Objective and subjective outcomes following external dacryocystorhinostomy and inferior tear duct stenting in patients with acquired lacrimal drainage system obstruction

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Abstract

Background: We compared objective and subjective outcomes of dacryocystorhinostomy (DCR) vs. inferior tear duct stenting (stenting) in acquired infrasacccal stenosis.

Methods: In this retrospective study 114 eyes of 100 patients who underwent 50 DCRs and 64 stentings between August 2009 and September 2018 were evaluated. Subjective success was quantified by interviewing the patients (complete, some or no improvement) at 10 days, 3 months and 17.2±17.2 months postoperatively. Success was objectified by postoperative clinical examinations at 10 days, 3 months and 9.3±7.8 months postoperatively and clinical scoring. Complete improvement was defined as complete success. Complete and some improvement was considered qualified success. Intra- and postoperative complications were evaluated.

Results: At the last time point, DCR (78.0%) had significantly higher complete subjective success rates than stenting (59.4%, p=0.044). Qualified subjective success rates were comparable (DCR 88.0% vs. stenting 76.6%, p=0.147). DCR (76.0%) had significantly higher complete objective success rates than stenting (51.6%, p=0.006) and similar qualified objective success rates (88.0% vs. 75.0%, p=0.097).

There were no significant differences between subjective and objective success rates at any time point (p=0.125-1.0). At the last time point, patients with the stent left in place for at least 4 months had significantly higher objective qualified success rates (92.7%) than those who had the stent removed (43.5%, p<0.001; mean removal interval 2.9±1.0 months). The stent-in-place group had comparable complete (obj. p=0.067, subj. p=0.344) and qualified (obj. p=0.506, subj. p=0.556) success rates to DCR at the last time point, while the stent-removal group performed worse (complete: obj. p=0.007, subj. p=0.031; qualified: obj. p=0.002; subj. p<0.001).

No major intra- or postoperative complications occurred.

Conclusion: DCR lead to high subjective and objective success rates. Stenting can be a minimally invasive alternative to DCR, particularly when the stent remains in place. Subjective and objective evaluation of symptom improvement showed high agreement.

Introduction

Acquired nasolacrimal drainage system obstruction (NDSO) is considered one of the most common reasons for epiphora in adult patients with an average annual incidence rate of 20.2 per 100,000 [1].

The most common form of NDSO is primary acquired nasolacrimal duct obstruction (PANDO), an idiopathic disease with unclear pathogenesis [2]. It is believed to be caused by fibrosis and chronic inflammation of the tear duct [3], associated with the presence of a wide range of bacteria, such as Staphylococcus species, Escherichia coli, as well as actinomyces and fungi [4].
Secondary acquired nasolacrimal duct obstruction (SANDO), on the other hand, can be attributed to a number of pathologies, such as immunologic inflammation, trauma, neoplasia, mechanical and post-infection (e.g. dacryocystitis) [5]. Stenosis of the lacrimal duct frequently occurs in sites of predilection, where natural constrictions facilitate the formation of irreversible NDSOs, such as the valve of Rosenmüller (connection between the canaliculus communis and the lacrimal sac) or the valve of Krause (connection between the lacrimal sac and the nasolacrimal duct) [6].

Generally, women are more frequently affected by NDSO, which is thought to be due to a narrower anatomy of the tear duct [7]. Further clinical signs of NDSO comprise pus, secretions and swelling of the lacrimal sac [8].

A wide range of diagnostic methodology has been used for the evaluation of NDSO, such as fluorescein passage tests (Jones) [9], magnetic resonance imaging, dacryocystography and dacryoscintigraphy [2]. However, the most common clinical approach is probing and irrigation of the lacrimal system to localize the site of stenosis.

The gold standard treatment for infrasaccal stenosis to date is dacryocystorhinostomy (DCR), creating a permanent fistula between the lacrimal sac and the nasal cavity [10]. Success rates range between 82.7–94.1% [11, 12].

The temporary stenting of the inferior tear duct with a silicone tube (stenting; Masterka, FCI Ophthalmics, Pembroke, USA) has been applied for complex nasolacrimal duct obstruction in children, not yet in adults, leading to success rates of 71.0–85.0% [13–15].

In this study, we examined objective and subjective success rates of the established procedure DCR as well as stenting as an alternative, minimally invasive treatment for infrasaccal stenosis in adults. Additionally, we compared cases with stent removal to cases with stents left in place.

**Materials And Methods**

In this retrospective study, we included a consecutive series of 114 eyes of 100 patients with acquired NDSO who underwent 50 DCRs and 64 stentings between August 2009 and August 2019. All patients were treated at the Department of Ophthalmology, RWTH Aachen University. Included were patients with NDSO due to PANDO and SANDO patients in case of stenosis following dacryocystitis. Complex SANDO cases e.g. following neoplasm, radiation or complex trauma involving bone fractures were excluded. Patients with previous nasolacrimal drainage system surgery were excluded. Additionally, we collected data on age, sex and ocular history. The study adhered to the tenets of Helsinki. It was approved by the medical ethics committee of the RWTH Aachen (EK 326/17). Informed consent was given by all participants for objective and subjective data analysis.

Lacrimal duct probing and irrigation was used for assessing the localization and degree of stenosis preoperatively. The technique has been described before [16]. DCR and stenting were only performed in
infrasaccal stenosis. Indications for surgery were signs of epiphora, pus and acute or chronic inflammation due to lacrimal stenosis unresponsive to conservative treatment. All procedures in this study were performed by two experienced surgeons in standardized techniques.

**Surgical Techniques:**

**External dacryocystorhinostomy (DCR):**

The technique of DCR has been described previously [17]. The procedure was performed under general anesthesia. Briefly, the skin was incised 1.5 cm, 8 mm medial to the inner canthus, followed by a preparation of the periosteum anterior to the lacrimal sac and the creation of a foramen within the nasal bone with a 10 mm trephine. The nasal mucosa was detached and the lacrimal sac incised. Upper and lower canaliculus were probed and the silicone tube (Silicone tubing, 0.6 mm, Geuder, Heidelberg, Germany) was pulled out of the nose through lacrimal sac and foramen. The anterior part of the incised lacrimal sac was then sutured to the anterior mucosal flap closing the anastomosis using absorbable Vicryl 5−0 (Ethicon, Johnson & Johnson Medical GmbH, Norderstedt, Germany) sutures. The wound and the skin were then successively closed with absorbable sutures. The silicone tube was removed 2–3 months postoperatively. Figure 1 shows the preoperative swelling of the saccus in a patient (a) and the postoperative appearance of the surgery site 3 months after DCR (b).

**Stenting of the inferior tear duct (stenting):**

The technique of stenting has been described previously in children [14]. Briefly, the stent was pre-assembled over a metallic guidewire. The infrasaccal localization of stenosis was confirmed by probing and irrigation. The stenosis was perforated and dilated by metallic cannula probing until a free flushing through the sac into the nose was possible. A 40 mm (length) stent (Masterka, FCI Ophthalmics) was then introduced into the inferior canaliculus, pushed into the saccus indicated by a hard stop, then angulated 90° and advanced into the nose without resistance. During this movement the punctum plate of the stent usually automatically locks into the inferior punctum, so that the guidewire can be withdrawn, fixing the stent in position with non-toothed forceps. In contrast to conventional pulled intubations, the stent does not require any intranasal retrieval [18]. In children, the stent is left in place for at least 1 month [19]. In our cohort, at the early period of the series, the stent was left in place for approximately 2 months. After a preliminary evaluation of success rates with the stent in place vs. removed, it was decided to leave the stents in place for as long as possible. Figure 2 shows the postoperative appearance of a stent in a patient with infrasaccal stenosis.

The surgical interventions were followed by postoperative antibiotics. For stenting a combination of dexamethasondihydrogenphosphat-dinatrium 1.0 mg/ml and gentamicinsulfat 5.0 mg/ml eye drops (Dexa-Gentamicin, Ursapharm, Saarbrücken, Germany) was applied 5 times daily for 3 weeks. For DCR Dexa-Gentamicin was given five times daily for 3 weeks, followed by 3 times daily for another 6 weeks. Additionally, 0,1 % xylometazolinhydrochlorid 1 mg/ml nose spray (Otriven, GlaxoSmithKline, Brentford, UK) was given 3 times daily for two weeks.
For DCR surgery anticoagulation and platelet inhibitors were paused when possible. For stenting surgery, anticoagulation treatment was continued.

Surgical success was subjectively quantified by interviewing the patients 10 days, 3 months and at a mean postoperative time of 17.2±17.2 months (last time point) after DCR and stenting (Table 1). Patients were asked for remaining symptoms and were classified into complete, some or no improvement. Complete improvement meant no remaining symptoms, some improvement referred to less, yet some remaining symptoms, and no improvement indicated the same symptoms or even worse than preoperatively. Objective success was evaluated by clinical examination after 10 days, 3 months and at the last recorded time point at a mean postoperative time of 9.3±7.8 months (Table 1). We allocated the clinical findings to the categories complete, some and no improvement by a clinical score, in which 1 point was given for each of the following clinical signs (4 points max): epiphora or an increased tear meniscus (1 point), pus or secretions (1 point), swelling in the area of the saccus (1 point), acute or chronic inflammation as indicated by redness of the skin or localized elevated temperature (1 point). We calculated the score, both preoperatively and postoperatively at 10 days, 3 months and at the last time point. When the postoperative score was 0, we called the result "complete improvement", when it was not 0 but less than the preoperative score, we classified the corresponding patient as "some improvement". When the preoperative and postoperative scores were identical or when the preoperative score was even smaller than the postoperative score, the result was "no improvement". Complete improvement was considered complete success, both complete and some improvement together were considered qualified success. Moreover, we evaluated intra- and postoperative complications.
Statistical Analysis

Statistical analysis was performed using the Statistical Package for Social Sciences (IBM SPSS Statistics for Windows, Version 25, Armonk, NY: IBM Corp.). Student's t-test was used for comparison of continuous variables and chi-square test and Fisher's exact test for categorical variables. The McNemar test was used to compare related nominal, dichotomous data. P-values were adjusted by Bonferroni correction when applicable. A p-value of <0.05 was considered statistically significant.

Results

Patient characteristics

Our study included 65 left (57.0%) and 49 right (43.0%) eyes. The mean age of all patients was 59.6±20.1 (5.0-93.0) years. DCR patients (65.7±15.9 years) were significantly older than stenting patients (54.8±21.8 years, p=0.002). Female gender was significantly more frequent (81 of 114 cases, 71.1%, p<0.001, Figure 3). There were no significant differences in the gender distribution between DCR vs. stenting (p=0.838).

The most common cause of NDSO was PANDO (n=90, 78.9%), followed by dacryocystitis (n=24, 21.1%)

The main clinical signs before treatment were epiphora (93.0%, n=106), acute or chronic inflammation in the area of the sac (55.3%, n=63), pus or secretions (44.7%, n=51) and swelling (28.9%, n=33).

| Procedure                  | Last follow-up subjective | Last follow-up objective |
|----------------------------|---------------------------|-------------------------|
| DCR                        | 23.5 ± 24.1               | 7.7 ± 9.4               |
| Stenting (overall)         | 12.3 ± 5.1                | 10.5 ± 6.1              |
| Stent-removal cohort       | 13.7 ± 5.6                | 11.5 ± 7.8              |
| Stent-in-place cohort      | 11.5 ± 4.6                | 10.0 ± 4.9              |
| Overall                    | 17.2 ± 17.2               | 9.3 ± 7.8               |

Subjective success was quantified by interviewing the patients at 10 days, 3 months and 17.2±17.2 months postoperatively. Success was objectified by clinical examinations at 10 days, 3 months and 9.3±7.8 months postoperatively.
Subjective Results:

At 10 days post-surgery, complete subjective success rates evaluated by telephone interview were significantly higher in DCR (69.4%) than in stenting (48.4%, p=0.035, Table 2). Qualified subjective success rates did not differ significantly between DCR and stenting at 10 days (p=0.075). At 3 months, subjective success rates were comparable between DCR and stenting (complete p=0.156, qualified p=1.0).

At the last time point, complete subjective success was significantly higher in DCR (78.0%) than in stenting (59.4%, p=0.044). Qualified subjective success rates were comparable in DCR (88.0%) vs. stenting (76.6%, p=0.147).

Objective Results:

Objective success rates graded by a clinical score did not differ significantly between DCR and stenting at 10 days (complete p=0.159, qualified p=0.771, Table 2). At 3 months post-surgery, complete objective success was significantly higher in DCR (74.0%) than in stenting (41.7%, p=0.001) while qualified success rates were comparable (p=0.784).

At the last time point, complete objective success was significantly higher in DCR (76.0%) than in stenting (51.6%, p=0.006). DCR (88.0%) had similar qualified objective success rates compared to stenting (75.0%, p=0.097).
Table 2: Complete and qualified subjective and objective success rates

| Post-operative period | DCR (n = 50) | stenting (n = 64) |
|-----------------------|--------------|-------------------|
|                       | Complete subjective success | Complete objective success | P   | Complete subjective success | Complete objective success | P   |
| 10 days               | 69.4% (n = 49) | 72.9% (n = 48) | 1.0 | 48.4% (n = 64) | 59.0% (n = 61) | 1.0 |
| 3 months              | 75.0% (n = 48) | 74.0% (n = 50) | 1.0 | 60.9% (n = 64) | 41.7% (n = 61) | 0.102 |
| Last time point       | 78.0% (n = 50) | 76.0% (n = 50) | 1.0 | 59.4% (n = 64) | 51.6% (n = 64) | 1.0 |
|                       | Qualified subjective success | Qualified objective success | P   | Qualified subjective success | Qualified objective success | P   |
| 10 days               | 87.8% (n = 49) | 89.6% (n = 48) | 1.0 | 96.9% (n = 30) | 86.9% (n = 61) | 0.186 |
| 3 months              | 87.5% (n = 48) | 88.0% (n = 50) | 1.0 | 85.9% (n = 64) | 85.2% (n = 61) | 1.0 |
| Last time point       | 88.0% (n = 50) | 88.0% (n = 50) | 1.0 | 76.6% (n = 64) | 75.0% (n = 64) | 1.0 |

Complete and qualified subjective and objective success rates at 10 days, 3 months and the last time point (subjective: 17.2±17.2 months, objective: 9.3±7.8 months) in DCR and stenting. DCR: external dacryocystorhinostomy, stenting: inferior tear duct stenting. The subjective and the objective success rates did not show significant differences at any time point (p=0.102-1.0).

Table 3 shows the pre- and postoperative (last time point) clinical scores for DCR and stenting. DCR resulted in a significantly higher clinical score reduction than stenting (p=0.022).
Comparison of stent-removal and stent-in-place cohort

For stenting, we differentiated whether the stent was removed postoperatively (stent-removal cohort, n=23) or left in place (stent-in-place cohort, n=41) until the last time point. The stent-in-place cohort had a significantly higher clinical score reduction than the stent-removal cohort (p=0.040, Table 3).

Table 4 shows the subjective and objective findings at the last time point in the stent-removal vs. stent-in-place cohort. The mean time to stent removal was 2.9±1.0 (1.0-4.0) months in the stent-removal cohort. At the last time point, significantly better objective qualified success rates were obtained for the stent-in-place compared to the stent-removal cohort (92.7% vs. 43.5%, p<0.001), while differences in subjective (complete and qualified) as well as objective complete success rates did not reach significance (complete: subj. p=0.067, obj. p=0.193, qualified: subj. p=0.132).
The stent-in-place cohort had comparable complete (obj. p=0.067, subj. p=0.344) and qualified (obj. p=0.506, subj. p=0.556) success rates to DCR at the last time point, while the stent-removal cohort performed worse (complete: obj. p=0.007, subj. p=0.031; qualified: obj. p=0.002; subj. p<0.001).

Comparison of subjective and objective results

The complete and qualified subjective and objective success rates at 10 days, 3 months and at the last time point are displayed in Table 2. The subjective and the objective success rates did not show significant differences at any time point (p=0.102-1.0).

Complications

No severe intraoperative complications occurred. In a case of DCR following dacryocystitis, increased bleeding after removal of benign papillomatous structures within the sac was witnessed, which could be controlled by coagulation of the resection bed.

No severe postoperative complications were witnessed. In a case of DCR in a 90-year-old female patient, increased postoperative bleeding from the surgery site occurred most likely due to continued factor Xa inhibitor anticoagulation, which was not paused during the treatment period. The bleeding stopped spontaneously after 4 hours of wound compression by pressure bandage. A 46-year-old female patient was diagnosed with steroid response syndrome 2 months post-DCR with a maximum elevated intraocular
pressure (IOP) of 50 mmHg. She was started on IOP-lowering eyedrops and steroid treatment was discontinued. IOP normalized within 12 hours and after six days, the antiglaucoma eye drop medication could be stopped. IOP remained normal. In a 43-year-old female patient, the stent disappeared 4 months post-surgery. In a 49-year-old female patient, the major part of the silicone tube dislocated into the lower fornix 3 weeks post-DCR and could neither be repositioned from the nasal cavity nor from externally. It was removed; the patient remained symptom-free. In a 90-year-old female patient with dementia, the silicone tube disappeared between the 10 days and 3 months follow-up after DCR. The patient remained symptom-free.

Discussion
In this study on 114 eyes undergoing 50 DCRs and 64 stentings we found that 76.0% of DCR and 51.6% of stenting patients showed no more clinical signs of nasolacrimal drainage system obstruction (complete objective success) at the last follow-up visit at 9.3±7.8 months. Similarly, 78.0% of DCR and 59.4% of stenting patients described complete improvement of symptoms (complete subjective success) at 17.2±17.2 months post-surgery during a telephone interview. The success rates of stenting were significantly higher, when the stent was not removed electively. Interestingly, objective and subjective findings showed high agreement and did not differ significantly at any time point. No severe complications occurred.

The age range and the gender distribution in our study agree with previous publications [1]. Women were more frequently affected by NDSO in all our groups, which has previously been attributed to a narrower anatomy of the female tear duct [7] as well as the augmented deposition of cellular debris in the female tear duct, because of a higher epithelial cell turnover rate [20].

External DCR was initially described by the Florentine otolaryngologist Addeo Toti in 1904 [21]. With success rates, usually defined as complete or significant improvement of symptoms, of about 82.7-94.1% [11, 12], DCR is considered the gold standard in lacrimal duct surgery for infrasaccal stenosis [11]. The subjective and objective qualified success rates in our study of 88.0% emphasize previous results and the very high success rates of this procedure. Our DCR cohort showed the highest preoperative clinical score, which is most likely due to cases of SANDO following dacryocystitis, which is generally associated with high grades of patient discomfort [8]. DCR led to the highest absolute reduction in clinical score emphasizing it as a valuable first line treatment strategy.

However, external DCR is a challenging invasive procedure which requires surgeon experience [22], and pausing of anticoagulation therapy [23]. It also causes a small scar at the site of skin incision [8]. Even though theoretically in some institutes, DCR is also performed in local anesthesia [24], most surgeons prefer general anesthesia [8, 11, 25, 26].

In contrast to infrasaccal stenosis in acquired NDSO, the congenital form most commonly describes a persisting membrane at Hasner's valve [27]. Probing of the lacrimal system is the treatment of choice in such cases, leading to very high success rates of 75.0-97.0% [28, 29].
In case of failed primary probing, temporary intubation with a silicone stent is a viable option [30]. In some centers, however, this technique has become a primary procedure for congenital NDSO in children [31]. In previous studies on stenting in congenital NDSO in children as a primary treatment, success rates of 83.3-88.3% have been reported [13-15, 18]. Khatib et al. described a success rate of 71.0% in complex cases of congenital NDSO, which was defined as serial sites of obstruction as well as cases where the primary site of stenosis was within the nasolacrimal duct and not at the Hasner’s valve [13].

Unlike in children, in adults with acquired NDSO, a single probing procedure as well as silicone intubation with or without balloon dacryocystoplasty only yielded limited success rates of approximately 50% [32]. The unsatisfactory outcomes of these procedures in adults are thought to be due to the high rates of restenosis of the nasolacrimal duct over time [33].

To our knowledge, this is the first study reporting the outcomes of stenting in adults with infrasaccal stenosis. The success rates were significantly worse than DCR, when the stents were removed after approximately 3 months, which is most likely due to the occurrence of restenosis [33]. However, the outcomes improved, when the stents remained in place, reaching success levels comparable to DCR. In our opinion, stenting can be a viable first option for patients who are unwilling to undergo major surgery (DCR) under general anesthesia, or that are under anticoagulation. We did not observe any severe complications, which arose from permanently placed stents with the longest follow-up of 17 months. Fayet et al. reported complications of stent displacement and disappearance in children [18]. In our study, there was one case of stent disappearance 4 months post-surgery. In addition, there is a risk of creating a false passage during the surgical intervention [18]. In previous studies on children, the authors describe canaliculits, keratitis and intralacrimal migration as further complications of stenting [18, 19]. No such cases were witnessed in our cohort. Nevertheless, the procedure can easily be repeated and does not impede a DCR at a later date.

In agreement with previous publications [34], we defined success both objectively and subjectively. Interestingly, we found that subjective outcomes, evaluated by telephone interview and objective scores showed high agreement. The value of interrogating patients has previously been demonstrated [11] and seems to be a vital tool in assessing treatment strategies. While our results suggest that clinical success essentially determines patient satisfaction, there have been previous reports of discrepancies between subjective and objective outcomes: Some authors reported higher subjective than objective success rates [35], hypothetically due to a placebo effect in patients feeling improvement after surgery [36]. However, others reported about higher objective than subjective success rates [37], which can be attributed to the persistence of epiphora even after resolution of NDSO due to its multifactorial aetiology [38] (e.g. dry eye disease [2]). In our study, no indication of a significant placebo effect was found. Unlike other previous studies that only analysed the absence of epiphora [35], we objectified success by various clinical parameters of NDSO.

In conclusion, DCR lead to high subjective and objective success rates. Our study suggests that stenting can be a minimally invasive alternative to DCR, particularly when the stent remains in place. Moreover,
subjective and objective evaluation of symptom improvement showed high agreement.

**Abbreviations**

DCR: dacryocystorhinostomy, IOP: intraocular pressure, NDSO: nasolacrimal drainage system obstruction, PANDO: primary acquired nasolacrimal duct obstruction, SANDO: secondary acquired nasolacrimal duct obstruction, stenting: inferior tear duct stenting

**Declarations**

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**Declaration of Interest:** The authors declare that they have no conflict of interest.

**Authors’ contributions:** Research conception and design: MF, PW, JP; Data Acquisition: JP, DK, HS; Data Interpretation: JP, MF, NP, AK; Manuscript Preparation: JP, MF; Revising the manuscript: MF, PW, NP, DK. All authors read and approved the final manuscript.

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**Consent for publication:** Not applicable.

**Competing interests:** The authors declare that they have no competing interests.

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