• Clinical Research •

Efficacy and satisfaction analysis of biodegradable amniotic lacrimal duct repair stent for acquired lacrimal obstruction

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Abstract

● **AIM:** To evaluate the efficacy, degradation characteristics, safety, and patient satisfaction of biodegradable amniotic lacrimal duct repair stent (ALDRS) in adult patients with acquired lacrimal obstruction.

● **METHODS:** A multicenter, retrospective cohort study. Patients were stratified by anatomical site and obstruction severity into three cohorts: incomplete upper lacrimal pathway obstruction (punctal, canalicular, or common canalicular, cohort 1), incomplete nasolacrimal duct obstruction (cohort 2), and complete nasolacrimal duct obstruction (cohort 3). The primary endpoint was anatomical patency on lacrimal irrigation at 6mo. Secondary endpoints included functional success, stent degradation, complications, and validated patient-reported outcomes.

● **RESULTS:** A total of 54 patients (54 eyes, 10 males) with a mean age of 53.36±12.42y (range 29–88) were enrolled. ALDRS insertion was successful in 98.15% of procedures. Complete degradation was observed in 90.74% of eyes at 30d and in 100% by 6mo, with no residual material. The overall anatomical patency rate at 6mo was 81.48%. By cohort, patency was 100% (11/11), 88.89% (16/18), and 68.00% (17/25) for cohort 1, 2, and 3, respectively. No granuloma, punctal laceration, or silicone tube related complications occurred. Pre-existing chronic dacryocystitis was an independent risk factor for reduced patency [*B*=0.607, 95% confidence interval (CI): 0.165–1.048, *t*=2.763, *P*=0.008]. Overall satisfaction was comparable among cohorts, with all patients ranking preoperative communication and explanation highest.

● **CONCLUSION:** Biodegradable ALDRS combines avoidance of secondary removal with promotion of epithelialization, offering a safe and patient friendly option for adult acquired lacrimal obstruction. Lacrimal probing with ALDRS achieves favorable outcomes in cohort 1 and 2. In cohort 3, ALDRS is best reserved as a prophylactic adjunct after dacryocystorhinostomy. Chronic dacryocystitis or severe lacrimal sac fibrosis compromises efficacy.

● **KEYWORDS:** amniotic membrane; lacrimal stent; lacrimal obstruction; dacryocystorhinostomy; patient satisfaction

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INTRODUCTION

Lacrimal obstruction is among the most common causes of epiphora in ophthalmic practice, accounting for approximately 3% of patients seen in outpatient ophthalmology clinics[1-2]. The condition predominantly affects middle-aged and elderly women, and its prevalence rises progressively with age[2]. Persistent epiphora not only compromises visual comfort but may also lead to chronic dacryocystitis and keratoconjunctival infections, significantly impairing patients' quality of life. Dacryocystorhinostomy (DCR) combined with artificial lacrimal intubation has become the mainstream therapeutic strategy[3]. Traditional silicone stents, however, require a second procedure for removal, and several studies

have reported associated complications including granuloma formation, pericanalicular infection, and lacrimal punctal laceration[4-5].

To avoid secondary removal and cut down surgery related risks, surgeons have recently brought in a new set of absorbable scaffolds. These implants come from two sources. One group is made of natural materials such as acellular extracellular matrix, chitosan and human amniotic membrane. The other group is made of synthetic polymers, mainly polyesters like poly L lactic acid and poly lactic co glycolic acid[6-7]. These nasolacrimal stents degrade at a uniform, predictable rate over 3–6mo, and their degradation products are eliminated *via* physiological metabolic pathways, thereby obviating device extraction and eliminating long term foreign body irritation.

Amniotic membrane is a clinically validated biomaterial that exhibits excellent biocompatibility, potent anti-inflammatory activity, and broad spectrum antimicrobial properties[6]. Its epithelial and mesenchymal layers are rich reservoirs of growth factors and extracellular-matrix proteins that accelerate epithelial wound healing and suppress fibrosis[8]. When fashioned into a tubular stent, the membrane functions as a temporary conduit that steadily degrades within 2–6mo post-implantation, obviating the need for a second surgical extraction and markedly reducing patient burden[9-10].

However, the current evidence is confined to pre-clinical studies and small case series. Prospective clinical cohorts with follow up ≥3mo and patient reported outcome measures are still lacking. Moreover, neither domestic nor international guidelines or consensus statements have issued formal recommendations or conclusive opinions on the efficacy and safety of biodegradable stents in adult lacrimal stenosis or obstruction[11]. The temporal relationship between stent degradation and epithelial remodeling, together with changes in patient satisfaction and quality of life, remains to be rigorously elucidated.

This multicenter, retrospective study enrolled consecutive adult patients with lacrimal stenosis or obstruction who received an amniotic lacrimal duct repair stent (ALDRS). Patients were stratified by anatomical level and obstruction severity to delineate indication specific efficacy. Anatomical patency, symptomatic improvement, and patient satisfaction were assessed at 6mo post-insertion, providing an evidence base for future investigations.

PARTICIPANTS AND METHODS

Ethical Approval This multicenter, retrospective cohort study was approved by the Institutional Review Board (IRB) of Peking University Third Hospital (No. IRB00006761-M20250921) and was conducted in accordance with the Declaration of Helsinki. Owing to the retrospective nature of the analysis, the requirement for written informed consent was waived. Nevertheless, all patients provided general consent for the use of their de-identified data for research purposes at the time of initial treatment and during follow-up questionnaire surveys.

Participants Between August 2024 and February 2025, 54 consecutive patients who underwent either lacrimal probing or DCR with lacrimal stent insertion for lacrimal duct obstruction. All patients received concurrent placement of ALDRS. Among them, patients were classified into 3 cohorts based on anatomical site and obstruction severity: 1) upper lacrimal pathway incomplete obstruction, comprising punctal stenosis, canalicular membranous occlusion, and common canalicular stenosis (n=11); 2) nasolacrimal duct (NLD) incomplete obstruction, defined as partial patency or stenosis with irrigation diameter ≤3 mm (n=18); 3) NLD complete obstruction, defined as total non-patency with reflux (n=25). Patients in cohorts 1 and 2 underwent lacrimal probing combined with ALDRS implantation. Patients in cohort 3 underwent DCR combined with ALDRS implantation. The selection of surgical approaches was determined in accordance with the Expert Consensus on Endoscopic Dacryocystorhinostomy for Chronic Dacryocystitis in China (2020)[12] and routine clinical practice guidelines. The comparison between subgroups was designed to assess safety, degradation, and appropriate clinical indications of ALDRS.

Inclusion criteria were: 1) age≥18y; 2) complete medical and operative records; 3) minimum post-operative follow-up of 6mo; 4) pre-operative lacrimal irrigation demonstrating either complete obstruction or functional stenosis (irrigation diameter ≤3 mm). Exclusion criteria comprised congenital nasolacrimal-duct obstruction, active dacryocystitis, complete obstruction of the lacrimal duct, lacrimal-sac or paranasal-sinus neoplasia, patients with lacrimal duct trauma and tear of lacrimal punctum, and loss to follow-up within 6mo.

Surgical Procedure DCR: Under the operating microscope, a curved skin incision was made medial to the anterior lacrimal crest. After dissection and exposure of the lacrimal sac, an H-shaped anterior and posterior flap was fashioned. An 8 mm×10 mm segment of the anterior wall of the bony lacrimal fossa was removed with rongeur, and a corresponding incision was created in the nasal mucosa to form an anterior flap. After adequate dilation of the inferior punctum with a punctal dilator, a lacrimal probe (stylet pre-loaded) was advanced along the physiological curve of the canaliculus and NLD until the stylet tip emerged in the anterior naris. The suture leader of the ALDRS (Eyeren®, RUIJI-BIO, China; Figure 1) was threaded between the two strands of the stylet wire. The probe body was then withdrawn while gentle traction was applied to the proximal end of the stylet, pulling the leader

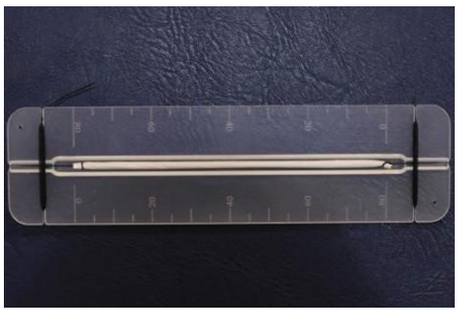


Figure 1 Physical picture of amniotic lacrimal duct repair stent.

and the attached stent retrograde through the punctum. Direct traction on the leader advanced the stent until its upper margin lay flush with the punctal orifice. Excess amniotic membrane was then trimmed level with the punctum, with care taken not to sever the leader. Finally, the leader was gently withdrawn from the punctum, leaving the biodegradable stent *in situ*. The anterior lacrimal-sac flap and the anterior nasal-mucosal flap were opposed with three interrupted sutures of 8-0 absorbable material; the posterior flaps were left unsutured. Patency was confirmed by irrigation, and the wound was closed in layers.

Lacrimal probing with ARDRS insertion: With the patient supine, routine disinfection and draping were performed. A cotton pledget soaked in 2% lidocaine with 1:200 000 epinephrine was placed in the inferior meatus to shrink the inferior turbinate, and 0.75% ropivacaine was infiltrated at the medial canthus. After the upper and lower puncta were dilated, a Bowman probe was advanced sequentially through the canaliculi and NLD until its tip reached the inferior meatus. The ALDRS was subsequently inserted through the punctum using the same technique described in the preceding paragraph (Figure 2).

Data Collection Baseline data were extracted from the electronic medical record and comprised: 1) demographic variables (age, sex, *etc*.); 2) past medical history; 3) lacrimal-pathology characteristics: a) anatomical site of the primary obstruction: punctum, canaliculus, NLD, or multiple levels; b) stenosis severity: complete obstruction versus incomplete stenosis; c) disease duration.

Surgical variables: 1) procedure type, 2) operative time, 3) intra-operative complications (*e.g.*, bleeding, false-passage formation).

Postoperative follow-up parameters: 1) Efficacy evaluation: a) Lacrimal irrigation at 6mo; patency documented. Patient reported outcomes: obstruction severity was classified as either complete or incomplete lacrimal blockage. Complete obstruction was defined as irrigation demonstrating total non-patency with clear or mucoid reflux, whereas incomplete obstruction was characterized by minimal reflux during irrigation. b) Reduction in epiphora and discharge. 2) Stent degradation: Progress monitored by slit-lamp and nasal endoscopy; onset and completion dates recorded. Standardization standards for ALDRS degradation: a) Complete degradation: no visible residual stent material; The lacrimal duct mucosa is smooth and intact. b) Incomplete degradation: Residual stent material can be seen during lacrimal flushing, but it accounts for less than 10% of the original stent volume, without mucosal irritation or stenosis. c) No degradation: The stent material is still visible, with a residual volume of ≥50%. 3) Complications: Infection, stent migration, granuloma, recurrent stenosis, residual material. 4) Re-intervention: Number and interval of secondary procedures for insufficient efficacy or complications.

Patient reported outcomes: preoperative and 6mo postoperative data on epiphora, ocular discharge, pain intensity, and ease of care (rated 0-10 on a visual analogue scale), together with overall satisfaction, were collected during telephone calls or outpatient visits at the 6mo follow up[13-14].

Endpoints: Primary endpoint: Anatomical patency at 6mo was defined as complete or incomplete passage without reflux on lacrimal irrigation.

Secondary endpoints: 1) Functional success: defined as significant improvement or complete resolution of epiphora (absent or mild tearing without daily inconvenience) plus anatomical patency at 6mo. 2) Stent degradation time: documented by slit lamp and nasal endoscopy. 3) Complication rate and re-intervention rate. 4) Validated patient reported outcomes.

Statistical Analysis The data were analyzed using SPSS version 27.0 (IBM Corp., Armonk, NY, USA). Normality was assessed using the Shapiro-Wilk test. Continuous variables are presented as mean±standard deviation or median (interquartile range, IQR). Between-cohort comparisons were descriptive only. Age, sex, operative time, preoperative patency status, obstruction site, and chronic dacryocystitis were entered into a multivariable linear regression model with 6-month postoperative anatomical patency as the continuous dependent variable. Two-tailed P values<0.05 were considered statistically significant. Multicollinearity was evaluated using the variance inflation factor (VIF), with VIF<5 indicating no significant collinearity.

RESULTS

This study enrolled 54 patients (54 eyes) with a mean age of 53.36±12.42y (range 29–88y). Ten patients (10 eyes) were male and 44 (44 eyes) were female. Eleven eyes presented with upper lacrimal pathway incomplete obstruction, 18 eyes with NLD incomplete obstruction, and 25 eyes with complete NLD obstruction. Baseline characteristics are summarized in Table 1. ALDRS placement was successfully accomplished in 53 of 54 procedures (98.15%). Among them, nylon leader breakage occurred in 3 eyes (5.56%) during stent insertion.

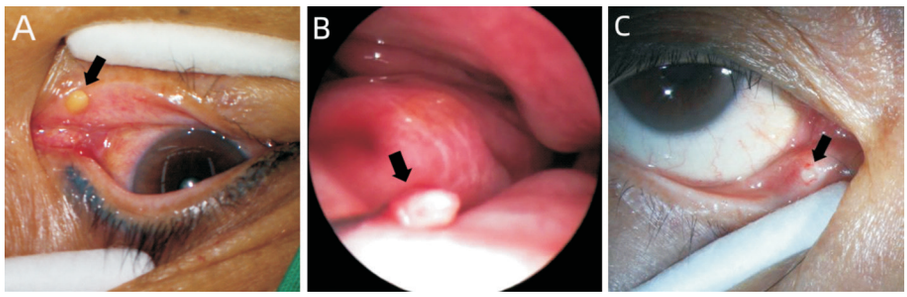


Figure 2 Images of successful implantation of the ALDRS A: Intraoperative photograph showing the punctal end after successful ALDRS implantation (arrow); B: Endoscopic view captured after successful ALDRS implantation (arrow); C: ALDRS visible at the punctum on postoperative day 1 (arrow). ALDRS: Amniotic lacrimal duct repair stent.

Each eye received a new ALDRS and the procedure was completed successfully. One case (1.85%) was classified as failure because severe fibrosis at the obstruction site led to false passage formation. The mean operative time for all procedures was 25.37±12.94min, and stent implantation did not significantly prolong the procedure.

The 30-day stent degradation rate and the 6mo anatomical patency on lacrimal irrigation are summarized in Table 2. Complete degradation of the ALDRS was observed in 90.74% of eyes at 30d, with no significant difference between the three cohorts. During the follow-up visit 1wk postoperatively, one case of mild wound infection and dehiscence was identified, which improved after treatment. By the 6-month visit, complete degradation had reached 100%. At 6mo, the overall rate of complete anatomical patency on lacrimal irrigation was 81.48%. Complete anatomical patency was achieved in 100% (11/11) of patients with incomplete upper lacrimal pathway obstruction, 88.89% (16/18) with incomplete NLD obstruction, and 68.00% (17/25) with complete NLD obstruction. Postoperative lacrimal irrigation revealed partial reflux in 11.11% (2/18) of patients with incomplete NLD obstruction, compared with 12.00% (3/25) with partial reflux and 20.00% (5/25) with complete obstruction in the complete NLD obstruction cohort, the latter requiring additional intervention. The functional success rate was essentially consistent with the anatomical patency rate.

The distribution of preoperative symptoms is summarized in Table 3. Figure 3 illustrates the subjective scores across five dimensions (intraoperative pain, postoperative pain, symptom improvement, convenience of postoperative care, and overall satisfaction) in the three cohorts.

Figure 4 presents the subjective importance ratings for preoperative communication and explanation, surgical techniques and procedures, and postoperative care and guidance across the three cohorts. Patients were permitted to select multiple items. The proportion of patients who considered preoperative communication and explanation important was highest across all cohorts. For surgical

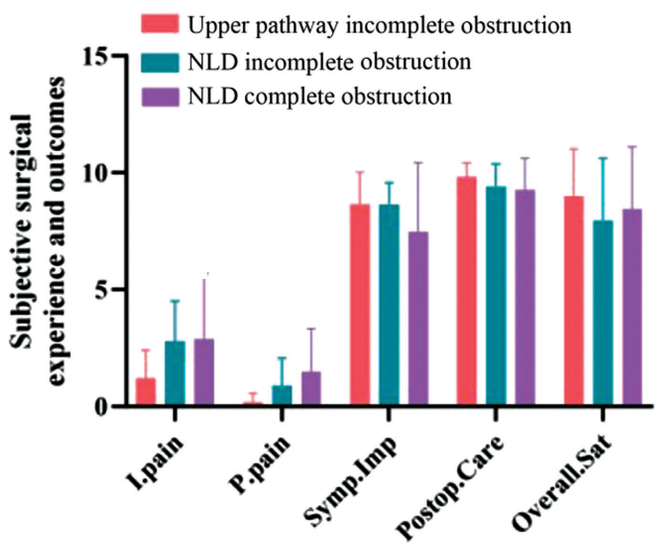


Figure 3 Comparative chart of surgical experience and outcomes between three cohorts I.Pain: Intraoperative pain level; P.Pain: Postoperative pain level; Symp.Imp.: Degree of symptom improvement; Postop.Care: Convenience of postoperative care; Overall.Sat: Overall satisfaction; NLD: Nasolacrimal duct.

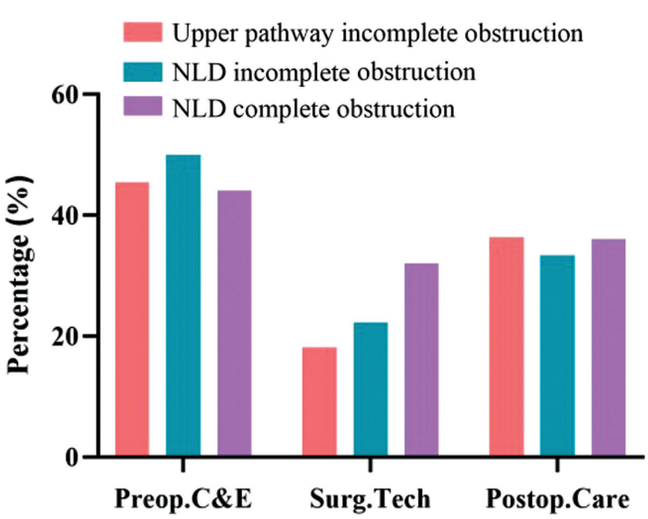


Figure 4 Subjective importance ratings of key surgical experience dimensions across three cohorts Preop.C&E: Preoperative communication and explanation; Surg.Tech: Surgical techniques and procedures; Postop.Care: Postoperative care and guidance; NLD: Nasolacrimal duct.

Table 1 Baseline characteristics of patients

Obstructed site	Number	Age (y)	Sex (male/female)	Surgical success (%)
All patients	54	53.36±12.42	10/44	53 (98.15)
Upper pathway incomplete obstruction	11	45.09±10.75	3/8	11 (100.00)
NLD incomplete obstruction	18	54.06±11.59	4/14	18 (100.00)
NLD complete obstruction	25	56.32±12.26	3/22	24 (96.00)

NLD: Nasolacrimal duct.

Table 2 Degradation rate of amniotic lacrimal duct stent and anatomical patency rate of the lacrimal duct in patients

Parameters	Degradation rate (%)			Anatomical patency rate (%)		
	Complete degradation	Incomplete degradation	Undegraded	Completely unobstructed	Incompletely unobstructed	Obstructed
All patients	49 (90.74)	5 (9.26)	0	44 (81.48)	5 (9.26)	5 (9.26)
Upper pathway incomplete obstruction	10 (90.91)	1 (9.09)	0	11 (100.00)	0	0
NLD incomplete obstruction	16 (88.89)	2 (11.11)	0	16 (88.89)	2 (11.11)	0
NLD complete obstruction	23 (92.00)	2 (8.00)	0	17 (68.00)	3 (12.00)	5 (20.00)

NLD: Nasolacrimal duct.

Table 3 Preoperative ocular symptoms of the patient

Symptoms	Upper pathway incomplete obstruction (%)	NLD incomplete obstruction (%)	NLD complete obstruction (%)	Total
Epiphora				
Yes	11 (100.00)	17 (94.44)	23 (92.00)	51 (94.44)
No	0	1 (5.56)	2 (8.00)	3 (5.56)
Increased lacrimal discharge/mucopurulent discharge				
Yes	4 (36.36)	13 (72.22)	20 (80.00)	37 (68.52)
No	7 (63.63)	5 (27.78)	5 (20.00)	17 (31.48)
Ocular pain				
Yes	2 (18.18)	3 (16.67)	5 (20.00)	10 (18.52)
No	9 (81.82)	15 (83.33)	20 (80.00)	44 (81.48)
Eyelid edema and erythema				
Yes	2 (18.18)	3 (16.67)	8 (32.00)	13 (24.07)
No	9 (81.82)	15 (83.33)	17 (68.00)	41 (75.93)
Decreased visual acuity				
Yes	0	1 (5.56)	1 (4.00)	2 (3.70)
No	11 (100.00)	17 (94.44)	24 (96.00)	52 (96.30)
Total	11	18	25	54

NLD: Nasolacrimal duct.

techniques and procedures, the three cohorts demonstrated a marked gradient. The importance ratings for postoperative care and guidance were comparable among the cohorts.

Age, sex, operative time, preoperative lacrimal patency, site of lacrimal obstruction, and chronic dacryocystitis were entered as independent variables, and postoperative anatomical patency served as the dependent variable in a multivariable linear regression model. The model R^2 was 0.252 (adjusted R^2=0.174), and the overall fit was significant (F=3.239, P=0.013). Multicollinearity diagnostics showed that all VIF were below 5, indicating no collinearity issues (Figure 5). The regression coefficient for chronic dacryocystitis was 0.607 [95% confidence interval (CI) 0.165–1.048, t=2.763, P=0.008], indicating a significant positive association with postoperative lacrimal obstruction or lack of patency.

DISCUSSION

This multicenter retrospective cohort study systematically evaluated the midterm efficacy, degradation behavior and patient reported satisfaction of a biodegradable ALDRS in adults with acquired NLD obstruction. In the present study, patients with incomplete obstruction at any level (upper pathway or NLD) underwent lacrimal probing combined with ALDRS implantation, as partial stenosis can be managed by mechanical dilation and temporary biodegradable scaffolding. Patients with complete NLD obstruction underwent DCR combined with ALDRS insertion, because

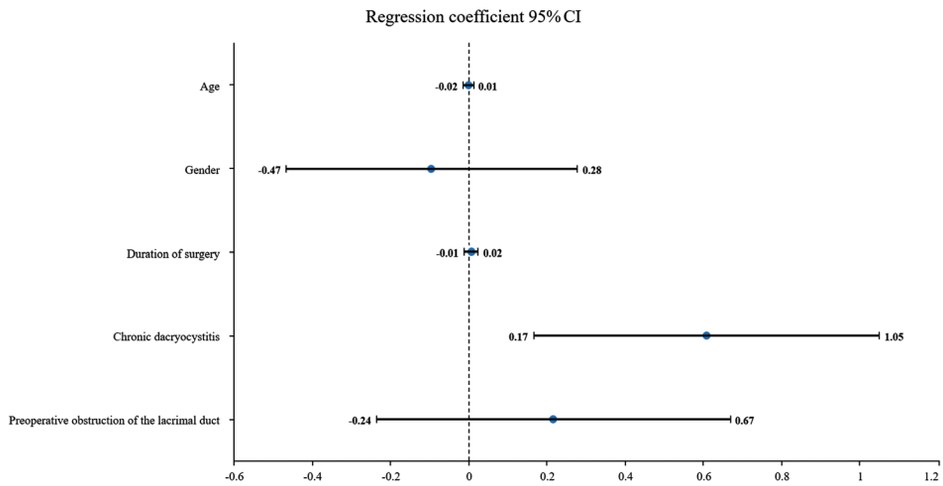


Figure 5 Multivariable linear regression analysis of factors influencing anatomical patency at 6mo after surgery CI: Confidence interval.

complete obliteration of the NLD requires creation of a new drainage pathway, with the stent serving as a temporary ostial scaffold. Therefore, disease severity and surgical methods were confounding factors that could not be separated. The between subgroup comparison was not intended as a comparative effectiveness study of the ALDRS stent. Instead, it was designed to investigate the safety, biodegradation, and appropriate clinical indications of ALDRS in different clinical scenarios, so as to clarify which patient population and obstruction type might benefit more from this biodegradable amniotic stent.

Technical success of implantation was 98.15%. Complete degradation was observed in 90.74% of stents at 30d and in 100% by 6mo, with no foreign material remaining. The overall anatomical patency rate at 6mo was 81.48%. We observed none of the complications commonly linked to traditional silicone tubes, such as granuloma formation or lacrimal punctal laceration that would require a second removal procedure. These results indicate that the biodegradable amniotic stent provides two key advantages. It eliminates the need for removal and it promotes epithelialization. From the perspective of anatomical patency rate, the device is especially suitable for patients with upper pathway incomplete obstruction, NLD incomplete obstruction or for those who cannot tolerate a second operation. For individuals with NLD complete obstruction, individualized assessment remains essential.

Compatibility Between Degradation Time and Histological Repair Window This study observed that the ALDRS essentially degraded within 1mo postoperatively. Cui *et al*[10] compared the efficacy of ALDRS with silicone tubes in treating lacrimal duct obstruction through an randomized controlled trial (RCT), but they did not record the degradation time of the amniotic membrane stent. Epithelialization of the lacrimal mucosa is a hallmark of postoperative wound healing and constitutes the biological basis for surgical success. Its timely and complete occurrence is crucial for preventing re-obstruction, maintaining ostium patency, reducing complications, and improving patient comfort. Therefore, promoting and protecting the epithelialization process should be regarded as one of the core strategies in postoperative management after lacrimal surgery[15]. Based on previous studies, epithelialization of the lacrimal mucosa is generally estimated to require 3–6wk, as inferred from postoperative management protocols, stent removal timing, and wound healing patterns[10,16]. The degradation profile of ALDRS was observed within 1mo, which appears consistent with the typical timing of mucosal epithelialization reported in previous studies. This may help avoid prolonged foreign body stimulation, although this mechanism was not directly examined in the current study. In this study, neither granulation tissue nor peritubal infection was observed, presumably because the amniotic membrane contains a variety of cytokines that, after covering the wound surface, enhance cell proliferation, differentiation, and migration, thereby accelerating wound healing[17]. Previous studies have suggested that amniotic membrane may inhibit neutrophil extracellular trap (NET) release and reduce inflammatory fibrosis. In the present study, no granuloma or excessive fibrosis was observed, which may be related to the anti-inflammatory and anti-fibrotic properties of amniotic membrane reported in the literature[18]. In contrast, conventional silicone tubes left in place for 3–6mo are associated with a 5%–12% incidence of granulation tissue, necessitating secondary removal and increasing the risk of restenosis[10,16,19]. Thus, a biodegradable lacrimal stent achieves near synchronous scaffold disappearance and mucosal healing at the histological level, theoretically lowering the long term re-occlusion rate.

A fundamental principle of lacrimal surgery is the maintenance of unobstructed drainage. A theoretical limitation of biodegradable amniotic stents is that the degrading scaffold

could transiently impede tear flow or retain mucoid secretions within the lacrimal passage, particularly during the first 2–4wk when the material is partially intact. This concern is especially relevant for NLD applications, where drainage depends on both gravity and the lacrimal pump mechanism. In our cohorts, however, this theoretical risk was not borne out clinically. The 6-month anatomical patency rates were high across the incomplete obstruction cohorts (100% and 88.89%), and no cases of symptomatic epiphora, mucus pyocele, or stent related infectious retention were observed. The rapid degradation profile, with 90.74% of stents completely degraded by 30d, suggests that the window of potential intraluminal interference is brief and self-limited.

Chronic Dacryocystitis as a Pivotal Determinant of Anatomical Patency Multivariate linear regression in this study identified pre-existing chronic dacryocystitis as a significant risk factor for reduced anatomical patency of the lacrimal passage at 6mo postoperatively (B=0.607, 95%CI: 0.165–1.048, t=2.763, P=0.008). Kamao *et al*[13] using a PF catheter for sheath guided bicanalicular nasal intubation, reported (TORAY, Tokyo, Japan) an overall anatomical patency rate of 96.9% at 6mo after surgery, whereas the patency rate in patients with post saccal obstruction was 83.1%. That study likewise suggested that the anatomical location of obstruction may influence surgical patency. However, it did not further investigate the impact of chronic dacryocystitis on postoperative anatomical success. Wang *et al*[20] performed endoscopic dacryocystorhinostomy (En-DCR) in patients with chronic dacryocystitis and reported a 6mo anatomical patency rate of 68.18%, a figure comparable to that observed in the present study. Impaired lacrimal drainage in patients with chronic dacryocystitis is primarily attributable to ostium occlusion, most commonly caused by granulation or scar tissue. Such tissue proliferation originates from chronic inflammation and mucosal injury induced by stent impaction[21]. This excessive tissue formation results from chronic inflammation and mucosal injury caused by stent impaction. Therefore, meticulous surgical technique, meticulous mucosal preservation, and sustained ostial patency are crucial for preventing recurrence[20]. Patients with complete NLD obstruction superimposed on chronic dacryocystitis frequently exhibit marked lacrimal sac fibrosis or even bony occlusion. A stent alone cannot counteract the consequent retractile forces[22]. In the present study, approximately 20% of eyes in the NLD complete obstruction subgroup required secondary surgery. The lower success rate in our complete NLD obstruction subgroup could be related to the high incidence of chronic dacryocystitis in this cohort. A plausible explanation is that inadequate intraoperative irrigation of purulent secretions may lead to postoperative stasis of inflammatory debris, thereby compromising epithelialization and luminal patency. Therefore, we propose that future indications for ALDRS should incorporate inflammatory status alongside anatomical severity. For individuals with chronic dacryocystitis accompanied by advanced fibrosis, more extensive mucosal flap anastomosis should be combined, and future work should explore novel drug eluting stents capable of suppressing fibroproliferation[23].

Nonparallel Relationship Between Patient Reported Outcomes and Anatomical Success and its Clinical Implications Notably, anatomical patency and patient reported satisfaction did not demonstrate a simple linear correspondence. This finding aligns with the conclusion of Penttilä *et al*[24] that patient reported outcomes are weakly correlated with objective anatomical patency. While the upper lacrimal pathway incomplete obstruction cohort exhibited both the highest 6mo anatomical patency rate and the most favorable satisfaction trend, the complete NLD obstruction cohort sustained high overall satisfaction despite markedly reduced anatomical success. This observation suggests that patient reported outcomes are modulated by multiple non-anatomical factors, including baseline symptom burden, procedural invasiveness, and convenience of postoperative care. Specifically, the three cohorts exhibited a gradient in intraoperative and postoperative pain that paralleled procedural complexity, despite these graded difference, pain scores remained modest across all cohorts, suggesting that ALDRS insertion itself contributes minimally to surgical morbidity. Notably, the use of a biodegradable lacrimal stent eliminates the need for secondary removal, significantly reducing procedure-related fear and pain as well as the number of clinic visits. Moreover, subjective importance ratings of surgical experience dimensions (Figure 4) revealed that all cohorts ranked preoperative communication and explanation highest, even surpassing surgical technique, suggesting that patients undergoing lacrimal surgery prioritize information transparency and expectation alignment. Conversely, the complete NLD obstruction cohort assigned greater weight to surgical technique, reflecting the influence of DCR complexity and perceived operative risk on patient expectations. Collectively, these findings indicate that the clinical value of biodegradable amniotic lacrimal stents should not be defined solely by anatomical patency. Rather, the humanistic benefits of reshaping the postoperative patient journey and eliminating the fear of secondary surgery constitute an essential element of patient centered ophthalmic care.

Several limitations remain. The retrospective design inevitably introduces selection bias. Patients with complete NLD obstruction underwent DCR. This procedure takes longer and causes more trauma. As a result, the true benefit of the

biodegradable stent may have been underestimated. The sample size was small. This limited power makes it hard to detect rare complications. Follow up lasted only 6mo. Restenosis rates beyond one year and cost effectiveness remain unreported. A multicentre prospective RCT is therefore planned. The biodegradable stent will be compared with conventional silicone tubing followed by secondary removal. The target enrolment is at least one hundred and twenty participants per arm with 12mo of follow up. Standard surgical protocols masked assessors and centralized imaging review will be used to reduce both selection and measurement bias. At the same time, we will build a biospecimen bank. Mucosal healing biomarkers will be explored. The goal is to provide evidence for precision intubation and individualized treatment strategies.

In summary, the biodegradable ALDRS offers a safe, convenient, and patient-friendly solution for acquired lacrimal obstruction, with efficacy that varies by anatomical level and disease severity. For upper lacrimal pathway incomplete obstruction (punctal, canalicular, and common canalicular lesions), ALDRS achieves excellent anatomical patency. For NLD incomplete obstruction, ALDRS is effective after probing based pre-treatment. In complete NLD obstruction, ALDRS is best utilized as a prophylactic adjunct following DCR, rather than as a primary treatment. Concomitant chronic dacryocystitis and severe lacrimal sac fibrosis may compromise stent efficacy, warranting meticulous mucosal handling and infection control at the time of DCR. Future drug-eluting stent formulations may be required to improve outcomes in this subset.

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