The Consequence of Premature Silicone Stent Loss after External Dacryocystorhinostomy

Matthew G. Vicinanzo, MD, Gerald McGwin, PhD, Michael Boyle, MD, John A. Long, MD

**Purpose:** To investigate the clinical affects of premature silicone stent loss after external dacryocystorhinostomy (DCR).

**Design:** Retrospective chart review.

**Participants:** Two hundred thirty-three consecutive external dacryocystorhinostomies.

**Methods:** Demographic information was recorded, including length to follow-up, age, gender, number of days until stent removal, and success of surgery. All patients who extruded their silicone stent prematurely were identified. All were primary DCRs (i.e., all reoperations were excluded). All patients had had documented nasolacrimal duct obstruction before surgery, with or without current or prior dacryocystitis.

**Main Outcomes Measures:** Failure of DCR surgery was accepted as symptomatic epiphora with notable nasolacrimal duct blockage and/or infection at long term follow-up.

**Results:** Of the 233 DCRs, 42 stents extruded or had to be removed before the planned 2-month period. The overall success rate of the surgery was 94.9%, with a 90.5% success for those who had early extrusion and 95.8% for those who did not (P = 0.24). Moreover, of the 4 people who had a failed surgery (of 42 early extrusions), none had a recurrent infection or pain, and only 1 opted to have a revision of the surgery. Patient age, gender, or timing of the extrusion was not found to affect surgical success significantly.

**Conclusions:** Our experience and this study suggest that concerns over early stent extrusion or removal may not be wholly warranted. Moreover, our review of the literature shows no evidence-based recommendations that longer stent retention or reintubation after early extrusion results in a higher success rate. Although other surgeries (e.g., canalicular laceration, congenital epiphora) may benefit from intervention or reinserterion after early extrusion, we cannot extrapolate such a practice for the DCR. *Ophthalmology* 2008;115:1241–1244 © 2008 by the American Academy of Ophthalmology.

In 1979, Anderson and Edwards first made us aware of the plethora of possible complications related to silicone intubation, including punctal erosion, corneal abrasion, fistula formation, granuloma formation, and chronic mucopurulent discharge. However, over the past 3 decades it has become common practice for surgeons to place silicone intubation tubes at the time of dacryocystorhinostomy (DCR). Although no large prospective study has been done to show that there is an advantage to employing a stent at the time of surgery, it has been assumed and propagated that silicone tubing offers a stable nonantigenic material that allows for stenting of the common canaliculus and rhinostomy, thereby increasing the success rate of the procedure. Moreover, although no definitive time frame for stent retention has ever been established, it has been suggested that the silicone stent should remain in place for 2 to 12 months. Thus, early extrusion of the stent has long been thought to be detrimental.

The purpose of our investigation was to determine whether or not this was true. Does early stent extrusion truly decrease the success of DCR surgery? If it does not, then are interventions to prevent stent prolapse or the reinsertion of new tubes warranted? Furthermore, if early extrusion of the silicone stent does not decrease the success of the DCR, should not a large prospective study be considered to determine if they are a useful augmentation to the surgery in the first place?

**Materials and Methods**

A retrospective chart review of 233 consecutive DCRs with silicone stent placement over a 4-year period found 42 patients who lost their silicone stent or had to have it removed before the planned 2-month period. All had documented nasolacrimal duct obstruction with or without concomitant dacryocystitis before surgery. All were primary DCRs (reoperations were excluded). The surgery was done from an external approach with direct visualization of all steps (i.e., a large anterior lacrimal crest/fossa rhinostomy was made, flaps formed from both the lacrimal sac and nasal mucosa were joined, a bicanalicular silicone stent was passed through the patent upper and lower canaliculi, the stent was tied and released back into the nose, and no other method of...
stent fixation was used). All were done by or directly supervised by one surgeon. Patients were typically seen at 1 week, 2 months, and 6 months postoperatively. Success of the surgery was determined by the patient’s lack of symptomatic epiphora (i.e., the patients were directly asked if they had continued tearing) and/or infection at long-term follow-up. Failure was accepted as symptomatic epiphora and/or infection at long-term follow-up, as well as documented obstruction by simple irrigation of upper and lower canalicular systems. Demographic information on all 233 cases was recorded, including number of follow-up visits, age, gender, and number of days until stent removal or loss. Institutional review board/ethics committee approval was obtained.

The Fisher exact test was used to compare the risk of surgery failure among those who did and did not experience an extrusion as well as the risk of extrusion and failure according to gender. t tests were used to compare continuous variables (e.g., age) with respect to surgery outcome (e.g., success vs. failure). $P$ values $\leq 0.05$ (2 sided) were considered statistically significant.

Results

The overall success rate of the surgery was 94.9%. Of the 42 (18.0%) patients who had early extrusion, 4 had complaints of residual tearing on long-term follow-up and were found to have obstructions on simple irrigation. None complained of or had signs of recurrent infection. Thus, 90.5% had no residual problems despite early extrusion (and only 1 of 4 patients after the failed surgery opted for surgical revision). This compares to a 95.8% success rate for those who did not lose their stents prematurely. This is not a statistically significant difference ($P = 0.24$).

All patients were to have their stents removed at their 2-month follow-up visit, extrusions occurred as early as 2 days and as late as 49 days. Among patients with early extrusion, the mean time to extrusion was 16.8 days (median, 12.5). For those with early extrusion and a surgical failure, the mean was 15.5 days, versus 16.9 for those with early extrusion and surgical success. The comparison between these 2 means is not statistically significant ($P = 0.83$).

The mean age of the 233 patients was 58.9 years; the majority (77.3%) were female. Overall, the risk of early stent extrusion was 18.0%, with the risk of premature stent loss higher among females (19.4%) than among males (13.2%); this difference is not statistically significant ($P = 0.42$). Moreover, there is no significant difference with respect to age for those who did and did not lose their stent prematurely (60.1 vs. 58.6 years, respectively; $P = 0.66$).

Of note, the average number of days of postoperative follow-up on all cases was 168.2, whereas for those with early stent loss, it was 221.5.

Discussion

The highly effective DCR, first developed by Toti in 1904 and further refined by Dupuy-Dutemps and Bourguet in 1921, had changed little over the first 75 years of its existence. Yet, over the past 25 years there has been a gradual shift toward the standard-of-practice use of silicone stents to augment the external DCR. However, in an age that places a greater and greater emphasis on evidence-based medicine, questions about safety, efficacy, and cost-effectiveness have not been conclusively answered necessarily to warrant this practice.

Like Anderson and Edwards before them, in 1982 Dortzbach et al made us aware that silicone intubation is not without its complications; case reports subsequently showed up in the literature that seemed to support their work (e.g., Jordan and Nerad). Later animal models and human studies have shown that histopathologic changes are in fact induced by the presence of these tubes. Unfortunately, a debate continues to rage as to whether these changes are the result of simple mechanical irritation or are actually chemically induced by the silicone itself. Furthermore, retrospective chart reviews by Older in 1982 and Rosen et al in 1989 did not find a significant difference in surgical success between DCRs done with stents and those done without stents. (Yet, they did not suggest the cessation of their use, and in fact, Rosen et al still concluded that they were advantageous. Nor did they call for a prospective study.) In 1989, Allen and Berlin went so far as to say that silicone intubation at the time of DCR was “associated with a statistically significant increase in the failure rate of primary DCR.” After retrospectively looking at 242 consecutive DCRs with stents, they stated that “routine use of silicone tubing in DCR should be avoided” unless a specific canalicular obstruction was present. Although Allen and Berlin’s conclusions differ from those of Older and Rosen et al, both raised the question of whether stents helped, hindered, or ultimately had no affect on the DCR in general.

Paradoxically, multiple authors of this period were advocating different and ingenious surgical techniques to prevent the early extrusion of silicone stents employed for DCRs, thereby increasing the duration that the stent was kept in place. Some authors even advocated double-stent intubation to further the success of the surgery because, as one author stated, “intubation with silicone tubes is a well-known technique for keeping the canalicular system open.” Similarly, “silicone tube have improved the outcome in lacrimal surgery,” and “the placement of these tubes during dacryocystorhinostomy has become routine.” Yet, no study, to our knowledge, existed to back up these assertions.

Over the past decade, some have come to question the necessity of silicone intubation at the time of DCR and whether they are a real factor in surgical success. In 1994, Walland and Rose retrospectively compared the success rates of 238 DCRs employing silicone intubation and 150 DCRs not employing them. They found no statistically significant difference in their failure rates. In 2003, this was reaffirmed by Kashkouli et al in a comparative case series of 276 surgeries. Both groups of authors indicated that other factors such as postoperative infection, history of preoperative trauma, and size of the rhinostomy may be much more important in surgical success. However, again neither group went so far as to call for the discontinuation of silicone stent use with the DCR. Nonetheless, both obviously rouse the question, if no study showing that stents positively affect the surgery’s outcome, why are so many surgeons concerned about early intervention when the stent extrudes?

Again, paradoxically, during the past decade a multitude of other authors still called for more complicated ways of
incorporating stents in DCR surgery. Whether advocating a “wider-diameter Crawford tube” or “simultaneous intubation” of the rhinostomy and the nasolacrimal duct, all seem to say similarly that “silicone tubing . . . may contribute to the favorable success rate of the operation.” Still, nothing in the literature exists to support this assertion.

Possibly most confusing is the advocacy of silicone stent placement during the DCR by the American Academy of Ophthalmology’s Lifelong Education for the Ophthalmologist (i.e., as seen in the Basic and Clinical Science Course book series and the Ophthalmology Monographs series that are used for the didactic education of residents in training). These books are the basis of the Ophthalmology Knowledge Assessment Program and are employed by most doctors in training while studying for their American Board of Ophthalmology certification examinations. In the Basic and Clinical Science Course series, it is stated that a lacrimal stent “may be needed” for a DCR, especially in cases of common canalicular stenosis; yet, no criteria for what that means is discussed. In the Monographs series, it is assumed that a stent should be used, and its placement is described in great detail in both words and pictures. The alternative of not using a tube is never mentioned (while, e.g., the alternative of flapless surgery is). In fairness to the Academy, this line of thinking is not unique to Lifelong Education for the Ophthalmologist. The authors found similar advocacy in every one of the oculoplastics textbooks we investigated.

Today, the vast majority of surgeons employ silicone tubes in nearly all DCRs, the authors included. It has been assumed that the longer a silicone stent is kept in after a DCR, the more successful the outcome. Yet, there is a paucity of evidence-based medicine being practiced. To our knowledge, little or no data suggest that anchoring the stent in the nose at the time of surgery or reinserting it when it extrudes prematurely affects the success of the surgery (not to mention is in any way cost-effective). Moreover, even if silicone stents were found to aid in the surgical success, no conclusive timeframe for their retention has been noted. Thus, although other surgeries (e.g., canalicular laceration repair, congenital epiphora) may benefit from longer intubation or early reinsertion after extrusion, from this investigation we cannot extrapolate that such a practice is clinically significant or cost-effective for the DCR without further investigation.

In fairness, we also cannot call for the cessation of their use without further study, as it is obvious that a retrospective investigation can be fraught with bias and pitfalls. Although the results of this study suggest no statistically significant difference in the rates of DCR surgery failure among patients who did and did not experience early stent extrusion, these results must be interpreted in light of the fact that this was a nonrandomized observational study and, therefore, subject to limitations. Patients were not randomized, and therefore, inherent demographic, behavioral, or clinical differences between the groups may confound the observed results. Moreover, the patients in the current study were not selected and observed prospectively using a standard protocol; therefore, selection bias cannot be ruled out. Finally, it is possible that any observed differences are real yet failed to reach statistical significance due to limited statistical power. Despite the lack of statistical significance, the failure rate was approximately 5% higher among those with early stent extrusion. If this is a true difference (and, more importantly, clinically important), then the current study may have had limited power to detect it as statistically significant.

Ultimately, a prospective randomized study may provide definitive evidence regarding early stent extrusion. Assuming that a failure rate of <10% would be considered acceptable, then such a study would not be prohibitive from a sample size perspective, requiring approximately 900 patients. The resources required to undertake a study of this magnitude should not be minimized. Although there are less rigorous designs requiring fewer resources that could be proposed, the need for a high-quality definitive study on this topic suggests that a large prospective randomized study may be needed to determine if the use of a silicone stent is in fact advantageous for all DCRs.

References


