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REVIEW ARTICLE

A Review of the Complications of Lacrimal Occlusion with Punctal and Canalicular Plugs

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ABSTRACT

Punctal and canalicular plugs are widely used for both temporary and permanent occlusion of the lacrimal puncta in dry eyes. There are many designs and materials available on the market. While their efficacy in improving dry eye symptoms is widely proven, the gamut of complications associated with these devices have never been subject to a general review, although there are numerous case series in the literature associated with one particular device. This review aims to examine the track record of a variety of plugs currently in use, to review the management of complications, and propose strategies for both the prevention of these complications and their treatment.

Keywords: Dry eyes, punctal plugs, complications

INTRODUCTION

Dry eye is a multifactorial disease of the tears and ocular surface that results in symptoms of discomfort, visual disturbance, and tear-film instability with potential damage to the ocular surface. Dry eye has been shown to cause a significant deterioration of quality of life and affect many activities of daily living.

Current dry-eye treatment is aimed at lubricating the ocular surface and conserving naturally produced tears or prolonging the contact time of artificial tears and treating underlying inflammatory conditions that aggravate the condition, both topically and systemically.[1] Occluding the nasolacrimal system to conserve the tear film – either temporarily or usually permanently – is the most common nonpharmacological therapy that is aimed to treat the ocular surface of patients with deficient aqueous tear production. Currently, a wide range of materials and designs of punctal and canalicular plugs are available on the market. Punctal and canalicular plugs provide a simple method of reversibly blocking the nasolacrimal outflow, preventing the need for surgery and associated discomfort. Although their efficacy in improving the symptoms and decreasing the need for artificial tears has been demonstrated by many publications,[2–5] punctal and canalicular plugs are associated with complications including loss, migration, epiphora, corneal abrasion, suppurative canaliculitis, and distal lacrimal system blockage.

The aim of this article is to review the literature for complications of permanent punctal and canalicular plugs, to postulate the reasons for these complications (effects of design, sizing, and insertion method) and review proposed strategies to minimize complications, and to discuss whether there is truly a safe complication-free product on the market.

TEMPORARY AND PERMANENT PUNCTAL AND CANALICULAR PLUGS

Absorbable implants for short-term occlusion are usually made of collagen and nonabsorbable punctal plugs (usually silicone) or canalicular plugs are used for permanent occlusion. To date, almost all available designs and models of punctal and canalicular plugs have been associated with complications.

PLUG MATERIAL, DESIGN, AND ASSOCIATED COMPLICATIONS

Silicone Plugs

Silicone punctal plugs were first described by Freeman in 1975.[6] Silicone is inert and well tolerated, and has

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the longest track record. The first large series of complications associated with the Herrick intracanalicular plug (Lacrimedics Incorporated Rialto, CA) was published in 2001 by White et al[7] from a survey of members of the American Society of Plastic and Reconstructive Surgery. Forty-one patients in this series were reported to develop permanent irreversible symptomatic lacrimal obstruction with 18 patients requiring Dacryocystorhinostomy (DCR) and two conjunctivo-DCR (Table 1).

Different designs of silicone plugs have since been developed and in widespread use, mainly for punctal not canalicular occlusion. These included FCI plugs (FCI Ophthalmics, Issy-les-moulineaux Cedex, France), EaglePlug™ (Eagle Vision, Memphis, TN), Parasol® (Odyssey Medical), Soft Plug® (OASIS Medical, Inc, Glendora, CA), and many similar designs. They usually consist of a conical head, a cylindrical body which is sometimes ribbed, and a cap. Different modifications exist (see Table 2) that includes the following:

Tapered shaft: E.g. EaglePlug (Eagle Vision). This design exerts extra force horizontally to help keep the punctal plug in place.

Hollow: E.g. Parasol (Odyssey). Straight shaft with collapsible hollow nose to help the punctal plug adhere to the shape of the ampulla.

Reservoir: E.g. AquaFlo™ (AlphaMed). This design captures and holds tears, which help reduce foreign body sensation and increase comfort.

Low profile cap: E.g. UltraPlug™ (Angiotech). To help maintain comfort while providing extra stability.

Perforated plugs: E.g. PVP perforated plug™ (FCI Ophthalmics). This has a slanted collarette and a central patent lumen, designed to be used for punctal stenosis and partial occlusion

Acrylic Polymer (SmartPlug™)

The SmartPlug is made of a biologically compatible acrylic polymer with thermodynamic qualities. It is a slender rod that is solid at room temperature but expands in diameter and increases in length assuming the shape of the punctal ampulla upon insertion into the punctum. It has been available for clinical use since 2002.

The SmartPlug is an intracanalicular plug which was originally designed to avoid the complications associated with other silicone plugs. It has the advantage of having a standard size, which makes it fit fully within the puncta, reducing the risk of irritating the ocular surface, and of extrusion. A study of 31 patients with the SmartPlug showed that 100% of the plugs were removed by irrigation 3 months after plug insertion.[8] Its efficacy compared to silicone plugs was also demonstrated, with the SmartPlug showing a significantly better tear meniscus height (mean follow-up of 11.2 weeks).[9] However, long-term follow-up has generated a large case series of 28 patients developing canaliculitis,[8] and a large cohort study reported a 7.23% complication rate with 4.34% developing canaliculitis.[10]

Hydrogel (Form Fit™)

The Form Fit plug has been available since 2004, and is made of a hydrogel material that expands into a soft, pliable, gelatinous material when it contacts the tear film. It comes in one size, and after 10 min of insertion it becomes fully hydrated and fills the vertical canalicular cavity.[11] Data on its complications are limited.

TYPES OF COMPLICATIONS

Extrusion/Spontaneous Loss

Rates of spontaneous loss vary according to the type of the plug. The silicone plugs (FCI Ophthalmics) were investigated for long-term retention rates and complications in a study involving 93 eyes of 47 patients, with most plugs being inserted in the lower puncta. Retention rates of the plugs were 84.2% after 3 months, 69.5% after 1 year, and 55.8% after a median of 2 years.[12] Spontaneous loss happened in 14.7% after 3 months, 27.3% after 1 year, and 36.8% after 2 years. In a study of 203 eyes where 312 arrow-shaft silicone plugs (CIBA Vision, Atlanta, GA; or Eagle Vision plugs) were implanted, the rate of spontaneous total extrusion was 50.7% with a mean survival time of 85.1 ± 7.3 weeks. There was no difference in the extrusion rate between upper and lower puncta.[13] Another study looking at the modified Freeman "tapered-shaft" plug (Eagle Vision) and Soft Plug™ (OASIS Medical, Inc) found that a significant proportion was spontaneously lost (47% at 6 months), with the majority being lost in the first 3 months. Plugs placed in the upper puncta were more prone to spontaneous loss, as were plugs that were refitted after the initial loss.[4]

A lower rate of spontaneous loss was found when the FCI plugs were compared with the Eagle Vision plugs (16% at 48 days and 42% at 55 days, respectively).[14]

In their histopathological study, Fayet et al.[15] suggested that punctal plug extrusion may result from mucosal dissection by the plug edges causing the formation of an encircling tissue band, which when necrosed leads to plug loss.

Obata et al. described a technique for suturing the punctal plugs (Eagle FlexPlug™, Eagle Vision) with a 10-0 polypropelene suture in patients who had recurrent spontaneous loss. They reported an 80% retention rate of the plugs at 6 months, with no associated complications. The study, however, only included 10 puncta of seven eyes (four patients), and definite conclusions on the efficacy of this technique could not be drawn.[16]

Plug retention is particularly problematic in eyes with graft versus host disease, which may be attributed

TABLE 1 Summary of Studies on Punctal Plug Complications

Author	Plug	Study Design and Sample Size (No of Plugs)	Sizing Method	Follow-Up	Plug Loss	Canaliculitis (or Migration Causing Infection)	Granulomas	Canalicular Stenosis	Plug Fragmentation/ Extrusion	Patients Requiring Surgery
Joganathan et al.[25]	Form fit (intracanalicular)	Case series (7 plugs, 3 pts)	Not mentioned	5 months–5 years	None	2	1	1	None	3
Hill et al.[10]	SmartPlug	Single practice Case series (31 plugs of 402 in 17/235 patients)	Not mentioned	Range 5 months–6 years, Average 3 years	Not mentioned	19 plugs infected 4.73% per plug (7.23% per patient)	None	Not measured	Not measured	17
Kaido et al.[19]	Superflex (Eagle Vision), Soft Plug (OASIS)	Interventional non-randomized comparative study (252 plug insertions, 132 old technique, 120 new technique)	PG	At least 3 month	39.4% standard tech, 30% with new tech	13.6% of old technique plugs, none of new tech	Not measured	Not measured	Not measured	Not measured
Boldin et al.[20]	FCI	Retrospective observational case series of stenoses(17)	VI	Mean 39 months (12–87)		None	None	17	None	None
Burgess et al.[9]	50% Soft Plug, (OASIS)and 50% Smart Plugs	Comparative case series (36 eyes)	PG	Mean 11.2 weeks	33% Soft Plugs, SmartPlug not assessed	None	None	None	None	None
Horwath-Winter et al.[12]	FCI	Prospective cohort study (95 plugs)	PG	Median 2 years (17–93 months)	14.7% at 3 months, 27.3% at 1 year, 36.8% after median of 2 years	None but 3 (3.1%) had migrated to proximal drainage system	3.2%	34.2% of the lost plugs (12 of 35)	1 of 95 (1%)	None
Mazow et al.[18]	Different types	Retrospective case series	Not mentioned	Not mentioned	Not measured	8%	6%	Not measured	Not measured	66 eyes (6.6% of lacrimal surgery)
Chou et al.[23]	SmartPlug	Case report (2)	Not mentioned	2 years	None	None	2	None	None	1 (50%)
SmartPlug Study group[8]	SmartPlug	Retrospective case series (28 pts, 41 plugs)	Not mentioned	Immediate–3 years	Not measured	17 pts (60.7%), 25 plugs (61% of plugs)	4 plugs (2 pts)	3 plugs(3 pts)	1	22 pts required surgery (2 refused) 5 of 20 pts had b/l surgery
Sakamoto et al.[14]	Eagle + FCI	38 of each (76 total)	PG	Mean 7.9 months	42% Eagle average 55 days. 16% FCI average 48 days	2 infections but not migration	1(FCI)	None	None	None
Tai et al.[13]	Eagle + CIBA vision	312	VI	Mean 85 weeks	60.7%	None	None	None	0.5% 1% extrusion	None
Balaram et al.[4]	Variety of silicone plugs (modified freeman, Eagle Vision, Soft Plug [OASIS])	Cohort retrospective study 132 plugs (50 patients) 167 including the replacements	PG	Minimum 6 months	27% at 6 months replacement plugs 63% overall 37% at 6 months upper puncta 4.3 time more	None	None	None	None	None
Fayet et al.[15]	FCI	Case series (6 pts, 22 plugs + 3 replacements)	Not mentioned	6–14 months	7/22 (31.8%)	None	None	1	6 with retaining membrane	0
White et al.[7]	Herrick	Retrospectve case series (41 patients, 48 plugs)	Not mentioned	Immediate–48 months	Not measured	Not measured	2	Not measured	Not measured	37 pts (3 had B/L DCR)

Sizing method: VI = visual inspection; PG = punctal gauging system.

TABLE 2 Lacrimal Plugs Available on the Market (List not Comprehensive)

Plug	Material	Intended Location	Features
Herrick (Lacrimedics)	Silicone	Canalicular	Shape of a golf tee
SmartPlug™ (Medennium)	Acrylic polymer	Canalicular	Thermodynamic properties – changes shape upon insertion
Form Fit™	Hydrogel	Canalicular	Hydrate on insertion and expands
Snug Plug™ (FCI ophthalmics)	Silicone	Punctal	Change to their natural shape on insertion
EaglePlug (Eagle Vision)	Silicone	Punctal	Tapered shaft: exerts horizontal force to keep plug in place
Parasol (Odyssey)	Silicone	Punctal	Hollow nose
Soft Plug™ (OASIS)	Silicone	Punctal	Pointed nose
Aquaflo™ (Alphamed)	Silicone	Punctal	Reservoir: captures and holds tears
UltraPlug™ (Angiotech)	Silicone	Punctal	Straight shaft
PVP Perforate Plug™	Silicone	Punctal	Slanted collarette, central patent lumen
Flow Controller™ (Eagle Vision)	Silicone	Punctal	Tapered shaft

to structural abnormalities of the puncta or the associated conjunctival inflammation and fibrosis. It is important therefore that all patients are examined in the first 3 months after the insertion of punctal plugs to examine retention. Patients with frequent plug loss should be considered for permanent thermal punctal occlusion.

Migration

A major concern about punctal plug treatment is migration of the plug into the lacrimal drainage system, which may lead to surgical intervention to remove the plug. Plugs tend to erode through the posterior surface of the common canaliculus (see Figures 1 and 2), or lead to granuloma formation in the lacrimal sac or duct.

The dislocated plug may be tolerated for years but can lead to canaliculitis and dacryocysitis and may require surgery. The mechanism of the local inflammatory reaction is thought to be the negatively charged surface of the silicone attracting allergens and debris.[17]

Three out of 97 FCI silicone punctal plugs were reported to migrate in the Horwath-Winter et al study. All involved the proximal lacrimal drainage system, but required no or minor intervention.[12]

Intracanalicular silicone plugs were designed to be buried in the canaliculus and avoid extrusion and corneal erosion. Complications developed secondary to their inward migration and the difficulty of their removal. In a series of 66 patients with intracanalicular plug complications (60 of which had Herrick Plugs™), irrigation failed to remove the plug, and a considerable number of cases needed surgical intervention. Resolution of epiphora was not always achieved despite surgery. The authors suggested that insertion of a non-biodegradable material into the canaliculus caused the problem rather than the plug design itself.[18]

Kaido et al, however, demonstrated a new technique of inserting SuperFlex® plugs (Eagle Vision) and Soft Plug (OASIS Medical, Inc) in order to reduce migration. They described using a plug size one diameter bigger than the one measured with the gauging system and eliminating the space between the plug and the inserter body. The intracanalicular migration rate after at least

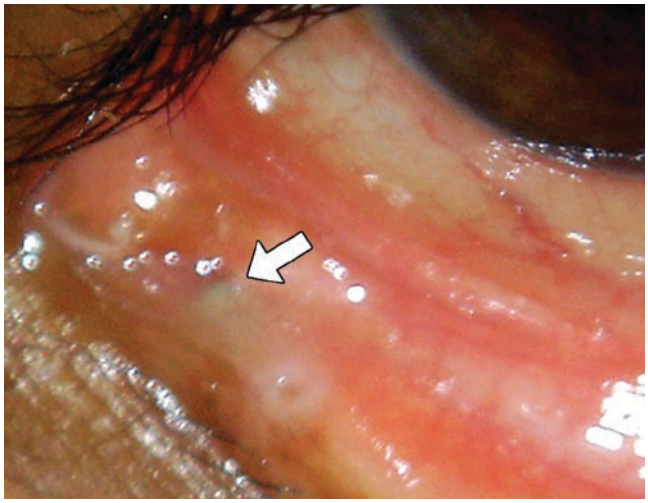

FIGURE 1 Herrick Plug in the Canaliculus – Courtesy of Mr David Verity.

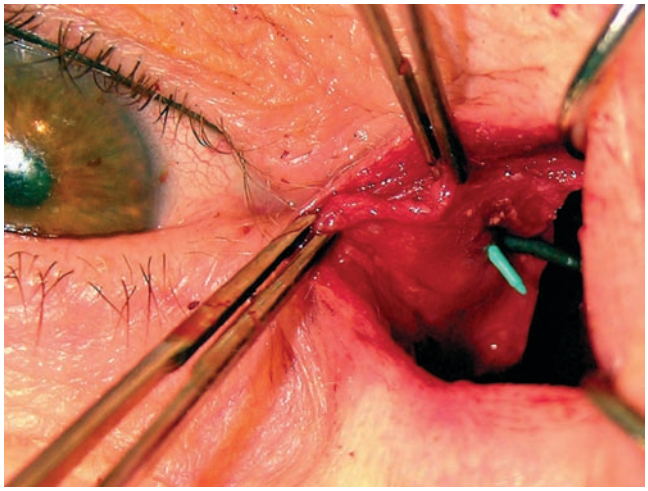

FIGURE 2 Herrick Plug Migration (Erosion through the Posterior Wall of the Common Canaliculus) – Courtesy of Mr David Verity.

a 3-month follow-up was 13.8% with the standard technique as opposed to no migration with the new technique.[19]

Migration should be considered whenever the plug cannot be visualized especially if there is tenderness or punctal discharge. Dacryocystography may help to establish the location of a migrated plug. Regular follow-up and careful intervention is therefore recommended.

Punctal and Canalicular Stenosis

Punctal and proximal canalicular stenoses are well-reported complications after spontaneous plug loss or migration, and have been reported in a frequency of 25.7% during a follow-up of 32 months.[15] In another study, canalicular stenosis after spontaneous loss occurred in 14.3% after 3 months, 26.9% after 1 year, and 34.2% after 2 years.[12]

Stenosis usually happens at the punctum, within the vertical portion or in the proximal horizontal canaliculus.[20] It tends to occur after the plugs are spontaneously lost from the canaliculus, and is thought to be due to abrasion and inflammation of the inner canalicular wall.[12] The localization of stenosis does not correlate to the plug size or the duration of punctal occlusion.[20]

Infection

Aspergillus fumigatus colonizing punctal plug holes was reported in two patients who presented with mucoid discharge and foreign-body sensation without conjunctivitis or keratitis. The fungus pigments are seen in the form of black deposits resembling eyeliner in the punctal plug. Such an appearance especially in immunocompromised patients should raise the suspicion of a fungal infection.[21]

Epiphora

Horwath-Winter et al.[12] reported a low epiphora rate of 1% with the silicone plugs (FCI Ophthalmics, Issyles-moulineaux Cedex, France), which was attributed to the prior use of temporary collagen plugs and the strict inclusion criteria. Balaram et al.[4] suggested that patients in whom lower punctal occlusion is not adequate, and combined occlusion of lower and upper puncta results in epiphora should undergo argon laser stenosis of the upper puncta in addition to lower punctal plug occlusion.

Granulomatous Proliferation

Pyogenic granuloma has been described with both the silicone plug and the SmartPlug. The pathogenesis of pyogenic granuloma in silicone punctal plugs remains uncertain. Mechanical force and consequent injury play an important role.

Kim and associates retrospectively reviewed 903 silicone punctal plugs in 404 patients (Parasol punctal occluder; Odyssey Medical Inc, Memphis, TN). Pyogenic granuloma resulted in extrusion of 4.2% of all plugs inserted after a median time of 141 days. Partial plug extrusion was associated with active pyogenic granuloma, and complete plug extrusion with sclerosing pyogenic granuloma. This led to the suggestion that active pyogenic granuloma initiated the plug extrusion. When all the risk factors were analyzed, large plug size was significantly associated with granuloma formation.[17]

There is no consensus on the management of pyogenic granuloma. Musadiq et al reported two similar cases of pyogenic granuloma resulting from Soft Plug (OASIS) which were managed differently. The first case underwent excision of the granuloma with no removal of the plug and developed no lacrimal complications. The second case had removal of the plug and a course of topical steroid drops, but developed punctal scarring.[22]

Pyogenic granuloma also occurred in patients who had the SmartPlug. Chou et al.[23] reported that pyogenic granuloma occurred approximately 2 years after plug insertion, and required irrigation in one case and DCR in the other.

Canaliculitis and Dacryocystitis

The SmartPlug Study Group reported a case series of 28 patients where 64.3% had canaliculitis, dacryocystitis, or conjunctivitis. The remaining cases had epiphora with minimal or no inflammatory signs. These complications were managed in the study by topical and oral antibiotics followed by retrograde massage of the plug through the canaliculus if necessary. And although lacrimal irrigation was described by the manufacturer as the treatment for epiphora and canaliculitis, the authors suggested that it may also dislodge the plug and result in permanent blockage of lacrimal drainage passages. They recommended that if conservative measures do not improve the symptoms, a surgical intervention such as canaliculotomy or DCR may be indicated.[8] Scheepers et al.[24] illustrated this in their case report of bilateral canaliculitis secondary to SmartPlug insertion, which was managed with bilateral canaliculotomy (see Figures 3 and 4).

In the US open label study by Medennium on SmartPlug, no canaliculitis or dacryocystitis cases were reported in the 120 patients cohort enrolled in the prospective comparative trial after 3 months' follow-up. However, the prevalence of canaliculitis after SmartPlug insertion was found to be 7.23% in a study of 235 patients from 2002 to2007. The prevalence of canaliculitis per SmartPlug inserted was 4.73%. The average time

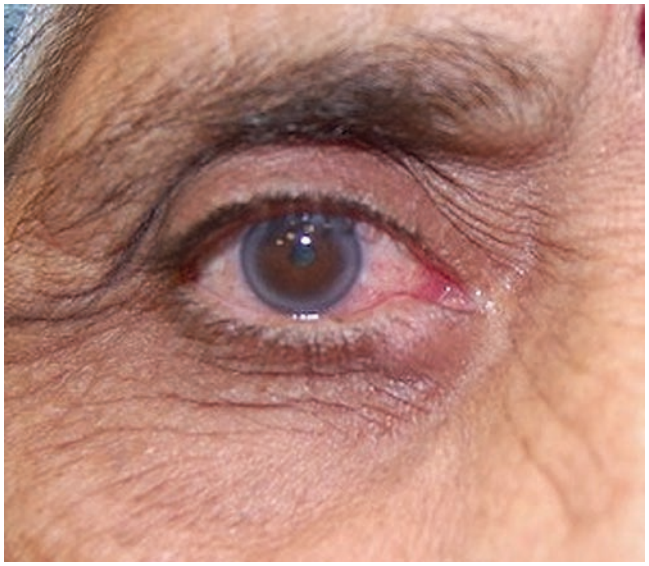

FIGURE 3 Canaliculitis – Plug Type Undetermined.

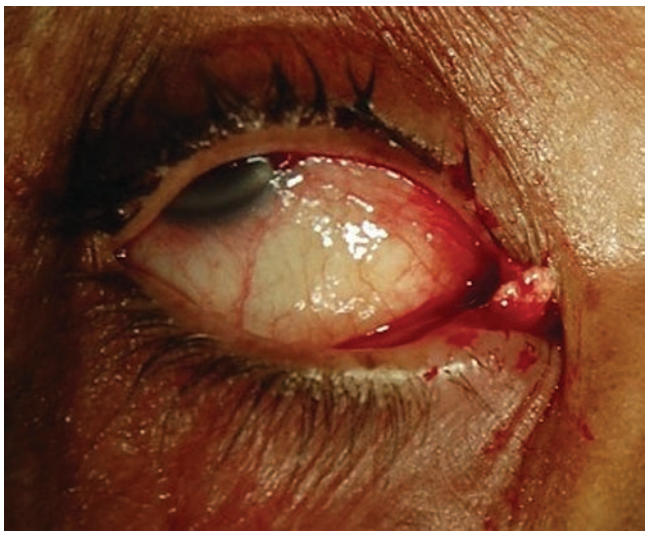

FIGURE 4 Canaliculotomy and Plug Removal for the Patient in Figure 3.

from SmartPlug insertion to the onset of symptoms was 3 years. All affected patients required canaliculotomy and plug removal.[10]

Form Fit plugs have also been recently reported to cause canaliculitis and canalicular abscess, approximately 5–6 months after insertion. *Klebsiella oxytoca* was the causative organism in the canaliculitis case. Both the canaliculitis and the canalicular abscess resolved with canaliculotomy and removal of the plug.[25]

DISCUSSION

Efficacy

The utility of punctal plugs in the management of tear-deficient dry eye is well established in the literature. Studies on the efficacy of plugs demonstrated both subjective improvement of patients' symptoms and improvement of the objective parameters such as corneal staining, tear break-up time, and tear osmolarity.[2–5]

Lack of Long-Term Complications Data and Unknown Denominator

This review shows the variety of complications associated with punctal plugs. However, it is likely that the complications reported in these studies are underestimated due to the lack of long-term follow-up. Only one study had follow-up of up to 5 years.[25] Hill et al reported that the average time before complications developed with the SmartPlug was 3 years. Moreover, often it is difficult to know how many plugs were inserted, especially with the rise in number of patients undergoing laser refractive surgery where plugs are widely used in the early postoperative period. Unless meticulous records are available combined with long-term follow-up, the individual complication rates of each plug design would be impossible to evaluate.

Migration and Importance of Sizing

The main advantage of punctal plugs is that they are nonsurgical, and should reversal of occlusion become necessary then they could be irrigated. A number of studies in this review report lacrimal surgical management of the complications resulting from migration (granuloma, canaliculitis, and dacryocystitis). Moreover, when a plug is not present in the punctum at follow-up, unless syringing or dacryocystography is performed a diagnosis of inward migration rather than plug loss cannot be excluded. Therefore it is impossible to know the true extent of asymptomatic migration with punctal plugs.

We believe that correct sizing of the plug plays an important role, and there is no universal consensus or evidence base in the literature regarding this issue. Whilesome studies used a gauging system to insert the appropriate plug, others relied on subjective visual inspection leading to possible over- or undersizing.

Since puncta vary considerably in size, there is no standard method of selecting the size for perfect fit. Inadequate sizing of punctal plugs may result in partial or total extrusion or inward migration. An oversized plug causes forced dilatation of the punctum which leads to mechanical stress to the canaliculus. This may lead to mucosal injury which may result in granuloma formation.[17] Mukherji et al. reported a case of a plug that reverse migrated through the lid tissue by pressure necrosis due to its large size, causing a sterile ulcer.

The ulcer healed four weeks following the removal of the plug.[26]

In a study of Parasol punctal occluder (Odyssey Medical Inc, Memphis, TN), a punctal gauging instrument was used to determine the plug size. The authors claimed that this resulted in no case of distal plug migration in over 400 patients.[17] The Soft Plug (OASIS), for example, is available in different sizes (0.5–1.0 mm). The size of the plug is determined by the size of the punctal opening measured by a special device before the plug is inserted.[11]

In recognition of the sizing problem FCI Ophthalmics are promoting a one-size-fits-all Snug Plug™, which is preloaded in a stretched position returning to its natural shape when released in the punctum. There are no details regarding this plug's long-term complication and migration rates.

Cost and Cost Effectiveness

With the relatively high spontaneous loss/extrusion rate of silicone plugs, the question arises as to the economic value of continuous replacement of the plugs as opposed to the value of punctal cautery. The cost of a plug procedure was estimated at $292 in 2008.[27] A study of the cost of dry-eye management found the annual direct cost per dry-eye patient using a punctal plug to be $744 for mild/moderate dry eye and $980 for severe disease assuming a mean number of procedures of 2.9.[28]

There is no head-to-head trial comparing the efficacy and complications of punctal plugs and permanent surgery such as cautery and argon laser occlusion. Similarly, to date there is no published data comparing the efficacy and complications of the PVP perforated plug against punctoplasty for epiphora.

Although serious plug complications are not frequent, when they do occur they may necessitate extensive surgical interventions, and given the high rate of plug loss and need for continuous replacement with associated cumulative costs we believe that in the treatment of chronic dry eye necessitating long-term punctal occlusion surgery may yet prove a more lasting and economical alternative.

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