

# Long-Term Retention Rates & Benefits of Painless Punctal Plug F Insertion in Patients with Dry Eye

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## INTRODUCTION:

Dry Eye affects many people and is due either to a deficiency in tear production or an increase in tear evaporation. Clinical presentation varies widely, from mild tearing and foreign body sensation to severe ocular discomfort leading to keratopathy and potential visual impairment. Conservative therapy includes use of artificial tears and other pharmacologic drops, warm compresses and lid hygiene. Although the most commonly used therapy for dry eye is instillation of artificial tears, the improvement in symptoms is short-lived, because the tears evaporate and drain through the lacrimal outflow system.

The efficacy of punctal occlusion in treatment of dry eyes is well known<sup>1,2</sup>. Punctal plugs are often used in refractory cases of dry eyes in order to occlude the tear drainage opening to increase the strength of the tear film. Punctal occlusion results in several immediate advantages. Increasing the tear lake volume provide aqueous support and prolongs the duration and amount of contact between the corneal epithelium and local growth factors and immunomodulatory cytokines<sup>3</sup>. There are also a number of ocular conditions that have been shown to benefit from occlusion as well<sup>3</sup>. Punctal plugs are available in absorbable and non-absorbable materials. There are numerous variations in the designs to facilitate ease of insertion and prolong its retention<sup>3</sup>.

Although widely acknowledged as a safe, effective and reversible means of punctal occlusion, complications occur with use of punctal plugs. Migration, infection and spontaneous loss are the most common. There have been recent modifications to the component sections and materials have improved comfort and fit while minimizing risks of spontaneous loss, extrusion or downward migration<sup>3</sup>.

## OBJECTIVE:

To evaluate the retention rates and benefits of Painless Punctal Plug F placed in patients diagnosed with dry eye.

## METHODOLOGY:

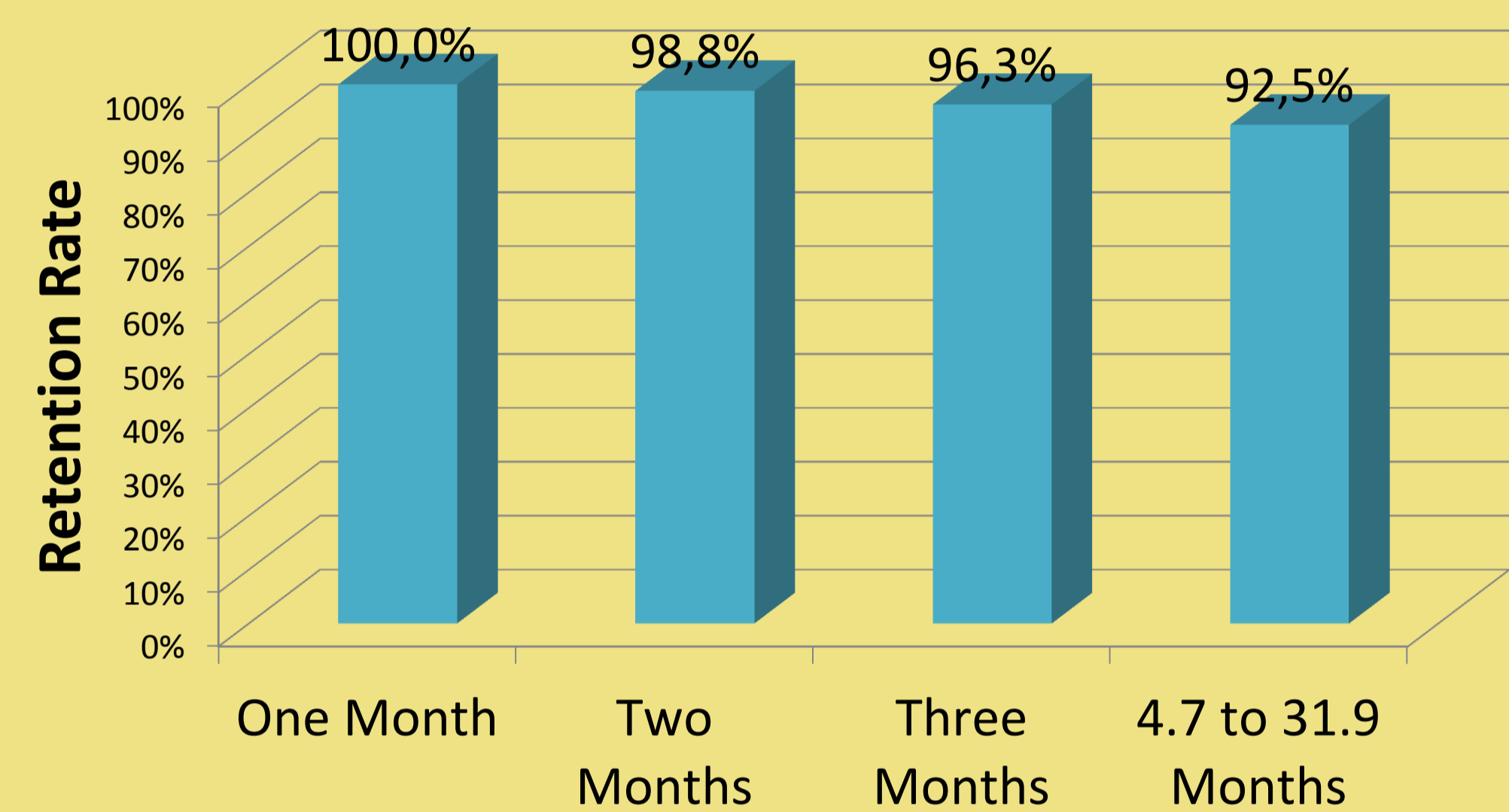
Patients diagnosed with dry eye at the Javate Lacrimal, Orbital and Oculofacial Plastic Surgery Clinic, University of Santo Tomas Hospital, University of Santo Tomas, Espana, Manila, Philippines were included in this study. The diagnosis of dry eye syndrome was given if the patient complained of burning, dryness, itchiness and tearing, and by getting the Schirmer test with anesthesia, Schirmer test with nasal stimulation, Tear break up time (TBUT) and Rose bengal test. A total of 40 patients were selected and enrolled in the study. **Painless Punctal Plug F**, a punctal plug developed by **FCI (FCI, 20-22 rue Louis Armand, 75015 Paris France)**, made of medical grade silicone material and FDA approved for commercial distribution were used. A total of 80 plugs were inserted.

Data collection began from January 2010 to March 2013. Informed consent was obtained from patients selected. All plugs were placed by a single medical assistant with an Oculoplastic surgeon checking placement after the procedure was completed. All punctal plugs were placed in the lower punctum of both eyes for uniformity. No topical *anesthesia was instilled. No punctal dilation was done.* After insertion, patients were followed up after one month for the assessment of dry eye parameters For the retention rates, patients were followed up after one month, two months, three months, and after a mean of 1.1 year (range, 4.7 to 31.9 months). Paired and Wilcoxon Signed Rank Tests were used to determine significant improvement of the dry eye parameters. Student's t-tests and Mann-Whitney Tests were used to compare the significant improvements of patients with Sjogren (SS group) and Non Sjogren syndrome (NSS

group) on the Schirmer tests, Tear break up time and Rose Bengal test before and after the punctal plug insertion. P-values of <0.05 indicate significant improvement.

## RESULTS:

Retention rates of patients with mean age of 58.6 years (range, 25 to 87) were 100% after one month, 98.8% after two months, and 96.3% after three months. A total of 74 (92.5%) punctal plugs were intact after a mean of 1.1 years (range, 4.7 to 31.9 months). Spontaneous loss of three (3.8%) punctal plugs were observed from three patients after two, four and seven months, while three punctal plugs (3.8%) were removed from two patients after three and five months due to local discomfort. There was a significant improvement in all the dry eye parameters.



**92.5% retention rate after a mean of 1.1 years (range 4.7 to 31.9 months)**

## Discussion:

Unlike previously designed silicone punctal plugs which has a conical head with a diameter of 1.4 mm which will necessitate prior dilation of the punctum before it can be inserted into the vertical section of the canaliculus which can cause damage to the fibroelastic punctal ring<sup>4</sup>, the Painless Punctal Plug F are preloaded in a stretched position with an extended, rounded end 0.3-0.4 mm which can enter the vertical section of the canaliculus without requiring prior dilation of the punctum. When released from the plug inserter, the plug resumes its natural expanded shape 1.2 mm in diameter which allows it to fit snugly in place and prevents plug pop-out. Once inserted, no cap protrudes to potentially irritate or scratch the patient's cornea.

Possible reasons for spontaneous extrusion of Painless Punctal Plug F in our study could be due to Pyogenic granuloma which has been known to occur at sites of chronic irritation and recent injury and mechanical stress on the canaliculus which may lead to injury and erosion of the epithelium and plug extrusion and Poor application of the collar to the punctal surface may contribute to plug displacement from traction forces created by eye rubbing or pressure forces induced by blinking movement<sup>5</sup>.

In summary, the following are the benefits of Painless Punctum Plug F, more comfortable for the patients, it has an ultra thin collarette, soft and round bulb for optimal comfort. May not need anesthesia based on patient's pain threshold and pain-free for the patient because no dilation is required

Easier for the ophthalmologist, because Plug is preloaded in an innovative design inserter, thus faster insertion, has a "one-size-fits-all" design for small & medium puncta, reversible easy to remove using forceps and no need for dilation prior to insertion

## Conclusion:

This study showed that Painless Punctal Plug F has a very high retention rate. Its one-size-fits-all design for small to medium puncta and extended round end that fits snugly inside the punctum make punctum dilation and inventory of multiple sizes of plugs unnecessary. The soft round bulb prevents plug pop-out which has led to a very high retention rate up to 31.9 months. Moreover, patient have improved dry eye symptoms.

## References:

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