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Original Research Article

A comparative study of Dacryocystorhinostomy with canalicular silicone tube intubation & application of Mitomycin-C in failed cases of chronic dacryocystitis

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Abstract

Background: Chronic dacryocystitis occurs because of persistent infection and inflammation of the lacrimal sac, mainly due to obstruction at the level of the nasolacrimal duct. This condition often leads to continuous tearing and ocular discharge. Common factors contributing to the failure of dacryocystorhinostomy (DCR) surgery include common canalicular stenosis, sump syndrome, high anastomosis of the flap, and suboptimal surgical technique.

Aim and Objective: To compare the post-operative surgical outcome in failed cases of chronic dacryocystitis.

Materials and Methods: The present study was designed as a prospective, interventional, comparative, single-centre investigation conducted at a tertiary care facility over one year. It included a total of 60 patients with previously failed cases who had undergone surgery elsewhere, divided into two groups of 30 patients each through random sampling. Following a thorough history taking and examination, all participants underwent re-dacryocystorhinostomy with silicone tube intubation, along with the application of Mitomycin-C to the flap and circum-osteal area. In Group A, the silicone tube was removed after 4 weeks, while in Group B, it was removed after 6 weeks. The surgical outcomes were compared at the 12-month postoperative mark.

Results: The success rate of a redo external dacryocystorhinostomy combined with silicone tube intubation was notably impressive. In Group A, the procedure achieved a success rate of 90% when the silicone tube was removed after 4 weeks. Conversely, Group B demonstrated an even greater success rate of 100% when the silicone tube was retained for an extended period of 6 weeks before removal. This highlights the potential benefits of optimising the duration of silicone tube placement in enhancing surgical outcomes.

Conclusion: External DCR surgery using canalicular silicone tube intubation, combined with intraoperative mucosal flap and circum-osteal application of Mitomycin-C, can lead to excellent outcomes. The post-operative result was higher with a significant difference in patients where the silicone tube was removed at the 6th post-operative week.

Keywords: Chronic dacryocystitis, Nasolacrimal duct obstruction, Failed dacryocystorhinostomy, Silicone tube intubation, Mitomycin-C, External DCR.

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1. Introduction

Chronic dacryocystitis (CDC) is defined as lacrimal sac infection and inflammation due to obstruction of the nasolacrimal duct, commonly involving its distal part. As a result, there is continuous watering and discharge from the eye. Nasolacrimal duct obstruction (NLDO) is one of the most important causes of chronic dacryocystitis. The disease is more frequently observed in females (82%) and among patients with abnormalities of the ethmoidal, nasal septum,

and turbinate regions. Occasionally, individuals exhibit familial association with alteration in genetic components, but the exact aetiology remains unknown.¹ Frequent watering and discharge from the lacrimal sac need early management of the underlying cause. The treatment modalities for the management of chronic dacryocystitis with NLDO are: a) Conventional external dacryocystorhinostomy (DCR) surgery, with or without canalicular silicone tube intubation;

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b) Endonasal DCR; c) Trans canalicular Laser DCR; and d) Pneumatic Balloon Dacryocystoplasty. Among these, conventional or external DCR surgery remains the preferred method for managing CDC.² In Dacryocystorhinostomy (DCR), a bridge is created between the medial wall of the lacrimal sac and the ipsilateral nasal mucosa, which makes an opening into the middle meatus for the smooth flow of tears. This process bypasses the NLDO and creates an alternative pathway, thereby alleviating the symptoms of watering. Studies reported that the success rate of DCR without silicone tube intubation ranges from 74% to 91%.³ The following are the common causes of failed DCR: a) Common canalicular stenosis, which accounts for 80% of failures, b) fibrous tissue proliferations around the opening of the lacrimal sac anastomosis, c) Improper positioning of the anastomosis between the lacrimal sac and nasal mucosa (high anastomosis) and d) Suboptimal surgical technique. Dacryocystitis has a high prevalence in India, particularly in rural areas.⁴ The success of DCR surgeries hinges on the effective formation and maintenance of epithelialization of the fistula between the medial wall of the lacrimal sac and the nasal mucosa, facilitating tear outflow. Conversely, fibrosis of the fistulous opening on the bony ostium is the primary reason for failure of DCR surgery.⁵ The use of topical or injected mitomycin-C has been demonstrated to reduce collagen synthesis by fibroblasts. This limits the progression of fibrosis and the formation of scar tissue around the bony ostium, thereby decreasing the likelihood of failure of the surgery.⁶ Topical MMC is used in various surgical procedures to slow the progression of fibrosis, particularly in recurrent pterygium and trabeculectomy surgeries, where scar formation leads to surgical failure.^{7,8} A study by Hu et al. highlighted that the efficacy of mitomycin C (MMC) is greatest at doses ranging from 0.1 to 0.4 mg/ml for 5 minutes, effectively inhibiting the nasal mucosa fibroblasts proliferation by inducing cell cycle arrest. However, concentrations exceeding 0.4 mg/ml for longer than 5 minutes can lead to significant cell death.⁹ This study aims to examine the outcomes of external DCR surgery with silicone tube intubation and intraoperative MMC application (0.3 mg/ml for 5 minutes) to improve postoperative results. The research compares surgical outcomes between two groups based on silicone tube retention duration and the method of MMC application. The goal is to assess the impact of tube placement duration on recovery rates in challenging chronic dacryocystitis cases, particularly those involving silicone tube placement and MMC usage.

2. Materials and Methods

This is a single-centric, prospective, comparative and interventional study conducted at a tertiary care centre over one year, with approval from the institutional ethics committee. The study adheres to the 1975 Declaration of Helsinki protocols. All patients were informed about every aspect of the study, and written consent was taken before enrolment. Patients were referred from private hospitals and

community health centres where primary DCR surgery had been performed. They presented to us with the complaint of watering due to unsuccessful primary surgery, specifically. Sixty patients were included in the study, equally divided into two groups through random sampling. The study had the following inclusion criteria: a) Watery eye with a history of previous DCR surgery, b) Positive regurgitation test on pressure over the lacrimal sac in failed cases of DCR, c) Lacrimal fistula in failed DCR surgery, d) Absence of gross nasal pathology. A comprehensive history of symptoms was recorded, with particular focus on epiphora. Diabetes, hypertension, and haematological disorders were ruled out, and necessary advice was taken from the physician in the presence of systemic anomalies. A thorough ocular examination was conducted to assess the condition of the ocular surface, the height of the tear meniscus, the position of the puncta, any swelling in the sac area and regurgitation of sac content upon applying pressure to the sac area. The tests included the lacrimal syringing test, canalicular probing test, Schirmer test, tear film breakup test and fluorescein dye disappearance test. Routine preoperative investigations were done in all patients, and an ENT opinion was taken to rule out nasal pathology. Patients on oral blood thinners were stopped one week before surgery. In all patients, Re-DCR surgery was performed by a single surgeon. Part preparation was done using a 10% w/v betadine solution. Under all aseptic conditions, a combined solution of 2% Lidocaine and 0.5% Bupivacaine in a 2:1 ratio was injected into the medial canthal area just above the anterior lacrimal crest. Nasal packing was done by a 5cm cotton gauze piece soaked in 25 ml of 4% xylocaine with two ampules of adrenaline injection in the ratio of 1:10000 and left until canalicular silicone tube intubation was done. A 12 mm J-shaped skin incision was made 6 mm medial to the medial canthus, just anterior to the anterior lacrimal crest, starting from the mid-point of the medial palpebral ligament. Subcutaneous tissues were explored, exposing the previously formed osteotomy site. The fibrotic flap was separated from the osteotomy site, and adhesion-lysis was performed to release fibrotic bands and adhesions. The osteotomy site was enlarged to 10x10 mm to ensure adequacy and reduce the likelihood of complications. 0.1ml of Mitomycin 0.3mg/ml was applied to the circumosteal area and over the fistula for 5 minutes to prevent fibrosis, granuloma and scar formation. A silicone tube with a diameter of 0.6 mm was passed through the inferior puncta to the ipsilateral nostril with both free ends tied together. The free margin of the lacrimal sac and nasal mucosa was sutured with a 6-0 Vicryl suture to create a fresh flap bridge. The flap was then secured to the supraosteal soft tissues to prevent collapse of the bridge. The medial palpebral ligament was refixed. Skin was sutured using 6-0 nylon suture, while the muscle tissue was sutured using 6-0 Vicryl suture. A fresh anterior nasal pack was applied at the end of surgery. Postoperatively, both groups received oral broad-spectrum antibiotics and nonsteroidal anti-inflammatory drugs for 5 days, along with topical antibiotics and steroid drops

administered four times daily in tapering doses for 4 weeks. Follow-ups were conducted on postoperative day 1, 1 week, 4 weeks, 6 weeks, 3 months and at the end of 12 months to evaluate the mobility of the silicone tube and patency of the lacrimal tract outflow up to 12 months. Nasal pack was removed on post-operative day 1, skin sutures on 10th day, and the silicon tube at the end of the 4th and 6th week in group A and group B, respectively. On each follow-up, patients were evaluated for symptoms and signs. The successful DCR is defined as no clinically evident epiphora, a Positive Jones 1 test, a Positive fluorescein dye disappearance test, and the patient feeling the topical medication in the throat after instillation of eyedrops at the end of three months. Results are analysed by using SPSS software, which is statistically significant.

3. Results

The study involved 60 patients, with 39 females (65%) and 21 males (35%). Patients were categorised into various age groups, with the maximum number falling within the 31 to 45 age range. The primary etiologies included conjunctivitis, meibomian gland disease (MGD), and sinusitis, with MGD being more prevalent. This study examines the relationships between these conditions and dacryocystitis, including their distribution, frequency, nuances of tube placement procedures and the importance of postoperative care. The results are shown in **Figure 1-Figure 3** and in **Table 1-Table 3**.

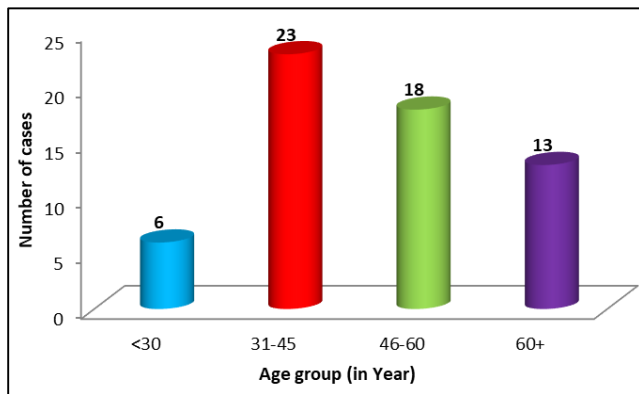


Figure 1: Age distribution of study subjects

Figure 1 presents the patient distribution across various age groups. The largest cohort consists of 23 individuals aged between 31 and 45 years, while the smallest group has 6 patients, who fall within the category of those under 30 years. There are 13 patients aged 60 or older. This highlights a significant distribution of patients in the middle-aged range.

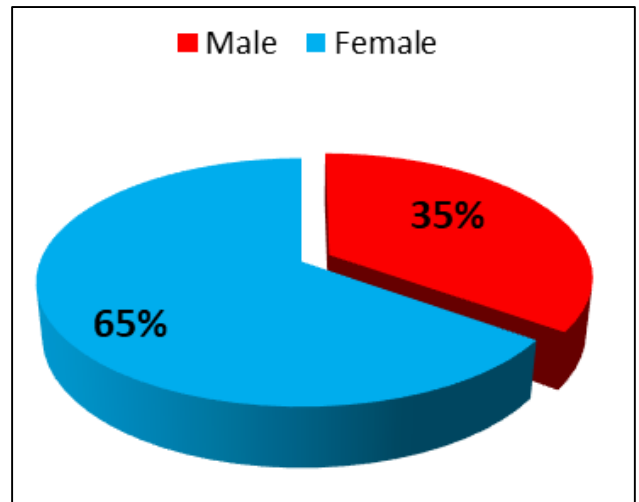


Figure 2: Gender distribution of study subjects

The gender distribution among the study subjects shows female patients comprising 65% while male patients comprise only 35% of all. This representation of female participants highlights an important aspect of our research. (**Figure 2**)



Figure 3: Post operative images of patients, showing mono-canalicular intubation through inferior canaliculus to ensure the patency of tear outflow tract

Table 1: Chronic dacryocystitis is frequently linked with conjunctivitis, meibomian gland disease, and sinusitis. Among these, Meibomian gland disease is most prevalent. This table shows the relationships between these associated conditions and dacryocystitis

Characteristics	Frequency	Percentage
Conjunctivitis		
Present	11	18.3
Absent	49	81.7
MGD		
Present	15	25.0
Absent	45	75.0
Sinusitis		
Present	9	15.0
Absent	51	85.0
Episodes of disease		
1st-time disease	43	71.7
More than once time	17	28.3
Tube Placement Duration		
Remove in 4 weeks	30	50.0
Remove in 6 weeks	30	50.0
Follow up at 12 months.		
Complaint of watering	6	10.0
No complain	54	90.0

In group A, the canalicular silicone tube placement was performed for 4 weeks, while in group B, it was maintained for 6 weeks to compare the surgical outcomes in terms of watering at the end of 1 year. This study reveals an association between CDC and conjunctivitis in 11 (18.3%) cases, Meibomian gland disease in 15 (25%), and sinusitis in 9 (15%) cases. These diseases have either underlying causes of chronic dacryocystitis or may develop as a result of chronic dacryocystitis. 43 (71.7%) cases presented with first episodes of CDC, while 17 (28.3%) cases complained about episodes of acute-on-chronic dacryocystitis. The last follow-up was done at the end of one year to evaluate the final outcome. In group A, 6 patients complained of watering, while in group B, all patients were asymptomatic. **Table 2** shows that the majority of patients of CDC with sinusitis, conjunctivitis, and meibomian gland disease were within the 50-year age group.

Table 2: The analysis shows that factors associated with chronic dacryocystitis include conjunctivitis, MGD and sinusitis, with MGD showing a significant association (P value = 0.01). The majority of patients are female. Following a 12-month postoperative follow-up, most patients are asymptomatic and do not experience any complaints

Characteristics	Age groups (in years)		Chi-square	p-value
	≤50 years	>50years		
Conjunctivitis				
Present	7(63.6)	4(34.4)	0.156	0.69
Absent	28 (57.1)	21 (6.7)		
Meibomian Gland Disease				
Present	13 (86.7)	2 (13.3)	6.606	0.01
Absent	22 (48.9)	23 (51.1)		
Sinusitis				
Present	5 (55.6)	4 (44.4)	0.034	0.85
Absent	30 (58.8)	21 (41.2)		
Episodes of disease				
1st-time disease	23 (53.5)	20 (46.4)	1.466	0.22
More than once time	12 (70.6)	5 (29.4)		
Tube Placement Duration				
Remove in 4 weeks	13 (43.3)	17 (56.7)	4.334	0.03
Remove in 6 weeks	21 (70.0)	9 (30.0)		
Follow up at 12 months.				
Complaint of watering	3 (50.0)	3 (50.0)	0.190	0.66
No complain	32 (59.3)	22 (40.7)		
Gender				
Male	14 (66.7)	7 (33.3)	0.923	0.33
Female	21 (53.8)	18 (46.2)		

Table 3: This table illustrates various factors, including age and sex distribution. A significant difference (p-value 0.01) was observed when comparing the results of postoperative watering between the two groups following silicon tube explantation. The percentage association between chronic dacryocystitis and other related conditions is also seen

Characteristics	Follow up at 12 months		Total (%)	Chi-square/Fisher's Exact test	p-value
	Watering present (%)	Watering absent (%)			
Group A	3(10.0)	27(90.0)	30 (100.0)	3.334	0.01
Group B	0 (0.0)	30 (100.0)	30 (100.0)		
MGD					
Present	1 (6.7)	14 (93.3)	15 (100.0)	0.247	0.98
Absent	5 (11.1)	40 (88.9)	45 (100.0)		
Sinusitis					
Present	1 (11.1)	8 (88.9)	9 (100.0)	0.015	0.99
Absent	5 (9.8)	46 (90.2)	51 (100.0)		
Episodes of disease					
1st-time disease	5 (11.6)	38 (88.4)	43 (100.0)	1.466	0.22
More than once time	1 (5.9)	16 (94.1)	17 (100.0)		
Tube Placement Duration					
Remove in 4 weeks	3 (10.0)	27 (90.0)	30 (100.0)	3.334	0.01
Remove in 6 weeks	0 (0.0)	30 (100.0)	30 (100.0)		
Gender					
Male	3 (14.3)	18 (85.7)	21 (100.0)	0.923	0.33
Female	3 (7.7)	36 (92.3)	39 (100.0)		
Age group (in years)					
<40	3 (13.6)	19 (86.4)	22 (100.0)	0.510	0.65
>40	3 (7.9)	35 (92.1)	38 (100.0)		

The success rate of external dacryocystorhinostomy with silicone tube intubation was 90% in Group A and 100% in Group B. On comparison between the groups, stenting the lacrimal anastomosis effectively eliminates the most common cause of failure due to blockage at the level of the common canaliculi. The success rate markedly improves when a stent is used. It was observed that the optimal timeframe for maintaining the tube in position was four weeks for group A and six weeks for group B. By this stage, the anastomosis, the surgical connection formed between the tear drainage system and the nasal cavity, usually heals completely. Extending its use beyond this period may increase the risk of complications, such as punctal erosion and damage to the delicate structures of the lower canaliculus, requiring further interventions.

4. Discussion

The external dacryocystorhinostomy with silicone tube intubation is widely recognised as the most effective method for treating post-traumatic or failed cases of CDC that have not responded to prior interventions. The age distribution shows a significant number of patients in the middle-aged group. The gender distribution reveals a distinct trend, with female patients comprising 65% of the cohort and male patients 35%. Females are more prone to develop chronic dacryocystitis, probably because of the narrowness of the

nasolacrimal canal. This method favours patients suffering from persistent epiphora, ensuring both restoration of normal tear drainage and relief from associated symptoms.¹⁰ Management of unsuccessful cases of dacryocystitis necessitates a surgeon's expertise, the application of appropriate surgical techniques, minimal handling of tissue, and a focused approach for the removal of fibrous tissue. In DCR, a connection is made between the lacrimal sac and the nasal mucosa for the smooth passage of tears into the medial meatus. Surgeons observe variations in the process of mucosal bridge formation. This technique can significantly reduce the likelihood of postoperative complications such as fibrosis, granuloma formation, and sump syndrome. The success rates of External DCR without canalicular STI range from 75% to 98%, based on various studies.¹¹ In this study, the success rate of external DCR with silicone tube intubation was 90% in group A, while group B had a 100% success rate. The significant difference ($P = 0.01$) indicates that a 6-week duration (Group B) is optimal for the highest success rate, especially in failed cases. Earlier tube removal leads to suboptimal outcomes, while extending beyond 6 weeks does not provide additional benefits. STI is a vital step in DCR surgery, creating a new tear drainage pathway and thus alleviating symptoms.¹² The common causes of post-intubation failure are common canalicular stenosis, inadequate site & size of osteotomy, scarring of osteotomy, fibrous closure of sac mucosa anastomosis, early removal of

tube, inadequate osteotomy, poor flap suspension, sump syndrome, high suspension, poor surgical procedure, injury of ethmoidal air cell and middle turbinate injury, nasal polyposis, active systemic disease, concha bullosa and rarely infection of surgical site.¹³⁻¹⁸ Fibrous tissue growth over the bony ostium is the most common cause of failed DCR surgery in our study. A study on DCR without stenting found that the main reason for failure is common canaliculus obstruction, which is caused by fibrous soft tissue proliferation in the early postoperative phase and hinders long-term connection between the sac and the nasal mucosa.¹⁹ A similar study shows that the closure of the common canaliculus opening is typically associated with the accumulation of fibrin and other inflammatory debris, which can lead to early fibrosis. Factors such as surgical trauma and unnecessary probing during procedures may also contribute to the condition.²⁰ To prevent this, the use of a stent in the lacrimal passage is highly recommended. Suitable options for stenting include: a) silicone tubes, b) fine rubber catheters, c) fine polyethylene tubes, and d) polyamide suture material. These solutions can help maintain patency and promote better outcomes for patients.^{21,22} Amongst these, silicone tubes are the most preferred due to their remarkable properties of being chemically inert, ensuring safety and versatility. Additionally, its flexibility allows for easy insertion and manipulation, making it an ideal choice.^{23,24} During repeat DCR surgery, the surgeon must assess potential complications and the risk of future failures. The altered anatomy from the initial surgery, along with granulation tissue and fibrosis at the site, can complicate the procedure. Precision and foresight are crucial for navigating these challenges.²⁵ DCR combined with silicone tube intubation (STI) remains the gold standard for treating complicated CDC with NLDO. Current literature highlights that the osteotomy must have a minimum anteroposterior diameter of 15 mm to enable secure suturing of the lacrimal sac wall to the nasal cavity and reduce the risk of canaliculus obstruction from scar tissue. This approach improves the chances of maintaining the surgical opening's patency and overall outcomes. According to Welham et al., the success rate for redo DCR surgery is 85%, which can increase significantly with silicone intubation and intraoperative mitomycin-C application.²⁶ Katuwa et al. reported that the overall success rate of external dacryocystorhinostomy was an impressive 89.2%, which involved an average follow-up period of 13.5 months with a standard deviation of 2.2 months. This highlights the effectiveness of the procedure in addressing NLDO, reflecting favourable outcomes among patients who underwent this surgical intervention.²⁷ A systematic review examining the outcomes of DCR in adults indicates that the success rates for external DCR (EX-DCR) can range from 65% to an impressive 100%. In comparison, the endoscopic DCR (EN-DCR) achieves success rates ranging from 84% to 94%. These findings highlight DCR as both a relatively safe and effective intervention for addressing NLDO. The outcomes for both EN-DCR and EX-DCR are quite

comparable, highlighting them as treatment options in the management of this condition.²⁸ A recent study showed that endonasal dacryocystorhinostomy had success rates at par with traditional external DCR while offering the advantages of a shorter operative time and the absence of visible cutaneous scarring. However, this approach is not without its challenges; it presents a steep learning curve for surgeons and is associated with higher costs.²⁹ Talpur et al. reported the success rate of 98.14% in 54 cases of DCR surgery.³⁰ When comparing the outcomes of DCR surgery conducted with versus without canaliculus intubation, a sequential meta-analysis revealed that DCR with intubation yielded a significantly higher success rate.³¹ Additionally, a meta-analysis of randomised controlled trials assessing DCR, both with and without silicone intubation, indicated a statistically significant improvement of 5% in the success rate when intubation was employed.³² Advani et al. reported a 95% success rate in 40 dacryocystorhinostomies with silicone intubation.³³ In the current case study, a silicone tube was inserted alongside the application of MMC over the mucosal bridge, resulting in a regression of fibrosis at the surgical site. A case study conducted by Ari et al. investigated the use of 0.2% mitomycin C in external dacryocystorhinostomy surgery for 30 minutes, comparing it to a control group. The findings revealed a remarkable response in the mitomycin C group, with the comparative analysis demonstrating statistically significant results in failed DCR cases compared to this study.³⁴ Liao et al. investigated the effect of 0.2% mitomycin C (MMC) administered for 30 minutes in a study involving 44 patients undergoing external dacryocystorhinostomy. When the outcomes were compared to a control group of 44 patients, the results measured at a minimum of 10 months post-surgery showed a success rate of 96% in the MMC group, compared to 89% in the control group. This result was statistically significant, with a P-value of 0.005.³⁵ A study conducted by Deka et al. involved allocating 20 patients into three groups. Group 1 served as the control, while Group 2 received mitomycin C (MMC) at a concentration of 0.05 mg/ml for 2 minutes, and Group 3 received a concentration of 0.4 mg/ml for the same duration. The post-operative results for each group were 90%, 95%, and 95%, respectively.³⁶ An analytical case study was conducted by Jawed et al. on external dacryocystorhinostomy, involving 30 patients who underwent the procedure using 0.2% MMC for 30 minutes, in contrast to a control group of 43 patients. The comparative data between the two groups revealed a statistically significant outcome, demonstrating a success rate of 97%.³⁷ The present study is also supported by You & Fang, which uses MMC in DCR surgery and shows significant improvement in post-operative watering in the MMC group when compared with the control.³⁸ Silicone intubation, while effective postoperatively, is associated with several short-term complications, including conjunctival irritation, punctal and canaliculus lacerations, tube loss, and foreign body sensation.^{39,40} It may also contribute to nasal granuloma

formation and potentially increase failure rates in external dacryocystorhinostomy. Tube prolapse occurs in about 2.5% of cases.⁴¹ Additionally, STI raises surgical costs by approximately 20-25%.⁴² The current study found no long-term tube-related complications or granulomas after external dacryocystorhinostomy with STI and mitomycin C (MMC) application. It is the first prospective investigation comparing postoperative outcomes based on the intraoperative use of MMC in the mucosal flap and circumosteal area. The research highlights the importance of timing silicone tube removal for achieving higher success rates, even in cases of dacryocystitis that have been previously unsuccessful. However, it has limitations, such as anatomical variations among patients with failed cases and concerns about long-term outcomes. While patients were monitored for up to one year, further research with follow-ups beyond three to five years is needed to confirm these findings.

5. Conclusion

External dacryocystorhinostomy (DCR) is generally recognised as an effective and safe treatment for chronic dacryocystitis. However, there are exceptional cases, such as failed DCR and post-traumatic dacryocystitis, which may necessitate an alternative approach. One such option is performing external DCR surgery with silicone tube intubation to achieve successful outcomes. Several factors can contribute to the failure of sac surgery, including common canalicular stenosis, inappropriate site, and size of the osteotomy, scarring of the osteotomy, fibrous closure of the sac mucosa anastomosis, premature removal of the tube, suboptimal surgical techniques, sump syndrome, the presence of intervening ethmoid sinus air cells, interference from the middle turbinate, nasal polyposis, active systemic diseases, and, although rarely, surgical site infections. In the current study, focusing on external DCR surgery with canalicular silicone tube intubation alongside an intraoperative mucosal flap and circumosteal application of Mitomycin-C, excellent results were observed, leading to a patent outflow tract. Post-operative outcomes were significantly improved in patients from whom the silicone tube was removed at the sixth week following surgery.

6. Clinical Significance of the Study

This study compares the postoperative outcomes of failed cases of dacryocystitis, providing a crucial clinical benchmark for the optimal duration of silicone tube intubation. Additionally, it highlights that the use of silicone tube intubation combined with Mitomycin-C in these challenging cases yields excellent results.

7. Statement of Ethics

Verbal & written consent were obtained to publish case details, including the clinical photograph.

8. Source of Funding

None.

9. Conflicts of Interest

The author states no conflicts of interest. All authors agree with the publication of this manuscript.

10. Disclosure Statement

The authors declare that they have no financial disclosures.

11. Authorisation for the use of Human Subjects

This clinical research complies with the standards of the Ethics Committee of the Dr KNS Memorial Institute of Medical Sciences, Lucknow, India, and adheres to the principles of the

12. Author Contribution

Dr Niraj Kumar Yadav played a key role in conceptualising the study, designing the research, interpreting data, and drafting the initial manuscript. Dr Deepti Joshi and Dr Priyanshi Priya were responsible for data collection, managing patient care, conducting statistical analyses, contributing to the methodology, and aiding in the interpretation of the results. Dr Apjit Kaur provided a critical review of the manuscript, contributed to revisions, and ensured the integrity of the intellectual content. Dr A.K. Srivastava supervised the entire project, provided essential resources, guided the manuscript preparation, and granted final approval for publication. All authors have read and approved the final manuscript and agreed to be accountable for all aspects of the work.

13. Ethical Approval

Ethical No.: IEC/2024/70.

14. Acknowledgements

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