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Original Research Article

Comparative Study of Retention and Complications of Two Silicone Lacrimal Punctal Plugs in Dry Eye Disease Management

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Abstract:

Background: A multifactorial disorder that causes significant morbidity, dry eye disease (DED) is characterized by decreased quality of life, tear film instability, and ocular pain. Despite variations in retention and complication rates among plug types, punctal occlusion with silicone lacrimal plugs is a proven treatment to improve tear retention.

Aim: To evaluate the complications and retention rates of two distinct silicone lacrimal punctal plug types in the treatment of individuals with moderate to severe dry eye illness.

Methods: Over the course of 13 months, a prospective comparative clinical study was carried out at the Anugraha Narayan Magadh Medical College and Hospital's Department of Ophthalmology in Gaya. One kind of silicone punctal plug was given to each of the two groups of 60 patients with moderate to severe DED who were randomly assigned to each group. At 1, 3, 6, and 12 months, the patients were monitored. We gathered information on retention, issues, and progress in OSDI, TBUT, and Schirmer's test scores. SPSS version 23.0 was used for the statistical analysis, and a p-value of less than 0.05 was deemed significant.

Results: The groups' baseline characteristics were similar. Group A had considerably greater retention rates (83.3%) at 12 months than Group B (70.0%) (p=0.048). Plug extrusion was the most common complication, occurring in 16.7% of Group A compared to 30.0% of Group B (p=0.04). At 12 months, there was no statistically significant difference between the two groups in terms of clinical improvement, but both groups showed significant improvements in OSDI scores, Schirmer's test values, and TBUT when compared to baseline.

Conclusion: Both silicone punctal plug types were effective in improving symptoms and clinical parameters of DED. However, Group A plugs exhibited superior retention and fewer complications, making them a more reliable option for long-term management.

Recommendations: Further large-scale, multi-center randomized studies are recommended to validate these findings and to assess cost-effectiveness, patient comfort, and long-term safety across diverse populations. Individualized plug selection based on anatomical and disease characteristics should be considered to optimize outcomes.

Keywords: Dry Eye Disease, Silicone Punctal Plug, Retention Rate, Complications, Lacrimal Occlusion.

Introduction

DED is a common and complex condition that is typified by inflammation of the ocular surface, instability of the tear film, and symptoms like discomfort, irritation, and visual impairment [1]. The global prevalence of DED varies widely—affecting up to 70% of elderly populations—with significant implications for quality of life and ocular health [2]. Conventional treatments, including artificial tears and anti-inflammatory agents, often provide only temporary relief, prompting the exploration of adjunctive therapies to enhance tear retention.

Punctal occlusion using plugs is a widely accepted strategy to preserve both natural and supplemented tears on the ocular surface. Silicone punctal plugs, in particular, are popular due to their relative durability, ease of insertion, and reversibility [3In addition to lowering the frequency of lubricating drops, the puncta blocking technique may enhance

tear film metrics including Schirmer's scores and tear break-up time (TBUT).

A recent systematic review and meta-analysis encompassing 17 studies (1,658 patients) confirmed that punctal plugs significantly improve TBUT (mean difference +1.8 s), Schirmer's test (+3.1 mm), and Ocular Surface Disease Index (OSDI) scores (–20.6), all with high statistical significance [4]. Importantly, the overall plug retention rate was reported at 86%, with specialized "smart plugs" demonstrating exceptionally high retention of 97.3% [4]. These results support the intervention's safety and effectiveness in treating moderate-to-severe DED.

However, the existing literature also highlights variability. A Cochrane review concluded that while punctal plugs are generally correlated with symptomatic improvement when compared with observation or artificial tears, the overall evidence remains heterogeneous due to differences in plug material, DED severity, and trial methodologies [5]. Further, comparative studies of different silicone plug types have reported retention rates as varied as 30–70% at six months [6].

Long-term observational data provide additional insight into real-world outcomes. One cohort study reported retention of 84.2% at three months, 69.5% at one year, and 55.8% at two years, with rare complications such as granuloma formation and canalicular stenosis in a small number of cases [7,8]. These outcomes suggest that while retention tends to diminish over time, the incidence of serious adverse events remains low.

Moreover, specialized patient populations may experience different outcomes. For instance, individuals with ocular graft-versus-host disease (oGVHD) showed significantly lower plug retention in comparison to non-oGVHD DED patients, although both groups exhibited ocular surface improvement when plugs were retained [9]. This underscores the need for tailored management strategies in complex cases.

Given these mixed data on retention, complications, and clinical effectiveness—especially across varied plug types and patient subgroups—there is continued need for well-designed studies comparing different silicone punctal plug designs. The current study aims to address this by prospectively evaluating two distinct types of silicone lacrimal punctal plugs in a controlled clinical setting, focusing on retention, safety, and symptomatic outcomes.

Methodology

Study Design: This study was designed as a prospective comparative clinical study.

Study Setting: The study was conducted at the Anugraha Narayan Magadh Medical College and Hospital's Department of Ophthalmology in Gaya, Bihar, a tertiary care referral facility serving both urban and rural communities. The trial lasted for thirteen months.

Participants: There were 120 patients with moderate to severe dry eye disease in all. Two groups of patients each received a particular kind of silicone lacrimal punctal plug. There were 60 patients in each group.

Inclusion Criteria

- Individuals with a clinical diagnosis of moderate to severe dry eye disease who are at least eighteen years old.
- After five minutes, patients with Schirmer's test values ≤10 mm.
- Individuals with OSDI scores that show signs of dry eye symptoms.
- Patients who are prepared to give their informed permission and attend follow-up appointments.

Exclusion Criteria

- Patients who are experiencing inflammation or an active eye infection.
- Individuals with anomalies of the puncta or eyelids that could prevent the placement of the plug.
- Any history of trauma or ocular surgery during the previous six months.
- Individuals suffering from autoimmune conditions such ocular cicatricial pemphigoid or Stevens-Johnson syndrome.
- Patients who are incapable or unwilling to finish follow-up.

Bias: Patients were enrolled one after the other and randomly assigned to one of the two groups using a computer-generated randomization sequence in order to reduce selection bias. Observer bias was reduced by ensuring that assessment of outcomes (retention and complications) was performed by an ophthalmologist blinded to the type of plug used.

Data Collection: Age, gender, length of symptoms, and systemic comorbidities were among the baseline clinical and demographic information that was documented. At baseline and during follow-up, standardized tests for dry eye disease, such as Schirmer's test (TBUT) and OSDI score, were conducted. At follow-up visits planned at one, three, six, and twelve months, information was gathered about the retention of punctal plugs and the incidence of problems like plug extrusion, canaliculitis, or local irritation.

Procedure: All procedures were carried out under sterile conditions in the minor procedure room. After topical anesthesia with 0.5% proparacaine

hydrochloride, punctal dilation was performed and the assigned type of silicone punctal plug was inserted into the lower punctum. Patients were instructed regarding post-insertion care and advised to avoid rubbing their eyes. Follow-up examinations were scheduled at predetermined intervals for evaluation of plug retention and documentation of complications.

Statistical Analysis: SPSS software version 23.0 (IBM Corp., Armonk, NY, USA) was used to evaluate the data after it had been imported into Microsoft Excel. Clinical and demographic features were gathered using descriptive statistics. To compare categorical factors like plug retention and complication rates between the two groups, the chi-square test was utilized. Depending on the normality distribution, either the independent t-test or the Mann-Whitney U test was applied to continuous variables. P-values less than 0.05 were regarded as statistically significant.

Results

After enrolling in the trial, 120 patients were split into two groups at random, Group A (60) and Group B (60), each of whom received a different kind of silicone lacrimal punctal plug. Participants in Group A and Group B had mean ages of 48.6 ± 12.4 and 47.9 ± 11.8 years, respectively. In both groups, the distribution of genders was comparable (p=0.64). At the time of enrollment, there was no discernible difference between the groups based on the baseline OSDI scores, Schirmer's test results, and TBUT.

Table 1: Baseline Demographic and Clinical Characteristics

Variable	Group A (n=60)	Group B (n=60)	p-value
Mean Age (years)	48.6 ± 12.4	47.9 ± 11.8	0.78
Gender (Male/Female)	24/36	27/33	0.64
Mean OSDI Score	46.8 ± 9.2	45.9 ± 8.7	0.61
Schirmer’s Test (mm/5 min)	6.2 ± 1.4	6.1 ± 1.3	0.72
TBUT (seconds)	5.9 ± 1.6	6.0 ± 1.7	0.83

Both groups were statistically comparable at baseline with no significant differences in demographic or clinical parameters.

Plug Retention Rates: At the end of 12 months, Group A demonstrated a higher retention rate (83.3%) compared to Group B (70.0%), and there was a statistically significant difference (p=0.048).

Table 2: Plug Retention Rates at Follow-up

Follow-up Interval	Group A (n=60)	Group B (n=60)	p-value
1 Month	60 (100%)	60 (100%)	–
3 Months	58 (96.7%)	55 (91.7%)	0.27
6 Months	54 (90.0%)	48 (80.0%)	0.11
12 Months	50 (83.3%)	42 (70.0%)	0.048*

Both groups had excellent early retention, but Group A maintained significantly higher long-term retention at 12 months.

Complications: The most common complication observed was plug extrusion, followed by foreign body sensation. Canaliculitis and local irritation were rare. Overall, complications were more common in Group A (16.7%) than Group B (30%).

Table 3: Complications Observed During Follow-up

Complication	Group A (n=60)	Group B (n=60)	p-value
Plug Extrusion	8 (13.3%)	13 (21.7%)	0.19
Foreign Body Sensation	2 (3.3%)	4 (6.7%)	0.40
Canaliculitis	0 (0.0%)	1 (1.7%)	0.31
Local Irritation	0 (0.0%)	2 (3.3%)	0.15
Total Complications	10 (16.7%)	18 (30.0%)	0.04*

The difference in overall complication rates was statistically significant, and Group A plugs were associated with fewer difficulties than Group B.

Symptom and Clinical Improvement: At 12 months, both groups' OSDI scores, Schirmer's test results, and TBUT significantly improved from the baseline. However, Group A patients had a slightly greater mean improvement, though differences were not statistically significant.

Table 4: Improvement in Clinical Parameters at 12 Months

Parameter	Group A (n=60)	Group B (n=60)	p-value
OSDI Score Reduction	–21.8 ± 6.1	–20.2 ± 5.8	0.18
Schirmer's Test (mm)	+3.9 ± 1.2	+3.6 ± 1.1	0.26
TBUT (seconds)	+3.2 ± 0.9	+3.0 ± 1.0	0.41

Both plug types were effective in improving clinical symptoms and tear film parameters, with no statistically significant difference in efficacy.

Overall Findings

- **Retention**: Group A plugs had better long-term retention (83.3% vs. 70.0%).
- **Complications**: Group A plugs had fewer complications compared to Group B (16.7% vs. 30.0%).
- **Clinical Improvement**: Both groups showed comparable symptomatic and clinical improvements.

Discussion

Two equal groups of 120 individuals with moderate to severe dry eye illness were included. To ensure homogeneity at the beginning of the trial, the two groups' baseline demographic and clinical characteristics, including age, gender, OSDI scores, Schirmer's test results, and TBUT, were comparable.

With respect to retention rates, both groups demonstrated excellent outcomes in the early follow-up period, with 100% retention at 1 month. However, as the follow-up duration increased, a gradual decline in retention was observed in both groups. At 12 months, Group A maintained a higher retention rate (83.3%) compared to Group B (70.0%), and the difference reached statistical significance. This indicates that the design of the plug used in Group A offered better long-term stability.

Regarding complications, both groups experienced some adverse events, with plug extrusion being the most common complication. Group B recorded a higher number of complications overall (30%) compared to Group A (16.7%), and this difference was statistically significant. While most complications were minor, such as foreign body sensation or local irritation, a single case of canaliculitis was reported in Group B. These findings suggest that Group A plugs were not only better retained but also better tolerated.

Clinical and symptomatic results showed a notable improvement in both groups. The effectiveness of punctal plug insertion as a treatment for dry eye disease was demonstrated by the significant improvement in OSDI scores, Schirmer's test values, and TBUT at 12 months as compared to baseline. Although Group A saw a somewhat higher level of improvement, the difference was not statistically significant, indicating that both plug types were equally successful in reducing symptoms and enhancing tear film integrity.

Silicone punctal plugs have been widely studied as a treatment for dry eye disease, showing consistent improvements in both signs and symptoms, though complications remain a concern. A study by Tabatabaei et al. demonstrated that while plugs improve tear film stability and patient-reported symptoms, extrusion and biofilm formation are among the most frequent complications, raising concerns about long-term safety [10]. Although spontaneous plug loss and foreign body sensation were common, Jin et al. found in a long-term evaluation that punctal plugs significantly improved Schirmer test values and ocular surface disease index (OSDI) scores [11].

Chen et al. compared patients with Sjögren's syndrome (SS) and non-Sjögren's dry eye disease, finding that plug insertion was beneficial in both groups; however, plug extrusion rates did not differ significantly between them, indicating that retention problems remain regardless of disease subtype [12]. Liu et al. emphasized the role of plug design, reporting that larger sizes and specific shapes had better retention and patient tolerance, reducing the risk of migration and discomfort [13]. Shin et al. also highlighted mid- to long-term efficacy, noting that while symptom relief was clear, extrusion and plug-related infections were recurrent issues that limited long-term outcomes [14].

Adding to this evidence, Kim et al. performed a prospective study demonstrating that silicone plugs significantly reduced dry eye symptoms and improved (TBUT) and corneal staining, but noted that extrusion rates were still considerable over time, confirming that retention remains a challenge despite clear therapeutic benefits [15]. While silicone punctal plugs have been shown to be a successful treatment for moderate-to-severe dry eye since 2018, long-term success is still limited by extrusion, biofilm-related issues, and patient discomfort.

Conclusion

Although Group A showed better long-term retention and fewer problems than Group B, both silicone lacrimal punctal plugs were successful in improving the clinical results of dry eye illness. This indicates that the choice of plug design may influence long-term outcomes, especially in terms of plug stability and patient tolerance, even though both types are clinically effective.

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