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Assessment of Lacrijet monocanalicular intubation for congenital nasolacrimal duct obstruction

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Abstract

Purpose: To assess the success rate and complications of Lacrijet monocanalicular stent (FCI S.A.S, Paris, France) intubation in children treated for congenital nasolacrimal duct obstruction (CNLDO).

Methods: Retrospective review study which included children with CNLDO that were intubated with Lacrijet monocanalucilar silicone tube.The Lacrijet tube remained in place for 11–15 weeks post operatively and was removed in the clinic with topical anesthesia. Operative time was recorded for each case. All children were evaluated using the following parameters preoperatively and postoperatively: tear meniscus height, Fluorescein dye disappearance test (FDDT), and MUNK score.

Results: The study included 20 eyes with mean age of 26.25 ± 11.25 months. 17 eyes (85%) had undergone probing previously. Mean operation time of Lacrijet intubation was 8.5 min (95% CI 7.04–9.95). Mean follow-up period was 204.65 ± 105.27 days. Lacrijet intubation resulted in statistically significant improvements in tear meniscus height ($P < .001$), FDDT ($P < 0.001$), and MUNK score ($P < 0.001$) in all children. Two different sizes of Lacrijet intubations were used. Complete success was obtained in all cases. No complications were observed.

Conclusions: Lacrijet lacrimal intubation has a high rate of success, shortens surgical time and has a low rate of complications in children with CNLDO.

Keywords

Congenital nasolacrimal duct obstruction, Lacrijet, lacrimal intubation, monocanalicular intubation, epiphora

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Introduction

Congenital nasolacrimal duct obstruction (CNLDO) is usually secondary to a blockage at the valve of Hasner by a membranous tissue. The prevalence of CNLDO ranges from 1.25% to 12.5%.[1,2] Approximately 90% of all the symptomatic CNLDO resolves spontaneously by the first year of life.[3,4] Silicone lacrimal intubation is indicated if conservative and/or probing treatments fail to resolve CNLDO. There are various classifications for the silicone tubes: Bicanalicular versus monocanalicular and pulled versus pushed intubation devices. Bicanalicular tubes (for example: Crawford, BIKA, and Ritleng) are passed through both puncta to the lacrimal system whereas, monocanalicular tubes (for example: Monoka, Masterka, and Lacrijet) are passed through one punctum. There are advantages and disadvantages to each technique. Few previous studies have compared the two kinds of stents in CNLDO,[5–7] but the results were not consistent between the studies. The second classification for the

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silicone tubes is: pulled intubation devices (e.g. Monoka, Crawford, BIKA and Ritleng) in which the stent is advanced through the nasolacrimal duct system and retrieved through the nose by pulling it, and pushed intubation devices (e.g. Masterka, Lacrijet [monocanalicular] and Nunchaku [bicanalicular]) in which the stent is pushed into the nasolacrimal duct and anchored in place at the punctum by a plug-like fixation head. There is less nasal manipulation while intubating the pushed devices, which reduces the considerable risks from using air masks under general anesthesia.

Lacrijet silicone tube (FCI S.A.S, Paris, France) is a new monocanalicular pushed intubation stent which is indicated for use in case of epiphora, CNLDO, and for the repair of canalicular laceration. The aim of this present study was to assess the success rate and complications of Lacrijet intubation in children treated for CNLDO.

Methods

A retrospective review was conducted on children with CNLDO who were intubated with Lacrijet monocanalucilar silicone tube at Baruch Padeh Medical Center, from June 2019 to August 2020.

Patients included in this study were children less than 5 years old at the time of the operation who suffered from CNLDO. Exclusion criteria included children with canalicular obstruction, previous lacrimal intubation, complex nasolacrimal duct obstruction, corneal pathology, congenital glaucoma, eyelid malposition, allergic conjunctivitis, and Down syndrome.

This study was approved by the local institutional review board and adhered to the principles of the Declaration of Helsinki.

CNLDO was diagnosed as a history of persistent epiphora and/or discharge since birth with one of the following criteria:

1. Positive reflux when expressing over the lacrimal sac.
2. Positive fluorescein dye disappearance test.

All surgeries were performed under general anesthesia by the same surgeon (S.H.A.). A single use sizer was used to probe through the upper punctum and its position exiting the inferior meatus was confirmed through metal-on-metal touch technique. According to the sizer, an appropriate length of Lacrijet tube (different lengths exist from 30 mm to 50 mm) was chosen to be intubated through the upper punctum (shown in Figure 1). In children, smaller sizes are usually chosen. During the monocanalicular intubation, the surgeon retracts a sliding piston, which releases the silicone tube (shown in Figure 2). The proximal end of the tube maintains in place by a punctal anchor. The operative time was defined as the time between start of the surgery (post anesthesia) and the completion of the surgery (after ointment was applied to the eye(s)).

Patients were prescribed a topical Maxitrol drops (Neomycin-Polymyxin B-Dexamethasone) three times a day for 14 days postoperatively.

The silicone tube remained in place for 11–15 weeks post operatively and was removed in the clinic with

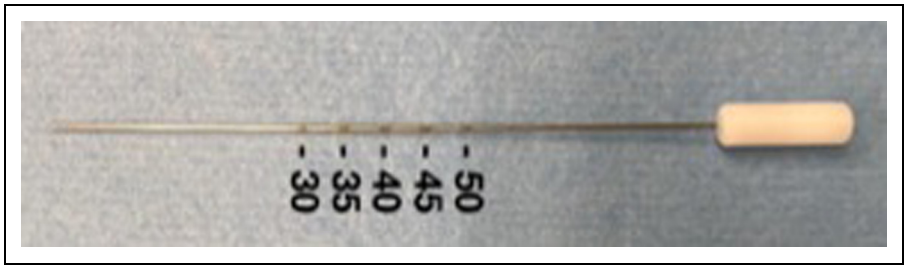

Figure 1. A single used sizer is probed in order to choose the appropriate length of the lacrijet tube from 30 mm to 50 mm.

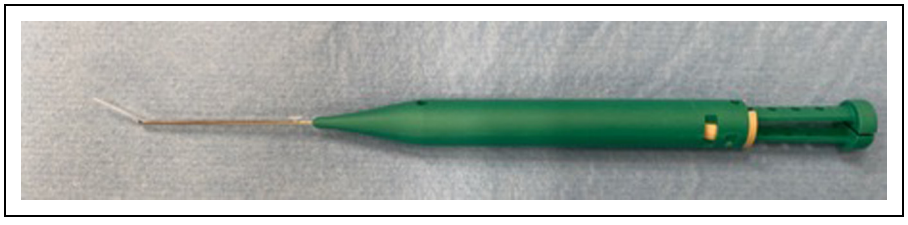

Figure 2. Lacrijet silicone tube is preloaded inside a metallic probe. The surgeon retracts the sliding piston, that releases the silicone tube.

topical anesthesia localin drops (Benoxinate Hydrychloride, Fischer Pharmaceutical labs, Tel Aviv). While aparent/assistant secured the child, the head of the tube was grasped with gentle retraction at the punctual anchor by forceps.

All enrolled patients underwent pre- and post-operative (20–30 min after removal of the silicone tube) examinations that included:

- Tear meniscus height-the distance between the lower eyelid margin and the top of the reflex from the tear strip. A value of ≥0.25 mm indicates reflex tearing and/or sub-optimal tear drainage, while ≤0.1 mm is normal.[8]
- Fluorescein dye disappearance test (FDDT) was performed by fluorescein staining of the tears without topical anesthesia.[9] The amount of the stained tear meniscus that is remained after 5 min was assessed by cobalt light according to:
  Grade 0 = no fluorescein in the conjunctival sac.
  Grade 1 = thin fluorescein tear strip.
  Grade 2 = between grade 1 and 3.
  Grade 3 = wide fluorescein tear strip.
  FDDT above grade 1 is considered as positive test.

Postoperative epiphora was evaluated by the parents with the MUNK questionnaire, a minimum 6 weeks after silicone tube removal with a scale of 0–4[10]: 0 = No epiphora, 1 = occasional epiphora requiring dabbing with a tissue less than twice a day, 2 = epiphora requiring dabbing two to four times a day, 3 = epiphora requiring dabbing five to ten times a day, 4 = epiphora that requiring dabbing more than ten times a day, 5 = constant tearing.

A complete successful Lacrijet intubation was defined as negative FDDT, and absence of the symptoms that existed preoperatively. Partial success was defined as improvement of epiphora but with residual symptoms.

We also recorded any postoperative complications, including tube loss.

Statistical analysis

Categorical variables were described using frequencies and percentages, whereas, continuous variables were described using means and standard deviations. Outcomes were compared using Wilcoxon signed-rank test. *P*-values of less than 0.05 were regarded as statistically significant. All analyzes were performed using "R" software (version 4.0.2).

Results

This study included 20 eyes of 16 children (14 males, 2 females) with mean age of 26.25 ± 11.25 months (range 12–50 months). 17 eyes (85%) had undergone probing previously. The results of the demographic data and study variables are summarized in Table 1.

Mean operation time of Lacrijet intubation was 8.5 min (95% CI 7.04–9.95). The mean follow-up period was 204.65 ± 105.27 days.

According to Wilcoxon signed-rank test, Lacrijet intubation resulted in statistically significant improvements in tear meniscus height ($P < 0.001$), FDDT ($P < 0.001$), and MUNK score ($P < 0.001$) in all children (Table 2).

Two different sizes of Lacrijet intubations were used according to the sizer: 30 mm and 35 mm. No significant differences were found between the two intubation sizes in tear meniscus height, FDDT and MUNK results pre- and post-operatively ($P > 0.05$).

There was one case of partial success due to recurrent epiphora post-Lacrijet removal. Therefore, a second procedure of Lacrijet intubation was performed and complete success was obtained. No complications were observed including spontaneous tube loss.

Discussion

Lacrijet silicone tube is a third generation of monocanalicular intubation that is preloaded inside a metallic probe, in a single use injector handpiece. The tube is contained within a protective sleeve that provides better protection and minimizes the risk of the stent bunching during the intubation. The appropriate Lacrijet length is chosen according to a sterile, single-use sizer that is used to probe prior the intubation.

The main advantage of monocanalicular intubation is that it avoids potential damage to the unprobed canaliculi. In this case series all children were intubated through the upper punctum as it makes a less acute angle with the lacrimal duct than going through the lower punctum. Therefore, this decreases the risk of bunching the tube within the lacrimal sac or duct.[11] The advantage of a pushed monocanalicular

Table 1. Summary table of background variables (N = 20).

	N (%)	Mean ± SD
Sex		
Female	6 (30%)	
Male	14 (70%)	
Age (months)		26.25 ± 11.25
Previous probing	17 (85%)	
Side		
Right	12 (60%)	
Left	8 (40%)	
Placement		
Upper punctum	20 (100%)	
Lower punctum	0 (0%)	
Time of removal (days)		99.55 ± 17.13
Duration of Operation (min)		8.5 ± 3.32
Operation to MUNK time (days)		204.65 ± 105.27

Table 2. Wilcoxon signed-rank test results for the change in outcomes post Lacrijet intubation.

	Pre operation	Post operation	change	*P*
Tear meniscus height				
Mean (SD)	2.45 (0.51)	0.13 (0.05)	−2.32 (0.53)	<0.001
Median [range]	2 [2, 3]	0.1 [0.1, 0.2]	−1.9 [−2.9, −1.88]	
FDDT				
Mean (SD)	2.9 (0.31)	0.1 (0.45)	−2.8 (0.52)	<0.001
Median [range]	3 [3, 3]	0 [0, 0]	−3 [−3, −3]	
MUNK score				
Mean (SD)	4.4 (0.82)	0.35 (0.59)	−4.05 (0.89)	<0.001
Median [range]	5 [4, 5]	0 [0, 1]	−4 [−5, −3.75]	

tube is that there is no need for retrieval the tube out of the nose and the potential mucosal trauma this entails.

Previous studies have evaluated monocanalicular intubation success rate. Andalib and colleagues reported success rate of 86.2%, whereas Kominek and Lee demonstrated rates of 88.57% and 90.0%, respectively.[5,6,12] Recently, Fayet et al. published initial results for the performance of Lacrijet intubation in 45 children. Their patients were stratified according to the degree of lacrimal duct stenosis. The overall success rate was 88.8%, whereas it increased to 92.2% in what they defined as cases of simple mucosal stenosis.[13]

The differences in the success rates among these studies can be explained by the varying definitions of complete success, study-design differences and the type of silicone tube that was used. Our definition of success was similar to that in Kominek's study and included absence of preoperative symptoms in addition to negative FDDT. However, despite the fact that our patient group included older age children than in the group Kominek analyzed, we still achieved higher success rate. This may be attributed to several factors: They intubated the monocanalicular tube through the lower punctum which may increase the risk of bunching the tube within the sac, whereas in our series the tube was intubated through the upper punctum.[11] In addition, we used the push design of the Lacrijet tube, whereas Kominek used a pulled moncanalicular set. During the lacrimal intubation of the pushed design, there is less manipulation during the surgery compared to the pulled tubes, which may decrease the risk of false passage. However, the data in this series is not sufficient to make an accurate determination and further studies comparing the two designs should be performed. Lee et al. used a Monoka tube and defined success as complete disappearance of symptoms without including objective tests in their definition as we did in our study.

There are two previous studies besides ours which examined the Lacrijet tube. Mihailovic et al. presented a retrospective study of children and adults who were intubated with Lacrijet tube.[14] It is a smaller cohort study of 12 patients with CNLDO, canalicular laceration and eyelid reconstruction. They concluded that Lacrijet can be used in the above mentioned indications, but they did not discuss the success rate and nor did they measure the operative time. The Fayet paper was largely a description of how to perform an intubation using the Lacrijet tube (Fayet holds the patent on the device). There were no definitive parameters for success rate like we did and there were three different groups of CNLDO. Our study included a higher average age than Fayet's, we assessed clearly defined objective parameters for measurement, and our success rate was comparable and actually higher than the group of simple CNLDO with metal-on-metal contact group in Fayet paper.

In our study, the mean average time of Lacrijet Intubation procedure was 8.85 ± 3.31 min. This represents an additional advantage over the previous generations of pushed and pulled silicone tubes as it shortens the procedure time significantly. Lee et al. published results with an operating time of 51.4 min and 45.6 min for bicanalicular and monocanalicular intubation, respectively.[5] This is longer operating time compared to our study which may be secondary to the use of bicanalicular and Monoka tubes (FCI Ophthalmics) in their study. The main potential difficulty of those pulled intubation methods is the retrieval of the probe from the inferior meatus. Due to narrow and oblique angled inferior meatus, there may be a need for an endoscope, or a hook to retrieve the bicanalicular tube or a suture fixation of the distal end of the monocanalicular tube. During Lacrijet intubation, there is no need for hook retrieval which can be traumatic and result in a mucosal bleeding. After probing with the sizer and confirming its location below the inferior meatus through metal-on-metal contact, the Lacrijet tube is inserted with no need for nasal retrieval, knots or securing sutures. Therefore, nasal mucosal trauma is minimized, and operating time is shortened by eliminating the retrieval step, and the postop course can be quieter. Fayet et al. published a mean Lacrijet operating time of 2.8 min,[15] which is faster than our study. Our operative time was defined as the time between post anesthetization and after the ointment was applied. Therefore, probing step was included in the

time, whereas in Fayet study, there was no definition of the operating time and the probing step could be not included, which may explain the difference in the results.

The timing of tube removal is still controversial. In our study, tubes were removed after three months on average, and a high success rate was achieved in all cases. No post-operative complications were observed. The recommended time to leave tubes in has ranged from 6 weeks to 18 months.[15,16] Migliori and Putterman, found that complications occur usually 2 to 4 months post tube replacement such as erosion of the canaliculus and formation of a scar tissue within the punctum and canaliculus post tube removal.[17]

In our study, all Lacrijet tubes were removed in the clinic with topical anesthesia and no complications were observed. Tube loss may occur after monocanalicular intubation, with rates ranging from 2.4% to 35.4%.[6,7,13,18] In the retrospective case series of Mihailovic et al. 3 out of 12 patients post lacrijet intubation experienced an early tube dislocation or a complete loss of the tube.[14] Fayet et al. also described several difficulties when using the Lacrijet system that occurred more in his preliminrary study. The techqniue has been gradually modified.[19] In his more recent study there were fewer intraoperative complications without incidence which were secondary to minor equipment problems. In our series, there were no casse of tube loss, separation of the plug collar from the bulb or retention of the punctual plug within the introducer. Corneal abrasion is another complication that may occur after monocanalicular intubation and may require removal of the stent. Fayet et al. described one case of post-operative corneal abrasion that was treated with medical management. In our series no abrasions occurred.

The advantages of the Lacrijet intubation include: achievement of a high success rate for the treatment of CNLDO, less nasal manipulation and overall a simple pushed intubation, short operation time, and a low post operative complication rate. The disadvantages include an it is more expensive compared to the previous lacrimal intubation devices, and a learning curve. Recent studies have demonstrated the usefulness of endoscopic-assisted probing, which allows for direct visualization of the distal NLD, and this has been shown to increase the success rate of the procedure when compared to blind probing.[20,21] This may soon become the universal standard of care. Endoscopic-assisted probing may also reduce the need for placement of silicone tubes. However, lacrimal intubation can still play a role in the treatment of CNLDO particularly in the following cases: canalicular stenosis of any type, difficult endoscopic probing where there is poor visualization or it is not possible to remove all membranes and flaps, mild bony obstruction during probing, absence of endoscopic equipment at the particular operating center, and lack of surgical experience with the use of the endoscope in young children.

Intubation with the Lacrijet has an important role specifically in the cases stated above and in children who are at high risk for general anesthesia and will not tolerate long procedures. Fayet et al. published an intraoperative observation for the lacrijet intubation as preliminary results.[19] They demonstrated endoscopic observation for the metal to metal touch, and found it was a reliable and sufficient sign for detecting possible submucosal false passages. The aim of the use of endoscope during their study was not to improve the results of nasolacrimal intubation, but rather to monitor the effectiveness of intraoperative stent deployment without any endoscopic guidance. The new Lacrijet device was designed to be inserted by means of a blind technique, and this was confirmed by the Fayet study as well as our study with its success rate.

Lacrijet has not been investigated yet in acquired NLDO. A previous systematic review by Vinciguerra et al. analyzed the best treatment for distal acquired NLDO.[22] They reported a mean success rate of 54.4% for stenting probing procedure, whereas 89.8% and 89.5% for external and endoscopic dacryocystorhinsotomy procedures, respectively. Therefore, they concluded that the treatments of choice for distal acquired NLDO are external and endoscopic dacryocystorhinsotomy surgeries. Thus, it would be of interest in the future to investigate Lacrijet intubation in acquired epiphora cases and compare it to other modalities.

The limitations of our study were lack of randomization and low sample size. However, this is the second largest study in the literature. Furthermore, none of the previous studies performed the pre- and post-operative tests for evaluations included in this study and the children were followed up for long period of time. This study paves the way for a larger randomized study as it demonstrates favorable effects for Lacrijet intubation in CNLDO.

Our patient cohort included a wide range of ages, including some patients who had previously failed probing, and all demonstrated improvement across a range of objective parameters: tear meniscus height, FDDT, and MUNK score. Our experience suggests that Lacrijet lacrimal intubation has a high rate of success, shortens surgical time and has a low rate of complications in children with simple NLDO.

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