

## Original Article

# Comparison of early versus standard timing for silicone stent removal following External Dacrocystorhinostomy under local anaesthesia

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## Abstract

**Introduction:** The first line treatment for nasolacrimal duct obstruction (NLDO) is external dacrocystorhinostomy (DCR). Following DCR, patients are required to return to Tilganga Institute of Ophthalmology (TIO) six weeks postoperatively for the removal of a silicone stent. As the majority of patients travel large distances at significant cost to reach TIO, most often patients remain within Kathmandu during this six weeks interval. This places a large financial burden on patients.

**Methods:** A randomized controlled trial was designed to compare patient outcomes after early (two weeks postoperatively) versus standard (six weeks postoperatively) removal of silicone stents. 50 selected patients were randomized into two equal groups.

**Results:** At the time of publication, 31 patients (14 in group A and 17 in group B) had completed three months follow up. A success rate of 92.9% was noted in Group A and a success rate of 94.1% observed in group B. No significant difference was found between the two groups for success rate and rate of complications.

**Conclusion:** Early tube removal post DCR appears to cause no significant difference in outcome or complication rates compared to standard tube removal.

**Key words:** Dacryology, Oculoplastic, Nasolacrimal duct obstruction, External dacrocystorhinostomy, lacrimal gland

## Introduction

NLDO is relatively common and usually an idiopathic condition that presents with epiphora. First line treatment for uncomplicated idiopathic

NLDO is external DCR (NICE, 2005). Failure to treat NLDO may lead to complications within the lacrimal drainage system, the surrounding skin or the eye (Lefebvre et al, 2015; Mandal et al, 2008). External DCR involves forming an anastomosis between the lacrimal sac and nasal mucosa proximal to the NLDO, thereby allowing tears to drain directly from the lacrimal sac into the nasal cavity (Mohammad, 2018). Failure most often results from post-operative iatrogenic stenosis of the common canaliculi, and so a silicone stent is placed intra-operatively along the new lacrimal drainage

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tract to maintain its patency as the wound heals (Xie et al, 2017).

TIO receives patients from all over the country and many patients choose to remain in Kathmandu for the duration of their treatment and follow up. Current international guidelines indicate that the silicone stent should be removed between six weeks and three months postoperatively; our surgeons opt to remove stents at six weeks in order to minimize the inconvenience to patients (Kamal et al, 2016; Nair et al, 2017). Nevertheless, the costs associated with accommodation and food substantially outweigh the cost of the surgery itself. In an effort to minimize these indirect healthcare costs, we have decided to assess whether the silicone stents may be removed at 2 weeks.

## Methods

Our study population included all patients more than 16 years old who can co-operate for surgery under local anesthesia, presented to TIO with primary acquired nasolacrimal duct obstruction (PANDO) for whom external DCR was indicated as the primary treatment modality. 50 patients were equally randomized to the two treatment arms, stent removal at two weeks and six weeks. The patients were randomized using the envelope method and were age and gender matched. Letters A and B were printed on same sized card and placed in opaque envelopes for the patient to choose. Doctors who performed the surgery and conducted the follow up appointments were blind to the patients' assignments.

Data was collected using a Proforma before surgery and at follow up appointments. For both groups this data was initially collected one day post operative and one week post operative. Group A had their third follow up at two weeks post op (when the tube was removed), and group B was six weeks post op. Both groups then resumed their follow up appointments

at three months and six months post op. 31 patients (14 in group A and 17 in group B) had completed three months follow up, and these are the focus of this report.

## Surgical Techniques

All patients underwent similar surgical procedure. Pre-operatively, intramuscular injection of diclofenac sodium 1.5 mg/kg in upper part of arm was used for all patients. After prepping and draping the surgical area in the usual sterile fashion, local anesthetic (2% lidocaine with adrenaline 1:10,000 plus 0.5% bupivacaine) was injected over the medial canthal tendon area and the inferior orbital rim close to the medial canthal area. A nasal gauze pack soaked in oxymetazoline 0.05% plus adrenaline 1:1000 nasal drops were inserted into the desired nostril. Using a number 15 Bard Parker surgical blade, a straight incision 10 mm in length was made 10 mm medial to the medial canthal tendon. The orbicularis muscle was bluntly dissected to expose the medial canthal tendon attachment site and the overlying periosteum. A sufficient flap of periosteum was made after incision near the anterior lacrimal crest. A rectangular-shaped osteotomy of approximately 15 mm by 15 mm was made with Kerrison rongeurs. An H-shaped incision at the posterior-inferior lacrimal sac was made, with a long anterior flap and shorter posterior flap. A similar H-shaped incision was made at the nasal mucosa. The posterior flap of the lacrimal sac was trimmed without suturing. Subsequently, anterior flap reconstruction (with anterior nasal and anterior lacrimal flap) using 6-0 Vicryl was considered with placement of a silicone tube to stent open the lacrimal passage. Finally, the orbicularis muscle and skin was closed with 6-0 Vicryl sutures. Each patient received postoperative nasal packing with gauze soaked in oxymetazoline 0.05% plus adrenaline 1:1000 nasal drops, and cotton gauge after antibiotic ointment over the external wound was applied to patch the wound.

Any complications during surgery were noted. After 30 minutes of observation, patients were discharged with oral antibiotics (ampicillin 250 mg plus cloxacillin 250 mg, four times daily) and oral antiinflammatory medication (serratiopeptidase, three times daily), for 1 week. Analgesics were prescribed as needed, and topical antibiotics (ciprofloxacin 0.3% eye drops, three times daily) were administered.

Success of surgery was considered when patient had:

1. No watering or occasional watering plus freely patent on irrigation of nasolacrimal apparatus at three months or
2. Partial patency on syringing plus subjectively, no watering at three months

Failure of the surgery was considered if:

1. Patient complaint of persistent watering and partial patency at three months or
2. Complete regurgitation of fluid back to punctum at three months regardless of watering or not

Data was analyzed using R Commander (R software, version 3.3.2). The chi square test of association was used to evaluate baseline characteristics of the two treatment arms, whilst Fisher's exact test was chosen to assess surgical outcome. A p value of  $<0.05$  was considered significant.

Institutional review board approval was obtained before conducting this study and all subjects have given their informed consent.

## Results

There were no significant differences in the baseline characteristics of the two groups. There was also no significant difference in age

with a mean (SD) age of 47.9 (15.3) and 55.8 (17.4) in group A and group B respectively (p value 0.19).

There is some evidence that group B appears noticeably older (average 7.9 years older) and less well educated (almost twice as many patients in group B were illiterate compared to those in group A).

With regards to the outcome, table 2 illustrates that no significant difference was found between the two groups. It should be noted that the low power of the study makes it difficult to draw any conclusions from this finding.

No significant differences were found in the complication rates between the two groups at all follow up appointments, as shown in table 3. At the first follow up clinic, four complications were noted in group A and five complications in group B. These complications included periorbital hematoma, haemorrhage and edema. Subsequently, only one complication was recorded amongst all the patients, namely a periorbital hematoma in one patient in-group A that persisted from the first until the third follow up appointment. Only one important early complication occurred, namely a haemorrhage in one patient from group A. However, this was controlled effectively at the first appointment, and was absent at subsequent follow up. No complications were recorded in any of the study patients at the time of the fourth follow up appointment, three months after surgery. Given that all complications were recorded prior to stent removal in both groups, it should be noted that the timing of stent removal does not appear to have influenced complication rates in this small cohort.

**Table 1: Baseline characteristics of those who completed three months follow up**

Characteristic		Group A n(%)	Group B n(%)	p value
Gender	Female	12 (85.7)	16 (94.1)	0.58
	Male	2 (14.3)	1 (5.9)	
Region	Hills	12 (85.7)	14 (82.4)	1.0
	Mountains	0 (0)	1 (5.9)	
	Tarai	2 (14.3)	2 (11.8)	
Education	Illiterate	5 (35.7)	11 (64.7)	0.15
	Literate	5 (35.7)	4 (23.5)	
	Up to School Leaving Certificate	4 (28.6)	1 (5.9)	
	Higher Education	0 (0)	1 (5.9)	

**Table 2: Comparison of patient surgery outcomes by Group**

Outcome	Group A (n%)	Group B n(%)	p value
Success	13 (92.9)	16 (94.1)	1
Failure	1 (7.1)	1 (5.9)	

**Table 3: Complications identified at the third month follow up by Group**

Complications	Group A n(%)	Group B n(%)	p value
No	13 (92.9)	17 (100)	0.45
Yes	1 (7.1)	0 (0)	

## Discussion

Our analysis has demonstrated no marked difference in the final outcome or complication rates when comparing silicone stent removal at two weeks to stent removal at six weeks. This is reassuring given some evidence that the two groups differed in baseline characteristics. With regard to the overarching aim of this study, this result offers the promise of substantially mitigating the indirect healthcare costs for patients by reducing the duration of their stay in Kathmandu by two thirds.

Our success rate was 93.5%, which is comparable to other countries where the success rate is more than 90% (Tarbet & Custer 1995). This is the first review that has looked at success of DCR and complications for 6 weeks versus 2 weeks. Charalampidou et al. (2009) found no statistical difference between early (less than 2 months), routine (2 to 4 months) and late (more than 4 months) tube removal.

## Conclusion

The preliminary results of our pilot study have served firstly to demonstrate that silicone stents have been removed in a small group of patients two weeks after DCR without any significant impact on outcome or complication rates. This can lead the way for surgeons to remove stents at 2 weeks and relieve the financial burden placed on patients. They have also identified that educational attainment may vary significantly within the two arms of the study.

An important point identified during analysis was the inability to discount the absence of a significant result as a false negative due to the low power of the study. However, it should be emphasized that the goal of this study was not to form any firm conclusions, but to act as a pilot for the development of a larger, appropriately powered randomized controlled trial.

## Disclosure Statement

The authors have no conflicts of interest to disclose. Himalayan Cataract Project supported this research study.

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