, 5.1%), sjogren's syndrome (26, 4.5%), and neurotrophic keratopathy (19, 3.3%). The most common location of punctal plug placement was in the bilateral lower punctum (344, 60.1%) and only 14(2.4%) patients had occlusion of all four puncta. The average retention rates during the first follow-up were 75.6% and 70.7% at the final follow-up compared to baseline, respectively (Table 1).

Table 1: Baseline patient demographics along with clinical indications, locations, and retention rates of punctal plugs.

Characteristics	Range
Eligible patients	754
Included in the study	572
Excluded from the study	182
Department-n(%)	
UOA	385(67.3)
ECP	187(32.7)
Age(years)	62.2 ±16.2
Gender-n (%)	
Female	441(77.1)
Male	131(22.9)
Clinical indication-n(%)	
Dry eye syndrome	440(76.9)
Exposure keratopathy	32(5.6)
Meibomian gland dysfunction	29(5.0)
Sjogren's syndrome	26(4.5)
Neurotrophic keratopathy	19(3.3)
Other	26(4.5)
Punctal plug location-n(%)	
Only 1 plug	155(27.1)
2 plugs in 1 eye	35(6.1)
Bilateral lower lids	344(60.1)
Bilateral upper lids	11(1.9)
Complete occlusion	14(2.4)
3 plugs	9(1.6)
2 plugs other	4(1.0)
Retention rate(%)	
First follow-up	75.60%
Final follow-up	70.70%

Note: UOA: University Ophthalmology Associates; ECP: Eye Center Physician

There was a statistically significant improvement in two key symptoms of ocular surface diseases at the first follow-up when compared to baseline: eye pain (0.64, $p=0.02$) and blurry vision (0.70, $p=0.04$). Visual acuity also showed a statistically significant improvement during the first follow-up (-0.03, $p=0.01$). Eye pain was the only parameter that remained statistically significant at the final follow-up when compared to baseline (0.57, $p=0.03$). Subjective improvement (first follow-up: 0.82, $p=0.12$; final follow-up: 1.26, $p=0.19$ and dryness (first follow-up: 0.61, $p=0.36$; final follow-up: 0.64, $p=0.40$) did not show improvement in either follow-up period compared to baseline. None of the clinical findings associated with dryness, such as tear break-up time (first follow-up: 0.73, $p=0.11$; final follow-up: 1.48, $p=0.08$) and corneal staining (first follow-up: 0.95, $p=0.78$; final follow-up: 0.82, $p=0.34$), showed significant improvement during both follow-up periods when compared to baseline. When stratified by disease etiology, there was no significant difference in any of the parameters based on the clinical indication for plug placement. An outcome based on complete punctal occlusion could not be determined due to insufficient number of patients. There were no statistically significant differences in the clinical outcomes between providers, clinics and sex. The most common complications associated with punctal plugs were punctal plug extrusion (168, 29.3%) and epiphora (86, 15%), followed by eye irritation (82, 14.3%) (Table 2).

Table 2: Baseline patient demographics along with clinical indications, locations, and retention rates of punctal plugs.

Characteristics	Range
Punctal plug extrusion-n(%)	168(29.3)
Epiphora	86(15.0)
Eye irritation	82(14.3)
Punctal stenosis	9(1.6)
Punctal migration	7(1.2)
Plug prolapse	7(1.2)
Corneal ulceration	4(0.7)
Pyogenic granuloma	3(0.5)
Punctal extrusion	3(0.5)
Dacryocystitis	1(0.2)
Canalculitis	0(0.0)

DISCUSSION

In this retrospective chart review, punctal plugs provided clinically significant improvements in blurry vision and eye pain within 60 days of implementation. This is consistent with the existing literature which reports significant improvement with dry eye treatment at two months following punctal occlusion [15]. Only improvements in eye pain remained significant within one-year. While there was a statistically significant improvement in VA, a clinically relevant improvement was not seen, as the difference was minuscule. Additionally, the patients did not endorse an overall improvement in their ocular condition during the first and final follow-up period. Furthermore, when stratified by the most common indication within these two clinics, punctal

plugs did not confer improvements in any of the ocular surface disease symptoms. This signifies that punctal plugs may not be an efficacious stand-alone treatment option for various ocular surface diseases. Punctal plug extrusion was the most common complication and may account for the lack of efficacy in managing these ocular surface conditions. Other common adverse complications associated with punctal plugs include epiphora and eye irritation, as reported in previous studies [16].

The lack of clinical improvement of these ocular surface diseases to punctal plugs may reflect the mechanism of action of this treatment. The tear film is a distinct aqueous environment composed of a deep aqueous and mucin layer those transitions to a superficial lipid layer [17]. This thin layer of fluid produced by the lacrimal and meibomian glands provides homeostasis to the ocular surface by eliminating harmful substances and providing nutrients to the avascular cornea. However, the tear film can also contain foreign particles as well as proinflammatory cytokines produced when the ocular surface is damaged [18,19]. By blocking the outflow of tears, punctal plugs can paradoxically worsen various ocular surface diseases by preventing the drainage of these harmful substances. Thus, the buildup of these proinflammatory cytokines and foreign material can exacerbate the symptoms and corneal disease severity associated with these ocular conditions [20-22]. This could explain how the various ocular surface conditions that were assessed failed to respond to punctal plugs.

This study has several limitations. First, given the retrospective nature of our study, there was no standardized method to evaluate clinical findings, such as TBUT and corneal staining. The TBUT and corneal staining results were categorized as normal or abnormal by some providers. Due to the lack of standardization across reporting outcomes, further stratification of these parameters could not be evaluated. Another limiting factor was the small sample size of the patients with complete punctal occlusion. This prevented us from fully assessing the efficacy and complications of punctal plug therapy. Future studies should include a large enough sample size to provide sufficient statistical power to appropriately analyze clinical outcomes.

CONCLUSION

In conclusion, punctal plugs offer a simple and effective treatment for improving blurry vision and eye pain associated with various ocular surface diseases. Punctal plugs were shown to improve two key symptoms related to various ocular surface diseases as early as 60 days after installation. Although punctal plugs offer a fast and reversible treatment for some key symptoms of ocular surface diseases, plugs alone may not effectively treat all associated symptoms of these complex conditions and benefit from adjuvant therapy. Patients should be informed that while punctal plugs may not treat the entire spectrum of symptoms associated with ocular surface conditions, they may improve certain aspects of their condition. Thus, punctal plugs can be offered to patients as a potential treatment option with the understanding that they may also benefit from supplemental therapy for a more comprehensive ocular surface disease management.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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