Abstract:

This thesis is based on a large prospective, observational study on the various factors affecting the success of endoscopic dacryocystorhinostomy (endo DCR). There are 3 components to this study. Canalicular closure has long been thought to be a major cause for early failure and the reason behind routine silicone intubation. The first component investigated the incidence of canalicular closure in patient who underwent endo DCR without silicone intubation. In our prospective series of non-intubation for primary nasolacrimal duct obstruction, there were no cases of canalicular closure or stenosis at 12 months. Ostium closure is another major cause for failure and the degree of ostium shrinkage has been inconclusive in the literature. The second component investigated the degree of ostium shrinkage following endo DCR and if ostium shrinkage affects success of endo DCR. Following endoscopic DCR, the final ostium size on average is 35% of the original at 12 months post-operation. The majority of the ostium shrinkage occurs within 4 weeks post-operatively with a lesser degree of shrinkage between 1-12 months post-operatively. We found that ostium size was not predictive of overall surgical outcome. Finally while endo DCR has traditionally been performed under general anesthetics, there are various perioperative and cost benefits of a local anesthetic approach. We investigated the tolerability of endo DCR under local anesthesia. We found 98% of patients are happy to have powered endoscopic DCR performed again under assisted local anaesthetic.
**Declaration**

I am aware of no conflicts of interest, of any nature, pertaining to this manuscript. The design of the study and its execution, analysis, interpretation, and publication were carried out independently by myself (WengOnn Chan) and those acknowledged within this manuscript.

This work contains no material which has been accepted for the award of any other degree or diploma in any university or other tertiary institution to WengOnn Chan and, to the best of my knowledge and belief, contains no material previously published or written by another person, except where due reference has been made in the text.

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The studies in this thesis are solely the brainchild of Prof. Dinesh Selva. His meticulous planning and execution made this thesis possible. This thesis would not have been possible without the ongoing support and guidance from my principle supervisors Prof. Dinesh Selva and Prof. Robert Casson.

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I would like to acknowledge all the feedback and support provided by all my co-authors.

Prof. Dinesh Selva is the chief investigator in this study. He is responsible for study conception, planning, execution, data collection, drafting and revising the manuscript. Dr. Paul Cannon is involved in execution of study, data collection, data analysis, drafting and critically revising the manuscript. Dr. Douglas Fahlbusch was involved in execution of study, data analysis and critically revising the manuscript. Dr. Premjeet Dhillon was involved in execution of study, data analysis and critically revising the manuscript.

Finally, I would like to thank my wife and daughter, family and friends for their continuing patience, support and encouragement.
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**Abbreviations**

aLa: Assisted local anaesthetic

ANOVA: Analysis of variance

cf.: Compared to

CI: Confidence interval

DCG: Dacryocystogram

DCR: Dacryocystorhinostomy

DSG: Lacrimal scintillography

Endo DCR: endoscopic Dacryocystorhinostomy

MMC: Mitomycin C

n/a: Not applicable

NLDO: Naso-lacrimal duct obstruction

PANDO: Primary acquired naso-lacrimal duct obstruction

PEDCR: Powered endoscopic DCR

VAS: Visual analogue scale
Chapter 1
How did it all start? The history of Dacryocystorhinostomy

To relieve watery eye or epiphora, surgeons have been creating alternate pathways from the lacrimal sac to the nose to bypass the nasolacrimal blockage for more than two millennia(1; 2). The Code of Hammurabi contains probably the earliest mention of lacrimal surgery where it dictates the loss of the surgeon’s fingers if patients were blinded following lancing of abscess(3). Earliest descriptions of DCR involved boring red-hot cautery iron through the lacrimal bone by Celsus in the first century(1). Galen in the second century used a trephine to bore a hole into the nose(1).

The precursor of modern DCR was probably the Woolhouse technique that was recorded in the Chirurgie by Platner in 1724(1; 2). Woolhouse’s technique involved lifting and excising the entire lacrimal sac, perforating the lacrimal bone and placing of a drain which was frequently irrigated and changed. This remained the predominant technique practiced during the eighteenth(1).

A true bypass between the lacrimal sac to the nasal cavity i.e. dacryocystorhinostomy was described in 1836 by Montaigne where a hole is punched through from the sac into the nose(1). This was followed by a gut drain that was changed daily and skin wound allowed to heal after 10-20 days(1).

In 1904, Toti described his technique which was to become the basis for modern external DCR. A dacryocystorhinostomy that involved only the medial wall of the nasolacrimal sac, an osteotomy site and only the nasal mucosa over the osteotomy site was excised(1). This technique minimized collateral damage to other structures and maximized tissue preservation.
In contrast to Toti's technique where the lacrimal and nasal mucosa was left to granulate, Kuhnt in 1914 sutured the nasal mucosa to the periostium(1). True continuous epithelium-lined fistula was introduced in 1920 by Ohm when he created both anterior and posterior lacrimal and nasal flaps and sutured them together(1). This technique were subsequently popularized by Dupuy-Dutemps and Bourguet(4; 1)

The History of Endonasal DCR

The first endonasal approach was described by Caldwell in 1893, a metal probe was passed through the canaliculus into the lacrimal sac down to the nasolacrimal duct(1). An electric burr was then used to create an opening through bone and nasal mucous membrane until the probe can pass freely into the nasal cavity(1). This idea was extended by West in 1910 and he removed the lacrimal bone and superior maxilla to access the nasolacrimal duct via a window osteotomy; the inner wall of the nasolacrimal duct and the inferior nasolacrimal sac was then excised(5; 1). Polyak in 1911 reported a similar operation and hence the procedure was known as West-Polyak operation(1).

Even though endonasal DCR was first described in the 1893 by Caldwell, the popularity this approach only increased in the 70s and 80s(5). There was major limitation to the endonasal approach due to limited visibility from poor illumination and bleeding of the nasal mucosa(5). It was not until 1989 that McDonough and Meiring first introduce endoscopic endonasal DCR that helped revive interest in the endoscopic technique(6). Inadvertent exposure of the nasolacrimal duct during functional endoscopic nasal surgery gave them the idea of introducing a rigid Storz Hopkins Rodlens endoscope with a 30° viewing angle for endoscopic DCR(6). The
use of endoscope allows surgeons to precisely locate the site of proposed rhinostomy and also to address any concurrent pathology that may contribute to epiphora.

**The use of drain and intubation**

The use of drain in the nasal opening started from the time of Woolhouse and Platner. Back then drains that were made from gold, silver or lead were left in situ for up to several months and irrigated regularly (1). This idea of leaving a stent in an attempt to maintain ostium closure persisted and subsequent co-workers used a variety of material for intubation and stenting.

Koster in 1908 initially left a thread through the nasolacrimal duct but later modified his approach to leave a thread from the lacrimal sac through to the middle meatus (1). Van Lint introduced the use of gauze drain in 1920 (1). Glass tube was advocated by Herrmann in 1924 and a wire was introduced by Graham in 1922 (1). Pooley in 1925 left bundle of cat gut in the osteotomy (1). Morax and Vialiex in 1925 left skin graft wrapped around wax instead in the opening. Rubber drains were introduced by Poljak and Raverdino (1).

The first trans-canalicular stent were attributed to Graue whom placed a silver wire through the punctum into the nose (7). Henderson described in 1950 the use of polyethylene tube with DCR for the treatment of canalicular strictures (8). Polyethylene was a relatively new material then. After leaving the tube in site for 46 days without any adverse reaction, Henderson concluded that polyethylene is ideally suited for canalicular intubation (8). Bi-canalicular intubation in the modern fashion was described by Huggert in 1959 (9). This was introduced in response to chances of tubes being extruded or left out externally that may require unsightly fixation. In this
early series of 20 patients, Huggert achieved 75% patency rate with this method(9). In 1966 Bjork introduced bi-canalicular intubation with polyethylene tubes in endoscopic DCR(10). Bjork stated that if intubation were not performed; it should be replaced with regular probing and irrigation to maintain patency of the rhinostomy site(10). However the author also remarked that intubation should not be performed for routine DCR and should only be reserved for cases of congenital or traumatic atresia of canalicular system and in revision DCRs(10). While polyethylene was popular with early adopters, it was stiff and was prone to cause punctal erosion or slitting and corneal irritation(11). Silicone intubation was introduced in response to this by Gibbs in 1967 and it was popularized by Quickert and Dryden(12).

A series of papers in the 1980s demonstrated high surgical success rates of >90% when intubation with DCR were performed(7). This was suggested as one of the reason why routine intubation was performed. In Chapter 2, the evidence for and against intubation will be presented together with our own experience with selective non-intubation.

**Relevant anatomy: The lacrimal excretory system**

The lacrimal excretory system comprise of the lacrimal punta, lacrimal canaliculi, the lacrimal sac and the nasolacrimal duct(13). Drainage of tears start at the lacrimal punti located 5-6mm from the medial canthus(14). The normal resting position of the punta is slightly inverted to be in contact with the tear lake(14). The puncta is connected to the canaliculus which has an initial vertical 2mm component and bend acutely to join a horizontal portion of the canaliculus which is about 8-10mm long(13). In 90-98% of cases, both canaliculi may join to form the common canaliculus prior to entering the lacrimal sac(14);
The canaliculus is lined with stratified squamous epithelium and the epithelium in turn is surrounded by dense ordinary connective tissue rich in elastin (13). The point of entry is posterior to the medial canthal ligament as 4-5mm inferior to the fundus.
of the lacrimal sac(13). Tucker et al showed in plastic cast of lacrimal outflow system that the canaliculi bend posteriorly behind the medial canthal tendon, before entering the sac at an acute angle of 58° to the lateral wall of the sac(16). The opening of the common canaliculus into the lacrimal sac is an important landmark during endo DCR. Wormald et al found that the mean distance from canalicular opening to the superior limit for the lac to be 5mm(17). Adequate exposure of the lacrimal sac during DCR to expose at least the common canalicular opening will ensure that the majority of the sac is exposed(17).

The nasolacrimal sac that is about 10-15mm long is located in the lacrimal fossa(5; 6). The fossa is bounded between the anterior lacrimal crest of the frontal process of the maxilla bone and the posterior lacrimal crest of the lacrimal bone(6). The lacrimo-maxillary suture (LMS) is the junction between these two bones. The lacrimal fossa has a reported diameter of 3-8mm(18; 19; 20). While the majority of LMS lies in the middle of the lacrimal fossa, between 8-32% will lie closer to the posterior lacrimal crest(20; 21).

Medially the lacrimal sac is bound by the anterior and posterior crus of the medial canthal tendon. The sac continues as the nasolacrimal duct which passes through the nasolacrimal canal has an average diameter of 3.5-6.8mm and length of between 6mm to 20mm(22; 23; 6). Studies have shown that women, Caucasian and elderly patients have smaller diameter NLD; these may account for increased incidence of NLD obstruction in these groups(24). In 80-90% of patients, the bony nasolacrimal canal is directed more posteriorly compared to the lacrimal sac(25). The nasolacrimal duct opens into the lateral nasal wall beneath the inferior nasal meatus(6). The opening of the NLD is situated right below the superior attachment of the inferior turbinate(26). The shape of the opening varies and it can be a vertical,
horizontal or oblique slits or sulcus(26). This opening is often covered by a fold of mucosa; the valve of Hasner(26)

**Lacrimal pump and endonasal approach**

One major benefit often quoted for endonasal DCR is the preservation of the lacrimal pump. Tears get produced by the gland and travel across the surface of the eye. About 10-25% of tears will lost by evaporation and some by absorption at the level of the lacrimal sac. The others are excreted by active pump mechanism. The exact mechanism of how this active pump works is debated. As the canaliculus are passed through eyelid; it is encased in the in the superficial pretarsal orbicularis oculi. The pretasal orbicularis oculi is firmly attached to the medial canthal ligament. The pretarsal orbicularis oculi attaches to the posterior lacrimal crest and the preseptal orbicularis oculi attaches to the lacrimal septum(27).

Jones and Wobig postulated a negative pump theory where with eyelid closure, the canaliculi are compressed by the orbicularis oculi and the lacrimal septum is pulled medially by the attachments which generates negative pressure in the sac. With eyelid opening; the sac collapses and empties(28). In contrast, Doene et al based on high speed photography proposed the positive pressure theory. Here tears in the cannaliculi and sac are drained during positive pressure generated during lid closure. With opening, a temporary negative pressure together with capillary action refills the canalicular system(29). In both theories, the orbicularis and its attachment at the around the lacrimal sac plays a crucial role in a dynamic pump mechanism.

Endonasal DCR ensures the preservation of these structures therefore making the more physiologically superior option when compared with external DCR. In theory
this may translate to better outcome for patients that have epiphora in the presence of a patent nasolacrimal system(30).

**Relevant Nasal anatomy:**

The identification of the nasolacrimal apparatus in relation to the lateral nasal wall is paramount to a successful endonasal surgery. As previous studies have suggested incomplete exposure of the lacrimal sac superiorly may lead to failure and incomplete inferior exposure may lead to lacrimal sac sump syndrome(17).

The nasal vestibule leads into the nasal atrium which is bound superiorly by the ethmoidal crest and inferiorly by the conchal crest of the maxilla(6). Anteriorly the atrium is concave and posteriorly the atrium ends at a vertical convex ridge, this ridge is also known as the maxillary line(5; 6). This ridge extends from the superior most point of the inferior turbinate to end at the front of the middle turbinate’s attachment. The ridge corresponds to the location of the frontal process of the maxilla. 3mm posterior to this ridge lies the junction between the frontal process and the lacrimal bone. This junction extends about 5mm superior to the ridge. The location of the nasolacrimal duct in relation to the maxillary line is variable. Kim et al in a cadaveric study showed that in 67% of patients, the NLD overlapped with the maxillary line. In 28% of patients, it can lie posteriorly and in 5% anterior to the maxillary line. In another cadaveric study, Orhan et al showed a higher percentage of overlap at 90%(31) while Chastain et al showed that in 100% overlap(32).

Other important landmarks include the middle turbinate, uncinate process, agger nasi and the bulla ethmoidalis. The middle turbinate is part of the ethmoidal bone and can be pneumatized(5). The anterior point of insertion of the middle turbinate is
termed the axilla or the operculum of the middle turbinate. This is an important landmark as most co-workers consider the axilla to correspond to the superior limit of the lacrimal sac(5; 6). However in a computer tomographic anatomical study by Wormald et al, the majority of the lacrimal sac, 8-10mm lies superior to the axilla and only 1-2mm of the sac lies below it. In a cadaveric study of 50 half heads, Calhoun et al also found that the axilla always lies superior and posterior to the inferior edge of the nasolacrimal sac(33). The lacrimal sac is typically situated posterior to the axilla but Kim et al showed that it can lie immediately lateral to the axilla in 30% of patients and in 10% anterior to the axilla(26). In contrast, Fayet et al found in a computer tomographic study that the axilla always lies anterior to the lacrimo-maxillary suture and the majority of the sac lies superior to the axilla(34).

The agger nasi lies anterior to the axilla of the middle turbinate. It is the anterior most ethmoid cell and presents as a bony protuberance that lies directly superior lateral to the atrium of the middle meatus(35). The agger nasi is present in 81.8% to 98.5% of the patients and typically lies anterior to the uncinate process(35; 36). To achieve complete exposure of sac, the agger nasi may be removed as a significant portion of patients have agger nasi that overlies the lacrimal sac(37). The uncinate process is a bony plate with mucosal covering located lateral and anterior to the middle turbinate. The uncinate is divided into 3 parts: the middle portion of the attaches to the lacrimal bone and lamina papyracea. The horizontal portion attaches to the ethmoidal process of the inferior turbinate and palatine bone. The superior portion of the uncinate extends to a varying degree into the frontal recess(38). It serves as a landmark for the lacrimal bone which lies immediately anterior to it(5). Liu et al found that the uncinate process attaches to the lamina papyracea in 70.4% and 10.2% to the middle turbinate and 6.1% to the skull base(35).
Also the nasolacrimal duct also passes 3mm anterior to the uncinate process(33). There is significant variability in the overlap of uncinate process and the lacrimal fossa. Soyka et al found that in 63% of individuals had an uncinate process that covers at least 50% of the lacrimal fossa(37). Studies in the Asian population demonstrated overlap rates up to 100%(39). Given the high rates of overlap co-workers have suggested uncinectomy may be required to fully expose the lacrimal sac; especially in the Asian population(37). The bulla ethmoidalis lies posterior to the uncinate process and lateral to the middle turbinate. It is a round projection of the lateral wall(5).

It has been suggested that endonasal DCR has much lower success rates in the past as surgeons didn’t have a full understanding of the correlations(30). A good understanding of the intranasal anatomy and its correlations with the nasolacrimal sac is fundamental to achieving full marsupialization of the lacrimal sac during DCR. Only with an adequately sized ostium that one can fully expose the lacrimal sac; both playing an important role in the success of DCR. In chapter 4 we will discuss the change of ostium with time, the sizing of the osteotomy and the effect of ostium on the success rate.

**Why do DCR? The impact of epiphora and the benefit of DCR**

While rarely a symptom of sight threatening condition, epiphora can cause significant morbidity to the patients. On top of the inconvenience from regularly wiping their eyes, more serious issue with reduction in vision, skin excoriation, embarrassment and social activities avoidance have been associated with severe epiphora(40). The impact of epiphora to vision is highlighted in a study by Kafil-Hussain et al(41). They compared the subjective visual function using the visual
functioning index (VF 14) in patients with epiphora and patients with second eye cataract (42; 41). Patients with epiphora were significantly more affected in reading small print, watching television, doing fine work, and seeing steps and stairs (41). They concluded that patients with epiphora suffer similar levels of visual handicap with patients awaiting second eye cataract surgery (41). With regards to physiological impact, Leung et al demonstrated that more than 65% of their patients with nasolacrimal duct obstruction suffered from embarrassment due to epiphora (40).

With the ever diminishing public funding for ever increasing health care cost; benefits from intervention will have to be justified (43). Improvement to patient’s health status following intervention has been used as a yardstick to determine the benefits of an intervention. In a study by Spielman et al, the benefit of endo DCR was measured using a validated post interventional health questionnaire; the Glasgow benefit index (43). The benefit of endo DCR on the patient’s health status was graded with a score range between -100 to +100 and 0 representing no change; the higher the score the higher the benefit and vice versa. They found that the mean score for DCR for patients were +32.7 which was comparable to other rhinological procedures (43). Ho et al also demonstrated similar scores of +34 following successful surgery and -19 when the surgery was unsuccessful (44). Recently, Jutley et al also demonstrated in a large retrospective cohort of 282 patients that, patients that underwent endoDCR had an overall GBI score of +15 (45). With regards to physiological impact, Leung et al demonstrated that more than 65% of their patients with nasolacrimal duct obstruction suffered from embarrassment due to epiphora. With regards to social improvement, all of the aforementioned studies documented improvement in the GBI social subscale. Psychologically, Leung et al also showed
that following successful DCR, the perceived symptom severity and embarrassment
due to watery eyes was significantly reduced(40).

Co-workers have also compared patient satisfaction between external and endonasal
DCR. Between these groups of patients, both Feretis et al and Matthew et al found
there was no difference in patient satisfaction even though patients that
underwent endo DCR perceived less symptomatic improvement compared to external
DCR(46; 47). Bakri et al compared the GBI score between patients who had external
and patient who underwent endonasal laser DCR. They found that there were no
significant differences in the Glasgow benefit index score between the two
groups(48). Hii et al investigated the patient satisfaction and cost between external
and endo DCR(49). They found that endo DCR had higher GBI score of +24.1 vs.
+16.1 for external DCR; however this was not statistically significant. They found
endo DCR cost more than external DCR when calculated with activity-based
costing(49). This method accounts and estimates the staff cost, consumables, drugs
and cost of inpatient stay. The main cause for higher endo cost is from the increased
consumables and capital equipment cost(49). The cost saving aspect of endonasal
DCR is a greater percentage of patients only having same day admission(49).

In summary, epiphora can cause significant morbidity to the patients and DCR is a
highly successful and established surgical procedure that significantly improves
patient’s symptoms and their overall health status. Performing DCR under local
anesthesia can not only remove the morbidity related to general anaesthesia, it can
also significantly reduce the cost of the procedure. However the tolerability of
powered drill used in DCR under local anesthesia has not been evaluated. In chapter
5, we will investigate the tolerability of powered endoscopic DCR with assisted local
anesthesia.
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Incidence of canalicular closure with endonasal dacryocystorhinostomy without intubation in Primary Nasolacrimal Duct Obstruction

Ophthalmology: 2013 In press

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Analysis and interpretation of data, drafting of the manuscript, critical revision of the manuscript.

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Acquisition of data, data entry, drafting and critical revisions of manuscript.

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Incidence of canalicular closure with endonasal dacryocystorhinostomy without intubation in Primary Nasolacrimal Duct Obstruction

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Running Head: Canalicular closure with endonasal DCR without intubation

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Abstract

**Purpose:** To describe the incidence of canalicular closure with powered endonasal dacryocystorhinostomy (DCR) without canalicular intubation in primary acquired naso-lacrimal duct obstruction (PANDO)

**Design:** A single surgeon, prospective, non-randomized, non-comparative, interventional case series

**Participants:** Consecutive patients attending a specialist clinic of an oculoplastic surgeon (DS) with radiologically confirmed diagnosis of PANDO. Cases of canalicular disease were excluded.

**Methods:** Patients with radiologically confirmed PANDO without canalicular involvement underwent endonasal DCR without intubation. The operation was performed by one surgeon (DS) and follow-up was at 4 weeks and 12 months.

**Main Outcome Measures:** Outcomes were recorded as subjective symptomatic relief at 12 months and endoscopic evidence of ostium patency and canalicular patency.

**Results:** 132 cases fulfilled the inclusion criteria. 3 cases were lost to follow-up. Pre-operatively, 96.3% of cases had Munk scores of more than 2. 98.5% (127/129) of cases had endoscopic evidence of a patent ostium with a positive endoscopic dye test at 12 month follow-up. All cases had a patent canalicular system as demonstrated
by syringing and probing. 90.7% (117/129) of cases had subjective improvement of epiphora at 12 months with 88.4% of cases reporting Munk scores of 1 or less.

**Conclusion:** In this prospective series of non-intubation for PANDO, there were no cases of canalicular closure or stenosis at 12 months. Anatomical and functional success was similar to reported outcomes for DCR with intubation for PANDO. We advocate that routine intubation for the purpose of maintaining canalicular patency is not necessary when performing endonasal DCR in PANDO.
Introduction

Endonasal dacryocystorhinostomy (DCR) as a procedure in management of naso-lacrimal duct obstruction (NLDO) has continued to evolve since it was first described by Caldwell. Its success rate is comparable to the “gold standard” of external DCR with reports ranging from 75 to 99%. The proposed advantages of endonasal DCR over external DCR include absence of a skin wound, preservation of the lacrimal pump, direct visualization of the rhinostomy site, improved hemostasis from mucosal surfaces, and the ability to address any relevant nasal pathology.

Silicone intubation has been commonly used in naso-lacrimal surgery for the past 40 years. The primary rationale for the use of routine intubation in DCR for NLDO is that it maintains patency of the common canalicular opening into the sac preventing closure due to possible trauma or inflammation. Most advocates of intubation would accept that it does not prevent ostial closure across the rhinostomy which would generally require a larger and more rigid stent. However, there is no significant evidence base for the role of routine silicone intubation in dacryocystorhinostomy for nasolacrimal duct obstruction. Nevertheless, a recent survey among oculoplastic surgeons in Australia and New Zealand revealed that silicone intubation was routinely used in 93.5% of external DCRs and in 96.2% of endonasal DCRs for acquired NLDO.

In this paper, we report the incidence of canalicular closure and outcome of powered endoscopic DCR without intubation in cases of primary acquired naso-lacrimal duct obstruction (PANDO).
Methods

This was a prospective, non-randomized, non-comparative, interventional case series. We included consecutive patients attending a specialist clinic of an oculoplastic surgeon (DS) with a diagnosis of PANDO from January of 2007- to December of 2009. Patients were invited to participate in the study if they required a DCR. All patients underwent a full lacrimal clinical examination. Patients were specifically asked about symptoms of discharge and epiphora. Epiphora was subjectively graded with Munk scores obtained pre and post-operatively. Epiphora is graded from a scale of 0-4 (0=no epiphora at all, 1 = occasional epiphora requiring dabbing with a tissue or handkerchief 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 requiring dabbing more than 10 times a day or constant tearing) 11. Past history of dacryocystitis, chemotherapy, radiotherapy, burns, trauma and severe conjunctival disease were specifically obtained.

All patients also underwent bilateral syringing of the tear ducts and radiological imaging with dacryocystogram (DCG) and lacrimal scintillography (DSG).

The following inclusion and exclusion criteria were applied:

Inclusion criteria:

- 18 years old or more
- Confirmed diagnosis of PANDO based on lacrimal syringing, DCG and DSG

Exclusion criteria:

- Previous DCR
- Patients with punctal stenosis, ectropion, and facial palsy were excluded.
Patients with canalicular disease (obstruction of stenosis) demonstrated preoperatively (DCG and DSG) or intraoperatively were excluded.

We recorded any additional procedures performed intraoperatively e.g. septoplasty and turbinectomy. Any intraoperative and post-operative complications were recorded.

Follow-up reviews were at 4 weeks and at 12 months. At 4 weeks, the patency was assessed. At 12 months, the patient underwent a final clinical examination, nasal endoscopy with endoscopic dye test, syringing and probing of both upper and lower canaliculi. At 12 months, patient were asked to grade their epiphora and if they would define they surgery as successful.

The following outcomes were measured:

1. The prevalence of anatomical success, defined as endoscopic evidence of ostium and canalicular patency with evidence of fluorescein in the nasal cavity (positive endoscopic dye test) and patent syringing at 12 months follow-up.

2. The prevalence of functional success, defined as subjective improvement of epiphora as reported by the patient at 12 months follow-up. The patients were also asked if they would define the surgery as successful.

Overall objective success was defined as the patient having both an anatomical and a functional success at 12 months follow-up.
The study was approved by the Research Ethics Committee of the Royal Adelaide Hospital, Adelaide, Australia.

**Procedure:**

All the surgical procedures were carried out by a single experienced surgeon (DS). The endonasal DCR was performed under general anesthesia or local anesthesia with sedation. The nostril was sprayed with phenylephrine 0.5% and lignocaine 5% (Co-phenylcaine Forte, ENT Technologies Pty Ltd, Malverin, Victoria, Australia). Neurosurgical cottonoids soaked in 5% cocaine were then placed anterior to the middle turbinate for 10 minutes. The nasal mucosa was injected with 2% lignocaine hydrochloride with adrenaline 1:80,000 (Lidospan, Septodent, Maidstone, United Kingdom). A nasal mucosa flap was fashioned anterior to the middle turbinate with a number 15 blade and elevated with a Freer periosteal elevator. The flap was retracted and the underlying bone exposed. The osteotomy was performed with a punch (HajekKoffler, Martin, Tutlingen, Germany) and powered rough-diamond burr (Medtronic-Xomed, Jacksonville, Fla., USA). The frontal process of the maxilla, lacrimal bone and root of the middle turbinate were removed to create an osteotomy size of approximately 10×15 mm. The lacrimal sac was fully exposed. The inferior canaliculus was probed and used to tent the medial wall of the lacrimal sac, which was incised with a keratome. The lacrimal sac was opened to create anterior and posterior flaps that were then reflected onto the lateral nasal wall. Redundant nasal mucosa was removed to achieve mucosal apposition with the posterior lacrimal flap. Post-operative instructions included daily nasal douching with a saline spray and avoidance of nose blowing for 2 weeks.
Results

There were a total 158 patients and 5 of them required bilateral DCRs. This brought the total cases of DCR during the study period to 163. Of the 163 cases of DCR, 2 patient declined participation in the study. 29 cases were excluded based on the exclusion criteria. Both patients that declined surgery were in their twenties and had nasolacrimal duct stenosis.

A total of 132 cases of confirmed PANDO were included in the study. There were 5 patients with bilateral PANDO, 4 patients had DCR done sequentially and 1 simultaneously. There were 79 cases of complete nasolacrimal duct obstruction and 53 cases of nasolacrimal stenosis. No cases had canalicular stenosis intraoperatively. The mean age of patients at the time of surgery was 64.2 years with a range of 21-94 years old. 49 patients were males and 79 patients were females. The indication for surgery and significant past histories are summarized in Table 1. Additional intraoperative procedures and complication rates are summarized in Table 2.

At 4 weeks follow-up:
98.5% (130/132) of cases had a patent ostium and a positive endoscopic dye test and normal irrigation test. All cases with patent ostia had patent common canalicular openings.

At 12 months follow-up:
3 cases were lost to follow-up at 12 months. One patient died of cardiac arrest 7 months post operatively and another 2 patients were not contactable.
90.7% (117/129) of cases had subjective improvement of epiphora and considered the surgery as successful at 12 months. 98.5% (127/129) of cases had endoscopic evidence of a patent ostium with a positive endoscopic dye test and normal lacrimal syringing at the 12 month follow-up. All cases with patent ostia had patent common canalicular openings. The 2 cases with ostial closure both underwent successful revision endoDCR. These 2 cases were both found to have patent canalicular systems and common canalicular openings at the time of revision surgery. Hence no case in this study was found to have canalicular stenosis or obstruction.

Pre-operatively, 96.3% of cases had Munk scores of more than 2. At 12 months follow-up 88.4% of cases had Munk scores of 1 or less. There were 2 cases with Munk score of 2 and 1 case with a Munk score of 4 post-operatively that still regarded the surgery as successful. Table 3 summarizes the pre and post-operative Munk scores stratified by overall outcome at 12 months. 90.7% (117/129) of cases had overall success at 12 months. Of the 10 cases who had continued epiphora despite patent ostia, 9 underwent further procedures such as Jones tubes, intubation or lid tightening with 8 of these achieving subjective improvements.

Table 4 summarizes the outcome of the 12 cases who had failed initial DCR and the subsequent procedures performed.

**Discussion**

In our prospective series of cases that was had endoscopic DCR without intubation, the incidence of common canalicular closure at 12 months was zero. We also demonstrated a combined functional and anatomical success rate of 90.7%. Our study suggests that intubation in endoscopic DCR is not required to maintain
common canalicular patency and routine intubation in PANDO for this reason is not warranted.

Prevention of ostium and common canalicular opening closure are commonly cited reasons for intubation. Our study is the first prospective study with large number of participants to investigate the incidence of canalicular closure with non-intubation following endoscopic DCR. For each of our cases we confirmed the patency of the common canalicular opening by direct visualization on endoscopic dye test in addition to syringing and probing of the canalicular system. Our findings do not support the notion that non-intubation leads to common canalicular closure. Other authors have also reported success rates of 81.3-100% with their series of DCR with non-intubation.

There were a high proportion of patients with nasolacrimal duct stenosis in our series of patients. This may limit the generalizability of the findings to other cohort of patients. The senior author is often referred patients who are termed “functional obstructions” as they are patent on syringing and the general ophthalmologists in the city are usually happy to perform DCRs on those with complete obstruction on syringing. Hence those with patency constitute a disproportionally higher component of the senior author’s practice. When these patients are assessed they are often found to have some reflux on syringing and the DCGs demonstrate definite narrowing of the NLD and the DSGs often will support this with evidence of post sac delay. Therefore NLD stenosis constitutes a large group in this particular practice.

Our anatomical patency rate of 98.5% and overall success rate of 90.7% are certainly comparable to previously reported success rates of between 89.8% and 94% when
using silicone intubation in DCR surgery regardless of the variation in how the mucosal flaps were created. Silicone intubation has gradually become a standard, well-accepted step in DCR surgery. However, there is lack of level 1 evidence on the use of routine use of intubation. Previous studies investigating the role of intubation in endoscopic DCR were limited by small numbers. In a recent meta-analysis investigating the outcomes of endoscopic DCR with or without intubation, Gu and Cao concluded that there were no significant difference in outcome between the two approaches. The main limitations of the analysis were that only 2 randomized controlled trials were included and the small number of total subjects.

Allen and Berlin compared patients without canalicular disease who underwent primary DCR in which the silicone intubation was the only variable factor. They found a failure of 14.5% in the intubated group and 5.0% in the non-intubated group. The failures did not appear to be related to canalicular damage. They went as far as to state that intubation was associated with a statistically significant increase in the failure rate of primary DCR. Indeed the possible complications associated with intubation are well documented and include punctual erosion, corneal abrasion, fistula formation, granuloma formation, chronic mucopurulent discharge, tube prolapse and the necessity of a second procedure to remove the tubes. Walland and Rose investigated the role of silicone intubation in DCR and found no statistical difference in the failure rates between patients who were intubated and those who were not. Kashkouli et al came to a similar conclusion in their study. Vicinanzo et al have observed that there remain significant concerns pertaining to the safety, efficacy and cost-effectiveness of routine intubation to conclusively affirm its role in DCR surgery.
Other authors have advocated selective silicone intubation when there is the intraoperative appearance of a tight common canaliculus and in situations where lacrimal sac features may predispose to failure\textsuperscript{19,32}. Other putative indications were previous history of dacryocystitis, revision procedures, situations of excessive intraoperative hemorrhage and poor mucosal flap formation\textsuperscript{10, 28}. Previously we reviewed the literature to assess the definitive support for the role of intubation in routine DCR surgery and found the evidence to be lacking\textsuperscript{9}. Although we believe that intubation is appropriate in the setting of canalicular disease further studies are required to assess its role in the other scenarios. The benefits of non-intubation are reduced surgical time, reduced cost, simpler follow-up regime and no intubation associated complications.

Although we believe the current evidence and the results of our study do not provide support to the contention that routine intubation results in an improved anatomical patency rate, we do acknowledge the possibility that intubation may improve functional outcomes in the presence of a patent system following DCR. Possible mechanisms may include temporary dilation and stenting of the canalicular system improving clinically unrecognized transit delay through the proximal system. However, the incidence of functional failure with a patent system in our study appears to be commensurate with the previous literature for cases who had been routinely intubated. Nevertheless, further research into this problematic group of patients who appear to comprise the majority of functional failures in many recent series, is undoubtedly required\textsuperscript{19; 33-35}. 
The strengths of this study are its prospective nature, and it follows the outcomes of procedures performed by a single surgeon and contains a large number of patients. We acknowledge that there are a number of limitations with this study. It has no controls and is not randomized. A large prospective randomized study as suggested by Vicinanzowould be required to definitively address the issue of silicone intubation in all DCRs\(^8\). Previous acute and recurrent dacryocystitis may predispose patients to canalicular closure. As our cohort contained only 12.9% of cases with such a background the findings of study may not be generalizable to population with high proportion of NLDO due to previous dacryocystitis.

In conclusion, we did not observe any common canalicular closure at 12 months in 129 consecutive patients that underwent endoscopic DCR without intubation. We also demonstrated a combined functional and anatomical success rate of 90.7%. We believe that for PANDO without canalicular involvement, intubation is not required to maintain canalicular patency and should not be used routinely for this reason.
References


### Appendix I

**Table 1**

**Indication for surgery and significant past histories**

<table>
<thead>
<tr>
<th>Indication for surgery</th>
<th>No. of cases (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epiphora only</td>
<td>92 (69.7%)</td>
</tr>
<tr>
<td>Epiphora and Discharge</td>
<td>25 (18.9%)</td>
</tr>
<tr>
<td>Discharge only</td>
<td>11 (8.3%)</td>
</tr>
<tr>
<td>Acute dacryocystitis</td>
<td>2 (1.5%)</td>
</tr>
<tr>
<td>Chronic dacryocystitis</td>
<td>2 (1.5%)</td>
</tr>
</tbody>
</table>

**Significant past histories**

<table>
<thead>
<tr>
<th>Significant past histories</th>
<th>No. of cases (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dacryocystitis</td>
<td>17 (12.9%)</td>
</tr>
<tr>
<td>Chemotherapy</td>
<td>1 (0.75%)</td>
</tr>
<tr>
<td>Trauma</td>
<td>1 (0.75%)</td>
</tr>
<tr>
<td>Severe viral conjunctivitis</td>
<td>1 (0.75%)</td>
</tr>
</tbody>
</table>
Ostium shrinkage following endoscopic dacryocystorhinostomy

Ophthalmology: 2013 In press

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Analysis and interpretation of data, drafting of the manuscript, critical revision of the manuscript.

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Responsible for study conception, planning, execution, data collection, drafting and revising the manuscript.

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Ostium shrinkage following endoscopic dacryocystorhinostomy

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Short title: Endoscopic DCR ostium shrinkage over time

Key Words: ostium size, endoscopic dacryocystorhinostomy

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Abstract

Objective: Ostium closure following endoscopic dacryocystorhinostomy (DCR) is the commonest cause for anatomical failure. We aim to determine the changes in size of the dacryocystorhinostomy ostium over time and investigate the correlation of ostium size and surgical outcome.

Design: A single surgeon, prospective, non-randomised, non-comparative, interventional case series

Participants: Consecutive series of patients who underwent powered endonasal DCR. All patients had radiologically confirmed nasolacrimal duct or canalicular obstruction.

Methods: The patients were operated on by one surgeon (DS) and follow-up was at 4 weeks and 12 months. Ostium sizes were measured at the end of surgery and at 4 weeks and 12 months after surgery.

Main outcome measures: Intraoperative and postoperative ostium size, correlation of ostium size and surgical outcome.

Results: 161 patients fulfilled the inclusion criteria. 3 patients were lost to follow-up. The ostium measured 8.6 (95% confidence interval [CI] = 5.0–12.2) by 13.4 (95% CI = 10.3–16.5) at the time of surgery and 5.7 (95% CI = 2.3–9.0) by 9.5 (95% CI = 6.0–13.0) at 4 weeks, and 4.8 (95% CI = 1.9–7.7) by 8.2 (95% CI = 4.5–11.9) at 12 months. There were statistically significant ostial shrinkage from surgery to 4 weeks (mean shrinkage of 50%) and from 4 weeks to 12 months (mean shrinkage of further 15%). The intraoperative ostium size and postoperative size were positively correlated.
Ostial size was not predictive of final ostial patency and symptomatic resolution of epiphora.

Conclusion: Following endoscopic DCR, the final ostium size on average is 35% of the original at 12 months post-operation. The majority of the ostium shrinkage occurs within 4 weeks post-operatively with a lesser degree of shrinkage between 1-12 months post-operatively. Ostium size was not predictive of overall surgical outcome.
Introduction

Dacryocystorhinostomy (DCR) remains the definitive surgical treatment for nasolacrimal duct obstruction (NLDO). Anatomical failures of DCR are commonly due to ostium closure.\(^1\), \(^2\), \(^3\), \(^4\) Adequately sized surgical ostium has been hypothesized to prevent ostium closure and improve surgical outcome.\(^5\), \(^6\) However, longitudinal studies looking at postoperative ostium shrinkage are limited. Furthermore, studies have not been able to demonstrate a definite correlation between ostium size and surgical success.\(^5\), \(^6\), \(^7\), \(^8\), \(^9\), \(^10\)

The reported postoperative ostium shrinkage has also been quite variable, with studies reporting decreases between 40-95% of the original size.\(^5\), \(^6\), \(^7\), \(^8\), \(^9\), \(^10\) There are also lack of comparability between these studies as there is considerable variability between the studies in flap formation, use of antifibrotic agents, intubation, degree of lacrimal sac exposure and the location of sac opening. The potential confounders between the studies make interpretation of the effect of ostium size difficult.

In the current study, we seek to establish the course of ostium shrinkage and the relationship of ostium size and surgical success in a prospective and consecutive series of patients having endoscopic dacryocystorhinostomy.
Methods
This was a prospective, non-randomised, non-comparative, interventional case series. We included consecutive patients attending a specialist clinic of an oculoplastic surgeon (DS) who underwent primary endoscopic DCR. The surgery was conducted from 2007-2009. Patients having revision endoscopic DCR were excluded. All patients underwent a full lacrimal clinical examination. Patients were specifically asked about symptoms of discharge and epiphora. Epiphora was subjectively graded with Munk scores obtained pre and post-operatively. Epiphora is graded from a scale of 0-4 (0=no epiphora at all, 1 = occasional epiphora requiring dabbing with a tissue or handkerchief 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 requiring dabbing more than 10 times a day or constant tearing). Past history of dacryocystitis, chemotherapy, radiotherapy, burns, trauma and severe conjunctival disease were specifically obtained.

All patients also underwent bilateral syringing of the tear ducts and radiological imaging with dacryocystogram (DCG) and lacrimal scintillography (DSG). The findings of syringing including hard or soft stop, distance in millimetres (mm) until soft stop and degree of reflux in percentage was noted. DCG findings were classified as proximal, middle and distal common canalicular block, proximal, middle and distal nasolacrimal stenosis or obstruction. DSG findings were classified as delay or obstruction at the pre-sac, post-sac or intra-duct. Patients with complete obstruction or stenosis of the lacrimal drainage system on DCG were included.
The study was approved by the Research Ethics Committee of the Royal Adelaide Hospital, Adelaide, Australia.

**Procedure:**

All the surgical procedures were carried out by a single experienced surgeon (DS). The endonasal DCR was performed under general anaesthesia or local anaesthesia with sedation. The operation is performed using a 30° 4-mm endoscope (KARL STORZ GmbH & Co. KG, Tuttlingen). The nostril was sprayed with phenylephrine 0.5% and lignocaine 5% (Co-phenylcaine Forte, ENT Technologies Pty Ltd, Malverin, Victoria, Australia). Neurosurgical cottonoids soaked in 5% cocaine were then placed anterior to the middle turbinate for 10 minutes. The nasal mucosa was injected with 2% lidocaine hydrochloride with adrenaline 1:80,000 (Lidospban, Septodent, Maidstone, United Kingdom). A nasal mucosa flap was fashioned anterior to the middle turbinate with a number 15 blade and elevated with a Freer periosteal elevator. The flap was retracted and the underlying bone exposed. The osteotomy was performed with a punch (HajekKoffler, Martin, Tutlingen, Germany) and powered rough-diamond burr (Medtronic-Xomed, Parkway, Minneapolis, USA). The frontal process of the maxilla, lacrimal bone and root of the middle turbinate were removed to create an osteotomy size of approximately 10×15 mm. The lacrimal sac was fully exposed anteriorly, superiorly and posteriorly to the junction of the sac with the surrounding periosteum. Inferiorly, the junction bony ostium was continued to expose the junction of the sac and the nasolacrimal duct. The inferior canaliculus was probed and used to tent the medial wall of the lacrimal sac, which was incised with a keratome (Clear cut dual bevel 3.0mm, Alcon, Hünenberg, Switzerland). The lacrimal sac was opened to create anterior and posterior flaps that were then reflected onto the lateral nasal wall. Careful inspection of the common ostium was done to evaluate the nature of any obstructions. Where a membrane was seen
overlying the tip of the probe at the common ostium, a membranectomy was performed utilizing a keratome (Clear cut dual bevel 3.0mm, Alcon, Hünenberg, Switzerland). Where solid obstruction was encountered in the canaliculus proximal to the internal os, (identified by appreciating an emerging probe in the medial wall of the open lacrimal sac but not visualizing the metal tip at the common ostium), trephination was performed using a canalicular trephine (Sisler disposable canalicular trephine, BD Visitec, NJ, USA), angled to emerge from the common ostium. Redundant nasal mucosa was removed to achieve mucosal apposition with the posterior lacrimal flap. If membranectomy or trephination was performed, O’Donoghue silicone tubes (BD Visitec, Bidford-Upon-Avon, UK) were inserted and were then fastened together at a point just distal to the ostium using two Ligaclips (Ethicon Inc., Somerville, NJ, USA), and then trimmed. Post-operative instructions included daily nasal douching with a saline spray and avoidance of nose blowing for 2 weeks. A single dose of 1g IV Ceftriaxone is given intraoperatively and patient is given 1 week of oral Cephalexin post-operatively.

With this technique, we were able to achieve complete exposure of the lacrimal sac and apposition of nasal and lacrimal mucosa. A 1mm notched 00-0 Bowman Probe is used to measure the vertical and horizontal diameter of the bony ostium at the end of surgery and the dimensions of the soft tissue ostium at each follow-up visit. If intubated, patients were intubated for approximately 3 months.
Analysis of variance (ANOVA) was used to compare the vertical diameter, horizontal diameter, and surface area immediately after surgery and at 4 weeks and 12 months after surgery. Logistic regression was used to predict the effect of ostium size on overall success

Success in surgery was defined as follow:

(3) Anatomical success; defined as endoscopic evidence of ostium and canalicular patency with evidence of fluorescein in the nasal cavity (positive endoscopic dye test) and patent syringing at 12 months follow-up.
(4) Functional success; defined as subjective improvement of epiphora as reported by the patient at 12 months follow-up. The patients were also asked if they would define the surgery as successful.

Overall objective success was defined as the patient having both an anatomical and a functional success at 12 months follow-up.

All statistics are performed a commercially available statistical software package (SPSS for Windows, version 17.0, SPSS Inc., Chicago, IL).
Results

161 cases of powered endoscopic DCR were performed for 156 patients. 5 patients underwent bilateral DCRs. 29 patients underwent intubation for canalicular obstruction. 3 patients were lost to follow-up at 12 months.

The female to male ratio is 1.7:1. The age distribution of our patients were between 19-94 years old with a mean of 63 years old (95% CI= 31.3-94.8).

Intraoperatively, the mean horizontal height of the ostium measured 8.6mm (95% confidence interval [CI] = 5.0-12.2) and the mean vertical height measured 13.4mm (95% CI = 10.3–16.5). The mean surface area of the ostium measured 117.0mm² (95% CI = 50.7–183.2). During follow-ups, the ostium measured 5.7mm (95% CI = 2.3–9.0) by 9.5mm (95% CI = 6.0–13.0) at 4 weeks, and 4.8mm (95% CI =1.9–7.7) by 8.2mm (95% CI = 4.5–11.9) at 12 months.

The surface area of the ostium at 4 weeks was significantly smaller than the ostium created at surgery when the data were analyzed using one-way ANOVA ($P < 0.001$). The size of the ostium at 12 months was also significantly smaller when compared to measurements at 4 weeks when analysed with one-way ANOVA with Bonferroni correction ($p<0.001$).

The percentage of ostium shrinkage during first 4 post-operative weeks averaged 51.6% (95% CI = 19.8-83.4) and averaged 64.7% (95% CI = 36.7-92.7%) thereafter up to 12 months.

Table I presents the mean height, width, surface area (calculated by multiplying the height and the width) and degree of shrinkage (calculated by the percentage surface area of the ostium) at different time points.
area at follow-up in relation to intraoperative surface area) at each of the follow-up dates.

On Pearson correlation analysis, there were statistically significant correlations between the size of intraoperative ostium and the ostium at 4 weeks (r= 0.642 with p <0.001) and at 12 months (r=0.544 with p<0.001). Additionally, the ostium size at 4 weeks are significantly correlated to ostium size at 12 months (r=0.814 with p<0.001)

There were 3 (2 from non-intubated group and 1 from intubated group) cases of anatomical failure at 4 weeks follow-up; all three cases had ostial closure and underwent successful revision endoscopic DCR. At 12 weeks, there were no ostial closure, however 3 cases from the intubated group has negative endoscopic dye test.

The detailed subjective and objective surgical outcome of this cohort of patients is outlined in other studies. Stratified by pathology, 132/161 of the patients had primary nasolacrimal duct obstruction and 29/161 had canalicular obstructions. The overall functional success rates for these 2 subgroups were 90.7% and 82.75% respectively. The anatomical patency rates for the 2 groups were 98.5% (127/129) and 86.21% respectively(25/29). The intubated group consistently had larger ostium when compared to the non-intubated group. This reached statistical significance for the intraoperative measurement (133.4mm² vs 113.4 mm²; p =0.02) and at 4 weeks (63.9 mm² vs 53.7 mm²; p=0.03) but was not statistically significant at 12 months follow-up (47.0 mm² vs 39.7 mm²; p=0.053). There was no statistical difference in the ostial shrinkage between the intubated and non-intubated group at 4 weeks (51.6% vs 51.6%; p=0.99) and 12 months(64.3% vs 64.8%; p=0.86)
On independent sample T-test, comparing patients with failed surgical outcome and patients with successful outcome, there was no significant difference between ostium size intraoperatively (p=0.90), at 4 weeks (p=0.36) and at 12 months (p=0.50).

On logistic regression, the sizes of ostium intraoperatively (p=0.35), at 4 weeks (p=0.34) and at 12 months (p=0.88) were not predictive of successful surgical outcome.
**Discussion**

In our cohort of patients, there were a strong positive correlation between the initial ostial size and the final ostial size. Additionally we demonstrated that majority of ostial shrinkage occurs during 1st four post-operative weeks and lesser degree of shrinkage between 1-12 months post-operatively. Our study also suggests that ostium size intra and post-operatively is not predictive of a successful surgical outcome.

With regards to ostial shrinkage, our study showed similar rate and degree of shrinkage to previous reports. Additionally, we showed that the majority of healing and scar formation occurs during the first 4 weeks although ostial remodelling continues beyond this time. Our study is also consistent with previous reports that found intraoperative ostial size was not predictive of surgical outcome. We also found that post-operative ostial size were not predictive of surgical outcome, this is in contrast with Ezra et al’s study where postoperative soft tissue anastomosis at 2 weeks and 6 months was predictive of success. Our finding of strong correlation between intraoperative bony ostial size and final soft tissue ostial size are in support of Ben Simon et al’s study but in contrast to several previous studies.

There are several reasons for the different findings between the studies. Even with a standardized approach, most of the previous studies including our own study still had significant intra-study variability in the ostial size. This is likely a reflection of the variable healing process between patients and individual variations in anatomy. In addition, some of the previous studies had small numbers of participants which may lead to type two errors. Some of the inter-study variability may be secondary to various surgical techniques employed e.g. external vs.
endoscopic DCR, anterior vs. anterior and posterior flap, use of suture, use of antifibrotics, use of perioperative antibiotics etc. While it is possible to investigate the effect of these factors on ostial size, we believe it would be more useful to investigate their effect on the surgical outcome. However, in order to clarify the role of individual factors on the surgical outcome would require 457 patients in each arm to demonstrate a difference of 5% in success rate. Other potential causes for inter-study variability is the method of how the ostium is measured e.g. direct visualization with endoscope, dacryocystogram, ultrasound, MRI. Although in the past the common canalicular opening may have been measured instead of the true nasolacrimal ostium, this no longer is a source of confusion as surgeons have gained proficiency in assessing ostia endonasally.

Does a larger ostium result in better outcome? Most of the studies investigating the effect of ostial size and outcome of DCR have not been able to demonstrate this. Indirect evidence against this notion can also be found in the use of antifibrotics in DCR e.g. topical mitomycin C (MMC). While the use of MMC appears to result in a larger ostium size, this has not consistently been shown to correlate with a higher success rate when compared to controls. However for patients undergoing revision DCR due to ostium closure, MMC appears to improve the success rate. Co-workers have previously shown that initial ostial shrinkage is mainly due to soft tissue granulation. Perhaps MMC may be useful in halting the healing process during the initial stages where the shrinkage is the greatest and potentially help reduce early anatomical failure.

Although our findings suggest that size of the bony ostium is not predictive of surgical success, it must be noted that in all cases the entire lacrimal sac from the fundus to proximal nasolacrimal duct was exposed. Individual variations in anatomy
undoubtedly lead to the variations seen in the ostium sizes. For instance, patients with chronic mucoceles or acute dacryocystitis who have large sacs will necessarily have larger bony ostiums to enable full exposure of the sac when using our technique.

Our results may lend some support to the paradigm that instead of striving for a standard ostium size in all cases, the primary aim during ostium formation is to completely expose and maruspialize the entire lacrimal sac and ensure adequate apposition of the mucosa. This is supported by previous reports of better surgical outcome with a larger lacrimal sac, greater flap mobility and better lacrimal sac marsupialization. The fact that many of our patients remain asymptomatic irrespective of ostium size also suggests that a larger ostium may not be required for a better functional outcome. Hence, our goal is to marsupialize the sac fully rather than create a standard bony ostium in all cases. The question of whether smaller bony ostia with marsupialization of the inferior two thirds or half of the sac result in equivalent functional and anatomical success rates is a separate one and cannot be answered by this study. Further studies might investigate whether degree of sac exposure affects outcome.

With regards to clinical follow-up, none of our patients had anatomical failure beyond four weeks. Others have shown the majority of ostial closures occur within the first 3 months. Follow-up regimes could potentially be streamlined to shorter follow-up periods unless intubation was performed. Hence, our current practise with endonasal DCR is to see patients once postoperatively at 4 weeks and discharge if asymptomatic and anatomically patent as demonstrated by an endoscopic dye test.
The strength of this study includes that it is prospective which allows us to track the progression of ostium shrinkage up to one year. Inter-observer variation is removed as the surgical technique, measurement and examination was performed by a single experienced surgeon.

The limitations of this study are there were limited numbers in the intubated subgroup to allow for useful analysis. Additionally, as the last follow up is only up to 1 year, further shrinkage and late failures can potentially be missed. Finally, our surface area is calculated based on the maximal vertical and horizontal dimension. The accuracy could be improved by calculating the surface area based on the ostium shape or by mapping the exact surface area using image processing software.

In conclusion we found that ostium size is not predictive of surgical success and ostium shrinkage is quite variable with 79.4% of shrinkage occurring in the 1st four weeks and a lesser degree of shrinkage up to 12 months follow-up. Our study further extends the notion that a larger ostium irrespective of sac size may not be necessarily better.
References


Appendix II

Table 1

Mean Values ostium measurements and degree of shrinkage intraoperatively and at 4 weeks and 12 Months follow-up.

<table>
<thead>
<tr>
<th></th>
<th>Horizontal diameter (mm) (95% CI)</th>
<th>Vertical diameter (mm) (95% CI)</th>
<th>Surface area (mm²)(Vertical x horizontal diameter)</th>
<th>Degree of shrinkage (%) (cf. intraoperative measurements)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intraoperative</td>
<td>8.6 (5.0-12.2)</td>
<td>13.4 (10.3-16.5)</td>
<td>117.0 (50.7-183.2)</td>
<td>n/a</td>
</tr>
<tr>
<td>At 4 weeks</td>
<td>5.7 (2.3-9.0)</td>
<td>9.5 (6.0-13.0)</td>
<td>55.5 (9.5-101.5)</td>
<td>51.6% (19.8-83.4)</td>
</tr>
<tr>
<td>At 12 months</td>
<td>4.8 (1.9-7.7)</td>
<td>8.2 (4.5-11.9)</td>
<td>41.0 (4.8-77.2)</td>
<td>64.7% (36.7-92.7%)</td>
</tr>
</tbody>
</table>

CI = confidence interval, cf. = compared to, n/a = not applicable
Chapter 4
Assisted local anaesthesia for powered endoscopic dacryocystorhinostomy

Orbit: Submitted

WengOnn Chan (Candidate)  Master of Ophthalmology, Adelaide University

Analysis and interpretation of data, drafting of the manuscript, critical revision of the manuscript.

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Acquisition of data, drafting and critical revisions of manuscript.

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**PremjeetDhillon**  
Acquisition of data, drafting and critical revisions of manuscript.

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Dinesh Selva

Responsible for study conception, planning, execution, data collection, drafting and revising the manuscript.

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Assisted local anaesthesia for powered endoscopic dacryocystorhinostomy

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Abstract

Purpose:

The role of assisted local anaesthetic (aLA) for both endoscopic and external dacryocystorhinostomy is a well-tolerated and established approach. However the tolerability of aLA is unclear with powered burrs used in powered endoscopic DCR (PEDCR). We aim to evaluate the acceptability of aLA for PEDCR.

Design:

This is a prospective, interventional, non-randomized, non-comparative, single surgeon study.

Methods:

Consecutive series of patients that underwent PEDCR performed under aLA were included in the study. Tolerability was assessed by intra-operative pain score on 100 point visual analogue scale (VAS) and if patients were willing to have aLA-PEDCR again.

Results:

A total of 44 PEDCR was performed on 42 patients. 56% of patients reported 0 on 100 point VAS, 65.9% (29/44) reported <10, 88.6% (39/44) reported <20 and no patients had score of >30/100. 97.7% (43/44) of patients are happy to have PEDCR performed again under aLA. The one patient unwilling to have a repeat aLA-PEDCR was not because of pain but intolerance to the sound of drilling.

Conclusion:
PEDCR with assisted local anaesthetic is well tolerated and accepted by patients.
Introduction

Endoscopic DCR (endoDCR) is well established treatment for nasolacrimal duct obstruction that has comparable outcome to external DCR (1). Traditionally, endoDCR is performed under general anaesthesia but the literature shows that local anaesthetic with or without sedation for cold steel, laser, and balloon endoscopic DCR appears to be safe and well tolerated (2; 3; 4; 5; 6; 7). The benefits of being able to perform DCR under aLA includes avoidance of general anaesthesia in high risk patients, less intraoperative bleeding, reduced operating room time, shorter recovery period and less post-operative nausea and vomiting (2; 8). However the tolerability of powered burrs used in powered endoscopic DCR (PEDCR) under aLA has not been documented.

Mechanical endoscopic DCR is a well-established technique described by Wormald where powered burrs are used to fully expose the superior aspect of the lacrimal sac that lies behind the thick frontal process of the maxillary bone. This technique allows for complete intranasal lacrimal sac exposure with apposition of the nasal and lacrimal sac which is thought to increase the success rate of endo DCR (9; 10). While PEDCR has been performed under both local without sedation and general anaesthesia; patient satisfaction and tolerability has not been investigated for PEDCR with sedation (10; 11; 7).

In the current study, we aim to evaluate patient’s tolerability of PEDCR with aLA.
Methods

This study was part of a prospective, non-randomised, non-comparative, interventional case series conducted on consecutive series of patients attending a specialist clinic of an oculoplastic surgeon (DS).

We included consecutive series of patients that had PEDCR performed under assisted local anaesthesia. Patients considered unsuitable for local anaesthesia by the surgeon or who specifically declined aLA were excluded from this study and had general anaesthesia. All the patients that had DCR-aLA were discharged on the day of operation.

All patients underwent a full lacrimal clinical examination. We recorded patients demographics, presenting symptoms, indication for surgery and pertinent past medical history were documented. All patients had syringing, dacryocystogram and lacrimal scintillography to confirm their diagnosis.

All surgeries were performed by a single surgeon (DS). The surgical and anaesthetic techniques are as follow:

Surgical Technique:

A nasal mucosa flap was fashioned anterior to the middle turbinate with a number 15 blade and elevated with a Freer periosteal elevator. The flap was retracted and the underlying bone exposed. The osteotomy was performed with a punch (HajekKoffler, Martin, Tutlingen, Germany) and powered rough-diamond burr (Medtronic-Xomed, Jacksonville, Fla., USA). The irrigation rate for the burr was reduced to 15% to
minimise the risk of aspiration. The frontal process of the maxilla, lacrimal bone and root of the middle turbinate were removed to create an osteotomy size of approximately 10×15 mm. The lacrimal sac was fully exposed. The inferior canaliculus was probed and used to tent the medial wall of the lacrimal sac, which was incised with a keratome. The lacrimal sac was opened to create anterior and posterior flaps that were then reflected onto the lateral nasal wall. Redundant nasal mucosa was removed to achieve mucosal apposition with the posterior lacrimal flap. Post-operative instructions included daily nasal douching with a saline spray and avoidance of nose blowing for 2 weeks.

Anaesthetic Technique:

Patient’s vitals (systolic blood pressure, oxygen saturation, pulse rate) were periodically monitored throughout the procedure. Low-flow oxygen was delivered during the procedure via nasal prongs taped to patients' lower lip. The nostril was sprayed with phenylephrine 0.5% and lignocaine 5% (Co-phenylcaine Forte, ENT Technologies Pty Ltd, Malverin, Victoria, Australia). Neurosurgical cottonoids soaked in 5% cocaine were then placed anterior to the middle turbinate for 10 minutes. The nasal mucosa around the anterior root of the middle turbinate was injected with 2% lignocaine hydrochloride with adrenaline 1:80,000 (Lignospan, Septodent, Maidstone, United Kingdom).

Sedation was achieved with midazolam, fentanyl and propofol. Propofol infusion was delivered and titrated using a target-controlled infusion system (TCI) (AstraZeneca DiprifusorTM TCI Module and a Graseby 3500 infusion pump, Graseby Medical, Watford, UK). A starting target plasma concentration of 3-4 mcg/ml is used during initiation of anaesthesia. The plasma concentration range is then maintained at 1.0-
2.0 mcg/ml. During injection of local anaesthetic, patients are kept unconscious (Ramsay sedation score of 6). Sedation was lightened until patients are responsive to command (Ramsay sedation score of 3) during drilling to minimise the risk of aspiration due to the irrigation from the drill. The range of premedication required was between 1-3mg of midazolam and 50-100mcg of Fentanyl.

Post-operative:

Prior to discharge from hospital, patients were asked to grade intra-operative pain score on a hundred point visual analogue scale (VAS). Intra-operatively they were periodically asked if they required additional sedation to diminish awareness or local anaesthetic for pain. Intraoperative blood pressure was maintained to be less than 150mmHg systolic and 90mmHg diastolic. We recorded any additional procedures performed intra-operatively e.g. septoplasty and turbinectomy. The ostium was also measured with a calibrated size 00 Bowman’s probe. Post-operatively, the patients were monitored for nausea, vomiting and epistaxis. Follow-up reviews were at 4 weeks and at 12 months. At 4 weeks, the ostium size and patency was assessed and the patients were asked if they would be happy to have DCR-aLA again. At 12 months, the patient underwent a final clinical examination, nasal endoscopy with endoscopic dye test, syringing and ostial measurement. Success of operation was defined as:

(5) The prevalence of anatomical success, defined as endoscopic evidence of ostium and canalicular patency with evidence of fluorescein in the nasal cavity (positive endoscopic dye test) and patent syringing at 12 months follow-up.
The prevalence of functional success, defined as subjective improvement of epiphora as reported by the patient at 12 months follow-up. The patients were also asked if they would define the surgery as successful.

Overall objective success was defined as patient having both anatomical and functional successes at 12 months follow-up.

The study was approved by the Research Ethics Committee of the Royal Adelaide Hospital, Adelaide, Australia.
Results

Forty-four operations for 42 patients were performed with assisted local anaesthetic. There were 2 exclusions that underwent surgery under general anaesthesia; one was an intellectually disabled 27-year-old woman who did not speak English and the second was a 19-year-old woman who requested general anaesthesia due to a prior bad experience with local and sedation for wisdom teeth extraction. Two patients had bilateral disease and both had DCR performed sequentially. The mean age of patients at the time of surgery was 75.5 years with a range of 49-94 years old. 21 patients were males and 23 patients were females.

7 patients had additional procedures performed intra-operatively. (4 patients had lacrimal intubation, 2 had turbinectomy and 1 had septoplasty). Additional intraoperative procedures are summarized in Table 1.

Prior to discharge, the patients were asked to grade their intra-operative pain score on a 100 point visual analogue scale. All patients reported no pain or mild discomfort only (pain score <30/100). 56% of patients reported a pain score of 0/100, 65.9% (29/44) reported <10/100, 88.6% (39/44) reported <20 and no patients had score of >30/100. Patient reported intra-operative pain score on VAS is summarized in Figure 1.

No patients required additional local anaesthetic infiltration during the procedure. There were 2 patients that requested additional sedation during the procedure. One patient was unwilling to have it again but this was not because the procedure was painful but because the patient did not like the sound of drilling.
97.7% (43/44) of patients were happy to have DCR performed again under assisted local anaesthetic.

Complications

No patients required additional pharmacological titration to maintain blood pressure below <150/90 mmHg. There were no episodes of post-operative nausea and vomiting. 1 patient had epistaxis during recovery which resolved with ice packs within 30 minutes.

Surgical success rate

93.2% (41/44) of patients had subjective improvement of epiphora and considered the surgery as successful at 12 months. 93.2% (41/44) of patients had endoscopic evidence of a patent ostium with a positive endoscopic dye test at the 12 month follow-up. 93.2% (41/44) of patients had overall success at 12 months. Stratified by pathology, 40/44 of the patients had primary nasolacrinal duct obstruction and 4/44 had canalicular obstructions. The overall success rates for these 2 subgroups were 95% and 75% respectively.
Discussion

Our study demonstrates that PEDCR with aLA is well tolerated by patients. 56% of the patients were completely pain free intra-operatively and no patients had pain score of >30/100. Intra-operative pain appears to be well tolerated but the drilling sound generated by the powered burr may not be tolerated by the occasional patient. In our consecutive series of 44 PEDCR, 97.7% of patients were happy to have the same procedure again under aLA.

The acceptability of PEDCR with aLA appears comparable to other form of DCR performed under local anaesthetic with or without sedation. The reported range of acceptability for external DCR is 88.4-100% (12; 13; 14; 8) and 62.9% to 98.7% for endonasal DCR (7; 2; 6; 15; 16). While DCR with LA is tolerable, it may not be suitable for everyone. For patients that can tolerate aLA, benefits would include less intraoperative bleeding, reduced operating room time, shorter recovery period, avoidance of sore throat from intubation and less post-operative nausea and vomiting (2; 8). One drawback of aLA is the potential fire risk with diathermy and high flow oxygen delivered via nasal prongs; this risk is increased if alcohol based skin-prep is used (17). General anaesthesia may be more suited for patients with high level of anxiety, poor cooperation and requiring additional procedures. Also with general anaesthesia, controlled hypotension can lead to improved operative field; this effect is improved if vasodilating inhalation anaesthetics used in traditional balanced anaesthetic are avoided (18; 19). We found that for mechanical endoscopic DCR, aLA without controlled hypotension was sufficient to maintain adequate
surgical field. Additional controlled hypotension can always be supplemented if intra-operative bleeding becomes problematic.

The role of sedation during DCR is unclear; as some authors have reported good tolerability of external DCR with regional and local anaesthesia alone without sedation (8; 20). In contrast, Ragab et al have reported up to 37% of patients having endoscopic DCR with diamond burr under local anaesthetic and minimal sedation were uncomfortable during the procedure and would preferred the procedure under general anaesthesia (7). The high proportion of uncomfortable procedure occurred despite the authors utilizing a combination of infratrochlear, infraorbital and intra-nasal anaesthesia. This role of sedation is also supported by Tuladhar et al’s report where 100% of patients without sedation compared to 50% of patients with sedation experienced pain during DCR (15). We found that when combined with sedation, intranasal local anaesthesia alone provided sufficient anaesthesia for PEDCR. Others has previously raised the concern that aLA may not be suitable for PEDCR(11). Putative reasons were intolerance to the sound of drilling and increased risk of aspiration. In addition to intra-operative blood loss, the fluid used for irrigation during drilling and to defog the endoscope poses an additional fluid load that reaches the patients oropharynx which may induce gagging or airway obstruction (21). In our setup, we use a 2.9mm diamond burr attached to a powered microdebrider, and Endo-Scrub 2 Lens Cleaning Sheaths with our rigid endoscope (Medtronic-Xomed, Jacksonville, Fla., U.S.A). The irrigation rate of the burr was set at 15% or less which translates to a maximum flow rate of 25mls/min. The average drill time for cases was approximately 3 minutes. However, as there is continuous suction on the drill, estimating the amount of fluid that might reach the oropharynx is difficult. However, we found that patients had no difficulty swallowing during the procedure and the
sedation can be lightened if necessary during the drilling phase to minimize the risk of aspiration. This can be achieved by reducing the blood concentration for the TCI to 1-2mcg/ml and the level of consciousness of the patient can also be subjectively assessed by the ability to follow commands such as squeezing the anaesthetist’s hand.

We found with TCI, we are able to predictably titrate patients’ level of sedation by adjusting the target plasma concentration. The predefined plasma concentration is maintained by the TCI’s onboard processor which determines the infusion rate based on pharmacokinetic models. These models consider the rate of drug movement between different compartments in the body (e.g. plasma, brain, adipose) at equilibrium and use these constants to predict the plasma or brain concentrations.

Previous studies have shown that noise generated from drilling and suction-irrigation during mastoid surgery can reach 60-130dB (22; 23; 24). The level of sound varied with the frequency, type of drill and size of drill used. Patient exposed level of noise generated during mechanical endoscopic DCR with a diamond burr has not been measured. However Prasad et al found that at the level of the operating surgeon’s ear, microdebrider used for sinus surgery generated an average sound level of 60dB (22). This implies that noise that patients are exposed to during mechanical endoscopic DCR would be significantly higher than 60dB due to proximity to the inner ear and bony conduction and this need to be highlighted to the patients.

Our findings establish aLA as a viable alternative to general anaesthetic for PEDCR. Additionally we found that pain levels were acceptable with only intra-nasal anaesthesia even in patients that underwent additional procedures such as lacrimal
intubation, limited septoplasty and turbinectomy. When educating patients about PEDCR under aLA, it is important to highlight that patients may feel tolerable levels of pain and they may find the sound of drilling unpleasant. It should also be stressed that additional anaesthetic and sedation can be provided if necessary.

Future directions include direct comparison of aLA with general anaesthesia and comparing the efficacy of the various local anaesthetic techniques for PEDCR. It would also be worthwhile establishing the intraoperative parameters such as total blood loss, volume of irrigation reaching the oropharynx and peak and mean intraoperative blood pressure during assisted local anaesthetic. It would also be worthwhile establishing the exact level of sound exposure during PEDCR. Finally, determining the level of pain during each stage of the procedure would be helpful in anticipating when sedation should be deepened.

The strengths of this study include a prospective design, large consecutive series of patients and a standardized surgical and anaesthetic procedure performed by a single surgeon. Patients’ report of intraoperative pain score was also done on the same day prior to discharge which minimizes recall bias. Potential limitation include firstly, patients were given the choice of general anaesthesia and this may have led to self-selection of patients more amendable to local anaesthetic; however there was only one patient who wished to have a general anaesthetic and one who was deemed unsuitable for local anaesthetic. In addition, there were no controls for this study and patients were not randomized.

In conclusion, we found PEDCR performed under aLA is well tolerated by patients. Complete anaesthesia with only intra-nasal anaesthesia was achieve in 56% of the patients and no patients had pain score of >30/100. While we found patients may
find the drilling sound unpleasant, 97.7% of patients were happy to have the same procedure again under aLA.

References


### Appendix III

#### Table 1

**Summary of additional intraoperative procedures performed.**

<table>
<thead>
<tr>
<th>Additional procedures</th>
<th>No. of patients (%)</th>
<th>Intraoperative Pain (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intubation</td>
<td>4/44 (9.1%)</td>
<td>¼ (25%)</td>
</tr>
<tr>
<td>Turbinectomy</td>
<td>2 (4.5%)</td>
<td>2/2 (100%)</td>
</tr>
<tr>
<td>Septoplasty</td>
<td>1 (2.3%)</td>
<td>0/1 (0%)</td>
</tr>
</tbody>
</table>
Summary of patient reported intra-operative pain score on 100-point Visual Analogue Score (VAS)
Conclusion

From this series of patient whom underwent endonasal DCR, we established the following:

In experienced hands, endonasal DCR can achieve comparable success rate to external DCR. Routine intubation is not indicated for patients with primary nasolacrimal duct obstruction without canalicular involvement. The premise that canalicular stenosis occurring without intubation in DCR is not borne out in this series. We established the rate of ostium shrinkage and showed that ostial size was not predictive of the success of endonasal DCR. Finally, we showed that powered endonasal DCR with only assisted local anesthetic is well tolerated. Randomized controlled trial with enough power to investigate each factor is inherently difficult to conduct. In the meantime, we can only be guided by large prospective studies like this.