Comparison of the efficacies of 1.0mm and 1.5mm silicone tubes for the treatment of nasolacrimal duct obstruction

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Abstract

This study was designed to compare the postoperative outcomes of bicanalicular intubation using different diameters of silicone tubes to treat post-saccal nasolacrimal duct obstruction. A total of 130 patients diagnosed with post-saccal obstruction who underwent endoscopic-assisted silicone tube intubation were included in the study. The patients were divided into two groups; those intubated with a 1.5-mm large diameter tube (Group LD) and those with a 1.0-mm normal diameter tube (Group ND). The patency rates of the two groups at one year after tube removal were compared using the Kaplan–Meier's curve and Restricted mean survival time (RMST) method with $\tau = 365$ days. Results showed that the recurrence rate after tube removal was significantly lower in the LD group compared to the ND group ($p = 0.001$). The patency rates at one year after removal in the LD and ND group were 0.857 (0.754-0.919) and 0.739 (0.617-0.828), respectively. When comparing the patency rates by the RMST method at $\tau = 365$ days, the RMST difference, RMST ratio, and RMTL ratio were significantly higher in the LD group at $p = 0.045$, 0.052 , and 0.046 , respectively.

Introduction

Primary acquired nasolacrimal duct obstruction (PANDO) is an organic obstruction of the lacrimal tract that can occur anywhere from the punctum to the nasolacrimal duct opening.¹ *Pre-saccal obstruction* refers to an obstruction from the punctum to the internal common punctum, while a *post-saccal obstruction* can be found from the lacrimal sac to the nasolacrimal duct opening. Although the pathophysiology of PANDO is still unclear, it is suggested that descending inflammation from the eye or ascending inflammation from the nose triggers mucosal membrane swelling, connective tissue remodeling, and subepithelial cavernous body dysfunction with reactive hyperemia, resulting in temporary lacrimal duct obstruction.² Furthermore, chronic recurrent inflammation in the lacrimal duct leads to structural alterations in the epithelium and subepithelial tissue, resulting in the fibrous organic obstruction of the lumen.

The first-line treatment for post-saccal obstruction in adults is a bypass surgery, namely dacryocystorhinostomy (DCR). Meanwhile, with the development of the dacryoendoscope and the advancement of the fiber-optic system, the recanalization procedure is steadily becoming more utilized. Lacrimal recanalization surgery includes endoscopic-guided trephination dacryocystorhinostomy, dacryorhinotomy, microdrill dacryoplasty, laser dacryoplasty, and antegrade balloon dacryoplasty.³⁻¹⁰ Silicone intubation or antegrade balloon dacryoplasty with a silicone tube intubation is commonly employed to treat a partial obstruction or stenosis of the lacrimal duct.¹¹⁻¹³ In Northeast Asia, silicone intubation has been proposed as an alternative to DCR in the treatment of post-saccal obstruction. This is primarily due to the improving postoperative outcomes with refined silicone tubes¹⁴ and the expansive application of endoscopic-assisted nasolacrimal duct intubation (ENDI) as a minimally invasive treatment for PANDO in Northeast Asia.¹⁵⁻¹⁸ The ENDI procedure is conducted while directly observing the obstructed site in the lacrimal

duct with a dacryoendoscope and observing the nasal cavity with a nasal endoscope. This procedure reduces complications from false passage formation compared to conventional blind direct silicone intubation. ENDI is typically performed under local anesthesia, and it has evolved into a less invasive and more secure procedure, which results in its increasingly widespread use in Northeast Asia. Furthermore, Northeast Asians have relatively flat facial features, with a less elevated superior orbital rim than other ethnical populations, allowing a relatively easy manipulation of the dacryoendoscope.¹⁹ Since the first report of nasolacrimal duct intubation using silicon tubes by Gibbs et al. and Keith et al. in the 1960s^{20,21}, various improvements have been made in terms of surgical techniques, instruments for stent placement, tube materials, and designs.^{4,22} The silicone tubes inserted into the lacrimal duct prevents adhesion of the mucosal surface of the duct while the mucosal membrane heals, promoting regeneration of the lacrimal duct epithelium and helps to maintain long-term patency after tube removal. Typical silicon tubes include the Ritleng® lacrimal intubation set and the Crawford tube (FCI Ophthalmics, Pembroke, MA), which have been used in many institutions worldwide for many years. Nevertheless, these tubes require a thin metal probe for insertion and that carries the risk of iatrogenic trauma to the canaliculi and nasolacrimal ducts.²² The Nunchaku-style tube (NST) is a “push-style” stent designed with a metal guide probe concealed inside the tube.²³ In addition, the NST has improved surgical efficacy since it does not require stent retrieval or tying of the distal end of the tubes within the nose during placement.^{23,24} The diameter of a typical NST is 1.0 mm, which is thicker than that of a typical Crawford tube, which has a diameter of 0.64 mm. It has been reported that the larger the diameter of the tube, the wider the maintained isolation between the walls of the lumen.^{25,26} Recently, a thicker 1.5-mm diameter NST has been introduced and is currently available for clinical use. Accordingly, this study aimed to compare the patency rates of ENDI treatment for post-saccal obstruction in adults with 1.0-mm and 1.5-mm NSTs at one year after tube removal.

Results

An overview of the LD and ND groups is shown in Table 1. The composition of the LD group was as follows. Out of the 70 cases and 85 sides with post-saccal obstruction, males comprised 23 cases and 29 sides (32.8% and 34.1%, respectively), while females comprised 47 cases and 56 sides (67.1% and 65.9%, respectively). The mean age of the cases was 72.5 ± 11.1 years. The mean period of preoperative obstruction was 29.6 ± 40.0 months. The mean observation period after tube removal was 9.8 ± 5.9 months. In the LD group, recurrence after ENDI treatment occurred in 12 cases (14.0%), and the average time from tube removal to recurrence was 3.4 ± 4.6 months. On the other hand, the composition of the ND group was as follows. Out of the 60 cases and 72 sides with post-saccal obstruction, males comprised 17 cases and 21 sides (28.3% and 29.2%, respectively), while females comprised 43 cases and 51 sides (71.7% and 70.8%, respectively). The mean age of the patients was 72.9 ± 11.5 years. The mean period of preoperative obstruction was 63.0 ± 91.8 months. The mean observation period after tube removal was 14.0 ± 14.7 months. In the ND group, recurrence after ENDI treatment occurred in 27 cases (37.5%), and the average time from tube removal to recurrence was 11.0 ± 16.0 months.

No statistically significant differences were found in the age, gender ratio, and observation period after tube removal between the LD and ND groups ($p > 0.05$). Meanwhile, the period of preoperative obstruction was significantly longer in the ND group ($p < 0.05$, Figure 1, Table 1). The number of recurrences after ENDI was significantly lower in the LD group than in the ND group ($p = 0.001$). The time to recurrence after tube removal was 3.4 ± 4.6 months in the LD group and 11.0 ± 16.0 months in the ND group, with no significant difference between the two groups ($p = 0.82$). Since the preoperative obstruction period was significantly longer in the ND group than in the LD group, we conducted a logistic regression analysis with “period of preoperative obstruction” and “Group” as explanatory variables and “recurrence” as the objective variable to examine whether the longer duration of preoperative obstruction contributed to recurrence after ENDI surgery. The results showed that OR for “period of preoperative obstruction” was 0.999 (0.994–1.000, $p = 0.699$) and OR for “Group” was 3.770 (1.71–8.34, $p = 0.001$). Hence, the “period of preoperative obstruction” was not significantly correlated with “recurrence.”

The Kaplan–Meier's curve of lacrimal duct patency at one year after tube removal is shown in Figure 2. The patency rate of the lacrimal duct was 0.857 (0.754–0.919) in the LD group and 0.739 (0.617–0.828) in the ND group. There were 11 recurrences and 23 censored cases in the LD group, while in the ND group, there were 18 recurrences and 14 censorings within one year after tube removal. The RMST with $\tau = 365$ days in LD and ND groups were 326.65 and 284.59, respectively. $\text{RMST (LD)} - (\text{ND}) = 42.058$ (0.996–83.121, $p = 0.045$), $\text{RMST (LD)} / (\text{ND}) = 1.148$ (0.999–1.319, $p = 0.052$), and $\text{RMTL (LD)} / (\text{ND}) = 0.477$ (0.230–0.988, $p = 0.046$). The survival rate of the LD group was significantly higher than that of the ND group at one year after tube removal (Figure 3).

Discussion

There is limited literature on the contribution of tube caliber on the prognosis of PANDO treatment. Several reports introduced attempts to enlarge lacrimal ducts with silicone tubes to prevent restenosis after tube removal. One method is to insert double 0.64-mm Crawford tubes into one canaliculus.^{10,27,28} These studies reported a higher patency rate after canaliculoplasty surgeries. Another study demonstrated that almost similar therapeutic effects were reached with double silicone intubation using a 0.64-mm Crawford tube and a single wide-diameter 0.94-mm Crawford tube.²⁵ Our study demonstrated that one year after NST intubation for post-saccal obstruction, the patency rate was 0.857 (0.754–0.919) when a 1.5-mm NST was utilized and 0.739 (0.617–0.828) when a standard 1.0-mm NST was applied. In recent years, the 1.5-mm diameter NST was developed and applied clinically. Consequently, the period for determining the effectiveness became shorter than that of the conventionally used 1.0-mm NST. The RMST method was then applied to compare the treatment efficacy between the two groups because the proportional hazard property was not established in the late stage of the Kaplan–Meier curve (Figure 3). The τ of RMST was determined as 365 days, considering the following conditions. 1) Clinically, recurrence was mostly observed within one year after tube removal. 2) In our institution, follow-up was usually completed at one year after tube removal without detecting recurrence. 3) The ratio of censoring in Kaplan–Meier's curve increases after one year of removal due

to various factors, such as completion of follow-up or transfer to other facilities. Results showed that comparison of survival rates between the two groups by the RMST method showed that the patency rate of the 1.5-mm NST-intubated group was significantly higher, suggesting that larger diameter tubes had better outcomes for the treatment of post-saccal obstruction.

Additionally, comparing the preconditions between the two groups, the preoperative obstruction period was significantly longer in the ND group. Previous studies identified that the preoperative occlusion period conferred a risk for recurrence after silicone intubation.²⁹ Therefore, we performed a logistic regression analysis to determine the correlation of preoperative obstruction period to recurrence between the two groups; however, we found no significant correlation in our cohort ($p = 0.69$).

In general, the long-term therapeutic outcomes of ENDI are not equivalent to DCR. Nevertheless, much evidence has shown that the outcomes of ENDI are almost as effective as DCR for canaliculus obstruction and PANDO (in cases of non-inflammatory or partial obstruction).^{15,17,18,29-31} However, it has been reported that patients with prolonged preoperative occlusions, extended length obstruction, or a history of dacryocystitis tend to relapse ENDI.^{17,22,29,31,32} Meanwhile, ENDI, which are generally performed under local anesthesia, is beneficial as it is a minimally invasive procedure for the treatment of PANDO. Furthermore, there are various advantages in terms of surgical time, facial surgical scars, bleeding, and downtime compared to DCR.^{3,4,11,17,18,22,23,31,33} ENDI can also be performed in patients receiving systemic anticoagulation and antiplatelet therapy because the risk of bleeding is minimal. Hence, further studies are needed to compare the long-term treatment outcomes of DCR and ENDI in PANDO in terms of pathological conditions (e.g., site of obstruction, cause of obstruction, and duration of obstruction).

This study has several limitations. First, this study was a single facility retrospective cohort study; thus, long-term follow-up was limited. It is necessary to evaluate the prolonged outcomes with a larger number of postoperative patients in a multi-center study. Second, since 1.5-mm NST was only recently applied clinically, the period to evaluate its efficacy was relatively shorter than that of the conventional 1.0-mm NST. The long-term outcome of the 1.5-mm NST requires extended follow-up time to be determined.

In conclusion, to the best of our knowledge, this is the first report to compare the postoperative outcomes of bicanalicular silicone tube intubation according to the difference in the tube caliber for the treatment of post-saccal obstruction. We propose that the use of larger diameter tubes could provide improved therapeutic outcomes.

Methods

Subjects

We investigated 157 sides of 130 patients diagnosed with post-saccal obstruction. Patients were treated by three ophthalmologists (TK, AM, AS) at Ehime University Hospital between August 2013 and November 2020. The mean age was 72.6 ± 11.3 years. Out of the cases, 40 were male (50 sides) and 90

(107 sides) were female. The diagnosis of post-saccal obstruction was made based on the dye disappearance tests, lacrimal irrigation test, cone beam computed tomography digital subtraction dacryocystography, and dacryoendoscopic examinations. Patients with functional nasolacrimal duct obstruction were excluded. Patients with a previous history of systemic chemotherapy, radiation therapy, or post-traumatic bone deformity were also excluded. In addition, patients with unsuccessful surgery, such as cases in which the stent could not be placed because the occlusion was too solid or those in which a false passage was created, were excluded from the present evaluation. Patients with a previous history of lacrimal duct reconstruction, i.e., postoperative recurrence, were also excluded; hence, all patients were treated for the first time.

Treatment protocols

All patients were treated with ENDI as previously described.^{16,17} In this procedure, the surgeons performed lacrimal duct reconstruction while observing the lacrimal canal under the dacryoendoscope instead of performing the procedure blindly. In summary, the procedure was performed as follows: after applying infratrochlear anesthesia and topical nasolacrimal anesthesia, the upper and lower lacrimal punctum were dilated. Dacryoendoscope (FT-201, Fibertech, Tokyo, Japan) was inserted through the punctum, and the endoscope was then advanced to the occlusion site while monitoring the lumen. An 18-gage catheter (SR-FF1864, Terumo, Tokyo, Japan) attached to the tip of the endoscope was used to release the obstruction (sheath-guided endoscopic probing technique).³⁴ Self-retaining bicanalicular lacrimal stents were inserted using the sheath as a guide after the obstructed area of the lacrimal canal was released. The sheath with the tube connected was removed from the open end of the nasolacrimal duct on the inferior meatus using a nasal endoscope. The same procedure was performed on the other punctum, and the tube was retained in the lacrimal duct. The NST stent used was either a large diameter 1.5 mm (Lacrifast EX[®]; Kaneka Co., Ltd., Osaka, Japan) or a conventional diameter 1.0 mm (Lacrifast[®] or Lacrifast CL[®]; Kaneka Co., Ltd., Osaka, Japan). The only difference between the 1.0-mm diameter Lacrifast[®] and Lacrifast CL[®] was whether the tube stent has an open end or a blind end, and the rest of the components, including the tube diameter, total length, and material, were identical. After the ENDI surgery, all patients were treated with topical 0.1% fluorometholone and 0.3% gatifloxacin four times a day. The tear ducts were flushed by saline irrigation periodically until the stent was removed. The silicone tube was routinely removed 10 to 12 weeks after ENDI surgery.

Postoperative outcome assessments

Patients who were eligible to follow-up for at least six months after tube removal were evaluated. The present study was conducted to evaluate the patency rate of pos-saccal obstruction after ENDI treatment; hence the cases of pre-saccal obstruction were excluded. *Recurrence* was defined as no passage or pus

or viscous fluid reflux in the postoperative irrigation test with structural re-occlusion in the dacryoendoscope findings.

The group intubated with a large diameter tube (1.5 mm) was designated as the LD group, and the group intubated with a normal diameter tube (1.0 mm) was designated as the ND group. To avoid selection bias, the LD group consisted of patients treated after the deployment of the 1.5-mm NST at our institution (treated between August 2017 and November 2020), and the ND group consisted of patients treated with the 1.0-mm NST before the deployment of the 1.5-mm NST (treated between August 2013 and July 2017). Gender, age, period of obstruction, observation period after removal, number of recurrences, and time from tube removal to recurrence for each group were evaluated. The period of obstruction was denoted based on the duration of chronic epiphora symptoms as described in the patient questionnaire. Furthermore, by defining “recurrence” as an event, Kaplan–Meier's curve was created. Based on the rationale listed below, restricted mean survival time (RMST) was compared between the two groups with $\tau = 365$ days. 1) Clinically, recurrence is usually observed within one year after removal. 2) In our institution, follow-up is usually completed when no recurrence is observed for one year after removal; therefore, the censoring rate increases beyond one year after removal.

Statistical analysis

All statistical analyses were performed with EZR (Saitama Medical Center, Jichi Medical University, Saitama, Japan), a graphical user interface for R (The R Foundation for Statistical Computing, Vienna, Austria).³⁵ In comparing the two groups, the ratio of male to female and the number of recurrent cases were tested by Pearson's χ^2 test. Meanwhile, age, period of obstruction, and observation period after tube removal were tested by Mann–Whitney's U test. The creation of Kaplan–Meier's curve and comparing survival rates between the two groups using the RMST method were analyzed with the survRM2 package.^{36,37} A p -value of <0.05 was considered statistically significant.

Declarations

Ethical approval and consent to participate

This investigation and data collection protocol were authorized by the institutional review board of Ehime University (Ethical approval number: 1601003). The research was recorded with the University Hospital Medical Information Network Clinical Trials Registry (UMIN 000025180). Each patient provided documented informed consent before registration. All procedures employed in this study were conducted following the principles of the Declaration of Helsinki.

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Conflict of interest

The authors declare that they have no competing interests. The authors are solely responsible for the content and writing of the paper.

Author contributions

JN contributed to the conception, data extraction, analysis, and drafting. TK, AM, and AS worked on the surgical operations, data extraction, interpretation of the results, and drafting. TK, AM, and AS provided statistical advice. NM and AS were responsible for the general management of the study and critically revised the protocol and main manuscript.

Data availability

The datasets analyzed during the current study are available from the corresponding author (JN) on reasonable requests.

Tables

Table 1. Overview of the comparison of the elements that constitute the LD and ND groups

	Group		p-value
	LD	ND	
Tube diameter (mm)	1.5	1	
Number of cases	70	60	
Number of sides	85	72	
Age (years)	72.5 ± 11.1	72.9 ± 11.5	0.73
Gender (male / female)	23 / 47	17 / 43	0.58
Period of preoperative obstruction (months)	29.6 ± 40.0	63.0 ± 91.8	0.009
Observation period after tube removal (months)	9.8 ± 5.9	14.0 ± 14.7	0.38
Number of recurrences	12 (14.0%)	27(37.5%)	0.001
Time from tube removal to recurrence (months)	3.4 ± 4.6	11.0 ± 16.0	0.82
Number of recurrences within 1 year	11 (92%)	18 (67%)	0.13

In comparing the LD and ND groups, the ratio of male to female, the number of recurrent cases, and the number of recurrences within 1 year were tested by Pearson's χ^2 test. Meanwhile, age, period of preoperative obstruction, and observation period after tube removal were tested by Mann-Whitney's U test. Results showed the period of preoperative obstruction was significantly longer in the ND group ($p = 0.009$).

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Abbreviations

ENDI: Endoscopic-assisted nasolacrimal duct intubation, PANDO: Primary acquired nasolacrimal duct obstruction, NST: Nunchaku-style tube, DCR: Dacryocystorhinostomy

Figures

Figure 1

Plot displaying the duration of preoperative occlusion in each group

The period of obstruction was denoted based on the duration of chronic epiphora symptoms as described in the patient questionnaire. The period of preoperative obstruction was significantly longer in the ND group ($p < 0.05$).

Figure 2

The Kaplan–Meier's curve of lacrimal duct patency at one year after tube removal

The Kaplan–Meier's curve indicated that the lacrimal duct patency rate was 0.857 (95% CI; 0.754–0.919) in the LD group and 0.739 (95% CI; 0.617–0.828) in the ND group at 365 days after the tube removal.

There were 11 recurrences and 23 censored cases in the LD group, and 18 recurrences and 14 censorings in the ND group. The y-axis displays the patency rate, and the x-axis indicates the number of days.

Figure 3

Comparison of survival rates between the two groups at 1 year after tube removal by the RMST method

The RMST with $\tau = 365$ days was 326.65 and 284.59 in LD and ND groups, respectively. $\text{RMST (LD)} - \text{(ND)} = 42.058$ (0.996–83.121, $p = 0.045$), $\text{RMST (LD)} / \text{(ND)} = 1.148$ (0.999–1.319, $p = 0.052$), and RMTL

(LD) / (ND) = 0.477 (0.230–0.988, $p = 0.046$). The y-axis denotes the patency rate, and the x-axis shows the number of days.