Evaluation of silicone stent intubation procedure in management of punctal stenosis combined with dry eye syndrome

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Running Title: Silicone stent intubation in management of epiphora

Abstract

Purpose: To evaluate the effectiveness of silicone stent intubation procedure in management of punctal stenosis combined with dry eye syndrome.

Methods: This was a prospective interventional case study carried out in Mansoura Ophthalmic Center – Mansoura University on 40 eyes with epiphora combined with dry eye syndrome to detect the effectiveness of Silicone Stent Intubation in management of epiphora during the period from 1 November 2019 to 31 October 2020. All individuals were subjected to full history and ocular examination. In addition, assessment of epiphora according to Sahlin et al. score, fluorescein dye disappearance test and lacrimal syringing to recognize the site of blockage.

Results: The study included 40 patients with punctal stenosis associated with dry eye syndrome: 26 males (65%) and 14 females (35%) with a mean age of 61.95 ± 6.04 and age range from 51 to 72 years. Epiphora grade 3 (permanent epiphora) occurred in 36 cases (90%), and grade 2 (moderate epiphora) occurred in 4 cases (10%). Six months after removal of the plugs, epiphora improved in 75% of patients, and fluorescein dye disappearance test results improved in 90% of patients; 10% of cases had early extrusion of the silicone stent tube.

Conclusion: Bicanalicular silicone stent intubation seems to be an effective tool in the management of acquired punctal stenosis combined with dry eye syndrome.

Key words: Epiphora, Dry eye syndrome, Silicone stents, punctal stenosis.

INTRODUCTION:

Epiphora can annoy patient's quality of life by causing discharge, blurring of vision, sore skin, and persistent weepy look[1]. Thus, epiphora can interfere with social behaviors[2]. A previous study divided etiology of epiphora into numerous groups such as dry eye with reflex lacrimation, nasolacrimal duct obstruction and lid malposition. It is difficult to make a perfect grouping. Inflammatory ocular diseases like dry eye syndrome, chronic blepharitis, toxic epidermal necrosis or graft-versus-host disease can affect the puncti and canaliculi by stenosis or even nasolacrimal duct obstruction[3].

Patients complaining of dry eye syndrome were managed by tear film substitutes, but epiphora was not treated. Then, the lacrimal system irrigation is performed to assess the patency of the lacrimal drainage system. These patients were diagnosed with nasolacrimal duct stenosis combined with dry eye syndrome complaining of annoying epiphora due to cold wind or air cooler. Silicone stent intubation set has been performed to manage the stenosis of the nasolacrimal duct resulting in

improved epiphora symptoms. Silicone intubation for nasolacrimal duct stenosis was tried for the first time by Keith in 1968[4].

This prospective interventional case study of patients admitted in Mansoura ophthalmic center over a six-month period focuses on management of epiphora combined with dry eye syndrome. We will try through this prospective interventional case study to evaluate the using of silicone stent intubation procedure in management of epiphora combined with dry eye syndrome

PATIENTS AND METHODS:

This was a prospective interventional case study carried out in Mansoura Ophthalmic Center – Mansoura University on sample size of 40 eyes with epiphora combined with dry eye syndrome to detect the effectiveness of bicanalicular silicone set stent in management of epiphora during the period from 1 November 2019 to 31 October 2020 after approval from Institutional review board (IRB) code number M.19.10.851, Faculty of Medicine, Mansoura University

Full general and ophthalmic history which include age, gender, occupation and socioeconomic status and history of similar condition were performed. Also, ocular history to exclude any previous refractive or ocular surgery and ocular injury was performed. Full ophthalmic examination including assessment of epiphora according to Sahlin et al. score[5] and slit lamp examination including, Break up time test by fluorescein dye 2% and exclude eye lid malposition. Schirmer test, fluorescein dye disappearance test and lacrimal system syringing.

In this prospective interventional case series, 40 eyes from 40 patients with punctal or canalicular stenosis were included. Punctal stenosis was detected on slit-lamp examination and diagnostic probing. Diagnosis of canalicular stenosis was made on the basis of a diagnostic lacrimal system syringing. The patients underwent silicone stent intubation under general anesthesia from November 2019 to October 2020. Patients were excluded if they had previous eyelid and/or lacrimal surgery, a lump overlying or involving the punctum and/or other parts of the tear drainage system, long complete upper lacrimal system obstruction (canaliculi and common canaliculus) on diagnostic probing, or nasolacrimal duct stenosis or obstruction on irrigation testing. The surgical options were explained, and informed consent was obtained.

Surgical procedure

Bicanalicular lacrimal intubation silicone set stent (Eagle silicone tube) was performed in the operating room under general anesthesia. Serially enlarging Bowman probes were inserted (ranging from number 00 to number 1) in the stenotic canaliculi to enlarge them prior to silicon intubation without creation of a false passage. Lacrimal silicone intubation set stent was inserted immediately after dilatation through the upper punctum till reach under the inferior turbinate of the nose and delivered outside by mosquito forceps if done successfully the other end was inserted into the lower punctum and advanced within the lacrimal passage like the other end till delivered outside the nose . Antibiotic and steroid eye drops were applied and the patients were instructed to continue them four times daily for one week. Postoperative follow-up examinations were performed at one day, one month, 3 months, and 6 months thereafter. Tubes were left in place for a minimum of 6 months unless they became extruded.

Outcome measures

Epiphora was subjectively evaluated based upon patient satisfaction and clinical improvements by Sahlin et al. score[5] (table 1). At each follow-up visit, epiphora was determined according to the patient's grading scale, fluorescein dye disappearance test[6] (table 2) and the results were recorded in a database.

Table 1: Epiphora Grading according to Sahlin et al. score [5].

Grade	Description	Epiphora assessment
Grade 0	No epiphora	No tearing
Grade 1	Mild epiphora	Tearing only outdoors in wind
Grade 2	Moderate epiphora	Tearing only outdoors but not indoors
Grade 3	Permanent epiphora	Tearing outdoors and indoors

Table 2: Fluorescein dye disappearance test[6]

Grade	Dye disappearance time, min
1	<3
2	3-5
3	>5

Statistical Analysis of the Data:

Results were statistically analyzed by using statistical package of social sciences (SPSS 26.0, IBM/SPSS Inc., Chicago, IL). Two types of statistical analysis were conducted:

Descriptive statistics

It included estimates for summarizing the continuous data as mean (X) and standard deviation (SD) median and range. Frequency with percentage (%) was used for presenting qualitative data.

Analytical or inferential statistics

- ***Marginal Homogeneity test*** was used to assess the difference between two dependent groups of categorical variables in more than 2 classes.
- ***McNemar's test*** was used to assess the difference between two dependent groups of categorical variables in 2 classes.

RESULTS:

Patient's characteristics

This study was carried out on 40 eyes of 40 patients complaining of punctal stenosis with canalicular stenosis associated with dry eye syndrome during the period between 1 November 2019 to 30 October 2020, including 26 males (65%) and 14 females (35%) with the mean age of 61.95 ± 6.04 and age range from 51 to 72 years.

Preoperative epiphora grading among the patients in our study was 36 cases (90%) on grade 3 permanent epiphora, 4 cases (10%) on grade 2 moderate epiphora.

One day Postoperatively assessment of epiphora grading as 36 cases (90%) on grade 0 no epiphora at all and 4 cases (10%) on grade 1 mild epiphora, the difference from preoperative epiphora was statistically significant ($p < 0.001$) and marginal homogeneity test = 68.415.

One month postoperative 34 cases (85%) on grade 0 no epiphora, 6 cases (15%) on grade 1 mild epiphora, the difference from preoperative epiphora was statistically significant ($p < 0.001$) and marginal homogeneity test = 68.415.

Three months postoperative 32 cases (80%) on grade 0 no epiphora, 7 cases (17.5%) on grade 1 mild epiphora and 1case (2.5%) on grade 2 moderate epiphora, the difference from preoperative epiphora was statistically significant ($p < 0.001$) and marginal homogeneity test = 68.415.

Six months postoperative 30 cases (75%) on grade 0 no epiphora, 8 cases (20%) on grade 1 mild epiphora and 2 cases (5%) on grade 2 moderate epiphora with p value < 0.001 and marginal homogeneity test = 68.415.

Consequently, the fall in the number of cases with improved epiphora compared with the early postoperative results, the difference from preoperative epiphora was still statistically significant ($p < 0.001$) and marginal homogeneity test = 68.415 (Table 3).

Table 3: Assessment of Epiphora grading in the cases of the study along the duration of follow up

Epiphora grading	Follow up					Test of significance
	Preoperative	At 1 day	At 1 month	At 3 Months	At 6 Months	
Grade 0 (No epiphora)	**0 (0%)**	**36 (90%)**	**34 (85%)**	**32 (80%)**	**30 (75%)**	
Grade 1 (Mild epiphora)	**0 (0%)**	**4 (10%)**	**6 (15%)**	**7 (17.5%)**	**8 (20%)**	**MH= 68.415**
Grade 2 (Moderate epiphora)	**4 (10%)**	**0 (0%)**	**0 (0%)**	**1 (2.5%)**	**2 (5%)**	**P < 0.001***
Grade 3 (Permanent epiphora)	**36 (90%)**	**0 (0%)**	**0 (0%)**	**0 (0%)**	**0 (0%)**	

Preoperative fluorescein dye disappearance test grading among the patients participating our study was 26 cases (65%) on grade 3 (>5minutes), 10 cases (25%) on grade 2 (3-5 minutes) and 4 (10%) on grade 1(<3 minutes).

One day postoperative 40 cases (100%) on grade 1 (<3 minutes) and was statistically significant compared with preoperative data (p value <0.001) and marginal homogeneity test = 44.543.

One month postoperative 39 cases (97.5%) on grade 1(<3 minutes) and 1 case (2.5%) on grade 2 (3-5 minutes) and was statistically significant compared with preoperative data (p value <0.001) and marginal homogeneity test = 44.543.

Three months postoperative 38 cases (95%) on grade 1 (<3 minutes) and 2 cases (5%) on grade 2 (3-5 minutes) and was statistically significant compared with preoperative data (p value <0.001) and marginal homogeneity test = 44.543.

Six months postoperative 36 cases (90%) on grade 1 (<3 minutes), 3 cases (7.5%) on grade 2 (3-5 minutes) and 1 case (2.5%) on grade 3 (>5minutes) with p value < 0.001 and marginal homogeneity test = 44.543.

Consequently, the drop in the success rate of fluorescein dye disappearance time test compared with the early postoperative results, the difference compared with the preoperative fluorescein dye disappearance time test data was statistically significant (p < 0.001) and marginal homogeneity test = 44.543 (Table 4)

Table 4: Assessment of Fluorescein dye disappearance test grading in the cases of the study along the duration of follow up

Fluorescein dye disappearance test grading	Follow up				Test of significance
	Preoperative	At 1 day	At 1 month	At 3 Months	At 6 Months	
Grade 1	4 (10%)	40 (100%)	39 (97.5%)	38 (95%)	36 (90%)	MH= 44.543
Grade 2	10 (25%)	0 (0%)	1 (2.5%)	2 (5%)	3 (7.5%)	P < 0.001*
Grade 3	26 (65%)	0 (0%)	0 (0%)	0 (0%)	1 (2.5%)	

Silicone tube stability among 40 patients was stable for 1 month postoperative without any discomfort from it, but instability of the stent appeared between 2 patients at 3 months postoperative follow up and we removed it and 2 patients at 6 months and epiphora persist after removal of the silicone stent (table 5).

Table 5: Assessment of silicone stent stability in the cases of the study along the duration of follow up

silicone stent stability	Follow up				Test of significance
	At 1 day	At 1 month	At 3 Months	At 6 Months	
Yes	40 (100%)	40 (100%)	38 (95%)	36 (90%)	MCN= 3.462 P = 0.094
No	0 (0%)	0 (0%)	2 (5%)	4 (10%)	

DISCUSSION

Epiphora can occur when tears don't drain into the lacrimal drainage pathway due to punctal stenosis, obstructed punctum or due to an abnormal lid position, even in the presence of a normal punctum [7].

Punctal stenosis can be secondarily triggered by many factors, such as conjunctivitis, dry eye syndrome, eyelid malposition, topical medications, trauma, other systemic diseases, and cancer chemotherapy, accompanied by canalicular stenosis, nasolacrimal duct stenosis or obstruction[8].

Now there are no standardized clinical strategies for the treatment of epiphora caused by punctal stenosis, and therapeutic approaches vary among oculoplastic surgeons Several procedures have been used in the management of AEPS including self-retaining bicanalicular stents, dilatation of the puncti with Nettleship punctal dilator, snip punctoplasty, punctal punching, punctoplasty with mitomycin-C, perforated punctal plugs and mini-monoka [9].

In the present study, the role of a silicon stent intubation operation in the treatment of epiphora and dry eye condition is investigated. All of the patients suffered from dry eye syndrome. Dry eye syndrome, chronic blepharitis, graft-

versus-host disease, or toxic epidermal necrosis can produce punctal, canalicular, or Nasolacrimal duct stenosis or occlusion. As a result, Patients with dry eyes and reflex crying who also have a problem with the nasolacrimal passage will have more epiphora.

We feel that silicone stent intubation could help people with dry eye condition who have reflex weeping due to NLD stenosis. We chose patients based on the following inclusion criteria to evaluate this idea. The first group included patients who had epiphora and were diagnosed with dry eye syndrome using Schirmer, TBUT, and fluorescein dye disappearance tests. Although the patients were given lubricants, they were not healed of their epiphora. After that, a lacrimal syringing test was carried out. Patients were eventually identified with stenosis of NLD and dry eye disease.

Oh et al., 2015 stated that the mean age of the patients with stenosis of the nasolacrimal duct combined with dry eye syndrome included in their study was 58.5±12.0 years ranging from 33 to 84 years[8].

In the study carried out by NX et al., 2016 total of 37 eyes of 37 patients with the mean age 52.8 ± 9.0 with symptomatic epiphora without nasolacrimal duct obstruction[10].

Alsulaiman & Alsuhaibani, 2019 included 98 eyes of 51 patients: 20 men and 31 women with a male to female ratio of 1:1.55. The average age was 46.3 ± 8.3 years with a range of 25–67 [11].

As shown in this study dry eye syndrome is a risk factor for nasolacrimal duct stenosis or even nasolacrimal duct obstruction and reflex tearing due to ocular surface irritation leading to epiphora, variation of epiphora grading according to the degree of stenosis which affect any portion of the nasolacrimal duct.

Settlement of a silicone stent permits dilation of the soft tissue portion of the nasolacrimal duct so decrease the resistance of the flow of the tears through the lacrimal drainage system. The increasing flow of the tears allows preserve an enlarged passage (riverbed phenomena). The reduction in resistance of the lacrimal system is more when using 2 stents instead of one (Poiseuille law) [12].

We found that the lacrimal intubation silicone set as a treatment procedure for NLD stenosis is thought to be a quick operation with few risks and minimal invasiveness. Unlike snip punctoplasty, there are no incisions made with this surgery, which could contribute to subsequent restenosis and scarring, especially in individuals with uncontrolled ocular surface inflammation.

Bicanalicular silicone stent intubation for management of epiphora is the most common procedure. Partial and functional nasolacrimal duct obstruction on lacrimal irrigation may be considered for stenting. Failed stenting for partial or functional nasolacrimal duct obstruction should perform DCR[13].

Silicone stent intubation is less invasive than DCR. Also, silicone intubation has advantage of reestablish the normal anatomical pathway of the lacrimal drainage system instead of creating a non-physiologic bypass of the nasolacrimal duct and improves the lacrimal pump function[12].

In the present study, we chose the Sahlin scoring of epiphora to assess the efficacy of silicone intubation set to improve the grading of epiphora.

We performed lacrimal syringing test followed by silicone stent intubation by lacrimal intubation silicone set stent and judge the success rate by Sahlin epiphora scoring at 6 months postoperative which was 75% (30/40 patients) grade 0 (no epiphora), 20% (8/40 patients) grade 1 (mild epiphora) and 5% (2/40 patients) grade 2 (moderate epiphora) and fluorescein dye disappearance test which was 90% (36/40 patients) grade 1 (<3 minutes), 7.5% (3/40 patients) grade2 (3-5 minutes) and 2.5% (1/40 patients) grade 3 (>5 minutes).

In our study we report complete resolution of epiphora in 75% and partial improvement in a further 5 %.

In recent years, Crawford-style Persistent epiphora with partial lacrimal system obstruction has been proven to benefit from the use of an olive tip stent. Intubation has

been shown to be useful in patients with NLDO, according to a growing body of evidence in the literature. Other causes such as punctal stenosis and canalicular obstruction were not eliminated in these trials, which revealed that intubation was successful in patients with a diagnosis of functional obstruction, with a success rate ranging from 47 percent to 79 percent [14].

Using the National Eye Institute Visual Function Questionnaire, Y et al. (2011) revealed that effective SI increased patients' vision-related quality of life[15].

G Jutleyet al., 2013 The GBI questionnaire indicated subjective improvement in QOL following DCR for NLD obstruction in adult patients with a subscale score of 22.16, a total score of 15.04, and a social support score of 4.67. A favorable score implies a successful surgery[16].

As a result, if people suffering from epiphora also have problems with their nasolacrimal passages, the epiphora is likely to worsen.

We hypothesized that silicone stent intubation would be effective for epiphora in patients who suffered from dry eye syndrome through resolving of the nasolacrimal duct stenosis and functional improvement of the lacrimal sac.

In a retrospective study by Moscato et al, the success rate with BCI was 77%. In this study, the patients with patent lacrimal system without resistance in irrigation (functional nasolacrimal duct obstruction) were included[17].

Using the 25-item National Eye Institute Visual Function Questionnaire, Kabata et al. reported that effective SI enhanced patients' vision-related QOL. The NLD Obstruction Symptom Score is made up of five elements that focus on the most prevalent ocular symptoms of NLD obstruction[15].

Complication rates have been recorded in prior trials of different bicanalicular stent systems with longer stent preservation durations. Ahmed and coauthors studied planned long-term stent placement in trachoma patients and found that stent maintenance took an average of 29.6 ± 10.2 months. They found that 23.1 percent of patients had difficulties that necessitated stent removal, and they hypothesized that a prolonged stent maintenance time would be beneficial in patients who are prone to re-stenosis after tube removal[18]. Veloudios et al evaluated the long-term retention of Crawford bicanalicular nasolacrimal stents for various causes. The reported rate of complications was 41% and 10% after 3 months and 6 months respectively. Based on the results that no complications were reported in 11 patients who had stents in place for more than 36 months, conclusion was made that stents could be left in place "forever.". The appropriate period for stent withdrawal is 4 months and the longest duration of retention of the stent is 24months with rate of complication about 9.1% [19]. In another study, Moscato and colleagues studied the effect of use of bicanalicular silicone intubation in management of functional NLD obstruction. The mean duration to remove the stents among the included cases was 4 months and the maximum stent retention period was 24 months. The overall complications rate was 9.1% [14]. In another study performed by Connell and colleagues that evaluated the long-term follow-up of bicanalicular intubation for NLD and canalicular obstruction, the mean duration of stent retention was 4.8 months with 3 months as a minimal duration and 10 months as the longest duration. There were no tube-related problems noted by the authors along 69.7 months follow up period [20].

Our investigation found no punctal/canalicular problems, except for two patients who had three-month silicone stent extubation and another two patients who experienced it at six months. Despite the existence of epiphora, immediate removal of silicone stent was done. In ten patients, little discomfort was noticed, which cleared spontaneously with conservative therapy.

Despite the obtained results in our study, some limitations do exist. Small number of recruited cases and short follow up duration after the surgery were the main limitations. A larger randomized comparative clinical trial is needed to support the superiority of Silicone intubation is superior to other treatments during the management of NLD stenosis induced dry eye and epiphora.

CONCLUSION:

Bicanalicular silicone stent intubation procedure appears to be an effective operation in the management of acquired punctal stenosis which is combined with dry eye syndrome.

This is an interventional case series study, our study is significant as it offers valued visions for other clinicians and can serve as good results for larger studies with a longer follow-up period. We assessed the patients after the operation for 6 months. Long-term anatomic and functional success could not be concluded based on the short follow-up.

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DATA AVAILABILITY

All data are included in this article.

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Ethics declarations

Conflict of interest

Haitham I.Regal, Sameh M. Saleh, Nader R.El-Metwaly2, Abd El-Monem A. El-Hessy. all authors have no conflicts of interest that are directly relevant to the content of this review.

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