






ORIGINAL ARTICLE

American Rhinologic Society expert practice statement part 1: Skull base reconstruction following endoscopic skull base surgery

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Abstract

The goal of this American Rhinologic Society expert practice statement (EPS) is to summarize the best available evidence for technical factors that optimize outcomes in skull base reconstruction following endoscopic skull base surgery for intradural pathologies. These topics include the use of free mucosal grafts versus vascularized pedicled nasoseptal flaps; the use of autologous versus synthetic grafts; and the roles of lumbar drains, dural sealants, and nasal packing. This EPS was developed following the recommended methodology and approval process as previously outlined. As there are a myriad of techniques and limited agreement on the accepted principles of skull base reconstruction, this EPS aims to summarize the existing evidence and provide clinically meaningful guidance on these divergent practices. Following a modified Delphi approach, five statements were developed, four of which reached consensus and one of which reached near consensus. These statements and the accompanying evidence are summarized along with an assessment of future needs.

KEYWORDS

CSF leak repair, dural sealants, endoscopic skull base surgery, evidence-based medicine, lumbar drain management, nasal packing, nasoseptal flap, skull base reconstruction, skull base surgery

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1 | INTRODUCTION

Endoscopic approaches to the skull base have shown significant growth over the last two decades as surgical experience, reconstructive techniques, and technological developments have improved, making it possible to manage larger and more complex lesions via the endonasal corridor.¹ When compared to transcranial approaches with appropriately matched pathologies, endoscopic approaches have demonstrated comparable or even improved extent of resection,² comparable or even lower morbidity and complication rates,³⁻⁵ better visual outcomes,⁶ and more stable quality of life (QOL)⁷ when compared to transcranial approaches with appropriately matched pathologies. Endoscopic skull base surgery (ESBS) is now a mainstay in the management of skull base disease both in the adult and pediatric populations.⁸⁻¹⁰

The most important risk specific to endoscopic approaches to the skull base is postoperative cerebrospinal fluid (CSF) leak, which is associated with meningitis, morbidity, and possible mortality. Thus, a primary focus of optimizing outcomes following ESBS includes the reduction of this risk of postoperative CSF leak via a multi-layered repair of the surgically created skull base defect. Considerations in reconstruction include both intraoperative (layered closure, the use of free mucosal grafts or vascularized pedicled flaps, allografts or autografts, tissue sealants, nasal packing) and postoperative (CSF pressure monitoring and titration via lumbar drainage [LDs]) management. However, there is little consensus as to the best approaches, with some equivalence of techniques, which remain highly institution and surgeon dependent.

Recent publications have included rigorous primary studies that evaluate novel products on the market, as well as systematic reviews and meta-analyses that review the historic literature.¹¹⁻¹⁴ Here, we seek to provide an objective, evidence-based evaluation of the current literature surrounding skull base reconstruction for intradural pathology with recommendations for best clinical practices.

2 | MATERIALS AND METHODS

This expert practice statement (EPS) was created as previously described.¹⁵ The thematic idea was developed by the senior author (ECK), submitted to and supported by the chair of the sponsoring committee (GWC, chair of Skull Base and Orbital Section Education Committee), and submitted to the chair of the American Rhinologic Society (ARS) Quality Improvement Committee for review and approval. Once approved, a working group of subspecialty

experts was proposed and approved by the ARS Executive Board before performing the literature review, drafting the EPS, and undergoing consensus among the working group.

For this EPS, the working group was comprised of nine fellowship-trained rhinologists and skull base surgeons. All working group members are members of the ARS. Evidence was based on six existing systematic reviews in the literature, as well as updated with a review of the current literature in areas where systematic reviews did not previously exist. A series of five topic areas addressing techniques for skull base reconstruction following ESBS were produced based on the literature review. A second forthcoming manuscript will encompass recommendations for postoperative precautions and management principles following ESBS. ESBS was defined as endoscopic endonasal approaches to the skull base for intradural pathologies. Each working group member was then asked to score each statement using a nine-point Likert scale, where 1 = strongly disagree, 3 = disagree, 5 = neutral, 7 = agree, and 9 = strongly agree. The surveys were disseminated, responses were aggregated and analyzed, and results were distributed to the members for in person discussion. A statement was considered to have reached consensus if a mean score of ≥ 7.00 was achieved with no more than 1 outlier (defined as any score ≥ 2.0 Likert points from the mean in either direction).¹⁶ A statement was categorized as reaching near consensus if a mean score of ≥ 6.50 was achieved with no more than two outliers.¹⁶ Those statements that did not meet the criteria of either category were classified as not having reached consensus.¹⁶ These statements and accompanying evidence are summarized below and in Table 1.

3 | EXPERT PRACTICE STATEMENTS WITH SUMMARY OF EXISTING EVIDENCE

This section includes the expert practice statements and accompanying evidence definitions.

1. High-flow CSF leaks are those defined as dural defect $>1 \text{ cm}^2$ or greater in size, and/or in continuity with a ventricle or cistern.
2. Patients with higher risk of postoperative CSF leak include, but are not limited to those with:
 - elevated body mass index (BMI),
 - elevated intracranial pressure (ICP) (i.e., intracranial hypertension),
 - a prior history of or those who require adjuvant radiotherapy (e.g., skull base malignancy),
 - limited reconstructive options (e.g., prior surgery),

TABLE 1 Expert practice statement (EPS) consensus statements.

| EPS statements | Mean score | Final outcome |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|------------------|
| Vascularized pedicled nasoseptal flaps: Vascularized pedicled NSF should be used in the primary reconstruction of large defects with high-flow CSF leaks ^a or patients with risk factors for postoperative CSF leak. ^b They remain an option for reconstructing low-flow leaks. | 8.38 | Strong consensus |
| Autologous and/or synthetic grafts: When utilized as inlay grafts during multilayer skull base reconstruction, autologous and synthetic graft material offer similar rates of successful skull base reconstruction, and overall acceptable donor site morbidity for autologous graft harvest. | 7.63 | Near consensus |
| Lumbar drains: The routine use of lumbar drain placement for sellar and suprasellar defects is not recommended but may be an option for certain high-flow CSF leaks in this location, especially in patients with risk factors for postoperative CSF leak. Postoperative lumbar drainage may be considered following ESBS resulting in large anterior or posterior cranial fossa skull base defects, or in patients with risk factors for postoperative CSF leak. ^b | 7.50 | Consensus |
| Tissue sealants: Tissue sealants have consistently demonstrated increased burst pressure in vitro. They are an option for providing additional support for skull base reconstruction, but there is not sufficient evidence to suggest improved outcomes. | 7.38 | Consensus |
| Nasal packing: Absorbable and non-absorbable nasal packing appear to have acceptable safety profiles. They are an option for providing additional support for skull base reconstruction, especially for extended endonasal approaches. | 7.50 | Consensus |

Abbreviations: CSF, cerebrospinal fluid; NSF, nasoseptal flap.

^aHigh-flow CSF leaks are those defined as dural defect >1 cm² or greater in size, and/or in continuity with a ventricle or cistern.

^bPatients with higher risk of postoperative CSF leak include, but are not limited to:

elevated body mass index,

elevated intracranial pressure (i.e., intracranial hypertension),

a prior history of or those who require adjuvant radiotherapy (e.g., skull base malignancy),

limited reconstructive options (e.g., prior surgery),

risk for poor wound healing (e.g., poor nutritional status, poorly controlled diabetics, history immunosuppression, connective tissue disorders, and active smoking),

significant exposure of critical neurovascular structures (e.g., internal carotid artery),

noncompliance with postoperative instructions and precautions.

- risk for poor wound healing (e.g., poor nutritional status, poorly controlled diabetics, history immunosuppression, connective tissue disorders, and active smoking),^{17,18}
- significant exposure of critical neurovascular structures (e.g., internal carotid artery),
- noncompliance with postoperative instructions and precautions.

3.1 | When should vascularized pedicled nasoseptal flaps be used during skull base reconstruction?

Statement 1 (strong consensus = mean score 8.38): Vascularized pedicled NSF should be used in the primary reconstruction of large defects with high-flow CSF leaks (see statement 1) or patients with risk factors for postoperative CSF leak (see statement 2). They remain an option for reconstructing low-flow leaks.

Aggregate grade of evidence: B.

Benefit: For the pedicled NSF, there is a reduction in postoperative CSF leak in high-risk defects, large skull

base defects, and high-flow leaks. Versatile and generally straightforward flap harvest technique. No external incisions required.

Harm: There may be some impact on olfactory or rhinologic QOL outcomes with NSF harvest (generally temporary), donor site discomfort, and risk of complications related to harvest (e.g., septal perforation, dorsal nasal collapse).

Cost: Nominal additional operative time.

Benefit-harm assessment: Benefits outweighs risks in high-risk defects and patients.

Value judgment: Large surface-area of vascularized tissue available, limited donor site morbidity, and marginal added operative time make vascularized NSFs a good method for skull base reconstruction in appropriate patients.

The NSF, first described by Hadad et al.¹⁹ and Kassam et al.²⁰ in 2006, is the most commonly utilized locoregional vascularized pedicled flap available for skull base reconstruction. Pedicled on the posterior septal branch of the sphenopalatine artery, the NSF is ideal for a variety of reconstructions given close proximity, large area of available tissue, low donor site morbidity, ease of harvest, and

familiarity of anatomy for the skull base surgeon.¹ However, flap harvest does place the olfactory epithelium of the superior septum at risk.

A systematic review and meta-analysis in 2012 by Harvey et al.²¹ showed that ESBS reconstruction utilizing the NSF was associated with lower CSF leak rate as compared with free grafts. Subsequent retrospective studies found significantly reduced postoperative CSF leak rates with use of the NSF.^{22,23} In contrast, one study has supported the use of a free graft.²⁴ A subsequent updated systematic review confirmed that vascularized reconstruction is particularly beneficial in large skull base defects.²⁵ It is important to note, however, that there is no consensus definition for what is considered a “large” defect, with reports of greater than 1,²⁶ 2,²⁷ and 3 cm²⁵ as cutoffs.

Until recently, the literature focused on surgical rather than QOL outcomes. This was addressed by a double-blinded, randomized control trial (RCT) evaluating ESBS for sellar pathologies and associated olfactory (University of Pennsylvania Smell Identification Test²⁸) and QOL outcomes (22-item SinoNasal Outcomes Test²⁹).¹¹ Results found no impact on olfaction or QOL with the use of the NSF. Additionally, these results appear to be consistent independent of whether cold steel or electrocautery is utilized to harvest the flap.^{30,31} However, preservation of the olfactory epithelium in the superior olfactory strip may be associated with improved olfactory outcomes.^{11,30–35}

Combining over a decade’s literature, recent, more extensive retrospective studies and systematic reviews note that in specific patients (those with a high-flow intraoperative CSF leak, morbid obesity, or requiring adjuvant radiotherapy), the use of vascularized pedicled flap reconstruction should be strongly considered when available.^{36–38} Other considerations for NSF use, which are largely experiential, include skull base support for postoperative positive airway pressure devices or for coverage of critical neurovascular structures (i.e., internal carotid artery) (Table 2).

3.2 | Does the use of autologous or synthetic grafts affect reconstructive outcomes?

Statement 2 (near consensus = mean score 7.63): When utilized as inlay grafts during multilayer skull base reconstruction, autologous and synthetic graft material offer similar rates of successful skull base reconstruction, and overall acceptable donor site morbidity for autologous graft harvest.

Aggregate grade of evidence: C.

Benefit: No clear benefit to using autologous versus synthetic graft material, as both graft types appear to be associated with favorable outcomes.

Harm: Potential donor site morbidity (e.g., thigh for fascia lata, abdomen for fat) with autologous graft harvest, added operative time and surgical utilization required for autologous graft harvest. Potential prolonged crusting with some synthetic materials, which may be mitigated with nasal debridements and cleansing.

Cost: Additional cost of synthetic grafts. Potential additional procedural cost with autologous graft harvest.

Benefit–harm assessment: Balance of benefit and harm.

Value judgment: No clear evidence exists to support the preferential use of either autologous or synthetic grafting material in skull base reconstruction.

Various grafts have been described as a component of a comprehensive multilayered skull base repair. This includes both autologous (i.e., mucosa, fascia, fat, bone grafts) and synthetic grafts (e.g., collagen, acellular dermal matrix, dehydrated amniotic matrices, porcine small intestine submucosa). Multiple single-institutional case series have demonstrated that the various synthetic graft materials are safe and have equivalent outcomes to autologous grafts in terms of rates of postoperative CSF leak and other infectious complications.^{27,39–41} Additionally, a systematic review by Oakley et al.²⁵ analyzing five studies showed low level of evidence to support the favored use of either autologous or synthetic grafts. What does appear to be clear is that the adjunct of grafting material, either autologous or synthetic, enhances closure rates when combined with an NSF.^{42,43}

A more recent systematic review by Abiri et al.⁴⁴ analyzed 29 studies with a combined 2275 patients and evaluated postoperative CSF leak rate and other major complications. There were no significant differences in postoperative CSF leak or other major complications between the autologous and synthetic material groups, though there was a slightly lower rate of meningitis noted in the synthetic graft group.

Rigid buttresses such as bone grafts or absorbable plates can be considered as part of the reconstructive ladder. In what is known as the gasket seal technique, a piece of fascia is held in place between two rigid buttresses, and has been described by Garcia-Navarro et al.⁴⁵ for the repair of high-flow CSF leaks (see statement 1), or in those patients at increased risk (see statement 2) of postoperative leak. Importantly, a more recent study in 2019 evaluating the risk of postoperative leak has suggested that the presence of a buttress, and less importantly the type (soft vs. rigid), is of greatest importance in reconstructive outcome with this technique.⁴⁶ In evaluating postoperative sinonasal morbidity, a study by Roxbury et al.⁴⁷ showed that use

TABLE 2 Use of vascularized pedicled flaps.

| Study | Year | LOE | Study design | Study groups | Clinical endpoint | Conclusion |
|---------------------------------|------|-----|------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Chou et al. ¹¹ | 2020 | 1 | Double blinded, randomized control trial | EEA for sellar pathology <ul style="list-style-type: none"> • Recon with NSF • No NSF | 1. UPSIT 2. SNOT-22 | 1. Use of NSF had no impact on olfaction 2. Use of NSF had no impact on rhinologic QOL |
| Khan et al. ³⁶ | 2021 | 2 | Systematic review | 193 studies | Repair protocols, CSF rhinorrhea | Modern reconstructive protocols are heterogeneous with limited evidence to suggest optimal repair technique |
| Kim and Hong ³⁸ | 2021 | 2 | Meta-analysis, systematic review | 56 studies (11,826 patients) | Postoperative CSF leaks | 1. Obesity, perioperative radiotherapy, high intraoperative CSF flow rate raise the risk of CSF leak 2. A pedicled vascularized flap can effectively reduce the risk of postoperative CSF leakage |
| Puccinelli et al. ³⁰ | 2019 | 2 | Prospective cohort | 22 patients <ul style="list-style-type: none"> • Cold steel (<i>n</i> = 10) • Electrocautery (<i>n</i> = 12) | Postoperative olfactory function (UPSIT) | Use of cold steel versus electrocautery does not impact short or long-term olfactory outcomes |
| Oakley et al. ²⁵ | 2016 | 2 | Systematic review | 39 studies | Predictors of postoperative CSF leaks | Large skull base defects may benefit from vascularized reconstruction |
| Soudry et al. ⁵² | 2014 | 2 | Systematic review | 22 studies (673 patients) | Postoperative CSF leak | 1. For low-flow leaks, multi-layered free and synthetic grafts offer similar outcomes to vascularized tissue 2. For high-flow leaks, vascularized tissue is superior 3. Clival defects show reduced leak rate when vascularized tissue employed |
| Harvey et al. ²¹ | 2012 | 2 | Systematic review, meta-analysis | 38 studies <ul style="list-style-type: none"> • Vascularized (<i>n</i> = 12) • Free grafts (<i>n</i> = 7) • Mixed (<i>n</i> = 3) | Postoperative CSF leak | 1. ESBS with vascularized tissue associated with lower CSF leak rate versus free grafts 2. ESBS with vascularized tissue has similar CSF leak rates to open repair |
| Kilic et al. ³¹ | 2022 | 4 | Systematic review | 9 studies (610 patients) <ul style="list-style-type: none"> • Olfactory strip preservation (<i>n</i> = 504) • Cold steel (<i>n</i> = 70) • Electrocautery (<i>n</i> = 36) | Postoperative olfactory function | 1. Use of cold steel versus electrocautery does not improve postoperative olfactory function 1. Olfactory strip preservation may improve postoperative olfactory function |

(Continues)

TABLE 2 (Continued)

| Study | Year | LOE | Study design | Study groups | Clinical endpoint | Conclusion |
|--------------------------------------|------|-----|---------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Papagiannopoulos et al. ⁸ | 2022 | 4 | Retrospective cohort | ESBS with high-flow leak (repair with NSF, DuraGen, fat, fascia lata, collagen matrix) <ul style="list-style-type: none"> • Adult ($n = 67$) • Pediatric ($n = 57$) | <ol style="list-style-type: none"> 1. Postoperative leak 2. Viability of NSF in pediatric population | <ol style="list-style-type: none"> 2. No significant difference in leak rates between adult and pediatric patients 3. NSF is a viable reconstructive option in the pediatric population |
| Torres-Bayona et al. ³⁷ | 2021 | 4 | Retrospective cohort | EEA with CSF leak <ul style="list-style-type: none"> • Persistent leak • No persistent leak | Clinical risk factors | <ol style="list-style-type: none"> 1. Secondary vascularized pedicled flaps should be considered (e.g., extracranial–pericranial), especially for posterior fossa reconstruction 2. Flap necrosis may play a role in persistent leak |
| Roxbury et al. ²⁴ | 2016 | 4 | Retrospective cohort | EEA for sellar pathology closed with free mucosal graft | Postoperative CSF leak | Postoperative CSF leak rate 6.85% |
| Koutourousiou et al. ²² | 2013 | 4 | Retrospective case series | Craniopharyngioma <ul style="list-style-type: none"> • Adult ($n = 47$) • Pediatric ($n = 17$) | Postoperative CSF leak | Leak rates reduced (23.4%–10.6%) following introduction of NSF |

Abbreviations: CSF, cerebrospinal fluid; EEA, expanded endonasal approach; ESBS, endoscopic skull base surgery; LOE, level of evidence; NSF, nasoseptal flap; QOL, quality of life; SNOT-22, 22-item SinoNasal Outcomes Test; UPSIT, University of Pennsylvania Smell Identification Test.

of synthetic graft material (acellular dermal matrix) was associated with an increased risk of postoperative crusting, though there was no significant difference in the risk of developing rhinosinusitis. Together, the weight of the literature appears to support the use of either autologous or synthetic grafts as part of a multi-layered skull base closure.

3.3 | When should lumbar drains be used following skull base reconstruction?

Statement 3 (consensus = mean score 7.50): The routine use of lumbar drain placement for sellar and suprasellar defects is not recommended but may be an option for certain high-flow CSF leaks in this location, especially in patients with risk factors for postoperative CSF leak. Postoperative LD may be considered following ESBS resulting in large anterior or posterior cranial fossa skull base defects, or in patients with risk factors for postoperative CSF leak (see statement 2).

Aggregate grade of evidence: B.

Benefit: Ability to continuously monitor and titrate CSF pressure, divert pressure from fresh repair.

Harm: Risks of meningitis, intracranial hypotension (headaches, herniation), activity limitations, venous

thromboembolism, pneumocephalus, and retained catheter. Increased length of stay.

Cost: Increased level of care and length of stay

Benefit–harm assessment: Harm outweighs benefit in sellar and parasellar defects. However, in select large anterior or posterior fossa dural defects benefit may outweigh risk.

Value judgment: LD benefit does not outweigh risk in routine sellar and suprasellar surgery; however, in select large high-flow dural defects associated with anterior and posterior fossa pathologies, select cases with large defects in the sellar diaphragm or suprasellar region, or in patients with risk factors for postoperative CSF leak, it is an option.

Lumbar drain placement offers the ability to both monitor and titrate CSF pressure to reduce strain on the skull base reconstruction. Their placement is, however, associated with additional risk including infectious (meningitis), hematologic (venous thromboembolism), and neurologic (headache, pneumocephalus, uncal herniation) complications, as well as added financial burden due to increased level of care and length of stay required.^{48,49} For this reason, the routine use of LDs in patients undergoing ESBS has remained controversial.¹

Early literature evaluating the efficacy and risks of LD placement in the skull base surgery population were based on retrospective case series noting the associated

morbidity and increased resource utilization, without a clear reduction in postoperative CSF leak.^{50,51} Given the paucity of literature, a systematic review in 2014 was unable to draw conclusions on the value of LDs in reducing risk of postoperative leak.⁵² As the volume of ESBS increased over the following years, the rigor of studies performed also increased, such as those by Hu et al.⁵³ and Dehdashti et al.,⁵⁴ which reported a more clear benefit of LD placement, specifically in cases of persistent leaks, or in the setting of an unexpected major opening of the sellar diaphragm. The growth in literature prompted two additional systematic reviews, which showed evidence that LDs may be useful in specific individuals such as those with elevated BMI, underlying intracranial hypertension, and/or in the setting of limited vascularized reconstructive options, but that the overall quality of literature remained poor.^{25,55,56}

Two prospective RCTs were published on LD drain use after ESBS, in which patients were managed either with or without LD placement.^{12,13} The largest of these is by Zwagerman et al., which enrolled 170 total patients (85 with and without LD placement). Results showed that LD after ESBS significantly reduced the risk of postoperative CSF leak, and that was it particularly advantageous in cases of large dural defects (defined as 1 cm²) of the anterior cranial fossa, and defects involving the posterior cranial fossa (e.g., transclival). However, the routine use of LDs in the management of suprasellar defects was not recommended unless there were other risk factors for CSF leak.¹³ This recommendation against the routine use of LDs in suprasellar defects was reconfirmed by a smaller RCT by Huo et al. enrolling 38 patients undergoing extended endoscopic transsphenoidal surgery for a variety of suprasellar pathologies (meningioma, craniopharyngioma, sinonasal tumor, dermoid cyst, and Langerhans cell histiocytosis), which also found that routine LD placement did not reduce the risk of postoperative CSF leak.¹²

A recent meta-analysis also concluded that LD placement should not be routinely performed in all patients undergoing ESBS, but may be considered in high-risk patients (i.e., those with large, high-flow intraoperative CSF leaks located at difficult-to-reconstruct anatomic sites of the anterior and posterior cranial fossae).⁵⁷ This, together with the most updated systematic review on the topic by Abiri et al.,⁵⁸ forms the basis of the current recommendations. Data regarding the balance of risk of drain-related complications with the benefit of LD placement generally suggests low morbidity profile.^{1,59} Considering individual patient factors, LD placement may be considered in a unique subset of high-risk patients. Other judgment-based considerations for LD use include (1) when watertight seals are unachievable, (2) in patients whose medical conditions place them

at higher risk for repair failure (e.g., immunosuppression, vasculopathy, impaired mental status limiting compliance with post-operative precautions), and (3) in patients with suspected intracranial hypertension for ICP monitoring.

3.4 | Do tissue sealants help with improving skull base reconstruction outcomes?

Statement 4 (consensus = mean score 7.38): Tissue sealants have consistently demonstrated increased burst pressure in vitro. They are an option for providing additional support for skull base reconstruction, but there is not sufficient evidence to suggest improved outcomes.

Aggregate grade of evidence: C.

Benefit: Placement of dural sealant over the repair may keep it in place and reduce risk of disruption, as well as providing a temporary seal along edges of the graft/flap.

Harm: Risk of local tissue reactions, anaphylaxis, and infections, with potential for scarring.

Cost: Added cost of tissue sealant that may be substantial.

Benefit-harm assessment: Balance of benefit and harm but cost is a major consideration.

Value judgment: Whether or not tissue sealants lead to improved clinic outcomes is uncertain.

Creating a hermetic seal is one of the cornerstones of successful skull base reconstruction.¹ Given this, a variety of tissue sealants are commercially available which aim to plug the dural opening, stabilize graft position while additional packing can be placed, and accelerate healing of the reconstruction. The earliest published evaluation of the potential benefit of tissue sealant was by Eloy et al.,⁶⁰ evaluating high-flow CSF leaks repaired using an NSF with or without sealant. The use of sealant showed no clear benefit. Two case series evaluated different sealants head-to-head (Adherus, Stryker vs. DuraSeal, Integra LifeSciences⁶¹; DuraSeal vs. Tachosil, Baxter⁶²) and found no significant differences in postoperative CSF leaks or QOL measures between the groups. A separate cadaveric study found that Adherus had higher burst pressure, suggesting better sealing properties.⁶³

There have been several historical in vitro studies evaluating burst pressure, a measure of seal strength, with a variety of reconstructive approaches. Notably, de Almeida et al.⁶⁴ found that the addition of a tissue sealant (Tisseel; Baxter) significantly increased the burst pressure when added to a pure pericranial reconstruction, and that this was stronger when performed in an underlay rather than an overlay fashion. This principle was recapitulated in a porcine model.⁶⁵ Fandiño et al. compared DuraSeal and

Tisseel in a variety of reconstructive approaches, and found Tisseel offered greater burst pressure.⁶⁶

Several more recent studies detail CSF leak rates after the use of dural sealant in ESBS. A case series by Asmaro et al. details 73 patients in which dural sealant was always used for closure, with a 97.4% initial success rate.²⁶ McDowell et al. performed a prospective cohort study with 300 patients undergoing ESBS with intraoperative CSF leak, 150 managed with and 150 managed without sealant. Results indicated no significant reduction in postoperative CSF leak rates.¹⁴ This study represents the highest level of evidence evaluating the use of dural sealant in ESBS. In summary, while in vitro studies demonstrate measurably increased repair integrity with tissue sealants, these findings have not reliably translated to improved clinical outcomes, and the benefits of sealant use remain controversial (Table 3).

3.5 | Does nasal packing help with improving skull base reconstruction outcomes?

Statement 5 (consensus = mean score 7.50): Absorbable and non-absorbable nasal packing appear to have acceptable safety profiles. They are an option for providing additional support for skull base reconstruction, especially for extended endonasal approaches.

Aggregate grade of evidence: C.

Benefit: Directed pressure against reconstruction along a broad front, able to be contoured (all packing); reduced risk of epistaxis and synechiae formation (non-absorbable packing).

Harm: Temporary reduction in sinonasal QOL due to nasal obstruction, increased mucopurulence, and risk of toxic shock syndrome. Additionally, potential risks of sinus scarring (reduced with absorbable packing) and large surface area of mucosal trauma (increased with non-absorbable packing). Need for removal for non-absorbable packing.

Cost: Additional cost of packing material.

Benefit-harm assessment: Balance of benefit and harm.

Value judgment: The literature surrounding the utility of nasal packing in improving skull base reconstruction outcomes is limited but may show improved outcomes in extended approaches at the cost of decreased short-term sinonasal QOL. There are no standardized packing protocols, with variation in duration, location, and type of packing.

The use of nasal packing for ESBS reconstruction has the potential to provide counter-pressure on the reconstruction against ICP, minimize postoperative epistaxis, and limit the formation of sinonasal synechiae.¹ A

variety of packing materials exist, including absorbable (e.g., Gelfoam, Pfizer; Nasopore, Stryker; and Merogel, Medtronic) and non-absorbable (e.g., Merocel, Medtronic; petroleum gauze, Covidien) materials. While the use of nasal packing has been well studied in the endoscopic sinus surgery (ESS) literature, it has been lacking in the field of ESBS.

ESS patients, however, represent a distinct population from ESBS patients in whom approaches are extended and are in close proximity to critical neurovascular structures. A case series in 2015 by Little et al. evaluating 100 patients undergoing ESBS with placement of absorbable packing found that the use of packing was associated with more severe mucopurulence as well as lower sinonasal QOL at 6 months postoperatively.⁶⁷ Notably, this study is limited by its low rate of NSF use (5%), a lack of reporting of intraoperative CSF leak rates, and a low rate of otolaryngology involvement both at the time of surgery and postoperatively (55%). However, this finding was recently re-demonstrated by Abiri et al.⁶⁸ who showed an increased risk of post-operative infections specifically with non-absorbable packing, however, there was no short or long-term change in QOL scores.

More recently, Fathalla et al.²³ were able to demonstrate a reduction in postoperative CSF leak rate in extended endonasal approaches with the use of nasal trumpet as a support material (though not formally nasal packing), and Cai et al.⁶⁹ showed superiority of Merocel packing over balloon. In the recent publication by Abiri et al.,⁶⁸ there was no association of packing type with rate of post-operative CSF leak. However, a recent prospective case series questioned this conclusion, demonstrating consistently successful repair of both low- and high-flow skull base defects without the use of nasal packing, though dural sealants were utilized.²⁶ Finally, the systematic review by Abiri et al.⁵⁸ concluded that current literature on the use of nasal packing is mixed, limiting the rigor of evidence-based recommendations.

Though there is a paucity of data, recent work has shown that packing placement may be a beneficial adjunct to reconstruction in extended approaches, though with an associated reduction in postoperative QOL. More standardized and systematic evaluation of nasal packing, with consideration of type and location and duration of placement, with preoperative, postoperative, and longitudinal assessments, is needed.

4 | NEEDS ASSESSMENT

ESBS is now a mainstay in the management of complex skull base lesions in both the adult and pediatric populations. Currently, among experts in the field of endoscopic

TABLE 3 Use of tissue sealants.

| Study | Year | LOE | Study design | Study groups | Clinical endpoint | Conclusion |
|-------------------------------|------|-----|-------------------------|-------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Oakley et al. ²⁵ | 2016 | 2 | Systematic review | N/A, systematic review | N/A, systematic review | No known benefit of dural sealant or glue |
| McDowell et al. ¹⁴ | 2022 | 2 | Prospective cohort | 300 patients • <i>n</i> = 150 with sealant • <i>n</i> = 150 without sealant | Postoperative CSF leak | Use of sealant did not reduce rate of postoperative CSF leak |
| Asmaro et al. ²⁶ | 2021 | 3 | Prospective case series | 73 patients • <i>n</i> = 46 Adherus • <i>n</i> = 15 Tisseel • <i>n</i> = 12 DuraSeal | 1. Postoperative CSF leak 2. Postoperative epistaxis 3. Postoperative sinusitis | 1. Two cases of initial CSF leak resolved with LD placement 2. Due to lack of comparison group, unable to analyze the impact of dural sealant use on clinical endpoints |
| Soneru et al. ⁶¹ | 2020 | 3 | Prospective case series | 50 patients • <i>n</i> = 26 Adherus • <i>n</i> = 24 DuraSeal | 1. Postoperative complication rates 2. Imaging characteristics 3. Postoperative SNOT-22 scores | 1. No CSF leaks observed in either group 2. Adherus more likely visible on postoperative MRI; NSF opposed to skull base equally in both groups 3. No difference in SNOT-22 total or subdomain scores |
| Spitaels et al. ⁶² | 2022 | 4 | Retrospective cohort | 198 patients (219 cases) • 65 fibrin-coated collagen fleece (Tachosil) • 154 dural sealant (DuraSeal) | Postoperative CSF leak | No significant difference in postoperative CSF leak rate between groups |
| Eloy et al. ⁶⁰ | 2012 | 4 | Retrospective cohort | 74 patients • <i>n</i> = 32 NSF alone • <i>n</i> = 42 dural sealant + NSF | Postoperative CSF leak | No significant difference in postoperative CSF leak rate between groups |
| Campbell et al. ⁶³ | 2021 | 5 | In vitro study | n/a | Average burst pressure | Electrospun NOCA fiber membranes have higher sealing capabilities than other commercially available sealants (Adherus) |

Abbreviations: CSF, cerebrospinal fluid; LD, lumbar drain; LOE, level of evidence; MRI, magnetic resonance imaging; NOCA, n-octyl-2-cyanoacrylate; NSF, nasoseptal flap; SNOT-22, 22-item SinoNasal Outcomes Test.

skull base reconstruction, there are a myriad of highly varied reconstruction techniques and practice patterns. This EPS seeks to review the current literature and to provide evidence-based recommendations for clinical practice. This consensus is limited by the quality of the literature currently available, which has been summarized here for review.

In evaluating the use of vascularized pedicled flaps, the NSF has become almost ubiquitous in its use in complex skull base reconstruction, particularly in high-risk defects and patients, with reliable and consistently reported outcomes. However, it would be interesting to more thoroughly examine other vascularized pedicled flaps and associated outcomes. The use of autologous versus synthetic graft materials also exhibits a relative

dearth of studies, which are limited to small retrospective studies that appear to support a relative non-inferiority between grafting materials. Choice of graft material has largely been dictated by surgeon experience and institutional resources. Future studies should thus include RCTs and cost assessments to better delineate any potential differences.

The consensus in the selective use of LD following ESBS is particularly strong, with one high-quality meta-analysis and two recent RCTs available. This is in addition to numerous historic retrospective studies and systematic reviews creating a significant volume of literature. Similarly, the use of tissue sealants features recent, more rigorous studies (i.e., prospective cohort). It is challenging, however, to apply these recommendations universally

given the significant variety that exists in extent and location of skull base defects, and patient factors affecting the management of skull base reconstruction. Future tissue sealant studies should seek to stratify or match based on these characteristics to provide greater detail about how tumor type, location, repair technique, and patient factors should influence their use.

While nasal packing following ESS has been studied extensively, this same rigor has not been applied to ESBS. These same studies could be applied to the ESBS population to bring benefit and understanding to an evidence-based approach to skull base reconstruction. Going forward, it is critical that granular detail is provided regarding the definition of ESBS, location and extent of approach, and patient factors to increase the quality of data in the literature.

It should also be noted that many additional postoperative precautions (e.g., pain and nausea management, activity restrictions, diet, antibiotic prophylaxis, and nasal hygiene) are felt to influence outcomes in ESBS reconstruction, but are generally poorly studied in the literature.⁵⁸ These management approaches are not addressed in this EPS but represent an important area for future study. We additionally acknowledge that there are often individual patient factors that while impossible to name every influencing factor here, may contribute in part or in whole to a surgeon's preferred reconstructive approach. Herein, we have sought to provide evidence-based guidance for approaches to skull base reconstruction following ESBS for intradural pathologies as it relates to the use of vascularized pedicled flaps, autologous or synthetic grafts, lumbar drains, tissue sealants, and nasal packing.

5 | QUALIFYING STATEMENT

This EPS should serve only to help guide the decision making for approaches to skull base reconstruction following ESBS for intradural pathologies. Medical and surgical care should be individualized to the patient and their contextual situation.

6 | EXPIRATION

This EPS should be reviewed within 3 years from the date of publication and updated if current evidence and common practice has significantly changed.

CONFLICT OF INTEREST STATEMENT

Garret Choby is a consultant for Tissium and Medtronic. Raj Sindwani is a consultant for Acclarent, Stryker, and Optinose, and he receives royalties from Sage Publications

(EIC of American Journal of Rhinology and Allergy) and Elsevier (textbooks). Bradford A. Woodworth is a consultant for Cook Medical, Medtronic, and Smith and Nephew. Edward Kuan is a consultant for Stryker ENT. These conflicts of interest are not relevant to this article. The remaining authors report no relevant conflicts of interest or financial disclosures.

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