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Original Article

Success rate of placement of a bicanalicular stent for partial nasolacrimal obstruction in adults under local, monitored anesthesia care and general anesthesia

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Abstract

Purpose: To study The Kaneka Lacriflow Stent, a self-retaining bicanalicular intubation set that can be placed under local anesthetic, providing a new option to treat epiphora and partial NLDO.
Design: Retrospective chart review.
Subjects: 93 adult patients requiring treatment for a partial NLDO were evaluated. Stents were placed in office setting under local/topical anesthetic or in OR (MAC or GEN). The stent is placed with a stylet, and self-retains due to a widened portion sitting distal to the common canaliculis. It does not require recovery from the nose.
Methods:: Outcomes analyzed to evaluate success of stent placement.
Main outcome measure: Success rate of placement of the stent in adults.
Results: Stents left in place for 3 months. Results recorded 1 month after removal. Stents successfully placed in 124 of 136 (91%) eyes. Under local anesthesia in the office setting, 83 of 92 (90%) were placed successfully. Records were complete in 59 patients (78 eyes) and were analyzed further. 33 patients (52 eyes) had stents retained for the full 90 days and had follow-up recorded one-month post removal. Of the patients who retained the stents for 90 days and had full follow-up, 32 patients (51 eyes, 98%) reported improvement in their symptoms, while 1 patient reported no improvement.
Conclusion: Silicone intubation of the NLD in adults is rarely done due to need for general anesthesia. The Lacriflow stent can be successfully placed in the office under local anesthesia offering a new approach for tearing in adults.

Keywords: Nasolacrimal duct obstruction, Kaneka Lacriflow stent, Epiphora

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Introduction

Epiphora is an issue impacting the quality of life for many individuals. The incidence of tearing is poorly studied. Dalgeish et al. reported on the results of the nasolacrimal irrigation of every patient presenting for intraocular surgery at the Clinics of Manchester Royal Eye Hospital. He found an incidence of lacrimal obstruction of 11% at age 50 increasing to over 30% at age 80 in a series of 3487 patients.[1] Although this is not a true population study, it is likely representative of the general population.

Woog et al. reported the incidence of symptomatic acquired lacrimal outflow obstruction (SALOO) in Olmsted County, Minnesota, from 1976 to 2000.[2] In reviewing the

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records in Olmstead County, he identified five hundred eighty-seven patients for an average annual incidence rate of 30.47 per 100,000.

Woog noted that the incidence of nasolacrimal duct obstruction incidence increased with age, slowly beginning at age 40, and then more rapidly increasing beginning at age 60. He noted that over one-half of all patients with nasolacrimal duct obstruction in the study were older than 65 years. He also noted a higher incidence in women. In his study fully 67 percent had nasolacrimal duct obstruction as the cause of their epiphora. This is likely representative of a selection bias with only the more severe epiphora presenting to the Mayo Clinic for treatment. Woog noted that it would be difficult to determine the true incidence of acquired lacrimal obstruction, as this would entail performing a population based prospective lacrimal evaluation of every individual in the population under study. Woog noted a general increase in incidence of epiphora over the reported period most likely due to an increase in reporting versus a real increase in incidence.

Shin et al. studied the impact of epiphora on quality of life. They found that outdoor activities were the most significantly hindered by epiphora.[3] They also found that indoor activities such as working at a computer, work-related activities, and interpersonal relations showed relatively high scores, indicating that epiphora is a significant issue for patients.

Based on clinical experience, the frequency of epiphora is likely much higher than that reported in the literature. Patients with functional or partial obstruction likely outnumber those patients with complete nasolacrimal obstruction. Thus far there have been few viable, cost effective treatments available for partial nasolacrimal obstruction and given this, little reported on the frequency of non-complete obstruction of the nasolacrimal system. In this paper we report on the use of a novel self-retaining bicanalicular intubation set that can be placed in the canaliculus and nasal lacrimal system under local anesthetic. This offers the possibility of placing the stents in the office under local anesthetic at significantly decreased cost, providing an entirely new option for treating partial nasolacrimal obstruction.

In 2012 Kaneka (Kaneka Corporation, Osaka, Japan) received FDA clearance for a self-retaining bicanaliculi intubation set. The Lacriflow stent is indicated for the treatment of epiphora due to conditions including the obstructions of lacrimal punctum, lacrimal canaliculus or the nasolacrimal duct. It is also intended for use during dacryocystorhinostomy, and congenital nasolacrimal obstruction. The Lacriflow stent is approved for patients 12 months and older. The lacriflow stent consists of a bicanalicular lacrimal duct tube, with a thinner intra-canalicular portion, and 2 stainless steel bougies used for insertion via the canaliculus then removed leaving the tubes in place.

Methods

This study is a retrospective review of our results placing the Kaneka Lacriflow Stent in adults with epiphora due to nasolacrimal obstruction due to punctal stenosis, canalicular stenosis, or partial nasolacrimal duct obstruction. This study was approved by the Lancaster General Hospital Institutional Review Board; a waiver of consent was granted because of the low risk of this research. The stents were placed in the office setting under local and topical anesthetic. Although in office placement was our primary concern, stents were also placed in the operating room under Monitored Anesthesia Care (MAC) or General Anesthesia (GEN) and were also analyzed. Most cases performed in the operating room were secondary to another procedure, such as ptosis repair, ectropion or entropion repair or in cases where an endoscopic dacryocystorhinostomy (enDCR) was being performed on a patient with complete obstruction on one side while the Lacriflow stent was placed on the other side for a partial obstruction.

The Lacriflow stent self-retains due to the differential gauge of the narrower portion of the stent sitting in the superior and inferior canaliculis and a widened portion distal to the common canaliculus in the nasolacrimal duct. This serves to self-retain the stent without the need to tie it in the nose. It also allows easy removal in the office via the canaliculus. The stent is placed via the upper and lower canaliculus utilizing a bougie and does not require recovery from the nose. Due to a hydrophilic polymer coating on the stent, made of polyurethane resin mixture, the stent passes exceptionally easily allowing placement under topical or local anesthetic in the office or in the operating room. In this study, the stent was typically left in place for 3 months.

There are two sizes of stents to choose from, standard and short. The short stent is typically used for women, and for men with a facial structure of average size or smaller. The standard stent can be used in larger individuals. The stent is prepackaged with two bougies. One end of the stent has a blue tip while the other is clear. The surgeon may wish to consistently place the blue tip through either the upper or lower punctum. In this way the surgeon can identify which portion of the stent is in place in the nose when viewing intra-nasally. In practice, it was not that important as we did not view the stent intra-nasally except in cases in which an endoscope was being used. The intra-canalicular rod length measures 25 mm in length and 0.7 mm wide. The nasolacrimal duct portion is a hollow tube measuring 1 mm in width with an open core measuring 0.5 mm intended to facilitate drainage of fluid. The length of the standard tube is 105 mm while the length of the short tube is 90 mm.

If the stents are placed under local or MAC anesthetic, an infratrochlear nerve block is performed as well as a block over the canaliculus and punctum. Lidocaine gel is also infiltrated into the nasolacrimal system with the soft portion of a 24-gauge angiocath. The puncta are dilated with a punctal dilator. One half of the stent with bougie in place is passed through the superior canaliculis perpendicular to the lid for 2 mm then directed nasally with a slight inferior and posterior direction toward the nasolacrimal sac until a hard stop is felt when boney contact is achieved. At this point the bougie is directed inferiorly and slightly posteriorly in a similar manner as probings are performed for congenital nasolacrimal obstruction. Due to the hydrophilic nature of the stent, it is very easy to pass, typically easier to pass than a standard metal probe. Care needs to be taken not to use too much force and create a false passage. Tactile feel will allow the surgeon to feel passage through both the valve of Rosenmueller and the valve of Hasner. There is a blue hash mark indicating the middle of the intracanalicular portion of the stent. If less than half the stent is passed it is likely the stent is too long and a short stent will need to be utilized instead.

Once the first portion of the stent is in place, the stent should be grasped near the punctum holding only the soft portion, and the bougie is removed leaving the stent in place. At this point, the inferior portion is passed through the lower punctum in a similar manner. The bougie is then directed inferiorly and posteriorly as done with the superior portion. Once the stent is fully seated the tube is grasped and the bougie is removed. In patients with smaller anatomy where the stent could not be fully seated before the floor of the nasal cavity was contacted, the last 1.5 cm of the bougie was pre-bent allowing rotation nasally and inferiorly to completely pass the stent.

The intracanalicular portion of the tube can now be manipulated slightly if necessary. The tube should fit securely between both punctum. Ideally, the blue hash mark should be centered but occasionally it will be hidden. As long as the tube sits securely and the narrow portion sits intracanalicularly no further manipulation is necessary. If it is not sitting properly, the tube is removed, the bougie replaced and the tube passed again.

The procedure can be performed in the operating room under sedation or general anesthesia if desired. The procedure can be combined with other procedures such as ectropion or ptosis repair in order to more fully improve epiphora in patients with tearing from combined mechanisms.

An antibiotic steroid drop was used for 2 weeks four times daily post- operatively. The tubes were typically kept in place for three months but were removed earlier if there were signs of tube related inflammation to the eye or canaliculis or if there was noted to be cheesewiring.

The stents were removed easily in the office by grasping the intra- canalicular portion between the two punctum with a blunt forceps or a muscle hook and slowly withdrawing them from the puncta.

An additional 1–2 weeks of antibiotic and steroid drops were used after stent removal. The patient was then re-evaluated at 1 month to re-irrigate the nasolacrimal system and assess patency. Figs. 1–6.

Results

Stents were placed by one surgeon in two successive practices from June 2013 through March 2017. One hundred and thirty-six stents were placed in 93 adult patients. Adult patients were analyzed for the study. Of the 136 stents placed, 60 patients (92 eyes) were placed under local anesthetic in the office, 17 patients (27 eyes) were placed under MAC anesthesia and 16 patient's (17 eyes) under

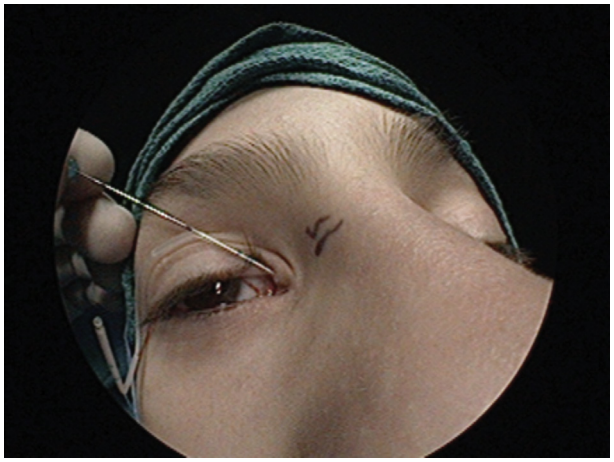

Fig. 1. Passage of superior arm of stent through canaliculus until hard-stop with bougie in place.

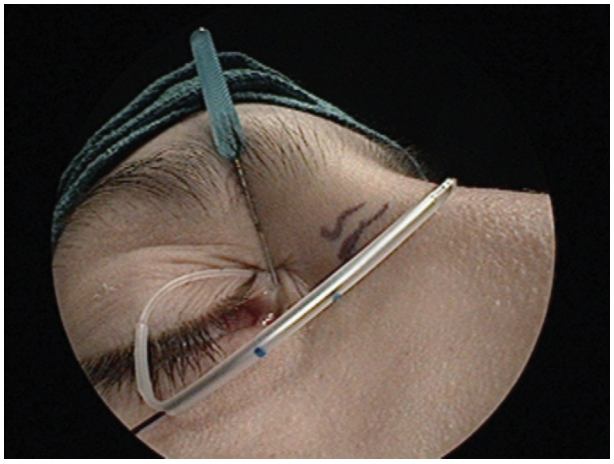

Fig. 2. Directing tube inferiorly and posteriorly down duct. Bougie in place.

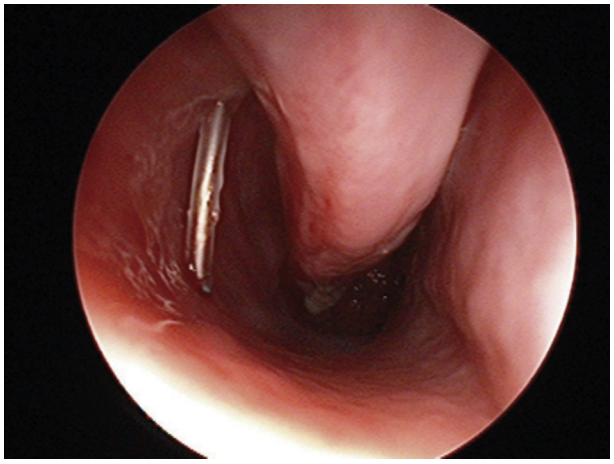

Fig. 3. Intranasal view of stent beneath inferior turbinate with Bougie in place.

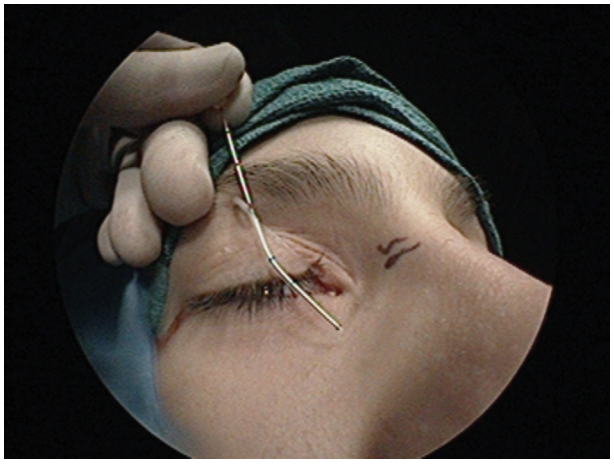

Fig. 4. Alternate insertion bending last 1.5 cm of bougie. Aids in placing stent in smaller nasal cavity.

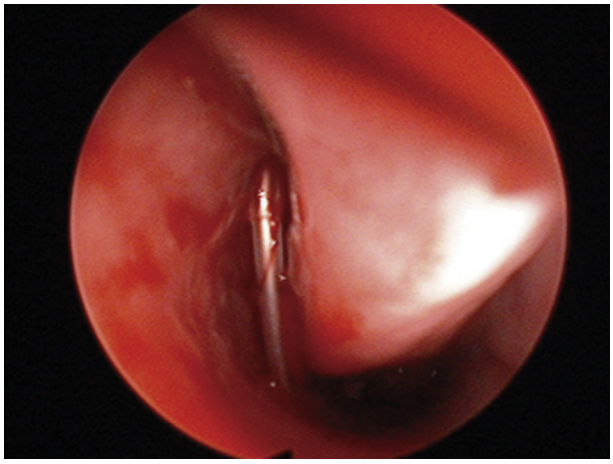

Fig. 5. Intranasal view. Nasal floor curves temporally. Bent Bougie can be rotated nasally and posteriorly easing passage.

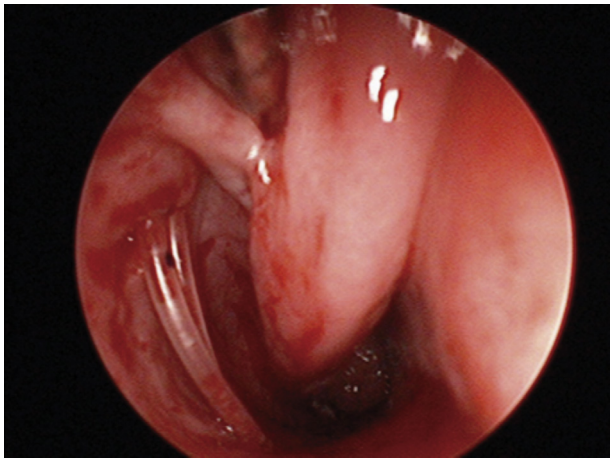

Fig. 6. Bougie removed. Intranasal image of both arms of stent through valve of Hasner.

GEN anesthesia. Stents were successfully placed in 124 of 136 (91%) eyes. Under local anesthesia in the office setting, 83 of 92 (90%) were placed successfully. Under MAC anesthesia, 24 of 27 (89%) were placed successfully while under GEN anesthesia 17 of 17 (100%) were placed successfully.

59 patients (78 eyes) had complete records and underwent further analysis. Records were incomplete on 34 patients (46 eyes). 33 patients (52 eyes) had stents retained for the full 90 days and had follow-up recorded one-month post removal. In 26 eyes of 26 patients stents were not retained for the full 90 days (average 63 days range 13–87 days). Of the patients who retained the stent's for 90 days and had full follow-up, 32 patients (51 eyes, 98%) reported improvement in their symptoms, while 1 patient reported no improvement.

Seven stents in 4 patients were removed prematurely. One patient removed the stent, himself. Four stents were said to have fallen out on their own and two stents were removed by the physician due to conjunctival irritation.

In the 2 patients (2 eyes) in which the patient inadvertently removed the stent the patient had an improvement in their symptoms Overall, of the 80 eyes in the secondary analysis, 71 eyes reported improvement for a rate of improvement of 89%.

It is not clear how long the stent must stay in place to have an adequate treatment effect. In one patient who had a stent placed in both eyes and non-retention in one eye at 10 days, the patient noted a significant difference in symptoms post removal of the second stent with no epiphora in the eye with stent retention for 90 days and continued epiphora in the eye with 10 day stent retention. The patient opted to have the stent replaced in the eye in which the stent had not been retained.

In one patient the intracanalicular portion of the stent irritated the patient and was found to be seated poorly. The stent was removed the first week and a new stent was placed without difficulty.

In one patient the tube was found to rub against a pre-existing pinguecula. It was found that the patient's inferior punctum was temporally displaced causing too much tube to be present between the punctum. The tube had to be removed prematurely.

One patient who had previously had a crawford tube in place a number of years earlier for punctal stenosis, declined to have the stent removed due to symptom improvement with the stent in place, and at last followup had them in place for 9 months without incident. This patient was not included in the secondary analysis

Munk scores preoperatively and post-operatively were obtained in 24 patients. Average score preoperatively was 4.0 and postoperatively was 1.3.

Discussion

There are very few effective in-office treatments presently available to treat epiphora caused by partial nasolacrimal duct obstruction, punctal or canalicular stenosis. There have been reports on nasolacrimal intubation and the use of balloons in adults with varying success. Typically however, these procedures must be performed under general anesthesia increasing the cost and significantly decreasing the utility of these procedures.

Fulcher et al. reported on silicone intubation in adults noting resolution of symptoms in 54.3% (a partial improvement in 14.3%, a transient improvement in 10%, and no improvement in 21.4%).[4] They noted a better outcome in patients with canalicular obstruction with complete resolution of symptoms in 75.9%. Psilis et al. reported on 115 adult patients (four bilaterally) with chronic nasolacrimal duct obstruction.[5] Silicone tubes were placed remaining in place for a mean of 5.5 months (±2.5 SD). Patency was maintained in 89% of cases with uncomplicated obstruction and in 69% of those with chronic dacryocystitis for a total success rate of 78%.

Perry et al. reported prospectively on balloon dacryocystoplasty on a series of 15 partial nasolacrimal duct obstructions in 13 adults with epiphora.[6] Balloon dacryocystoplasty was performed under local anesthesia using an antegrade insertion technique. Silicone intubation of the nasolacrimal system was performed immediately after balloon catheter dilation, and the tubes were removed 2 months postoperatively. At 2 months, 73% were open on irrigation, with subjective success (Munk, grade 0 or grade 1) reported in 87%. While the authors concluded that balloon dacryocystoplasty may be a satisfactory primary treatment for adults with acquired partial nasolacrimal duct obstruction, in their study it is not possible to separate the effect of the

tubes from the balloon. Although they were able to perform all procedures under local anesthesia in the office, this technique has not been adopted widely possibly due to the difficulty in providing adequate patient comfort under local anesthesia. Other issues with performing balloon dacryoplasty in the office setting are high cost of the balloon and inadequate reimbursement to cover the balloon.

Veloudios et al. reported on the complication rate of silastic stents placed long term in patients treated for congenital and acquired obstructions of the lacrimal system.[7] They noted complications including tube prolapse, extrusion or breakage, punctal erosion, conjunctival irritation, intranasal discomfort, and tube inspissation with mucoid debris (''dirty tubes'') with a rate of 41% in the first 3 months decreasing to 10% after 6 months. Although they concluded that tubes could be left in place long term, the initial high complication rate is problematic.

Mimura et al. reported on the use of Nunchaku-style silicone tube intubation (NSTI) for primary acquired complete lacrimal drainage obstruction.[8] NSTI is a precursor device to the Kaneka lacriflow stent. They found a 94.6% success rate in the treatment of upper obstruction and 71.4% for lower obstruction. They utilized the stent for complete obstruction, which is common practice in Japan prior to undergoing DCR, but unusual in the United States. In the United States, the Kaneka Lacriflow Stent is FDA approved for partial nasolacrimal obstruction and in this study we confined investigation to partial obstruction and not complete obstruction.

In this current study we have described a technique to place a bicanalicular self-retaining stent under local anesthesia in the office. The stent is left in place for 3 months then removed in the office. The rationale for leaving the stent in place this length of time is to maximize the enlargement of both upper and lower nasolacrimal systems while minimizing inflammation caused by the stents. It is not clear how long the stents should be left in place for optimal results. Studies on silastic stents used in DCR have shown that by 4 weeks, the stents become encased in biofilms, complex microbial communities, which could result in inflammation, infection and scarring.[9,10]

It is unclear whether the stents used in this study, due to their unique polymer, might be more resistant to development of biofilms than typical silastic tubes. It is also unclear whether development of biofilms on stents in the intact nasolacrimal system are of as much concern as biofilms on stents passing through a created osteotomy as seen in DCR with respect to infection, inflammation and failure. More research will need to be done to determine the optimal time for intubation for partial nasolacrimal obstruction.

Stents were able to be placed successfully in 90% of adult patients under local anesthetic in the office. Ninety-four percent of these patients had improvement in their epiphora. Due to the hydrophilic nature of the stent and the self-retaining design, the rate of extrusion and other complications was low. The treatment was well tolerated by patients and was cost effective versus previous procedures typically requiring general anesthesia.

Conclusion

Silicone intubation of the nasolacrimal system has been previously shown to be a successful procedure in the management of adult epiphora. Typically the procedure requires retrieval of the tubes from the nose requiring the tubes to be placed under general anesthesia. The need to secure the tubes in the nose makes removal in the office difficult. Despite the effectiveness of the procedure, it is rarely used due to the difficulty in intubating the nasolacrimal system in adults, cost of general anesthesia, difficulty in removing the stents and problems with extrusion of the stents. In light of the difficulties inherent in the placement of typical crawford type tubes in adults, the procedure is rarely performed.

In this report the effectiveness of the Lacriflow stent as a solution for adult epiphora for partial nasolacrimal duct obstruction as well as canalicular and punctal stenosis has been demonstrated. With limited training, the stent can be placed under local anesthesia in the office without the need to retrieve the tube from the nose. The hydrophilic nature of the stent allows it to be quite slippery in the nasolacrimal system easing passage through the adult nasolacrimal system. The differential diameter of the stent with a decreased thickness for the intra-canalicular portion and a wider diameter for the intra-ductal portion allows the stent to self retain obviating the need to tie it in the nose, knot it to itself or suture it to the nasal wall. This significantly simplifies removal in the office. The Lacriflow Stent and the procedure we describe to insert the stent in the office offers a new and effective treatment for epiphora caused by partial nasolacrimal duct obstruction, as well as stenosis of the punctum and canaliculus in adults.

Conflicts of interest

The authors declared that there is no conflict of interest.

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