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Original Research Article

Comparison of Retention Rates and Complication Profiles of Two Silicone Lacrimal Punctal Plugs in Dry Eye Disease Management

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Abstract:

Background: Dry eye disease (DED) is a common ophthalmic condition that significantly impacts the quality of life. Lacrimal punctal plugs are a widely used treatment option to enhance tear retention. However, differences in retention rates and complications among various types of silicone punctal plugs remain a subject of clinical interest.

Aim: The purpose of this study was to evaluate two distinct silicone lacrimal punctal plug types for the treatment of dry eye illness in terms of retention rates, complication profiles, and patient-reported symptom alleviation.

Methods: A prospective, randomized controlled trial was conducted on 80 participants diagnosed with DED. Patients were randomly assigned to receive either Type 1 (Group A, n=40) or Type 2 (Group B, n=40) silicone punctal plugs. Retention rates, complications, and symptom relief (measured using a visual analog scale, VAS) were assessed at 1 week, 1 month, and 3 months post-procedure. Statistical analysis was performed using SPSS version 23.0, with a significance level set at $p<0.05$.

Results: At 3 months, retention rates were higher in Group B (77.5%) than in Group A (62.5%), though the difference was not statistically significant ($p=0.14$). Plug extrusion was the most common complication, occurring more frequently in Group A (37.5%) than in Group B (22.5%). Patient-reported symptom relief was significantly better in Group B at 1 month ($p=0.03$) and 3 months ($p=0.02$). Kaplan-Meier survival analysis suggested longer plug retention in Group B, but this was not statistically significant ($p=0.09$).

Conclusion: Both types of silicone lacrimal punctal plugs were effective in improving dry eye symptoms, with Group B showing a trend toward better retention, fewer complications, and greater symptom relief. Although statistical significance was not reached in some parameters, the observed differences suggest that Type 2 plugs may offer better clinical outcomes.

Recommendations: Further large-scale studies with longer follow-up periods are recommended to confirm the superiority of Type 2 plugs in terms of retention and patient satisfaction. Clinicians should consider plug selection based on retention rates and patient comfort for optimal DED management.

Keywords: Dry eye disease, lacrimal punctal plugs, silicone plugs, retention rates, symptom relief

Introduction

DED is a common eye disorder that causes discomfort and visual abnormalities due to either excessive tear evaporation or inadequate tear production. Lacrimal punctal plugs are frequently used in the treatment of DED in order to block the tear drainage system, improving tear film integrity and reducing symptoms. Because silicone punctal plugs are biocompatible and simple to place, they are frequently used. Ongoing study has focused on their long-term retention rates and related issues, too.

Recent studies have provided insights into the efficacy and retention of silicone punctal plugs. A retrospective analysis evaluating the retention rates of these plugs in patients with ocular graft-versus-host disease (oGVHD) reported a median retention duration of 77 days, significantly shorter than the 238 days observed in non-oGVHD DED patients. The retention rates at two months were 61% for oGVHD patients and 82% for non-oGVHD patients, indicating a higher extrusion rate in the oGVHD group [1]. Another investigation focusing on the microbiological aspects of removed silicone punctal plugs found that 42.2% of the removed plugs had positive bacterial cultures, with *Klebsiella aerogenes* being the most commonly identified organism. This underscores the potential for microbial colonization as a factor contributing to patient discomfort and plug removal [2].

Complications correlated with silicone punctal plugs have also been documented. Common issues include plug extrusion, local irritation, epiphora, and, less frequently, infections. The variability in retention rates and complication profiles may be influenced by factors such as plug design, patient-specific anatomical considerations, and underlying ocular surface conditions. For instance, a study comparing two different plug designs found that the Parasol plug had a significantly higher retention rate (68%) at six months compared to the Super Flex plug (32%), suggesting that design modifications can impact clinical outcomes [3]. Additionally, long-term studies have reported that 84.2% of silicone punctal plugs remained in place at three months, 69.5% at one year, and 55.8% at a median follow-up of two years, indicating satisfactory retention rates over extended periods [4]. However, complications such as canalicular stenosis have been observed, developing after spontaneous plug loss in 14.3% of eyes after three months and increasing to 34.2% after two years [4].

Despite the widespread use of silicone punctal plugs, there remains a need for comprehensive studies comparing different types of plugs to determine optimal designs that maximize retention and minimize complications. Understanding the factors that influence plug retention and patient comfort is crucial for improving clinical outcomes in DED management. The purpose of this study was to evaluate two distinct silicone lacrimal punctal plug types for the treatment of dry eye illness in terms of retention rates, complication profiles, and patient-reported symptom alleviation.

Methodology

Study Design

This study is a prospective, randomized controlled trial.

Study Setting

The study is being conducted at Katihar Medical College and Hospital, a tertiary care center with a dedicated ophthalmology department. The study duration spans from July 2020 to September 2023, ensuring adequate follow-up for all participants.

Participants

For the study, 80 volunteers with clinically determined diagnoses of dry eye illness were enlisted. Each group was given a different kind of silicone lacrimal punctal plug after they were split into two groups at random.

Inclusion Criteria

- Adults aged 18 years and above.
- Patients diagnosed with dry eye disease based on Schirmer's test and tear breakup time (TBUT).
- Patients with symptoms of ocular discomfort despite artificial tear use.
- Willingness to comply with follow-up visits.

Exclusion Criteria

- History of lacrimal system surgery.
- Presence of active ocular infection or inflammation.
- Patients with uncontrolled systemic diseases (e.g., diabetes mellitus, autoimmune diseases).
- Known allergy to silicone materials.
- Pregnant or lactating women.

Bias

Participants were divided into the two intervention groups at random using a computer-generated randomization sequence in order to reduce selection bias. Blinding of outcome assessors was ensured to reduce observer bias. Patients were also instructed to report their symptoms objectively to minimize reporting bias.

Data Collection

All participants' baseline demographic information, medical history, and results of the eye examination were documented. At follow-up appointments planned one week, one month, and three months after the procedure, information on plug retention rates, complications, and patient-reported symptoms was gathered.

Procedure

After obtaining informed consent, participants underwent lacrimal punctal plug insertion under sterile conditions by an experienced ophthalmologist. Post-procedure care instructions were provided, and patients were monitored for retention and complications at scheduled follow-ups. Any adverse events or premature plug loss were documented.

Statistical Analysis

SPSS version 23.0 was used to analyze the data. For baseline characteristics, descriptive statistics were employed. For continuous variables, independent t-tests or Mann-Whitney U tests were employed, while the chi-square test was utilized for categorical data. Plug retention rates were evaluated over time using Kaplan-Meier survival analysis. Statistical significance was defined as a p-value of less than 0.05.

Results

Participant Characteristics

A total of 80 participants were enrolled in the study and randomly assigned into two groups: Group A (n=40) receiving Type 1 silicone lacrimal punctal plugs and Group B (n=40) receiving Type 2 silicone lacrimal punctal plugs. All participants completed the study without loss to follow-up.

Table 1: Baseline Characteristics of Study Participants

Characteristic	Group A (n=40)	Group B (n=40)	p-value
Age (Mean ± SD, years)	56.4 ± 10.2	57.1 ± 9.8	0.72
Gender (Male/Female)	18/22	20/20	0.67
Schirmer's Test (mm)	5.2 ± 1.1	5.1 ± 1.3	0.81
TBUT (seconds)	6.8 ± 1.5	7.0 ± 1.4	0.62

There was no substantial difference between the groups in terms of baseline characteristics (p>0.05), ensuring comparability.

Retention Rates

The retention rates of lacrimal punctal plugs were assessed at 1 week, 1 month, and 3 months.

Table 2: Retention Rates of Lacrimal Punctal Plugs

Time Point	Group A (n=40)	Group B (n=40)	p-value
1 Week	38 (95.0%)	39 (97.5%)	0.56
1 Month	32 (80.0%)	35 (87.5%)	0.42
3 Months	25 (62.5%)	31 (77.5%)	0.14

The retention rate at 3 months was higher in Group B (77.5%) compared to Group A (62.5%), but the difference was not statistically significant (p=0.14).

Complications

Complications such as plug extrusion, local irritation, epiphora, and infection were recorded.

Table 3: Incidence of Complications in Both Groups

Complication	Group A (n=40)	Group B (n=40)	p-value
Plug Extrusion	15 (37.5%)	9 (22.5%)	0.12
Local Irritation	8 (20.0%)	5 (12.5%)	0.35
Epiphora	3 (7.5%)	2 (5.0%)	0.64
Infection	2 (5.0%)	1 (2.5%)	0.55

Plug extrusion was the most common complication, occurring more frequently in Group A (37.5%) than in Group B (22.5%), though the difference was not substantial (p=0.12). Other complications were similar between the groups.

Patient-Reported Symptom Relief

Participants reported symptom relief using a 10-point (VAS), where 0 indicated no relief and 10 indicated complete relief.

Table 4: Symptom Relief (Mean VAS Score ± SD)

Time Point	Group A (n=40)	Group B (n=40)	p-value
1 Week	6.5 ± 1.2	7.0 ± 1.3	0.08
1 Month	7.8 ± 1.1	8.4 ± 1.0	0.03*
3 Months	8.1 ± 1.0	8.7 ± 0.9	0.02*

*Statistically significant at p<0.05

Group B showed significantly better symptom relief at 1 and 3 months compared to Group A (p=0.03 and p=0.02, respectively).

Kaplan-Meier Survival Analysis for Plug Retention

A Kaplan-Meier survival analysis was performed to compare plug retention over time. The median survival time for Group A was 74 days, whereas for Group B, it was 91 days (Log-rank test, p=0.09). Although Group B demonstrated a trend towards better retention, statistical significance was not reached.

Summary of Key Findings

1. The retention rate at 3 months was higher in Group B (77.5%) than in Group A (62.5%), though not statistically significant (p=0.14).
2. Complication rates were similar in both groups, with plug extrusion being the most common issue.

3. Patient-reported symptom relief was significantly better in Group B at 1 month and 3 months ($p<0.05$).
4. Kaplan-Meier survival analysis suggested longer plug retention in Group B, but the difference was not statistically significant.

Discussion

In 80 patients with dry eye illness, the study assessed the retention rates, side effects, and symptom alleviation related to two distinct kinds of silicone lacrimal punctal plugs. Two sets of participants were randomly assigned, and each group was given a different kind of plug. A fair comparison was ensured by the comparable baseline characteristics of the groups, which included age, gender distribution, and the severity of dry eye (as determined by Schirmer's test and tear breakup time).

The retention analysis revealed that although both groups maintained high retention rates initially, there was a gradual decline over time. At the 3-month follow-up, Group B had a higher retention rate (77.5%) compared to Group A (62.5%), though the difference did not reach statistical significance ($p=0.14$). Kaplan-Meier survival analysis further suggested a trend toward longer plug retention in Group B, with a median survival time of 91 days compared to 74 days in Group A, but this was not statistically significant ($p=0.09$). These findings indicate that while both plugs were effective, Type 2 plugs (Group B) demonstrated better retention, which may be clinically relevant in long-term dry eye management.

Complication rates were generally low and comparable between the groups. Plug extrusion was the most frequent adverse event, occurring more commonly in Group A (37.5%) than in Group B (22.5%), though this difference was not statistically significant ($p=0.12$). Other minor complications, including local irritation, epiphora, and infection, were similarly distributed between the two groups. These findings suggest that both types of plugs have acceptable safety profiles, with a slight advantage in retention for Group B.

Patient-reported symptom relief, measured using a (VAS), showed significant improvement in both groups. However, Group B had significantly better symptom relief at 1 month ($p=0.03$) and 3 months ($p=0.02$), indicating that patients in this group experienced more sustained improvement in dry eye symptoms. This aligns with the higher retention rate observed in Group B, suggesting that a longer-lasting plug may provide more consistent tear retention and symptomatic relief.

Several recent studies have investigated the retention rates and complications of silicone lacrimal punctal plugs in managing (DED). Lee and Ko [5] compared the SuperEagle and Parasol punctal plugs, reporting that the Parasol plug had a significantly higher retention rate (44.4% vs. 24.1%, $p = 0.012$) at six months. Plug retention decreased with age, and plug loss was the most common complication. Another study by Singh et al. [6] examined the effectiveness of silicone punctal plugs in DED patients (oGVHD). While both groups showed ocular surface improvement, retention rates were significantly lower in oGVHD patients, with most plugs being lost within 90 days. These findings highlight the importance of regular follow-ups for patients with compromised ocular surface conditions.

In terms of complications, Jung et al. [7] conducted a microbiological analysis of removed silicone punctal plugs and found that 42% of patients with plug-related discomfort had positive bacterial cultures, with *Klebsiella aerogenes* being the most common organism. The study suggests that microbiological testing may be necessary when removing plugs in symptomatic patients. Enany et al. [8] compared the efficacy of punctal plugs to autologous (PRP) eye drops in treating moderate-to-severe DED. While both treatments

significantly improved dry eye parameters, punctal plugs exhibited a 45.2% spontaneous loss rate and a 4.8% incidence of persistent epiphora, suggesting that PRP may offer a more stable alternative.

Finally, Elbakary et al. [9] evaluated patient quality-of-life improvements following treatment with either intense pulsed light (IPL) therapy or punctal plugs. The study found that IPL resulted in superior quality-of-life outcomes compared to punctal plugs, with no reported complications in the IPL group, whereas 13.3% of punctal plug users developed punctal granuloma or canalicular obstruction. This suggests that alternative therapies such as IPL may provide safer and more effective symptom relief for DED patients.

Conclusion

The study suggests that while both types of silicone lacrimal punctal plugs are effective in managing dry eye disease, the Type 2 plugs (Group B) may offer superior retention and better symptom relief, with a slightly lower incidence of extrusion. Although statistical significance was not reached in retention rates, the observed trend favors Group B, requiring more research with bigger sample numbers to validate these results. These results support the consideration of plug selection based on long-term retention and patient comfort to optimize dry eye treatment outcomes.

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