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## **Treatment of recurrent nasolacrimal duct obstructions with balloon-expandable metallic stents: results of early experience.**

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# Treatment of Recurrent Nasolacrimal Duct Obstructions with Balloon-Expandable Metallic Stents: Results of Early Experience

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**PURPOSE:** To evaluate the efficacy of Palmaz balloon-expandable metallic stents for the maintenance of luminal patency in the treatment of recurrent nasolacrimal duct obstructions after failed transluminal balloon dilatation. **METHODS:** Metallic stents were implanted in the nasolacrimal duct of four patients with recurrent epiphora. All the patients had already undergone transluminal balloon dilatation of the nasolacrimal duct with no or only temporary improvement. In two eyes, 9.5-mm-long Palmaz stents were used; in the other two eyes, 20-mm-long articulated-design Palmaz stents were placed under digital fluoroscopic monitoring. In each case, the upper tip protruded slightly into the lacrimal sac and the lower end was positioned inside the nasolacrimal duct. **RESULTS:** The stents were placed accurately in all cases, and no complications were observed. After stent placement, all patients had complete resolution of epiphora. During the follow-up period of 10 months, although complete obstruction did not occur in any case, complete resolution of epiphora was maintained only in one of four eyes. In two eyes, improvement was remarkable. In one eye with partial improvement, intrastent balloon dilatation was performed. **CONCLUSION:** Treatment of recurrent nasolacrimal duct obstructions with balloon-expandable metallic stents is a noninvasive, efficient, and safe outpatient procedure that may be an alternative to surgery as a means for managing epiphora.

**Index terms:** Eyes, lacrimal gland and duct; Interventional instruments, stents

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Epiphora, the inadequate drainage of tears through the nasolacrimal drainage system caused by obstruction of the nasolacrimal outflow, is a common problem in ophthalmologic practice and can cause considerable annoyance for patients (1–3).

Dacryocystorhinostomy has a high success rate (79% to 99%) and is the standard surgical treatment of epiphora resulting from obstructions of the nasolacrimal sac and duct. However, this is an invasive surgical procedure and is usually performed on an inpatient basis under general anesthesia. In addition, it may leave a permanent facial scar, even when performed by

experienced hands (1–10). Failure of dacryocystorhinostomy can be caused either by delayed obstruction of the surgical anastomosis site due to granuloma formation, fibrotic scarring, and osteogenic activity or by secondary stenosis of the canalicular system. Alternative, minimally invasive treatment methods are currently under investigation.

Transluminal dilatation of the nasolacrimal drainage system under fluoroscopic guidance for the nonsurgical treatment of epiphora was first performed by the introduction of probes from the superior canaliculus (11). Angioplasty balloon catheters were successfully used to dilate the lacrimal sac and anastomotic obstructions of the nasal mucosa in patients in whom dacryocystorhinostomy had failed as well as in patients who had not had prior lacrimal surgery. The procedure has been reported as safe, simple, and effective, and has been termed *balloon dacryocystoplasty* (6–9, 12, 13). Recently, self-expandable Gianturco-style metallic stents and plastic stents used in the treatment of obstruc-

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tions of the nasolacrimal drainage system have been reported to maintain patency of this mucosa-lined tract (14, 15).

The purpose of our study was to evaluate the effectiveness of commercially available balloon-expandable metallic stents for the maintenance of luminal patency in the treatment of recurrent nasolacrimal duct obstructions after failed transluminal balloon dilatation. We report the preliminary results of balloon-expandable metallic stent implantation in four patients who had no or only temporary improvement with balloon dacryocystoplasty.

## Materials and Methods

Balloon-expandable metallic stents were implanted in four patients who had idiopathic severe recurrent epiphora. Each patient had already undergone transluminal balloon dilatation of the nasolacrimal drainage system without or with only temporary improvement. All patients had a symptom-free period of 1 to 3 weeks after balloon dacryocystoplasty. All patients were women and ranged in age from 29 to 58 years (mean, 41.5 years).

We performed digital subtraction dacryocystography to determine the site and length of the reobstruction before stent placement, and compared the findings with the dacryocystograms obtained before and after the initial balloon dacryocystoplasty. Subtraction dacryocystography before the procedure revealed complete obstruction in two eyes and incomplete obstruction in the other two. The site of the obstruction was at the junction between the nasolacrimal sac and the nasolacrimal duct in two eyes and in the nasolacrimal duct in the other two. Epiphora was evaluated subjectively to assess clinical improvement and graded on a scale originally described by Munk et al (7) (0: no epiphora, 1: epiphora requiring dabbling less than twice a day, 2: epiphora requiring dabbling 2 to 4 times a day, 3: epiphora requiring dabbling 5 to 10 times a day, 4: epiphora requiring dabbling more than 10 times a day, 5: constant tearing). Before stent placement, all patients had constant tearing (grade 5 epiphora).

Medium-type Palmaz balloon-expandable stents (Johnson & Johnson Interventional Systems Co, Warren, NJ) consist of a slotted, seamless stainless steel tube with a wall thickness of 0.010 cm (0.004 in) (16). The commercially available articulated design (Palmaz-Schatz stent) consists of two 9.5-mm slotted tubes connected by a 1-mm central bridging strut (17). The unexpanded length of the stent is 20 mm. Placement of the stent into the nasolacrimal duct is done with a special delivery system that was originally developed for coronary artery stenting. The 5F delivery system consists of an angioplasty balloon catheter and a retrievable plastic protective sheath (17). The balloon of the delivery system is 2 cm long and 4 mm in diameter.

The procedure, with its potential risks and benefits, was explained and a signed informed consent was obtained from each patient. All the patients were familiar with the procedure, as they had already undergone balloon dacryocystoplasty. The site and length of the obstruction was determined on the basis of the previous and present dacryocystograms, and stent placement was attempted at the same sitting.

In our procedure, topical 0.4% benoxinate hydrochloride was used to anesthetize the conjunctival sac. Topical 2% lidocaine and 0.5% phenylephrine spray was delivered to the nasal mucosa through a nebulizer. Neither infiltration anesthesia nor oral sedation was used in any of our patients.

After topical anesthesia, a 20-gauge soft plastic arterial sheath fitted over a stump-guiding metal probe was introduced through the superior canaliculus into the nasolacrimal apparatus. The metal probe was then removed and contrast medium was injected through the sheath to confirm the intraluminal position and to obtain the digital subtraction fluoroscopic images. A 0.041-cm (0.016-in) steerable guidewire (Stubbie, Target Therapeutics, Fremont, Calif) with a flexible tip angled at 45° was introduced through this plastic sheath, gently manipulated to cross the site of obstruction, advanced into the inferior meatus of the nasal cavity, and brought forward through the external nare. The introducer sheath was removed superiorly from the canaliculus. The guidewire has a one-piece steel core construction providing smooth torque transmission and superior proximal stiffness with an atraumatic, flexible, shapeable platinum tip.

The stent was crimp-mounted on the angioplasty balloon catheter and covered with the protective sheath. The delivery system was passed retrogradely over the guidewire through the nasal aperture to the site of obstruction in the nasolacrimal drainage system. Digital subtraction fluoroscopic (road-mapping) or high-resolution digital fluoroscopic monitoring in lateral projection was used during the passage of the guidewire through the nasolacrimal drainage system and for exact positioning of the stent at the obstruction site. After the stent was positioned at the desired level, the protective sheath was withdrawn and the stent was expanded and released by inflation of the balloon with 50% water-soluble contrast medium (Fig 1). Following the expansion and deployment of the stent, the delivery system was pulled out inferiorly, and the guidewire was pulled out superiorly.

In two eyes, with diffuse nasolacrimal duct obstruction, 20-mm-long articulated stents were placed with the upper tip slightly protruding into the dilated lacrimal sac inferior to the common canalicular opening and the lower end just inside the inferior opening of the nasolacrimal duct (Figs 1 and 2). In the other two eyes, with segmental obstruction at the junction between the lacrimal sac and the lacrimal duct, 9.5-mm-long stents were used with the upper tip slightly protruding into the dilated lacrimal sac and the lower end inside the proximal nasolacrimal duct (Figs 3 and 4). These stents were half the length of the original

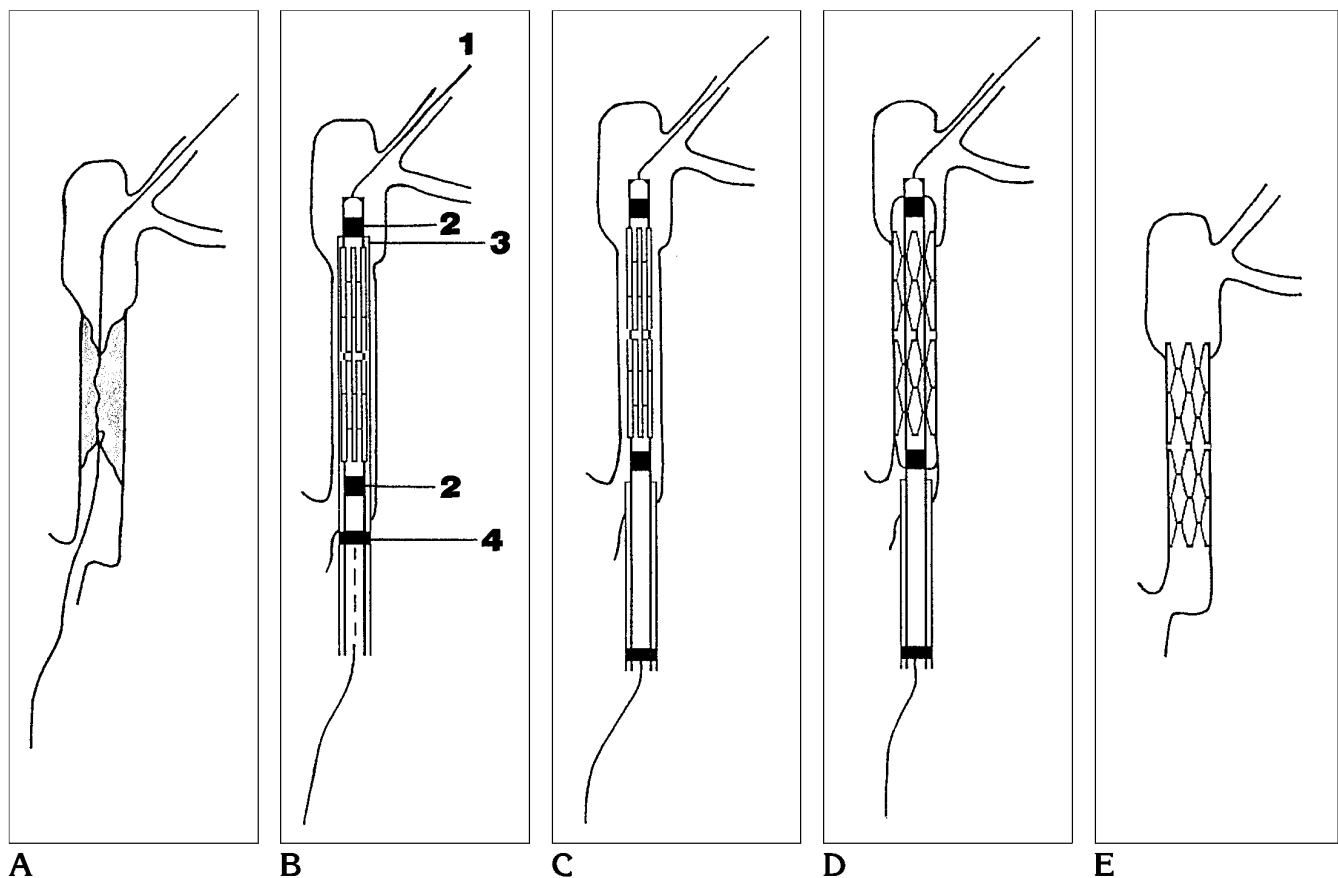


Fig 1. Diagrams show placement of a balloon-expandable metallic stent (articulated design) for the treatment of recurrent diffuse nasolacrimal duct obstruction.

A, The guidewire is introduced through the superior canaliculus and passes the obstruction.

B, The 20-mm-long articulated metallic stent is crimp-mounted on the angioplasty balloon catheter and covered with the plastic protective sheath. (1 indicates guidewire; 2, the radiopaque markers of the balloon catheter; 3, the protective sheath; and 4, the radiopaque marker of the protective sheath located 2 cm proximal to its tip). The stent-balloon catheter assembly is passed retrogradely over the guidewire through the nasal aperture and positioned at the level of the obstruction.

C-E, The protective sheath is retrieved (C) and the balloon is inflated for the expansion and deployment of the stent (D). The delivery system is pulled out inferiorly, and the guidewire is pulled out superiorly (E).

articulated stents that had been disconnected from the central bridging strut.

After the stent was placed, the nasolacrimal drainage system was irrigated with saline through the superior canaliculus. Subtraction dacryocystography was performed immediately after the procedure to verify the position of the stent and the patency of the nasolacrimal drainage system. Topical antibiotic and steroid eyedrops were given for 1 week. All patients were examined and the nasolacrimal drainage system irrigated with saline within the first week following the procedure. Follow-up subtraction dacryocystography was performed and the postprocedural grade of epiphora determined in all patients between 1 and 3 weeks after the stent placement. Patients were contacted every 2 months to obtain follow-up information.

## Results

In all four eyes, junctional or nasolacrimal ductal obstruction was crossed with the guidewire uneventfully. The metallic stent on the delivery system was passed retrogradely over the guidewire through the nasal aperture and placed accurately at the desired level in all cases under digital subtraction fluoroscopic monitoring. No major complications, such as misplacement, dislodgement, or migration of the stent, occurred in any patient. All patients expressed temporary mild pain during insertion of the delivery system and two patients had slightly blood-stained nasal discharge at the

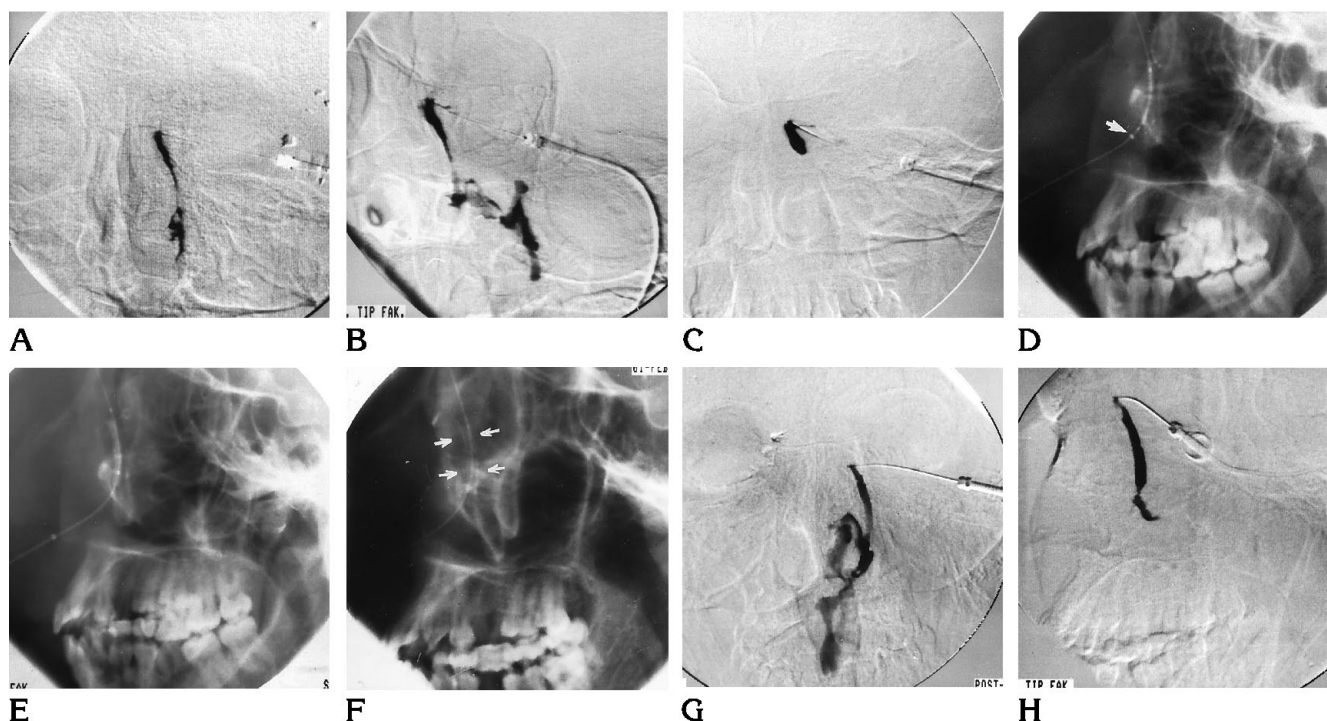


Fig 2. Case 1: 35-year-old woman with obstruction of the nasolacrimal duct causing grade 5 epiphora of 1 year's duration.

A and B, Subtraction dacryocystography of the left nasolacrimal drainage system in anteroposterior and lateral projection reveals patency of the nasolacrimal duct after transluminal balloon dilation, but intraluminal irregularity is still visible.

C, Dacryocystogram obtained at 2-month follow-up shows complete obstruction of the nasolacrimal drainage system and distended nasolacrimal sac.

D, The stent-balloon catheter assembly is positioned at the level of the obstructed nasolacrimal duct. Arrow indicates the radiopaque marker of the protective sheath.

E, The plastic protective sheath is retrieved and the balloon is inflated for the deployment of the stent.

F, Note deployment of the completely expanded articulated stent (arrows). The guidewire is still within the stent lumen.

G and H, Postprocedural subtraction dacryocystogram shows the patency and smooth stented lumen of the nasolacrimal duct in posteroanterior (G) and lateral (H) projections. The lacrimal sac has returned to normal and passage of the contrast medium is not impeded.

end of the procedure. Subtraction dacryocystography obtained immediately after stent placement revealed free flow of the contrast medium into the inferior meatus through the smooth stented lumen of the nasolacrimal duct. In all patients, complete resolution of epiphora and patency of the nasolacrimal drainage system was evidenced on dacryocystograms obtained 1 to 3 weeks after stent placement.

During the follow-up period of 10 months, migration of the stent did not occur in any patient, but subtraction dacryocystography revealed narrowing of the intrastent lumen in all cases. In the follow-up period, complete resolution of epiphora was maintained in one eye; two patients had grade 1 epiphora, which was maintained at that grade; and in one patient, who had grade 4 epiphora 3 months after the procedure, subtraction dacryocystography showed almost

complete occlusion of the intrastent lumen. We performed intrastent balloon dilatation in this case and epiphora was relieved; the patient was asymptomatic (grade 0) for 4 more months, but improvement was temporary and epiphora stabilized at grade 3 in the follow-up period. Patient data, results, and follow-up information are presented in the Table.

## Discussion

For many years, nasolacrimal duct prostheses—such as gauzes, suture materials, rubber or silicone catheters or tubings, absorbable gelatin sponges, polyethylene, and glass tubes—have been used and placed at the time of surgery to maintain the postoperative patency of the surgically created anastomosis between the lacrimal sac and the nasal mucosa (4, 5, 18).

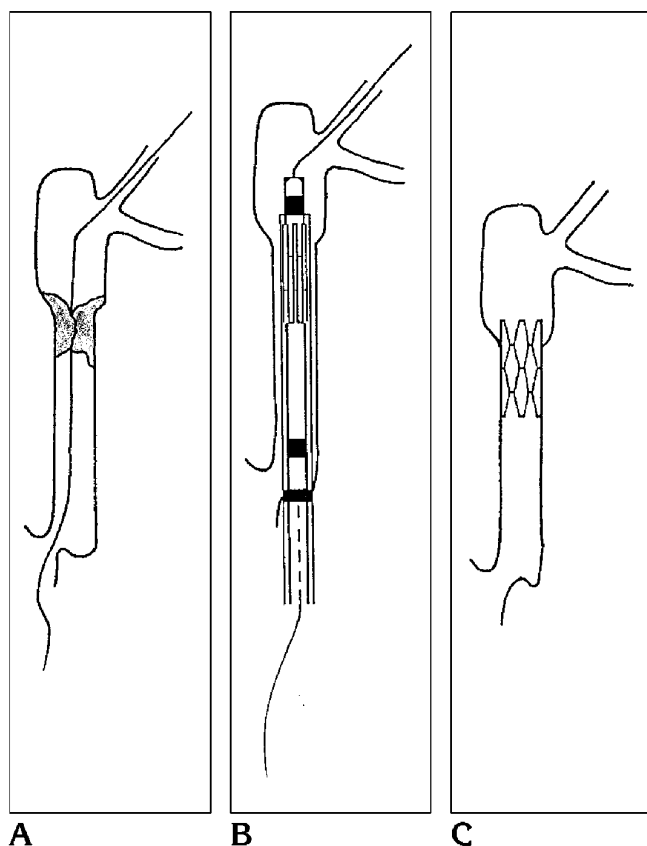


Fig 3. Diagrams show placement of a balloon-expandable metallic stent for the treatment of recurrent obstruction of the lacrimal sac and nasolacrimal duct junction. The 9.5-mm-long stent is crimp-mounted on the angioplasty balloon catheter closer to the distal radiopaque marker. The placement (B) and deployment (C) of the stent are performed as described previously.

Insertion of polyethylene or glass nasolacrimal tubes through the canaliculus as indwelling stents have been reported to be a relatively simpler and less traumatic procedure, and have preserved the normal anatomic relationships (15, 19, 20).

In recent years, metallic stents have been widely and successfully used for endovascular purposes as well as in the biliary system, the esophagus, the stomach, the tracheobronchial tree, and the urethra (14, 16, 21–23). The main advantage of expandable metallic stents for the management of obstructions in the mucosa-lined tracts is the creation of a larger, stable lumen with a relatively small entry site.

The basic mechanism of action of Palmaz balloon-expandable metallic stents is the plastic deformation of metal beyond its elastic limit (16, 21). During deployment of the stent, the expansile force of the coaxial balloon dilates the

lumen and the stent simultaneously. The expanded stent creates and maintains a lumen in a predetermined diameter.

Commercially available medium-type Palmaz stents with a wall thickness of 0.010 cm (0.004 in) are less expensive than the small stents used for coronary arteries and may be used with the sheathed delivery system. The sheathed delivery system has the advantage of avoiding contact between the stent and the nasal mucosa before deployment. The system also prevents stent dislodgement and minimizes the risk of stent misplacement (17). The outer diameter of the delivery system is 1.65 mm (5F), and it is possible to create a stented nasolacrimal duct lumen 4 mm in diameter by balloon dilatation.

The nasolacrimal duct is 4 mm in diameter and has an inferior opening with a diameter of 3 to 4 mm when the Hasner valve is open. The length of the lacrimal sac below the entrance of the common canaliculus is 8 to 12 mm, and the length of the nasolacrimal duct is about 18 mm (14, 15). Anatomic data reveal, and we believe, that metallic stents about 20 mm in length are appropriate for the diffuse nasolacrimal duct obstructions if the stent is to be placed with the upper tip slightly protruding into the dilated lacrimal sac inferior to the common canicular opening and the lower end just inside the inferior opening of the nasolacrimal duct. Also, the expanded metallic stent diameter of 4 mm is suited to the anatomy of the nasolacrimal drainage system. The upper tip of the stent is placed slightly protruding into the sac below the common canicular entrance so as not to impede adequate drainage of tears. The lower end of the stent is placed just inside the inferior opening of the nasolacrimal duct so that the Hasner valve may function as a barrier to the retrograde passage of air and nasal discharge. In two patients with diffuse obstruction of the nasolacrimal duct, we placed 20-mm-long articulated stents, which were 19 mm long when expanded to 4 mm, and managed to stent the nasolacrimal duct obstruction completely. In the other two eyes, with segmental obstruction at the junction, a 9.5-mm-long stent was implanted in the same manner and only a shorter segment was stented, excluding the patent distal part of the nasolacrimal duct.

In a study similar to ours, Song et al (14) had good results with the use of Gianturco-type metallic stents to treat epiphora caused by obstruc-

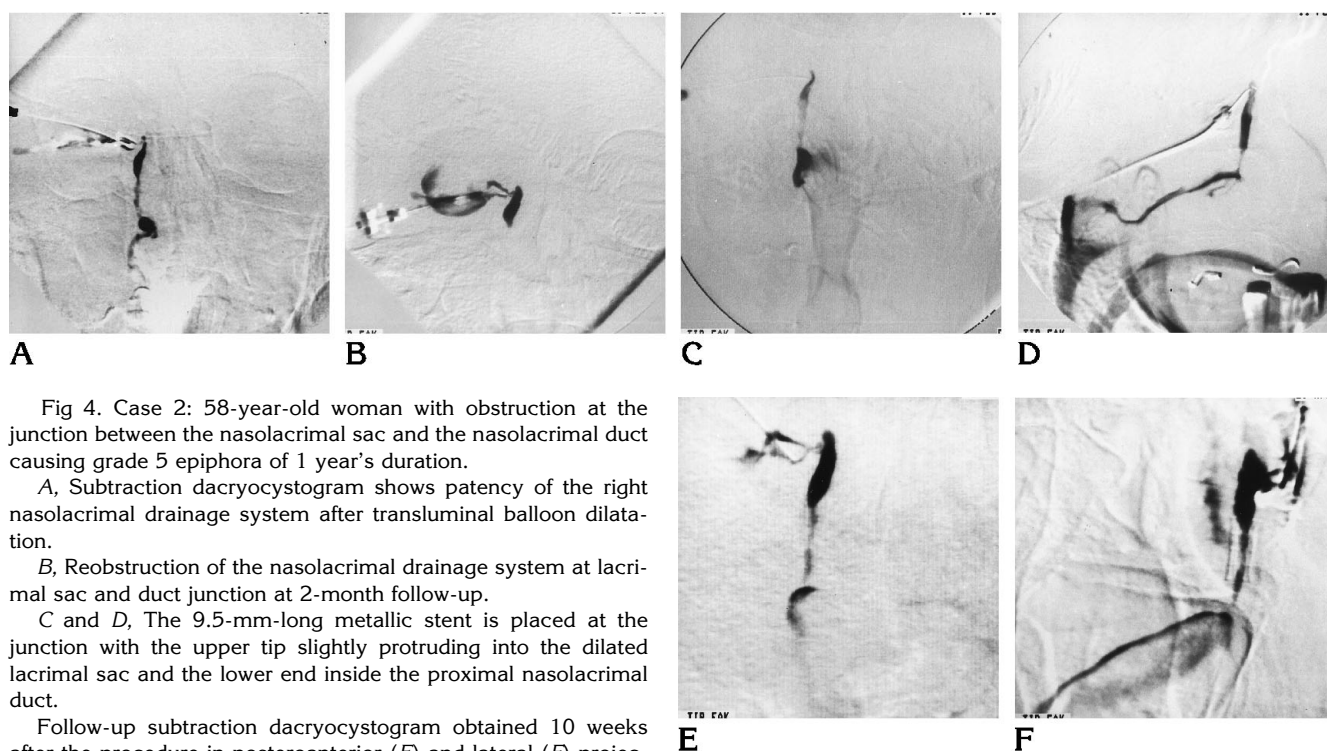


Fig 4. Case 2: 58-year-old woman with obstruction at the junction between the nasolacrimal sac and the nasolacrimal duct causing grade 5 epiphora of 1 year's duration.

A, Subtraction dacryocystogram shows patency of the right nasolacrimal drainage system after transluminal balloon dilatation.

B, Reobstruction of the nasolacrimal drainage system at lacrimal sac and duct junction at 2-month follow-up.

C and D, The 9.5-mm-long metallic stent is placed at the junction with the upper tip slightly protruding into the dilated lacrimal sac and the lower end inside the proximal nasolacrimal duct.

Follow-up subtraction dacryocystogram obtained 10 weeks after the procedure in posteroanterior (E) and lateral (F) projections reveal free flow of contrast medium to the nasal cavity through the stent lumen. Irregular narrowing of the intrastent lumen caused by soft-tissue ingrowth is visible.

tion of the nasolacrimal ducts in seven cases. The lack of longitudinal flexibility of the stents and the difficulty in removing them surgically when they become blocked have been reported to be their main limitations (14, 15).

We had no difficulty during the retrograde placement of the 20-mm-long stents. The non-articulated, shorter (9.5-mm) stent and the newer, articulated design of Palmaz stents, with their greater longitudinal flexibility, allowed simple and safe stent deployment.

It is a well-known fact that metals are not well tolerated by mucosa-lined tracts (16, 21–23). No information is available on the long-term effects of metallic stents in the nasolacrimal

drainage system. Although experimental studies of tissue-metal stent interactions in mucosal passages elsewhere in the body cannot be used as models for the nasolacrimal drainage system, they may help us to understand the possible histologic changes. Mucosal hyperplasia and local inflammatory foreign tissue reaction to the metallic stent of the ductal wall are possible causes of stent obstruction or stenosis (21–23). We think that tissue ingrowth through the metal struts, resulting from mucosal hyperplasia and local inflammatory foreign tissue reaction, was responsible for the irregular narrowing of the intrastent lumen seen on the follow-up dacryocystograms in all our cases. However,

Patient data, results, and follow-up information in the treatment of recurrent nasolacrimal duct obstructions

Patient	Age, y/Sex	Grade of Epiphora	Duration of Epiphora, y	Site of Obstruction	Stent Length, mm	Grade of Epiphora at Four Follow-up Examinations*
1	35/F	5	1	Nasolacrimal duct	20.0†	0/1/1/1
2	58/F	5	1	Nasolacrimal duct junction	9.5	0/0/0/0
3	29/F	5	3	Nasolacrimal duct	20.0†	0/4‡/0/3
4	44/F	5	3	Nasolacrimal duct junction	9.5	0/0/1/1

\* Follow-up examinations immediately after the procedure/at 2 to 4 months/at 4 to 6 months/at 6 to 10 months.

† Articulated stent.

‡ Intrastent balloon redilatation.

despite the apparent narrowing seen at subtraction dacryocystography, contrast material was noted to flow freely into the inferior meatus. In the biliary system, tissue ingrowth reaches a certain level and then stabilizes, without completely occluding the intrastent lumen (22). Unfortunately, in the nasolacrimal drainage system, the intrastent lumen may be occluded, as the expanded stent diameter is only 4 mm. We believe that tissue ingrowth through the metal struts in the nasolacrimal drainage system also stabilizes in 2 to 4 months, since, in our study, the grade of epiphora did not increase during the follow-up period of 10 months. Expandable metallic stents with thin plastic or silicone coating covering the struts (22) may solve this particular problem, and it may be possible to remove the coated stents, as there will be no tissue ingrowth through the metal struts. Although the occluded metallic stent cannot be retrieved without surgery, reconstitution of the lumen by intrastent balloon redilatation is a possible procedure, such as in one of our cases.

The results of a study on the use of plastic stents for the complete obstruction of the nasolacrimal duct are encouraging, showing complete resolution of epiphora in 15 of 19 eyes (15). The small internal diameter of the plastic tubing and/or the long head portion of the stent, which interfere with the adequate drainage of tears, are thought to be the limitations and the causes of failure of plastic stents. However, these stents have the major advantage of being easy to remove, as the distal tip protruding into the inferior meatus can be grasped and pulled out.

In this era of minimally invasive therapy, results of our early experience indicate, and we believe, that balloon-expandable metallic stents represent a noninvasive, relatively simple and safe outpatient procedure that may be an alternative nonsurgical treatment for epiphora resulting from recurrent nasolacrimal duct obstruction. Having a metallic stent in the nasolacrimal duct for the rest of one's life seems to be the major disadvantage for the patient, and further clinical trials with long-term follow-up of larger number of patients are necessary to define accurately the role of this procedure. Moreover, the histopathology of the occluding tissue ingrowth and tissue-stent interaction in the nasolacrimal drainage system should be studied in terms of possible new stent designs.

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