

## Comparative study of Endonasal Dacryocystorhinostomy with Silicone or polypropylene stents using Mitomycin-C

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### Abstract

**Background** Endoscopic dacryocystorhinostomy (EDCR) is a minimally invasive surgery used in the treatment of nasolacrimal duct obstruction and chronic dacryocystitis. It involves fistulization of the lacrimal sac into the nasal cavity. **Objective** The aim was to compare the efficacy and safety of endoscopic dacryocystorhinostomy (En-DCR) with Silicone and polypropylene stents for treatment of primary nasolacrimal ductal obstructions with and without using of MMC. **Patients and methods** a prospective randomized clinical study involved forty patients with epiphora due to of primary acquired nasolacrimal duct obstruction (PANLDO) attending to the outpatient clinic of departments of Otorhinolaryngology and Ophthalmology of Benha University Hospitals at the period from January ٢٠١٧ to December ٢٠١٩. Patients were allocated into two groups. Group (١) Includes ٢٠ patients treated by dacryocystorhinostomy (DCR) with Silicone stent. Group (٢) Includes ٢٠ patients treated by dacryocystorhinostomy (DCR) with polypropylene (Prolene) stent. Each group subdivided into two subgroups each of ١٠ patients (A: used MMC intraoperatively and B: without use of MMC). Ophthalmology and otolaryngology clinics evaluated the patients preoperatively with endoscopes, lacrimal system syringing and dacryocystography. The success of the stents was evaluated after surgery with symptom relief and ostial patency. **Results** The overall success rate of the En-DCR (as regard to symptom relief and observed duct patency) was ٩٥% and ٨٠% in silicone and prolene groups, respectively. The efficacy of the procedures was slightly increased with use of MMC. Prolene was found to be related with higher incidence of complications. **Conclusion** The results of our study suggest that efficacy, defined as anatomic and functional success, is higher for silicone than Prolene stents. Also the intraoperative use of MMC is safe and improves the success rate of En-DCR.

**Keywords:** Endoscopic, dacryocystorhinostomy, Nasolacrimal duct, Prolene, Silicone, Mitomycin C.

### ١.Introduction

Primary acquired nasolacrimal duct obstruction (PANDO) is the most common clinical syndrome of acquired nasolacrimal duct obstruction in adults. Patients may present with symptoms of chronic epiphora, conjunctivitis, and low-grade infections or with acute dacryocystitis. This clinical syndrome is most common in elderly white women (١).

Endoscopic dacryocystorhinostomy (EDCR) is a minimally invasive surgery used in the treatment of nasolacrimal duct obstruction and chronic dacryocystitis. It involves fistulization of the lacrimal sac into the nasal cavity. In addition to being minimally invasive, it has advantages such that its short operation duration, little bleeding, not leaving an external scar, not causing injury of medial chancel anatomy or lacrimal sac pump dysfunction (٢,٣).

Different types of stent materials have been used to prevent the obliteration of the surgically created rhinostomy site either in a selective or nonselective manner (٤). A stent should be reliable, readily available, easily applicable, and preferably cheap. The efficacy of the previously reported materials has not been validated in prospective controlled trials

Mitomycin-C is a systemic chemotherapeutic agent derived from *Streptomyces caespitosus* that inhibits the synthesis of DNA, cellular RNA, and protein

by inhibiting the synthesis of collagen by fibroblasts (٥).

So, we conducted this prospective randomized controlled trial to compare the clinical efficacy and outcomes of silicone and polypropylene for stenting in endoscopic dacryocystorhinostomy with and without MMC.

### ٢.Patients and Methods

a hospital-based prospective interventional study involved forty patients with epiphora due to of primary acquired nasolacrimal duct obstruction (PANLDO) attending to the outpatient clinic of departments of Otorhinolaryngology and Ophthalmology of Benha University Hospitals at the period from January ٢٠١٧ to December ٢٠١٩. Patients were allocated into two groups. Group (١) Includes ٢٠ patients treated by dacryocystorhinostomy (DCR) with Silicone stent. Group (٢) Includes ٢٠ patients treated by dacryocystorhinostomy (DCR) with polypropylene (Prolene) stent. Each group subdivided into two subgroups each of ١٠ patients (A: used MMC postoperatively and B: without use of MMC).

Patients older than ١٨ years of age were eligible. The indication for surgery was primary acquired NLDO with epiphora. Exclusion criteria were bleeding disorders and any history of ophthalmic (including previous DCR) or nasal surgery. Patients with traumatic, neoplastic, mechanical (i.e., foreign

body, external compression), or presaccal obstruction and nasolacrimal fistulization.

Initially, all patients underwent Ophthalmology and otolaryngology evaluation, including lacrimal system syringing and dacryocystography. Patients with a confirmed blockage of the lacrimal ductal system were included. Endoscopic evaluation of the nose, paranasal sinuses, and nasopharynx was performed to rule out any concomitant nasal pathology that may have interfered with the surgery.

All operative and non-operative procedures were explained in full details to the patients, who signed informed consents and accepted to be involved in the study. In addition, approval from the Ethical Committee of ENT Department, Benha University, was obtained.

### Operative procedure

Advocate placement of a Bowman lacrimal probe into the lacrimal sac to guide location of the ostium (**figure ۱**). Hopkins rigid endoscope attached to a camera is then placed to view the field. A sickle knife is used to incise the nasal mucosa anterior to the middle turbinate. This incision is carried out vertically or curvilinear fashion down to the bone (**figure ۲**). Approximately ۱-۱.۵ cm of nasal mucosa is removed with Blakesley forceps.

Once the lacrimal fossa is exposed, the osteotomy is formed initially by fracturing the thin lacrimal bone using Kerrsuns forceps. Enlargement of the opening more anteriorly is performed to remove the thicker bone of the maxilla.

Once the lacrimal sac mucosa is encountered after creation of the bony osteotomy, the lacrimal sac is tented into the surgical site either with a light pipe, lacrimal probe or lacrimal cannula. Incision of the medial wall of the sac is performed with ۱۱-blade and the mucosal opening enlarged with angled endoscopic forceps.

Once the ostium is formed, bicanalicular intubation with Silicone or polypropylene stents is placed (**figure ۳**). The application of MMC to the nasal and lacrimal sac mucosal surfaces used a cotton tip applicator soaked in MMC applied under the nasal and lacrimal flaps for the desired duration followed by copious irrigation with normal saline. We used ۰.۰۳% solution of MMC in a ۲ml syringe with a ۲۶-gauge lacrimal cannula to irrigate the newly trephined canaliculus via the punctum into the nose, with the stents in place. Nasal packing is effective for hemostasis.

The patients were followed-up for period of ۶ months for early post-operative and late complications.

If nasal packing is placed intraoperative, it should be removed at the post-operative day-one visit. Systemic antibiotics are recommended for ۷-۱۰ days.

Each postoperative visit included debridement of crusting around ostium, lacrimal irrigation, and inspection of the surgical site with nasal endoscopy. Stents advocate removal after ۶ to ۸ weeks.

**Data management and statistical analysis** were done by using SPSS version ۲۲ medical statistics software and Microsoft Excel v. ۲۰۱۳ (SPSS Inc., Chicago, Illinois, USA). Descriptive statistics were calculated in the form of mean  $\pm$  SD for quantitative data and frequency and distribution for qualitative data.

In the statistical comparison between the different groups, the significance of difference was tested by using analysis of variance test (P value) to compare mean of more than two groups of quantitative data or Fisher's exact test for intergroup comparison of categorical data ( $P < ۰.۰۵$  was considered statistically significant).

### ۲. Results

Demographic criteria of patients are shown in **Table ۱**. Age and sex distribution were not statistically different among the groups.

As regard **Munk Scale for epiphora grading (figure ۴)**, the overall improvement was ۱۹ patients (۹۵%) and ۱۶ patients (۸۰%) in silicone and prolene groups, respectively. A very good improvement (grade ۱) was achieved in ۱۴ patient (۷۰%) and ۱۱ patients (۵۵%) of silicone and prolene groups, respectively. Good improvement (grade ۲) was achieved in ۳ patients (۱۵%) and ۲ patients (۱۰%) of silicone and prolene groups, respectively. Partial improvement (grade ۳) was observed in ۲ patients ۱۰% and ۳ patients ۱۵% of silicone and prolene groups, respectively. However, failure (grade ۴) was observed in only ۱ patient (۵%) and ۴ patients (۲۰%) of silicone and prolene groups, respectively. They all showed statistically significant difference in comparison between the two groups ( $P < ۰.۰۵$ ) **Table ۲**.

As regard to effect of MMC application on success rates of En-DCR in silicone group: there is very good improvement (grade ۱) achieved in ۸ patients (۸۰%) and ۶ patients (۶۰%) of patients with and without MMC, respectively with statistically significant difference ( $P = ۰.۰۱۷$ ). Good improvement (grade ۲) was achieved in ۲ patients (۲۰%) of both with and without MMC

application. Partial improvement (grade ٣) was observed in ١ patient (١٠٪) of patients without MMC only. All patients (١٠٠٪) had recovery by using MMC and ٩٠٪ had recovery in patients operated without MMC application with statistically insignificant significant difference in comparison between with and without MMC ( $P > ٠.٠٥$ ) **table ٤**.

Also, the effect of MMC application on success rates of En-DCR in prolene group: there is very good improvement (grade ١) achieved in ٧ patients (٧٠٪) and ٣ patients (٣٠٪) of patients with and without MMC, respectively with statistically significant difference ( $P = ٠.٠٢٢$ ). Good improvement (grade ٢) was achieved in ٧ patients (٧٠٪) and ١ patient (١٠٪) of both with and without MMC application, respectively ( $p = ٠.٠٣٤$ ). Partial improvement (grade ٣) was observed in ١ patient (١٠٪) of patients without MMC only ( $p = ٠.٠٢٨$ ). The overall success was achieved in ٩ patients (٩٠٪) and ٧ patients (٧٠٪) of patients with and without MMC, respectively with statistically highly significant difference in comparison between with and without MMC ( $P = ٠.٠٠١$ ). However, failure (grade ٥) was observed in ١ patient (١٠٪) and ٣ patients (٣٠٪) in patients with and without MMC application, respectively, they showed a statistically significant difference ( $P = ٠.٠٣٧$ ) **table ٥**.

As regard to postoperative complications in silicone group: postoperative hemorrhage was observed in ١ patient (١٠٪) and ٧ patients (٧٠٪) of patients with and without MMC, respectively with statistically significant difference ( $P = ٠.٠٣٤$ ). While adhesions were observed in ١ patient (١٠٪) of patients without MMC. Granulation was observed in ٧ patients (٧٠٪) of patients without MMC. Complete tube closure was observed in ١ patient (١٠٪) of patients without MMC and Fibrosis around the tube was observed in ٧ patient (٧٠٪) of patients without MMC. They all had statistically insignificant difference in comparison between patients with and without MMC ( $P > ٠.٠٥$ ) **table ٦**.

**Finally** postoperative complications in prolene group: postoperative hemorrhage was observed in ٧ patients (٧٠٪) of patients with and without MMC with statistically insignificant difference ( $P > ٠.٠٥$ ). Wall adhesion was observed in ٣ patients (٣٠٪) of patients without MMC only with statistically significant difference ( $P = ٠.٠٢٨$ ). Granulations was observed in ١ patient (١٠٪) and ٤ patients (٤٠٪) of patients with and without MMC, respectively with statistically significant difference ( $P = ٠.٠٣٢$ ). Conjunctivitis, Canalicular laceration, and infection were

observed in ١ patient (١٠٪) of both patients with and without MMC in each complication with statistically insignificant difference ( $P > ٠.٠٥$ ).

Also, Punctal slitting was observed in ١ patient (١٠٪) of patients without MMC ( $P > ٠.٠٥$ ). Complete tube closure was observed in ٣ patients (٣٠٪) of patients without MMC with statistically significant difference ( $P = ٠.٠٢٨$ ) and Fibrosis around the tube was observed in ٤ patients (٤٠٪) of patients without MMC with statistically significant difference in comparison between patients with and without MMC ( $P = ٠.٠٠٧$ ) **table ٧**.

#### ٤. Discussion

In this study, we compare the clinical efficacy, safety and outcomes of silicone and polypropylene for stenting in endoscopic dacryocystorhinostomy with and without MMC.

Our study showed high success rate and low failure rate with group ١ (silicone stenting), with statistically significant difference in comparison between the two groups ( $P < ٠.٠٥$ ).

These results coincide with **Viswanatha and Vijayashree** (١٠) who reported that the success rate with polypropylene stenting in endoscopic DCR procedures was ٨٠٪ and success rate with silicone tube stenting was ٩٠٪, failure reported in one patient (١٠٪) in both groups.

Our results not coincide with **Okuyucu et al.** (٨) Who reported that There were no significant differences between the silicone and Prolene ( $p = ٠.٧١٨$ )

The overall complication rate was significantly higher in group ٢ (prolene stenting). However, orbital complications including orbital injury, Conjunctivitis, Punctal slitting and Canalicular laceration were insignificantly higher in prolene than silicon stenting.

These result not coincide with **Okuyucu et al.** (٨) who compare efficacy of Silicone, Polypropylene, and T-tube Stents in Endoscopic Dacryocystorhinostomy and concluded that the overall complication rate was not significantly different among the stents ( $P = ٠.٢٠$ ). However, Prolene had significantly higher orbital complications than other stent materials ( $P = ٠.٠٠٢$ ).

Mitomycin-C (MMC) is currently in use as an adjuvant treatment to improve success rates in En-DCR. The procedure is well-recognized surgical techniques and is associated with very high success rates. MMC is a systemic chemotherapeutic agent derived from *Streptomyces caespitosus* that inhibits the synthesis of DNA, cellular RNA, and protein

by inhibiting the synthesis of collagen by fibroblasts (۱۱).

While the use of MMC has been increasingly popular in DCR, there is a lack of consensus regarding multiple variables; namely the dosage, the route of delivery/application, the time of exposure and subsequently what role each of these variables plays in the final outcome of the surgery. Ever since the intraoperative use of MMC has been a part of DCR, various studies have put forth their data with varying concentrations of MMC (۱۲).

In Our study there are significant improvement on success rates of En-DCR with intraoperative MMC application in both silicone and prolene groups.

These results were in agreement with **Sousa et al.** (۱۳) in their meta-analysis indicates a slightly higher chance of success of silicone tube En-DCR with the intraoperative use of MMC. The analysis of the isolated studies revealed a significant difference favoring the use of MMC in just a study involving En-DCR.

Another met analysis done by **Qian et al.** (۱۴) showed MMC can improve the results of DCR with or without stents.

**Cheng et al.**(۱۵) in their recently published meta-analysis of endoscopic DCRs to compare the clinical results with and without MMC concluded that in addition to being safe, MMC helps reduce the closure rate of the osteotomy and enhance the success rate after both primary and revision endonasal DCR.

**Feng et al.** (۱۶) reported in their meta-analysis of primary DCR with and without MMC that there was a significantly higher success rate in the MMC group in comparison with the control group. The meta-analysis also found that intraoperative MMC application seems to be a safe adjuvant and helps in maintaining the patency of the ostium.

However, these results not coincide with Ghosh et al. (۱۷) who concluded that Intraoperative Mitomycin C application does not alter the long-term results in endoscopic DCR. A properly and adequately performed surgery is more vital for successful result.

#### •.Conclusion And Recommendations

The efficacy, defined as anatomic and functional success, is higher for silicone than Prolene stents with minimal post-operative complications in silicon group. Also the intraoperative use of MMC is safe and improves the success rate of En-DCR significantly.

Although the silicone outcome considered better than prolene, polypropylene is cheaper

and it is readily available in all operation theaters. They added that it is a good alternative to silicone stents.

We recommend more studies comparing other types of stent with En-DCR, In addition, we recommend doing these studies on larger scales and longer periods of follow-up.

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