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Original Research Article

Role of punctal plugs as a primarily treatment modality in moderate to severe dry eye

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ABSTRACT

Background: In dry eye syndrome tear film disrupts which lead to ocular discomfort. Treatment of dry eye is very challenging and time consuming. Multiple treatment options are available for treating dry eye and one of them is punctal plugs. It blocks the drainage of tear by occluding puncta which helps in the preservation of natural tears on the ocular surface and relieve dry eye symptoms. This study was conducted to assess the safety and efficacy of punctal plugs as a primary treatment modality in moderate to severe dry eye.
Methods: Fifty patients were included in this study and they were divided into two groups. In group A which included 25 patients punctal plugs were inserted and in group B (25 patients or 50 eyes) artificial tear drop was prescribed. The primary treatment outcome was the improvement in dry eye symptoms and secondary outcome was Schirmer test score, tear break up time and rose bengal staining score.
Results: There was drastic improvement in dry eye symptoms in group A (punctal plugs) compared to group B (artificial tear group). Schirmer test score, tear break up and rose bengal staining score also improved in punctal plug group.
Conclusions: This study has shown that punctal plug can be used as a primary treatment modality in moderate to severe dry eye as it improves greater symptomatic relief and also improves the condition of damaged ocular surface.

Keywords: Punctal plug, Dry eye, Artificial tears, Symptoms

INTRODUCTION

Dry eye is a most common eye condition for which patients seek ophthalmic care as it impairs quality of life and it affects the physical, social and mental well being of the patients. Dry eye is a tear film dysfunction involving a plethora of ocular discomfort varying from itching, burning sensation to photophobia and pain.[1] Dry eyes can be a natural result of aging, low tear production, improper tear composition, due to effect of certain topical eye medications, certain diseases such as rheumatoid arthritis and diabetes and various surgical procedures in the eye. Basically, two mechanisms are involved in dry eye pathology. Either it can be due to increased tear evaporation or decreased tear production and sometimes both the mechanisms are involved in pathology.[2]

The treatment of dry eye depends on its severity and comprises a large number of therapeutic strategies. Principle of management of dry eyes aimed at supplementing and preserving or conserving existing tears. Supplementation is done by artificial tear which is the most common therapy for dry eye. However, the artificial tears provide only temporary and incomplete symptomatic relief. In addition to this, the long term topical treatment of dry eye syndrome is costly as patients affected with this clinical condition frequently have to administer drops. Hence to overcome these

shortcomings punctal plugs were introduced way back in 1970. Punctal plugs basically block punctal ducts which reduce tear drainage and thus retain moisture in the eye, bringing long lasting relief to the dry eye patients. Punctal plugs insertion is a simple, effective, safe and provides reversible treatment for dry eye patients. Punctal plugs are non invasive, swift to insert and offer cost effective solution for dry eye patients seeking relief.[3]

Though an approved technique for treating dry eye patients, very limited studies are currently available regarding the use of punctal plugs as a primary treatment modality in moderate to severe dry eye patients among both among Indian and western population.[4] Hence, this study was conducted to evaluate the safety and efficacy of punctal plug as a primary treatment modality in dry eye patients on Indian population and to find out the differences between artificial tears and punctal plugs with respect to their influence on dry eye symptoms and tear film quality.

METHODS

The study design was prospective interventional study carried out over a period of 06 months in the eye department of a tertiary care centre. A total of 50 patients diagnosed with moderate dry eye in our out patient department from Jan 19- June 19 were enrolled in this study after taking informed consent. The diagnosis of dry eye was made on the basis of symptoms of dry eye, Schirmer test 1 result of less than 05 mm without anaesthesia, tear break up time less than 10 sec, Rose Bengal score 3.[5-10] Patients with prior ocular surgery, with history of using topical ocular medication and prior experience with punctal plug were excluded. At the baseline all patients were asked certain set of questions related with dry eye such as itching or burning, sandy or gritty sensation, redness, blurring of vision, ocular fatigue or excessive blinking. All patients were also subjected to baseline comprehensive ophthalmic evaluation which included best corrected visual acuity, slit lamp examination, Schirmer test, tear film break up time with fluorescein dye, rose bengal staining of the cornea and conjunctiva and dilated fundus examination.[8-10]

After completion of the baseline examination all patients were divided into two groups. In group A (25 patients or 50 eyes) punctal plugs were inserted in both superior and inferior punctum and in group B other (25 patients or 50 eyes) artificial tear eye drops (preservative free) 06 times a day were started. For patients who received punctal plug, in these patients each punctum was measured and an appropriately sized temporary plug was inserted under topical anaesthesia (small: 0.3-0.6 mm, medium: 0.6-0.8 mm, large: 0.9 mm).

The primary outcome measure was the change in subjective symptoms of dry eye. A score of 0-3 was assigned to the common symptoms of dry eye such as burning sensation, itching, sandy or gritty sensation, ocular fatigue and blurring of vision. When absent (0), sometimes present (1), frequently present (2) and always present (3). The secondary outcome measures were the Schirmer test for tear production, tear break up time, the rose bengal score as a measure for ocular surface integrity. Subjects were seen on first day after allocating them into artificial tears group and punctal plug group and then at 2 weeks,1 month,3 months,6 months. At each visit all patients underwent detailed ocular examination which included best corrected visual acuity, slit lamp examination, Schirmer test, tear break up time test and rose bengal staining. After 2 weeks patients in whom temporary punctal plugs were inserted, they were asked about punctal plug related discomfort. Permanent silicon plug was inserted in patients who had no complaints with temporary punctal plug. Results were collated and analyzed after six months of starting the treatment. Statistical analysis was done by using Epi Info version 3.4.3 and by entering the collected data in Microsoft excel 2007. Descriptive statistics such as proportion, mean and standard deviation were calculated. Student t test was used as test of significance. P value <0.05 was considered as statistically significant.

RESULTS

All 50 patients (100 eyes) completed the study and reported in the department for follow up on regular basis. In the punctal group there were 32 females and 18 males. The age of patients in this group ranged from 40years to 62 years with average age being 50.5 years. There were 32 females and 18 males in the artificial tear and punctal plug group combined. Patients who received punctal plug, no loss of punctal plug occured during the study. In artificial tear group there were 29 females and 21 males. The age of patients in this group ranged from 42 years to 65 years with average age being 48.6 years.

After one month of instituting treatment, there was drastic improvement in dry eye symptoms in group A patients in whom we inserted punctal plug compared to artificial tear group (Table 1). 80% of the symptomatic patients were asymptomatic and 20% had mild to moderate improvement in symptoms in the plug group. Where as in artificial tear group 60% of the symptomatic patients were asymptomatic and 40% had mild to moderate improvement in symptoms. After 03 and 06 months the same pattern was noticed.

Schirmer test

Mean Schirmer scores at baseline ranged from 4.5 to 5 mm/5 min between the 2 treatment groups (Table 2). After 01 month, both the artificial tear and plug groups showed statistically significant improvement relative to baseline ($p<0.005$). Initial response was good in the both group, however Schirmer score continued to improve over the course of the study in the punctal group but in the artificial tear group after initial improvement Schirmer scores did not change at 03 and 06 months visit (Table 2).

Table 1: Change in symptoms score post-intervention.

Change in symptoms	Baseline	1 month	3 months	6 months
Punctal group	03	20-0	23-0	23-0
		05-01	02-01	02-01
Artificial tear group	03	15-0	15-0	15-0
		05-02	05-01	05-01
		05-01	05-01	05-01

Table 2: Outcome of Schirmer test post interventions.

Group	Schirmer test			
	Mean±SD			
	Baseline	1 month	3 months	6 months
Punctal plug	5±0	6.56±1.24	6.56±1.24	6.54±1.25
Artificial tear group	5±0	5.6±0.80	5.62±0.81	5.62±0.81

P<0.0001.

Table 3: Improvement in rose bengal staining score in punctal group and artificial tears treated eyes.

Group	Rose bengal staining score			
	Mean±SD			
	Baseline	1 month	3 months	6 months
Punctal plug	3±0	1.76±0.87	1.76±0.87	1.76±0.87
Artificial tear group	3±0	2.2±0.76	2.2±0.76	2.2±0.76

P<0.0001.

Table 4: Tear breakup time in punctal plug group and those treated with artificial tears.

Group	Tear breakup time			
	Mean±SD			
	Baseline	1 month	3 months	6 months
Punctal plug	<10 sec	13.32±1.88	13.32±1.88	13.32±1.88
Artificial tear group	<10 sec	11.64±2.23	11.64±2.23	11.64±2.23

P<0.0001.

Rose bengal staining

The mean staining grade at baseline ranged from 2.0 to 2.3 between the treatment groups, corresponding to staining of both the nasal and temporal conjunctiva (Table 3). Although no statistically significant changes from baseline were seen in any group at the one month visit (Table 3), but the punctal group experienced significant improvement in staining by the 3-month visit (66%). At 6 months, in the punctal group 80% showed improvement in staining score whereas in artificial tear group 40% showed improvement.

The tear break up time improved significantly in both groups but the improvement was greater in groups in patients who received punctal plug (Table 4).

Few patients complained of mild irritation and discomfort after plug insertion in the initial few days which got over a period of one month. No other adverse effects of the treatments were noted during the study.

DISCUSSION

Dry eye patients in present scenario want freedom from eye drops and get rid off from their symptoms as early as possible if they can afford to. To provide a long term solution to patients affected with dry eye, the punctum plug was introduced.[11] It treats dry eye by stopping the drainage of tears through the punctum. Tears are produced as a natural part of body's eye cleansing and lubrication. Almost 25% of these tears are lost to evaporation, while the remaining tears drain from the eyes through the lacrimal punctum and finally they drain through the nose via the nasolacrimal duct. Punctal plug blocks the punctum, hence restrict the drainage of tears and maintains a high level of moisture in the eye. The procedure is minimally invasive and provides a long term solution to costly, ineffective and troublesome lubricating eye drops in dry eye patients.[12-16] Although the punctal plugs have in market since 04 decades, but they are recommended in severe dry patients when they have not responded to lubricating eye drops. In addition to this, there are very few prospective studies regarding the use

of punctal plug as a primary treatment modality in moderate dry eye patients. Ours is a prospective interventional study to assess the role of punctal plug as a primary treatment modality in dry eye patients among Indian population. Outcome measures which were analyzed included improvement in dry eye symptoms, change in Schirmer test reading, tear break up time and rose bengal score.

In our study at one month post-intervention, there was an improvement in symptoms score, (Table 1) in both groups, however there was a significant improvement in the plug group. The study showed the same pattern after 03 and 06 months. This finding is in accordance with Nava-Castaneda et al (compared collagen and silicone punctal plugs to sham treatment in 61 patients with dry eyes) which found significant improvement of symptoms such as dryness, itching and burning at four and eight weeks among patients with occluded puncta. The investigators also observed a 93% reduction in conjunctival findings and 91% reduction in the use of adjunctive artificial tears among those treated with silicone and collagen plugs at eight weeks post-implant.[17] Mansour et al also reported improvement in symptoms in 74% of eyes at four weeks.[18,19]

Ocular surface health evaluation in this study was done by using rose bengal score. Our study reported improved rose bengal score in the punctal group after one month of intervention which was statistically significant ($p<0.001$) in contrast to the artificial tear group ($p=0.250$) which remained same after 03 and 06 months. The study done by Mansour et al reported significant improvement in both rose bengal score treated with punctal occlusion compared to untreated contralateral eyes.[17] Their sample size, however, was limited to 13 patients after excluding 6 participants who suffered spontaneous plug loss and one who developed an inflammatory reaction to the plug material. Nava-Castaneda et al found differences in fluorescein ocular surface staining scores at two, four, and eight weeks follow-up among participants receiving collagen and silicone punctal plugs compared to those receiving sham occlusion (scores of 0: absent to 4: severe) with active treatment participants showing reduced staining. The mean±standard deviation scores were 1.3±0.8 collagen/silicone; 2.1±0.9 sham; $p=0.001$, t test at two weeks; 0.7±0.7 collagen/silicone; 2.1±1.0 sham; $p<0.001$, t test at four weeks, and at eight weeks 0.2±0.4 collagen/silicone; 1.7±1.0 sham; $p<0.001$, t test.[16]

In our study we found in the plug group there was a statistically significant improvement in the tear breakup time scores at one month (from baseline) as compared to artificial tear group. Altan-Yaycioglu et al also reported improvement in tear break up time with the plugs in place.[20]

Both the treatment regimens increased tear volume over the course of the study. However, at 1 and 3 months, regimens that included punctal plugs were superior to artificial tear group in improving Schirmer scores. A study conducted by Weiqiang et al on 56 consecutive eyes showed the Schirmer 1 test result of the plug group improved significantly and were significantly more improved than those in the artificial group, confirming the efficacy of the plug in maintaining tear volume.[1] Farrell et al showed that treatment with collagen punctal plugs improved tear status in aqueous-deficient dry eyes. This effect was seen when occluding either the lower puncta only, or after insertion of collagen plugs in both the lower and upper puncta. Nevertheless, since no sham group was used in the study, treatment efficacy of punctal occlusion must be inferred from comparisons to baseline measurements.[21] Burgess et al reported similar subjective and objective improvement in dry eyes treated with either silicone or acrylic punctal plugs.[22] A lack of a sham/no treatment group, however, limits the study's interpretability to pre- and post-treatment comparisons. These results are consistent with the known function of punctal occlusion in physical conservation of existing tears.

In our study we encountered plug related complication only in 5% of cases like epiphora, foreign body sensation and pain but for this we did not remove punctal plug in any patient.

The limitation of this study is that data from larger population are needed to further analyze the role of punctal plug as a primary treatment modality in dry eye patients.

CONCLUSION

This study has shown that punctal plug therapy not only provides greater symptomatic relief to dry eye patients but also improves the health of damaged ocular surface in these patients. The study has confirmed that plugs increase the tear volume and has a better effect on stabilizing tear film compared to lubricating eye drops. The complications associated with this therapy are minimal which is easily tolerated by most of the patients. The procedure of implanting plugs is simple, safe, not time consuming and reversible. It is a one time procedure and produces good result without costing a lot of money to dry eye patients and hence it has an edge over expensive lubricating eye drops.

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