Punctal Plug Retention Rates for the Treatment of Moderate to Severe Dry Eye: A Randomized, Double-Masked, Controlled Clinical Trial

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• PURPOSE: **To compare retention rates of Super Flex (Eagle Vision, Memphis, Tennessee, USA; Softplug-Oasis Medical Inc, Glendora, California, USA) vs Parasol (Odyssey Medical, Memphis, Tennessee, USA; Beaver Visitec International, Waltham, Massachusetts, USA) punctal plugs.**

• DESIGN: **Randomized, double-masked, interventional controlled clinical trial.**

• METHODS: **Institutional study at Hotel Dieu Hospital (Queen's University) of 50 eyes, from patients with moderate to severe dry eye. Each eye from eligible patients was separately randomized to receive Super Flex or Parasol punctal plugs. The main outcome measure was plug retention at 6 months. Secondary outcome measures included objective tests of Schirmer I (mm), tear meniscus height (mm), tear break-up time (s), inferior fluorescein corneal staining (National Eye Institute [NEI] scale), and average lissamine green conjunctival staining (NEI scale).**

• RESULTS: **Punctal plug retention was significantly different at 6 months ($P = .011$). Sixty-eight percent of Parasol plugs were retained compared to 32% of Super Flex plugs. Parasol plugs required less frequent artificial tear use at 6 months ($P = .024$). There was a statistically significant improvement in all secondary outcome measures (Schirmer, tear meniscus height, tear break-up time, fluorescein corneal staining) at 6 months within plug groups except conjunctival staining. There were no additional significant differences between groups and no plug complications reported.**

• CONCLUSIONS: **Punctal plugs improve symptoms of moderate to severe dry eye; however, retention rates differ significantly. These data will allow us to guide patient decision making for the safe and effective treatment of punctal plugs for moderate to severe dry eye. (Am J Ophthalmol 2015;160(2):238–242. © 2015 by Elsevier Inc. All rights reserved.)**

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THE SYMPTOMS OF OCULAR SURFACE DRYNESS ARE some of the most common patient concerns in ophthalmology practices. Not only are symptoms painful and irritating, but dry eye can also affect visual acuity and quality-of-life measures.[1–4] Punctal plug insertion is a safe and easy office procedure for the treatment of moderate to severe dry eye.[5,6] Punctal plugs help to maintain aqueous and artificial tears on the ocular surface to reduce both the subjective and objective symptoms of dry eye.[3] Patients often require the insertion of 2–4 plugs and may pay out of pocket for this procedure. Despite their success in reducing the symptoms of dry eye, spontaneous plug loss is a frequent complication. Reportedly this occurs between 20% and 70% of the time and many different designs and materials have been tried to increase retention rate.[7–10]

In an effort to minimize plug loss a new plug design, Parasol punctal occluder (Parasol; Odyssey Medical, Memphis, Tennessee, USA; Beaver Visitec International, Waltham, Massachusetts, USA), was designed. This design contains a hollow nose, which collapses on insertion and expands within the puncta, thereby limiting the rate of spontaneous loss, promoting a 92% retention rate.[11] No independent studies to date have confirmed this claim.

Thus, the purpose of the study is to compare the retention rate of the commonly used Super Flex (Eagle Vision, Memphis, Tennessee, USA; Softplug-Oasis Medical Inc, Glendora, California, USA) vs the Parasol punctal plug.

METHODS

• STUDY DESIGN AND OVERVIEW: This randomized, double-masked prospective interventional control trial, comparing Parasol punctal plugs and Super Flex punctal plugs, was conducted at Hotel Dieu Hospital, Queen's University in Kingston, Ontario, Canada and adhered to the tenets of the Declaration of Helsinki. The Queen's University and Affiliated Teaching Hospitals Health Sciences Research Ethics Board approved the study prior to enrolling study participants. The study is listed on ClinicalTrials.gov, under the identifier NCT01947517.

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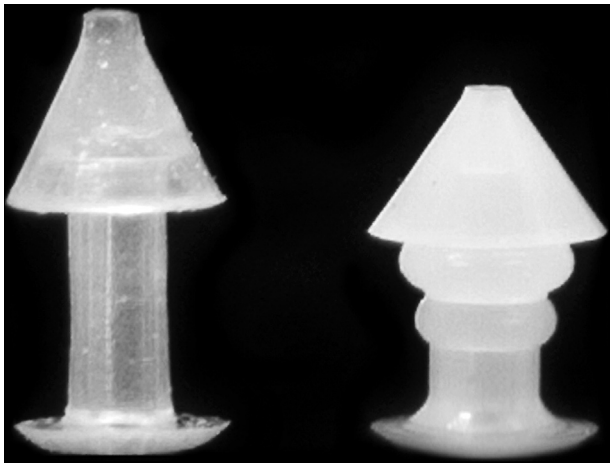

FIGURE 1. Comparative photograph of equivalent sizes demonstrates the design of the plugs for the treatment of moderate to severe dry eye. The Parasol is the left plug (size medium), and the Superflex is the right plug (size 0.7).

TABLE 1. Baseline Characteristics of Patients by Treatment Assignment in the Comparison of Punctal Plug Retention Rate for the Treatment of Moderate to Severe Dry Eye

Characteristics	Parasol (n = 25)	Super Flex (n = 25)	*P*
Mean (SD) age, y	61.7 (17.67)	58.4 (16.18)	.497
Sex			
Male, n (%)	3 (12)	2 (4)	
Female, n (%)	10 (40)	11 (44)	
Punctal plug size, n (%)			
0.4		2 (8)	
0.5		9 (36)	
0.6		7 (28)	
0.7		4 (16)	
0.8		2 (8)	
0.9		1 (4)	
X-small (0.2–0.35)	4 (16)		
Small (0.35–0.6)	12 (48)		
Medium (0.6–0.8)	7 (28)		
Large (0.9)	2 (8)		
CDEA severity,[a] n (%)			
Moderate	6 (12)	2 (4)	
Severe	19 (38)	23 (46)	
Mean (SD)	2.76 (0.44)	2.75 (0.46)	.990
Artificial tear use per day, mean (SD)	4.56 (1.39)	4.72 (1.97)	.741
Schirmer I, mm (SD)	7.00 (3.45)	8.68 (4.83)	.163
Tear meniscus height, mm (SD)	0.472 (0.50)	0.468 (0.63)	.980
Inferior corneal staining, NEI scale (SD)	3.28 (0.94)	3.60 (1.16)	.287
Conjunctival staining, NEI scale (SD)	2.08 (0.57)	2.08 (0.95)	>0.999
Tear break-up time, s (SD)	4.04 (1.59)	4.00 (2.16)	.941

CDEA = Canadian Dry Eye Assessment; NEI = National Eye Institute.

[a]CDEA severity: normal = 1, mild = 2, moderate = 3, severe = 4.

• **STUDY POPULATION AND INCLUSION/EXCLUSION CRITERIA:** Patients were recruited from 1 cornea specialist (S.B.) and 2 general ophthalmology practices (K.S., M.B.). Inclusion criteria included moderate to severe subjective dry eye symptoms as per the Canadian Dry Eye Assessment (CDEA), a validated dry eye symptoms questionnaire based on the Ocular Surface Disease Index (OSDI).[6] The CDEA is a questionnaire that assesses the patient's dry eye symptoms, environmental influences, and quality-of-life measures. Each response is awarded a score and the final score is determined from the summation of all of the sections. The final score is classified along a scale of mild, moderate, or severe dry eye. Treatment recommendations are then made based on the severity. Exclusion criteria included dry eye secondary to systemic inflammatory conditions, punctal cautery, punctal stenosis, silicone allergy, and inability to attend multiple follow-up visits for 6 months.

• **TREATMENT ASSIGNMENT:** Randomization was achieved using a mathematical computer-generated allocation schema based on permuted blocks with blocks of random sizes. Randomization assignment was not released until eligibility was confirmed and signed consent obtained. Each eye was assigned randomly with equal probability to receive either Super Flex or Parasol brand punctal plugs. A comparative photograph of the Parasol and Super Flex punctal plug designs is shown in Figure 1.

• **STUDY PROCEDURES:** Participants and all study staff, except an unmasked investigator (A.B.) who inserted punctal plugs, were masked to treatment arms. A punctal gauge was used to correctly measure punctal size, and an appropriately sized punctal plug was selected based on manufacturer's instrument.[5,12] One unmasked investigator (A.B.) inserted all plugs to limit any differences in plug insertion technique and all plugs were inserted in the lower puncta. Plug retention and all other secondary outcomes were evaluated by 1 examiner masked to the treatment arms (Z.M.). Disclosures were tracked and none were recorded.

• **OUTCOME MEASURES:** Punctal plug retention was assessed at monthly intervals for a total of 6 months. Retention was characterized by last examined date with the punctal plug in place. For example, if a patient returned for his or her 4-month visit, and the plug was gone, the plug was recorded as 3 months of retention. Secondary outcome measures including objective tests of Schirmer I (mm), tear meniscus height as measured at the slit lamp (mm), tear break-up time (TBUT, in seconds), inferior fluorescein corneal staining (National Eye Institute [NEI] scale), and average lissamine green conjunctival staining (NEI scale) were evaluated for each eye. The NEI scale of corneal