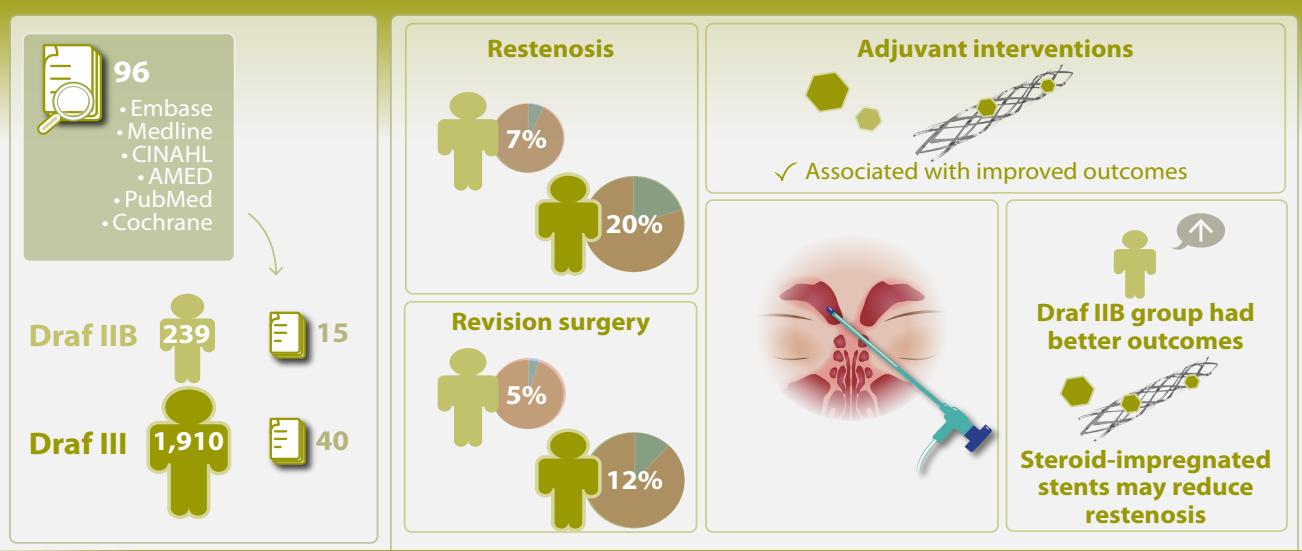


# Comparison of outcomes for Draf IIB vs Draf III in endoscopic frontal sinus surgery: a comprehensive systematic review and meta-analysis

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## Comparison of outcomes for Draf IIB vs Draf III in endoscopic frontal sinus surgery: a comprehensive systematic review and meta-analysis



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## Abstract

**Background:** Understanding the factors associated with increased rates of restenosis following Draf procedures is crucial for developing targeted strategies to mitigate complications such as mucocele formation, reduce the need for revision surgeries, and improve long-term patient outcomes.

**Methodology:** A systematic search was conducted using Embase, Medline, CINAHL, AMED, PubMed, and the Cochrane Database on January 17th, 2024. Research articles published in English language were included. Abstracts were independently screened by two reviewers, and data were extracted and assessed for quality in adherence to PRISMA guidelines. Meta- and sub-group analyses were conducted using the REML model and random-effects model to address high heterogeneity and  $I^2$  values.

**Results:** A total of 96 studies met the inclusion criteria. For the Draf IIB subgroup (15 studies, 239 sinuses), the restenosis rate was 7%, compared to 20% in the Draf III subgroup (40 studies, 1,910 sinuses). Revision surgery rates were 5% for Draf IIB versus 12% for Draf III. Adjuvant interventions, such as steroid-impregnated stents, were associated with improved outcomes, showing an ostium patency OR of 2.20.

**Conclusion:** Draf IIB had superior outcomes compared to Draf III with respect to restenosis and revision surgery. The use of steroid-impregnated stents appears effective in reducing restenosis rates.

**Key words:** drug-eluting stents, frontal sinus, nasal surgical procedures

## Introduction

The Draf classification system outlines three types of frontal sinusotomy procedures based on their invasiveness and objectives<sup>(1-5)</sup>. Draf Type I involves the removal of obstructing tissue below the frontal ostium without altering the ostium itself, targeting the anterosuperior ethmoidal cells. Draf Type II expands the frontal sinus drainage pathway, with Type IIA involving the removal of ethmoidal cells that extend into the frontal sinus, creating a larger opening between the lamina papyracea and the middle turbinate. Type IIB further enlarges the drainage area by resecting the frontal sinus floor between the lamina papyracea and the nasal septum. Draf Type III, also known as endoscopic modified Lothrop procedure (EMLP), is the most extensive, providing maximal access through bilateral enlargement, involving the removal of the frontal sinus floor and parts of the intranasal and frontal septum.

Historically, the endoscopic treatment of frontal sinus disease has been challenging due to the narrow frontal sinus ostia, its anatomical location, and variations that limit visualization<sup>(6)</sup>. Despite the recent advancements in endoscopic techniques and technology that have markedly improved access to the frontal sinus, endoscopic frontal sinus surgery is still at high risk of failure<sup>(7)</sup>. Neo-osteogenesis and persistent mucosal inflammation can cause the frontal neo-ostium to narrow or close entirely. This, along with mucocele formation, is a major factor necessitating revision surgery<sup>(7,8)</sup>. A recent meta-analysis on 11 studies and 778 patients found that restenosis of the neo-ostium occurred in 17.1% of cases and 9.0% of cases underwent revision surgery<sup>(7,9)</sup>.

Previous studies have explored the application of stents, mucosal grafts, and pedicle flaps to prevent restenosis of the frontal neo-ostium, with promising results in individual studies<sup>(6,7,10-15)</sup>. Currently, no meta-analyses are available comparing the success rates of additional interventions or directly evaluating outcomes between Draf IIB and Draf III procedures. This review aims to fill that gap by comparing Draf IIB and Draf III outcomes in terms of revision rates, neo-ostium restenosis, and mucocele formation and to assess the impact of using steroid-impregnated stents, silastic stents, and mucosal flaps or grafts on these outcomes.

## Materials and methods

### Protocol registration and search strategy

A systematic literature review was conducted on 17th January 2024 in accordance with the preferred reporting items for systematic reviews and meta-analyses (PRISMA) guidelines<sup>(16)</sup>. The protocol was registered in the PROSPERO database (CRD42024496239). In consultation with a librarian trained in MeSH terms and literature search, a comprehensive search was conducted in Embase and Medline via Ovid, as well as in

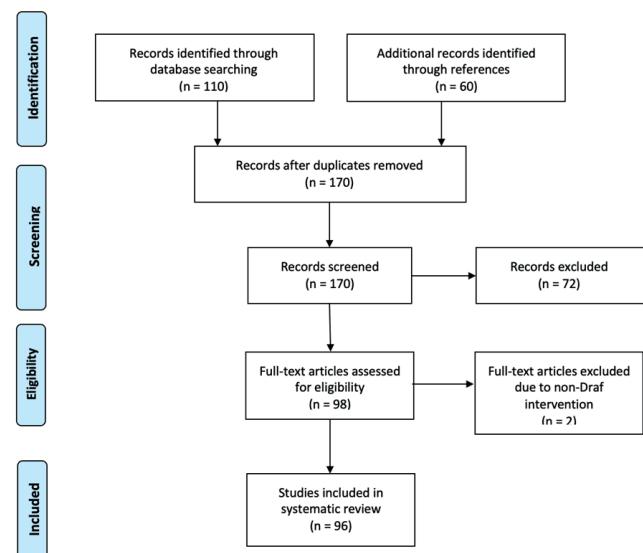


Figure 1. PRISMA flow diagram.

CINAHL, AMED, PubMed and Cochrane database on January 17th 2024, utilising the terms "endoscopic frontal sinus surgery" or "frontal sinus surgery" or "draf III" or "draf II" or "modified lothrop" and ("adjuvant intervention" or "steroid" or "stent" or "flap" or "mucosal flap" or "mucosal graft" or "frontal sinus stent" or "steroid impregnate stent" or "silicon stent" or "free mucosal graft"). All key terms were standardised for each search engine, and suitable Boolean operators were employed (Appendix1).

### Screening

The study selection was conducted independently by two authors (Y.H. and H.F.). They initially screened the titles and abstracts, followed by a full-text evaluation of selected articles for final inclusion in our study. Additionally, references from the selected full-text articles were screened for potential papers for inclusion. In case of any disagreement between the two authors, the third author (H.I.) was consulted to resolve the concerns. Data extraction was performed after the final study selection using a pre-formulated data extraction sheet to record study parameters and outcome measures.

### Population, intervention, comparison, and outcome (PICO)

Our study included papers evaluating adult patients undergoing frontal sinus Draf IIB or Draf III procedures for any indication, with interventions including the use of steroid-impregnated stents, silicon stents, and mucosal flaps (either rotated flaps or free mucosal grafts). Steroids could be administered via absorbable stents impregnated with steroids or drug-eluting steroid stents. The comparison group received no intervention with stents, steroids, or flaps/free mucosal grafts. Outcomes measured were frontal sinus restenosis, frontal sinus mucocele formation, and the need for revision. The inclusion criteria

encompassed all primary research articles relevant to the PICO, published in English. Papers that were excluded were as follows: conference abstracts, letters to editors, commentaries, non-English articles, animal studies, and articles not fully accessible for analysis.

#### Assessment of risk of bias

Manuscripts with various study designs were included in our review, requiring different quality assessment tools. Risk of bias assessment was performed by Y.H. and H.F. using the Cochrane Risk of Bias 2 (RoB 2) tool<sup>(17)</sup> for randomised control trials, the Risk of Bias in Non-randomized Studies of Exposure (ROBINS-E)<sup>(18)</sup> for observational studies of exposures, and the JBI critical appraisal tool<sup>(19)</sup> for case reports.

#### Data analysis

Meta-analysis and sub-group analysis were performed using STATA 18. A meta-analysis for the proportion of restenosis was conducted using the restricted maximum likelihood (REML) model to account for the methodological and clinical heterogeneity across the studies. The same was used to perform sub-group analysis. The random effect model was used given the high heterogeneity amongst the study population and as indicated by high  $I^2$  values.

For studies reporting outcomes on two arms, meta-analyses for dichotomous outcomes were conducted using Review Manager version 5.4. The Mantel-Haenszel method with random-effects modelling was applied to account for heterogeneity between studies. Odds ratios (OR) for events and non-events were selected as the effect measures.

## Results

The database searches and reference screening initially identified 170 studies (Figure 1). The abstracts were screened based on PICO relevance, leading to the selection of 98 papers for full-text review. Two studies were excluded because their interventions were not Draf procedures, leaving 96 studies<sup>(6–8,10–15,20–105)</sup> for inclusion in the final systematic review (Table 1). The definitions for restenosis and follow-up periods for each study are detailed (Table 1).

#### Proportional meta-analyses

##### Draf IIB vs III

###### Restenosis

A total of 49 studies<sup>(6,8,10–13,20,28–30,33,36,40–42,44,45,48,51,53,54,58,60,62,64,71,73,75–78,80–82,84,86,87,90,91,93–101,103)</sup> reporting restenosis outcomes following Draf IIB and Draf III procedures were included in this analysis (Table 2). Data was reported on 2,149 operated sinuses, with 443 cases of restenosis observed. The definition for restenosis and follow-up periods for each study are detailed in Table 1. Pooling

all Draf IIB and III populations yielded a weighted restenosis proportion of 0.18 (95% CI: 0.12–0.24) with high heterogeneity ( $I^2 = 96.8\%$ ).

To assess outcomes by procedure type, studies were grouped by Draf type. The Draf IIB subgroup (15 studies) included 239 sinuses with 15 restenosis cases, while the Draf III subgroup (40 studies) included 1,910 sinuses with 428 restenosis cases (Figure 2). The weighted restenosis proportion was 0.07 (95% CI: 0.02–0.13) for Draf IIB and 0.20 (95% CI: 0.13–0.27) for Draf III, with high heterogeneity ( $I^2 > 50\%$ ). The significant difference ( $p < 0.01$ ) suggests the Draf type influences restenosis rates.

###### Revision procedures

A total of 29 studies<sup>(6,8,10,12,13,28,34,38,48,50,58,62,67,71,73,75,81,83,84,87,89,91,95–97,99,100,102,105)</sup> reported data on revision outcomes following Draf IIB and Draf III procedures. Data included 1,503 operated sinuses, with 227 requiring revision surgery. Pooling all Draf IIB and III populations resulted in a weighted restenosis proportion of 0.12 (95% CI: 0.08–0.16) with significant heterogeneity ( $I^2 = 85.9\%$ ). Data was segregated by Draf procedure type, with revision surgery calculated for each. The Draf IIB subgroup (5 studies) included 89 sinuses, with 4 requiring revision surgeries. The Draf III subgroup (28 studies) included 1,414 sinuses, with 223 requiring revision surgeries (Figure 3). The weighted revision proportion was 0.05 (95% CI: -0.02–0.12;  $I^2 = 20.8\%$ ) in Draf IIB, and 0.12 (95% CI: 0.08–0.17;  $I^2 = 85.8\%$ ) in Draf III. The significant difference ( $p < 0.01$ ) suggests the Draf procedure type affects the revision rate.

###### Mucocele formation

Three studies reported data on rates of mucocele formation following Draf IIB and Draf III procedures<sup>(38,44,98)</sup>. However, the proportional meta-analysis revealed that none of the intra-group or inter-group effect sizes or comparisons reached statistical significance (Figure S1).

##### Additional interventions

###### Restenosis

Analysis was conducted to evaluate the impact of specific interventions on rates of restenosis following Draf procedures (Figure 4). 16 studies investigated the impact of mucosal flaps/grafts on the rate of restenosis<sup>(6,11,12,20,35,42,44,45,54,71,72,78,85,86,96,100)</sup>, 3 studies investigated the impact of mucosal flaps/grafts used in conjunction with stents<sup>(10,64,73)</sup>, 19 studies investigated the impact of stents alone<sup>(13,21,26,27,30,32,58,59,61,66,68,75,77,79,80,94,97–99)</sup>, and 2 studies reported the impact of steroid-impregnated stents on the restenosis rate<sup>(48,57)</sup>. The weighted restenosis proportions were 0.10 (95% CI: 0.02–0.18;  $I^2 = 97.4\%$ ) for the mucosal flap/graf group, 0.03 (95% CI: 0.01–0.05;  $I^2 = 0.11\%$ ) for the mucosal flap/graf with stents group, 0.25 (95% CI: 0.12–0.37;  $I^2 = 95.2\%$ ) for the stents group, and 0.29 (95% CI: 0.21–0.36;  $I^2 = 0.00\%$ )

Table 1. List of studies included in the systematic review.

No.	Author (Year)	Country	Study design	Indication for frontal sinus surgery	Mean age SD	Type of frontal sinus surgery	Intervention type	Concomitant intervention	Intervention duration
1	Al Kadah et al. (2014)	Germany	Retrospective chart review	one-sided frontal sinus pathology, including frontal sinus osteoma, mucocle or pyocele, and sinusitis. CT scans indicating one-sided frontal sinus pathology and frontal septum position in the midline or close to it.	21	Draf II B	Mucosal flap	-	-
2	Al Komser et al. (2013)	USA	Retrospective case series	Chronic sinusitis	36.5	Draf II C	Silastic sheet	Stammberger sinus-foam infused with 8 mL of triamcinolone 40 mg/mL was placed in the defect.	4 weeks
3	Anand et al. (2005)	USA	Retrospective chart review	Patients that previously underwent image-guided ESS for isolated frontoethmoid disease that require re-do via osteoplastic flap technique	Mean age of 48.9 years (range, 23–73 years)	Not specified	No intervention	-	-
4	Askar et al. (2015)	USA	Prospective series	Chronic frontal sinusitis	16–76 years (mean, 46.2 ± 17.4)	Draf II A	No intervention	Debridement and postoperative antibiotics followed, saline douches	-
5	Banhiran et al. (2006)	USA	Retrospective case series	Not mentioned	Range 21 to 81 years (mean age, 51.5 years)	EMLP	1-mm-thick, soft, reinforced silastic stent	All stents were removed in the clinic during the patients' 2-month postoperative follow-up visit	-
6	Bastianelli et al. (2022)	Australia	Randomised pilot study	Not mentioned	The median age was 54.8, and age ranged from 23–72 years of age.	EMLP	Mucosal flap	The clinician endoscopically examined the patient after sufficient debridement and recorded the endoscopic exam for subsequent analysis.	Healing time; 40, range 2–60 in weeks
7	Benoit et al. (2001)	USA	Retrospective chart review	Patients with chronic frontal sinusitis refractory to medical management	Not stated	External + endoscopic	Stent placement	-	5 weeks (range, 3–12 weeks)
8	Brar et al. (2023)	USA	Retrospective cohort	Not mentioned	TICP cohort 51.5 years (SD 17.8), MPFLG cohort 57.5 years (SD 14.5)	Not specified	Triamcinolone-impregnated chitosan polymer (TICP) stent in FSO	None 1 week (removed at f/u)	-
9	Casiano et al. (1998)	USA	Retrospective chart review	Persistent frontal sinusitis	Ranged from 27 to 80 years of age (mean, 51 years)	EMLP	No extra procedure (i.e. no mucosal flap/stent)	-	-

Table 1. List of studies included in the systematic review. *continued*

No.	Author (Year)	Country	Study design	Indication for frontal sinus surgery	Mean age SD	Type of frontal sinus surgery	Intervention type	Concomitant intervention	Intervention duration
10	Chaabani et al. (2012)	USA	Prospective case series	Posterior table fractures	Mean age 37 years	Draf II A, Draf II B, or III, Draf III (1 patient)	-	24 hours of intravenous ceftriaxone and then converted to oral amoxicillin/clavulanic acid or clindamycin for 2 weeks postoperatively	-
11	Chan et al. (2009)	USA	Retrospective chart review	Chronic rhinosinusitis	Not stated	EMLP	Soft 0.01 inch thick silastic sheeting	Routine postoperative medical therapy (culture directed antibiotic therapy and/or oral steroids) and endoscopic debridement	-
12	Chandra et al. (2003)	USA	Retrospective chart review	Chronic rhinosinusitis	a mean age of 47.6 years	Not defined	No extra procedure (i.e. no mucosal flap/stent)	Postoperatively, debridement was performed in the office setting weekly for 4 to 6 weeks. All patients received antibiotics for at least 2 to 3 weeks postoperatively	-
13	Chiu et al. (2003)	USA	Retrospective chart review	Chronic sinusitis and/or sinus mucocles unresponsive to a minimum of 3 weeks of antibiotics and oral and nasal steroid	Not stated	Not specified	3 patients - stent used	Standardized postoperative care regimen, weekly office debridements x 3 weeks followed by monthly visit for 4 months after surgery, nasal steroid sprays, acute infections - oral steroids	6 weeks. Total duration of treatment: Until follow up
14	Cho et al. (2023)	USA	Retrospective cohort study and chart review	Patients treated for inverted papilloma involving the frontal sinus. Patients with a history of tumor removal were regarded as revision cases.	60.6 ± 16.2	18 Draf IIA, 13 Draf IIB, 13 EMLP	No extra procedure (i.e. no mucosal flap/stent)	-	-
15	Choudhury et al. (2016)	UK	Retrospective cohort study and chart review	alternative frontal sinus pathology (not refractory chronic frontal sinusitis)	Mean 45.2 years (range, 16–78 years)	EMLP	No extra procedure (i.e. no mucosal flap/stent)	-	-
16	Citardi et al. (2001)	USA	Retrospective chart review	Patients with chronic frontal sinusitis after previous sinus surgery	Not stated	Not specified	Mucoperiosteal flap	Postoperative serial endoscopic examination with removal of crusts	-
17	Close et al. (1994)	USA	Retrospective chart review	Chronic frontal sinusitis + pts failing routine endoscopic sinus surgery	Mean 40 years (range 15 to 73 years)	EMLP	No extra procedure (i.e. no mucosal flap/stent)	Nasal douching	-

Table 1. List of studies included in the systematic review. *continued*

No.	Author (Year)	Country	Study design	Indication for frontal sinus surgery	Mean age SD	Type of frontal sinus surgery	Intervention type	Concomitant intervention	Intervention duration
18	Conger et al. (2014)	USA	Prospective case series	Patients with frontal sinus pathology located lateral to the plane of the lamina papyracea (lateral disease)	47.9 years; range, 14-84 years	Draf II A 76; Draf II B 52; Draf III 23	Mucosal flap	-	-
19	Conger et al. (2012)	USA	Prospective cohort study	Pts undergoing the Draf III procedure for infectious, inflammatory, or neoplastic disease	Mean 58 years	Draf III	Mucosal flap + silastic stent	bilateral middle meatal cotton spacers in a non latex glove finger inserted into the middle meatus	Stent removed 8 to 13 days postoperatively
20	Crocetta et al. (2021)	Italy	Retrospective case series	Patients with frontal sinus pathologies following previous frontal craniotomies	52 years (range 21-81)	7 DRAF II A, 1 DRAF II b, 11 DRAF III and 3 DRAF II C (modified DRAF III) approaches	free mucosal grafts or pedicled septal flaps	-	-
21	DelGaudio et al. (2006)	USA	Retrospective case series	Pts that underwent ESS for CRS	Mean age of 50.8 years, range of 15-75 years	Not specified	Steroid drops	If purulent discharge was noticed, antibiotic drops were also used. 27.8% of patients requiring the use of oral steroids (given because of continued edema or stenosis of the target sinus ostia)	Mean time of drop initiation was 0.9 months postoperatively.
22	Eloy et al. (2011)	Belgium	Retrospective chart review	Unilateral frontal sinus obstruction	Mean 55.4 years (range: 40-53)	Draf III	No extra procedure (i.e. no mucosal flap/stent)	no packing was put in place in 94 patients Merocel was used for one or two days in 18 patients a Vaseline gauze was used for 5 to 8 days in 8 patients. All the patients received broad spectrum antibiotics	-
23	Eloy et al. (2012)	USA	Retrospective case series	Patients who failed maximal medical management of frontal sinusitis, and in whom the ipsilateral frontal recess was inaccessible surgically	mean 48.25 (range, 15-78) years	Draf II B	No extra procedure (i.e. no mucosal flap/stent)	10 days of oral corticosteroid and a broad spectrum antibiotic, Nasal irrigation	-

Table 1. List of studies included in the systematic review. *continued*

No.	Author (Year)	Country	Study design	Indication for frontal sinus surgery	Mean age SD	Type of frontal sinus surgery	Intervention type	Concomitant intervention	Intervention duration
24	Erdur et al. (2018)	Turkey	Case report	Patient that underwent endoscopic modification of the Lothrop procedure (for treatment of frontal sinus osteoma)	46	Draf III	A vascularised, posteriorly based, septal mucosal flap was used in reconstruction	The flap was packed with gel foam and supported by a 12-French Foley catheter balloon. Nasal silicon buffers were inserted on both sides of the septum	-
25	Eviatar et al. (2017)	Israel	Retrospective case series	Pts with advanced frontal sinus disease	mean age of 50.3 (range 25–70) years	Mini Lothrop (extended Draf IIb)	No extra procedure (i.e. no mucosal flap/stent)	Merocel pack was left in the middle meatus overnight. Nasal saline spray four times daily and nasal steroid spray twice a day for a month. Antibiotics were not prescribed to any of our patients when discharged.	-
26	Florini et al. (2016)	France + UK	Prospective case series	Patients with radiologically confirmed frontal sinus disease	Mean age 52 years (range 20 to 84)	Draf IIb	Septoturbinal mucosal flap over the drilled posteromedial wall of the frontal neo-ostium	Silastic roll positioned in the frontal sinusotomy for 2 weeks	Until end of follow-up (minimum of 6 months)
27	Fischer et al. (2022)	Germany	Retrospective cohort	Not mentioned	mean age at time of surgery $52.6 \pm 12.9$ years, 18–85 years	Draf III	Lateral pedicle mucosal flap (revision in 87 however reported together)	the flap is covered in its new position by resorbable gelatinous foam	Since a relevant proportion of restenosis occurs in the first two years after surgical treatment, the study period was limited to 24 months
28	Friedman et al. (2006)	USA	Retrospective chart review	patients who had frontal sinus endoscopic surgery performed by the senior author (M.F.) in conjunction with other nasal and sinus procedures deemed necessary by initial assessment	Not stated	Not mentioned	No extra procedure (i.e. no mucosal flap/stent)	-	-
29	Friedman et al. (2000)	USA	Retrospective case series	persistent chronic sinusitis or polyposis despite medical therapy that included antibiotics, intranasal steroids, or systemic steroids or, in certain cases, prior surgical therapy	ranged from 14 years to 76 years, with a mean of 41 years.	Draf I	No extra procedure (i.e. no mucosal flap/stent)	-	-

Table 1. List of studies included in the systematic review. *continued*

No.	Author (Year)	Country	Study design	Indication for frontal sinus surgery	Mean age SD	Type of frontal sinus surgery	Intervention type	Concomitant intervention	Intervention duration
30	Georgalas et al. (2011)		Retrospective chart review	Not mentioned	mean 47 (range 11 to 78 years)	Draf III	Steroid impregnated gauze	advised to rinse their nose with saline and use steroid nasal drops, gentle debridement of the neo-ostium and removal of clots and crusts after 1 week	10 days
31	Gotlib et al. (2015)	Poland	Retrospective case series	Mucocle was the most common indication for surgery (5 cases), followed by osteoma (2 cases), inverted papilloma (1), carcinoma (1), and chronic rhinosinusitis (CRS) without polyps (1). One of the patients with frontal sinus osteoma had concurrent CRS with polyps. Three patients had undergone prior endoscopic surgery, and another 3 had undergone external approach procedures	Not stated	Mini Lothrop (extended Draf II B)	No extra procedure (i.e. no mucosal flap/stent)	saline nasal douches for 3 weeks postoperation, starting the day after surgery, and intranasal steroids starting 3 weeks after surgery	-
32	Grayson et al. (2017)	USA	Case-series	patients undergoing endoscopic surgery for frontal sinus fracture, performed by surgeon B.A.W.	Mean 24 years (SD not stated)	Draf II b, III	mucosal grafts were placed on the drilled-out nasofrontal area	Gelfoam and rolled stent(s) carved to fit from 0.5-mm silastic sheeting	Until end of follow-up
33	Gross et al. (1997)	USA	Retrospective chart review	all patients who were candidates for the modified transnasal Lothrop procedure: persisting chronic frontal sinus disease that has been refractory both to aggressive medical therapy and to surgical correction via endoscopic or external sinus procedures.	aged 29 to 89, with an average age of 46 years	EMLP	No extra procedure (i.e. no mucosal flap/stent)	-	-
34	Hahn et al (2009)	USA	Retrospective case series	Chronic frontal sinusitis, frontal bone osteomyelitis, mucocle	Not available	Not specified	No extra procedure (i.e. no mucosal flap/stent)	-	-
35	Hajbeygi et al. (2016)	Iran	Retrospective chart review	Fifteen patients with chronic frontal sinusitis, two patients with mucocles, two with malignancy, and one with osteoma	Mean 40.4 years (range, 17–70 years)	Draf III	No extra procedure (i.e. no mucosal flap/stent)	Pt. with CRS continued inhaled nasal corticosteroid spray	-
36	He et al. (2022)	China	Observational, case series	Unilateral recurrent frontal sinus disease	median age of 48.0 years (range 19–83 years)	Draf II B	lateral inferior pedicle flap	All pt - saline irrigation. Nasal nebulization inhalation of budesonide for CRS patients, nasal packing removal at 1 weeks.	-

Table 1. List of studies included in the systematic review. *continued*

No.	Author (Year)	Country	Study design	Indication for frontal sinus surgery	Mean age SD	Type of frontal sinus surgery	Concomitant intervention type	Intervention duration
37	Hildenbrand et al. (2012)	Germany	retrospective case series	Inclusion: All patients who underwent a DrafII with reconstruction of the frontal sinus drainage pathway using mucosal transplants.	43.8 years (range, 20–82 years)	DrafII	Mucosal transplants from the area of the septum that will be resected	silicone foils can be placed on top of the transplants. Humid healing environment created by taping the nose with sticking plaster, thereby preventing breathing through the nose Until end of follow-up
38	Hong et al. (2012)	South Korea	Prospective, randomized, single-blind case-control study	Patients who underwent frontal sinusotomy with a neofrontal ostium of 4 mm.	48.2 (19–62)	DrafI	No extra procedure (i.e. no mucosal flap/stent)	Steroid sprays/drops applied. Nasal packing using Merocel 8 weeks of steroids
39	Hosemann et al. (1997)	Germany	Retrospective chart review	107 patients - chronic paranasal sinusitis. Endonasal tumor surgery was performed in three cases (a meningioma, an inverted papilloma, and an osteoma respectively).	Not stated	DrafII	No extra procedure (i.e. no mucosal flap/stent)	-
40	Hosemann et al. (2003)	Germany	Retrospective chart review	Chronic rhinosinusitis	Not stated	Not specified	Steroid impregnated stent	3–4 weeks, removed at f/u
41	Huang et al. (2019)	China		recalcitrant chronic FRS in three patients while four patients had mucocele secondary to the closure of the frontal neo-ostium after complete resection of a tumour of the frontal sinuses	45.16 ± 16.6 years	Draf 3 (revision)	bioabsorbable steroid-eluting sinus stent.	A topical corticosteroid; gentamicin and saline irrigation were recommended for postoperative care one month after surgery. Most patients returned 1 week following the procedure and then every 2 weeks for gentle debridement.
42	Hunter et al. (2010)	UK	Retrospective case studies	CRS + left osteoma (pt 1), right fronto-ethmoid mucocele (pt 2); fronto-ethmoid mucocele with destruction of ant + post walls (pt 3)	69 +/- 23	Not specified	Self-retaining Rains frontal sinus stent (Medtronic)	One patient also had an osteoplastic flap created 6 months placement of stent
43	Illing et al. (2016)	USA	Prospective case series	patients undergoing a Draf III procedure with mucosal grafting by the senior author B.A.W.	Average age of 54 years (range: 15–84 years)	Draf III	Mucosal flap	Silastic frontal sinus stents, 0.5 mm thickness, were then inserted to support the mucosal grafts 8 to 13 days postoperatively
44	Janisiewicz et al. (2015)	USA	Case reports	Refractory CRS	63	Draf IIIB	No extra procedure (i.e. no mucosal flap/stent)	patient was discharged home with a steroid taper and a three-week course of antibiotics

Table 1. List of studies included in the systematic review. *continued*

No.	Author (Year)	Country	Study design	Indication for frontal sinus surgery	Mean age SD	Type of frontal sinus surgery	Intervention type	Concomitant intervention	Intervention duration
45	Jones et al. (2012)	USA	Prospective case series	All patients with skull-base defects involving the frontal sinus requiring surgery.	average age 46 years calculated includes all 37 patients)	Draf II A, II B, III	Nasoseptal flap based on the posterior septal artery was used in most cases. Free grafts were used when the septum was involved.	Durepair (Medtronic Neurosurgery, Goleta, CA) or Surgisis (Cook Medical, Bloomington, IN) are used as an underlay repair followed by mucosal graft.	Until end of follow-up
46	Kang et al. (2010)	South Korea	A nonrandomized, prospective study	Chronic frontal sinusitis	43 ± 11.9 years	Not specified	Expandable polyvinyl acetate packing	Injected saline into the EPA to get the expansive effect	48 hours later removed for 4 days, repeated the same procedure three times for 3 weeks
47	Karligkiotis et al. (2015)	Italy	Retrospective cohort study and chart review	mucocles, osteomas, and inverted papillomas; that extend far lateral into the frontal sinus and/or involve the supraorbital recess by also taking advantage of the endoscopic endonasal orbital transposition in selected cases	ranged 20 to 79 years (mean age, 48 years)	Draf II B or EMLP	No extra procedure (i.e. no mucosal flap/stent)	-	-
48	Khafagy et al. (2020)	Egypt	Prospective cohort study	Refractory chronic frontal sinusitis	mean age of 34.12 ± 12.38 years	Draf II A	No extra procedure (i.e. no mucosal flap/stent)	Systemic corticosteroids, Regular nasal wash using normal saline, budesonide nasal irrigation was given twice daily for one month. middle meatus meroce was applied, removed two days later	-
49	Khong et al. (2004)	Australia	Retrospective, consecutive case review	complicated frontal mucoceles and endoscopic marsupialization for other paranasal sinus mucocles.	range 15-83 years	EMLP	No extra procedure (i.e. no mucosal flap/stent)	-	-
50	Khoueir et al. (2018)	France	Retrospective study	recalcitrant CRS and when a Draf II B was not enough to expose a benign tumour or to drain a mucocele with supraorbital extension	Not stated	Draf II B, Draf III	Double mucoperiosteal flap	A 5mm silicone roll is used to stabilise the flaps and removed after 2 weeks	-
51	Khoueir et al. (2018)	Not stated	1 case study	Frontal mucocele	25	Draf II B	2 local mucoperiosteal flaps and stent (silicone)	0.5 mm silicone roll was placed in the cavity to apply and stabilise the flaps for 2 weeks	-
52	Kikawada et al. (1999)	Japan	Retrospective chart review	obstructive frontal sinusitis caused by postoperative scarring	Range 14 to 61 years	Draf II (16) and Draf III (9)	Silicone stent (Y or I shaped)	Average 7 months (range 3-12)	-

Table 1. List of studies included in the systematic review. *continued*

No.	Author (Year)	Country	Study design	Indication for frontal sinus surgery	Mean age SD	Type of frontal sinus surgery	Concomitant intervention	Intervention duration
53	Lin et al. (2008)	Canada	Retrospective case series	Not mentioned	Mean 54.36 SD 11.89 years	Not specified	T tube stent	-
54	Loehrl et al. (2000)	USA	Retrospective chart review	Thirty patients of the 31 were undergoing surgery for chronic inflammatory disease. One patient had a recurrent inverted papilloma with extension into the frontal sinus. A	Mean 44.7 years (age range, 17–71y)	Draf I (12), Draf II (14), Draf II (5)	No extra procedure (i.e. no mucosal flap/stent)	-
55	Luong et al. (2018)	USA	RCT (prospective, multicenter, randomised clinical trial using an inpatient control design)	CRS based on AAO-HNS guidelines, <sup>3</sup> who were scheduled to undergo primary or revision bilateral ESS and had evidence of bilateral frontal sinus disease based on computed tomographic (CT) scan	Mean (SD) age of 49.5 (13.4) years	Draf IIA or IIB	A biabsorbable steroid releasing implant with hourglass shape containing 370 µg of mometasone furoate	10-day course of antibiotics, Intranasal steroid sprays were allowed starting 14 days after ESS, and oral steroids were prescribed, if medically required.
56	Mansour et al. (2013)	Saudi Arabia	Retrospective case series	Recurrent frontal sinusitis despite previous surgery	aged from 17 to 54 years	Not stated	Revision surgery - a double J stent was introduced using the wire supplied with the stent	antibiotic (levofloxacin 500 mg once daily) for 10 days Stent removed after 6 months
57	May et al. (1995)	USA	Not mentioned	nasofrontal recess and frontal sinus inflammatory disease.	Average age - 44	Not specified	2 patients - flap used (after 1st endoscopic sinus surgery failed)	Out of the 37, 3 - first op not successful underwent second naofrontal approach, <sup>2</sup> underwent an external osteoplastic procedure with creation of a flap and fat obliteration of the frontal sinus.
58	Metson et al. (1998)	USA	Retrospective chart review	Chronic frontal sinusitis	Mean age of 42.7 years for the drillout group; age range of 14–73 years	Draf IIB, Draf III	No extra procedure (i.e. no mucosal flap/stent)	-
59	Morrissey et al. (2016)	Australia	Prospective case series	CRS failing medical therapy	No revision cohort 51.39, revision cohort 47	EMLP	Mucosal graft	No packing was placed. In the postoperative period the patient was instructed to perform saline douches 4 to 6 times per day
60	Naidoo et al. (2013)	Australia	Retrospective chart review	previously failed at least a 2-month course of maximal medical treatment for CRS that included culture-directed antibiotics, saline douches, topical nasal steroids, and a 3-week course of oral steroids. All patients had persistent symptoms of nasal blockage (NAB), facial pain/headache (FP), rhinorrhea, postnasal drip (PND), and/or anosmia.	47.2 – 54.1 years	Draf IIA (or revision Draf IIA)	Axillary flap AND trephine cannula	Oral antibiotic therapy for 7 to 10 days, and in nasal polyposis patients a tapering dose of oral prednisolone was given. Saline douches and a debridement at 2 weeks was performed

Table 1. List of studies included in the systematic review. continued

No.	Author (Year)	Country	Study design	Indication for frontal sinus surgery	Mean age SD	Type of frontal sinus surgery	Intervention type	Concomitant intervention	Intervention duration
61	Naidoo et al. (2012)	Australia	Retrospective chart review	All patients who underwent surgery had previously failed at least a 2-month course of maximal medical treatment + symptomatic (in addition, primary endoscopic frontal sinusotomy (Draf 2A) was performed only if there was objective evidence of persistent postoperative mucosal thickening in the frontal recess or frontal sinus on paranasal CT scans, and endoscopic evidence of ongoing disease such as polyposis, mucosal edema, and/or mucopurulence.	48.5 years (SD 15.2; range, 14–78 years)	Draf IIA	Axillary flap	oral antibiotic therapy for 7 days, and a tapering dose of oral prednisolone, nasal douching	-
62	Naidoo et al. (2014)	Australia	Retrospective cohort study and chart review	All patients who underwent surgery had previously failed at least a 2-month course of maximal medical treatment for CRS.	average age of 49 years	EMLP	Axillary flap AND trephine cannula	oral antibiotic therapy for 21 days, and in nasal polyposis a tapering dose of oral prednisolone, saline douches	mini trephine canula is left in place for 5 days
63	Nakagawa et al. (2007)	Japan	Prospective case series	Postoperative frontal mucocele	Average 67.4 years	EMLP	Stented with thin silastic sheeting	-	3 months
64	Nguyen et al. (2019)	Canada	Case studies	Frontal sinus osteoma	47 years	Draf III	No mucosa flap - or stent.	-	-
65	Nishikie et al. (2015)	Japan	Retrospective cohort study and chart review	frontal sinusitis or cyst, revision surgery for failed frontal sinusotomy or Lynch procedure, or trauma cases, intractable frontal sinusitis, tumor, mucocele, and trauma	Not stated	EMLP	stented with a silicone tube or sheet	-	Several weeks
66	Omura et al. (2018)	Japan	Retrospective chart review	Mean 61.9 (range 36–79)	Draf II/III	Superior lateral anterior pedicled mucosal flap (SLAP)	fully exposed the lacrimal sac during the Draf procedure to reduce the amount of bone surface area exposed for quick epithelialization	-	-
67	Omura et al. (2019)	Japan	Retrospective case series	Chronic frontal sinusitis, inverted papilloma, Frontal mucocele, Eosinophilic rhinosinusitis, Tumour, Trauma	mean 62.3 (range 36–82)	Draft type IIA 6; Draf type IIb 9; Draf type III 11	Mucosal graft (SLAP flap)	nasal cavity was loosely packed with the Sorban. The Sorban was gently washed out by nasal irrigation with saline, which was started on postoperative day 2 SLAP flap was repositioned to cover the anterior wall of the neo-ostium	-
68	Orlendi et al. (2009)	USA	Retrospective case series	Not mentioned	Mean 53.2 years	Not specified	Rainfrontal sinus stents (Gyrus-ENT, Bartlett, TN.)	mean length of stenting in these patients was 31.6 month	-

Table 1. List of studies included in the systematic review. *continued*

No.	Author (Year)	Country	Study design	Indication for frontal sinus surgery	Mean age SD	Type of frontal sinus surgery	Concomitant intervention	Intervention duration
69	Rotenborg et al. (2016)	USA	Retrospective study	Chronic rhinosinusitis (primary surgery) 8 Chronic rhinosinusitis (revision surgery) 19 Fungal sinusitis 1 Frontal abscess 3 Mucocele	Average 53.2 years	Draf II	T-tube stent	24–48 hours of irrigation with bacitracin-infused saline solution
70	Sama et al. (2014)	UK	Retrospective case series	Frontal sinus mucocles	56 years (range 27 – 86 years)	Draf IIA, IIB (41%), III (59%)	No extra procedure	-
71	Samaha et al. (2003)	USA	Retrospective case-control study	Chronic frontal sinusitis	mean age of 47.1 ± 13.1 years	EMLP	No extra procedure (i.e. no mucosal flap/stent)	-
72	Schlosser et al. (2002)	USA	Retrospective chart review	Surgery was performed for one osteoma, one inverted papilloma, and two mucoceles. The remainder were performed for chronic frontal sinusitis.	Mean 45 years (range, 24–89 years)	EMLP	No extra procedure (i.e. no mucosal flap/stent)	All patients are treated with broad-spectrum antibiotics, nasal steroids, mucolytics, and saline irrigations
73	Schulze et al. (2002)	USA	Retrospective chart review	Chronic frontal sinusitis	Ranged from 21 to 67 years old with a mean of 42 years	EMLP	No extra procedure (i.e. no mucosal flap/stent)	debridement was performed on days 6 and 13 and then weekly for 6–8 weeks
74	Seresirikachorn et al. (2023)	Not mentioned	Observational, case series	Consecutive adult patients with inflammatory and neoplastic sinus disease.	49.1+/−17.9 years	Draf IIA	Carolyn's window technique was applied for frontal sinus dissection, Mucosal flap	-
75	Seyedhadi et al. (2013)	Iran	Case studies	Patients with extensive adhesions in frontal recess or bony stenosis of frontal recess due to refractory sinusitis, mucocele or other causes of chronic inflammation or trauma.	Not stated	Draf II	Septal flap based on the anterior ethmoidal artery	Packed with gel foam. Two to 3 weeks after the surgery, endoscopy was performed to remove the crusts
76	Shirazi et al. (2007)	USA	Retrospective case series	The most common indication (94%) for the procedure was chronic frontal sinusitis and/or mucocele formation (Table II). Eighty-seven (90%) patients had some degree of nasal polyposis. Thirty-two (33%) had sensitivity to aspirin, nasal polyposis/chronic rhinosinusitis, and asthma (Samter triad)	Range of 19 to 83 years (mean age, 44 y)	EMLP	No extra procedure (i.e. no mucosal flap/stent)	-
77	Singh et al. (2019)	USA	RCT (pooling of data from two RCT)	patients diagnosed with CRS who were scheduled to undergo bilateral ESS (primary or revision) and had evidence of bilateral frontal sinus disease based on CT.	49.7(13.59) on all 160 patients	Draf II	1 steroid-releasing implant (PROPEL Mini or PROPEL Contour; Intersect ENT, Inc, Menlo Park, CA	Steroid (oral or spray), haemostatic packing material, oral abx, saline irrigation

Table 1. List of studies included in the systematic review. *continued*

No.	Author (Year)	Country	Study design	Indication for frontal sinus surgery	Mean age SD	Type of frontal sinus surgery	Concomitant intervention	Intervention duration
78	Smith et al. (2016)	USA	Prospective, multicenter randomised, blinded trial using an inpatient control design.	patients diagnosed with CRS based on American Academy of Otolaryngology-Head and Neck Surgery guidelines <sup>1</sup> who were scheduled to undergo primary or revision bilateral ESS and had evidence of bilateral frontal sinus disease based on computed tomography (Lund-Mackay score of 1 on each side)	49.9 years (13.9)	Not mentioned	Steroid releasing implant	The study implants or their remnants were required to be removed on day 21 to allow for blinded assessment of day-30 video-endoscopies
79	Stankiewicz et al. (2003)	USA	Retrospective chart review	persistent frontal sinusitis after an osteoplastic flap procedure	Age range, 19 to 49 years	Modified Lothrop	No extra procedure (i.e. no mucosal flap/stent)	-
80	Thompson et al. (2021)	USA	Prospective observational study	Frontal sinus osteomyelitis	Range from 8 to 84 years, mean of 48.3	Draf IIb, Draf III	No intervention	All patients received 6 weeks of culture-specific antibiotics
81	Ting et al. (2013)	USA	Retrospective chart review	chronic rhinosinusitis with polyps (32.8%), chronic sinusitis without polyps (43.6%), mucocoele (17.6%), and tumour (5.9%). Six of these tumours were inverted papillomas and six were fibro-osseous lesions	Mean 48.7	Modified Lothrop	No extra procedure (i.e. no mucosal flap/stent)	-
82	Ting et al. (2023)	USA	Cohort (prospective)	Patients with either recalcitrant frontal sinusitis, mucocoeles and benign tumours (osteomas and inverted papillomas)	47 years (range: 19–63 years)	Draf IIb, III	Frontal neo-ostium reconstruction with mucosal flaps	Rubber fingerstalls as packing, Nasal corticosteroids spray and saline irrigation
83	Tran KN et al. (2007)	Australia	Retrospective study	recalcitrant chronic frontal sinusitis	Not stated	Modified Lothrop	No extra procedure (i.e. no mucosal flap/stent)	-
84	Turner et al. (2016)	USA	Retrospective chart review	Failed medical treatment for sinusitis	mean age of 52.2 years	Draf IIb	Stent (silastic spacers)	9 days. In one patient, a Rainstent was kept in place long term (18 months)

Table 1. List of studies included in the systematic review. *continued*

No.	Author (Year)	Country	Study design	Indication for frontal sinus surgery	Mean age SD	Type of frontal sinus surgery	Concomitant intervention	Intervention duration
85	Ulualp et al. (2000)	USA	Retrospective chart review	All consecutive patients with frontal sinus disease who underwent osteoplastic flap procedure with abdominal fat obliteration technique or modified endoscopic Lothrop procedure	ranging from 24 to 86 years	EMLP	No extra procedure (i.e. no mucosal flap/stent)	-
86	Wang et al. (2019)	China	RCT	Not mentioned	48.4 ± 11.2 years	EMLP	Neo-ostium reconstructed with mucosal grafts and anterior pedicled flaps	After a 2-week nasal occlusion period, the nasal cavity was cleaned in the outpatient clinic with a 30-degree sinoscope nasal irrigation + steroids
87	Wormald et al. (2002)	Australia	Prospective review	CRS 68, nasal polyps (idiopathic) 30, Fungal sinusitis 20	Mean age 42.8 years (SD 14.9 y)	DrafIB	Axillary flap	-
88	Wormald et al. (2003) Retrospective chart review	Australia	Chronic frontal sinusitis	Average 44 years (SD, 12.3 years)	EMLP	Stent (mini trephine)	Patient underwent regular postoperative frontal sinus irrigation. In patients with fungal disease or extensive polyposis, steroid drops were also placed	5 days
89	Wormald et al. (2003)	Australia	Prospective non-randomized interventional case series	Chronic sinusitis, chronic fungal sinusitis, allergic fungal sinusitis, Nasal polyps, Mucocles, Previous osteoplastic flap with mucocle, Frontal Osteoma, Previous frontal sinus trauma	Mean 52.4 years (SD 13.6y)	EMLP	Stent (mini trephine cannula is left in place for 5 days)	5 days
90	Wormald et al. (2003)	Australia	Retrospective, consecutive case review	Chronic sinusitis + radiological evidence of complicated frontal sinus disease	Range 19-68 years	EMLP	Mini-Trephine cannula	Irrigation for 5 days
91	Wormald et al. (2003)	Australia	Prospective case series	patients who had previously undergone an OPF procedure with obliteration who presented with frontal headache	51.7 years (range 25-73)	EMLP	Mini-Trephine cannula	Minimum 5 days
92	Wormald et al. (2009)	Australia	Retrospective case series	Frontal sinus osteoma	Mean 47 years, Range from 22 to 79	Modified Lothrop	Mucosal flap	-

Table 1. List of studies included in the systematic review. continued.

No.	Author (Year)	Country	Study design	Indication for frontal sinus surgery	Mean age SD	Type of frontal sinus surgery	Intervention type	Concomitant intervention	Intervention duration
93	Ye et al. (2014)	China	Prospective case series	Chronic frontal sinusitis	Range of 25 to 57 years (mean = 46)	Draf III	No extra procedure (i.e. no mucosal flap/stent)	standardized postoperative care regimen, which included twice-daily nasal irrigation, topical nasal steroid spray, and a tapering dose of oral methylprednisolone	-
94	Yoon et al. (2009)	South Korea + USA	Retrospective case series	Frontal sinus inverted papilloma	Mean 53.8 years (range 34–75 years)	EMLP + EFT	no extra procedure	-	-
95	Zhang et al. (2018)	China	Retrospective case series	Refractory CRS	47.88 ± 1.70	EMLP	No extra procedure (i.e. no mucosal flap/stent)	Finger rubber stalls were used for postoperative nasal packing in each case and were removed 5 days postoperatively. Twice-daily nasal irrigation, topical nasal steroid spray, and a gradual reduction of methylprednisolone.	-
96	Varghese et al. (2019)	India	prospective, non-randomised study	Revision cases of recurrent nasal polypsis or fungal sinusitis involving frontal sinus	35 ± 5 years	Draf III	No extra procedure (i.e. no mucosal flap/stent)	using topical corticosteroids in postoperative management	-

for the steroid-impregnated stent group. Draf procedures without additional interventions had a restenosis proportion of 0.21 (95% CI: 0.15–0.27;  $I^2 = 88.4\%$ ), reported in 29 (8,23,28,29,33,36,40,41,43,47,49,51,53,55,56,60,62,63,76,81,82,84,87,90,91,93,95,101,103).

### Revision procedures

Further analysis was conducted to evaluate the impact of specific interventions on revision case proportions. Twelve studies reported the effect of mucosal flaps/grafts on the revision rate (6,12,35,37,50,69,71,72,96,100,105,107), 3 studies reported the effect of mucosal flaps or grafts used in conjunction with stents (10,73,74), 11 studies reported the effect of using stents alone (1,3,26,29,32,58,59,66,68,75,97,99), and 1 study (48) reported the revision rate following the use of steroid-impregnated stents (Figure 5). The weighted revision proportions were 0.05 (95% CI: 0.02, 0.07;  $I^2 = 51.6\%$ ) for the mucosal flaps/grfts group, 0.07 (95% CI: 0.00, 0.14;  $I^2 = 90.4\%$ ) for the mucosal flaps/grfts with stents group, 0.09 (95% CI: 0.05, 0.12;  $I^2 = 0.01\%$ ) for the stents group, and 0.32 (95% CI: 0.24, 0.40;  $I^2 = 0.00\%$ ) for the steroid-impregnated stent group. Draf procedures performed without any additional interventions had a revision rate of 0.16 (95% CI: 0.12, 0.20;  $I^2 = 72.3\%$ ), which was reported in 24 studies (8,22,28,31,34,38,39,43,46,49,56,62,63,67,70,81–84,87,89,91,95,102).

### Mucocele formation

Analysis was conducted to evaluate the impact of specific interventions on mucocele formation (Figure S2). The rate of mucocele formation was reported in 2 studies following the use of mucosal flaps or grafts (38,44) and in 2 studies following the use of stents (59,98). The mucocele formation proportions were 0.05 (95% CI: 0.00–0.10;  $I^2 = 0.00\%$ ) for the mucosal flaps/grfts group and 0.69 (95% CI: 0.11–1.27;  $I^2 = 78.7\%$ ) for the stents group. One study reported a mucocele rate of 0.01 following the Draf procedure without additional interventions (95% CI: -0.01 to 0.04;  $I^2 = 0.00\%$ ) (63).

### Two armed meta-analyses

#### Restenosis

##### *Stent vs. control*

Three studies (24,65,94) compared restenosis outcomes between surgery with and without a silastic stent (Table 3, Figure 6). The random-effects meta-analysis yielded an OR of 1.14 (95% CI: 0.46–2.82), with no significant heterogeneity ( $I^2 = 0\%$ ). The overall effect was not significant ( $p > 0.05$ ), and the OR confidence interval crossed 1, suggesting no significant impact of the silastic stent on restenosis rates.

##### *Steroid stent vs. control*

Three studies (14,15,88) compared restenosis outcomes between surgery with and without a steroid-releasing stent (Table 3, Figure 7). The random-effects meta-analysis yielded a non-

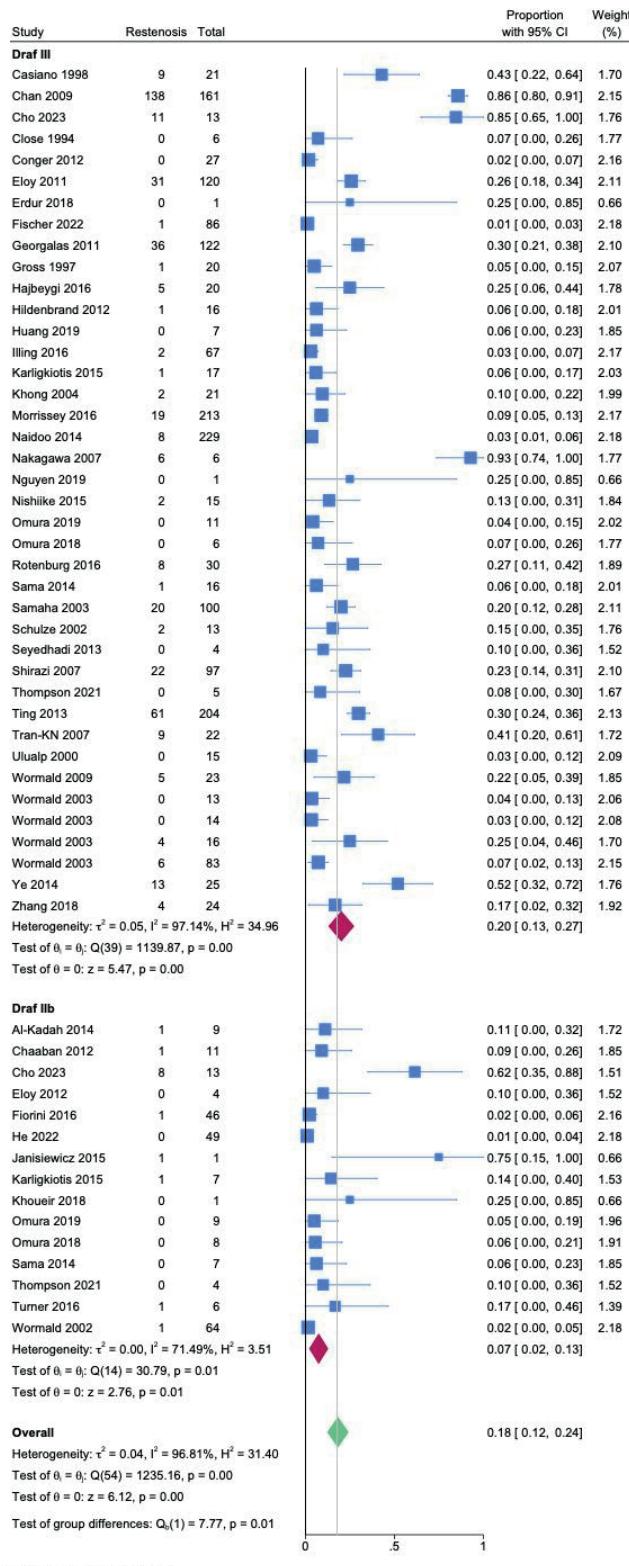


Figure 2. Proportional meta-analysis of single armed studies – restenosis rate of frontal neo-ostium following Draf IIB vs Draf III.

event OR of 2.20 (95% CI: 1.54–3.12), with no significant heterogeneity ( $I^2 = 0\%$ ). The overall effect was significant ( $p < 0.05$ ), suggesting that the steroid-releasing stent significantly reduced

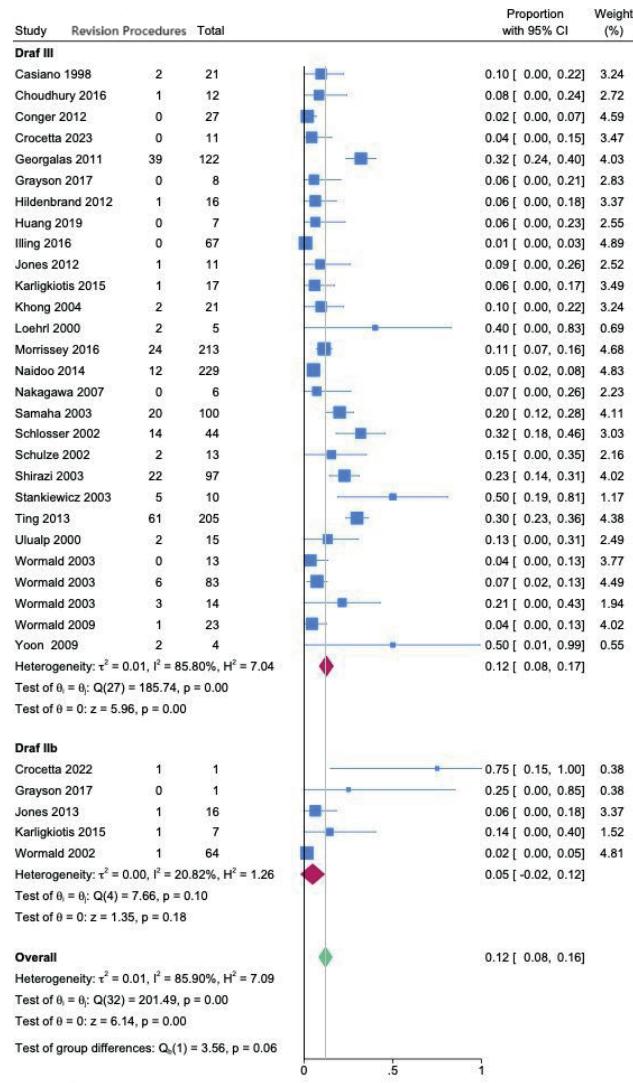


Figure 3. Proportional meta-analysis of single armed studies – revision rate following Draf IIB vs Draf III.

restenosis rates compared to surgery without a stent.

#### Mucosal flap/graft vs. control

Three studies (7,25,45) compared restenosis outcomes between surgery with a mucosal flap/graft and without additional intervention (Table 3, Figure 8). The random-effects meta-analysis yielded an OR of 2.74 (95% CI: 0.69–10.48), with no significant heterogeneity ( $I^2 = 8\%$ ). The effect was not significant ( $p > 0.05$ ), suggesting no impact of the mucosal flap/graft on restenosis rates.

#### Revision rates

##### Stents vs steroid stents vs flaps/grafts

Six studies (7,14,15,27,92,94) conducted a two-armed meta-analysis with subgroups for each intervention type. Stents had a revision OR of 0.79 (95% CI: 0.14–4.55;  $I^2 = 73\%$ ), steroid stents had a

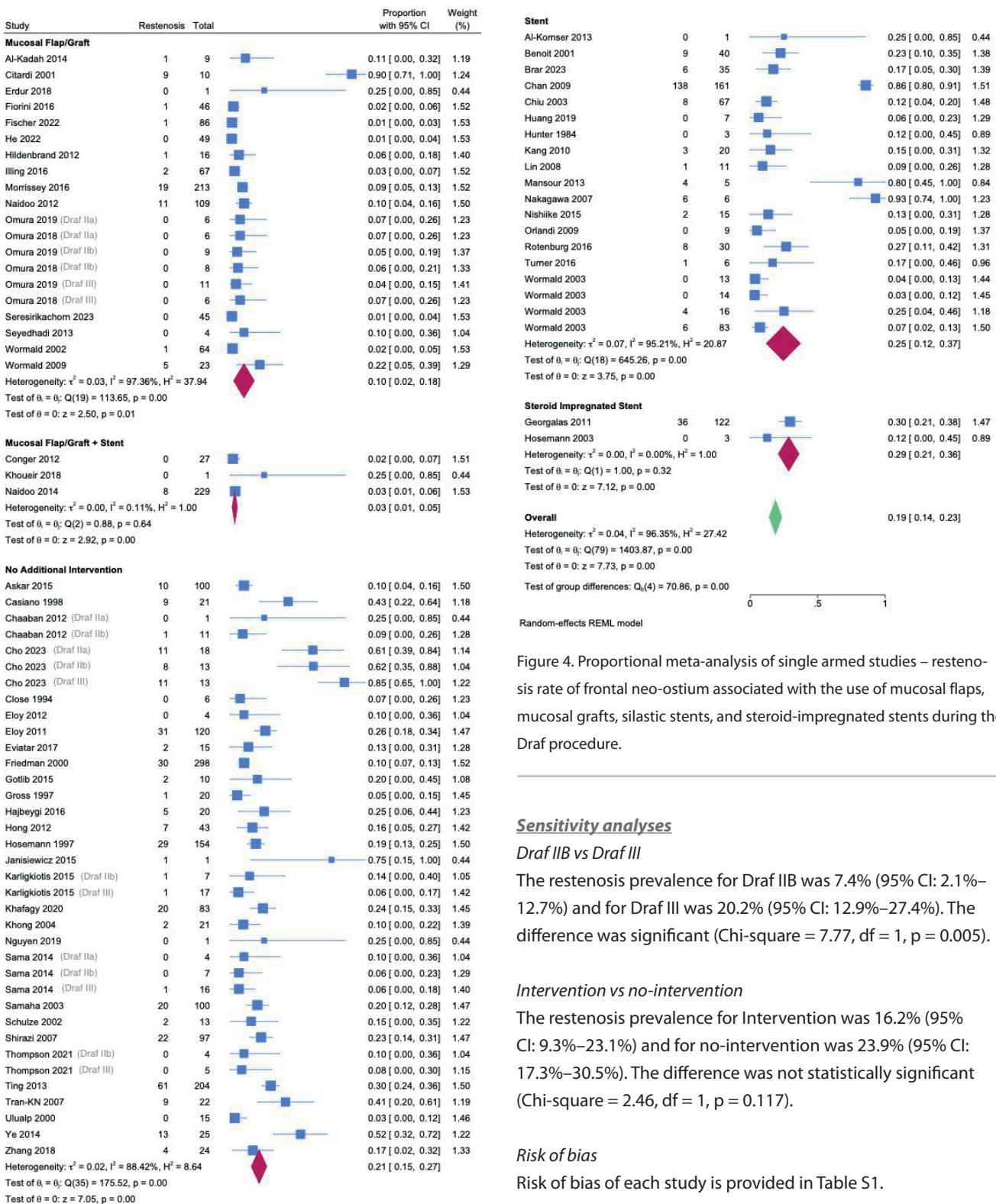


Figure 4. Proportional meta-analysis of single armed studies – restenosis rate of frontal neo-ostium associated with the use of mucosal flaps, mucosal grafts, silastic stents, and steroid-impregnated stents during the Draf procedure.

### Sensitivity analyses

#### Draf IIB vs Draf III

The restenosis prevalence for Draf IIB was 7.4% (95% CI: 2.1%–12.7%) and for Draf III was 20.2% (95% CI: 12.9%–27.4%). The difference was significant (Chi-square = 7.77, df = 1, p = 0.005).

#### Intervention vs no-intervention

The restenosis prevalence for Intervention was 16.2% (95% CI: 9.3%–23.1%) and for no-intervention was 23.9% (95% CI: 17.3%–30.5%). The difference was not statistically significant (Chi-square = 2.46, df = 1, p = 0.117).

#### Risk of bias

Risk of bias of each study is provided in Table S1.

### Discussion

Elucidating the factors associated with increased rates of restenosis following Draf procedures is essential to developing targeted strategies that mitigate complications such as mucocele formation, decrease the likelihood of revision surgeries, and enhance long-term patient outcomes. To date, no meta-analyses has directly compared the clinical outcomes of Draf IIB and Draf

revision ratio of 0.21 (95% CI: 0.07–0.69;  $I^2 = 0\%$ ), and flaps/grafts had a revision OR of 0.16 (95% CI: 0.02–1.41;  $I^2 = 0\%$ ). The overall test for subgroup differences was not significant ( $p = 0.41$ ) (Figure S3).

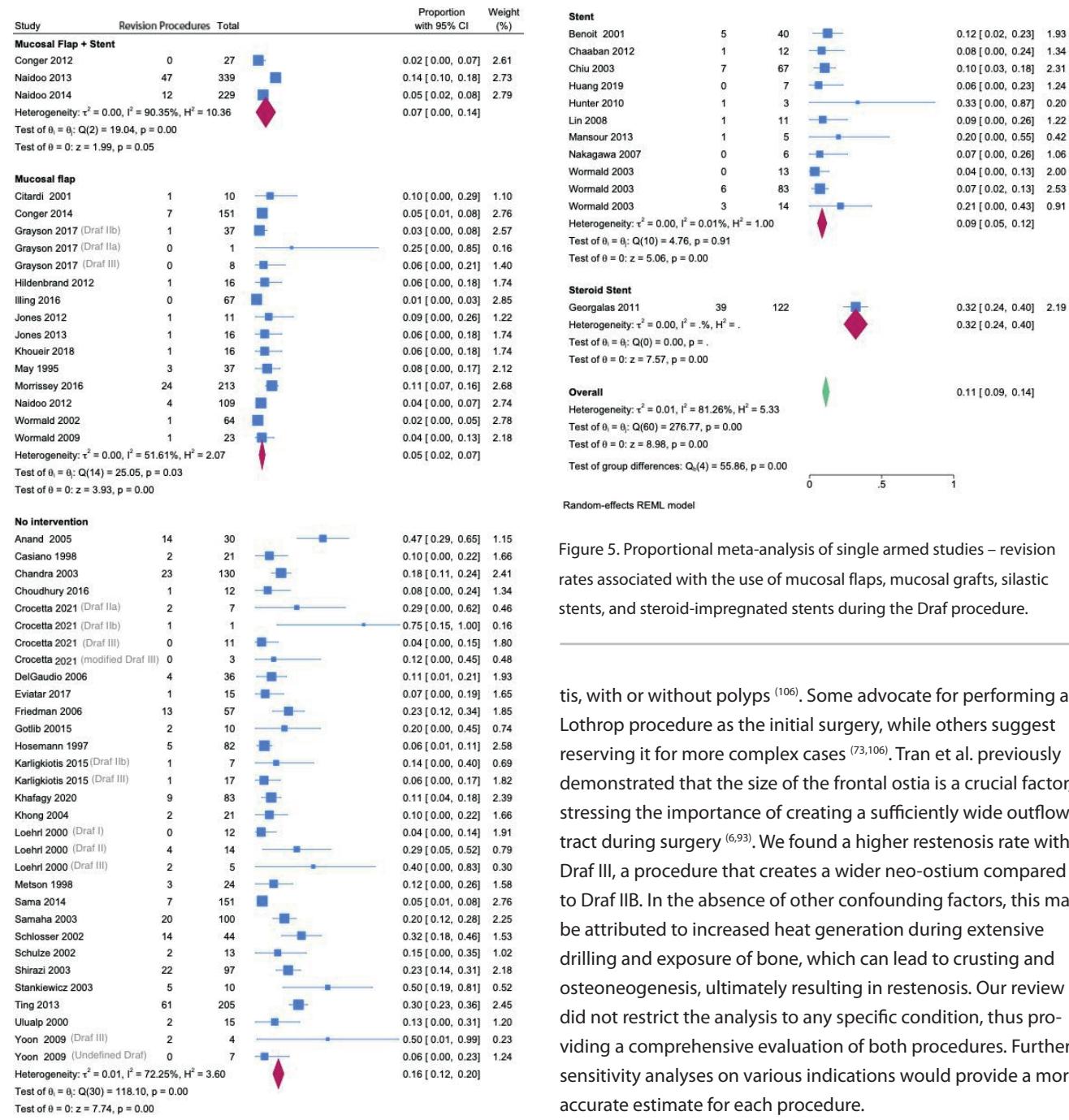


Figure 5. Proportional meta-analysis of single armed studies – revision rates associated with the use of mucosal flaps, mucosal grafts, silastic stents, and steroid-impregnated stents during the Draf procedure.

III procedures or systematically evaluated the efficacy of adjunctive interventions between them. This review sought to address this gap by assessing revision rates, neo-ostium restenosis, and mucocele formation associated with Draf IIB and Draf III, while also examining the potential impact of steroid-impregnated stents, silastic stents, and mucosal flaps or grafts on these outcomes. Our review reports a restenosis rate of 20% for the Draf III procedure and 7.4% for the Draf IIB procedure, with the difference found to be statistically significant. While there are various indications for each procedure, there is no consensus regarding the choice between Draf IIB and Draf III for chronic rhinosinusitis, with or without polyps<sup>(106)</sup>. Some advocate for performing a Lothrop procedure as the initial surgery, while others suggest reserving it for more complex cases<sup>(73,106)</sup>. Tran et al. previously demonstrated that the size of the frontal ostia is a crucial factor, stressing the importance of creating a sufficiently wide outflow tract during surgery<sup>(6,93)</sup>. We found a higher restenosis rate with Draf III, a procedure that creates a wider neo-ostium compared to Draf IIB. In the absence of other confounding factors, this may be attributed to increased heat generation during extensive drilling and exposure of bone, which can lead to crusting and osteoneogenesis, ultimately resulting in restenosis. Our review did not restrict the analysis to any specific condition, thus providing a comprehensive evaluation of both procedures. Further sensitivity analyses on various indications would provide a more accurate estimate for each procedure.

Additionally, it was observed that the use of mucosal grafts/flaps and stents reduced the restenosis rate. It has been suggested that mucosal grafting may prevent neo-osteogenesis from exposed bone, as osteitis caused by this exposure leads to inflammation, mucosal oedema and hypertrophy, narrowing of the frontal ostia, and ultimately, surgical failure<sup>(6)</sup>. Steroid stents possess both drug-eluting and mechanical stenting properties. The lack of statistical significance in the ability of silastic stents to reduce restenosis, compared to the steroid-impregnated stents, may be due to the more significant role of inflammation prevention in reducing restenosis of the neo-ostium<sup>(60)</sup>. This aligns with the rationale behind the effectiveness of mucosal flaps/grafts in preventing restenosis, namely by reducing inflam-

Table 2. Single arm studies of Draf IIb and Draf III: intervention and frontal sinus restenosis rate, mucocele formation rate, revision rates.

Author	Year	Type of intervention	Type of Draf	Total number of patients, n	Restenosis rate, n (%)	Definition of restenosis	Mucocele formation rate, n (%)	Revision rate, n (%)	Follow up details	Follow up duration
Close et al.	1994	None	Draf III	6	0 (0%)	Not defined	-	-	Endoscopic examination of FSO patency	3 – 8 months
Gross et al.	1997	None	Draf III	20	1 (5%)	Not defined	-	-	Endoscopic examination of FSO patency	1 – 21 months
Casiano et al.	1998	No intervention	Draf III	21	9 (42.9%)	<50% of intra-operative size	-	2 (9.52%)	Endoscopic examination of FSO patency	2 – 24 months
Ulualp et al.	2000	No intervention	Draf III	15	0 (0%)	Not defined	-	2 (13.33%)	Endoscopic examination of FSO patency	6 months – 60 months
Wormald et al.	2002	Mucosal flap	Draf IIb	64	1 (1.6%)	Visualization of the nasofrontal isthmus or probing of the frontal ostium	-	1 (1.56%)	Review of symptoms and endoscopic examination of FSO patency	11 – 24 months
Schulze et al.	2002	No intervention	Draf III	13	2 (15.4%)	Not defined	-	2 (15.4)	Endoscopic examination of FSO patency	12 – 56 months
Samaha et al.	2003	No intervention	Draf III	100	20 (20%)	Not defined	-	20 (20%)	Endoscopic examination of FSO patency	Mean 4.1 ± SD 1.53 years
Wormald et al.	2003	Stent	Draf III	13	0 (0%)	Not defined	-	0 (0%)	Endoscopic examination of FSO patency	6–20 months
Wormald et al.	2003	Stent	Draf III	14	0 (0%)	Not defined	-	3 (21.4%)	Review of symptoms and endoscopic examination of FSO patency	8–38 months
Wormald et al.	2003	Stent	Draf III	16	4 (25%)	Not defined	15 (93.8%)	-	Review of symptoms and endoscopic examination of FSO patency	10 – 26 months
Wormald et al.	2003	Stent	Draf III	83	6 (7.2%)	Not defined	-	6 (7.22%)	Endoscopic examination of FSO patency	7 – 55 months
Khong et al.	2004	No intervention	Draf III	21	2 (9.5%)	Not defined	-	2 (9.52%)	Review of symptoms and endoscopic examination of FSO patency	71–42 months
Shirazi et al.	2007	No intervention	Draf III	97	22 (22.7%)	Not defined	-	22 (22.7%)	No details	6 months to 4.5 years
Tran-KN et al.	2007	No intervention	Draf III	22	9 (40.9%)	<60% of original postoperative or intraoperative area	-	-	Endoscopic examination of FSO patency	At least 12 months
Nakagawa et al.	2007	Stent	Draf III	6	6 (100%)	Not defined	-	0 (0%)	Review of symptoms and endoscopic examination of FSO patency	8 – 48 months
Wormald et al.	2009	Mucosal flap	Draf III	23	5 (21.7 %)	Not defined	-	1 (4.35%)	Review of symptoms and endoscopic examination of FSO patency	Mean 60 ± SD 16.9 years
Chan et al.	2009	Stent	Draf III	161	138 (85.7%)	Not defined	-	-	Review of symptoms and endoscopic examination of FSO patency	Mean 45.9 ± SD 33.6 years
Eloy et al.	2011	No intervention	Draf III	120	31 (25.8%)	Not defined	-	-	Endoscopic examination of FSO patency	5 – 36 months
Georgalas et al.	2011	Stent (steroid)	Draf III	122	36 (29.5%)	Not defined	-	39 (31.96%)	Endoscopic examination of FSO patency	6 – 90 months
Chaabani et al.	2012	No intervention	Draf IIb	11	1 (9.09%)	Not defined	-	1 (8.3%)	Review of CSF leak, patency of FSO	2 – 206 weeks

Table 2. Single arm studies of Draf IIb and Draf III: intervention and frontal sinus restenosis rate, mucocele formation rate, revision rates. *Continued.*

Author	Year	Type of intervention	Type of Draf	Total number of patients, n	Resteno-sis rate, n (%)	Definition of restenosis	Mucocele forma-tion rate, n(%)	Revision rate, n(%)	Follow up details	Follow up duration
Hildenbrand et al.	2012	Mucosal flap	Draf III	16	1 (6.3%)	Not defined	-	1 (6.25%)	Endoscopic examination of FSO patency	Mean 25.6 months
Crocetta et al.	2012	Mucosal flap Stent	Draf III	27	0 (0%)	<50% original diameter	-	-	Endoscopic examination of FSO patency	3 – 40 months
Eloy et al.	2012	No intervention	Draf IIb	4	0 (0%)	Not defined	-	-	Endoscopic examination of FSO patency	8 weeks
Seyedhadi et al.	2013	Mucosal flap	Draf III	4	0 (0%)	<50% original diameter	-	-	Endoscopic examination of FSO patency	3 months
Ting et al.	2013	No intervention	Draf III	204	61 (29.9%)	Unable to pass 3mm suction cannula	-	61 (29.9%)	Endoscopic examination of FSO patency	10.8 – 204 months
Al-Kadah et al.	2013	Mucosal flap	Draf IIb	9	1 (11.1)	Not defined	-	-	Endoscopic examination of FSO patency	24 months
Naidoo et al.	2014	Mucosal graft Stent	Draf III	229	8 (3.5%)	Patent if the ostium could be visualized endoscopically, and stenosed if there was scarring, oedema, or polypsis occluding the frontal ostium	-	12 (5.24%)	Review of CSF leak, endoscopic examination of FSO patency	6 – 60 months
Sama et al.	2014	No intervention	Draf IIb Draf III	7 16	0 (0%) 1 (6.25%)	Not defined	-	7 (4.6%)	Endoscopic examination of FSO patency	8 months – 3 years
Ye et al.	2014	No intervention	Draf III	25	13 (52%)	<50% of original postoperative cross sectional area	-	-	Endoscopic examination of FSO patency	>12 months
Janisiewicz et al.	2015	No intervention	Draf IIb	1	1 (100%)	Complete obstruction	-	-	Review of symptoms and endoscopic examination of FSO patency	2 months
Karligkiotis et al.	2015	No intervention No intervention	Draf IIb Draf III	71 7	1 (14.3%) 1 (5.9%)	Not defined	-	1 (14.3%) 1 (5.88%)	Review of symptoms and endoscopic examination of FSO patency	12 – 120 months
Nishiike et al.	2015	Stent	Draf III	15	2 (13.3%)	Not defined	-	-	Review of symptoms and endoscopic examination of FSO patency	5–60 months
Fiorini et al.	2016	Mucosal flap	Draf IIb	46	1 (2.2%)	Not defined	2 (4.35%)	-	Review of surgical complication	6 – 36 months
Illing et al.	2016	Mucosal flap	Draf III	67	2 (3%)	AP diameter <50% of the intraoperative measurement	-	0 (0%)	Assessment of long-term success of the Draf III mucosal grafting technique. Review of symptoms and endoscopic examination of FSO patency.	12 – 85 months
Morrissey et al.	2016	Mucosal graft	Draf III	213	19 (2.3%)	Not defined	-	24 (11.26%)	Endoscopic examination of FSO patency	Mean 36 months
Hajbeygi et al.	2016	No intervention	Draf III	20	5 (25%)	<5mm	-	-	Endoscopic examination of FSO patency	Mean 17.5 months

Table 2. Single arm studies of Draf IIb and Draf III: intervention and frontal sinus restenosis rate, mucocele formation rate, revision rates. *Continued.*

Author	Year	Type of intervention	Type of Draf	Total number of patients, n	Restenosis rate, n (%)	Definition of restenosis	Mucocele formation rate, n (%)	Revision rate, n (%)	Follow up details	Follow up duration
Roten-burg et al.	2016	Stent	Draf III	30	8 (26.7%)	<50% patency of original ostium size	-	-	Endoscopic examination of FSO patency	1 month to 1 year
Turner et al.	2016	Stent	Draf IIb	6	1 (16.7%)	> 3 mm in diameter	-	0 (0%)	Endoscopic examination of FSO patency	1–64 months
Erdur et al.	2018	Mucosal flap	Draf III	1	0 (0%)	<50% patency of ostium size at the end of procedure	-	-	Review of osteoma recurrence and stenosis	24 months
Khoueir et al.	2018	Mucosal flap + stent	Draf IIb	1	0 (0%)	Not defined	-	-	Endoscopic examination of FSO patency	6 months
Omura et al.	2018	Mucosal graft	Draf IIb Draf III	8 6	0 (0%) 0 (0%)	Not defined	-	-	Endoscopic examination of FSO patency	>6 months
Zhang et al.	2018	No intervention	Draf III	24	4 (16.7%)	Not defined	-	-	Endoscopic examination of FSO patency	1 week post-op, 1 month, and every 3 months thereafter as needed
Nguyen et al.	2019	No intervention	Draf III	1	0 (0%)	Not defined	-	-	Endoscopic examination of FSO patency	1–38 months
Omura et al.	2019	Mucosal flap	Draf IIb Draf III	9 11	0 (0%) 0 (0%)	Not defined	-	-	Review of symptoms and endoscopic examination of FSO patency	6 months
Huang et al.	2019	Stent	Draf III	7	0 (0%)	Inability to visualise the frontal sinus or pass a standard olive-tipped curved suction into the frontal sinus	-	0 (0%)	Review of symptoms and endoscopic examination of FSO patency	Mean 16.5 months
Thompson et al.	2021	No intervention	Draf IIb Draf III	4 5	0 (0%) 0 (0%)	Not defined	-	-	Review of symptoms and endoscopic examination of FSO patency	Mean 24.4 months
Fischer et al.	2022	Mucosal flap	Draf III	86	1 (1.2%)	Inability to pass 5 mm curved suction tube through neo-ostium unhindered	-	-	Endoscopic examination of FSO patency	At least 3 months
He et al.	2022	Mucosal flap	Draf IIb	49	0 (0%)	Inability to visualize into the frontal sinus by endoscopic examination	-	-	Endoscopy, CT scan to assess patency, assessment of CRS symptoms	12–100 months
Cho et al.	2023	No intervention	Draf IIb Draf III	13 13	8 (61.5%) 11 (84.6%)	Patent if it was more than 50% of the size of the frontal recess developed at the end of the previous surgery	-	-	Endoscopic examination of FSO patency	Every 3 months for the first year, every 6 months in the second year and yearly afterwards

Table 2. Single arm studies of Draf IIb and Draf III: intervention and frontal sinus restenosis rate, mucocele formation rate, revision rates. *Continued.*

Author	Year	Type of intervention	Type of Draf	Total number of patients, n	Restenosis rate, n (%)	Definition of restenosis	Mucocele formation rate, n (%)	Revision rate, n (%)	Follow up details	Follow up duration
Choudhury et al.	2016	No intervention	Draf III	12	-	-	-	1 (8.33)	Endoscopic assessment of frontal ostium patency and patient reported symptoms	33.3 months (range 8–102 months)
Grayson et al.	2017	Mucosal flap	Draf IIb Draf III	37 8	-	-	-	1 (2.7%) 0 (0%)	Blinding not mentioned	26 months (range, 2 weeks to 79 months)
Jones et al.	2012	Mucosal flap	Draf IIb Draf III	16 11	-	-	-	1 (6.25%) 0 (0%)	Endoscopy was used to evaluate the repair and to identify evidence of CSF leak as well as patency of the frontal sinus outflow tract	50.8 (range, 2–164) weeks
Loehrl et al.	2000	No intervention	Draf III	5	-	-	-	1 (20%)	Endoscopic examination of FSO patency	Average 11.9, range 1 to 23 months
Schlosser et al.	2002	No intervention	Draf III	44	-	-	-	14 (31.8%)	Endoscopic examination of FSO patency	40.3 months (range, 10–90 months)
Yoon et al.	2009	No intervention	Draf III	4	-	-	-	2 (50%)	assessment for persistent or recurrent disease was performed by serial endoscopic exams, ± CT or MRI	Mean 36.6 months (range 11–114 months)
Stankiewicz et al.	2003	No intervention	Draf III	10	-	-	-	5 (50%)	Review of symptoms and complications. All patients were followed up at least for 1 year	Mean 34 months (range, 18 to 78 months)
Crocetta et al.	2021	Mucosal flap	Draf II b Draf III Modified Draf III	1 11 3	-	-	-	1 (100%) 0 (9%) 0 (0%)	Endoscopic examination of FSO patency	49 months (range 25–133 months, SD 29)
Conger et al.	2012	Mucosal flap + stent	Draf III	27	-	-	-	0 (0%)	Endoscopic examination of FSO patency	3 months of clinical follow-up (overall 14 months)

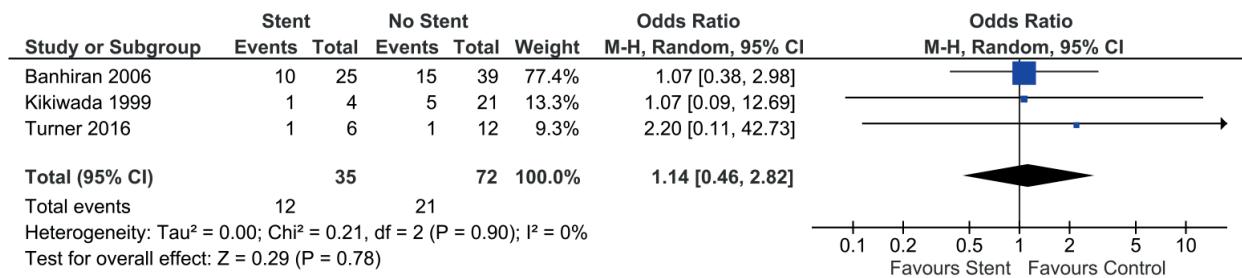


Figure 6. Meta-analysis of two-armed studies investigating the impact of stents on restenosis rates following Draf procedures.

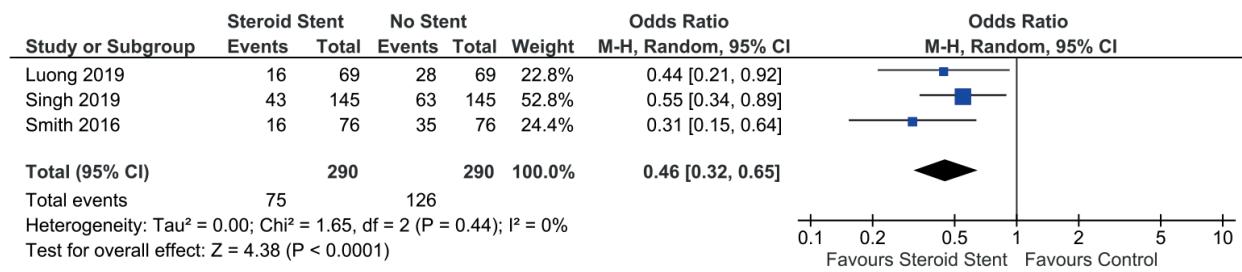


Figure 7. Meta-analysis of two-armed studies investigating the impact of steroid impregnated stents on restenosis rates following Draf procedures.

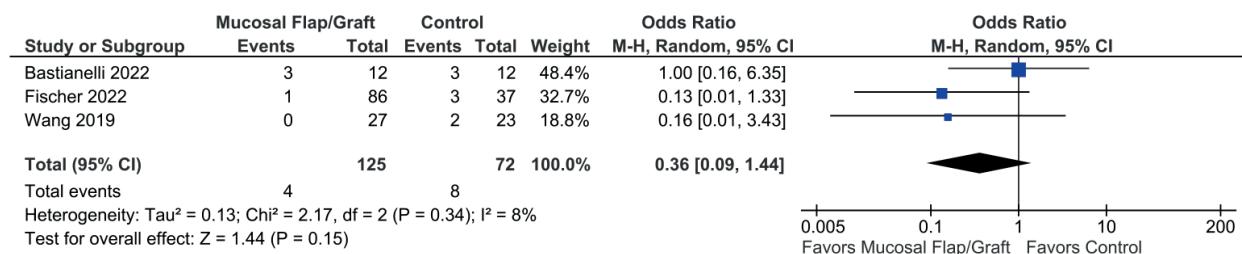


Figure 8. Meta-analysis of two-armed studies investigating the impact of mucosal flaps or grafts on restenosis rates following Draf procedures.

mation. The primary aim of the systematic review was to compare Draf IIB vs Draf III; however, in comparing the interventions, we included all available data, regardless of the type of Draf, to capture a broader picture of the effect of these interventions. Future research into the effect of the interventions for each Draf type will better elucidate the outcomes.

### Limitations

There are several limitations to our review, therefore the results should be interpreted with caution. We have highlighted some of these limitations as follows. There was significant heterogeneity in the definition of frontal sinus ostium restenosis, as well as in the duration of follow-up. Additionally, there was variability in post-operative concomitant interventions, such as saline douches, steroid sprays versus drops, antibiotics, splints, and patient compliance. The absence of post-operative blinding in some studies likely introduced bias in the selection and administration of post-operative treatments, potentially affecting the compara-

bility of the results.

Considerable variability was also observed in the perioperative use of antibiotics, including differences in duration, dosing, and selection. Furthermore, the use of oral or inhaled corticosteroids was inconsistent across studies, further complicating the standardisation of treatment protocols. The definitions of restenosis and the timing of follow-up assessments varied between studies, which may have introduced bias, particularly favouring short- to medium-term outcomes over long-term results, thereby contributing to unaccounted variance in the findings. Some subgroups had small sample sizes, which may limit the statistical power and generalisability of the results. It is plausible that baseline patient characteristics influenced the choice of Draf procedure, with patients presenting with more severe conditions or greater stenosis more likely to undergo Draf III rather than Draf IIB. This selection bias could impact the outcome comparisons between the two procedures. Moreover, not all two-arm studies included in the analysis were

Table 3. Two arm studies examining intervention (stent, steroid-stent or mucosal flap/graft) vs restenosis rate.

Author and year	Stent		No stent		Steroid stent		No steroid stent		Flap/Graft		No Flap/Graft	
	Total	Event	Total	Event	Total	Event	Total	Event	Total	Event	Total	Event
Kikawada et al. (1999)	4	1 (25%)	21	5 (13.3%)								
Banhiran et al. (2006)	25	10 (40%)	39	15 (38.5%)								
Smith et al. (2016)					76	16 (21.1%)	76	35 (46.1%)				
Turner et al. (2016)	6	1 (16.7%)	12	1 (8.3 3%)								
Luong et al. (2018)					69	16 (23.2%)	69	28 (40.6%)				
Singh et al. (2019)					145	43 (29.7%)	145	63 (43.4%)				
Wang et al. (2019)									27	0 (0%)	23	2 (7.40%)
Bastianelli et al. (2022)									12	3 (25%)	12	3 (25%)
Fisher et al. (2022)									86	1 (1.2%)	37	3 (8.1%)

randomised controlled trials, which led to variations in population sizes between study arms. These studies standardised additional interventions but not the surgical technique itself, introducing potential confounding factors. Variations in the brands of stents used and the quality of mucosal flaps or grafts across studies may also have contributed to differences in clinical outcomes.

## Conclusion

Draf IIb had superior outcomes compared to Draf III with respect to restenosis and revision surgery. The use of steroid-impregnated stents appears effective in reducing restenosis rates.

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## SUPPLEMENTARY MATERIAL

Appendix. List of studies excluded during sensitivity analysis: Draf IIb vs Draf III.

<b>Author</b>	<b>Year</b>	<b>Reason for exclusion</b>
May et al.	1995	Restenosis data not reported
Hosemann et al.	1997	Intervention was Draf II
Metson et al.	1998	Restenosis data not reported
Friedman et al.	2000	Intervention was Draf I
Loehrl et al.	2000	Restenosis data not reported
Benoit et al.	2001	Unspecified Draf classification
Citardi et al.	2001	Unspecified Draf classification
Schlosser et al.	2002	Restenosis data not reported
Chandra et al.	2003	Unspecified Draf classification
Chiu et al.	2003	Unspecified Draf classification
Hosemann et al.	2003	Composite data for all types of Drafts
Stankiewicz et al.	2003	Restenosis data not reported
Anand et al.	2005	Restenosis data not reported
DelGaudio et al.	2006	Unspecified Draf classification
Friedman et al.	2006	Unspecified Draf classification
Lin et al.	2008	Composite data for all types of Drafts
Hahn et al.	2009	Restenosis data not reported
Yoon et al.	2009	Restenosis data not reported
Orlandi et al.	2009	Unspecified Draf classification
Hunter et al.	2010	Unspecified Draf classification
Kang et al.	2010	Unspecified Draf classification
Hong et al.	2012	Intervention was Draf I
Jones et al.	2012	Restenosis data not reported/redo procedure
Al Komser et al.	2013	Intervention was Draf IIC
Mansour et al.	2013	Unspecified Draf classification
Naidoo et al.	2013	Restenosis data not reported
Conger et al.	2014	Restenosis data not reported
Gotlib et al.	2015	Intervention was mini Lothrop
Choudhury et al.	2016	Restenosis data not reported
Eviatar et al.	2017	Intervention was mini Lothrop
Grayson et al.	2017	Restenosis data not reported
Khoueir et al.	2018	Composite data for all types of Drafts
Crocetta et al.	2021	Restenosis data not reported
Brar et al.	2023	Unspecified Draf classification
Ting et al.	2023	Restenosis data reported in area not restenosis events

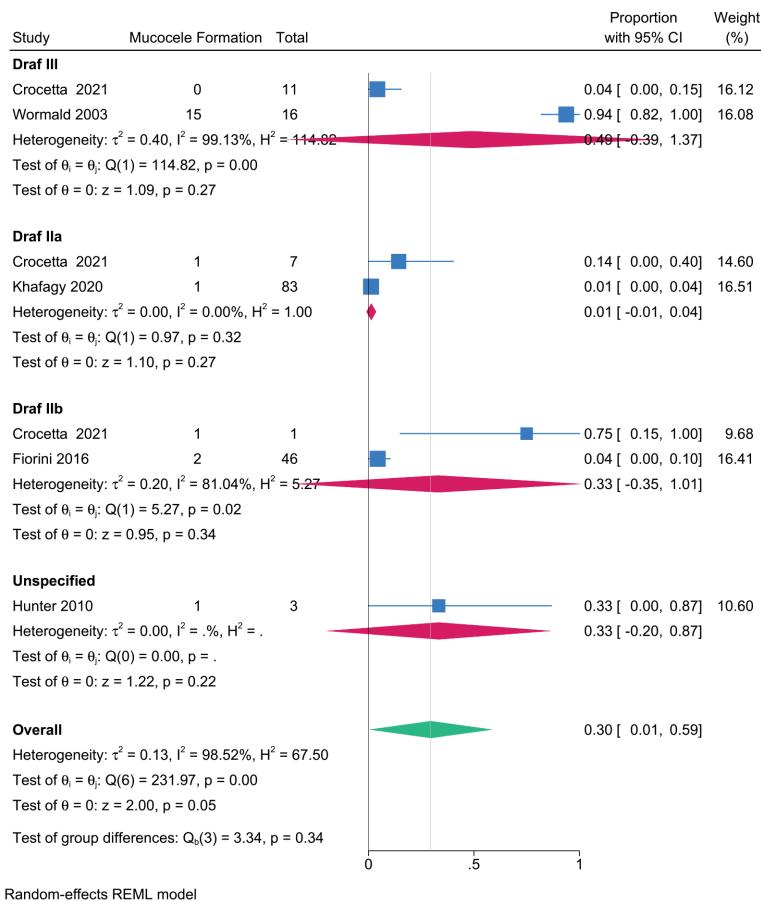


Figure S1. Proportional meta-analysis of single armed studies – mucocele formation following Draf IIB vs Draf III.

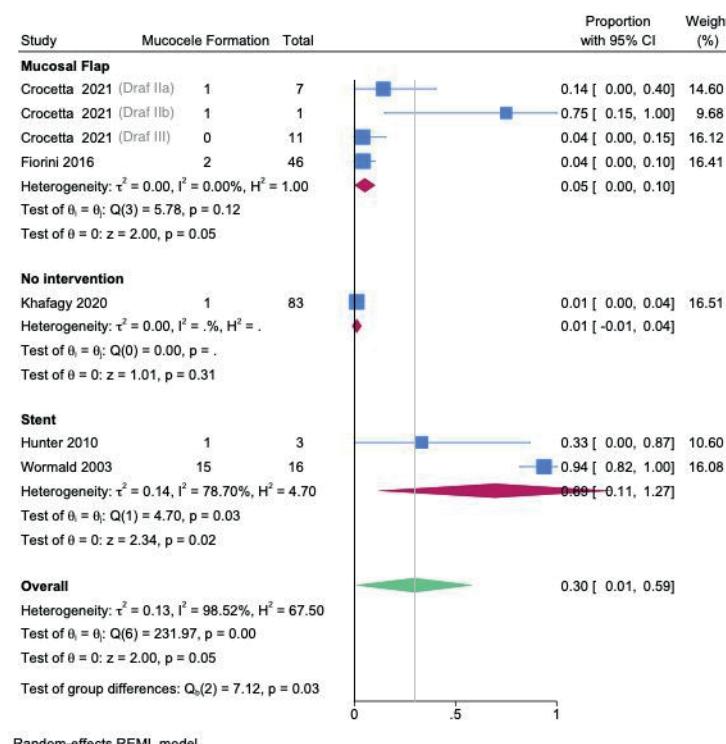


Figure S2. Proportional meta-analysis of single armed studies – mucocele formation associated with the use of mucosal flaps, mucosal grafts, silastic stents, and steroid-impregnated stents during the Draf procedure.

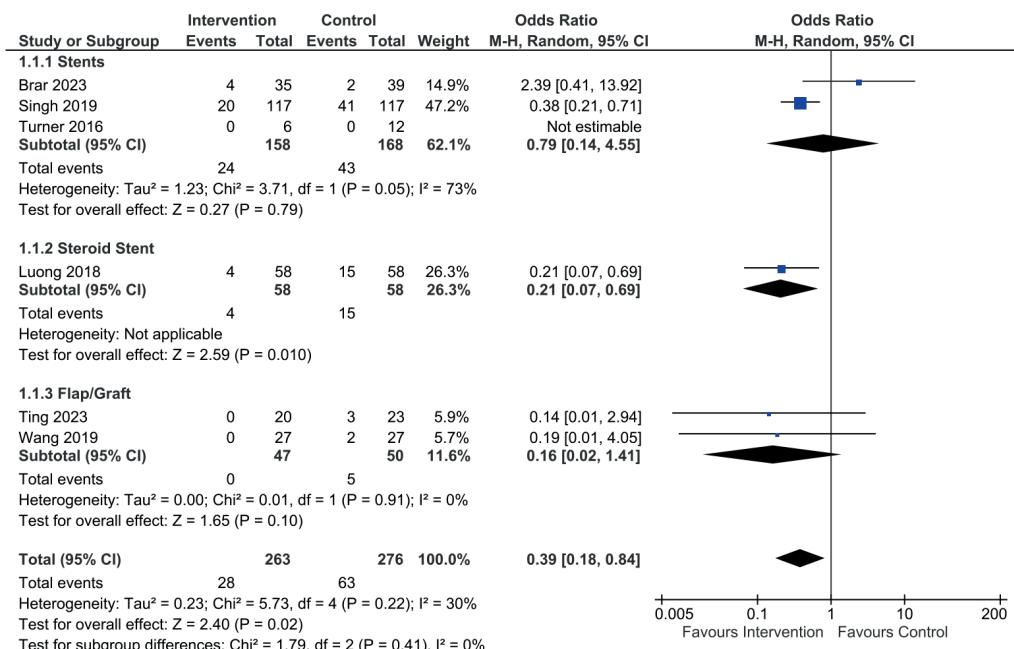


Figure S3. Meta-analysis of two-armed studies investigating the impact of additional intervention (stents, steroid impregnated stents, mucosal flaps/grafts) on revision rates following Draf procedures.

Table S1. Cochrane Risk of Bias 2 (RoB 2) assessment<sup>(17)</sup> for randomised control trials.

Author and Year	Selection Bias				Performance Bias		Detection Bias		Attrition Bias		Reporting Bias	
	Sequence generation		Allocation concealment		Blinding of participants and personnel.		Blinding of outcome assessment		Incomplete Data Outcome		Selective Outcome Reporting	
	Risk (High, Low or Unclear risk)	Justification on Judgement	Risk	Justification on Judgement	Risk	Justification on Judgement	Risk	Justification on Judgement	Risk	Justification on Judgement	Risk	Justification on Judgement
Singh et al. (2019)	Unclear	Sequence generation not detailed	Unclear	allocation concealment not detailed	Unclear	Blinding procedure not detailed	Unclear	Blinding procedure not detailed	Low	Reason for dropout justified	Low	Full reporting
Wang et al. (2019)	Low	Computer generated	Unclear	allocation concealment not detailed	Unclear	Blinding procedure not detailed	Low	Surgeon blinded	Unclear	Dropout recorded but reson not stated	Unclear	Dropout recorded but reson not stated, therefore unclear risk of selective reporting
Luong et al. (2017)	Unclear	Sequence generation not detailed	N/A	Control and intervention in same patient	Unclear	Blinding procedure not detailed	Low	Surgeon blinded	Low	Reason for dropout justified	Low	Full reporting

Table S2. Risk of Bias in Non-randomized Studies of Exposure (ROBINS-E) (18) for observational studies of exposures.

D1 - Risk of bias due to confounding	D2 - Risk of bias arising from measurement of the exposure	D3 - Risk of bias in selection of participants into the study or into the analysis)		D4 - Risk of bias due to post-exposure interventions		D5 - Risk of bias due to missing data		D6 - Risk of bias arising from measurement of the outcome		D7 - Risk of bias in selection of the reported result		Overall	
		Judge- ment	Justifica- tion	Judge- ment	Justifica- tion	Judge- ment	Justifica- tion	Judge- ment	Justifica- tion	Judge- ment	Justifica- tion		
Seresi- riachorn et al. (2023)	Some con- cerns	Uncon- trolled confoun- ding factors	Low	Exposure is standar- dised	Low	All consecu- tive surgical candidates chosen	Low	All received same post exposure inter- vention	Some con- cerns	Not stated whether both groups were equally compli- ant with post op instructions e.g. saline ir- rigation etc	Some con- cerns	Not stated that there is NO mis- sing data	Simple dichoto- mous data reporting, low risk
Ting et al. (2023)	Some con- cerns	Uncon- trolled confoun- ding fac- tors, small sample size, patient baseline characte- ristic not available	Low	Exposure is standar- dised	Some con- cerns	Implied that all patients undergoing this proce- dure were recruited but not clear.	High risk	Not stated whether both groups were equally compli- ant with post op instructions e.g. saline ir- rigation etc	Some con- cerns	Some con- cerns that there is NO mis- sing data	Some con- cerns	Clear de- finition of outcomes	Not stated explicitly that mea- surement of steno- sis are from all patients
Brar et al. (2023)	Low	Not mat- ched but $p>0.05$ between cohort charac- teristics	Some con- cerns	Not clear whether same surgeon perfor- med the procedure	Some con- cerns	Not clear whether all patients within the stated period were recruited	Some con- cerns	Post op in- structions not stated. Unclear whether groups were compli- ant to different extent	Low	Clear docu- mentation of missing data (excluded patients)	Low	Clear de- finition of outcomes	Simple dichoto- mous data reporting, low risk
Fischer et al. (2022)	Some con- cerns	trend to- wards use of the flap over the course of the study --> surgeon's skill im- proves	Low	Exposure is standar- dised	Some con- cerns	Not stated reasons why patient had flap or no-flap. Patient's background $p>0.05$ between 2 groups though.	Low	All received same post exposure inter- vention	Some con- cerns	Some patients lost to f/u but rea- sons not stated.	Low	Clear de- finition of outcomes	Simple dichoto- mous data reporting, low risk
He et al. (2022)	Some con- cerns	Uncon- trolled confoun- ding factors	Low	Exposure is standar- dised	Some con- cerns	Not clear whether all patients within the stated period were recruited	Low	All received same post exposure inter- vention	Some con- cerns	Not stated the reason for loss to f/u	Low	Clear de- finition of outcomes	Simple dichoto- mous data reporting, low risk

Table S2. Risk of Bias in Non-randomized Studies of Exposure (ROBINS-E) (18) for observational studies of exposures. *Continued.*

D1 - Risk of bias due to confounding	D2 - Risk of bias arising from measurement of the exposure	D3 - Risk of bias in selection of participants into the study (or into the analysis)	D4 - Risk of bias due to post-exposure interventions	D5 - Risk of bias due to missing data	D6 - Risk of bias arising from measurement of the outcome	D7 - Risk of bias in selection of the reported result	Overall
Judge-ment	Justifica-tion	Judge-ment	Justifica-tion	Judge-ment	Justifica-tion	Judge-ment	Justifica-tion
Naidoo et al. (2013)	In patients who underwent revision surgery, the type of primary surgery may differ	Low	Exposure is standardised	Low	Clear inclusion and exclusion criteria	Low	All received same post exposure intervention
Kang et al. (2010)	Matched within patient	Low	Exposure is standardised	Low	Consent obtained from all patients	Low	All received same post exposure intervention

Table S3. JBI critical appraisal tool<sup>(19)</sup> for case series.

<b>Were there clear criteria for inclusion in the case series?</b>	<b>Was the condition measured in a standard, reliable way for all participants included in the case series?</b>	<b>Were valid methods used for identification of the condition for all participants included in the case series?</b>	<b>Did the case series have consecutive inclusion of participants? the condition for all participants included in the case series?</b>	<b>Did the case series have complete inclusion of participants?</b>	<b>Did the case series have clear reporting of the demographics of the participants?</b>	<b>Was there clear reporting of clinical information of the participants?</b>	<b>Were the outcomes or follow up results clearly reported?</b>	<b>Was there clear reporting of the presenting site(s)/clinics)</b>	<b>Was statistical analysis appropriate?</b>	<b>Overall appraisal (include// Exclude/Seek further info)</b>										
Nguyen et al. (2019)	Yes	Unclear	Unclear - why was this one patient chosen to undergo endoscopic procedure?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Include		
Erdur et al. (2018)	Yes	Not applicable as 1 patient	Yes	Not applicable as 1 patient	Not applicable as 1 patient	No	Yes	Yes	No	Not applicable									Include	
Khoueir et al. (2018)	Yes	Not applicable as 1 patient	Yes	Not applicable as 1 patient	Not applicable as 1 patient	No	Yes	Yes	No	Not applicable									Include	
Grayson et al. (2017)	Yes	Yes	Yes	Unclear	Unclear	No	Yes	Yes	Yes	Yes									Include	
Fiorini et al. (2016)	Yes	Yes	Yes	Yes	No, but justified	Yes	Yes	Yes	Yes	Yes									Include	
Mansour et al. (2013)	Yes	Yes	Unclear	Unclear	Unclear	No	Yes	Unclear	Yes	Not applicable									Include	
Seyedhadi et al. (2013)	Yes	Unclear	Unclear	Yes	No	No	Yes	Yes	Yes	Unclear									Include	
Jones et al. (2012)	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	No	Not applicable									Include	
Hildenbrand et al. (2012)	Yes	Yes	Unclear	Yes	Unclear	Yes	Yes	Yes	Yes	Not applicable									Include	
Hunter et al. (1984)	Yes	Unclear	Yes	Unclear	Unclear	Yes	Yes	Yes	Yes	Not applicable									Include	
Thompson et al. (2021)	Yes	Unclear	Yes	Unclear	Yes	Yes	Yes	Yes	Yes	Not applicable									Include	
Khoueir et al. (2018)	Yes	Unclear	Yes	Unclear	Unclear	No	Yes	Yes	Yes	Not applicable									Include	
Rotenburg et al. (2016)	Yes	Yes	Yes	Unclear	Unclear	Yes	Yes	Yes	Yes	Not applicable									Include	

	Were there clear criteria for inclusion in the case series?	Was the condition measured in a standard, reliable way for all participants included in the case series?	Were valid methods used for identification of the condition for all participants included in the case series?	Did the case series have consecutive inclusion of participants?	Did the case series have complete inclusion of participants?	Was there clear reporting of the demographics of the participants in the study?	Was there clear reporting of clinical information of the participants?	Were the outcomes or follow up results of cases clearly reported?	Was there clear reporting of the presenting site(s)/clinic(s) demographic information?	Was statistical analysis appropriate?	Overall appraisal (Include//Exclude/Seek further info)
Illing et al. (2016)	Yes	Yes	Yes	Unclear	Unclear	Yes	Yes	Yes	Yes	Yes	Include
Conger et al. (2014)	Yes	Yes	Yes	Unclear	Unclear	Yes	Yes	Yes	Yes	Yes	Include
Sama et al. (2014)	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Not applica-ble	Include
Chaabani et al. (2012)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Not applica-ble	Include
Yoon et al. (2009)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Not applica-ble	Include
Orlandi et al. (2009)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Unclear (better if info on surgery indication is available)	Yes	Not applica-ble	Include
Wormald et al. (2009)	Yes	Yes	Yes	Unclear	Yes	Yes	Yes	Yes	Yes	Not applica-ble	Include
Hahn et al. (2009)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Not applica-ble	Include
Lin et al. (2008)	Yes	Yes	Yes	Unclear	Unclear	Yes	Yes	Yes	Yes	Not applica-ble	Include
Shirazi et al. (2007)	Yes	Yes	Yes	Unclear	Yes	Yes	Yes	Yes	Yes	Not applica-ble	Include
Banhiran et al. (2006)	Yes	Yes	Yes	Unclear	No	Yes	Yes	Yes	Yes	Yes	Include
DelGaudio et al. (2006)	Yes	Unclear (difficult to standardise through application of steroid)	Yes	Unclear	Yes	Yes	Yes	Yes	Yes	Not applica-ble	Include

	Were there clear criteria for inclusion in the case series?	Was the condition measured in a standard, reliable way for all participants included in the case series?	Were valid methods used for identification of the condition for all participants included in the case series?	Did the case series have consecutive inclusion of participants? the condition for all participants included in the case series?	Did the case series have complete inclusion of participants?	Was there clear reporting of the demographics of the participants?	Was there clear reporting of clinical information of the participants?	Were the outcomes or follow up results of cases clearly reported?	Was there clear reporting of the presenting site(s)/clinics) demographic information?	Overall appraisal (include// Exclude/Seek further info)
Anand et al. (2005)	Yes	Yes	Yes	Undeclared	Yes	Unclear - the data for all 30 patients that had the initial endoscopic surgery not available	Unclear - the data for all 30 patients that had the initial endoscopic surgery not available	Yes	Not applicable	Include
Stankiewicz et al. (2003)	Yes	Yes	Yes	Undeclared	Yes	Unclear - stated 4 patients had stents however not clear whether these patients had revision	Unclear - stated 4 patients had stents however not clear whether these patients had revision	Yes	Not applicable	Include
Wormald et al. (2003)	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Not applicable	Include
Hosemann et al. (2003)	Yes	Yes	Yes	Unclear	No	No	No	Yes	Not applicable	Include
Wormald et al. (2003)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Not applicable	Include
Schlosser et al. (2002)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Not applicable	Include
Benoit et al. (2001)	Yes	Yes	Yes	Undeclared	Undeclared	No	No	Yes	Not applicable	Include
Citardi et al. (2001)	No	Yes	Yes	Unclear	Unclear	No	No	Yes	Not applicable	Include
Conger et al. (2012)	Yes	Yes	Yes	Undeclared	Yes	Yes	Yes	Yes	Not applicable	Include
Al Kadah et al. (2014)	Yes	Yes	Yes	Undeclared	Undeclared	No	No	Yes	Not applicable	Include

	Were there clear criteria for inclusion in the case series?	Was the condition measured in a standard, reliable way for all participants included in the case series?	Were valid methods used for identification of the condition for all participants included in the case series?	Did the case series have consecutive inclusion of participants?	Did the case series have complete inclusion of participants?	Was there clear reporting of the demographic characteristics of the participants in the study?	Was there clear reporting of clinical information of the participants?	Were the outcomes or follow up results of cases clearly reported?	Was there clear reporting of the presenting site(s)/clinic(s) demographic information?	Was statistical analysis appropriate?	Overall appraisal (Include//Exclude/Seek further info)
Crocetta et al. (2021)	Yes	Yes	Yes	Unclear	Unclear	Yes	Yes	Yes	Yes	Yes	Include
Illing et al. (2016)	Yes	Yes	Yes	Unclear	Unclear	Yes	Yes	Yes	Yes	Not applicable	Include
Conger et al. (2014)	Yes	Yes	Yes	Unclear	Unclear	Yes	Yes	Yes	Yes	Not applicable	Include
Metson et al. (1998)	Yes	Yes	Yes	Yes	Unclear	Yes	Yes	Yes	Yes	Not applicable	Include
Gross et al. (1997)	Yes	Yes	Yes	Unclear	Unclear	No	Yes	Yes	Yes	Not applicable	Include
Uluap et al. (1999)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Not applicable	Include
Casiano et al. (1998)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Not applicable	Include
Close et al. (1994)	Yes	Yes	Yes	Unclear	Unclear	No	Yes	Yes	Yes	Not applicable	Include
Kikawada et al. (1999)	Yes	Yes	Yes	Unclear	Unclear	Yes	Yes	Yes	Yes	Not applicable (could have been done but not performed)	Include
Loehrl et al. (2000)	Yes	Yes	Yes	Unclear	Unclear	Yes	Yes	Yes	Yes	Not applicable	Include
McLaughlin et al. (1999)	Yes	Yes	Yes	Unclear	Yes	No	Yes	Yes	Yes	Not applicable	Include
Eloy et al. (2011)	Yes	Yes	Yes	Unclear	Unclear	Yes	Yes	Yes	Yes	Not applicable	Include
Georgalas et al. (2011)	Unclear	Yes	Yes	Unclear	Unclear	Yes	Yes	Yes	Yes	Not applicable	Include
Morrissey et al. (2016)	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Not applicable	Include
Hajibeygi et al. (2016)	Unclear	Yes	Yes	Unclear	Unclear	Yes	Yes	Yes	Yes	Not applicable	Include

Were there clear criteria for inclusion in the case series?	Was the condition measured in a standard, reliable way for all participants included in the case series?	Were valid methods used for identification of the condition for all participants included in the case series?	Did the case series have consecutive inclusion of participants? the condition for all participants included in the case series?	Did the case series have complete inclusion of participants?	Was there clear reporting of the demographics of the participants?	Was there clear reporting of clinical information of the participants?	Were the outcomes or follow up results of cases clearly reported?	Was statistical analysis appropriate?	Overall appraisal (include// Exclude/Seek further info)
Schulze et al. (2002)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Include
Ye et al. (2014)	Yes	Yes	Yes	Unclear	Yes	Yes	Yes	Not applicable	Include
Omura et al. (2018)	Yes	Yes	Yes	Unclear	Yes	Yes	No (duration)	Not applicable	Include
Tran KN et al. (2007)	Yes	Yes	Yes	Unclear	Yes	Yes	Yes	Not applicable	Include
Jonathan Y Ting et al. (2013)	Unclear	Yes	Yes	Unclear	Yes	Yes	Yes	Yes	Include
Chiu et al. (2003)	Unclear	Yes	Yes	Unclear	Yes	Yes	Yes	Not applicable	Include
Khafagy et al. (2020)	Yes	Yes	Yes	Unclear	Yes	Yes	Yes	Not applicable	Include
Turner et al. (2016)	Yes	Yes	Yes	Unclear	Yes	Yes	Yes	Not applicable	Include
Samaha et al. (2003)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Not applicable	Include
Khong et al. (2004)	Yes	Yes	Yes	Yes	Yes	Yes	Unclear	Yes	Include
Wormald et al. (2003)	Yes	Yes	Yes	Yes	Yes	Yes	Unclear	Yes	Not applicable
Wormald et al. (2003)	Yes	Yes	Yes	Yes	Yes	Yes	Unclear	Yes	Not applicable
Nakagawa et al. (2007)	Yes	Yes	Yes	Unclear	Unclear	Yes	Yes	Yes	Not applicable
Naidoo et al. (2014)	Yes	Yes	Yes	Unclear	Unclear	Yes	Yes	Yes	Include
Karligkiotis et al. (2015)	Yes	Yes	Yes	Unclear	Unclear	Yes	Yes	Yes	Include
Nishiike et al. (2015)	Yes	Yes	Yes	Unclear	Unclear	No	Yes	Yes	Not applicable

	Were there clear criteria for inclusion in the case series?	Was the condition measured in a standard, reliable way for all participants included in the case series?	Were valid methods used for identification of the condition for all participants included in the case series?	Did the case series have consecutive inclusion of participants?	Did the case series have complete inclusion of participants?	Was there clear reporting of the demographic characteristics of the participants in the study?	Was there clear reporting of clinical information of the participants?	Were the outcomes or follow up results of cases clearly reported?	Was there clear reporting of the presenting site(s)/clinic(s) demographic information?	Was statistical analysis appropriate?	Overall appraisal (Include//Exclude/Seek further info)
Choudhury et al. (2016)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Not applicable
Cho et al. (2023)	Yes	Yes	Yes	Unclear	Yes	Yes	No	Yes	Yes	Yes	Include
Askar et al. (2015)	Yes	Yes	Yes	Yes	Unclear	Yes	Yes	Yes	Yes	Yes	Include
Chan et al. (2009)	Yes	Yes	Yes	Yes	Unclear	Yes	No	Yes	Yes	Yes	Include
Friedman et al. (2006)	Yes	Yes	Yes	Unclear	No	No	No	Yes	Yes	Not applicable	Include
Chandra et al. (2003)	Yes	Yes	Yes	Unclear	Unclear	No	No	Yes	Yes	Not applicable	Include
Hosemann et al. (1997)	Yes	Yes	Yes	Unclear	Unclear	No	Yes	Yes	Yes	Not applicable	Include
Eloy et al. (2012)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Not applicable	Include
Al Komser et al. (2013)	Undeclar	Yes	Yes	Unclear	Unclear	Yes	Yes	Yes	Yes	Not applicable	Include
Wormald et al. (2002)	Yes	Yes	Yes	Yes	Unclear	Yes	Yes	Yes	Yes	Not applicable	Include
Gotlib et al. (2015)	Yes	Yes	Yes	Unclear	Unclear	Yes	Yes	Yes	Yes	Not applicable	Include
Evitar et al. (2017)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Not applicable	Include
Zhang et al. (2018)	Yes	Yes	Yes	Unclear	Yes	Yes	Yes	Yes	Yes	Not applicable	Include
Omura et al. (2019)	Yes	Yes	Yes	Unclear	Yes	Yes	Yes	Yes	Yes	Not applicable	Include
Naidoo et al. (2012)	Yes	Yes	Yes	Yes	Unclear	Yes	Yes	Yes	Yes	Not applicable	Include
Janisiewicz et al. (2015)	Yes	N/A	N/A	N/A	N/A	N/A	N/A	Yes	Yes	Not applicable	Include

	Were there clear criteria for inclusion in the case series?	Was the condition measured in a standard, reliable way for all participants included in the case series?	Were valid methods used for identification of the condition for all participants included in the case series?	Did the case series have consecutive inclusion of participants? the condition for all participants included in the case series?	Did the case series have complete inclusion of participants?	Was there clear reporting of the demographic characteristics of the participants in the study?	Were the outcomes or follow up results of cases clearly reported?	Were the outcomes or follow up results of cases clearly reported?	Was statistical analysis appropriate?	Overall appraisal (include// Exclude/Seek further info)	
Hong et al. (2012)	Yes	Yes	Yes	Unclear	Unclear	Yes	Yes	Yes	Yes	Not applicable	Include
Friedman et al. (2000)	Yes	Yes	Yes	Unclear	Yes	Yes	Yes	Yes	Yes	Not applicable	Include
Philpott et al. (2010)	Yes	Yes	Yes	Unclear	No	Yes	Yes	Yes	Yes	Not applicable	Include
Huang et al. (2019)	Yes	Yes	Yes	Unclear	Unclear	Yes	Yes	Yes	Yes	Not applicable	Include