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ORIGINAL ARTICLE

# Clinical results of botulinum toxin-a injection into the lacrimal gland in the treatment of chronic epiphora

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## Abstract

**Purpose:** To evaluate the clinical efficacy of botulinum toxin-A (BoNT/A) injection into the lacrimal gland for the treatment of functional and non-functional epiphora.

**Methods:** Twenty eyes of 10 patients who underwent transconjunctival application of 5 units (IU) BoNT/A (Botox®) to the palpebral part of the lacrimal gland were included. Demographic information, ophthalmological examinations (Schirmer test, tear break-up time, Munk score for ocular surface and tear dynamics), and a quality-of-life questionnaire of the patients were evaluated retrospectively before the application and at the 1<sup>st</sup>, 3<sup>rd</sup>, and 6<sup>th</sup> months after the injection.

**Results:** The study included 10 patients, all female, with a mean age of 61.5 years (range 54–69). Schirmer tests, T-BUT values, Munk score, and quality-of-life questionnaire scores were shown to be significantly decreased in the 1<sup>st</sup> and 3<sup>rd</sup> months ( $p < 0.001$ ). However, in the 6<sup>th</sup>-month measurements, it was observed that the Schirmer test, Munk score values, and quality-of-life questionnaire results returned to their pre-injection values.

**Conclusion:** In the treatment of chronic epiphora, botulinum toxin-A injection into the lacrimal gland may be one of the ways to relieve patients' complaints. The temporary effect of botulinum toxin and the fact that the clinical findings of the patients returned to their previous state at the sixth month in the present study indicated that repeat injections may be needed.

**Keywords:** Botulinum toxin; epiphora; lacrimal gland.

Epiphora, which can affect many patients, can cause blurred vision and irritation, and may have significant effects on the quality of life of patients. Despite its common occurrence, the management of epiphora involves various difficulties, according to the experience of many ophthalmologists.<sup>[1]</sup>

The classification of epiphora broadly encompasses two principal etiologies: inadequate lacrimal flow and hypersecretion of tears. Each of these etiologies is further

stratified into categories of functional and non-functional epiphora. Functional epiphora is characterized by an impairment in lacrimal drainage despite the anatomical patency of the lacrimal outflow system, often confirmed by irrigation or dacryoscintigraphy. In contrast, non-functional epiphora refers to cases with demonstrable anatomical obstruction, such as punctal stenosis or canalicular blockage, as evidenced by clinical examination and lacrimal probing/lavage.<sup>[2,3]</sup>



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Botulinum toxin injections into the lacrimal gland are increasingly being explored as a treatment for epiphora.<sup>[3]</sup> The primary objective of the present study was to ascertain the safety profile and therapeutic efficacy of botulinum toxin-A administered via lacrimal gland injection, specifically in the management of chronic epiphora attributable to both functional and non-functional etiologies.

## Materials and Methods

Twenty eyes of 10 patients who were admitted to Cukurova University Faculty of Medicine, Department of Ophthalmology, Oculoplasty Unit, between January 2021 and June 2024 with the complaint of epiphora and who were injected transconjunctivally with 5 units (IU) of BoNT/A (Botox®) into the palpebral part of the lacrimal gland were retrospectively analyzed for the evaluation of ocular surface with tear dynamics and the quality-of-life scoring system. This study was approved by the Cukurova University Faculty of Medicine Ethical Committee (01.09.2023-136-26) and conducted in accordance with the principles of the Declaration of Helsinki. Written informed consent forms were obtained from all patients.

Epidemiologic features and ophthalmological findings with tear dynamics of the cases were analyzed. Patients underwent an ophthalmological examination including the evaluation of the conjunctiva, lacrimal punctum, and lacrimal duct lavage with saline injection from the inferior lacrimal punctum. In case of lower punctal obstruction, lacrimal duct lavage was tested by saline injection from the upper lacrimal punctum. The dacryoscintigraphy test was performed in all cases. Patients were classified as having functional or non-functional epiphora based on clinical examination, lacrimal irrigation tests, and dacryoscintigraphy findings. Functional cases exhibited normal anatomical patency with delayed drainage, while non-functional cases demonstrated physical obstruction at any level of the lacrimal outflow system. Epiphora test dynamics and tear production were evaluated quantitatively by Schirmer-1 test, tear break-up time test (TBUT), questionnaire on quality of life (Table 1), and Munk score (Table 2) pre-injection and at the 1<sup>st</sup>, 3<sup>rd</sup>, and 6<sup>th</sup> months after injection, respectively.

All injections were performed in an outpatient setting under topical anesthesia (proparacaine hydrochloride 0.5%) using a biomicroscope with high magnification. The palpebral lobe of the lacrimal gland was visualized by everting the upper eyelid with a Desmarres retractor and applying gentle pressure. A 30-gauge needle

**Table 1.** Questionnaire for the evaluation of quality of life effects due to chronic epiphora

	Questions	Scoring 1/2/3/4
Quality of life -/20	Handkerchief addiction Daily house keeping Do it yourself Tear's splashing on glasses Take of glasses to wipe them	
Social life -/12	Public tearing(indoor or outdoor) Make up possible?/shaving? Indoor tearing: cooking, entertainment	
On the move -/12	Walking, trekking Biking Driving	
Lecture -/16	Blurred vision Book reading Computer screen reading Watching television	

**Table 2.** Munk score evaluation.

Munk Score
0 No Epiphora
1 Occasional epiphora requiring drying or dabbing less than twice a day
2 Epiphora requiring dabbing five to ten times per day
3 Epiphora requiring dabbing more than ten times per day
4 Epiphora requiring dabbing daily or constant tearing

attached to a 1 mL three-piece syringe was used to inject 5 units (0.1 mL volume) of BoNT/A (Botox®, diluted with preservative-free saline) directly into the visible palpebral lobe. Vascular structures were identified and carefully avoided during the procedure. The procedure was performed by an oculoplastic surgeon with over 5 years of experience in lacrimal gland interventions (Fig. 1). The average volume of BoNT/A (Botox®) injected was 0.1 mL. The average dose of BoNT/A injected into the palpebral gland was 5 units (0.1 mL volume, reconstituted with 2 mL preservative-free saline per 100 units). Follow-ups were performed at 1<sup>st</sup> week, 1<sup>st</sup> month, 3<sup>rd</sup> month, and 6<sup>th</sup> month controls.

## Statistical Analyses

Statistical analyses were conducted using the Statistical Package for the Social Sciences (SPSS) version 25.0 (SPSS Inc., Chicago, IL). Descriptive statistics for continuous variables are presented as mean±standard deviation, while categorical variables are expressed as frequencies



**Fig. 1.** Illustrative demonstration of botulinum toxin injection into the palpebral lobe of the lacrimal gland under outpatient conditions (the image does not reflect the actual clinical setup, which was performed under high-magnification biomicroscopy with lid eversion using a Desmarres retractor).

and percentages. The Kolmogorov-Smirnov test was employed to assess the normality of data distribution. Quantitative variables were summarized using the mean, range, and standard deviation. To evaluate differences

between preoperative and postoperative data within the study group, the paired t-test was applied. Depending on the type and distribution of the data, additional statistical tests used included the independent t-test, Mann-Whitney U test, one-way ANOVA, Kruskal-Wallis test, and Chi-square test. A p-value of less than 0.05 was considered statistically significant.

## Results

BoNT/A (Botox®) was applied to 20 palpebral lacrimal glands of 10 female patients with chronic epiphora. The mean age of the patients was  $61.5 \pm 4.9$  years. Two patients had functional epiphora, and eight patients had non-functional epiphora due to upper and lower punctum or canalicular stenosis. Botulinum neurotoxin was diluted at  $50 \mu\text{g/mL}$ , and 5 units of BoNT/A were injected into the lacrimal glands. The injected volume was 0.1 mL. No complications were observed during the injection.

At the first month, Schirmer test results decreased from an average of 27 mm to 13 mm, and Munk test scores decreased from an average of 3.4 to 0.7 (Tables 3 and 4, respectively). A significant decrease was observed in the Schirmer-1 test and tear break-up (T-BUT) time values of the patients in the 1<sup>st</sup>- and 3<sup>rd</sup>-month measurements compared to the pre-injection measurements ( $p < 0.001$ ) (Table 3).

**Table 3.** Analyses of tear break-up time and Schirmer-1 test measurements of the patients before and after lacrimal gland BoNT/A (Botox®) injection at 1<sup>st</sup> month, 3<sup>rd</sup> month and 6<sup>th</sup> month.

	Average $\pm$ SD	Median (min -max)	p
T-BUT before injection	18 $\pm$ 2.06	17 (14-21)	<0,001
T-BUT first month	11.55 $\pm$ 1.50	11 (8-14)	
T-BUT 3rd month	13.22 $\pm$ 2.53	12 (9-17)	0,002
T-BUT 6th month	11.22 $\pm$ 5.28	10 (3-17)	0,04
Schirmer-1 test before injection	27.44 $\pm$ 2.83	26 (21-35)	<0,001
Schirmer-1 test first month	13.33 $\pm$ 2.64	14 (10-18)	
Schirmer-1 test 3rd month	17.44 $\pm$ 4.09	16 (9-30)	
Schirmer-1 test 6th month	20.33 $\pm$ 6.24	20 (7-30)	0,03

**Table 4.** Munk score analyses of the patients who underwent BoNT/A (Botox®) injection into the palpebral lacrimal gland before and after injection at 1<sup>st</sup> month, 3<sup>rd</sup> month and 6<sup>th</sup> month

	Average $\pm$ SD	Median (min-max)	p
Munk score before injection	3.42 $\pm$ 0.53	3 (3-4)	<0,001
Munk score first month	0.71 $\pm$ 0.75	1 (0-2)	
Munk score 3 <sup>rd</sup> month	1.28 $\pm$ 0.75	1 (0-2)	0,001
Munk score 6 <sup>th</sup> month	3.14 $\pm$ 1.21	4 (1-4)	1,000

In the Munk score and quality-of-life questionnaire scores, a significant decrease in epiphora-related complaints was found when the scores of the patients who received botulinum toxin-A injection into the palpebral lacrimal gland were compared with the pre-injection and post-injection 1<sup>st</sup> and 3<sup>rd</sup>-month scores ( $p=0.004$ ,  $p<0.001$ , respectively) (Tables 4 and 5). In the quality-of-life questionnaire, satisfaction showed a dramatic response of up to 84%, with the score decreasing from 41/60 to 14/60 in the first month. Pairwise comparisons (1<sup>st</sup> vs. 3<sup>rd</sup>, 3<sup>rd</sup> vs. 6<sup>th</sup>, and 1<sup>st</sup> vs. 6<sup>th</sup> months) were conducted using the Wilcoxon signed-rank test with Bonferroni correction due to the non-parametric nature of the data. BoNT/A (Botox®) injection in the first month provided subjective clinical relief of epiphora in all patients.

No significant differences were observed in patients' Munk scores and quality-of-life questionnaire scores between the 1<sup>st</sup>-month and 6<sup>th</sup>-month measurements ( $p=0.180$ ,  $p=0.257$ , respectively). However, the 6<sup>th</sup>-month measurements were significantly higher than the 1<sup>st</sup> and 3<sup>rd</sup>-month measurements ( $p<0.001$ ). No significant differences were observed in tear break-up time (T-BUT) measurements among the 1<sup>st</sup>, 3<sup>rd</sup>, and 6<sup>th</sup> months ( $p<0.05$ ). The Schirmer test value at the 3<sup>rd</sup> month was found to be significantly higher compared to the 1<sup>st</sup> month ( $p<0.001$ ); however, the 6<sup>th</sup>-month measurements were not significantly different from the 1<sup>st</sup> and 3<sup>rd</sup>-month measurements ( $p<0.05$ ).

At the 6-month control examinations, the quality-of-life questionnaire resulted in a mean score of 43/60 and a mean Munk score of 3.1. In support of the observed increase, Schirmer's test increased to an average of 20 mm at 6 months. Tear break-up time was measured as 11 seconds on average in the 6<sup>th</sup> month, similar to the previous months. A subgroup comparison was conducted between patients with functional ( $n=2$ ) and non-functional epiphora ( $n=8$ ) to evaluate differential response to BoNT/A injection. Although both groups showed clinical improvement in Munk score, Schirmer test, and QoL scores, the small number of patients in the functional group limited

statistical power. No statistically significant difference was detected between the groups at any time point ( $p>0.05$ ). Post-procedural side effects of BoNT/A (Botox®) injection into the palpebral lacrimal gland were limited. No systemic side effects were observed in any patient. Unilateral ptosis was observed in only one patient as a complication of the procedure.

## Discussion

Epiphora caused by lacrimal drainage system obstructions affects the quality of life of patients. Surgical treatment of epiphora includes canalicular surgeries, conjunctivodacryocystorhinostomy (CDCR), dacryocystoplasty with silicone stent placement, and balloon dilatation, depending on the clinical features of the patient, the location, and the etiology of the obstruction.<sup>[4-6]</sup> Whilst dacryocystorhinostomy (DCR) remains the mainstay of treatment for nasolacrimal duct obstruction (NLDO), CDCR or some stents may be utilized for proximal obstruction, including severe canalicular obstruction.<sup>[2,7]</sup> Conjunctivodacryocystorhinostomy or other lacrimal drainage devices has a relatively higher risk of postoperative complications, including corneal erosions, diplopia, hemorrhage, infection, tube protrusion, and therefore requires regular follow-up and care.<sup>[7-11]</sup> Epiphora may persist in some patients after surgeries.<sup>[2,3,12]</sup> In recent years, lacrimal gland botulinum toxin-A injection for epiphora has gained increasing attention as a minimally invasive alternative with favorable safety and efficacy profiles. This approach offers symptom relief without the risks associated with anesthesia and surgery, particularly in refractory or high-risk patients.<sup>[13,14]</sup> BoNT/A inhibits the release of acetylcholine at presynaptic parasympathetic nerve terminals by cleaving SNAP-25, a synaptosomal-associated protein essential for vesicle fusion. This blockade prevents neurotransmitter release, leading to temporary denervation of the lacrimal gland's parasympathetic input. Consequently, the secretomotor

**Table 5.** Quality of life score analyses of the patients who underwent BoNT/A (Botox ®) injection into the palpebral lacrimal gland before and after injection at 1<sup>st</sup> month, 3<sup>rd</sup> month and 6<sup>th</sup> month

	Average±SD	Median (min-max)	p
Quality of life score before injection	41.71±4.60	41.5 (37-50)	<0,001
Quality of life score first month	14.71±4.57	16 (6-24)	
Quality of life score 3rd month	19.28±8.53	19 (6-30)	1,000
Quality of life score 6th month	43±12.66	49 (20-58)	



stimulation of the gland is suppressed, resulting in decreased tear production. The onset of action typically occurs within 3–5 days, with peak effect in 2 weeks and duration lasting approximately 3–6 months.<sup>[13,14]</sup>

In the literature, both Singh et al.<sup>[13]</sup> and Wojno et al.<sup>[14]</sup> reported subjective improvement ranging from 67% to 100% in their studies comparing groups according to the causes of epiphora.<sup>[13,14]</sup> According to Singh et al., there was no significant difference in median Munk score improvement between functional and non-functional groups.<sup>[13]</sup> In their study, Wojno et al. recorded subjective improvement among all patients in both groups.<sup>[14]</sup> Thus, overall efficacy and side effects are reportedly comparable for both functional and non-functional etiologies.<sup>[2,13-15]</sup> In the present study, an improvement was found in Munk score and quality-of-life questionnaire values in patients with epiphora due to both functional and non-functional causes compared to the pre-injection period. To define objective results, it was important to evaluate quality-of-life scoring, Schirmer test, and tear break-up time before injection. In accordance with the literature, improvement was also found in tear break-up time and Schirmer test measurements in this study.

So far, studies comparing transcutaneous and transconjunctival injections of botulinum toxin A have failed to show a significant difference in efficacy.<sup>[16-19]</sup> A consistent finding across all studies was that transient ptosis represented the most common complication.<sup>[20-25]</sup> Ptosis was reported to develop in an average of 15% of patients who received transcutaneous injections.<sup>[16]</sup> The average ptosis rate reported in studies using the transconjunctival approach was 10%.<sup>[16-19]</sup> Lee et al.'s randomized controlled study, comparing transconjunctival and transcutaneous botulinum toxin A injections, reported transient ptosis in 10.7% of transconjunctival cases and diplopia in 8% of transcutaneous cases, with no significant intergroup differences in these complications.<sup>[16]</sup> In the present study, botulinum toxin A injections were administered transconjunctivally to all patients for ease of administration and safety profile.

Another consideration regarding the use of botulinum toxin A injections for the treatment of epiphora is the need for long-term follow-up and potential re-injections for continued successful management of the condition. In the patient group included in the study, significant improvement in epiphora complaint was seen in the first 3 months of follow-up. However, the 6<sup>th</sup>-month results showed an increase in the quality-of-life questionnaire and

Munk scores. In support of this, an increase in Schirmer test in quantitative measurements was noted. Tear break-up time was similar to the previous averages at the 6<sup>th</sup> month. The fact that the return to pre-injection values seen in the sixth month was not seen in the T-BUT test was thought to be due to changes in ocular surface dynamics in the patients. Observation of a return to pre-injection values at the 6<sup>th</sup> month suggested that the duration of the effect of the toxin was limited to 6 months. Many published studies report that even when patients' symptoms were well controlled, continuous management required them to return for repeat injections every few months.<sup>[16-21]</sup> Therefore, it may be useful to plan injection after the 6<sup>th</sup> month for patients who need re-injection.

Prior studies on botulinum toxin A lacrimal gland injections utilized doses ranging from 1.25 to 15 units per treatment, with the majority employing 2.5 to 5 units of BoNT/A (Botox®).<sup>[13-19]</sup> No correlation was established between the initial toxin dose and subsequent re-injection frequency. Insufficient initial dosing posed minimal risks of additional treatment.<sup>[2,3]</sup> Botulinum toxin A injection has been consistently demonstrated as safe for epiphora of both functional and non-functional etiologies across multiple studies, with all reported side effects being limited and transient.<sup>[17-26]</sup> Consequently, lacrimal gland botulinum toxin injection presents a valid treatment strategy for both functional and non-functional epiphora.<sup>[26]</sup>

The efficacy of botulinum toxin A injection spans a remarkable age range, from 8 to 94 years, as documented in the literature. This treatment stands out for its practicality: it is a minimally invasive, outpatient procedure that is easy to apply and has a positive side-effect profile. Its benefits extend to its repeatability, with subsequent injections maintaining similar effectiveness. A key advantage is the avoidance of anesthesia and surgical complications often seen with lacrimal surgery, especially beneficial for adolescents and adults. While young children might need sedation, this injection offers a valuable option for those unable to undergo surgery, such as elderly patients with poor surgical candidacy or individuals with malignancies. Moreover, it reduces the burden of extensive postoperative follow-up, simplifying patient management.<sup>[2-5,26]</sup>

## Limitations

This single-center retrospective study on lacrimal gland botulinum toxin injections for epiphora has several limitations. The relatively small sample size may have influenced the statistical outcomes. Additionally, the retrospective design inherently introduces selection bias.

All participants in the study were female. This gender distribution was not a predetermined inclusion criterion but occurred coincidentally. It is possible that female patients are more likely to seek treatment for epiphora or are more commonly referred for such interventions. Further studies with larger and more balanced populations are needed to determine whether gender plays a role in treatment response or disease prevalence. Nevertheless, despite these constraints, we believe that our findings provide meaningful insights and contribute to the existing literature, particularly concerning quality of life and tear dynamics in the context of botulinum toxin treatment for epiphora.

## Conclusion

Ultimately, botulinum toxin A administration to the lacrimal gland presents a significant advancement in managing epiphora. This cost-effective and safe outpatient procedure offers a compelling alternative or complement for many chronic epiphora sufferers. The current evidence strongly supports botulinum toxin injection as a safe, minimally invasive, and effective treatment. Nevertheless, ongoing research is crucial to fully establish the optimal toxin type, dosage, and injection frequency for lacrimal gland BoNT/A treatment protocols.

**Ethics Committee Approval:** The Cukurova University Ethics Committee granted approval for this study (date: 01.09.2023, number: 2023-136-26).

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