Interventional procedure overview of corticosteroid-releasing bioabsorbable stent or spacer insertion during endoscopic sinus surgery for chronic rhinosinusitis

Contents

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Table 1 Abbreviations

Abbreviation	Definition
CI	Confidence interval
CRS	Chronic rhinosinusitis
ESS	Endoscopic sinus surgery
FDA MAUDE	Food and Drug Administration Manufacturer and User Facility Device Experience
FESS	Functional endoscopic sinus surgery
MD	Mean difference
OR	Odds ratio
POSE	Perioperative sinus endoscopy
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-analyses
SD	Standard deviation
SES	Steroid-eluting stent
SNOT	Sino-nasal outcome test
VAS	Visual analogue scale

Indications and current treatment

The paranasal sinuses are air-filled cavities, located in the bony structures of the face. Small openings (ostia) connect the sinuses with the nasal space. Rhinosinusitis occurs when the mucosal lining of the paranasal sinuses becomes inflamed and infected. Typical symptoms include fever, pain and tenderness over the infected area, together with a blocked or runny nose. Acute rhinosinusitis frequently resolves spontaneously with little or no treatment, but in some cases it becomes chronic.

The symptoms of chronic rhinosinusitis (CRS) are usually managed with a combination of analgesics, antibiotics, topical corticosteroids, and nasal irrigation. If these interventions fail, surgical procedures may be needed to enhance drainage from the sinuses and allow topic medical therapy to reach the sinus mucosa. But adhesions and scarring may develop after surgery, compromising drainage. Scarring occurs less frequently if the mucosa remains intact. Foam

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dressings, nasal packing and middle meatal spacers are sometimes used after surgery to try and maintain sinus patency.

Unmet need

Endoscopic sinus surgery is used to treat CRS that is refractory to medication. The aim is to open the sinuses and allow topical medical therapy to reach the sinuses. Adhesions and scarring can develop after such surgery, and further interventions may be needed. Dissolvable nasal packing is often used after surgery to try to prevent adhesions. Postoperative interventions aimed at minimising complications include nasal douches and corticosteroids. The efficacy of topical corticosteroid drops or sprays is limited by postoperative oedema, discharge and crusting, and oral corticosteroids have systemic risks.

Insertion of corticosteroid-eluting bioabsorbable stents or spacers aims to decrease the rate of adhesions after endoscopic sinus surgery and maintain better longer-term patency.

What the procedure involves

Inserting a corticosteroid-releasing bioabsorbable stent or spacer during surgery for chronic rhinosinusitis aims to deliver topical corticosteroids directly to the sinus mucosa after surgery and to maintain patency of the newly created drainage system. It is usually done with the patient under general anaesthesia, during functional ESS. At the end of the surgery, the corticosteroid-eluting stent or spacer is inserted into the relevant ostium under endoscopic guidance. The stent or spacer dissolves over time.

Outcome measures

The main outcomes included endoscopic evaluation scores (Lund-Kennedy and POSE), recurrent polyposis, adhesions or scarring, reintervention rate and

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disease-specific quality of life and symptom scores (SNOT-22). The main measures used are detailed in the following paragraphs.

The POSE score is based on 10 parameters (each 0 to 2 points: middle turbinate, middle meatus, maxillary sinus contents, ethmoid cavity; crusting, mucosal oedema, polypoid change, polyposis, and secretions, frontal recess/sinus, and sphenoid sinus) for a bilateral total possible score of 40, with higher scores indicating more severe disease.

The Lund-Kennedy endoscopy scoring system grades visual pathologic states within the nose and paranasal sinuses including polyps, discharge, oedema, scarring, and crusting. Scores range from 0 to 20, with higher scores indicating more severe disease.

The SNOT-22 scale determines disease-specific health status by evaluating the severity of distinct parameters specifically related to physical problems, functional limitations, and emotional consequences of rhinosinusitis. Scores for each parameter are rated from 0 to 5, with higher scores indicating more severe symptoms. The total score ranges from 0 to 110.

Evidence summary

Population and studies description

This interventional procedures overview is based on 4,897 people with CRS from 2 systematic reviews (Goshtasbi 2019, Zhang 2021), 1 retrospective cohort study (Hoffman 2023), 4 randomised controlled trials (Huang 2022, Samarei 2022, Wierzchowska 2021, Wang 2023), 1 prospective cohort before-after study (Pou 2017), and 2 case reports (Shipman 2022, Tang 2019). It also includes a review of adverse events reported on the US FDA MAUDE database (Shah 2022). This is a rapid review of the literature, and a flow chart of the complete selection

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process is shown in figure 1. This overview presents 11 studies as the key evidence in table 2 and table 3, and lists 52 other relevant studies in appendix B, table 5.

The systematic review by Goshtasbi et al. (2019) included a meta-analysis of 7 studies, all of which were described as randomised controlled trials. The methodology was compliant with the PRISMA guidelines. The SES implants were placed in the frontal or ethmoid sinuses. Of the 6 studies that described intraoperative insertion of the SES, all used intrapatient controls. The remaining study described in-office placement of a stent after ESS, which is not within the remit of this overview. Most of the reported primary outcomes were based on 1month data. Overall, the mean age ranged between 42 and 51 years and females comprised 34% to 68% of the cohorts. The proportion of people with polyps ranged from 16 to 76%. Of the 7 studies, 6 prescribed a 10- or 14-day course of antibiotics postoperatively and 1 study prescribed daily doses of steroid nasal spray. Some studies permitted additional postoperative treatment, such as corticosteroids for asthma control.

The systematic review by Zhang et al. (2021) was conducted as per PRISMA guidelines and included 8 randomised controlled trials in a qualitative analysis. The trials compared absorbable nasal packing impregnated with steroids against absorbable nasal packing alone, inserted during ESS. Sample sizes of the included studies ranged between 19 and 80 people. Of the 8 trials, 5 included only people with polyps, 2 included people with or without polyps and 1 included only people without polyps. All 8 included studies described the use of saline irrigation, topical steroids, and systemic antibiotics after the procedure. The follow up periods were up to 12 months.

The cohort study by Hoffman et al. (2023) aimed to assess the impact of using SES on healthcare resource use in the US, during the 2 years after surgery. It

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was a retrospective observational study using multisource databases containing healthcare claims and electronic medical record data in the US. People who had ESS with an SES were matched with those who had ESS without an implant using propensity scores. The overall cohort was subdivided according to the presence or absence of polyps. The mean age of the whole cohort was 48 years and 52% were female. The specific sinuses where the implants were placed was not reported.

Two randomised controlled trials were based in China and used intrapatient controls. The trial by Huang et al. (2022) included 181 people who had implants placed in the ethmoid sinus after bilateral ethmoidectomy. An SES was placed in the treatment side and synthetic absorbable packing material without steroids was placed in the control side. The primary outcome was the rate of postoperative interventions within 30 days. The mean age of the study population was 42 years, 29% were female and 96% had polyps. Efficacy outcomes were reported up to 90 days after the procedure and adverse events were recorded up to a year. After the ESS, a 7-day course of antibiotics was offered. Nasal saline irrigation and oral mucolytics were routinely used during the follow-up period. Intranasal steroid sprays were allowed starting 30 days after the ESS. The trial by Wang et al. (2023) included 95 people who had 1 side randomised to have 1 SES implanted in the ethmoid sinus and if possible, another in the frontal sinus, whereas the contralateral side had surgery alone. The primary outcome was the Lund-Kennedy endoscopic score within 12 weeks of the surgery. Everyone in the study population had polyps, the mean age was 48.8 years and 52% were male. The follow up period was 12 weeks. After the ESS, prescribed nasal steroid sprays were permitted, but oral corticosteroids were not allowed up to week 12. Patients were instructed to use sprays or irrigation during the follow-up period.

The randomised controlled trial by Samarei et al. (2022) included 104 people, all with polyps, who had bilateral ESS. The middle meatus of each nostril was

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packed with either steroid-impregnated gelatine sponge or saline-impregnated gelatine sponge. The packing was suctioned from the middle meatus after 7 days. Of the 104 people, 27% were female and the mean age was 46 years. Postoperative oral antibiotics were offered for 14 days. Nasal saline irrigation and intranasal topical corticosteroid spray were resumed from 24 hours after the packing was removed. Follow up was 18 months.

The randomised controlled trial by Wierzchowska et al. (2021) included 120 people with or without polyps who had bilateral ESS. A biodegradable synthetic polyurethane foam soaked with antibiotic, steroid or both was inserted into the treatment side and the same packing soaked with saline was inserted into the control side. The mean age of the study population was 44.7 years and 41% were women. After the surgery, everyone was advised to rinse the nose with saline solution once a day for 2 weeks and to use a nasal steroid for 3 weeks. Follow up was 180 days.

The prospective cohort study by Pou et al. (2017) aimed to assess how the severity of inflammation before the procedure affected the outcomes. It included 136 people who had an SES implanted in 1 or both ethmoid sinuses. Of the total study population, 37% had polyps, 60% were female and 52% were aged over 50. The follow up period was 6 months.

Shah et al. (2022) is a review of the FDA MAUDE database, describing adverse events reported in association with use of the PROPEL SES. The MAUDE database includes mandatory reports from manufacturers and device importers when a device may have caused injury to a patient, and voluntary reports from other sources including healthcare professionals and patients. Limitations of the database include under-reporting, duplicate reporting, incomplete reports and uncertainty if the device caused the complication being described. The true

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denominator for these events is not captured and the database is not designed to calculate or compare complication rates.

The 2 case reports describe adverse events associated with the procedure that have not been reported elsewhere. One is a case of non-invasive fungal sinusitis (Shipman 2022) and the other describes the introduction of an SES through a dural defect (Tang 2019).

Table 2 presents study details.

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Figure 1 Flow chart of study selection

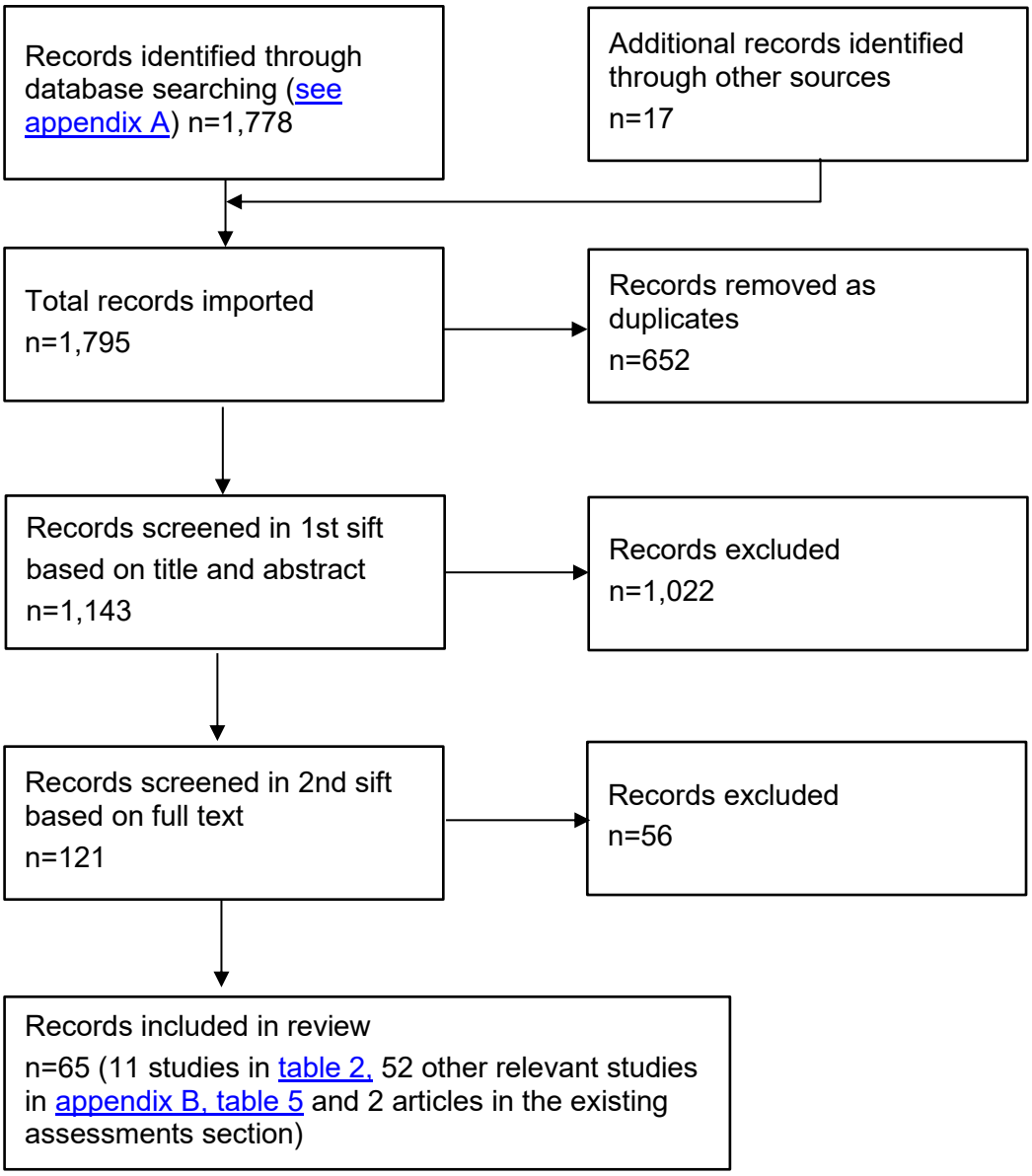

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Table 2 Study details

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
1	Goshtasbi K, 2019 Country of individual studies not reported	n=444 (888 sinuses; 444 SES, 444 control as stated in the paper although total number for the 7 individual studies was higher [533 SES and 527 control]). Proportion of people with polyps ranged from 16 to 76% 34 to 68% female Mean age ranged from 42 to 51 years	Systematic review and meta-analysis (7 studies were included for quantitative analysis, all of which were described as randomised controlled trials) Search date: December 2018 6 studies used intrapatient controls (using different sinuses in the same patient) and 1 used interpatient controls with sham surgery	Patient inclusion criteria were similar across the studies, including adults aged 18 to 65 years with CRS indicated for ESS. Study inclusion criteria mandated that the authors report both SES and control (interpatient or intrapatient) outcomes following ESS.	**SES** Devices used: Propel Mini or Contour (Intersect ENT), unnamed SES (Intersect ENT), SinuBand Fluticasone Propionate. Implants were placed in frontal or ethmoid sinuses. 2 additional studies used a non-bioabsorbable device, but these were not included in the meta-analysis.	Outcome variables were reported at a mean follow up of 30 days. Maximum follow up ranged from 2 to 3 months in most of the studies included in the meta-analysis.

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Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
			(in-office treatment for recurrent polyposis after ESS).			
2	Zhang M, 2021 Australia, Canada, China, Iran, Poland, South Korea	n=397 5 studies included only CRS with nasal polyposis, 2 studies included all CRS, and 1 included only CRS without nasal polyposis.	Systematic review 8 randomised controlled trials were included in a qualitative analysis. All included studies were published between 2010 and 2019.	Prospective, randomised, placebo-controlled trials investigating the efficacy of the intraoperative placement of absorbable nasal packing subsequently impregnated with steroid (post-production) in patients having FESS for CRS were eligible for inclusion.	**Absorbable steroid-impregnated nasal packing** Of the 8 studies, 4 used a synthetic proprietary bioabsorbable polymer (Nasopore), 3 used bioabsorbable gels and 1 used calcium alginate packing.	Up to 12 months
3	Hoffman V, 2023 US	n=3,418 (1,709 in each of the implant and non-implant cohorts) 48% with polyps 52% female, 48% male Mean age 48 years	Retrospective cohort study, with propensity score matching. The study population was derived from multisource	Adults with CRS who had ESS between January 2015 and December 2019, with at least 24 months of claims data before and after ESS. People with a previous history of ESS and those who	• **SES (type of implant not specified)** • **No implant** Maxillary, ethmoid, frontal and sphenoid	24 months

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Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
			databases containing healthcare claims and electronic medical record data in the US.	had balloon sinus dilation only were excluded.	sinuses were treated.	
4	Huang Z, 2022 China	n=181 96% with polyps 29% female, 71% male Mean age 42 years	Prospective multicentre, single-blind, randomised controlled trial. Intrapatient controls September 2014 to August 2015	Age 18 to 65 years, males or nonpregnant females, diagnosed with bilateral CRS, confirmed by CT. Exclusion criteria included: allergy or contraindication to the device material and its degradation products; need for long-term oral hormones; immunosuppressive therapy or immunosuppressive or autoimmune disease; diabetes, glaucoma, or ocular hypertension; acute bacterial sinusitis or acute fungal sinusitis.	• **BISORB bioabsorbable steroid-eluting sinus stent** (Puyi Biotechnology Co. Ltd, China) was placed in the treatment side. • **Nasopore pack without steroids** (Stryker Corp.) was placed in the control side. Implants were placed in ethmoid sinus after bilateral ethmoidectomy.	Up to 90 days for efficacy outcomes, up to 365 days for recording of adverse events.

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Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
5	Wang C, 2023 China	n=95 100% with polyps 52% male Mean age 48.8 years	Randomised controlled trial Intrapatient controls October 2018 to April 2021 Endoscopic image scoring was done by 2 otolaryngologists who were blinded to the trial design.	Age 18 to 65 years, Bilateral CRS with polyps. Exclusion criteria included known allergy to the device material or its degradation products, an oral steroid dependent condition, history of immune deficiency, glaucoma or ocular hypertension, cataract, severe diabetes or hypertension, or acute bacterial or fungal sinusitis.	**Bioabsorbable SES** (Xiangtong, Puyi Biotechnology, China) implanted in ethmoid sinus in 1 side. If the frontal ostium was wide enough, a second SES was placed in the ipsilateral frontal recess. **Bilateral full-house ESS**, middle turbinate resection, and nasal polypectomy. **Septoplasty** was permitted if there was severe nasal septum deviation.	12 weeks
6	Samarei R, 2022 Iran	n=104 100% with polyps 27% female, 73% male Mean age 46 years 65 were categorised as eosinophilic and	Single centre double-blinded randomised controlled trial Intrapatient controls	Age 18 to 60 years, bilateral ESS because of CRS with polyps refractory to medical treatment, inter-sinus Lund–Mackay score difference of 1 or less. Exclusion criteria included pregnancy or	• **Steroid-impregnated absorbable gelatine sponge** (Gelfoam, Pharmacia and Upjohn Company, US)	18 months

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Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
		39 were non-eosinophilic	April 2017 to April 2019	lactation, revision surgery or simultaneous septo- or rhinoplasty. People who had had oral steroids within 2 months before ESS or used systemic corticosteroid during the follow-up period were also excluded.	• **Saline-impregnated absorbable gelatine sponge** (Gelfoam, Pharmacia and Upjohn Company, US) The gelfoam sheets were suctioned from the middle meatus after 7 days.	
7	Wierzchowska M, 2021 Poland	n=120 With or without polyps 59% men, 41% women Mean age 44.7 years	Randomised double-blind placebo-controlled trial Intrapatient controls	Adults with CRS, with or without polyps, refractory to maximal medical treatment and suitable for bilateral FESS. Exclusion criteria included signs of acute infection.	• **NasoPore soaked with antibiotic (ciprofloxacin), steroid (beta-methasone), or both** was inserted in treatment side. • **NasoPore soaked with saline** was inserted in control side.	180 days

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Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
8	Pou J, 2017 US	n=136 37% with polyps 60% female, 40% male 52% were aged over 50	Prospective single centre cohort before-after study October 2014 to March 2016	Consecutive adults having ethmoidectomy for CRS. Exclusion criteria: people who had postoperative systemic corticosteroids (n=9), cystic fibrosis (n=5) incidental diagnosis of sinonasal neoplasm (n=1).	**Bioabsorbable SES** (Propel, Intersect ENT, US) implanted in 1 or both sides. Implants were placed in each treated ethmoid cavity but treatment of other paranasal sinuses was permitted.	6 months
9	Shah V, 2022 US	25 medical device reports, describing 40 adverse events	Review of FDA MAUDE database January 2012 to December 2020	Adverse events associated with PROPEL bioabsorbable drug-eluting sinus stents	**Bioabsorbable SES** (Propel, Intersect ENT, US)	Not reported
10	Shipman P, 2022 US	69 year old male with CRS without polyposis	Case report	First reported case of a symptomatic fungal tissue infection associated with SES.	**Revision ESS with SES** (Propel, Intersect ENT, US) inserted into bilateral frontal outflow tracts at the time of surgery.	4 months
11	Tang D, 2019 US	70 year old male with CRS	Case report	Reported case of SES introduced through a skull base defect.	Septoplasty, bilateral maxillary antrostomies, total ethmoidectomies, frontal sinusotomies,	1 year

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Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
					and sphenoidotomies with **placement of multiple SES**.	

Table 3 Study outcomes

First author, date	Efficacy outcomes	Safety outcomes
Goshtasbi, 2019	Outcomes for SES compared to control **Need for postoperative intervention (5 studies; follow up was 1 month in 4 studies [n=826] and 6 months in 1 study [n=98])** OR=0.45 (95% CI 0.33 to 0.62, p<0.001, I^2=7%) • Postoperative surgery (4 studies), OR=0.30 (95% CI 0.18 to 0.52, p<0.001, I^2=0%) • Postoperative oral steroid (3 studies), OR=0.58 (95% CI 0.40 to 0.84, p=0.004, I^2=0%) **Frontal sinus ostia patency (3 studies; follow up was 1 month in 2 studies [n=302 sinuses] and 3 months in 1 study [290 sinuses])** OR=2.53 (95% CI 1.61 to 3.97, p<0.001, I^2=31%) **Recurrent polyposis (3 studies; 1 month follow up)**	No safety outcomes were reported.

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First author, date	Efficacy outcomes	Safety outcomes
	OR=0.42 (95% CI 0.25 to 0.74, p=0.002, I^2=0%) **Moderate to severe adhesions or scarring (3 studies; 1 month follow up)** OR=0.28 (95% CI 0.13 to 0.59, p<0.001) **Frontal sinus ostia or ethmoid inflammation (4 studies; follow up was 1 month in 3 studies [n=378 sinuses] and 3 months in 1 study [n=290 sinuses])** MD= -10.86 mm (p<0.001) **Frontal sinus ostia diameter (3 studies; follow up was 1 month in 2 studies [n=302 sinuses] and 3 months in 1 study [n=290 sinuses])** MD=+1.34 mm (p<0.001) **SNOT-22 scores** 1 of the 7 studies reported an overall statistically significant improvement in SNOT-22 scores at 1-month and 3-month follow-ups (from baseline 52 to 19); though there was no control-SES comparison as the study used contralateral sinuses as controls. **Middle turbinate lateralisation at 30 days** 2 of the 7 studies reported a statistically significant difference in middle turbinate lateralisation (2/38 for SES	

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First author, date	Efficacy outcomes	Safety outcomes
	compared to 6/38 for controls and 2/105 for SES compared to 7/105 for controls).	
Zhang, 2021	7 out of the 8 included studies concluded there were statistically significant positive outcomes following use of steroid-impregnated absorbable nasal packing. **Synthetic bioabsorbable polymer nasal dressing** Cote et al. reported statistically significant improvements in endoscopy-based scoring systems (Lund-Kennedy and POSE) of the interventional groups at days 7, 14, and at 3 and 6 months. They described statistically significant mean POSE score reductions of 1.5, 2.24, 1.22, and 1.30 ($p<0.05$ on all occasions) at 7 days, 14 days, 3 months, and 6 months, respectively, postoperatively. Xu et al. reported improvements at 1 and 2 months. Grzeskowiak et al. reported an improvement of 0.39 in mean Lund-Kennedy score at 90 days ($p=0.008$) but there were no statistically significant differences at 10, 30, or 180 days. Zhao et al. reported that a higher dose of steroid left in situ for 2 weeks compared to a lower dose or 1 week duration had better outcomes, with statistically significant improvements found in the interventional group at 14 days, 1, 2, and 3 months. **Calcium alginate-based bioabsorbable nasal dressing** Hwang et al reported insignificant reductions in mean POSE scores in the treatment group at 1 and 4 weeks	Within the included studies, no articles reported any severe adverse events.

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First author, date	Efficacy outcomes	Safety outcomes
	postoperatively, and a statistically significant reduction of 3.06 at 8 weeks postoperatively.	
Hoffman, 2023	**Repeat sinus surgery during follow up (24 months)** **Overall** • SES=3.7% (63/1,709) • No implant=5.1% (88/1,709), p=0.037 **Chronic rhinosinusitis with polyps** • SES=3.8% (31/819) • No implant=6.0% (49/819), p=0.039 **Chronic rhinosinusitis without polyps** • SES=3.6% (32/890) • No implant=4.2% (37/890), p=0.539 **All-cause outpatient visits during follow-up** **Overall** • SES=89.4% (1,528/1,709) • No implant=94.0% (1,606/1,709), p<0.001 **Chronic rhinosinusitis with polyps** • SES=90.0% (737/819) • No implant=93.9% (769/819), p=0.004 **Chronic rhinosinusitis without polyps** • SES=88.9% (791/890) • No implant=94.2% (838/890), p<0.001	No safety outcomes were reported.

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First author, date	Efficacy outcomes	Safety outcomes
	All-cause otolaryngologist visits during follow-up **Overall** • SES=58.7% (1,003/1,709) • No implant=75.4% (1,289/1,709), p<0.001 **Chronic rhinosinusitis with polyps** • SES=64.3% (527/819) • No implant=76.4% (626/819), p<0.001 **Chronic rhinosinusitis without polyps** • SES=53.5% (476/890) • No implant=74.4% (662/890), p<0.001 There were no statistically significant differences between the groups in all-cause visits to emergency room or urgent care. **Sinus endoscopy procedure during follow-up** **Overall** • SES=36.0% (615/1,709) • No implant=44.6% (763/1,709), p<0.001 **Chronic rhinosinusitis with polyps** • SES=40.5% (332/819) • No implant=47.4% (388/819), p=0.005 **Chronic rhinosinusitis without polyps** • SES=31.8% (283/890)	

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First author, date	Efficacy outcomes	Safety outcomes
	• No implant=41.7% (371/890), p<0.001 **Sinus debridement procedure during follow-up** **Overall** • SES=42.5% (727/1,709) • No implant=54.5% (932/1,709), p<0.001 **Chronic rhinosinusitis with polyps** • SES=48.8% (400/819) • No implant=55.6% (455/819), p=0.007 **Chronic rhinosinusitis without polyps** • SES=36.7% (327/890) • No implant=53.4% (475/890), p<0.001	
Huang, 2022	**Need for postoperative debridement (30 days)** Determined by clinical investigators • SES=33.7% (61/181) • Nasopore=66.3% (120/181), p<0.0001 Determined by panel of 3 independent reviewers • SES=14.4% (23/160) • Nasopore=75.0% (120/160), p<0.0001 **Polyp formation (grade 2 or 3) within 30 days** • SES=22.7% (41/181) • Nasopore=54.1% (98/181), p<0.0001	There were no statistically significant differences in intraocular pressure and lens opacities between the baseline and at postoperative days 14, 30, and 90 on the 2 sides. There were 26 adverse events that were judged by clinical investigators as having an indeterminate or unrelated relationship to the sinus stent and steroids (including nasal pain, nose bleeding, headache, acute rhinosinusitis).The authors state that there were no related safety events, such as crusting.

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First author, date	Efficacy outcomes	Safety outcomes
	Severe adhesions (grade 3 or 4) within 30 days • SES=0.6% (1/181) • Nasopore=2.2% (4/181), p=0.083 **Polyp formation (grade 2 or 3) within 90 days** • SES=6.8% (8/118) • Nasopore=25.4% (30/118), p<0.0001 **Severe adhesions (grade 3 or 4) within 90 days** • SES=7.6% (9/118) • Nasopore=25.4% (30/118), p=0.0003 There was no middle turbinate lateralisation within 90 days in either group.	

Wang, 2023	**Lund-Kennedy scores, mean (SD)**
	• Baseline
	  ○ SES=5.0 (0.5)
	  ○ Control=5.1 (0.6), p=0.204
	• 4 weeks
	  ○ SES=3.21 (1.40)
	  ○ Control=3.80 (1.50), p=0.001
	• 8 weeks
	  ○ SES=1.96 (1.26)
	  ○ Control=2.77 (1.49), p<0.001
		There were no implant-related adverse events.
		Plasma cortisol levels were not statistically significantly different at baseline or at follow up and were within the normal range.
		There were no symptoms of adrenal suppression or serious side effects.

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First author, date	Efficacy outcomes	Safety outcomes

	• 12 weeks
	  ○ SES=1.05 (1.15)
	  ○ Control=2.05 (1.32), p<0.001
	
	Polyp scores
	There was no statistically significant between-group difference in polyp scores at any time point.
	
	Oedema scores, mean (SD)
	• 2 weeks
	  ○ SES=1.35 (0.57)
	  ○ Control=1.65 (0.48), p<0.01
	• 4 weeks
	  ○ SES=0.95 (0.62)
	  ○ Control=1.30 (0.68), p<0.001
	• 8 weeks
	  ○ SES=0.74 (0.62)
	  ○ Control=1.03 (0.70), p<0.01
	• 12 weeks
	  ○ SES=0.65 (0.58)
	  ○ Control=1.00 (0.60), p<0.01
	
	Scarring scores, mean (SD)
	• 4 weeks
	  ○ SES=0.26 (0.51)	

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First author, date	Efficacy outcomes	Safety outcomes
	○ Control=0.41 (0.70), p<0.05 • 12 weeks ○ SES=0.3 (0.56) ○ Control=0.73 (0.72), p<0.001 **Crusting scores, mean (SD)** • 2 weeks ○ SES=1.53 (0.59) ○ Control=0.98 (0.60), p<0.001 • 12 weeks ○ SES=0.2 (0.40) ○ Control=0.36 (0.49), p<0.01 **Nasal obstruction score at 8 weeks, mean (SD)** • SES=0.92 (1.24) • Control=1.35 (1.64), p<0.01 **Total nasal symptom score (range 0 to 40) at 8 weeks, mean (SD)** • SES=5.47 (3.82) • Control=6.41 (3.74), p=0.001 There were no statistically significant between-group differences in any other symptom scores at other time-points.	

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First author, date	Efficacy outcomes	Safety outcomes
	Disease volumetric score measured on CT for ethmoidal sinus at 8 weeks, median (interquartile range) • SES=25.0 (7.5) • Control=30.0 (14.5), p=0.011 **Disease volumetric score measured on CT for frontal sinus at 8 weeks, median (interquartile range)** • SES=31.0 (33.0) • Control=35.0 (38.5), p=0.032 **Eosinophil counts of the ethmoid sinus mucosa at 4 weeks, median (interquartile range)** • SES=30.0 (20.0) • Control=60.0 (50.0), p=0.011	

Samarei, 2022	**Perioperative sinus endoscopy score, mean (SD)**
	• Baseline
	  ○ Treatment side=13.02 (3.48)
	  ○ Control side=12.82 (3.41)
	• Month 1
	  ○ Treatment side=3.43 (0.93), p<0.001
	  ○ Control side=4.31 (1.23), p<0.001
	Between groups p=0.072
		There were no adverse events during follow up.

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First author, date	Efficacy outcomes	Safety outcomes

	• Month 3
	  ○ Treatment side=3.64 (1.03), p<0.001
	  ○ Control side=5.73 (1.19), p<0.001
	  Between groups p=0.034
	• Month 6
	  ○ Treatment side=4.61 (1.39), p<0.001
	  ○ Control side=6.84 (1.54), p<0.001
	  Between groups p=0.029
	• Month 12
	  ○ Treatment side=6.16 (1.54), p<0.001
	  ○ Control side=7.22 (1.89), p<0.001
	  Between groups p=0.121
	• Month 18
	  ○ Treatment side=6.85 (1.68), p<0.001
	  ○ Control side=8.22 (2.02), p<0.001
	  Between groups p=0.117
	
	After stratifying the population by the subtypes of chronic rhinosinusitis with polyps, the average POSE score was statistically significantly lower in the treatment side of the eosinophilic group when compared with the contralateral control side in almost all postoperative follow-up visits (p<0.05), except for the first month.
	
	Intergroup comparisons revealed a statistically borderline difference between the treatment sides of the eosinophilic	

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First author, date	Efficacy outcomes	Safety outcomes
	group and non-eosinophilic group groups in terms of the total POSE score at months 12 (p=0.041) and 18 (p=0.044).	

Wierzchowska, 2021	**Endoscopic findings**
	Oedema scores
	• Day 10
	  ○ Steroid=0.25, control=0.40, p=0.083
	  ○ Antibiotic=0.41, control=0.46, p=0.527
	  ○ Steroid+antibiotic=0.20, control=0.53, p=0.002
	• Day 30
	  ○ Steroid=0.46, control=0.67, p=0.149
	  ○ Antibiotic=0.33, control=0.35, p=0.683
	  ○ Steroid+antibiotic=0.29, control=0.53, p=0.016
	• Day 90
	  ○ Steroid=0.37, control=0.68, p=0.007
	  ○ Antibiotic=0.46, control=0.46, p=1.00
	  ○ Steroid+antibiotic=0.22, control=0.43, p=0.011
	• Day 180
	  ○ Steroid=0.32, control=0.44, p=0.157
	  ○ Antibiotic=0.49, control=0.60, p=0.102
	  ○ Steroid+antibiotic=0.15, control=0.24, p=0.083
	Secretion scores
	• Day 10
	  ○ Steroid=0.55, control=0.65, p=0.285	

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First author, date	Efficacy outcomes	Safety outcomes
	○ Antibiotic=0.41, control=0.72, p=0.003 ○ Steroid+antibiotic=0.38, control=0.63, p=0.025 • Day 30 ○ Steroid=0.62, control=0.54, p=0.724 ○ Antibiotic=0.33, control=0.59, p=0.016 ○ Steroid+antibiotic=0.24, control=0.45, p=0.061 • Day 90 ○ Steroid=0.21, control=0.32, p=0.046 ○ Antibiotic=0.14, control=0.22, p=0.257 ○ Steroid+antibiotic=0.11, control=0.24, p=0.025 • Day 180 ○ Steroid=0.26, control=0.24, p=0.655 ○ Antibiotic=0.17, control=0.14, p=0.317 ○ Steroid+antibiotic=0.03, control=0.06, p=0.317 **Crusting scores** • Day 10 ○ Steroid=0.60, control=0.73, p=0.025 ○ Antibiotic=0.82, control=0.85, p=0.317 ○ Steroid+antibiotic=0.73, control=0.83, p=0.157 • Day 30 ○ Steroid=0.28, control=0.31, p=1.00 ○ Antibiotic=0.18, control=0.21, p=1.00 ○ Steroid+antibiotic=0.26, control=0.24, p=1.00 • Day 90	

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First author, date	Efficacy outcomes	Safety outcomes
	○ Steroid=0, control=0.5, p=0.157 ○ Antibiotic=0, control=0, p=1.00 ○ Steroid+antibiotic=0.03, control=0, p=0.317 • Day 180 ○ Steroid=0, control=0.6, p=0.157 ○ Antibiotic=0, control=0, p=1.00 ○ Steroid+antibiotic=0, control=0, p=1.00 **Lund-Kennedy scores** • Day 10 ○ Steroid=0.68, control=0.95, p=0.087 ○ Antibiotic=0.67, control=1.05, p=0.009 ○ Steroid+antibiotic=0.53, control=1.10, p=0.001 • Day 30 ○ Steroid=1.00, control=1.28, p=0.096 ○ Antibiotic=0.64, control=0.85, p=0.009 ○ Steroid+antibiotic=0.53, control=0.92, p=0.006 • Day 90 ○ Steroid=0.58, control=0.97, p=0.008 ○ Antibiotic=0.57, control=0.62, p=0.527 ○ Steroid+antibiotic=0.32, control=0.62, p=0.002 • Day 180 ○ Steroid=0.56, control=0.76, p=0.084 ○ Antibiotic=0.54, control=0.60, p=0.157 ○ Steroid+antibiotic=0.12, control=0.24, p=0.046	

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First author, date	Efficacy outcomes	Safety outcomes

	Complaints (measured on VAS 0 to 10)
	Facial pressure
	• Day 10
	  ○ Steroid=1.33, control=1.53, p=0.329
	  ○ Antibiotic=0.51, control=0.90, p=0.011
	  ○ Steroid+antibiotic=1.35, control=1.90, p=0.057
	• Day 30
	  ○ Steroid=1.00, control=1.00, p=0.822
	  ○ Antibiotic=0.38, control=0.90, p=0.066
	  ○ Steroid+antibiotic=1.05, control=1.61, p=0.024
	• Day 90
	  ○ Steroid=0.47, control=0.66, p=0.102
	  ○ Antibiotic=0.24, control=0.57, p=0.048
	  ○ Steroid+antibiotic=0.38, control=0.73, p=0.039
	• Day 180
	  ○ Steroid=0.47, control=0.53, p=0.414
	  ○ Antibiotic=0.54, control=0.57, p=0.317
	  ○ Steroid+antibiotic=0.29, control=0.35, p=0.317
	Nasal blockage
	• Day 10
	  ○ Steroid=1.33, control=1.80, p=0.098
	  ○ Antibiotic=1.67, control=1.92, p=0.356
	  ○ Steroid+antibiotic=2.25, control=3.43, p=0.005	

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First author, date	Efficacy outcomes	Safety outcomes

	• Day 30
	  ○ Steroid=1.15, control=1.31, p=0.596
	  ○ Antibiotic=0.95, control=1.46, p=0.032
	  ○ Steroid+antibiotic=1.39, control=2.34, p=0.022
	• Day 90
	  ○ Steroid=0.62, control=1.16, p=0.033
	  ○ Antibiotic=0.32, control=1.00, p<0.001
	  ○ Steroid+antibiotic=0.54, control=1.00, p=0.051
	• Day 180
	  ○ Steroid=0.44, control=0.85, p=0.019
	  ○ Antibiotic=0.54, control=0.83, p=0.041
	  ○ Steroid+antibiotic=0.38, control=0.38, p=1.00
	Smell
	• Day 10
	  ○ Steroid=6.50, control=6.33, p=0.246
	  ○ Antibiotic=5.28, control=4.92, p=0.008
	  ○ Steroid+antibiotic=6.33, control=5.58, p=0.002
	• Day 30
	  ○ Steroid=7.56, control=7.67, p=0.593
	  ○ Antibiotic=7.00, control=6.69, p=0.039
	  ○ Steroid+antibiotic=7.58, control=7.03, p=0.007
	• Day 90
	  ○ Steroid=8.55, control=8.53, p=0.785
	  ○ Antibiotic=8.08, control=7.95, p=0.102	

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First author, date	Efficacy outcomes	Safety outcomes
	○ Steroid+antibiotic=8.97, control=8.89, p=0.276 • Day 180 ○ Steroid=8.68, control=8.74, p=0.317 ○ Antibiotic=8.34, control=8.31, p=0.317 ○ Steroid+antibiotic=9.47, control=9.44, p=0.317 There were statistically significant differences between groups in the following parameters: need of suction (30th day), lateralisation (30th day), synechiae (90th day), and secretion (180th day).	
Pou, 2017	**SNOT-22 score, mean (standard deviation)** • Baseline=45.5 (19.4) • 3 months=18.8 (14.1), p<0.001 • 6 months=16.5 (14.0), p<0.001 3- and 6-month SNOT-22 scores were statistically significantly lower than the preoperative SNOT-22 scores in all subgroups (polyposis, serum eosinophilia, tissue eosinophilia, high-grade CT findings). The presence or absence of serum eosinophilia and the grade of disease on CT did not statistically significantly affect postoperative SNOT-22 scores. Postoperative SNOT-22 scores at 3 months were higher in people with tissue eosinophilia and polyps compared to those without, but the difference was not statistically significant at 6 months.	No safety outcomes were reported.

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First author, date	Efficacy outcomes	Safety outcomes

	Revision ESS=1.5% (2/136)
	
	Lund-Kennedy endoscopic score
	• Baseline
	  ○ With polyps=6.56
	  ○ Without polyps=3.48, p<0.001
	• 3 months
	  ○ With polyps=2.34
	  ○ Without polyps=1.51, p=0.006
	• 6 months
	  ○ With polyps=1.71
	  ○ Without polyps=0.87, p=0.032
	
	Baseline Lund-Kennedy scores were higher in the presence of eosinophilia or high-grade LMS, but these differences were not statistically significant at 6 months follow-up.	

Shah, 2022	No efficacy outcomes were reported	**Adverse events to patients (n=32 events)** • Infection, n=7 • Vasovagal reaction, n=1 • Cerebrospinal fluid leak, n=2 • Orbital cellulitis or increased intraocular pressure, n=3

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First author, date	Efficacy outcomes	Safety outcomes
		• Allergic reaction or foreign body reaction, n=2 • Epistaxis, n=1 • Oropharyngeal obstruction, n=5 • Septal perforation, n=1 • Headache/severe pain, n=4 • Middle turbinate lateralisation, n=2 • Pressure necrosis, n=3 • Herpes zoster ophthalmicus, n=1 In total, 18 implants were removed or replaced (for infection, cerebrospinal fluid leak, orbital cellulitis, allergic reaction, epistaxis, oropharyngeal obstruction, headache, middle turbinate lateralisation, and pressure necrosis) and there were 11 reports of revision surgery or debridement (for infection, cerebrospinal fluid leak, orbital cellulitis, headache, middle turbinate lateralisation, and pressure necrosis). Root causes behind the 32 adverse events were identified as device-related factors in 18 events, patient related factors in 18 events, and improper use or placement of the SES in 2 events. **Device malfunctions (n=8 events)** • Migration or expulsion of implant, n=7

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First author, date	Efficacy outcomes	Safety outcomes
		• Deployment apparatus malfunction, n=1 The authors noted that 350,000 people have had Propel SES implanted since 2011. Some complications such as infection, headache, and pain are expected postoperative complications of FESS alone, regardless of stent placement.
Shipman, 2022	The surgical and post-operative courses were otherwise uneventful. A routine debridement was done at 1 week after surgery and there were no concerning findings.	**Non-invasive fungal sinusitis** The patient was referred 2 weeks after revision ESS because of severe sinus and facial pain. Fungal elements and necrotic-appearing tissue were seen on endoscopy. The right-sided stent was easily removed, but the stent on the left could not be visualised. A left-sided revision maxillectomy, ethmoidectomy, and frontal sinusotomy with a Draf IIb procedure was done. Pathology showed tissue necrosis and fungal elements without any evidence of invasive fungal disease. Endoscopy at 2 weeks post-surgery showed no evidence of fungal disease and steroid rinses were resumed. At 4 months follow up, the sinonasal mucosa showed no evidence of fungal

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First author, date	Efficacy outcomes	Safety outcomes
		disease or necrosis, with widely patent frontal sinus and maxillary antrostomies.
Tang, 2019	Not reported.	**Introduction of SES through a dural defect** The postoperative course was complicated by epistaxis needing placement of nonabsorbable nasal packing. The patient developed headache, confusion, and nausea. A CT scan showed a right fovea ethmoidalis defect with associated massive pneumocephalus and a radio-opaque foreign body. During exploratory and repair surgery, a total of 7 SES were identified in the paranasal sinuses, which were extracted. A defect was noted in the right anterior fovea ethmoidalis just posterior to the frontal sinus and a SES was identified protruding through the defect from within the intracranial cavity. The SES was extracted and a dural defect was noted. A Draf IIB frontal sinusotomy was then done and the dural defect was repaired. Postoperatively, the patient recovered well and his mental status returned to baseline. At 1 year follow-up, the patient was doing well.

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Procedure technique

Several different bioabsorbable stents or spacers were used across the studies. Where it was specified, most were placed in the ethmoid sinuses. In the systematic review by Goshtasbi et al. (2019), the devices used were Propel Mini, Propel Contour and an unnamed SES (Intersect ENT) and Sinuband FP (BioInspire Technologies Inc.). The implants were placed in the ethmoid or frontal sinuses. The prospective cohort study by Pou et al. (2017) used the Propel SES implanted in the ethmoid cavity, and the review by Shah et al. (2022) was also focused on the Propel SES. The retrospective cohort study by Hoffman et al. (2023) did not specify the type of SES or the sinus in which the SES was placed. In 2 of the randomised controlled trials, a bioabsorbable SES from Puyi Biotechnology (China) was implanted in the ethmoid sinus (Huang 2022, Wang 2023). The systematic review by Zhang et al. (2021) included studies that used a synthetic proprietary bioabsorbable polymer (Nasopore), bioabsorbable gels and calcium alginate packing. Of the 8 included studies, 4 applied triamcinolone as the active steroid, the remaining studies applied betamethasone furoate, budesonide, mometasone furoate, and dexamethasone. The randomised controlled trial by Samarei et al. (2022) used an absorbable gelatine sponge impregnated with steroid (Gelfoam, Pharmacia and Upjohn Company, US) inserted into the middle meatus. The randomised controlled trial by Wierzchowska et al. (2021) used Nasopore soaked with antibiotic, steroid or both.

Efficacy

SNOT-22 score

SNOT-22 was reported as an outcome in 2 studies. In the prospective cohort study of 136 people, the mean score improved from 45.5 at baseline to 18.8 at 3 months ($p<0.001$) and 16.5 at 6 months ($p<0.001$; Pou 2017). In the systematic

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review by Goshtasbi et al. (2019), 1 study of 18 people reported an improvement in SNOT-22 scores from 52 at baseline to 19 at 1- and 3-month follow-up (p value not reported).

Nasal symptoms

Nasal obstruction and nasal symptom score were reported as outcomes in 1 study. In the randomised controlled trial of 95 people who had ESS with a SES placed in 1 ethmoid sinus and surgery alone in the other ethmoid sinus, the mean nasal obstruction score at 8 weeks was 0.92 in the SES group and 1.35 in the control group ($p<0.01$). The mean total nasal symptom score (range 0 to 40) was 5.47 in the SES group and 6.41 in the control group ($p=0.001$; Wang 2023).

Nasal blockage measured on a VAS from 0 to 10 was reported as an outcome in 1 study. In the randomised controlled trial of 120 people who had absorbable nasal packing with steroid, antibiotic or both in the treatment side, and absorbable nasal packing with saline in the control side, the scores were higher in the control side at most timepoints. In the group who had steroid only in the treatment side, the difference was statistically significant at day 90 (0.62 compared with 1.16, $p=0.033$) and day 180 (0.44 compared with 0.85, $p=0.019$). In the group who had a combination of steroid and antibiotic in the treatment side, the difference was statistically significant at day 10 (2.25 compared with 3.43, $p=0.005$) and day 30 (1.39 compared with 2.34, $p=0.022$; Wierzchowska 2021).

Endoscopic evaluation scores

The Lund-Kennedy score was reported as an outcome in 4 studies. In the randomised controlled trial of 95 people who had ESS with a SES placed in 1 ethmoid sinus and surgery alone in the other ethmoid sinus, the mean Lund-Kennedy score was statistically significantly lower in the SES side at 4, 8 and

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12 weeks compared with the control side. At 12 weeks, the score was 1.05 for the SES side and 2.05 for the control side ($p<0.001$) compared with 5.0 and 5.1, respectively, at baseline (Wang 2023). In the randomised controlled trial of 120 people who had absorbable nasal packing with steroid, antibiotic or both in the treatment side and absorbable nasal packing with saline in the control side, the Lund-Kennedy scores were higher in the control side at all timepoints from day 10 to day 180. The difference between steroid and control was only statistically significant at day 90. The difference between steroid combined with antibiotic and control was statistically significant at all timepoints (Wierzchowska 2021). In the cohort study of 136 people, the Lund-Kennedy score reduced from 6.56 at baseline to 1.71 at 6 months in people with polyps, and from 3.48 to 0.87 in people without polyps (between groups $p<0.001$ at baseline and $p=0.032$ at 6 months; Pou 2017). In the systematic review by Zhang et al. (2021), 1 study reported an improvement of 0.39 in the mean Lund-Kennedy score at 90 days ($p=0.008$) but there were no statistically significant differences at other timepoints.

The POSE score was reported as an outcome in 2 studies. In the systematic review by Zhang et al. (2021), 1 study described statistically significant mean score reductions of 1.5 at 7 days, 2.24 at 14 days, 1.22 at 3 months, and 1.30 at 6 months ($p<0.05$ on all occasions). Another study in the same review reported score reductions at 1 and 4 weeks that were not statistically significant and a statistically significant reduction of 3.06 at 8 weeks. In the randomised controlled trial of 104 people who had absorbable gelatine sponge impregnated with steroid or saline inserted in each middle meatus, the mean POSE score was statistically significantly lower in the treatment side compared to the control at 3 and 6 months after the procedure. The scores in both sides were statistically significantly reduced from baseline at 1 month and at all the follow up points to 18 months (Samarei 2022).

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Frontal sinus ostia patency

In the systematic review of 444 people by Goshtasbi et al. (2019), a meta-analysis of 3 studies showed the OR for frontal sinus ostia patency was 2.53 (95% CI 1.61 to 3.97, p<0.001) for the SES group compared to the control group, at 1 or 3 month follow up. In the same review, the mean difference in frontal sinus ostia or ethmoid inflammation was -10.86 mm (p<0.001; 4 studies) and the mean difference in frontal sinus ostia diameter was 1.34 mm (p<0.001; 3 studies).

Crusting

Crusting was reported as an outcome in 2 studies. In the randomised controlled trial of 95 people who had ESS with a SES placed in 1 ethmoid sinus and surgery alone in the other ethmoid sinus, the mean crusting score was statistically significantly higher in the SES side at 2 weeks compared with the control side (1.53 compared with 0.98, p<0.001). At 12 weeks, the score was statistically significantly lower for the SES side than the control side (0.2 compared with 0.36, p<0.01; Wang 2023). In the randomised controlled trial of 120 people who had absorbable nasal packing with steroid, antibiotic or both in the treatment side and absorbable nasal packing with saline in the control side, the crusting scores were similar between the groups at all timepoints. The only statistically significant difference was between steroid and control at day 10 (0.60 compared with 0.73, p=0.025; Wierzchowska 2021).

Need for postoperative intervention

The need for postoperative intervention was reported as an outcome in 4 studies. In the systematic review by Goshtasbi et al. (2019), the OR for postoperative intervention was 0.45 (95% CI 0.33 to 0.62, p<0.001; 5 studies) for the SES group compared to the control group, at 1 month follow up in 4 of the 5 studies. The OR for postoperative surgery was 0.30 (95% CI 0.18 to 0.52, p<0.001;

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4 studies) and the OR for postoperative oral steroids was 0.58 (95% CI 0.40 to 0.84, p=0.004; 3 studies).

In the cohort study of 3,418 people who had ESS with or without SES, repeat sinus surgery within 24 months was reported in 4% (63 out of 1,709) of those in the SES group and 5% (88 out of 1,709) of those in the control group (p=0.037). In the subgroup of people with polyps, the rate of repeat sinus surgery was 4% (31 out of 819) in the SES group and 6% (49 out of 819) in the control group (p=0.039). For people without polyps, the rate was 4% in both groups. The rate of sinus endoscopy procedures during follow up was 36% (615 out of 1,709) in the SES group and 45% (763 out of 1,709) in the control group (p<0.001) and the rate of sinus debridement was 43% (727 out of 1,709) in the SES group and 55% (932 out of 1,709) in the control group (p<0.001; Hoffman 2023).

The randomised controlled trial of 181 people who had bilateral ESS with a SES in 1 side and bioresorbable nasal dressing without steroid in the other side reported the need for debridement within 30 days of the procedure. When this was determined by clinical investigators, the rate was 34% (61 out of 181) in the SES group and 66% in the control group (120 out of 181; p<0.0001). When it was determined by a panel of 3 independent reviewers, the rate was 14% (23 out of 160) in the SES group and 75% (120 out of 160) in the control group (Huang 2022).

In the cohort study of 136 people, the rate of revision ESS was 2% (2 out of 136; Pou 2017).

Recurrent polyposis

Recurrence or formation of polyps after the procedure was reported as an outcome in 2 studies. In the systematic review by Goshtasbi et al. (2019), the OR for recurrent polyposis was 0.42 (95% CI 0.25 to 0.74, p=0.002; 3 studies) for the

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SES group compared to the control group, at 1 month follow up. In the randomised controlled trial of 181 people, polyp formation within 30 days was reported in 23% (41 out of 181) of the sinuses with SES and 54% (98 out of 181) of the control sinuses ($p<0.0001$). At 90 days, the rates were 7% (8 out of 118) in the SES group and 25% (30 out of 118) in the control group ($p<0.0001$; Huang 2022).

Adhesions or scarring

The presence of adhesions or scarring after the procedure was reported as an outcome in 3 studies. In the systematic review by Goshtasbi et al. (2019), the OR for moderate to severe adhesions or scarring was 0.28 (95% CI 0.13 to 0.59, $p<0.001$; 3 studies) for the SES group compared to the control group, at 1 month follow up. In the randomised controlled trial of 181 people, severe adhesions within 30 days was reported in 1% (1 out of 181) of the sinuses with SES and 2% (4 out of 181) of the control sinuses ($p=0.083$). At 90 days, the rates were 8% (9 out of 118) in the SES group and 25% (30 out of 118) in the control group ($p=0.0003$; Huang 2022). In the randomised controlled trial of 95 people, mean scarring scores were 0.26 in the SES group and 0.41 in the control group at 4 weeks ($p<0.05$) and 0.3 in the SES group and 0.73 in the control group at 12 weeks ($p<0.001$; Wang 2023).

Hospital visits during follow up

The number of hospital visits after the procedure was reported in the cohort study of 3,418 people, based in the US. The rate of all-cause outpatient visits was 89% (1,528 out of 1,709) in the SES group and 94% (1,606 out of 1,709) in the control group ($p<0.001$). The rate of all-cause otolaryngologist visits was 59% (1,003 out of 1,709) in the SES group and 75% (1,289 out of 1,709) in the control group ($p<0.001$; Hoffman 2023).

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Safety

Few of the studies reported any safety outcomes.

In the randomised controlled trial of 181 people, there were 26 adverse events that were judged by clinical investigators as having an indeterminate or unrelated relationship to the sinus stent and steroids (including nasal pain, nose bleeding, headache, acute rhinosinusitis). There were no statistically significant differences in intraocular pressure and lens opacities between the baseline and at postoperative days 14, 30, and 90 (Huang 2022).

Adverse events reported on the FDA MAUDE database

The review by Shah et al. (2022) searched the FDA MAUDE database for reports associated with a specific SES (Propel, Intersect ENT, US). It identified 25 medical device reports between 2012 and 2020, describing 40 adverse events. Although the denominator for this is unknown, the authors noted that 350,000 people have had a Propel SES implanted since 2011. The following adverse events or device malfunctions were identified:

- Infection, n=7
- Vasovagal reaction, n=1
- Cerebrospinal fluid leak, n=2
- Orbital cellulitis or increased intraocular pressure, n=3
- Allergic reaction or foreign body reaction, n=2
- Epistaxis, n=1
- Oropharangeal obstruction, n=5
- Septal perforation, n=1
- Headache/severe pain, n=4
- Middle turbinate lateralisation, n=2
- Pressure necrosis, n=3

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- Herpes zoster ophthalmicus, n=1
- Migration or expulsion of implant, n=7
- Deployment apparatus malfunction, n=1

Case reports

Two case reports of adverse events associated with the procedure were identified. The first described non-invasive fungal sinusitis that was diagnosed 2 weeks after a revision ESS. This was successfully treated by a left-sided revision maxillectomy, ethmoidectomy, and frontal sinusotomy (Shipman 2022). The second case report described someone who developed headache, confusion and nausea after ESS with insertion of multiple SES. Exploratory surgery showed that 1 of the SES was protruding through a dural defect. The SES was extracted, a frontal sinusotomy was done and the dural defect was repaired. After surgery, the patient's mental status returned to baseline and he was doing well a year later (Tang 2019).

Anecdotal and theoretical adverse events

Expert advice was sought from consultants who have been nominated or ratified by their professional society or royal college. They were asked if they knew of any other adverse events for this procedure that they had heard about (anecdotal), which were not reported in the literature. They were also asked if they thought there were other adverse events that might possibly occur, even if they had never happened (theoretical).

They described the following anecdotal adverse event:

- Fragmentation of the stent, which does not dissolve quickly

They listed the following reported or theoretical adverse events (additional to those already described in the safety summary):

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- Orbital or skull base injury
- Meningitis
- Injury to lamina/cribriform
- Granulation
- Biofilm formation
- Absorption of steroid if high dose is used

Nine professional expert questionnaires for this procedure were submitted. Find full details of what the professional experts said about the procedure in the specialist advice questionnaires for this procedure.

Validity and generalisability

- Evidence was identified from countries in Europe, North America, Asia and Australia.
- There is more than 1 type of stent or spacer, including proprietary SES with controlled delivery of the steroid, and bioabsorbable packing impregnated with steroid before use. In some cases, the addition of steroid may constitute off-label use.
- The evidence includes a number of randomised controlled trials, most of which used intrapatient controls. Some studies used no implant as the control and others used a similar implant impregnated with saline rather than steroid.
- Although the randomised controlled trial by Huang et al. (2022) was described as single-blinded, the reviewers could identify which side had the stent at the 30 day follow up.
- The systematic review by Zhang et al. (2021) noted that there was heterogeneity of the types and doses of interventions, measurement of the outcomes with different scoring systems and timing of outcome measurements.

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- The study populations included people with and without polyps. Two studies reported outcomes stratified according to the presence or absence of polyps (Hoffman 2023, Pou 2017).
- Some of the adverse events reported in the FDA MAUDE database could be caused by the ESS itself rather than the SES.
- Some people had concomitant procedures such as septoplasty at the same time as the ESS.
- Variation in postoperative regimens between studies affects the generalisability of the results.
- Although the packing was bioabsorbable, 1 study reported that it was removed after 7 days (Samarei 2022).
- The randomised controlled trial by Huang et al. (2022) reported the rate of debridement after the procedure but it did not assess whether the use of SES reduced the proportion of people needing revision ESS.
- One of the trials included in the systematic review by Goshtasbi et al (2019) used in-office treatment with SES for people with recurrent sinonasal polyposis after previous ESS. This is not within the remit for this overview, which only considers evidence on stent or spacer insertion during the ESS.
- All of the trials included in the systematic review by Goshtasbi et al. (2019) were industry sponsored. The systematic review by Zhang et al. (2021) did not include any information regarding potential conflicts of interest for the included studies.
- The studies by Hoffman et al. (2023) and Huang et al. (2022) were funded by industry.
- The authors of Pou et al. (2017), Wierzchowska et al. (2021), Wang et al. (2022), Samarei et al. (2022) and Shah et al. (2022) declared no conflicts of interest.

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Any ongoing trials

- Propel Drug-Eluting Sinus Stent Family Open Cohort (NCT05925985); cohort study; Germany and UK; n=200; estimated completion date September 2025
- A Clinical Study to Evaluate the Safety and Effectiveness of Novabel Bioabsorbable Steroid-releasing Stent for the Chronic Sinusitis (NCT06020690); randomised controlled trial; China; n=93; estimated study completion date September 2025

Existing assessments of this procedure

A state of the art systematic review by Calvo-Henriquez et al. (2024) posed 9 research questions and concluded that although several questions remain unanswered, there is 'no doubt' that SES will have a place in the day-to-day treatment of CRS. It did not include steroid-impregnated resorbable materials because they are not FDA approved and the amount of drug released into the sinus is not standardised. It concluded that there is ample evidence that SESs improve surgical healing in both ethmoidectomy and frontal sinus surgery but more evidence is needed on whether they improve symptom control after ESS. It also concluded that the SESs appear to be safe but more randomised controlled clinical trials are needed to draw firm conclusions.

The ‘International consensus statement on allergy and rhinology: rhinosinusitis 2021’ (Orlandi 2020) has the following recommendations:

‘Value Judgments: Corticosteroid-eluting stents have been demonstrated to have beneficial impact on postoperative healing although 1 study showed that Merocel in a finger cot had superior healing with less middle meatal adhesions. One study has shown steroid eluting stents to be cost-effective in preventing additional postoperative interventions. Specific usage should be at the clinician's discretion taking into consideration various important patient-specific factors.

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Policy Level: While the authors recognize the high cost of these implants, given the level of evidence, absorbable steroid-eluting implants are recommended in carefully selected patients that are similar to those included in the underlying clinical trials.

Intervention: Corticosteroid-eluting stents can be considered in the postoperative ethmoidectomy cavity.'

Related NICE guidance

Medical technologies

XprESS multi sinus dilation system for treating chronic sinusitis (2016) NICE medical technologies guidance [MTG30]

Professional societies

- ENT UK

Evidence from patient organisations

NICE received 1 submission from a patient organisation.

Company engagement

NICE asked companies who manufacture a device potentially relevant to this procedure for information on it. NICE received 2 completed submissions. These were considered by the interventional procedures technical team and any relevant points have been taken into consideration when preparing this overview.

References

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13. Orlandi RR, Kingdom TT, Smith TL et al. (2021) International consensus statement on allergy and rhinology: rhinosinusitis 2021. International Forum of Allergy & Rhinology 11: 213–739

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Appendix A: Methods and literature search strategy

Methods and literature search strategy

NICE has identified studies and reviews relevant to corticosteroid-eluting bioabsorbable stent or spacer insertion during endoscopic sinus surgery for chronic rhinosinusitis from the medical literature. Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

Search strategy design and peer review.

This search report is informed by the Preferred Reporting Items for Systematic reviews and Meta-Analyses literature search extension (PRISMA-S).

A NICE information specialist ran the literature searches on 24/02/2024. See the search strategy history for the full search strategy for each database.

The principal search strategy was developed in MEDLINE ALL (Ovid interface). It was adapted for use in each of the databases listed in table 4a, taking into account the database's size, search functionality and subject coverage. The MEDLINE ALL strategy was quality assured by a NICE senior information specialist. All translated search strategies were peer reviewed to ensure their accuracy. The quality assurance and peer review procedures were adapted from the Peer Review of Electronic Search Strategies (PRESS) 2015 evidence-based checklist.

Review management

The search results were managed in EPPI-Reviewer version 5 (EPPI-R5). Duplicates were removed in EPPI-R5 using a 2-step process. First, automated deduplication was done using a high-value algorithm. Second, manual

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deduplication was used to assess low-probability matches. All decisions about inclusion, exclusion and deduplication were recorded and stored.

Limits and restrictions

The CENTRAL database search removed trial registry records and conference material. The Embase search excluded conference material.

English language limits were applied to the search in adherence to standard NICE practice.

The date limit was included to update an earlier search for this topic.

The limit to remove animal studies in the searches is standard NICE practice, which has been adapted from Dickersin K, Scherer R, Lefebvre C (1994) Systematic Reviews: Identifying relevant studies for systematic reviews. BMJ 309(6964): 1286.

Main search

Table 4a Main search results

Database	Date searched	Database platform	Database segment or version
Cochrane Central Register of Controlled Trials (CENTRAL)	27/02/2024	Wiley	Issue 2 of 12, February 2024
Cochrane Database of Systematic Reviews (CDSR)	27/02/2024	Wiley	Issue 2 of 12, February 2024
Embase	27/02/2024	Ovid	1974 to 2024 February 26
INAHTA International HTA Database	27/02/2024	INAHTA HTA	-
MEDLINE ALL	27/02/2024	Ovid	1946 to 2024 Feb 26

The MEDLINE ALL search strategy:

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exp Sinusitis/
allergic rhinitis/
(Sinusit* or rhinosinusit* or (sinus* adj4 (diseas* or infect* or inflam*))).tw.
Natural Orifice Endoscopic Surgery/
Nasal Surgical Procedures/
((Sinus* or rhinosinus*) adj4 (surger* or surgic*)).tw.
CRS.tw.
FESS.tw.
or/1-8
Drug-Eluting Stents/
Drug Implants/
((drug-elut* or drug-coat* or (drug adj4 elut*) or (drug adj4 coat*)) adj4 (stent* or implant* or catheter* or spacer*)).tw.
DES.tw.
(steroid-releas* or drug-releas* or doxycycline-releas* or ((steroid* or doxycycline* or drug*) adj4 (releas* or elut* or deliver*))).tw.
mometasone furoate.tw.
Absorbable Implants/
(absorb* or bioabsorb* or biodegrad* or bioresorb*).tw.
or/10-17
9 and 18
(Propel adj4 (stent* or implant*)).tw.
19 or 20
animals/ not humans/
21 not 22
limit 23 to ed=20230101-20240229

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Appendix B: Other relevant studies

Other potentially relevant studies that were not included in the main evidence summary (tables 2 and 3) are listed in table 5 below.

Case series with fewer than 10 people were excluded.

Table 5 additional studies identified

Study	Number of people and follow up	Direction of conclusions	Reason study was not included in main evidence summary
Abd-Elmaksoud GA-E, Gouda MI, Khater KA (2019) Effect of steroid loaded middle meatal Gelfoam sheet on endoscopic sinus surgery outcome. The Egyptian Journal of Hospital Medicine 76: 4538–44	Randomised controlled trial n=31(62 nasal cavities) Follow up: 2 months	There was a statistically significant difference between the steroid side and the saline (control) side in reduction of synechia formation after ESS. Therefore, topical application of steroids is effective in minimising synechiae formation after ESS. It is also safe and no local or systemic complications were noted during the study.	Larger or more recent studies are included.
Adriaensen GFJPM Lim KH, Fokkens WJ (2017) Safety and efficacy of a bioabsorbable fluticasone propionate–eluting sinus dressing in postoperative management of endoscopic sinus surgery: a	Randomised controlled trial n=30 Follow up: 60 days	The dressing was well tolerated and showed evidence of efficacy. A larger study is needed to further evaluate and confirm the benefits.	Small study, which is included in the meta-analysis by Goshtasbi et al. (2019).

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randomized clinical trial. Int Forum Allergy Rhinol. 7: 813–820			
Brar T, Brown A, Miglani A et al. (2023) Outcomes of frontal sinus stenting with steroid impregnated microsponge versus steroid-eluting implant. American Journal of Rhinology & Allergy 37: 679–85	Retrospective non-randomised comparative study n=68 (96 frontal sinus ostia; SES versus steroid impregnated microsponge) Follow up: mean 249 days	For SNOT-22 scores, both cohorts were comparable in baseline scores and reduction from baseline. Further studies may offer insights into specific circumstances where one stent may be preferable over the other stent.	Retrospective non-randomised study comparing 2 different types of implant.
Bury S and Singh A (2017) Evaluation of a steroid releasing sinus implant for the treatment of patients undergoing frontal sinus surgery for chronic rhinosinusitis, Expert Review of Medical Devices 14: 93–101	Review 4 trials	The studies to date have demonstrated that steroid-eluting implants are beneficial in reducing postoperative medical or surgical interventions for patients with chronic sinusitis undergoing ethmoid sinus surgery. The results in the frontal sinus are similar to data generated for ethmoid surgery with a decreased need for medical and surgical postoperative interventions.	A more recent systematic review and meta-analysis is included.
Campbell RG, Kennedy DW (2014) What is new and promising with drug-eluting stents in sinus surgery? Current Opinion in Otolaryngology & Head & Neck Surgery 22: 2-7	Review 2 RCTs, 1 prospective single-cohort study and a meta-analysis (of 2 studies)	Steroid-eluting implants are well tolerated and an effective addition to the armamentarium utilised in the management of chronic rhinosinusitis.	A more recent systematic review and meta-analysis is included.

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Chang EH, Alandejani T, Akbari E et al. (2011) Double-blinded, randomized, controlled trial of medicated versus nonmedicated Merocel sponges for functional endoscopic sinus surgery. Journal of Otolaryngology - Head and Neck Surgery 40: S14–19	Randomised controlled trial n=48 (96 nostrils, medicated versus non-medicated sponge) Follow up: 7 days	The budesonide-soaked middle meatal spacers showed a trend toward reduced mucosal inflammation when compared to the control middle meatal spacers but the results were not statistically significant.	Larger or more recent studies are included.
Côté DWJ, Wright ED. (2010) Triamcinolone-impregnated nasal dressing following endoscopic sinus surgery: a randomized, double-blind, placebo-controlled trial. Laryngoscope 120: 1269–73	Randomised controlled trial n=19 Follow up: 6 months	Data analysis suggests a significant improvement in early postoperative healing in nasal cavities receiving triamcinolone-impregnated absorbable nasal packing following ESS and is also associated with improved healing up to 6 months postoperatively.	Larger or more recent studies are included. Study is included in systematic review by Zhang et al. (2021).
Dautremont JF, Mechor B, Rudmik L. (2014) The role of immediate postoperative systemic corticosteroids when utilizing a steroid-eluting spacer following sinus surgery. Otolaryngology and Head and Neck Surgery 150: 689–95	Randomised controlled trial n=36 Follow up: 2 months	Results from this study suggest that postoperative systemic corticosteroids immediately following endoscopic sinus surgery may not provide improved outcomes when using a steroid-eluting spacer.	Small study, assessing the role of oral corticosteroids after functional ESS with SES.
Forwith KD, Chandra RK, Yun PT et al. (2011) ADVANCE: a multisite trial of bioabsorbable	Prospective cohort n=50 (90 treated sinuses)	The implant was associated with favourable rates of sinus patency. At 1 month, minimal degrees of	More recent or larger studies are included.

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steroid-eluting sinus implants. Laryngoscope 121: 2473 80	Follow up: up to 6 months	inflammation and adhesions were observed.	
Gershnabel Milk D, Lam KK, Han JK (2023) Corticosteroid-eluting implants for the management of chronic rhinosinusitis with or without nasal polyps. Expert Review of Clinical Immunology 19: 831–36	Review	Corticosteroid-eluting sinus implants allow the controlled application of corticosteroids directly to the involved sinuses over different time frames. The efficacy of the devices is supported by well-designed clinical trials. Although not shown in the clinical trials, experience indicates that crusting around the stents, local infection, and facial pain are common, bothersome side effects, and are the leading cause of early removal of the stent. Although all patients are instructed to rinse the nose regularly, the stents are usually removed after 2 to 3 weeks because of crusting and discharge around them. This discrepancy between the clinical trials and real-world experience highlights the need to conduct more international, high-volume studies, to assess the prevalence of side effects and stent failures. The corticosteroid-eluting sinus implant is an evolving, promising technology with clear clinical advantages and broad use. Still, a few issues need to be addressed and investigated.	No meta-analysis.

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Grzeskowiak B, Wierzchowska M, Walorek R et al. (2019) Steroid vs. antibiotic impregnated absorbable nasal packing for wound healing after endoscopic sinus surgery: a randomized, double blind, placebo-controlled study. Brazilian Journal of Otorhinolaryngology 85: 473–80	Randomised controlled trial n=80 (160 ethmoid cavities, steroid or antibiotic versus saline impregnated absorbable packing) Follow up: 6 months	The results of this study reveal a statistically significant improvement of steroid and antibiotic impregnated biodegradable nasal packing influence on the postoperative healing process compared to saline soaked dressing. However, antibiotic impregnated packing demonstrated better advantage over the steroid dressing regarding patient comfort and satisfaction. Future investigations should be focused on the combination of both active drugs administered simultaneously in the ethmoid spaces.	Larger or more recent studies are included. Study is included in systematic review by Zhang et al. (2021).
Han JK, Kern RC (2019) Topical therapies for management of chronic rhinosinusitis: steroid implants. International Forum of Allergy and Rhinology 9: s22–s26	Review 4 studies on SES implant during ESS, 2 studies on SES implant after ESS for recurrent nasal polyps	The results from the clinical studies showed that the use of the various steroid-eluting sinus implants can improve postoperative results after ESS as well as treat the recurrence of nasal polyps after sinus surgery without the need for additional sinus surgery.	The 4 relevant studies are included in the meta-analysis by Goshtasbi et al. (2019).
Han JK, Marple BF, Smith TL et al. (2012) Effect of steroid-releasing sinus implants on postoperative medical and surgical interventions: an efficacy meta-analysis. International Forum of Allergy & Rhinology 2: 271–9	Meta-analysis (2 studies) n=143	According to the grading done by a panel, drug-releasing implants reduced postoperative interventions by 35% (p=0.0008), lysis of adhesions by 51% (p=0.0016), and oral corticosteroid need by 40% (p=0.0023), compared to controls. The relative reduction in frank polyposis was 46% (p<0.0001).	The 2 studies are included in the meta-analysis by Goshtasbi et al. (2019).

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Hauser LJ, Turner JH, Chandra RK (2017) Trends in the use of stents and drug-eluting stents in sinus surgery. Otolaryngologic Clinics of North America 50: 565–71	Review	Steroid-impregnated dressings and implants appear to be safe, although they likely have increased systemic absorption compared with topical nasal steroid sprays and rinses. There is evidence to support the use of steroid-releasing implants in the ethmoid cavity and frontal sinuses in the postoperative period; however, large trials have not been completed to show significant subjective and objective improvements over surgery alone with meticulous debridement and postoperative care.	A more recent systematic review and meta-analysis is included.
Hoffman V, Mortimer KM, Mulder K et al. (2022) Real-world evidence analysis of the impact of steroid-eluting implants on healthcare resource use among chronic rhinosinusitis patients undergoing sinus surgery. Current Medical Research and Opinion 38: 375–81	Retrospective cohort study n=3,966 (1,983 SES, 1,983 no implant) Follow up: 18 months	Use of implants statistically significantly reduced healthcare resource use, including all-cause outpatient visits (94% vs 97%, p<0.001), all-cause otolaryngologist visits (47% vs 60%, p<0.001), and all-cause emergency room or urgent care visits (9% vs 12%, p=0.007), as well as sinus endoscopy (39% vs 44%, p=0.003). Use of implants had no significant effect on sinus procedures such as debridement and polypectomy, as well as sinus-related imaging.	A more recent publication from the same study with longer follow up is included.
Huang Ao, Li T, Li M-S et al. (2023) Association of comorbid asthma and the efficacy of bioabsorbable steroid-eluting sinus	Post-hoc analysis of randomised controlled trial n=151 Follow up: 90 days	Asthma was identified as the only risk factor for a poor response to steroid-eluting sinus stents on postoperative day 30, with an OR of 23.7 (95% CI 2.81 to 200.2; p=0.004) for the	Post-hoc analysis of study already included in the key evidence (Huang Z et al., 2022)

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stents implanted after endoscopic sinus surgery in patients with chronic rhinosinusitis with nasal polyps. Current Medical Science 43: 1005–12		need for postoperative intervention and 19 (95% CI 2.20 to 164.2; p=0.003) for moderate-to-severe polypoid tissue formation.	
Huang Z, Hwang P, Sun Y et al. (2015) Steroid-eluting sinus stents for improving symptoms in chronic rhinosinusitis patients undergoing functional endoscopic sinus surgery. Cochrane Database of Systematic Reviews issue 6: CD010436	Systematic review No studies met inclusion criteria	21 trials had the potential to be included given that they had tested sinus stents, spacers and packing materials for patients with chronic rhinosinusitis undergoing functional ESS. However, the trials were excluded from the review because they met some but not all of the inclusion criteria.	Review did not include any trials.
Hwang CS, Al Sharhan SS, Kim BR et al. (2018) Randomized controlled trial of steroid-soaked absorbable calcium alginate nasal packing following endoscopic sinus surgery. The Laryngoscope 128: 311–16	Randomised controlled trial n=22 (44 nostrils)	Steroid-soaked, absorbable nasal packing can be used to enhance wound healing after endoscopic sinus surgery and to prevent polypoid changes in the nasal mucosa.	Larger or more recent studies are included. Study is included in systematic review by Zhang et al. (2021).
Javanbakht M, Saleh H, Hemami MR et al. (2020) A corticosteroid-eluting sinus implant following endoscopic sinus surgery for chronic rhinosinusitis: a UK-based cost-effectiveness analysis.	Cost effectiveness model	The use of a SES after ESS results in fewer postoperative complications than non-corticosteroid-eluting implants and may be a cost-saving technology over a 6-month time horizon. Although the cost of initial treatment with the SES is greater, cost savings are made due to a	Cost effectiveness is not within the remit of Interventional Procedures guidance.

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Pharmaco Economics – Open 4: 679–86		reduction in the number of complications experienced.	
Kennedy DW. (2012) The PROPEL steroid-releasing bioabsorbable implant to improve outcomes of sinus surgery. Expert Review of Respiratory Medicine 5: 493–8	Review	To date, 3 clinical trials have demonstrated that the implant is safe and maintains the results of sinus surgery by decreasing postoperative inflammation, polyposis, adhesions and middle turbinate lateralization. This implant reduces the need for oral corticosteroids with their associated risks and reduces the need for uncomfortable postoperative debridement and removal of scarring.	A more recent systematic review and meta-analysis is included.
Lee VS, Patel P, O'Brien D et al. (2022) Indications for absorbable steroid-eluting sinus implants: Viewpoint via the Delphi method. International Forum of Allergy & Rhinology 12: 1225–31	Delphi study (14 experts answered first survey and 12 answered the second)	Six of a total of 12 statements reached consensus and were accepted. Overall, experts largely agree that intraoperative or in-office use of SES could be considered for people with diabetes or intolerance to oral steroids, those having extended frontal sinus surgery, or with recurrent stenosis.	Delphi study.
Lelegren MJ, Bloch RA, Lam KK (2021) Intraoperative applications of topical corticosteroid therapy for chronic rhinosinusitis. Ear, Nose & Throat Journal 100: 320–28	Review 21 articles	A wide range of techniques and technologies have been introduced to enhance the topical delivery of corticosteroids into the neosinuses after ESS for CRS. Regarding efficacy, there is level 1A evidence to support the use of Propel stents. Most of the remaining strategies show some degree of efficacy. Direct comparisons across the	A more recent systematic review and meta-analysis is included.

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		different strategies are limited owing to the varied uses of delivery vectors, corticosteroid choices, and doses of corticosteroids. Propel stents and SinuBand have sufficient data to support systemic and ocular safety, whereas the remaining products have limited data to support their safety.	
Li W, Lu H, Wang H et al. (2020) Efficacy and safety of steroid-impregnated implants following sinus surgery: A meta-analysis. The Laryngoscope 130: 2754–59	Systematic review and meta-analysis 8 randomised controlled trials	Bioabsorbable steroid-impregnated implants following ESS are effective in improving the endoscopic appearance of the healing process, and the safety profile appears to be favourable for the treatment of CRS.	Some study overlap with another systematic review included in the key evidence.
Luong A, Ow RA, Singh A et al. (2018) Safety and effectiveness of a bioabsorbable steroid-releasing implant for the paranasal sinus ostia: A randomized clinical trial. JAMA Otolaryngology - Head and Neck Surgery 144: 28–35	Randomised controlled trial n=80 (SES versus no implant) Follow up: 3 months	The SES was safe and more effective in maintaining frontal sinus ostia patency and improving surgical outcomes compared with surgery alone in the setting where no other immediate postoperative corticosteroids were administered.	Included in the meta-analysis by Goshtasbi et al. (2019).
Marple BF, Smith TL, Han JK et al. (2012) Advance II: a prospective, randomized study assessing safety and efficacy of bioabsorbable steroid-releasing sinus implants. Otolaryngology - Head and Neck	Randomised controlled trial n=210 sinuses (105 SES, 105 control) Follow up: 3 months	Compared with control sinuses with non-drug-releasing implants, the drug-releasing implant provided a 29% relative reduction in postoperative interventions (p=0.028) and a 52% (p=0.005) decrease in lysis of adhesions. The relative reduction in frank polyposis was 45% (p=0.002). No clinically	Included in the meta-analysis by Goshtasbi et al. (2019).

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Surgery 146: 1004–11		significant changes from baseline in intraocular pressure or cataracts were observed.	
Massey CJ, Suh JD, Tessema B et al. (2016) Biomaterials in Rhinology. Otolaryngology - Head and Neck Surgery 154: 606–17	Review	Steroid delivery systems may play an increasingly important role in reducing disease recurrence after ESS, although more studies are needed to assess long-term outcomes.	A more recent systematic review and meta-analysis is included.
McCormick JP, Suh JD, Yang H-H et al. (2022) Triamcinolone-impregnated bioabsorbable middle meatus packing following endoscopic sinus surgery: A prospective randomized controlled trial. International Forum of Allergy & Rhinology 12: 1131–36	Randomised controlled trial n=22 (44 sinus cavities) Follow up: mean 47 days	There was no statistically significant difference in healing between the steroid treated and non-steroid-treated sinuses. There were no adverse effects identified from the use of steroid-impregnated packing.	Larger studies are included.
Murr AH, Smith TL, Hwang PH et al. (2011) Safety and efficacy of a novel bioabsorbable, steroid-eluting sinus stent. International Forum of Allergy and Rhinology 1: 23–32	Randomised controlled trial n=76 sinuses (38 SES, 38 control) Follow up: 2 months	Compared to the control stent, the drug-eluting stent provided statistically significant reduction in inflammation at days 21 to 45 ($p<0.003$), frequency of polyp formation ($p=0.0391$), and frequency of significant adhesion ($p=0.0313$). There were no device-related adverse events.	Included in the meta-analysis by Goshtasbi et al. (2019).
Narwani V, Torabi SJ, Kasle DA et al. (2022) Adverse events associated with corticosteroid-eluting sinus stents: A MAUDE database	Retrospective cross-sectional study 28 reported adverse events	The most common adverse event was related to postoperative infection, accounting for 39% (n=11) of all complications. Four of these patients developed periorbital cellulitis, and 5	A similar review of the same database, with a more recent search date is

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analysis. Otolaryngology - Head and Neck Surgery 166: 179–82		developed a fungal infection. The second-most common adverse event was migration of the stent, representing 21% of all complications (n=6). Overall, 8 people (29%) in the cohort required reintervention in the operating room, with subsequent removal of the SES.	included (Shah et al., 2022).
Orabi NA, Behnke J, Reyes C et al. (2023) Effect of absorbable nasal packing saturated with ciprofloxacin and dexamethasone following endoscopic sinus surgery: A prospective cohort study. International Forum of Allergy & Rhinology 13: 1801–4	Prospective cohort study n=32 Follow up: 3 months	Chitosan-based absorbable nasal packing saturated with ciprofloxacin-dexamethasone suspension was not associated with any significant differences on postoperative ESS wound healing. The small sample size was exacerbated by a lack of follow-up endoscopic examinations.	Larger studies are included.
Promentilla S, Onofre R, Campomanes B (2016) Effects of dexamethasone versus saline-impregnated nasal packing on the postoperative outcome of patients with chronic rhinosinusitis and nasal polyps after endoscopic sinus surgery: a randomized controlled trial. Philippine Journal Otolaryngology -	Randomised controlled trial n=19 Follow up: 28 days	Nasal cavities that had postoperative dexamethasone-impregnated nasal packs showed lower POSE scores than placebo on postoperative days 14 (p=0.0022, 95% CI -2.11 to -0.51) as well as lower Lund-Kennedy Scores on postoperative day 14 (p=0.0180, 95% CI -2.49 to -0.26) and day 28 (p=0.007, 95% CI -1.56 to -0.28).	Larger or more recent studies are included.

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Head and Neck Surgery 31: 10–13			
Rawl JW, McQuitty RA, Khan MH et al. (2020) Comparison of steroid-releasing stents vs nonabsorbable packing as middle meatal spacers. International Forum of Allergy & Rhinology 10: 328–33	Randomised controlled trial n=40 Follow up: 3 months	Nonabsorbable packing materials showed superior middle meatal spacing capacities as evidenced by greater middle turbinate medialisation capability at the first postoperative visit. There were also improvements in SNOT-22 scores at the 20-day postoperative visit. This study showed that there was no statistically significant improvement in postoperative outcomes with drug-eluting stents when compared to nonabsorbable packing.	Small study, comparing SES with nonabsorbable packing.
Rizan C, Elhassan HA (2016) Post-sinus surgery insertion of steroid-eluting bioabsorbable intranasal devices: A systematic review. The Laryngoscope 126: 86–92	Systematic review 7 studies Follow up: 2 to 6 months	Steroid-eluting bioabsorbable intranasal devices were effective in reducing adhesion formation, polyp formation, inflammation, Lund-Kennedy scores, and perioperative sinus endoscopy scores. The devices improved patient-reported outcomes and olfaction while reducing postoperative interventions. They were not associated with adverse events and pose no ocular safety risk. Complications were reported in 3 applications (headache, crusting, infection).	A more recent systematic review and meta-analysis is included.
Rizzo JA, Rudmik L, Mallow PJ et al. (2016) Budget impact analysis of bioabsorbable drug-eluting sinus	Budget impact model	This study has demonstrated the use of Propel following ESS procedures has a negligible impact on the budget of a US self-insured employer	Budget impact is not within the remit of Interventional procedures guidance.

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implants following endoscopic sinus surgery. Journal of Medical Economics 19: 829–35		or payer. The upfront cost of Propel was offset by savings associated with reduced probability for polyp recurrence, adhesion formation, and their subsequent treatment.	
Rudmik L, Soler ZM, Orlandi RR et al. (2011) Early postoperative care following endoscopic sinus surgery: an evidence-based review with recommendations. International Forum of Allergy and Rhinology 6: 417– 30	Systematic review 3 studies on drug-eluting stents or spacers	An evidence-based postoperative treatment protocol after endoscopic sinus surgery would include the use of nasal saline irrigation, sinus cavity debridement, and initiation of standard topical nasal corticosteroid spray. Due to a relative balance between possible therapeutic advantages and potential adverse effects, the use of postoperative antibiotics, systemic corticosteroids, off-label topical corticosteroid medications, and drug eluting materials are all options for postoperative care.	A more recent systematic review and meta-analysis is included.
Saito T, Okazaki K, Hamada Y et al. (2021) Therapeutic indications for sinonasal topical steroid treatment and its effects on eosinophilic chronic rhinosinusitis after endoscopic sinus surgery. The Journal of Laryngology and Otology 135: 858–63	Retrospective non-randomised comparative study n=30 (15 SES versus no topical steroid treatment after ESS)	Younger age, higher pre-operative CT score, severe postoperative olfactory loss and worse sinonasal conditions led to the need for sinonasal topical steroid treatment. Total nasal symptom scores were significantly improved and maintained for 4 weeks during this study.	Small, non-randomised study.
Santarelli GD, Han JK (2016) Evaluation of the PROPEL mini sinus implant for the treatment of frontal	Review	Devices such as the Propel and Propel Mini stents are the beginning of a trend towards medication-coated bioabsorbable implants that can be used for sinonasal	A more recent systematic review is included.

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sinus disease. Expert Opinion on Drug Delivery 13: 1789–93		disease to minimise complications or possible side effects of surgical treatment by an increase of topical drug delivery locally.	
Schneider AL, Racette SD, Kang AK et al. (2022) Use of intraoperative frontal sinus mometasone-eluting stents decreased interleukin 5 and interleukin 13 in patients with chronic rhinosinusitis with nasal polyps. International Forum of Allergy & Rhinology 12: 1330–39	Non-randomised comparative study n=52 Follow up: 8 months	Frontal SES placement may result in longer term changes in middle meatal mucus inflammation. The changes seen in the study did not correspond to statistically significantly different measures of symptomatic or radiographic disease severity.	Small, non-randomised study.
Shah SJ, Hawn VS, Zhu N et al. (2022) Postoperative infection rate and associated factors following endoscopic sinus surgery. The Annals of Otology, Rhinology, and Laryngology 131: 5–11	Cohort study n=378 (245 with SES) Follow up: 30 days	The postoperative infection rate was 10%. Multivariate logistic regression analysis showed that postoperative systemic corticosteroid use was the only risk factor independently associated with infection (OR 3.47, 95% CI 1.23 to 9.76, p=0.018). There was no correlation between postoperative infection and presence of a SES.	More comprehensive studies are included.
Shen J, Welch K, Kern R (2018) Mometasone furoate sinus implant-a new targeted approach to treating recurrent nasal polyp disease. Expert Review of Clinical Pharmacology 11: 1163–70	Review	Clinical evidence has demonstrated the safety and efficacy of steroid-eluting implant in the reduction of polyp size, symptom burden, and the need for revision sinus surgery.	A more recent systematic review is included.

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Singh A, Luong AU, Fong KJ et al. (2019) Bioabsorbable steroid-releasing implants in the frontal sinus ostia: a pooled analysis. International Forum of Allergy and Rhinology 9: 131–139	Pooled analysis of 2 randomised controlled trials n=160 (SES versus no implant) Follow up: 3 months	Bioabsorbable steroid-releasing sinus implants improve outcomes of frontal sinus surgery through 90 days, irrespective of asthma status, previous endoscopic sinus surgery, extent of surgery, extent of polyps, or Lund-Mackay computed tomography stage in the frontal sinus ostia.	Included in the meta-analysis by Goshtasbi et al. (2019).
Smith KA, Kingdom TT, Gray ST et al. (2020) Drug-eluting implants in chronic rhinosinusitis: an evidence-based review with recommendations. International Forum of Allergy & Rhinology 10: 856–70	Systematic review 31 studies	Absorbable steroid-eluting implants are recommended for carefully selected patients with CRS. Additional research to define appropriate patient selection is needed.	No meta-analysis. There is a lot of overlap with the studies included in Goshtasbi et al. (2019).
Smith TL, Singh A, Luong A, et al. (2016) Randomized controlled trial of a bioabsorbable steroid-releasing implant in the frontal sinus opening. Laryngoscope. 126: 2659–2664	Randomised controlled trial n=80 (SES versus no implant) Follow up: 3 months	SES provided a statistically significant reduction in the need for postoperative interventions compared to surgery alone at 30 and 90 days. There was a 56% reduction in the need for oral steroid (p=0.0015), 75% reduction in the need for surgical interventions (p=0.0225), 17% reduction in inflammation score, 54% reduction in restenosis rate (p=0.0002), and 32% greater diameter of frontal sinus ostia (p<0.0001). No implant-related adverse events were reported.	Included in the meta-analysis by Goshtasbi et al. (2019).
Sow YL, Tang IP, Kho J et al. (2018) Pilot study comparing steroid-	Randomised controlled trial n=8 (bilateral ESS)	Gelfoam can be used as nasal packing material to deliver topical steroid after endoscopic sinus surgery.	Studies with more people or longer follow

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impregnated and non-steroid-impregnated absorbable nasal dressing following endoscopic sinus surgery. Medical Journal of Malaysia 73: 244–48	Follow up: 3 months	Steroid-impregnated nasal dressing after endoscopic sinus surgery may not provide better long-term outcome.	up are included.
Taweewuthisub O, Chusakul S, Kanjanaumporn J et al. (2021) Is add-on budesonide-impregnated nasal dressing useful following endoscopic sinus surgery with perioperative oral steroid? Journal of the Medical Association of Thailand 104: 293–99	Randomised controlled trial n=18 (bilateral ESS) Follow up: 4 weeks	Budesonide-impregnated polyurethane foam did not provide additional benefits on mucosal inflammation and wound healing in the patients who underwent ESS and received a short course of oral steroid perioperatively.	Studies with more people or longer follow up are included.
Weber CM, Schmidtmayer U, Stolle SRO et al. (2019) The novel Propel mini stent - Indications, surgical technique and first clinical experience. Laryngo- Rhino-Otologie 98: 408–12	Prospective case series n=21 Follow up: 6 months	There were no complications and complete stent degradation. The follow-up examinations showed satisfactory results over 6 months.	Studies with more people or longer follow up are included.
Wu AW, Sharma D, Illing EA et al. (2023) Ostial patency measurements after endoscopic sphenoidotomies and frontal sinusotomies. The Annals of Otology, Rhinology, and Laryngology 132: 1584–89	Prospective cohort study n=50 (78 sphenoid sinuses and 71 frontal sinuses with 39 SES) Follow up: 6 months	Both the sphenoid and frontal sinus ostia had a significant decrease in size over the initial postoperative period of 3 months by 42% and 40%, respectively; however, there was no significant change in ostial size from 3 to 6 months postoperatively.	Small cohort study focusing on the patency of the sphenoid and frontal sinus ostia after FESS.

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		The ostial patency of the frontal sinus can be improved with the use of SES, particularly in patients with history of prior sinus surgery.	
Xu JJ, Busato G-M, McKnight C et al. (2016) Absorbable steroid-impregnated spacer after endoscopic sinus surgery to reduce synechiae formation. The Annals of Otology, Rhinology, and Laryngology 125: 195–8	Retrospective cohort study n=146 Follow up: 1 month	Synechiae formed in 2% of cavities with an absorbable spacer and 6% of cavities with a non-absorbable spacer, but this difference was not statistically significant (OR=0.34, p=0.052).	More recent studies with more people or longer follow up are included.
Xu J, Park SJ, Park HS et al. (2016) Effects of triamcinolone-impregnated nasal dressing on subjective and objective outcomes following endoscopic sinus surgery. European Archives of Oto-rhino-laryngology 273: 4351–57	Randomised controlled trial n=58 (28 steroid-soaked and 30 saline-soaked dressing) Follow up: 3 months	Steroid-impregnated biodegradable nasal dressing was not related to the improvement of subjective symptoms compared to saline- soaked dressing. However, it had a statistically significant advantage regarding postoperative wound healing and improvement of olfactory function during the short follow-up.	Small trial, which is included in the systematic by Zhang et al. (2021).
Zhao X, Grewal A, Briel M et al. (2013) A systematic review of nonabsorbable, absorbable, and steroid-impregnated spacers following endoscopic sinus surgery. International Forum of Allergy and Rhinology 3: 896–904	Systematic review 11 RCTs (5 steroid versus plain spacer; 6 nonabsorbable versus absorbable)	Comparison between nonabsorbable spacers and absorbable spacers showed that there was no significant difference in adhesion rates if nonabsorbable spacers are used for at least 48 hours after surgery. Corticosteroid spacers may reduce adhesions, but more consistent data reporting is required for meta-analysis.	A more recent systematic review and meta-analysis is included.

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Zhao K-Q, Yu Y-Q, Yu H-M (2018) Effects of mometasone furoate-impregnated biodegradable nasal dressing on endoscopic appearance in healing process following endoscopic sinus surgery: a randomized, double-blind, placebo-controlled study. International Forum of Allergy and Rhinology 8: 1233–41	Randomised controlled trial n=64 Follow up: 3 months	Mometasone furoate-impregnated biodegradable nasal dressings improve the endoscopic appearance in the healing process of CRS with nasal polyposis after ESS.	Small trial, which is included in the systematic by Zhang et al. (2021).
Zheng L, Chen Z, Jin J et al. (2023) The efficacy of steroid-eluting stents on the local inflammation of chronic rhinosinusitis with nasal polyposis after endoscopic sinus surgery: a multicenter prospective longitudinal study. European Archives of Oto-rhino-laryngology 280: 5417–31	Prospective cohort study n=57 (30 with SES, 27 without) Follow up: 12 weeks	Nasal obstruction, nasal discharge, loss of smell, and total VAS scores decreased at 12 weeks postoperatively compared to preoperatively ($p<0.01$) and POSE score outcomes were also lower at 8 and 12 weeks postoperatively compared to 2 weeks postoperatively ($p<0.05$). SES played a crucial role in ameliorating postoperative local inflammation levels, accelerating wound recovery, and promoting epithelialisation in CRS with nasal polyposis. Larger trials with longer duration are needed to validate the effect of SES on the local inflammation after ESS.	Studies with more people or longer follow up are included.

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