

Jimma University Institute of Health, Faculty of Medical Science, Department of Ophthalmology

Success rate and factors affecting External Dacryocystorhinostomy outcome at Jimma university medical center department of ophthalmology 2016-2021 G.C

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Research Thesis To Be Submitted To Department Of Ophthalmology, Faculty Of Medical Science, Institute Of Health, Jimma University In Partial Fulfillment Of The Requirements For The Specialization Degree In Ophthalmology Success rate and factors affecting External Dacryocystorhinostomy outcome at Jimma university medical center department of ophthalmology 2016-2021 G.C

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## Abstract Background

Epiphora has been the most common presenting symptom in Nasolacrimal duct obstruction.

Epiphora can cause socially undesirable effects with worsening vision-related quality-of-life, if untreated epiphora can develop into acute or chronic dacryocystitis.

Dacryocystorhinostomy is a highly successful procedure in managing epiphora. The success of external DCR has been variably reported in the literatures.

## Objectives

The purpose of the study is to present outcome of external DCR at Jimma university medical center, to assess factors that may influence surgical outcome,

## Method

Hospital based, retrospective analytic study was conducted among patients who have undergone DCR 2016-2021 G.C. structured questionnaire used to collect data and collected data coded and entered into epidata and then exported to SPSS version 26 for statistical analysis. A multinomial logistic regression, Chi-square test and fishers exact test was performed P < 0.05 considered as statistically significant.

## Result

A total of 105 patients were studied (mean age, 31.94 years), females to male ratio of nearly 3:1. The most frequent complaint was tearing (50%). Primary acquired NLDO (77%) was most common presumed etiology of NLDO. Silicone intubation used in 75% of surgeries. Overall complete resolution of symptoms seen in 80% of cases. Success rate of external DCR with silicone intubation was much higher than DCR without tube (83.8% versus 69.2%, respectively, P=0.018). Retention of silicone longer than 3 month and post-operative wound site infection is associated with reduced success rate 71.6% and 55.6% respectively.

## Conclusion

External DCR is a successful procedure and it is associated few complications. Silicone intubation improves surgical outcomes of external DCR But, Retention of silicone tube longer 3 month is associated with increased risk of failure

Post-operative cellulitis may lead to a higher risk of failure in addition retention of silicone tube longer than 3 month is associated with statistically significant risk of postoperative cellulitis

## Keyword

Nasolacrimal duct obstruction, dacryocystitis, Epiphora, Dacryocystorhinostomy, Silicone intubation

## Acknowledgment

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## List of Abbreviations and Acronym's

DCR: Dacryocystorhinostomy JUMC: Jimma University medical center KCMC: Kigali city medical center MMC: Mitomycin C NLDO: Nasolacrimal duct obstruction PANDO: Primary acquired nasolacrimal duct obstructions OR : odds ratio

RCT: Randomized clinical trial

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### **Chapter 1: Introduction**

#### 1.1 Background

Nasolacrimal duct obstruction (NLDO) is a blockage of the lacrimal outflow system that may be complete or incomplete with various degrees of tearing, discharge, and infection. Exquisite pain may accompany acute lacrimal sac distention due to dacryolithiasis and/or dacryocystitis. Mucopurulent discharge is often seen with distal obstruction of the lacrimal sac or duct, while clear tearing is often associated with punctal or canalicular obstruction(1).

Epiphora has been the most common presenting symptom and it's caused by mechanical obstruction to the lacrimal drainage system which may include puncta, canaliculi, lacrimal sac, or nasolacrimal duct obstruction. The second, but less frequent, cause is lacrimal pump failure due to lower lid laxity or weakness of the orbicularis muscle (1, 8-9). Epiphora can cause socially undesirable effects with worsening vision-related quality-of-life. Untreated epiphora can develop into acute or chronic dacryocystitis with associated inflammation in the surrounding area. Following appropriate diagnostic evaluation, surgical intervention through a DCR is often indicated.

DCR is the gold standard procedure for obstruction in the lacrimal sac and nasolacrimal duct (3, 5). The external DCR was first described in the literature by the Italian surgeon Toti, who described exposure of the sac via a small skin incision and absorption of that part of the sac adjacent to the canaliculi into the nasal cavity (3,) This technique was modified by Dupuy, Dutemps and Bourguet, who advocated an edge-to edge anastomosis between the lacrimal sac and the nasal mucosa (via flaps) over the bony margins of the formed ostium, thus constructing an epithelium lined tract (10). Today, over 100 years later, external DCR is still essentially performed in the same manner and remains the gold standard procedure for nasolacrimal duct obstruction(5).

#### **1.2** Statement of the problem

DCR is the treatment of choice for most patients with NLDO .Surgical indications include; Primary acquired NLDO, Functional NLDO due to lacrimal drainage system stenosis or lacrimal pump failure, Secondary (acquired) NLDO resulting from sinus or nasal disease, prior midfacial and orbital trauma, dacryolithiasis, or iatrogenic injury, Dacryocystitis and Congenital NLDO, persisting after initial attempts at probe and intubation (1, 2).

The success of external DCR has been variably reported in the literatures, with most series having a rate ranging from 69-93%. (4, 6, 7, 11-18). Although endonasal DCR has increasingly become more popular over the last decade, many oculoplastic surgeons still prefer external over endonasal DCR, the most popular reasons for choosing external DCR were higher success rate, physician preference, and more long-term data on outcome (4). Another advantage of external DCR is that it provides a wide and clear surgical field, allowing the lacrimal drainage system and surrounding structures to be directly and clearly visualized. Furthermore, the features of lacrimal drainage obstruction can be assessed more precisely intraoperative during external DCR (2)

There are a variety of reasons that account for the differences in success rates including surgical technique in different centers, patient selection, demographics, definitions of success, and etiology of nasolacrimal dysfunction. In addition, it is well accepted that there is a significant learning curve for external DCR and outcomes can be variable depending on whether an experienced consultant or trainee surgeon performs the procedure, studies has revealed that shorter duration of obstruction, surgery by consultant surgeon, silicone tube intubation, intraoperative use of MMC in the surgical site may have favorable results, increasing the chance of success in External DCR (11-19).

Reported causes of failure include inappropriate size and location of the bony ostium, surgeon inexperience, septal deviation, incomplete removal of bone between the lacrimal sac and the nasal cavity, synechiae formation, cicatricial ostial closure, Postoperative infections, scarring of the middle turbinate to the lateral nasal wall that results in obstruction of the internal lacrimal ostium, and canalicular obstruction (19,31,34). In some cases of recurrent epiphora, researchers have described a functional obstruction known as sump syndrome, with tear fluid pooling in the residual lacrimal sac. (12, 20),

The management of unsuccessful DCR poses a therapeutic problem; remains difficult, time consuming and challenging. Persistent tearing, mucous, and purulent discharge, painful swelling of the lacrimal sac from failed DCR can be bothersome and embarrassing to the patient thus changing healthcare environment will require that surgical procedures not only offer a high rate of success, but also be efficient regarding financial cost and physician time and achieve a high level of patient satisfaction

In an attempt to enhance surgical results, researchers have described the performance of various adjunctive procedures during DCR surgery. These ancillary procedures include septoplasty, lysis of intranasal adhesions, removal of diseased ethmoid air cells that overlie the lacrimal sac, resection of an enlarged middle turbinate, and application of Mitomycin C to decrease postoperative scar formation. Use of a silicone stent after surgery has been shown to be a safe and effective method of maintaining lacrimal patency (13, 17-19).

The aims of the study is to present outcome of external DCR at Jimma university medical center, to assess factors that may influence surgical success and standardize DCR in our unit based on evidence-based principles. It will also serve as baseline study for further studies in the future.

### **1.1.3.** Significance of the study

DCR very successful operation for treatment of Nasolacrimal obstruction but the success rate reports are variable. Improvements in healthcare will require that surgical procedures that offer not only a high rate of success, but also be efficient regarding financial cost, physician time and achieve a high level of patient satisfaction.

There are limited articles on DCR published from East Africa, even these articles were published before fifteen years ago.

Success rate of DCR has been variably reported and no such study has been conducted in our setup thus our study will serve us baseline study for further studies in the future

#### **Chapter 2: Literature Review**

DCR is a highly successful procedure in managing epiphora due to the nasolacrimal duct obstruction. It can be performed through a cutaneous incision, traditionally referred to as external DCR, or via a transnasal approach under either direct visualization or endoscopic guidance. In both approaches, the lacrimal sac mucosa is connected to the nasal mucosa above the level of the mechanical obstruction at the nasolacrimal duct (1, 3, and 8).

Endoscopic endonasal DCR has been popularized as an alternative option in the surgical management of NLDO, according to retrospective study done by utilizing a questionnaire sent to ASOPRS Members the number one reason for deciding endonasal DCR was patient preference, followed by lack of scar, and then prior failed DCR(4). Disadvantages of endonasal DCR include the need for expensive equipment (endoscopes, lasers), expertise with this equipment, longer operative times, more post-operative care, possible inability to detect and biopsy lacrimal sac pathology, preference for general anesthesia, varied success results.(4,21)

The success of external DCR has been variably reported in the literatures, with most series having a rate ranging from 69-93%. (4, 6, 7, 11-18). Comparing published success rates of lacrimal surgery is a difficult task because different studies use different criteria. Success after lacrimal surgery is ill defined, and this has led to confusion in the interpretation of results for various surgical methods. AS proposed by Rose (22). The most practical measure of success is the control of symptoms,

Retrospective cross sectional study done in Tel Aviv University, Israel on 185 patients who has undergone External DCR , The success rate of external DCR was 94.4% for patients with previous episodes of dacryocystitis and 86.7% for patients without(P = 0.337)(23). Similar study in Muenster, Germany 154 eyes with External DCR, The success rate was for patients with previous episodes of dacryocystitis was 82.7% compared to 83.4% for patients without dacryocystitis (24). Both studies there was no significant difference in the success rate of external DCR in patients with or without a previous episode of dacryocystitis

Retrospective descriptive and interventional case series of 662 records of patients with chronic dacryocystitis at Koirala Institute of Health Sciences, Nepal, and External DCR surgery withoutsilastic tube intubation is an effective Method (88.6%) for treating chronic dacryocystitis. It is encouraging to see the same results in 88.6% of the subjects in our study.

The silastic tubes for lacrimal intubation may not be easily available in developing countries. Moreover, they may not be affordable for the majority of the patients in need of this surgery.

Stenting the lacrimal canaliculi following DCR is a commonly used technique to maintain patency and prevent rhinostomy closure. This is a practice that was widely popularized from early studies comparing outcomes in external DCR with and without stenting. In 2010, Retrospective study at Sydney Eye Hospital, Australia from total of 338 cases reviewed, 77.3% of patients had full resolution of symptoms and Silicone intubation for greater than 6 months was associated with better outcomes (25). In 2013, prospective RCT in Srinagar, India, Success rate for external DCR without silicone intubation was 80% .Success rate for DCR with silicone intubation rose to 92% and demonstrated that silicone intubation in DCR prevented the closure of the ostium, thereby enhancing the success rate of DCR (24). In 2017. Xie et al.<sup>26</sup> analyzed 12 RCTs involving 969 cases revealed that the success rate of external DCR with silicone tubing was significantly better than that of DCR without silicone tubing. In 2009, Prospective randomized trial conducted at the Tilganga Eye Centre, Nepal, and The success rate at 6 months was 90% for DCR with silastic intubation and 87% for DCR without silastic intubation (13). Therefore, the benefit of silicone intubation remains controversial, with significant variability present between indications for usage, material of stent, and length of intubation.

The literature about infection after open lacrimal surgery is sparse; although it is widely held that infection is rare after such surgery and that antibiotic prophylaxis is therefore unnecessary (32). A discussion of antibiotic prophylaxis in oculoplastic surgery, however, suggested that an infection rate of 10% could reasonably be expected in the absence of antibiotic prophylaxis(34). Perioperative antibiotic and steroid use vary widely across the literature and no strong recommendations can be made given the heterogeneity of reported practice patterns, data on the effect of adjunctive steroid use in DCR (i.e., intraoperative injection, or postoperative topical or intranasal spray) is extremely limited.

MMC is utilized during DCR because it inhibits the formation of scar tissue and can maintain patency of the ostium. In Çukurova University, Turkey RCT consisting study group of 60 cases showed that intraoperative antiproliferative agents improve the success rate of external Dacryocystorhinostomy (27). In 2020 Systematic Review and Meta-Analysis done in Brazil 27 studies involving 2158 Surgeries has intraoperative use of MMC is safe and slightly improves the success rate of external DCR(19). In 2013 in King Saud University, Saud Arabia prospective comparative case study in which 50 patients ,Symptomatically 24 (96%) cases in the MMC group were asymptomatic while without MMC group 20 (80%) cases were symptom free (p = 0.085)(28).

Prospective study was done in Menelik II Hospital 2005 – 2006 on 128 cases, Success was recorded in 119 (93%) of operated eyes (14). Another study in East Africa retrospective cross sectional a Tanzanian referral hospital, 2001–2006 among 55 patients has revealed Discharge and epiphora were resolved in 90.9% and 84.4% of patients respectively (15). Up to the knowledge of the authors there are limited published article on this research topic in Africa in general particularly in East Africa. The above two articles had several flaws including small sample size in the study done in Tanzania and factors affecting the surgical outcome weren't assessed and longtime has elapsed since above articles published

In Conclusion, various treatment modifications have been developed to get better -surgical outcomes, this range from variations in specific surgical techniques, inclusion of concurrent procedures, utilization and duration of stents, augmentation with anti-mitotic agents, and the use of perioperative antibiotics or steroids. There is no similar study done at JUMC in addition contemporary articles on similar research are lacking in eastern Africa.

## **Chapter 3: Objectives of the Study**

## 3.1 General objective

To determine Success rate and factors affecting External DCR outcome at Jimma university medical center department of ophthalmology 2016-2021 G.C, Jimma, Ethiopia

## **3.2. Specific objectives**

To determine Success rate of External DCR at Jimma university medical center department of ophthalmology

To describe factors affecting External DCR outcome at Jimma university medical center department of ophthalmology

## **Chapter 4: Method and Materials**

### 4.1. Study Area and Period

### 4.1.1 Study Area

Jimma is located in Oromia region of Ethiopia, 352 km south west to the capital Addis Ababa. Jimma town is the administrative center of Jimma Zone. Based on the 2007 Ethiopian Census (no census recent of this), Jimma town has a total population of 120,960 of whom 60,824 are male and 60,136 are female.

JU was established as higher institution in December 1997 from the already functional Jimma Institute of Health Sciences (Public Health, and Medical Sciences faculty) and two new faculties (Faculty of Business and Economics, and Faculty of Technology).

Jimma Medical Center (JMC) is the only specialized center in the southwestern Ethiopia providing service for a catchment area of 15 million people, and serving about 15,000 inpatients and 160,000 out patients in a year. It has a total of 1448 staffs from which 816 are technical and the remaining 587 are supportive staffs.

#### 4.1.2 Study period

The study was conducted March, 2016 to December 2021

#### 4.2.3 Study design

Hospital based, retrospective analytic study will be employed on candidate patients who has undergone External DCR in JMC department of Ophthalmology

### 4.3 Populations

#### **4.3.1 Source population**

All patients who have undergone DCR at JMC department of Ophthalmology.

#### 4.3.2 Study population

All patients who have undergone DCR from March, 2016 to December 2021 at JMC department of Ophthalmology.

#### 4.3.3 Study unit

All patients who have undergone DCR from March, 2016 to December 2021 at JMC department of Ophthalmology.

### 4.3.4. Sample size and sampling procedures:

### 4.3.4. 1 Sample size calculation:

Study population is small thus there is no need to make sample size calculation all study subject who meet the inclusion criteria will be included .

### 4.3.4.2 Sampling procedures:

All medical records of patients who underwent DCR surgery, fulfilling the inclusion criteria will be included in the study.

## 4.4 Inclusion and exclusion criteria

### 4.4.1 Inclusion criteria

Patients who have undergone DCR from March, 2016 to December 2021 at JMC department of Ophthalmology

### 4.4.2 Exclusion criteria

Follow up less than 3 months Post-operatively & could not be accessed through telephone incomplete medical records

### 4.5. Variables of the study

### 4.5.1 Dependent variables

Success of DCR

### 4.5.1 Independent variables

Age

Sex

Use of stent,

Duration of symptoms,

Previous episode of dacryocystitis,

Previous failed DCR

Surgeon experience

Primary NLDO

Secondary NLDO

### 4.6 Data collection procedure

Medical records number (identification number ) of patients who have undergone DCR surgery from March, 2016 to December 2021 collected from Major operation theatre registration log book and /or out patients oculoplasty clinic follow up registration logbook and then the charts of the patients collected from medical records room . Data collection tool; questions & tables was used to guide extraction of data from the individual medical records.

Ophthalmology resident collected data in regards to patients' demographics, Presenting Symptoms ,duration Presenting Symptoms, indication for surgery, background diseases (systemic and ocular), History of facial trauma ,History sinus surgery, side of obstruction, previous external DCR, Operative details include postoperative complications, duration of the stenting tube, and surgical outcome.

Few Patients with incomplete documentation was contacted through telephone for inquiries about resolution of symptoms

#### 4.7 Data analysis

The data collected exported to SPSS version 26 after entering into Epi data version 3.1. Descriptive statistics (frequencies and percentages) computed to show the picture of the data. Statistical tests at 95% CI at a P value < 0.05 was used for determining the independent associated variables. Fisher's exact test and  $\chi^2$  analysis were used for comparison between categorical variables, a multinomial logistic regression was used to calculate to remove confounding factors and the odds ratio (OR) which was used to predict the odds of surgical outcomes.

#### 4.8 Data quality control

Trained ophthalmology residents collected data. Two-day training given for data collectors regarding study objective, interview techniques, and ethical issues during data collection and how to fill the predesigned format properly. Pretest done for 10 patients from total study population two weeks before the actual data collection time in order to assess its clarity, length, completeness and consistency. Data collection tool was checked daily for accuracy, consistency, and completeness. Data was cleared, cleaned by principal investigator.

#### 4.9 Ethical consideration

Before starting the research, as per the basic principles of World Medical Association Declaration of Helsinki, ethical review committee of Jimma University College of Health Sciences approved the proposal and provided a support letter. Confidentiality of information was be maintained during data collection, analysis, interpretation and publication of results. Study participant contacted through telephone, they was informed about the purpose of the study, oral consent taken and reassured of Confidentiality of information.

### 4.10. Operational definitions

Successful DCR defined as complete resolution of symptoms of tearing or discharge at the last postoperative follow-up visit, or patent lacrimal system demonstrated by irrigation

Functional success is resolution of symptoms of tearing or discharges at the last postoperative follow-up visit

Partial success (resolution symptoms) is a subjective improvement from preoperative symptom severity or minimal symptoms after surgery.

Anatomical success is a patent lacrimal system demonstrated by irrigation

Early DCR is DCR done within 12 month of onset of symptoms

Late DCR is DCR done 12 month after onset of symptoms

Epiphora defined as watering of the eye on most days of the week, with tears running down the cheek

Acute Dacryocystitis, defined as the appearance of pain, erythema, or pus discharge and swelling of the lacrimal sac.

Chronic dacryocystitis is defined as gradual onset and persistent the appearance of epiphora and purulent discharge from the punctum.

Primary acquired NLDO those resulting from inflammation of unknown causes that lead to occlusive fibrosis, or

Secondary acquired NLDO resulting from infections, inflammation, trauma, malignancies, toxicity, or mechanical causes

### **4.12 Dissemination of Findings**

Findings of this research will be distributed to Jimma University postgraduate and research study office. It will be presented on a national ophthalmic association meeting. It will also be made available for a publication on international journals. Further, it will be uploaded and made available on the Website of Jimma University.

#### **Chapter 5: Results**

This retrospective review identified a total 154 medical records of external DCR procedures which were performed from March, 2016 to December 2021. Of these, 105 patients of 107 external DCR surgeries met the inclusion criteria

There were 80 female (74.8 %) and 27 male (25.2%) with female-to-male ratio of nearly 3:1. The mean age was 31.94 years (SD=17.74, 3-70 years).

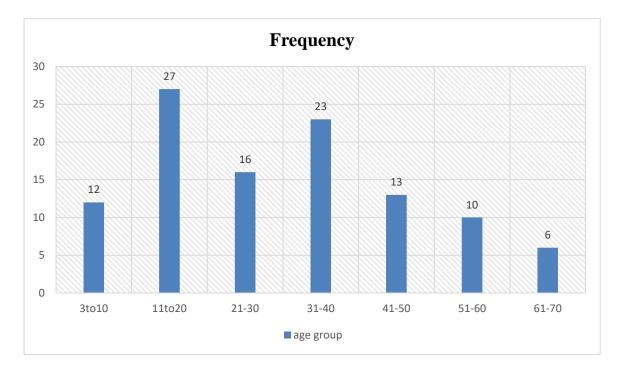
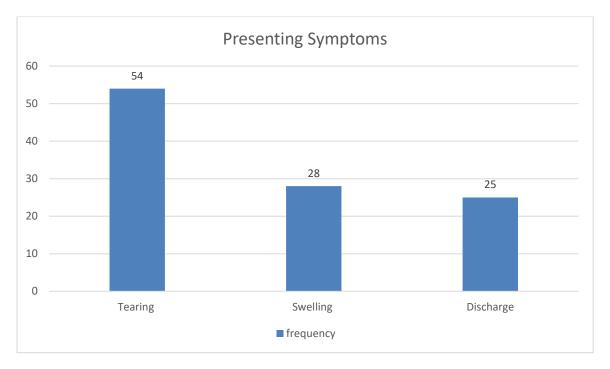
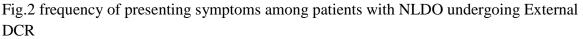


Fig.1 Age distribution among NLDO patients undergoing External DCR

The most frequent presenting symptoms were tearing accounting for 50.5 %( 54/107) followed by swelling in the lacrimal sac area and discharge accounting for 23.4 % (28/107) and 22.4 %( 25/107) respectively. The mean duration of the presenting symptoms was 35.55 months (SD = 33.50, 1-126 months).five patients had history of facial trauma involving lacrimal drainage system and there was also history of previous DCR in 5.7% of cases





The Diagnosis was based on presenting symptoms, regurgitation test and findings of probing and irrigation of lacrimal system. Probing and irrigation of lacrimal system was done in 46.8% (52/107) of cases. Among these, (46/52) found to have NLDO; two cases had partial nasolacrimal duct obstruction and the remaining site of obstruction is common canaliculi.

The most common presumed etiology of NLDO among patients undergoing external DCR were primary acquired NLDO accounts for 77 %, congenital NLDO (10%) and traumatic NLDO (8%). Among patients with primary NLDO 56% previous episode of dacryocystitis has been found in 56% cases. Peak age group for Dacryocystitis is at 5<sup>th</sup> decade among patients with primary acquired NLDO. Eighty percent (4/5) of traumatic NLDO is diagnosed in patients in 1<sup>st</sup> and 2<sup>nd</sup> decade of life. One patient with preoperative diagnosis of lacrimal sac mucocele intraoperatively found to have lacrimal sac mass which for which excisional biopsy was sent and pathological report showed lacrimal sac hamartoma.

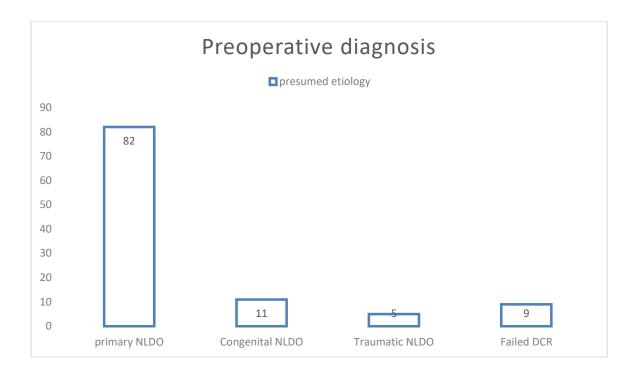


Fig. 3 Presumed etiology of NLDO in 107 patients undergoing external DCR

External DCR was done on the right side in 57 % of cases and 41.1% on the left. There were 2 cases bilateral external DCR: one of the two was performed on the same day under general anesthesia, while the other individual underwent bilateral procedures on separate dates. Of the 107 cases, 42 (39.3%) surgeries were performed by oculoplastic surgeon; fifty (46.7%) cases were operated by general ophthalmologist and the remaining eleven cases by ophthalmology residents. Eighty two case of External DCR was performed under local anesthesia and the remaining 25 cases operated under general anesthesia. Silicone tube intubation was done in 74.8 % of the study population

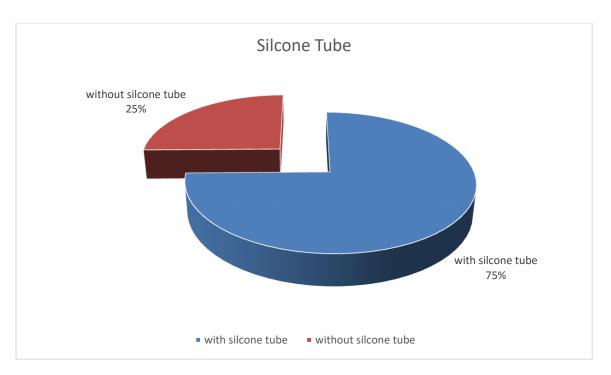


Figure 4 frequency of silicone intubation among NLDO undergoing External DCR

TTC ointment was applied for all patients intraoperatively and subsequently for more than 7 days, in addition to TTC ointment, variable type's topical antibiotic and steroids combination has been provided for 80 patients (80.4%). Post-operative systemic antibiotics were given in 39.3% of cases, either of Amoxicillin (78.6%) and Augmentin (21.4%) for 7-10 days. The median duration of skin suture was 8 days with range of 7-16 days. There was no report of use intraoperative steroids or ant fibrotic agent applications.

All patients were followed at 1<sup>st</sup> day, 1<sup>st</sup> week, and between 6 and 12 week postoperatively, and then variably thereafter. At each visit, subjective assessment for tearing, swelling and other complaints was asked and a lacrimal syringing test was performed in 62.6% of cases .The mean duration of post-operative follow up was 12.2 weeks ranging from 6-94 weeks. Telephone interviews made only for 9 patients because either telephone address weren't documented on medical records or even if the phone address is found majority of were not reached. The mean duration of silicone tube removal was 10.8 week, ranging from 5-34 week. The timing of lacrimal tube removal depended somewhat on etiology, with the tubes removed at an average of 10.7 weeks after surgery in the PANLDO cases. Indeed, 64% were removed between second and third month of postoperative visit. Congenital and traumatic patients typically had longer tube retention times.

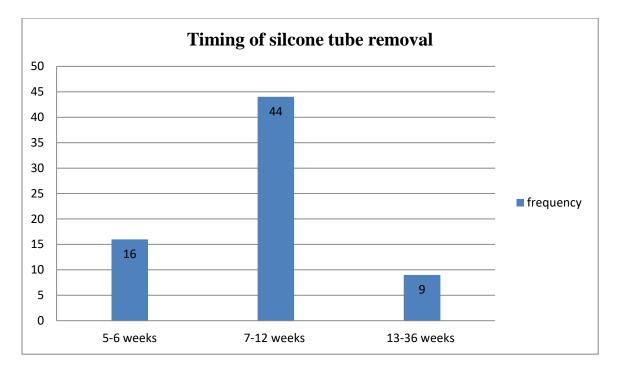


Fig.5 Frequency of timing of silicone removal among 107 patients who underwent external DCR

Preoperative Diagnosis	No. of patients	tubes V	Timing of tube		Mean of tube
			Within 3 month	After 3 month	retention (weeks)
PANLDO	81	60	55	5	10.7
Congenital NLDO	11	10	9	1	11.7
Traumatic NLDO	5	4	2	2	14.2
Failed DCR	9	6	5	1	9.4

Table 1 Duration of silicone Intubation based on Preoperative Diagnosis

There was no report of life threatening intraoperative but, Postoperative complications occurred in 8 (7.5%) procedures: In 7/8(6.5%) procedures there was infection of the surgical wound and one post-operative complication was epistaxis in the second post op day.

Overall complete resolution of symptoms following external DCR seen is 80% and partial resolution in 8.4% of cases. Anatomical success rate among patients for whom lacrimal irrigation was performed at last post-operative follow up was 92.5% (62/67). When stratified based on preoperative diagnosis, PANLDO 50/54, Traumatic 1/1, failed DCR 3/4, congenital NLDO 7/7 had anatomical success.

Multinomial logistic regression was calculated to predict factors that influence success of external DCR based on Age, age group, sex, history of previous DCR, presumed etiology of NLDO, categories of surgeons, type of anesthesia, silicone intubation, and postoperative prophylactic systemic antibiotics. Preliminary analysis were performed to ensure that there was no assumption of normality, linearity and multicollinearity. A significant logistic regression was found for silicone intubation (B=-2.063, SE=0.874, P=0.018 & OR=0.127). This suggest that Silicone stenting significantly increases the success of external DCR.

Primary acquired NLDO is the most indication for DCR in our study accounts for 77 % (82/107) and success rate for PANLDO was 82.9%. Subgroup analysis for PANLDO was made. The mean age was 34.34 years (SD=16.74, 8-70 years). Bimodal age distribution was found among patients with PANLDO (11-20 and 31-40 years) in these study. There were 66 female (80.5 %) and 16 male (19.5%) with female-to-male ratio of 4:1.

A multinomial logistic regression for subgroup of PANLDO to identify predictors of symptom resolutions was calculated and Overall the result suggest that risk of failure of DCR is lower with Silicone intubation compared to DCR without silicone intubation (B=-2.380, SE=1.166, P=0.04), success is higher when silicone is removed within 3 month compared to longer than 3 month retention of silicone and the odds ratio indicates the odds associated with complete resolution of symptoms for routine removal is 5 times that of the odds for late silicone removal(B=15.47, SE=7.3, P=0.035 & OR=5.34) and a patient of 21-30 years age group has higher risk of failure compared to all other age group and the odds ratio indicates the odds ratio indicates the odds associated with no resolution of symptoms for 21-30 years age group is 3 times that of the odds for all other age group (B=51.78, SE=25.40, P=0.042 & OR=3.08).

Ch-square statistics were used to examine the relationship between development Postoperative cellulitis and sex, presumed etiology of NLDO, categories of surgeons, timing of silicone removal, type of anesthesia, silicone intubation, and postoperative prophylactic systemic antibiotics. There was significant statistical association between wound site infections (cellulitis) and whether silicone tube is removed within 3 month i.e. routine removal or retained longer than 3 month i.e. late removal (X2 =5.838,df=1,p=0.016).

An odds ratio was also computed to assess the association between timing of silicone removal and Post-operative cellulitis. Retention of silicone tube longer than 3 month is six times likely to develop post-operative cellulitis [21.4% versus 4.3% respectively; OR=6.06, 95% CI, (1.20, 30.03)]. The odds ratio of post-operative cellulitis in patients without prophylactic postop PO antibiotics is 3.84 compared with patients receiving prophylactic postop PO antibiotics [6/67(9%) versus 1/40(2.5%) respectively; OR=3.84, 95% CI, 0.445, 33.091)], but this is not statistically significant.

# Success (symptoms resolution )

		Complete	Partial	Failed	P value
		N (%)	N (%)	N (%)	
Sex	Male	23(85.2%)	0	4(14.8)	
	Female	63(78.8%)	9(11.2%)	8(10%)	0.057*
Diagnosis	Primary acquired	68(82.9%)	6(7.3%)	8(9.8%)	
	NLDO				
	Congenital NLDO	9 (81.8%)	1(9.1%)	1(9.1%)	
	Failed DCR	6(66.7%)	2(22%)	1(11.1%)	0.241*
	Traumatic NLDO	3(60%)	0	2(40%)	
Trauma	Nontraumatic NLDO	83(81.4%)	9(8.8%)	10(9.8%)	
	Traumatic NLDO	3(60%)	0	2(40%)	0.151*
Dacryocystitis	With Dacryocystitis	40(87%)	2(4.3%)	4(8.7%)	
	Without Dacryocystitis	46(75%)	7(11.5%)	8(13.1%)	
Timing of	Early	35(76.7%)	5(10.9%)	6(13.0%)	
DCR	Late	51(83.6%)	4(6.6%)	6(9.8%)	0.591*
Surgeon	Oculoplastic surgeon	34(81%)	3(7.1%)	5(11.9%)	
	General	44(81.5%)	3(5.6%)	7(13%)	
	ophthalmologist				0.271*
	Resident	8(72.7%)	3(27.3%)	0	
Silicone tube	With	67(83.8%)	4(5%)	9(11.2%)	
	without	18(69.2%)	5(19.2%)	3(11.5%)	0.018^
Timing of	Routine	81(82.7%)	8(8.2%)	9(11%)	
Silicone	Late	5(71.4%)	1(1.1%)	3(33.3%)	$0.03^{\text{¥}}$
removal			0		0.075
Post op	Yes	5(71.4%)	0	2(28.6%)	0.275*
Cellulitis	No	80(81.6%)	9(9.2)	9(9.2%)	

Table -Statistical analysis of factors influencing postoperative resolution of symptoms (success) ^likelihood ratio test, <sup>¥</sup>Pearson chi-square test, \*Fisher' exact test.

#### **Chapter 6: Discussion**

The peak age group in our study was in the 2<sup>nd</sup> and 4<sup>th</sup> decades of life (Fig. 1). M.B. Kashkouli et al<sup>17</sup> reported 276 patients with NLDO ranging in age from 3 to 84 years with a peak age of 31–40 years in Iran. Emmerich et al<sup>24</sup>, Audited 1014 Ext-DCR procedures in Germany with an age distribution of 2–93 years and a maximum distribution in the5<sup>th</sup> to 7<sup>th</sup> decades. The difference in peak ages may reflect the population structure where the study was conducted.

Tearing has been the most common presenting symptom in different studies (6, 17) including our study. The primary acquired NLDO, however, could present with acute (7/98(7.1%)) in our study) or chronic (50/98(51%)) in our study) dacryocystitis. This type of presentation has been reported to be as high as 29% (acute dacryocystitis) and 36% (chronic dacryocystitis) (6). Similar to Walland and Rose's study<sup>31</sup>, we did not find any significant effect of the type of presenting symptoms on the success rate of External DCR.

Criteria for successful DCR differ among studies. Some defined success as marked resolution of symptoms with demonstration of a patent lacrimal drainage system by irrigation at the last postoperative visit. Other investigators take in account only subjective improvement of symptoms (4, 6, 7, 11-18). In the our study, success was defined as complete resolution symptoms at last postoperative visit because we believe ultimate purpose of DCR is the resolution of symptoms ; therefore, the functional aspect must be emphasized when analyzing surgical outcomes.

Subjective symptom resolution was the primary measure of success in our study. The overall rate of complete success was 80%, partial success 8.7%, with a failure rate of 11.2%. These rates are similar to those found in the with most literature series having a rate ranging from 69-93%. (4, 6, 7, 11-18). Prospective review of all cases scheduled at Menelik II Hospital from June 2005 until May 2006,the largest reported African study of external DCR (128), success rate of 93%(14). In retrospective review of 55 patients at KCMC, a Tanzanian referral hospital, 2001–2006; Discharge and epiphora were resolved in 90.9% (30/33) and 84.4% (27/32) of patients respectively(15). This result is consistent with our findings representing a good outcome.

Anatomical success rate among patients for whom lacrimal irrigation was performed at last post-operative follow up was 92.5% (62/67). Similar to previous reports (29, 31), Anatomical success rate was much higher than functional success in these study. There were five cases of anatomical but not functional success and one case of functional but not anatomical success. These could be explained by lacrimal paradox which has been proposed by Rose<sup>22</sup> in terms of lacrimal drainage hydraulics in a three compartment model. DCR is usually performed to improve quality of life thus patient satisfaction, measured by functional success, is very important; lacrimal system patency is secondary.

Of the 40 external DCR in which patency to irrigation was not done, 26 had complete symptoms resolution, seven had partial success and only six had no improvement. This is probably because when the patient was happy the examining physician regarded it unnecessary to subject the patient to syringing to identify anatomical success. Similarly symptom-free patients may have had less incentive to re attend, whereas those with persistent symptoms may have been more likely to return hoping their problem would be readdressed. It is unknown whether patients with initial anatomical success but functional failure may develop functional success over time.

It is generally agreed that posttraumatic DCR has a lower success rate compared with other groups (17). Failure rate external DCR for traumatic NLDO was high 2/5(40%) compared to non-traumatic NLDO 10/102(9.8%) (Fisher exact test p=0.151) in our study. Clearly, a surgery in an area with distorted anatomy may lead to declining surgical success rates. Our medical center serves as a tertiary referral center: The most of these patients sustained severe sino-orbital midface fractures and some underwent maxillofacial surgeries. The extensive nature of these midface injuries may have contributed to the high failure rate of posttraumatic DCR in our series, in a similar way to that reported by Ben Simon et al<sup>18</sup>.

Success rate of external DCR with silicone intubation 83.8% (67/80), was much higher than DCR without tube a success rate of 69.2 % (P=0.018), which is comparable to study by Rather and Singh<sup>24</sup> who reported, the Success rate for external DCR without silicone intubation 80% and rose to 92% with silicone intubation . Prospective randomized trial conducted at the Tilganga Eye Centre, Nepal, and the success rate at 6 months was 90% for DCR with silicone intubation and 87% for DCR without intubation (13). Xie et al.<sup>26</sup> analyzed 12 RCTs involving 969 cases revealed that the success rate of external DCR with silicone tubing was significantly better than that of DCR without silicone tubing . In the Basic and

Clinical Science Course series, it is stated that Intubation with a lacrimal stent is indicated for children who have recurrent epiphora following nasolacrimal system probing and for older children in whom initial probing reveals significant stenosis or scarring. Intubation is also useful for the treatment of upper- system abnormalities such as canalicular stenosis, trauma, and agenesis of the Punta (1). We have found similar advocacy in other oculoplastic textbooks (1, 2, 9-10). Majority of surgeons employ silicone tubes in nearly all DCRs, they advocated its use and reported an increased postoperative patency rate because of maintenance of the opening of the ostium (13, 17-19, 24-26).

Over the past four decade, some have come to question the necessity of silicone intubation at the time of DCR and whether they are a real factor in surgical success. Walland and Rose<sup>31</sup> retrospectively compared the success rates of 238 DCRs employing silicone intubation and 150 DCRs not employing them. They found no statistically significant difference in their failure rates. In 2003, this was reaffirmed by Kashkouli et al in a comparative case series of 276 surgeries (17). Both groups of authors indicated that other factors such as postoperative infection, history of preoperative trauma, and size of the rhinostomy may be much more important in surgical success (17, 31). However, again neither group went so far as to call for the discontinuation of silicone stent use with the DCR. The silastic tubes for DCR may not be easily available in developing countries. Moreover, they may not be affordable for the majority of the patients in need of this surgery.

Although our study shows good surgical outcomes with silicone intubation in external DCR a comparable to those in the literature, it does have limitations. Patients were not randomized, and thus, demographic, behavioral, or clinical differences between the groups may confound the observed results. Moreover, the patients in our study were not selected and observed prospectively using a standard protocol; therefore, selection bias cannot be ruled out. Future prospective studies are needed to truly compare the performance of the stenting in External DCR.

There is no definitive agreement among authors as to how long the tubes must remain in place. Although many surgeons remove the tubes after 8 weeks, some have recommended keeping them in place as late as 6 months<sup>25</sup>, while others routinely removed as early as 2 weeks after surgery. On the other hand, Rather and Singh<sup>24</sup> reported optimum period of keeping the tube in situ was 4 weeks during which time healing within the anastomosis is complete, keeping it for longer period's increases the risk of complications. in our study

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success of DCR is much lower in patients who retained silicone tube longer than 3 month (56 %) than those with silicone removed within 3 month(82%), this was statistically significant (p=0.028). In addition retention of silicone tube longer 3 month is associated with increased risk of postoperative cellulitis (p=0.036, fisher exact test). Vicinanzo et al<sup>30</sup> found no significant difference in the final surgical outcomes in 42 cases of premature silicone stent loss compared to the planned removal at 2 months. A study investigating the outcome of silicone tube removal at different time frames after external DCR (early- before 2 months, routine- 2 to 4 months and late- after 4months) suggested that the timing of stent removal does not influence the surgical outcomes (35). We would recommend early review of the silicone tube at the time of suture removal to try and anticipate development cellulitis especially if no prophylactic systemic antibiotics provided. Finally, prospective randomized study is needed to help answer firstly the question of the need for silicone tubes and to provide conclusive timeframe for their retention

Walland and Rose reported that the postoperative infection rate after DCR was 7.9% without systemic antibiotic prophylaxis and 1.6% with oral postoperative antibiotic prophylaxis (31), which is comparable to our study; the postoperative wound site infection rate after external DCR was 8.9% without systemic antibiotic prophylaxis and 2.5% with oral postoperative antibiotic prophylaxis.

Post-operative cellulitis occurred in 7/107(6.5%) and it is associated higher failure rate of External DCR 2/7(28.6%) compared to patients without postoperative cellulitis 9/98(9.1%) with p value of 0.275. These isn't statistically significant possibly because of the small sample size, but we are unlikely to have detected this effect on success; the success rate has fallen from 81.6% to 71.4% in patients with postoperative cellulitis. In addition to increased failure rate, Patients who develop such infections are subject to pain, anxiety, inconvenience, and expense.

Factors associated with increased risk of postoperative cellulitis include lack post-operative prophylactic systemic antibiotics 666(9.1%), episodes of acute dacryocystitis before the surgery 1/7(14.3%) and retention of silicone tube longer than 3 month.

It remains unclear whether postoperative Cellulitis is the cause or effect of failure: does infective inflammation and edema cause scarring of the operative anastomosis (and failure) or

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does inadequate surgical technique (increasing the risk of failure) also predispose to postoperative Cellulitis? The greater influence of infection on outcome in the non-antibiotic group compared with those receiving antibiotics, patients with episodes of acute dacryocystitis before the surgery acute dacryocystitis might suggest that infection predispose to failure.

Post-operative cellulitis are clearly associated with a higher risk of failure and infection may be the causal factor; acute dacryocystitis are associated with a greater risk of infection and infection may, therefore, contribute to the increased risk of failure in both patients who took prophylactic postoperative systemic antibiotics and those who didn't.. Because the risk of infection can be decreased by antibiotic prophylaxes (31), we recommend that all patients undergoing External DCR should receive prophylactic systemic per oral antibiotic postoperatively

The mean duration of post-operative follow up in these study was 3 month range, 1.5-24 month. Comparable to our report Patients were followed postoperatively for a mean follow up period of 9.3 months (6-12 months) at Menelik Hospital, Ethiopia. In contrast, study conducted among patients who underwent external DCR at Sydney Eye Hospital , the mean final follow-up time was 11 months (SD=8.7, range 0.5–60 month)(25). Similar study in London, UK reported mean duration of follow-up was 2.6 years (range, 6months to 8.3 years); median follow-up was 1.9 years (29). Having all the patients appear for long-term follow-up is difficult in our particular situation in developing countries like ours, probably due to socioeconomic reasons and transportation difficulties.

## Limitation of the study

Our study limited from Retrospective design; patients were not randomized, and thus, demographic, behavioral, or clinical differences between the groups may confound the observed results.

Use of secondary data sources from Medical records had many blanks and not all cards were accessible. Address of patients with incomplete data weren't found

Small number of study population is another limitation of these study.

## **Chapter 7: Conclusion and Recommendation**

### Conclusion

In conclusions, we obtained an overall success rate of 80% for External DCR regardless of the etiology at our medical center. This therefore reconfirmed that External DCR is a successful procedure and it is associated few complications.

Our study shows higher success rate of external DCR with silicone intubation in comparison to without silicone stenting However, retention of silicone tube longer 3 month is associated significant reduction in surgical outcomes.

Post-operative cellulitis may lead a higher risk of failure in addition retention of silicone tube longer 3 month is associated with statistically significant risk of postoperative cellulitis.

No significant difference b/n oculoplastic surgeon and general ophthalmologist in terms of external DCR surgical outcome

#### Recommendation

We recommend that patients undergoing External DCR with silicone intubation. We also recommend silicone tube removal within 3 month postoperatively

Our study was limited by its retrospective nature and reliance on full documentations in medical records, which was unfortunately not always the case. Prospective trials would be ideal to increase the validity of the results and to make further recommendations for clinical practice.

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### Annexes

### **Data collection tool**

**Demographic characteristics** 

MRN\_\_\_\_\_ Age\_\_\_\_ Sex\_\_ Code \_\_\_\_

Address \_\_\_\_\_\_phone number \_\_\_\_\_

#### **Preoperative Data**

- 1. Presenting Symptoms
  - a. Excessive tearing  $\square$
  - b. Discharge 🗖
  - c. Swelling
  - d. pain
  - e. others (specify) \_\_\_\_
- 2. Symptoms duration in months \_\_\_\_\_
- 3. History of previous DCR
  - a. No
  - b. Yes

• If yes, How many times \_\_\_\_\_

- 4. History of previous Sinus/Nasal surgery
  - a. No
  - b. Yes
- 5. Facial trauma
  - a. No
  - b. Yes

• If yes specify \_\_\_\_\_

- 6. History long term topical eye drop use
  - a. Yes
  - b. No
- If yes, specify\_\_\_\_\_
- 7. History of known ocular illness
  - a. No
  - b. Yes
  - c. If yes specify

•\_\_\_\_\_

- 8. History of ocular surgery
  - a. NO
  - b. Yes
  - c. If yes specify

- •
- 9. History of known chronic medical illnesses
  - a. No
  - b. Yes if yes specify
    - \_\_\_\_\_
    - •
    - •
- 10. Patency to irrigation

Partial 🗖

Full 🗖

- 11. Site of obstruction
  - a. Common canaliculi
  - b. distal NLD
  - c. other\_\_\_\_\_
- 12. Side of obstruction
  - a. Left
  - b. Right
  - c. Bilateral
- 13. Regurgitation test
  - a. Yes
  - b. No
- 14. Eyelid disorder
  - a. No
  - b. Yes ,if yes specify \_\_\_\_\_
- 15. Preoperative Diagnosis (presumed etiology)
  - a. NLDO 🗖
  - b. Acute Dacrocystitis
  - c. Chronic Dacrocystitis
  - d. Dacrolithiasis 🗖
  - e. Traumtic NLDO
  - f. others (specify) \_\_\_\_

### **Operative details**

- 1. Date of surgery \_\_\_\_\_
- 2. Surgeon
  - a. Oculoplastic surgeon
  - b. General ophthalmologist
  - c. Resident
- 3. Operated side
  - a. Right
  - b. Left
  - c. Bilateral
- 4. Type of Anesthesia
  - a. Local
  - b. General
- 5. Silicone tube stenting
  - a. Yes
  - b. No
- 6. Use MMC or 5 fluorouracil
  - a. Yes
  - b. No
- 7. Intraoperative use of steroids
  - a. No
  - b. Yes
    - i. if yes specify type and routes \_\_\_\_\_
- 8. Intraoperative complications
  - a. Hemorrhage
  - b. CSF Leak
  - c. Other specify \_\_\_\_\_

#### **Post-operative data**

- 1. Post-operative antibiotic
  - a. Route
    - i. Systemic specify
      - 1.

         2.

ii. Topical

1. \_\_\_\_\_ 2. \_\_\_\_\_

iii. Both

b. Duration in Days \_\_\_\_\_

- 2. Skin suture removal in days\_\_\_\_\_
- 3. Removal of silicone tube in weeks \_\_\_\_\_
- 4. Last Date of visits \_\_\_\_\_
- 5. Symptoms resolution at last visit
  - a. Full
  - b. Partial
  - c. No
- 6. Patency to irrigation at last visit
  - a. Full
  - b. Partial
  - c. Not done
- 7. Post-operative complications ( at any post-operative follow up )
  - a. Cellulitis
  - b. Excessive facial scarring
  - c. prolapse of the stent into the eye
  - d. cheese wiring of the canaliculus
  - e. pyogenic granuloma formation
  - f. Corneal erosions, from tube.
  - g. Epistaxis
  - h. Other specify \_\_\_\_\_
- 8. If patients are contacted through phone,
  - a. Resolution of symptoms

Full
Partial
No improvements

#### 1. <u>Table summary of surgical outcome and post operative follow up interval</u>

Post op		Symptoms resolution			Patency to irrigation		
	Date	Full	Partial	No	Full	Partial	Closed
1 wk							
3 mo							

6 mo				

## **DECLARATION**

### **ASSURANCE OF PRINCIPAL INVESTIGATOR**

The undersigned agrees to accept responsibility for the scientific ethical and technical conduct of the research project and for provision of required progress reports as per terms and conditions of the Faculty of Public Health in effect at the time of grant is forwarded as the result of this application.

Name of the student: \_\_\_\_\_

Date.\_\_\_\_\_ Signature \_\_\_\_\_

### **APPROVAL OF THE FIRST ADVISOR**

Name of the first advisor:\_\_\_\_\_

Date.\_\_\_\_\_ Signature \_\_\_\_\_

## **APPROVAL OF THE SECOND ADVISOR**

Name of the first advisor:\_\_\_\_\_

Date.\_\_\_\_\_

Signature \_\_\_\_\_