

EFFICACY OF FLUORESCEIN DYE DISAPPEARANCE TEST IN THE DIAGNOSIS OF LACRIMAL SYSTEM OUTFLOW OBSTRUCTION

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ABSTRACT: AIM: To evaluate the efficacy of Fluorescein Dye Disappearance Test in the Diagnosis of Lacrimal System Outflow Obstruction in comparison to Lacrimal Syringing. **SETTING AND DESIGN:** Prospective Non-randomized Non-interventional Case Series of 1000 eyes of 500 patients at a Tertiary Eye Care Hospital in South India over 6 months from June 2013 to November 2013. **METHODS AND MATERIALS:** Out-patient and inpatients posted for cataract surgery including those with complaints of epiphora were subjected to a Fluorescein Dye Disappearance Test (FDDT) followed by a Regurgitation on Pressure over the Lacrimal Sac Area (ROPLAS Test) and Lacrimal Syringing. The FDDT grade (Zappia and Milder Classification) and ROPLAS and lacrimal syringing results of each eye were recorded and tabulated and results compared to determine the efficacy of Fluorescein Dye Disappearance Test. **RESULTS:** Mean age of the patients included in our study was 59. 6 years (SD±14.3 years). History of epiphora was present in 272 (27.2%) of 1000 eyes in our study. ROPLAS was positive in 19(7%) of the 272 eyes with epiphora. Lacrimal syringing demonstrated a patent system in 904 (90.4%) of 1000 eyes. Sensitivity and Specificity of FDDT in the detection of lacrimal outflow system obstruction in our study was calculated to be 100% and 86. 62% (p value <0.0001, Fischer Test). **KEY MESSAGE:** Fluorescein Dye Disappearance Test is a simple, non-invasive highly sensitive method for evaluation of lacrimal system obstruction. Our study demonstrates a very high sensitivity indicating an abnormal FDDT is always suggestive of an outflow obstruction. Also, specificity of 86. 62% suggests that a severe anatomical obstruction of the lacrimal drainage system is highly unlikely in the presence of a normal fluorescein dye disappearance test. It can hence be used as a highly sensitive routine screening tool in the detection of a lacrimal outflow block. **KEYWORDS:** Lacrimal system obstruction, Dye Disappearance Test, ROPLAS, Lacrimal Syringing, Sensitivity.

INTRODUCTION: It is estimated that over a third of patients visiting the ophthalmic out-patient department have excessive tearing or problems associated with it.¹ The cause for the excessive tearing can be related to hypersecretion of tears or from a disorder of the lacrimal drainage system.

Epiphora can be assessed by various tests, including lacrimal syringing, probing, fluorescein dye disappearance test, nasal endoscopy, endocanalicular endoscopy, dacryocystography and dacryoscintigraphy.²

Detection of lacrimal drainage obstruction is important in the evaluation of epiphora as well as for all patients undergoing intra-ocular surgery. Such an obstruction can be catastrophic by causing post-operative endophthalmitis in patients undergoing intra-ocular surgery. The

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estimated incidence of post-operative endophthalmitis in the range of 0.05-0.21%.³ Lacrimal syringing is often used to rule out such an obstruction but being invasive, it has inherent problems such as pain, discomfort, creation of false passage, damage to lacrimal puncta and canaliculi.⁴

Fluorescein dye disappearance test is simple, non-invasive test, easier to perform. The purpose of this study is to demonstrate that it can be used as a valuable test in the evaluation of patients of epiphora and as a sensitive tool in the pre-operative lacrimal system evaluation of patients undergoing cataract surgery.

Subjects and Methods: A prospective, non-randomized, non-interventional, observer blinded case series of 1000 eyes of 500 patients was conducted over 6 months from June 2013 to November 2013.

Patients with epiphora attending the out-patient department and in-patients posted for routine cataract surgery (with/without epiphora) were included in the study. Patients excluded from the study included those with:

1. History of prior lacrimal sac surgery.
2. History of ocular/extra-ocular surgery in the recent past (<8 weeks).
3. Any cause of lacrimation (such as foreign body, trauma, blepharitis, lid disorders, ocular surface disorders).

A detailed clinical history including history of epiphora, past ocular or nasal problems was taken and complete ocular examination was done by a single Ophthalmologist. A Fluorescein Dye Disappearance Test (FDDT) was performed on all eyes using 1 drop (standard 5µl) of freshly prepared 2% Fluorescein dye solution instilled in the conjunctival cul de sac in an un-anesthetized eye, taking care not to touch the ocular surface directly. Patient was seated comfortably in a room with no air currents in ambient light and was asked to blink normally without wiping out the dye. At the end of 5 minutes, the presence or absence of dye was observed under a cobalt blue filter of a direct ophthalmoscope or slit lamp. Results were graded as per Modified Zappia and Milder Classification⁵ as grade 0-3 as demonstrated in Table 1 and Image 1. Observation and recording of the grading was done by a second single Ophthalmologist.

Patients were subjected to ROPLAS test and Lacrimal Syringing using standard techniques after the completion of Fluorescein Dye Disappearance Test after removing all residual dye using saline so as to not interfere with the interpretation of Fluorescein Dye Disappearance Test. Results recoded as Present/Absent and Patient, Partial Obstruction and Complete Obstruction for ROPLAS and Lacrimal Syringing respectively.

Clinical Evaluation, FDDT and Assessment of Lacrimal Drainage by ROPLAS and Lacrimal Syringing were all done by three different ophthalmologists with blinding to avoid observer bias and to ensure there is no inter-observer variability in interpretation of results. All results were tabulated and analyzed.

RESULTS: Mean age of the patients included in our study was 59.6 years (SD±14.3 years). 232 (46%) of the patients were males and 268 (54%) were females. Image 2 demonstrates the age

and sex distribution of our patients. 90(18%) of the 500 patients in our study were out patients and 410 (82%) were inpatients. History of epiphora was present in 272(27.2%) of 1000 eyes.

The results of FDDT test as per Zappia and Milder classification (4) were recorded as Grade 0, 1, 2 and 3 in 389 (38.9%), 396 (39.6%), 115(11. 5%) and 100 (10%) eyes respectively. History of epiphora was found in 111 (11.1%) eyes with Grade 0, 1 and 161 (16.1%) eyes Grade 2, 3 as demonstrated in Image 3.

ROPLAS was positive in 19(7%) of 272 of those with epiphora and in none of those without epiphora.

Lacrimal syringing demonstrated a patent system in 904 (90.4%) of 1000 eyes. 783 (78.3%) eyes had a patent syringing with grade 0, 1 on FDDT. 96 (9.6%) eyes with Grade 2, 3 showed obstruction on syringing. However, 121 (12.1%) eyes with Grade 2, 3 on FDDT had a patent Lacrimal Syringing.

Table 2 gives the correlation of findings of FDDT and Syringing with Lacrimal System Patency.

The eyes were divided into two groups – those without epiphora and those with epiphora and the results were analyzed.

Patients without epiphora consisted of 728 eyes of which 674 (92. 58%) eyes had grade 0, 1 of FDDT, all of which had a patent syringing. Of the 54 eyes with grade 2, 3 of FDDT, 3 (0.41%) and 2 (0.27%) eyes had obstruction and partial patency on syringing respectively while 49 (6. 73%) eyes were patent on syringing.

In patients with epiphora consisted of 272 eyes of which all 111 (40.81%) eyes with grade 0, 1 of FDDT had a patent syringing. The remaining 161 eyes with grade 2, 3 FDDT showed Obstruction in 75 (27.57%) eyes, partial patency in 15 (5.51%) eyes and patency in 71 (26.10%) eyes on syringing.

Table 3 demonstrates the inference of Lacrimal Syringing findings with the corresponding FDDT results in our patients.

Sensitivity and Specificity of FDDT in the detection of lacrimal outflow system obstruction was calculated to be 100% and 86. 62% (p value <0.0001, Fischer Test).

DISCUSSION: Anatomical patency of Lacrimal Outflow System include Palpation (ROPLAS), Lacrimal Syringing, Lacrimal probing, dacryocystography and nasal endoscopy while Functional patency can be concluded by physiological tests like Fluorescein Dye Disappearance Test (FDDT), Saccharin test, Jone's test and Scintigraphy.²

Our study included patients in middle age group (mean age of 59.6±14.3 years) as majority of them were in-patients for cataract surgery with almost equal male to female ratio (0.87). Our study is the first to include a large population (1000 eyes of 500 patients) for FDDT done in India. Majority (785 eyes, 78.5%) eyes were registered to be belonging to a normal FDDT class (grade 0, 1).

Table 4 demonstrates the correspondence of FDDT grade and lacrimal syringing along with the statistical inference and clinical interpretation of the same. Data was analyzed as with and without epiphora and compared to lacrimal syringing which was taken as the Gold standard.

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In the 728 eyes without epiphora, 674 (92.58%) eyes with a FDDT grade 0, 1 were confirmed to have a patent lacrimal drainage system on lacrimal syringing. 3 (0.41%) eyes with Grade 2, 3 FDDT were confirmed to have obstruction and 2 (0.27%) eyes with Grade 2, 3 FDDT had partial patency (partial obstruction). The remaining 49 (6.73%) eyes with Grade 2, 3 FDDT showed a patent system on lacrimal syringing. These represent the False Positive Cases which account for approximately seven percent (7%) of eyes tested – suggesting that FDDT can be used as a reliable specific tool in the evaluation of epiphora to identify those with some form of lacrimal system obstruction.

In those patients with epiphora, 111 (40.81%) eyes with Grade 0, 1 FDDT were confirmed to have a patent syringing. We observed that though these patients came with epiphora, FDDT was able to identify a patent system. In those eyes with Grade 2, 3 FDDT, 75 (27.57%) eyes had confirmed obstruction and 15 (5.51%) eyes had partial patency (some degree of obstruction) on syringing. However, 71 (26.10%) eyes with Grade 2, 3 FDDT had a normal patency on syringing. These represent the eyes having a functional obstruction. FDDT is able to identify an anatomical obstruction along with functional obstruction which cannot be detected by lacrimal syringing. We infer that in those eyes with epiphora, a Grade 2, 3 FDDT is suggestive of some form of lacrimal drainage system obstruction.

ROPLAS was found to be positive in only 19 (11.8%) of 161 eyes with epiphora and a blocked outflow and none without epiphora. FDDT was found to be positive in all 161 eyes (100%) with epiphora and a blocked system. FDDT is more reliable than ROPLAS in identifying lacrimal system outflow obstruction.

Sensitivity is the percentage of affected patients with positive result while specificity is the percentage of unaffected individuals who test negative. Our study shows that if FDDT is grade 3 or higher in patients with epiphora, the probability of having an obstructed lacrimal system is 100%. If it is normal, the chance of having a patent system is 86.62%. We recommend that for all patients without epiphora but a grade 2, 3 FDDT a subsequent lacrimal syringing is helpful in revealing false positive results.

FDDT was first described by Zappia and Milder in 1972.⁵ It is a rapid, non-invasive, objective, quantitative test that is especially useful in patients with poor compliance including infants. It can be used to identify the probable functional obstruction with the added advantage of identifying lesions of the cornea and conjunctiva. It can be used as a simple office tool due to its ease of administration. Also, it is a visual system of grading that is easy to interpret which can be taught to paramedical staff. This can reduce the burden on Ophthalmologists of syringing (which requires special training as opposed to the FDDT) for all cataract cases in a busy outpatient department. FDDT cannot however differentiate between anatomical and functional obstruction and is not useful to identify the site of obstruction. False positive results may be seen in nasal pathology like nasal polyp.

The efficacy of FDDT has been demonstrated to range from 82.3% (MacEwan CJ et al⁶) to as high as 92% (Kashkouli MB et al^{7,8}). Table 5 compares our study with other studies. We have obtained a similar efficacy (sensitivity and specificity) in the pre-operative evaluation of patients for intra-ocular (cataract) surgery. Hence FDDT is more reliable as a screening tool compared to ROPLAS in the diagnosis of lacrimal outflow obstruction in pre-operative screening of eyes for

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intra-ocular surgery. Our study shows that anatomical obstruction is unlikely in the presence of a normal FDDT and FDDT grade 2 or more in a patient with epiphora is conclusive of an obstructed lacrimal outflow system.

CONCLUSION: Fluorescein Dye Disappearance Test is a simple, non-invasive highly sensitive method for evaluation of epiphora.

Fluorescein dye is routinely used pre-operatively to identify ocular surface pathology and for applanation tonometry. An additional advantage is it can be used for the fluorescein dye disappearance test in the identification of lacrimal outflow system obstruction. It can thus be performed routinely without additional discomfort to the patient.

AIOS Guidelines to Prevent Intraocular Infection (2009) recommend no syringing prior to cataract surgery. Hence it is recommended to routinely supplement clinical tests with FDDT prior to cataract surgery to identify any lacrimal outflow system obstruction.

In view of the high sensitivity of FDDT, it can be used as a routine screening tool in the detection of lacrimal outflow obstruction suggesting a severe anatomical obstruction is highly unlikely in the presence of a normal fluorescein dye disappearance test.

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GRADE	DESCRIPTION	INTERPRETATION
Grade 0	No fluorescein remaining in the conjunctival sac	Negative (No obstruction)
Grade 1	Thin fluorescing marginal tear strip only	
Grade 2	Between Grade 2 and Grade 3	Positive (Obstruction present)
Grade 3	Brightly fluorescing tear strip	

Table 1: Zappia and Milder Grading of Fluorescein Dye Disappearance Test

FDDT	LACRIMAL SYRINGING	INTERPRETATION
0, 1	Patent	Patent
0, 1	Partial regurgitation of fluid	Partially patent
2, 3	Complete regurgitation of fluid	Anatomical obstruction
2, 3	Patent	Functional obstruction (probable)

Table 2: Correlation of FDDT with Lacrimal Syringing

FDDT GRADE	LACRIMAL SYRINGING		TOTAL
	PATENT	OBSTRUCTION	
Grade 0-1	783 (78.3%)	0 (0%)	783 (78.3%)
Grade 2-3	121 (12.1%)	96 (9.6%)	217 (21.7%)
Total	904 (90.4%)	96 (9.6%)	1000

Table 3: Inference of FDDT and Lacrimal Syringing

FDDT GRADE	LACRIMAL SYRINGING	STATISTICAL INFERENCE	CLINICAL INTERPRETATION	NUMBER OF EYES
Grade 0, 1	Patent	True Negative	Patent	783
Grade 0, 1	Obstruction	False Negative	-	0
Grade 2, 3	Patent	False Positive	Probable functional obstruction	121
Grade 2, 3	Obstruction	True positive	Anatomical obstruction	96

Table 4: Statistical and Clinical Correlation of FDDT and Lacrimal Syringing

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AUTHOR	STUDY GROUP	SAMPLE SIZE	SENSITIVITY	SPECIFICITY
MacEwen CJ et al (1991)(5)	Infants	288	82. 3%	85. 2%
Guzek et al (1997)(8)	Epiphora	27	95-100%	
Bowyer JD et al (2001)(9)	Childhood epiphora	176	94%	40%
Kashkouli MB et al (2008)(7)	Topical anti-glaucoma medication	130	92%	82. 7%
Joon Ho Roh et al (2010)(1)	NLD obstruction	42	High	High
Kashkouli MB et al (2013)(6)	PANDO	58	71. 1%	78. 6%
Our Study (2013)	Pre-cataract, Epiphora	1000	100%	86. 62%

Table 5: Comparison of Our studies with others

LEGEND OF IMAGES:

Image 1 – Zappia and Milder Classification of Fluorescein Dye Disappearance Test

- A. Grade 0
- B. Grade 1
- C. Grade 2
- D. Grade 3

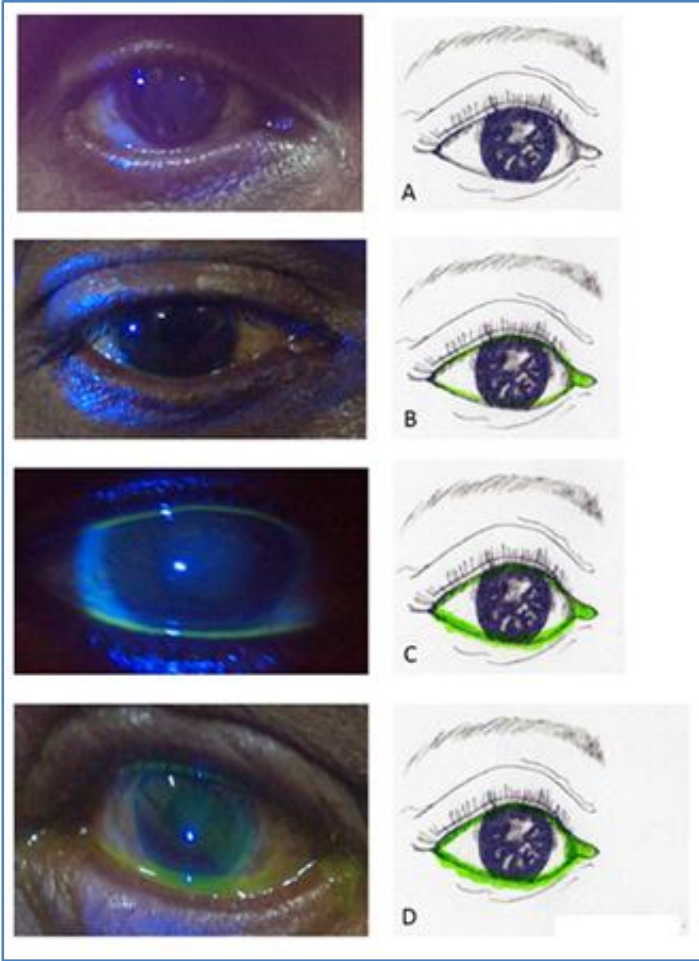


Image 1

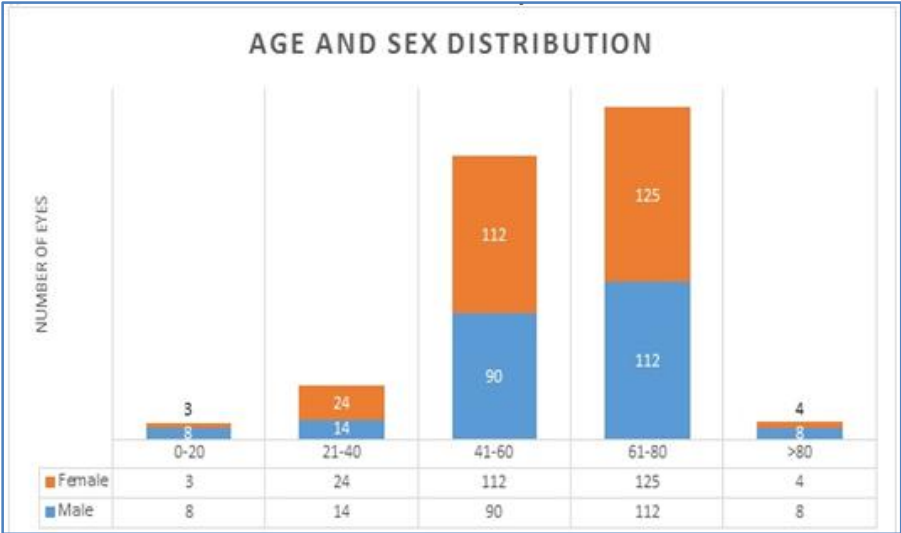


Image 2: Age and Sex Distribution of patients

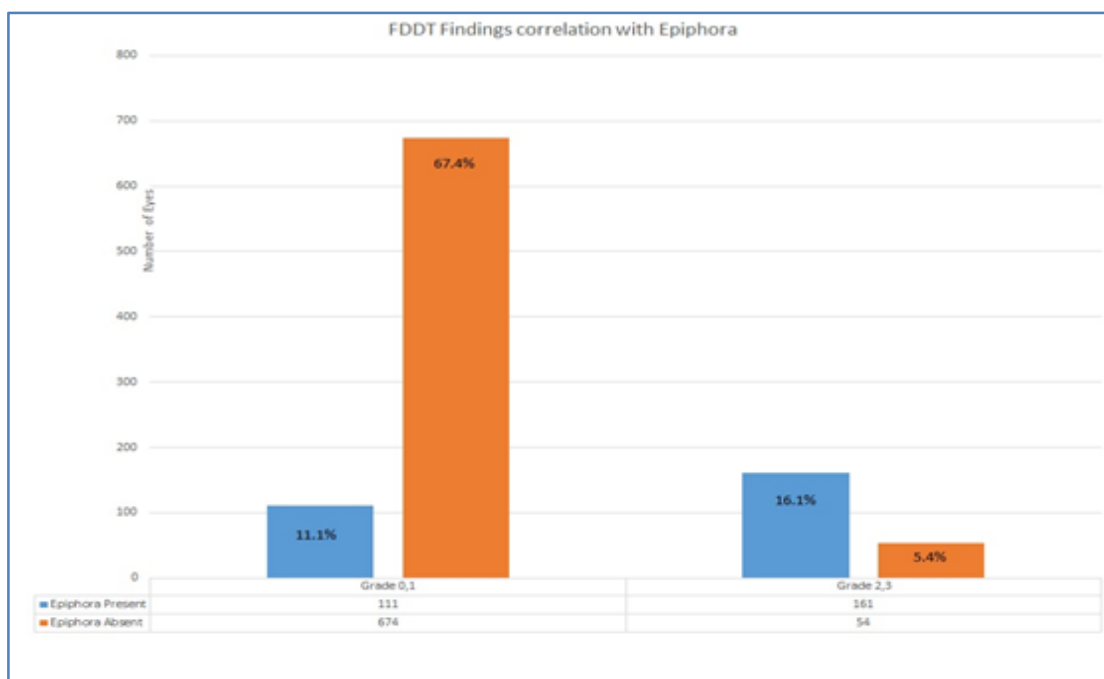


Image 3: Results of Fluorescein Dye Disappearance Test (FDDT)

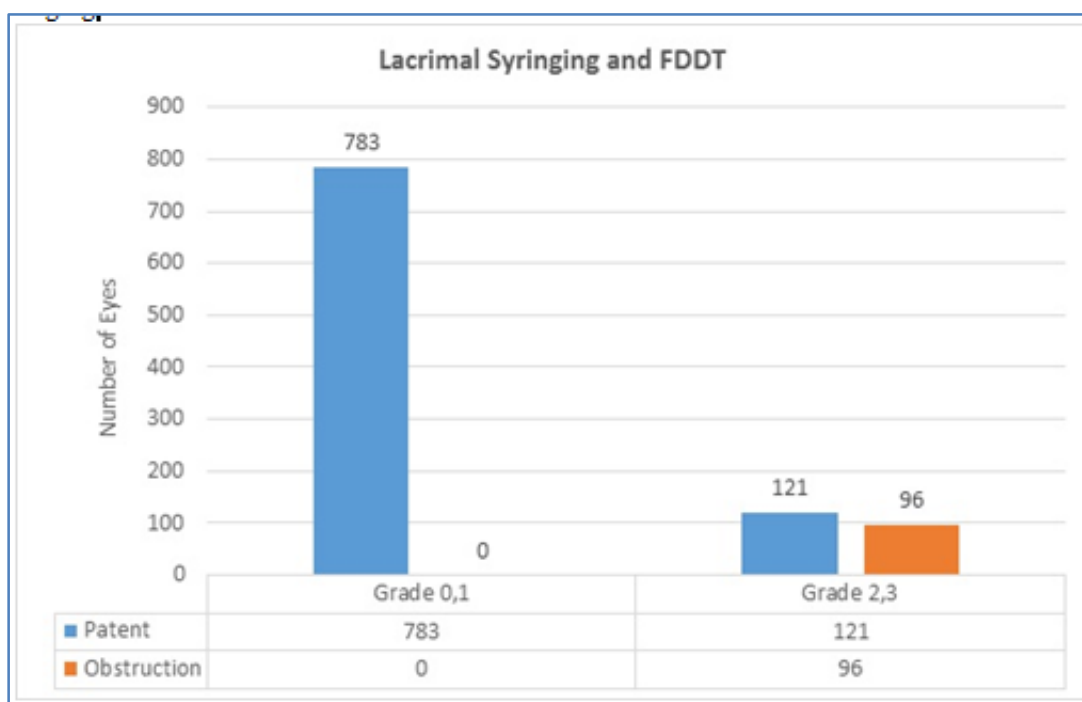


Image 4: Correlation of FDDT and Lacrimal Syringing

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