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Mucosal and lacrimal flaps for endonasal dacryocystorhinostomy (DCR) a systematic review

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Abstract

Background;

Historically dacryocystorhinostomy (DCR) has been performed externally with very good outcomes. Current literature shows comparable success rates between endonasal and external approaches. A common reason for the failure of a DCR is the re-closure of the nasolacrimal stoma by granulation tissue and synechiae.

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Objective of review;

A systematic review and critical evaluation of the evidence relating to the preservation of nasal mucosal flaps in DCR surgery.

Type of review and evaluation method;

A systematic review using the consort guidance for review of randomised control trials.

Search strategy;

A search of the following evidence-based medicine databases was performed: Cochrane database of systematic reviews (DSR), Database of abstracts of reviews of effectiveness (DARE), Cochrane central register of controlled trials (CCTR), Ovid, Medline, EMBASE, PubMed. The search was limited to English language articles and the following key words were used: Endonasal, Endoscopic, Dacryocystorhinostomy, DCR, Mucosal Flaps, between years 1970 and 2015.

Results;

The best available evidence was level 1B, comprising 2 randomised control trials and 3 comparative studies included in the review. The main outcome measures used were lacrimal irrigation and absence of epiphora. Two of the studies demonstrated a statistically significant benefit of mucosal sparing either with nasal mucosal flaps or lacrimal flaps. More debridement was needed and granulation tissue was also seen in the groups without mucosal preservation. There was no difference in surgical complications between a mucosal and non-mucosal sparing technique.

Conclusions;

The overall quality of current evidence is poor, there does however appear to be a trend towards improved outcomes and reduced granulation in groups where nasal mucosal and lacrimal flaps were preserved, but this is not clear-cut. There was no evidence of increased complication rates with mucosal sparing techniques. We recommend that until further good quality research is available we should be performing a mucosal sparing technique when performing DCR routinely.

Key Points

- Little evidence with only two level 1B RCTs and three comparative studies available to review
- There is some evidence that mucosal flaps improve outcome measures, such as lacrimal irrigation and absence of epiphora
- Evidence suggests that fewer granulations and nasal debridement required in mucosal sparing techniques
- No increase in surgical complications with mucosal sparing techniques
- We recommend future studies include the use of a validated quality-of-life (QoL)
 measure for outcome assessment.

Introduction

Historically dacryocystorhinostomy (DCR) has been performed externally with very good outcomes ¹. The development of endonasal instrumentation and modern visual technology has led to the endoscopic approach now being the preferred surgical technique in many centres. Current literature shows comparable success rates between endonasal and external approaches however the endonasal technique avoids an external scar ².

Endonasal DCR was first described by Caldwell in 1893, the major limitation being the equipment available at that time ³. The first clinical study of endonasal DCR was by McDonogh et al in 1989 ⁴. The technique describes the removal of the nasal mucosal flap and suturing the lacrimal flap to the inferior turbinate.

Conventional endonasal DCR had created a fistula between the lacrimal sac and the nasal cavity without the preservation of the nasal mucosa. A common reason for the failure of a DCR is the re-closure of the nasolacrimal stoma by granulation tissue and synechiae ⁵. Many approaches have been used to try and improve the success rates of endonasal DCR, from silicone stents to mitomycin C application. Another commonly held belief is that the preservation of nasal mucosal flaps can help reduce the rate of granulation and synechiae formation. There has been a progressive evolution of DCR surgery with several authors describing different techniques of nasal mucosal preservation and flap creation. These

include the U-shaped 6 , L-shaped mucosal flap 7 , free nasal mucosal flap 8 , and the preservation of the whole nasal mucosal flap 9 . We present a review of the current literature on this subject.

Objective of the review: To systematically review and critically evaluate the evidence relating to the preservation of nasal mucosal flaps in DCR surgery.

Methods: A systematic review of the literature was performed to identify papers on the subject of mucosal flap use in DCR surgery. A search of the following evidence-based medicine databases was performed: the Cochrane Database of Systematic Reviews (DSR), Database of Abstracts of Reviews of Effects (DARE), Cochrane Central Register of Controlled Trials (CCTR), Ovid, Medline, EMBASE and PubMed. The search was limited to English language articles. The search terms used were: Endonasal, Endoscopic, Dacryocystorhinostomy, DCR, Mucosal Flaps. Articles between years 1970 and 2015 were used. Titles and abstracts were screened and the all the RCTs that compared mucosal flaps to no mucosal flaps or compared differing mucosal flaps were included (Figure 1).

Two independent reviewers assessed the relevant articles using the CONSORT Statement guidance on reporting of randomised trials ¹⁰.

Results: The best evidence available was level 1B, there were 2 randomised control trials (RCTs). The 2 RCTs form the main basis of the review, there are also 3, level 2 comparative studies included that we felt were clinically relevant. Of the 3 comparative studies, 1 compares nasal mucosal flaps and 2 compare lacrimal flaps. The review is predominantly broken down in to mucosal flaps and lacrimal flaps.

Cumulatively there are 188 patients in the RCT groups with 373 in the comparative studies: n = 561 patients.

The five studies included for discussion with their surgical intervention, outcome measures, success rates and complications are listed in **Tables 1 and 2**.

Table 1. RCTs and comparative studies showing surgical intervention, outcome measures, success rates and complications for nasal mucosal flaps versus no flaps.

Table 2. Comparative studies showing surgical intervention, outcome measures, success rates and complications for differing lacrimal sac flaps.

Outcome measures;

Lacrimal irrigation and absence of epiphora: In the two RCTs the main outcome measures were lacrimal irrigation and absence of epiphora ^{11,12}. The three comparative studies all utilised lacrimal irrigation or a fluorescein test as the main outcome measures; Kansu et al also documented the absence of symptoms as well as episodes of dacryocystitis and obstruction of the neo-ostium ^{13,14,15}.

Ji et al demonstrated a statistically significant benefit in the mucosal flap group with a 98% success rate in group A compared to 84% in group B (p<0.05) 11 . The other 2 papers comparing nasal mucosal flaps showed an increased success in the nasal flap groups but this was not statistically significant 13,14 . Yuen et al illustrated a statistically significant benefit when comparing a lacrimal sac flap to lacrimal flap excision with success of 89.1% in the lacrimal flap group and 71.7% in the resection groups (p<0.05) 15 .

Other outcome measures: In the papers comparing nasal mucosal flaps, all demonstrated either more granulation tissue or needing more debridements in the groups with no mucosal flaps. In the 2 RCTs this was statistically significant ^{11,12,13}.

In the two studies comparing lacrimal flaps, Massegeur et al found an increased synechia rate in the no lacrimal flap groups although not statistically significant, and no difference in granulation ¹⁴. In the Yuen paper they found a granulation tissue rate of 6.5% in the lacrimal flap group and 17.0% in the no flap group, but again not significant ¹⁵.

Complications: In the 2 RCTs there were a total of 3 epistaxis with no difference between the groups ^{11,12}. In the comparative study comparing mucosal flaps 5 patients had periorbital oedema with 4 developing eyelid ecchymosis and 4 epistaxis but there was no significant difference between the groups ¹³.

In the two studies comparing lacrimal flaps there were 12 cases of eyelid haematoma but no difference between the groups ^{14,15}.

An assessment of the evidence and results provided was undertaken at our local Clinical Trials Unit – given the limited number of RCTs, a meta-analysis could not be performed.

Discussion

The variety of surgical methods and generally good success rates of them all indicates a lack of consensus regarding best management. The above results demonstrate some conflicting evidence but overall there appears to be a trend towards preservation of both the nasal mucosal tissue and the medial lacrimal sac. The arguments for mucosal preservation in DCR surgery are similar to those of frontal sinus surgery.

Overall completeness and applicability of the evidence;

The 5 studies reviewed cover slightly differing aspects regarding mucosal preservation. Our review aimed to focus on nasal mucosal flaps, which 3 studies did. In performing the literature search we identified the 2 studies comparing medial lacrimal sac flaps and have included them as it was felt there was clinical relevance with the nasal mucosal papers. Given that 2 of the papers are RCTs these understandably hold more weight when drawing any conclusions regarding the subject matter. We found the Khalifa et al RCT to be the most complete with a good description of patient selection, inclusion and exclusion criteria ¹². It sufficiently details their randomisation procedure and sample size calculations. Importantly, this is the only double blinded study.

Trial Limitations; Quality of the evidence

The obvious limitations are of the comparative studies. The data is retrospective, and in Kansu et al and Yeun et al different surgeons were performing the two different techniques ^{13,15}. Massegur et al describe the operations taking place at different periods - group A being performed from 1998-2000 and group B from 2000 onwards ¹⁴. Both of these issues introduce significant variability into the process.

There was variability in the type of mucosal or lacrimal sac flap used, the most commonly used being the posteriorly based nasal mucosa and lacrimal flaps (see Table 3).

Other than the difference in surgical procedure, there is a wide variation in terms of the other adjuncts used. In the two RCTs there is clear description of the surgical procedure and in Ji et al the patients were under general anaesthetic, and they used Merogel dressing on the flap with and no silicone stents¹¹. In Khalifa et al surgery was performed under local anaesthetic and sedation, using tissue glue to the mucosal and lacrimal edges with a gelfoam patch as well as silicone stenting ¹².

The variation in surgical techniques and adjuncts such as silicone stents and mitomycin C is the main limitation of the evidence. Silicone stents were used in both arms of all of the studies except Ji et al where they did not use any ^{11,12,13,14,15}. There was variation regarding stent removal in Kansu et al and Yuen et al with no documented protocol for their removal^{13,15}. Mitomycin C was only used in one of the comparative studies and appears to be used in both arms. The use of silicone stents and mitomycin C in both arms of the Yuen et al paper left the main difference between the groups being surgical technique and therefore improved the study's relevance and validity for review¹⁵.

Without a meta-analysis of the results, we feel that the Yuen et al paper is still valid when answering the question of mucosal preservation in DCR surgery ¹⁵. In Kansu et al other nasal procedures were performed from septoplasty to FESS, although there was no statistical difference between the number of procedures performed in each arm ¹³.

Another difference amongst all the papers was the postoperative treatment regimen. This differed from antibiotic and steroid eye-drops to nasal irrigation and steroid nasal sprays, along with oral antibiotics and anti-inflammatories with no two papers observing the same post-operative regime.

Both RCTs followed their patients up for 12 months with an acceptable dropout rate with no significant difference between the 2 groups in either study ^{11,12}. In the comparative studies however the follow up ranged from 2 to 78 months in Kansu et al, and a minimum of 3 months in Yuen et al and 6 months in Massegur et al ^{13,14,15}. This is important as not only does this illustrate a variability in practice; but also in Khalifa et al they demonstrated that in both groups there was a drop in success rates from the 6 to 12 months. This suggests that a longer follow up or at least follow up for 12 months is indicated given the potential for late failures ¹².

Potential bias in review;

In all but the Khalifa et al paper there is significant potential for bias. The retrospective comparative studies as well as the Ji et al RCT were not blinded and although there is mention of randomisation by Ji the details and quality of this are not discussed ¹¹. Interpretation of outcome measures should be done so with caution. None of the papers appeared to use a visual analogue score or other validated scoring system. Although the fluorescein/lacrimal irrigation test is commonly used, the variability of the technique used from drop application to length of time observing are varied and subjective and therefore open to bias. In our clinical experience we have found that a binary approach does not reflect the complexity of the symptoms as the patients are rarely either totally symptomatic or symptom free. Therefore in future studies we would advise the use of a validated patients assessment with a visual analogue score as well as a quality of life assessment, e.g. *Glasgow Benefit Inventory* or *Lac-Q* ^{16,17}.

Comparison with other reviews;

There are three reviews published recently that outline DCR in practice and include some mention of mucosal flaps ^{18,19,20}. They talk of the different techniques but only Marcet et al details the evidence behind these, however this is a brief summary of Khalifa et al's findings - there were no other papers included in this review ^{12,17}.

Implications for clinical practice; Implications for research;

Endonasal endoscopic DCR is still a work in progress that has been progressively refined over the last 20-30 years. It now has similar or better success rates than the external technique that had been the gold standard for so long ²¹. There is significantly more evidence surrounding other aspects of the surgical approach such as silicone stents and application of mitomycin C.

There are many factors which influence the success of DCR surgery, with an overall high success rate despite variation in surgical technique or adjunct used. The biggest issue with current evidence is the lack of control of the other confounding variables. Comparing study against each other was also difficult given the heterogeneous approach to the surgical technique and adjuncts used as well as the postoperative regimes. The placement of silicone tubes is still contentious and still often used by many surgeons although there is growing evidence, including two randomised controlled trails and a meta-analysis, showing no difference in primary DCR with or without stenting ^{22,23,24}. A meta-analysis of the application of mitomycin C in endoscopic DCR has shown improved success rates (p=0.004) but subgroup analysis found that benefit was only statistically significant if silicone stents were not used ²⁵. The perceived risks and representative success rates without using mitomycin C results in it still not being used commonly.

The overall quality of evidence is low but there does appear to be a general trend towards improved outcomes with reduced granulation in the groups where nasal mucosal and lacrimal flaps were preserved but this is not clear-cut. Case series have been published demonstrating that DCR with or without mucosal flap preservation has similar success rates to the other published literature, but these are non-comparative non-randomised studies

^{26,27,28}. It is known that minimal mucosal trauma helps to reduce wound contraction and therefore minimise scarring ²⁹. It is established in surgical practice that reducing mucosal trauma in frontal sinus surgery and minimisation of bone exposure helps reduce stenosis ³⁰. Mann et al. proposed that this is also the case in DCR, where careful approximation of nasal mucosa and lacrimal flaps allows healing by primary intention and thus reduces granulation ³¹

Further research is clearly necessary to clarify if mucosal preservation has a benefit in DCR surgery compared to mucosal sacrifice. The studies need to be significantly powered and a standardised surgical technique used. Also limitations to the number of variables that can affect the clinical outcome such as patient selection, the use of stents, mitomycin C and the method of performing osteotomies should be accounted for. There needs to be an adequate follow up period of at least a year due to late failures and changes to the rhinostomy site. Clear outcome measures both subjective and objective with Patient Related Outcome Measures (PROMs) should also be assessed in further studies. Given the limitations of current evidence we would recommend that until further good quality research is available we should be performing a mucosal-sparing technique when performing DCR routinely.

No conflict of interest.

Table 1.

		Numbers in	Surgical					
Type of Study	Paper	the study	intervention	Blinded	Follow up	Outcome measures	Success	Complications
							98% group A, 84% group B	
			Group A mucosal			Lacrimal irrigation,	p<0.05, significantly more	
	Ji et al	54 group A	flap		1,3,6,12	absence of epiphora and	granulations and scar tissue	
RCT	2012	57 group B	Group B no flap	No	(months)	discharge	in group B	1 epistaxis
					Weekly for 1		92.1% group A, 87.2% group	
					month,		B. No difference. Only	
					every 2		difference was regarding the	Pain under Local
	Khalifa		Group A mucosal	Yes	weeks for 3	Lacrimal irrigation,	number of debridement's	anaesthetic 45%, no
	et al	38 group A	flap	double	months then	absence of epiphora and	needed. Significantly more	difference in epistaxis and
RCT	2012	39 group B	Group B no flap	blind	monthly	discharge	for group B.	synechia
								Epistaxis, orbital oedema,
						Lacrimal irrigation,		ecchymosis, synechia,
	Kansu		Group A mucosal		1 week,	absence of epiphora,		granulation, re-
Comparative	et al	25 group A	flap		1,3,6,12,24	episode of dacryocystitis,	Group A 100%, group B	obstruction. No difference
(retrospective)	2008	39 group B	Group B no flap	No	months	obstruction of neo ostium	88.3% p 0.08	in groups

Table 2.

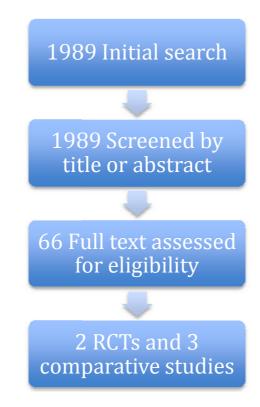
			Numbers in			Follow			
	Type of Study	Paper	the study	Surgical intervention	Blinded	up	Outcome measures	Success	Complications
									Group A, 5 eyelid
								Group A 92.7% group B	haematoma, 10 synechia,
4	Comparative	Massegur	96 group A	Group A no lacrimal flap		1,2,3,4,5,	Nasal permeability	87.5% not statistically	group B 7 eyelid
	(retrospective)	2003	40 group B	Group B lacrimal flap	No	6 months	fluorescein	significant	haematoma, 3 synechia
									Granulation tissue 6.5% in
									group A, 17.0% group B,
									didn't comment if
	Comparative	Yuen et al	46 group A	Group A lacrimal sac flap,		Differs	Fluorescein at 3	89.1% in group A, 71.7%	significant. One damage to
	(retrospective)	2004	53 group B	Group B no lacrimal flap	No	greatly	months	in group B, p<0.05	lacrimal punctum.

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Paper	Group A surgical technique	Group B surgical technique
Ji et al 2012	Posteriorly based nasal mucosa flap cut	Nasal mucosa removed
	into V shape	
Khalifa et al 2012	Posteriorly based nasal mucosal and	Nasal mucosa and medial lacrimal sac removed
	lacrimal lac flaps	
Kansu et al 2008	Posteriorly based nasal mucosal and	Nasal mucosa and medial lacrimal sac removed
	lacrimal lac flaps	
Yuen et al 2004	Nasal mucosa removed, large	Nasal mucosa and medial lacrimal sac removed
	posteriorly based lacrimal flap	
Massegur 2003	Inferior nasal mucosal flap	Inferior and posterior based nasal mucosal flap
		with posterior lacrimal sac flap

Table 3. Table showing the variation in nasal mucosal and lacrimal flaps used in each paper reviewed.

Illustration 1. Search results for systematic review on nasal mucosal flaps in DCR surgery.



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52.

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