

# Silicone perforated punctal plugs for the treatment of punctal stenosis

## Tampões perfurados de silicone no tratamento da estenose do ponto lacrimal

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**ABSTRACT | Purpose:** Punctal stenosis can result in symptoms such as epiphora and can significantly reduce the quality of life of patients. Perforated punctal plug insertion is an easy procedure that is commonly used as the first step of treatment for punctal stenosis. **Methods:** Clinical, demographic, and outcome data were retrospectively collected for 54 eyes of 21 males and 11 females who consecutively presented to our Oculoplastic Clinic and underwent silicone Micro Flow perforated punctal plug insertion. All patients had epiphora with punctal stenosis. **Results:** Of the 54 plugs, 26 plugs (48.1%) were lost and 28 (51.8%) stayed in place. Of the latter, eight were explanted because of the occlusion of the plug with secretions and recurrent conjunctivitis; moreover, two plugs migrated deep into the vertical canaliculus. Of the 54 plugs, only 18 (33.3%) were well-tolerated with significant symptomatic improvement. **Conclusion:** Plug loss is a prominent problem in patients implanted with perforated punctal plugs. Silicone punctal plugs failed in 66.7% of our patients over a mean follow-up of 14.2 months.

**Keywords:** Stenosis; Silicone, Lacrimal apparatus diseases; Punctal plugs

**RESUMO | Objetivo:** A estenose punctal pode resultar em sintomas como a epífora e diminuir significativamente a qualidade de vida dos pacientes. A inserção de um tampão perfurado é um procedimento fácil que é comumente usado como o primeiro passo do tratamento para a estenose punctal. **Métodos:** Dados clínicos, demográficos e de resultado foram coletados

retrospectivamente de 54 olhos de 21 homens e 11 mulheres que consecutivamente se apresentaram em nossa Clínica de Oculoplástica e foram submetidos a inserção de um tampão de silicone perfurado Micro Flow. Todos os pacientes tinham epífora com estenose punctal. **Resultados:** Dos 54 tampões, 26 (48,1%) foram perdidos e 28 (51,8%) permaneceram no local. Destes últimos, 8 foram removidos devido a oclusão do tampão com secreção e conjuntivite recorrente, além disso, 2 migraram profundamente no canalículo vertical. Dos 54 tampões, apenas 18 (33,3%) foram bem tolerados com significativa melhora dos sintomas. **Conclusão:** A perda de tampões é um problema de destaque em pacientes implantados com tampões perfurados. Tampões de silicone falharam em 66,7% dos pacientes durante um seguimento médio de 14,2 meses.

**Descritores:** Estenose; Silicone; Doenças do aparelho lacrimal; Plug lacrimal

## INTRODUCTION

Acquired punctal stenosis can result from infectious or inflammatory eyelid disorders, ocular surface diseases, systemic or topical medication use, eyelid tumors, and traumas. Complete congenital occlusion of the external punctum is known as punctal agenesis. Both punctal stenosis and punctal agenesis can be accompanied by canalicular or common canalicular ductal stenosis or may be isolated<sup>(1)</sup>.

The punctum comprises fibrous tissue that surrounds the entrance in a ring form, functioning as a sphincter<sup>(2)</sup>. The shape of the punctum is circular in childhood and becomes oval as the individual ages. The size of a normal punctum is 0.2-0.5 mm, and individuals with puncta smaller than this size are referred to have punctal stenosis<sup>(3)</sup>. The incidence of punctal stenosis has not been determined in large population-based studies; however, rates ranging between 8% and 54.3% have been reported in some relatively small studies<sup>(4-6)</sup>.

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Perforated punctal plugs (PPPs) have been successfully utilized in the treatment of punctal stenosis since 1989. These plugs have a central lumen allowing some tear flow through the plug<sup>(7)</sup>. The advantage of punctal plug implantation over surgery is that the lacrimal sphincter is preserved and the risk of re-stenosis that can occur because of wound healing after punctal snip procedures is not encountered.

PPP implantation is an easy procedure that can be performed in the clinic under topical anesthesia following the dilation of the punctum using a probe and letting the plug stay in place for some time. However, the efficacy of the procedure is still debatable, and the results observed till date may be temporary.

Most PPPs are made from silicone and polyvinylpyrrolidone (PVP)-coated silicone<sup>(7,8)</sup>. The Micro Flow (BVI,UK) punctal plug is a partial silicone occluder that is used for relieving symptoms of dry eye (Figure 1). The central patent lumen in the plug additionally allows for its use in punctal stenosis. It is available in three sizes, small (0.4-0.55 mm), medium (0.55-0.7 mm), and large (0.7-0.85 mm), with the values corresponding to the punctum size.

This study aimed to investigate the outcome and success of Micro Flow (BVI, UK) silicone PPP implantation in patients with punctal stenosis.

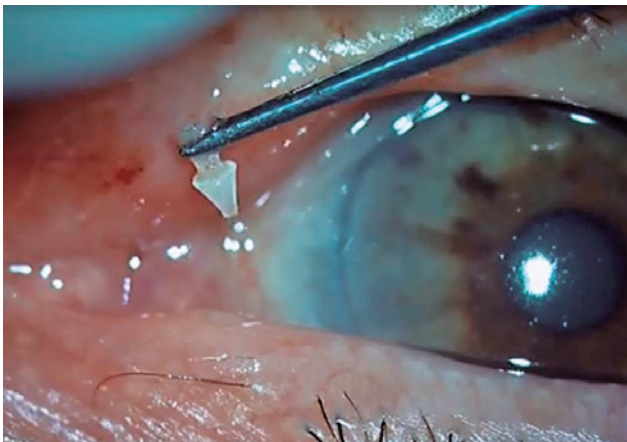
## METHODS

This study was approved by the Research Ethics' Committee of the Canakkale Onsekiz Mart University and was conducted in accordance with the Declaration of Helsinki of the World Medical Association regarding scientific research on human subjects.

Clinical, demographic, and outcome data were retrospectively collected for 54 eyes of 21 males and 11 females who consecutively presented to our clinic with epiphora and required dabbing for more than five times a day (epiphora was classified using the Munk scores of 3-5)<sup>(9)</sup>. Patients with other causes of epiphora such as punctal malposition, lower eyelid laxity, and dry eye were excluded from the study. Further, patients with canalicular or nasolacrimal duct obstruction or a history of prior eyelid or lacrimal drainage surgery were also excluded. Complete slit-lamp examinations, fluorescein dye disappearance test, punctal dilatation, lacrimal irrigation, and eyelid evaluation were preoperatively performed.

Punctal stenosis was graded as defined by Kashkoui et al.: grade 0, no visible punctum; grade 1, papilla covered with a membrane; grade 2, papilla is small but recognizable; grade 3, normal and easily recognized; grade 4, slit <2 mm; grade 5, slit >2 mm. Patients were included in the study if they had punctal stenosis of grades 1 and 2<sup>(10)</sup>.

All procedures were performed under topical anesthesia on an outpatient basis. After applying topical anesthesia using proparacaine chloride, the punctum was defined using a punctal finder, and punctal dilation and probing and irrigation were performed using a 26G lacrimal cannula in the operating room. Patients with canalicular membranous stenosis or a soft stop that could not be overcome were excluded from the study. Large-sized silicone plugs (punctum size, 0.7-0.85 mm) were implanted using their own preloaded inserter. The final position of the plug was checked to ensure an appropriate fit within the lid margin (Figure 2). Postoperatively, topical antibiotics and steroid eye drops were administered for 1 week.



**Figure 1.** Micro Flow (BVI,UK) silicone punctum plug.

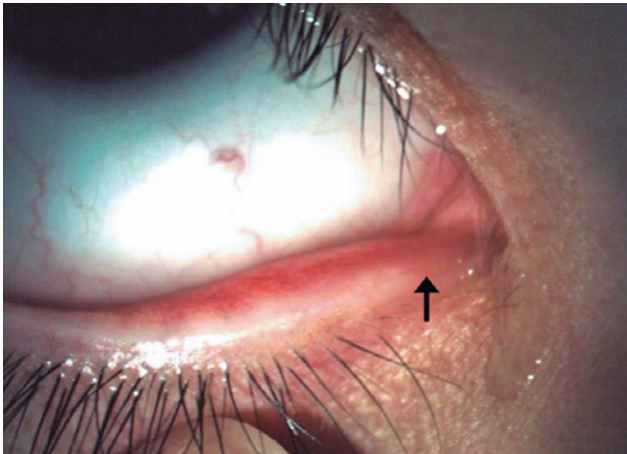


**Figure 2.** Position of the implanted punctum plug.

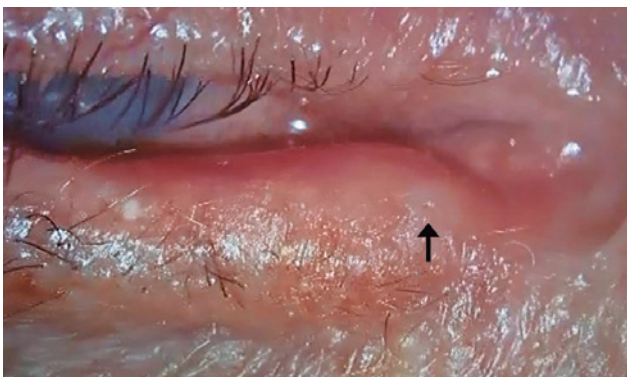
Patients were followed up on the first day, first month, third month, sixth month, and first year after implantation, with a mean follow-up time of  $14.2 \pm 3.7$  months.

## RESULTS

Thirty-two patients with a mean age of  $63.5 \pm 18.1$  years (range: 18-84 years) were included in this study. Twenty-one (65.6%) patients were male, and 11 (34.4%) were female. Bilateral inferior puncta were found in 20 (62.5%) patients, unilateral inferior puncta were found in 10 (31.3%) patients, and all four puncta were involved in two (6.3%) patients. Only inferior puncta were included in our study. Twenty-five (46.2%) puncta were in the right eye, and 29 (53.8%) were in the left eye. Forty-one (75.9%) eyelids (24 patients) had variable degrees of blepharitis, and all underwent lid hygiene treatments before and during plug therapy. All patients had permanent epiphora, with a mean duration of  $11.6 \pm 9.3$  months and a need for frequent wiping (Munk scores 3-5).



**Figure 3.** Grade 1 punctal stenosis; the punctum is hardly visible and is covered with a membrane



**Figure 4.** Grade 4 punctal stenosis; the punctum is visible but smaller than normal size.

In the preoperative examination, the fluorescein dye disappearance test took longer than 5 min in all eyes. Bio-microscopic evaluation showed that 23 (42.5%) puncta had membranous closure (Grade 1, Figure 3) and 31 (57.5%) eyes had a punctum diameter smaller than normal (Grade 2, Figure 4). Although correct care information was given for wiping and face washing, at the 1-month follow-up, 10 plugs had fallen out. At the 3-month follow-up, nine more had fallen out. By the sixth month, eight more had been lost. Thus, by the sixth month, of the 54 plugs, 26 plugs (48.1%) had fallen out (two were in the canaliculus) and only 28 (51.9%) had stayed in place.

Of the 28 plugs that had stayed in place, eight were explanted because of occlusion of the plug, with secretions and recurrent conjunctivitis. Of the 54 plugs, only 18 (33.3%) were well-tolerated and explanted at 6 months without epiphora with a mean follow-up of  $14.2 \pm 3.7$  months.

The mean age of the patients with a successful outcome was 44.1 years, compared to 65.3 years for those with an unsuccessful outcome ( $p=0.002$ ). Seventeen (94.4%) of the 18 symptom-free puncta belonged to patients younger than 60 years, and one (5.6%) punctum belonged to a patient over 60 years of age ( $p=0.0001$ ). Nine (25%) of the 36 unsuccessful plug implantations were in patients younger than 60 years, and 27 (75%) were in patients over 60 years ( $p<0.001$ ).

The most common complications were re-stenosis in 36 cases (66.7%) and early extrusion in 24 (44.4%). No granuloma formation was encountered.

At 14.2 months, the overall success rate for silicone PPP implantation was 33.3%.

## DISCUSSION

The success rates reported for PPP implantation in the literature for punctal stenosis are quite high, ranging 75-88.9%<sup>(8,11,12)</sup>. Chang et al. reported 100% anatomical and 85% functional success<sup>(13)</sup>. In the present study, only 18 (33.3%) of the 54 silicone plugs were well-tolerated, and significant symptomatic improvement was observed at a mean follow-up time of  $14.2 \pm 3.7$  months.

Our results were not consistent with those in the literature. This may be because of various reasons.

### Puncta diameter measurement

Textbook parameters for punctal diameter range from 0.2 to 0.5 mm<sup>(1,3,14,15)</sup>. However, some authors define punctal stenosis as a diameter smaller than 0.3 mm or puncta that cannot be intubated using a 26G cannula with an outer diameter of 0.47 mm<sup>(16)</sup>.



In the present study, we utilized Kashkouli et al.'s grading system, which is based on the punctal shape and size on slit-lamp examination as well as on the ease of introducing a punctal dilator<sup>(3,10)</sup>. This method, although examiner-dependent, appears to be the most clinically applicable method.

Mandelkorn developed a series of punctal gauges (Mandelkorn Gauge/Dilator system; Eagle Vision) for measuring punctum size. He suggests using these dilators to measure the punctum size accurately<sup>(17)</sup>. However, although specific probes have long been commercially available for this purpose, this measurement is not routinely performed. Additionally, while inserting the probe, it is very likely that the punctum will expand during insertion, leading to dilation of the opening, and thus, inaccurate measurement of the opening as larger than it is.

In a prospective study with 150 patients, the mean diameter of the lower puncta was 0.1 mm, with no gender predominance<sup>(18)</sup>. Recently, an OCT study of puncta by Allam et al. showed a mean inner diameter of the lower puncta of  $233.7 \pm 138.7 \mu\text{m}$ <sup>(19)</sup>. Three OCT studies reported conflicting mean outer puncta diameters, with Wawrzynski et al., Riham et al., and Timlin et al. reporting mean diameters of 247, 412.2, and 615  $\mu\text{m}$ , respectively<sup>(19-21)</sup>. This variation might have been caused by differences in the study samples, with different races and age ranges in the three studies, or possibly because of measurement using different OCT devices. Further, the exact alignment of the axis of the infrared beam used in OCT onto the punctum and canaliculus is essential to reach to the highest punctal size.

Even if measurement was objective using OCT, it is still difficult to define a clear cut-off value for normal puncta size or a cut-off value for defining stenosis, as well as defining the size of the plug to be inserted. Normative values for different populations and ages are needed to define appropriate cut-off values.

### Punctum plug size

The silicone plug used in this study is available in three sizes: small (0.4-0.55 mm), medium (0.55-0.7 mm), and large (0.7-0.85 mm). We used the large-sized plug in the study. Kaido et al. attributed spontaneous plug loss to the use of plugs that are bigger for the punctum in patients with plug implantation to treat dry eye<sup>(22)</sup>. Because we used Kashkouli et al.'s grading system and did not measure the punctum diameter using objective methods such as OCT, the discordance between the punctum diameter and plug size could have caused the plugs to fall out early<sup>(10)</sup>.

Conversely, in another study, Kaido et al. suggested using plugs one size bigger than the measured punctal size to prevent plug migration into the canaliculus<sup>(23)</sup>. In our study, two plugs (3.7%) migrated into the canaliculus, which might have resulted from implants smaller than the punctum diameter. However, there are no custom-made plugs available in the market. Some manufacturers make two sizes (small and large) of plugs, whereas others make three (small, medium, and large), and these sizes may not be suitable for all patients. These results suggest that large-sized plugs can lead to early plug loss; plugs that are the same size as or smaller than the punctum may be candidates for canalicular migration.

### Age

Age has been reported in several studies as being a leading cause of punctal stenosis<sup>(3,24,25)</sup>. Involutional changes, such as eyelid laxity and external lacrimal puncta, can cause the punctum to close. Further, horizontal laxity can cause the external punctum to be unopposed to the tear meniscus, leading to drying and the closure of the aperture with epithelization<sup>(3)</sup>.

Kashkouli et al. reported that the mean age for punctal stenosis diagnosis in their series was 69.4 years.<sup>(3)</sup> Kaido et al. also suggested that old age and lid laxity may be contributing factors, along with the plug size<sup>(22)</sup>. Of our patients, 80% were over 60 years old, and the patients whose treatment failed were older than those whose treatment was successful. Chang et al. reported that their patients whose procedures failed were older (67.7 vs. 36.8 years,  $p=0.019$ )<sup>(13)</sup>.

### Chronic blepharitis

Chronic blepharitis is another common cause of punctal stenosis owing to its etiology as well as because it increases the re-stenosis rate<sup>(3,5,26)</sup>. In our study, 75.9% of the eyelids had moderate to severe blepharitis following treatment or with previous treatment. Blepharitis seems to predispose patients to punctal stenosis and plug loss because of inflammation and cicatricial changes<sup>(3)</sup>.

### Plug material

Silicone is a flexible material with anti-adherence properties, which makes the plugs hydrophobic by preventing them from being wetted by tears, thus inhibiting the plugs from being filled with secretions. Any blockage could result in the accumulation of debris, bacteria, and inflammatory cells, leading to infection, fibrosis, scarring, plug loss, and stenosis.

Malet et al. compared the results of silicone plugs with PVP coated silicone plugs, that of the 20 silicone plugs they implanted, all 20 eyes showed epiphora again after 6 months; however, only 10 of the 20 eyes implanted with PVP-coated plugs were symptomatic<sup>(8)</sup>. High success rates of over 80% were reported in two studies by Konuk et al. and Ozgur et al., who both used PVP-coated plugs<sup>(11,12)</sup>. PVP coating modifies the hydrophobic nature of the plugs, making their surfaces hydrophilic, thus making the center opening repel tears, thereby protecting it from pus collection. However, the hydrophobic nature of silicone means that it collects pus and debris, leading to stenosis, inflammation, and plug loss<sup>(7,8)</sup>.

### Plug explantation time

In the literature, there is no generally accepted plug explantation time in punctal stenosis. PPPs are placed in the external punctum, usually after dilation, and left in place for a certain period; however, this period is still unclear. Bukhari suggested explantation at 2 months<sup>(5)</sup>. Malet et al. also explanted at 2 months, with failure rates of 100% for silicone plugs and 50% for PVP plugs<sup>(8)</sup>. Ozgur et al. explanted at 6 months and reported a re-stenosis incidence of 17.8% after 1 year<sup>(12)</sup>. Konuk et al. extracted 22 PVP-coated plugs at 2 months, with a success rate of 84.1% at 19 months<sup>(11)</sup>. Early extraction before 2 months may lead to re-stenosis, whereas late extraction may lead to granuloma and re-stenosis. However, Chang et al. suggested that PPP placement for only 1 month may be sufficient for successful treatment<sup>(13)</sup>. In the literature, the variations among the studies in terms of methodology, plug material, plug size, different numbers and ages of patients, and explantation time differences have resulted in differences in the outcomes. In order to come to real conclusions regarding the appropriate explantation time of the plugs, a controlled, prospective study using both silicone and PVP-coated PPPs should be performed with monthly follow-ups to determine a standard explantation time.

### Canalicular migration

Newer, smaller plugs are more prone to distal migration and can lead to infection. The Micro Flow (BVI, UK) silicone plug has a smaller lumen than others in the market; however, the outer diameters are similar. In our study, two plugs migrated into the canaliculus, in which the plugs expressed themselves at the time of planned canaliculotomy. Rumelt et al. reported dacryocystitis caused by the migration of a smaller-sized punctal plug that migrated into the lacrimal drainage system<sup>(27)</sup>.

### Gender

There was a male predominance among the patients in our study (65.6%) contrary to the female predominance reported by both Kashkouli et al. and Offutt et al. (70% and 71%, respectively)<sup>(3,26)</sup>. In both studies, the authors suggested that this female predominance might have been associated with postmenopausal hormonal changes. However, Bukhari et al. and Viso et al. reported no gender dominance in their respective studies<sup>(5,6)</sup>.

The present study has some limitations. Our study was retrospective and noncomparative; further, we had a relatively small sample size.

Based on the available data, plug loss, early extrusion, and re-stenosis are the most common causes of failure for PPP implantation and silicone punctum plug implantation failed in 66.7% of our patients at a follow-up time of 1 year.

Prospective studies with more patients, comparing different types of plugs, with longer follow-ups and the use of an objective, reliable, and reproducible punctum size measurement method are needed to determine the effectiveness of silicone perforated punctal plug implantation for treating acquired punctal stenosis.

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