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# Using diabetic patients once daily fingerprick autologous blood eye drops for diabetic dry eye disease- A modified regimen to treat and prevent diabetic dry eye disease

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### ABSTRACT

**Purpose:** Diabetic patients tend to suffer from dry eye disease due to associated various reasons. Autologous blood is both safe and effective for treating Dry Eye Disease (DED) according to studies. Several papers demonstrated feasibility and effectiveness of four times Fingerprick Autologous Blood (FAB) eye drops to treat dry eye disease. As some diabetic patients perform daily finger pricking to monitor blood glucose level, the blood that remains can be used to apply to eyes to treat and prevent dry eye disease. This study intends to investigate if once daily fingerprick autologous blood eye drop in conjunction with blood glucose test is feasible and effective for diabetic patients who suffer from mild to moderate dry eye disease also to avoid four times fingerprick. This may be the first study on using diabetic patients once daily fingerprick autologous blood eye drops for mild to moderate diabetic's dry eye disease.

**Design, setting and participants:** This case series study enrolled 25 diabetics patients with mild to moderate DED who received ophthalmological care at a single clinic in Honolulu, Hawaii. All patients were performing once daily finger prick tests to monitor their blood glucose level. Participants were instructed to instill the remaining FAB after blood glucose tests into the medial inner canthus of each eye for one month. Patients remained on their daily dry eye treatment regimen throughout the study.

**Main outcomes and measures:** The OSDI (Ocular Surface Disease Index) scores to categorize severity of DED were used for comparison before and after using FAB eye drop daily for one

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month. A questionnaire was used to evaluate the acceptability and compliance.

**Result:** 52% of patients after one month of the trial demonstrated improvement in categorization of the severity in DED and willing to continue in the future.

**Conclusion and relevance:** FAB that remained after routine once daily blood glucose testing applied to the eyes may be feasible to enhance prevention and treatment of mild to moderate Diabetic DED. It may be disseminated and used in conjunction with the general practice in diabetic's patient care.

**Keywords:** autologous blood, finger prick, dry eye disease, diabetic. Ocular surface Disease Index

## Introduction:

There was about 54% prevalence of asymptomatic and symptomatic DED in diabetes.<sup>[1]</sup>

Dry eye is correlated with the level of glycated hemoglobin: the higher the level of glycated hemoglobin, the higher the incidence of dry eye.<sup>[2]</sup> The corneal abnormalities caused by hyperglycemia include superficial punctate keratopathy, neurotrophic ulcers, persistent epithelial defects, and recurrent corneal erosions.<sup>[3]</sup>

The Lacrimal Function Unit (LFU) consists of cornea, conjunctiva, lacrimal glands, meibomian glands, eye lids, and the sensory and motor nerves that connect them. The LFU is responsible for maintaining the tear film and thus the normal functioning of the ocular surface. Disease of any component of LFU due to diabetic can leads to dry eye syndrome. Patients with diabetes are at increased risk of developing LFU dysfunction.<sup>[4]</sup>

Diabetic neuropathy is a risk factor for lacrimal gland dysfunction. Furthermore, in an earlier report by Nakata et al. suggested that autonomic control of lacrimal gland function is compromised by neuropathy in patients with Diabetic.<sup>[5]</sup>

Several studies have focused on autologous serum tear as an effective treatment for DED.<sup>[8-</sup>

<sup>13]</sup> However, the process used to generate "serum tears" can be quite expensive and limited to designated laboratories.

Human blood is a significant source of growth factors, vitamin A and fibronectin that can promote healing and maintain a healthy ocular surface.<sup>[14-15]</sup> Fingerprick autologous Blood (FAB) is the blood outflow after a finger prick. The study by Than et.al revealed that direct administration of FAB to the cornea was safe and effective for the treatment of DED.<sup>[6]</sup> Result from a recent study by Erikitola et.al also concluded FAB is effective, accessible and safe to treat severe DED.<sup>[7]</sup> However, in these two studies, patients were required to prick finger four time a day for their FAB. From a realistic prospective, this can be painful and thus presents a significant compliance issue.

Diabetic patients usually have multiple health issues and medications. Compliance and cost issues can affect the outcome of DED treatment. If the patient can tolerate and comply with the once daily finger pricking for blood sugar test, more likely can apply the remaining blood for their eyes daily if they are properly educated. The necessity of once daily finger prick for monitoring blood sugar usually is a long-time task. Subsequent FAB eye drops to the eye for a long time can maintain the health of diabetic cornea and can be effective treatment for

existing DED. Furthermore, this regimen can be more convenient, effective and economical compared to commercial eye drops.

#### Method:

The trial was conducted in accordance with the tenets of the declaration of Helsinki.

Twenty-five patients diagnosed with mild to moderate DED (categorized by OSDI score between 10 to 20) and diabetics who managed their blood glucose levels with daily finger pricks were included in this study from January through March 2022. The participants were all of Asian ethnicity and included three males and twenty-two females between the ages of 55 to 84 years old who resided in Honolulu. (table1) All 25 patients received instructions on how to collect excess FAB for eye drops and also educated with evidence of the safety and benefits of FAB eye drop for DED. All patients signed written consent form to participate in this study.

**Inclusion criteria:** All patients included in this study were diagnosed with Diabetic and mild to moderate DED. Subjects were compliant with routine daily finger pricks. Patients remained on their daily dry eye treatment regimen throughout the study.

**Exclusion criteria:** poor compliance of finger pricking, severe dry eye disease and those already on serum tear.

A survey with questionnaires was conducted by author. (table2)

#### Result:

Of the 25 patients enrolled in this study, three reported difficulties with the application of FAB, five did not comply regularly, two stopped the regimen before the end of this trial. While 13 patients reported they consider this therapy to be helpful and will continue. No adverse events were reported. (Table 2)

Before starting the regimen, according to OSDI score categorization, there was 0% normal, there were 20 patients (80%) had OSDI score between 10 to 15 were categorized in mild while 5 patients (20%) had OSDI score between 15 to 20 were categorized in moderate. (Table3)

After one month of the regimen, 10 patients (40%) OSDI score improved to normal compared to zero patients before treatment ( $P=0.003$ ,  $P<0.05$ ). There were reduced mild DED and moderate DED after the regimen: 20 patients (80%) with mild DED reduced to 15 patients (60%) ( $p>0.05$ ), 5 patients (20%) patients with moderate DED reduced to zero patient ( $P>0.05$ ). Fisher exact was used to calculate the p value. There were statistically significant of patients improved from mild DED to normal after the regimen. There were patients improved from mild and moderate DED but was not statistically significant. (Table 3)

**Table1: Patient Demographics:**

Age range in years	55 - 84
Male	3
Female	22
Ethnicity	Asian

**Table2: Primary result**

Total patients	Respond Difficulties	Poor compliance	Lost to follow up	Regimen stopped by the patients	Interested in continuing	Consider the therapy to be helpful	adverse events
25	3	5	2	2	13	13	0
100%	12%	20%	4%	4%	52%	52%	0%

**Table 3: Comparison of DED severity categorized by OSDI score before and after the regimen**

Number of patients	normal	mild	moderate
Before the regimen	0 (0%)	20 (80%)	5 (20%)
After one month of the regimen	10 (40%) (p=0.003<0.05)	15 (60%) (p=0.065>0.05)	0 (0%) (p=0.056>0.05)

**Discussion:**

DED is highly associated with Diabetic. Aggressive treatment for these patients is necessary in order to prevent progressive corneal damage. However, compliance and socio-economic issues are barriers that need to be overcome to achieve successful outcomes for these patients. Previous trials to had patients to prick finger four times a day for one to six months has achieved good result. Good result was reported even in one month. Yet, to prick finger four times a day could be painful and hard to comply. In this study, once a day together with daily blood sugar test demonstrated the majority (over 50%) can continue the regimen and had symptomatic improvement of DED. As DM patient need to continue daily finger prick for their blood glucose control, applying the remaining FAB may benefit the treatment of dry eye disease for long time. The current market available insurance covered, or non-insurance covered eye drops can be very expensive. Daily FAB may reduce the usage of those eye drops and reduce the cost for patients and insurance company. Even though once a day regimen may not be fully therapeutic compared to four times a day or serum tears, but long-term continuously application may provide effective treatment for mild and moderate DED due to the better compliance and long-term nature of once daily finger prick. The main purpose of this study is to suggest a modified regimen to the public and demonstrate the feasibility and efficacy pertinent to mild to moderate diabetic DED. However, there is limitation to this trial. First, as this is a feasibility study, the relatively small number of participants of only Asian and the short study time from a single private practice in Honolulu that reduce the external validity. Second, the

objective method of Oxford grade of fluorescein staining was not used in this study in consideration the observer bias cannot be excluded and based on the report of not significant of objective findings in Hassan's FAB study.<sup>[18]</sup> Finally, there is no control group for comparison. A multicenter multiracial long-term controlled study with a large population of study participants is necessary to validate this regimen.

**Conclusion:**

FAB that remained after routine once daily blood glucose testing applied to the eyes may be feasible to enhance prevention and treatment of mild to moderate Diabetic DED. It may be disseminated and used in conjunction with the general practice in diabetic's patient care.

**Disclosure:**

Author has no financial interest to disclose.

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