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Original Article



Outcome of Revision External DCR using Mitomycin C with or without Intubation in Failed Primary DCR

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Abstract

Objectives: The study evaluates revision dacryocystorhinostomy (DCR) outcomes with intra-operative mitomycin-C, addressing the need for intubation in unsuccessful primary DCR cases. It also examines the safety of mitomycin-C, complications of lacrimal intubation, and factors contributing to primary DCR failure. Methods: This Prospective study was conducted at AIIMS, New Delhi, involving patients with primary DCR failure lasting over 6 months. Adults aged 18 and above willing to participate were included, while exclusion criteria those with certain medical conditions or prior surgeries. The standard external DCR procedure included excising scar tissue and performing a bony osteotomy. Total 40 patients were randomly assigned to two groups: Group 1 (20 patients) underwent revision external DCR with lacrimal intubation and intraoperative mitomycin C treatment, while Group 2 (20 patients) received the same treatment without intubation. Results: Total of 40 adult patients with failed primary dacryocystorhinostomy (DCR) were studied. Mean ages were 37.05 years for Group 1 and 39.70 years for Group 2, with a higher prevalence of females in both groups. Major findings indicated fibrosis around the bony ostium, with some patients lacking an ostium. Postoperative complications like foreign body sensation were more common in Group 1 during tube placement, but outcomes post-tube removal were similar for both groups. Anatomical success was 100% for Group 1 and 95% for Group 2 at four months, while functional success was 90% for Group 1 and 80% for Group 2, with no significant differences overall indicating comparable results for both techniques in anatomical and functional success. Conclusion: Revision external DCR with Mitomycin C achieved 97.5% anatomical and 85% functional success rates in previously unsuccessful cases. Fibrosis was the primary reason for failure. Silicone tube intubation led to a slightly higher success rate (100% anatomical, 90% functional) compared to non-intubation, though differences were not statistically significant. Post-operative complications were more frequent with intubation but resolved after tube removal. The procedure is viewed as safe, reliable, and effective.

Keywords: dacryocystorhinostomy, Revision External DCR, Mitomycin C, nasolacrimal duct

Introduction

Epiphora is the excessive overflow of tears despite normal tear production, usually caused by obstructions in the tear drainage system. These obstructions can be physiological, due to conditions like lacrimal pump failure, or anatomical from blockages in the drainage pathway. Common causes include inflammation, trauma, neoplasms, and congenital issues such as nasolacrimal duct obstruction [11-3]. The history of surgical intervention for epiphora starts with Toti's 1904 description of external dacryocystorhinostomy, evolving through various techniques in the 20th century that yielded high success rates [4].

Nasolacrimal duct obstruction can lead to lacrimal sac infections, inflammation, epiphora, and ocular discharge [1-3]. When

medication fails, surgical options such as dacryocystotomy, syringing, probing, and dacryocystorhinostomy (DCR) are available. The external approach DCR is considered the gold standard for treatment, whereas endoscopic DCR shows less effectiveness, prompting some studies to combine it with intra-operative mitomycin [5-7].

Clinical pathologic studies by Linberg and McCormick ^[8] revealed that nasolacrimal duct obstruction leads to inflammation, vascular congestion, and edema in the early stages, ultimately resulting in fibrosis in later phases. Patients may benefit from medical therapies with anti-inflammatory drugs or nasolacrimal duct intubation to maintain duct patency. The use of anti-fibrotic agents like Mitomycin C, alongside dacryocystorhinostomy (DCR), could prevent fibrosis and maintain duct patency. Topical Mitomycin C

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application may inhibit bony ostium closure, with anti-metabolites, steroids, and lacrimal intubation showing success rates between 70-90% in enhancing DCR outcomes [9-11].

Mitomycin C is known to inhibit fibroblast activity in wound healing and is used in ophthalmic surgery, with recent investigations into its application in DCR surgery for its effects on nasal mucosal fibroblasts. The drug's capability to mitigate distal canalicular and osteotomy fibrosis and scarring is influenced by its concentration, duration of application, and surrounding tissue conditions. Its applications include preventing recurrent pterygium, treating glaucoma fistula restenosis, conjunctival corneal dysplasia, neoplasm, and ocular pemphigoid. Additional studies are required to further explore its effectiveness in DCR contexts, particularly with endoscopic approaches showing improved success rates [12-15].

Mitomycin C has been explored as an adjuvant in ocular surgeries, including procedures for ocular cicatrization and malignancies like ocular surface squamous neoplasia. Its use is still experimental in surgeries for strabismus, orbital implants, proliferative vitreoretinopathy, and others. Intraoperative application of Mitomycin C may improve surgical success by preventing ostium closure. The history of lacrimal path intubation began with Graue & Glenie's suggestion to use silver wire, followed by Henderson advocating polyethylene tubes in 1950. Gibbs advanced this field in 1967 by introducing silicone tubes for dacryocystorhinostomy (DCR), minimizing trauma to surrounding tissues [16-20].

The proposed philosophies of lacrimal intubation include ensuring a safe DCR procedure and preventing postoperative obstructions by maintaining an open pathway during healing. Indications for intubation encompass canalicular block, posttraumatic cases, and dysfunction of the lacrimal pump. Bicanalicular stents, typically made of silicone, involve probes passed through both puncta, secured in the nose, and left for three to twelve weeks to reduce scarring. Success rates for stent insertion are reported between 79% and 96% [21]. Complications of lacrimal intubation may include failure of DCR due to granuloma formation, nasal irritation, corneal abrasions, and persistent watering among others [22-25]. Despite careful surgery, failures of DCR typically arise from issues like granulation tissue, fibrosis, scarring at the osteotomy site, synechia between the lateral nasal wall and middle turbinate, small osteotomy and inadequate sac openings, bony spicule obstruction, and canalicular obstruction [26-28].

The study aims to evaluate the outcomes of revision dacryocystorhinostomy (DCR) utilizing intra-operative mitomycin-C, with a focus on whether intubation is necessary in cases of failed primary DCR. Additionally, it seeks to assess the safety of mitomycin-C and examine complications associated with lacrimal intubation, as well as analyze the reasons for failure following primary DCR.

Methods

This was a prospective, randomized, interventional study. Patients presenting to general OPD and Oculoplasty Clinic at Dr. R. P. Centre for Ophthalmic Sciences, AIIMS, New Delhi over a period of One year.

Inclusion criteria for the study consist of cases with primary DCR failure lasting over 6 months, participants aged 18 and above, those consenting to participate, and individuals amenable to follow-up. Exclusion criteria include patients with NLDO due to trauma, iatrogenic factors, radiotherapy, or nasal pathologies, individuals who have had multiple DCR surgeries, those unwilling to consent, pregnant participants, patients who previously used mitomycin C or

underwent intubation during primary DCR, or those suffering from acute dacrocystitis. Steps of standard external DCR were followed. Nasal and Lacrimal flaps (anterior) were sutured, where possible. All the surrounding scar tissues were removed. Bony osteotomy of approximately 14 mm size was made. Excess lacrimal and nasal mucosal flaps were excised. Total 40 Patients were divided into 2 groups. Patients in Group 1(n=20) had undergone revision external DCR with lacrimal intubation with intraoperative use of mitomycin C, 0.4 mg/ml for 5 minutes followed by irrigation with normal saline.

For patients in Group 2, (n=20) revision external DCR with intra-operative use of mitomycin C, 0.4mg/ml for 5 minutes followed by irrigation with normal saline was done. Intubation was not done.

Intra-operative findings were systematically analyzed to determine causes of failure during primary surgery. Key observations included the size of the bony ostium, the presence of fibrosis around it, closure state of the ostium, and the condition of the lacrimal sac. The ostium size was classified into three grades: no ostium, size less than 10 mm, and size greater than or equal to 10 mm. Closures were categorized as bony or fibrous, while the lacrimal sac's status was noted as either fibrotic or normal. Postoperative treatment included topical and oral medications, as well as nasal decongestant drops. Patient work-up involved a thorough ophthalmic history focusing on symptoms like watering, discharge, redness, and medial canthal swelling. Previous surgical routes, the use of intubation, and intra-operative mitomycin C were documented. The amount of watering was categorized based on Kraft and Crawford's classification. Examination procedures included general physical and nasal assessments, ocular evaluations, and lacrimal system examinations, with findings on discharge, medial canthal swelling, and tear meniscus height being recorded. Regurgitation tests and syringing were used to assess nasolacrimal duct obstruction. Routine investigations comprised complete blood counts and blood sugar checks, alongside conjunctival swabs in regurgitation-positive cases. Preoperative ENT consultations were conducted for nasal pathology evaluation and surgery clearance.

Follow-up was conducted at one week and subsequently at one month for four months. During each follow-up, both groups were assessed for symptoms such as epiphora, discharge, swelling at the medial canthus, and other ocular surface issues. In Group 1, complications included nasal bleeding, tube position, granuloma formation, and tube extrusion; similar complications were noted for Group 2. At the three-month follow-up, nasal endoscopy was performed and the silicone intubation tube was removed from Group 1 patients. By the four-month follow-up, syringing and dacryoscintigraphy assessments were carried out for both groups. Post-operative evaluations indicated subjective improvement in watering and discharge. Objective assessments of patency used both syringing and dacryoscintigraphy, with noted complications related to the intra-operative use of mitomycin C and the process of lacrimal intubation.

The data was plotted on Microsoft excel spread sheet and analyzed using SPSS software version 12. Qualitative data was analyzed using Pearson Chi-Square test. Quantitative data was analyzed using Mann- Whitney test. p value of <0.05 was taken significant.

Results

A study involving 40 patients with failed primary Dacryocystorhinostomy (DCR) involved random division into two groups of 20. The age of patients ranged from the 2nd to 7th decade

of life, with mean ages of 37.05 years for group 1 and 39.70 years for group 2, showing no significant difference (p = 0.525). Gender distribution included 14 males and 26 females, with similar proportions in both groups, resulting in an overall male-to-female ratio of 1:1.857 (p = 0.507).

Table 1: Distribution of demographic profile

Gender Group 1 Group 2
N=20(%) N=20 (%)

	N=20(%)	N=20 (%)
Male	8 (40%)	6 (30%)
Female	12 (60%)	14 (70%)
Age (Yrs) Mean±SD	37.05±13.839	39.70±11.174

9 out of 40 patients received an endoscopic approach for primary DCR, while 31 underwent the external approach, with no significant difference between groups (p = 0.256). The mean time interval between primary and revision DCR surgeries was also similar across both groups (p = 0.786), with median intervals of 20 months for group 1 and 22 months for group 2. The minimum interval for both groups was 6 months, with maximum intervals of 30 and 28 years, respectively. (Table 2)

Table 2: Surgical approach in Primary DCR surgery and Time Interval between Primary and Revision Surgery

Surgical approach	Group 1	Group 2	Total
	n (%)	n (%)	n (%)
Endoscopic	3 (15%)	6 (30 %	9 (22.5%)
External	17 (85%)	14 (70%)	31(77.5%)
Time interval between	46.30±	52.80±77.20	-
primary and revision	79.10		
DCR (Mean± SD)			

Preoperative findings in both groups were similar, with constant watering observed in all patients. Discharge was present in 7 patients from group 1 and 5 from group 2, characterized as mucopurulent. Medial canthal swelling was noted in 7 patients in group 1 and 9 in group 2. Additionally, 13 of 20 patients in both groups had a positive regurgitation test, with no significant differences between the groups. (Table 3)

Table 3: Preoperative finding in both groups

Findings	Group 1	Group 2	р	Total
	n (%)	n (%)	value	n (%)
Watering	20 (100%)	20(100%)	1.00	40(100%)
Discharge	7 (35%)	5 (25%)	0.490	12 (30%)
Medial Canthal	7 (35%)	9 (45%)	0.519	16(40%)
Swelling				
Regurgitation	13 (65%)	13 (65%)	1.00	26 (65%)

Intra-operative findings from a study of 40 patients revealed that 31 had fibrosis around the bony ostium, with similar occurrences in both groups (14/20 in group 1 and 17/20 in group 2). All patients underwent closure of the osteotomy opening, with bony closure found in 6 patients from group 1 and 5 from group 2, while fibrous closure occurred in 14 and 15 patients, respectively, showing no significant difference (p=0.72). The size of the bony ostium was predominantly small among the patients, with comparability between groups (p=1.00). Additionally, fibrosis of the lacrimal sac was observed in 35% and 25% of cases in groups 1 and 2, respectively, totaling 30% across all patients, with no statistically significant difference (p=0.490). (Table 4)

Table 4: Intraoperative findings of Fibrosis around bony ostium, closure of osteotomy opening, size of bony ostium

Fibrosis	Group 1	Group 2	Total
	n (%)	n (%)	n (%)
Present	14 (70%)	17 (85%)	31 (77.5%)
Absent	6 (30%)	3 (15%)	9 (22.5%)
Closure of osteotomy	pening		
Bony closure	6 (30%)	5 (25%)	11 (27.5%)
Fibrous closure	14 (70%)	15 (75%)	29 (72.5%)
Size of Ostium			
No ostium	5 (25%)	5 (25%)	10 (25%)
< 10 mm	11 (55%)	11 (55%)	22 (55%)
>10 mm	4 (20%)	4 (20%)	8 (20%)
Lacrimal sac			
Fibrotic	7 (35%)	5 (25%)	12 (30%)
Normal	13 (65%)	15 (75%)	38(70%)

Post-operative assessments revealed foreign body sensation in all silicone intubation patients (Group 1) until the intubation tube was removed at 3 months, after which none reported sensation. Epiphora was observed in both groups, persisting in Group 1 until tube removal, while in Group 2, rates decreased over time. By 4 months, Group 1 had no epiphora, while three patients in Group 2 continued to experience it (p=0.072). Discharge occurred in 5% of patients in both groups initially, with no significant differences throughout the follow-ups, as discharge resolved by 4 months in both groups (**Table 5**).

Table 5: Postoperative parameters in foreign body sensation epiphora, at discharge follow up duration

Epiphora	Group 1	Group 2	p value
	n (%)	n (%)	
Day 7	20 (100%)	11 (55%)	0.003
1 month post op	20 (100%)	9 (45%)	0.001
2 months post op	20 (100%)	6 (30%)	<0.0005
3 months post op	20 (100%)	5 (25%)	< 0.0005
4 months post op	0	3 (15 %)	0.072
Discharge			
Day 7	1 (5%)	1(5%)	1.00
1 month post op	1(5%)	0	0.311
2 months post op	3 (15%)	0	0.72
3 months post op	1 (5%)	0	0.311
4 months post op	0	0	-

Postoperative complications

One patient in Group 1 experienced abscess formation in the medial canthal region on day 7 post-operative follow-up. The lacrimal intubation tube was removed, and the patient received medical management with oral and topical antibiotics, ultimately leading to their removal from the study.

Nasal endoscopy at 3 months post-treatment showed healthy nasal mucosa in most patients across both groups. Complications included mucosal thickness increase in 15% of patients, a 5% nasal septum perforation in one patient from group 2, and 10% mucosal dryness in group 2. Discharge was noted in 5% of group 1 and 15% of group 2; nasal bleeding occurred in 5% of group 1 and 10% of group 2. No scarring or synechia was observed, and group 1 showed no tube extrusion or granuloma. Statistically, no significant differences were found between the groups (**Table 6**).

Table 6: Nasal Endoscopic Findings			
Nasal Endoscopic	Group 1	Group 2	p value
Findings	n (%)	n (%)	
Mucosal color			0.311
• Pink	20 (100%)	19 (95%)	
 Congested 	0	1 (5%)	
Mucosal Thickness			1.00
 Normal 	17 (85%)	17 (15%)	
• Thick	3 (15%)	3 (15%)	
Mucosal Dryness	0	2 (10%)	0.147
Discharge	3 (15%)	3 (15%)	1.00
Bleeding on touch	1 (5%)	2 (10%)	0.548
Any other finding	0	1(5%)	0.311
(Septal Perforation)			

Anatomical success was achieved in 100% of patients in group 1 and 95% in group 2 after four months, leading to an overall success rate of 97.5% (p=0.311). Functional success, assessed via dacryoscintigraphy, showed 90% in group 1 and 80% in group 2, with no statistically significant difference (p=0.495). Group 1 had two patients with functional blocks, while one of four in group 2 showed anatomical obstruction at the nasolacrimal duct or osteotomy site, with three others also having functional blocks (Table 7).

Table 7: Anatomical and functional Success				
Anatomical	Group 1	Group 2	Total	
Success	n (%)	n (%)	n (%)	
Patent	20 (100%)	19 (95%)	39 (97.5%)	
Block	0	1 (5 %)	1 (2.5%)	
Functional Success				
Patent	18 (90%)	16(80%)	34 (85%)	
Obstruction	2 (10%)	4 (20%)	6 (15 %)	

Discussion

Primary acquired nasolacrimal duct obstruction is prevalent in adults, primarily manifested through chronic epiphora, conjunctivitis, and infections. It is most frequently observed in elderly white females. In a study, the average age of participants was approximately 39 years, with a female-to-male ratio of 1:1.857. Histopathological analysis indicates early inflammatory changes in the duct, progressing to fibrosis and complete obstruction [4]. Management options include dacryocystotomy, probing, and dacryocystorhinostomy (DCR), with external DCR recognized as the standard surgical intervention. Endoscopic DCR yields lower success rates but can be enhanced through the use of mitomycin during surgery [5-7].

Despite careful surgical efforts, failures in dacryocystorhinostomy (DCR) can occur due to several factors, including granulation tissue, fibrosis, and scarring that block the osteotomy site, as well as synechia between the lateral nasal wall and middle turbinate. In a study, it was found that 70%-85% of patients experienced fibrosis around the bony ostium, while 30%-25% had bony closure. Additionally, 70%-75% suffered from fibrous closure, and lacrimal sac fibrosis was noted in 35%-25% of patients across two groups. A notable 25% of patients lacked an ostium altogether, while 55% had an ostium size under 10 mm, and 20% had one that was 10 mm or larger.

Revision DCR outcomes are generally inferior to primary DCR, primarily due to tissue scarring, which poses challenges for surgeons. To improve DCR results, treatments such as anti

metabolites (mitomycin C and 5-FU), steroids, and lacrimal intubation have been investigated, showing success rates between 70-90% [9-11,29,30].

External DCR is an effective surgical approach for treating chronic dacryocystitis due to nasolacrimal duct (NLD) obstruction, characterized by creating an anastomosis between the lacrimal sac and nasal mucosal flaps, allowing the sac to drain into the middle meatus. Can I *et al.*^[31] reported a notable success rate of 95% from 500 cases using this method. The failure rates after primary surgeries vary from 0% to 23%, with an average failure rate of 9.4%. For failed DCRs, patients can undergo endoscopic endonasal DCR or revision external DCR. The success rates for endonasal DCR in recurrent dacryocystitis range from 43% to 86%, while revision external DCR shows higher success rates of 85% to 92% [9-11,32]. These findings suggest that the success rate of revision external DCR surpasses that of endoscopic endonasal DCR for both failed cases and primary surgeries.

In patients who experienced failure with primary dacryocystorhinostomy (DCR), the subsequent revision through external DCR combined with silicone tube intubation has demonstrated a success rate between 60% to 80% [10,11]. Furthermore, the concurrent use of bicanalicular silicone tube intubation along with external DCR has been associated with an additional 12% increase in success rates [10,11].

In a study by Lone IA *et al.*^[33] a 95% success rate was achieved with silicone intubation in 40 patients who underwent revision external dacryocystorhinostomy (DCR) after initial failure. Following a follow-up of 12-18 months, 38 patients were asymptomatic after the removal of the silicone tube at one year. The study noted that 72.5% of patients exhibited dense fibrous scar closure of the bony ostium, highlighting the importance of ensuring a sufficiently large osteotomy opening to prevent surgical failure [33].

Linberg and McCormick ^[8] demonstrated that a sufficiently large osteotomy can reduce to approximately 2 mm due to tissue growth and scarring. The use of mitomycin C helps minimize fibrous proliferation and vascular ingrowth at the osteotomy site and the anastomosed flaps ^[16-20]. Research indicates that applying MMC at the osteotomy site results in a significantly larger osteotomy during the postoperative period ^[16-20].

In our study, we observed intra-operative fibrosis around the bony ostium in 77.5% of cases, with bony closure at 27.5% and fibrous closure at 72.5%. Additionally, 30% of the cases exhibited fibrosis of the lacrimal sac. To reduce postoperative fibrosis and scarring around the ostium, we applied MMC 0.4 mg/ml for 5 minutes in both groups.

Various studies indicate that the use of Mitomycin C (MMC) in primary surgeries has a success rate ranging from 90-100% with different concentrations and durations. Notably, Kao SC et al. [16] reported a 100% success rate using MMC at a concentration of 0.2 mg/ml for 30 minutes at the osteotomy site. You YA et al.[17] found success rates of 100% and 94% for 0.2 mg/ml and 0.5 mg/ml, respectively, with a control success rate of 83%. Their application involved MMC for 5 minutes on the nasal mucosa and lacrimal sac at the rhinostomy site. Similarly, Yeldrim C et al. reported primary success rates using comparable MMC in Dacryocystorhinostomy (DCR). Studies indicate a 70-90% success rate for mitomycin C in failed DCR cases, with no adverse effects reported.

Penttila *et al.*^[35] reported a 93% success rate in revision endonasal dacryocystorhinostomy (EN-DCR) with 0.4 mg/ml mitomycin C (MMC) used for 5 minutes at the ostium, compared to 60% without MMC, with no silicone intubation involved. Gorguru *et al.*^[36] achieved a 90% success rate in failed DCR utilizing 0.2

mg/ml MMC for 5 minutes on the osteotomy site of the lacrimal sac, noting no adverse effects. Ragab *et al.*^[37] observed success rates of 84.2% and 82.9% at 6 and 12 months respectively in revision external DCR for failed primary DCR using 0.5 mg/ml MMC for 10 minutes, with minor complications including 5 instances of epistaxis and 3 cases of minimal synechia.

In this study, MMC 0.4 mg/ml was applied to the osteotomy site for 5 minutes in two groups, with Group 1 undergoing silicone tube intubation and Group 2 receiving no intubation. Group 2 showed an anatomical success rate of 95% and a functional success rate of 80%. These results align with previous findings regarding MMC use in both primary and revision surgeries. Additionally, combining revision external DCR with mitomycin C and silicone tube intubation has shown improved success rates, with past studies reporting 73% for revision external DCR with intubation and 77% when combined with mitomycin C.

Tabatabie SZ *et al.*^[22] evaluated the efficacy of mitomycin C (MMC) application during silicone intubation in 88 patients with nasolacrimal duct obstruction. For patients with simple epiphora lasting less than 6 months, silicone intubation alone was effective in 83% of cases, with no benefit from MMC. Conversely, in patients with epiphora lasting 6 months or longer, MMC application during silicone intubation proved more effective than silicone intubation alone.

In the study, MMC at a concentration of 0.4 mg/ml was applied for 5 minutes to both groups, with bicanalicular silicone intubation utilized in group 1. The anatomical success in group 1 was 100%, while the functional success was 90%.

The use of Mitomycin C (MMC) in pterygium surgery has been associated with complications such as corneal perforation, scleral melting, cataract, secondary glaucoma, and scleral calcification. Additional complications like hypotony-related maculopathy, infection, and endophthalmitis have been noted in glaucoma surgery. However, no complications were observed in lacrimal surgery involving MMC, as reported by some studies suggesting the application of MMC in nasolacrimal duct procedures is safe [18,19,36].

In the study, mitomycin C usage showed no complications like nasal bleeding or mucosal necrosis. Complications related to lacrimal intubation included increased failure rates due to granuloma formation and various issues such as nasal irritation and stent extrusion. However, the study reported no significant complications from bicanalicular silicone tube intubation. All patients reported foreign body sensation and persistent watering during tube retention, but these symptoms resolved post-removal. Anatomical success rates were 100% for group 1 and 95% for group 2, with an overall success rate of 97.5%. Functional success rates were 90% for group 1 and 80% for group 2, leading to a combined functional success of 85%, with no statistically significant differences noted between the groups.

Conclusion

Revision DCR with mitomycin C in cases where initial DCR has failed yields comparable outcomes for patients regardless of whether intubation is performed. Both short-term anatomical and functional success rates for revision DCR with mitomycin C are favorable. However, intubation is associated with increased symptoms, specifically more watering and a sensation of a foreign body. The application of mitomycin C as an adjunctive anti-fibrotic agent is deemed safe.

Declaration

Ethical Approval and Consent to participate

This is a Prospective study. Ethical clearance was obtained, and written informed consent was taken from all participants

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Department of Ophthalmology, AIIMS, New Delhi

Consent for publication

Taken from all authors

Conflict of Interest

None

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Authors' Contributions

BK: initial intellectual content development, Data acquisition, and principal investigating author

NP: Study Design, Data acquisition, initial intellectual content development and principal investigating author.

DKY: Manuscript preparation, final intellectual content development and corresponding author

KR: Manuscript preparation, final intellectual content development, Data interpretation, manuscript integrity appraisal and critical reviewing author

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