Stereotactic navigation in sinus surgery

Clinical Policy ID: CCP.1455

Recent review date: 4/2025

Next review date: 8/2026

Policy contains: Computer-assisted sinus surgery; endoscopic sinus surgery; image-guided sinus surgery; surgical navigation.

Coverage policy

Stereotactic navigation (also known as three-dimensional image guidance or computer-aided surgery) is considered standard of care when added to general endoscopic sinus surgery; therefore, it is not separately reimbursable as an add-on to the general procedure.

<u>Limitations</u>

No limitations were identified during the writing of this policy.

<u>Alternative covered services</u>

- Clinical examination.
- Diagnostic rhinoscopy.
- Endoscopic or open sinus surgery.
- Preoperative and postoperative radiography, computed tomography, or magnetic resonance imaging.
- Professional consultation.

Background

Sinus surgery is one of the most frequently performed surgical operations in the United States, and the most common indication is chronic refractory rhinosinusitis. Since the late 1990s, there has been a shift from open procedures to endoscopic procedures and a decrease in the incidence of major complications associated with endoscopic approaches in adults. For example, in England from 2010 to 2019, the number of endoscopic sinus procedures increased by 21.1%, and the number of open procedures declined by 35.3% (Gupta, 2020).

Rhinosinusitis is a clinical diagnosis, dependent on clinical and rhinoscopic findings. Some diseases involving the sinonasal region and skull base are inaccessible to sinonasal endoscopy or are not directly visible on clinical examination. In such cases, imaging can determine the extent and possible nature of the disease and provide guidance for surgical planning.

Multidetector or cone-beam computed tomography is the preferred imaging modality for surgical planning in most circumstances for its clear delineation of the complex ethmoidal anatomy, ostiomeatal unit, and anatomic variations, including the presence of sphenoethmoidal (Onodi) air cells (American College of Radiology, 2021). Magnetic resonance imaging of the face and sinuses with inclusion of adjacent brain and orbits is preferred for soft-tissue masses, delineation of orbital, skull base, or intracranial involvement, and for suspected invasive fungal sinusitis.

Endoscopic sinus surgery is a set of minimally invasive techniques that apply endoscopic instrumentation to directly examine the sinuses, remove sinus blockages, and restore sinus ventilation and normal function. It is a treatment of choice for chronic rhinosinusitis refractory to medical treatment, and its role is expanding in the management of other sinus, orbit, and skull base diseases (Homsi, 2022).

Endoscopic sinus surgery is a technically demanding procedure due to anatomical complexity, variation in normal anatomy, and proximity to critical structures such as the olfactory fossa, skull base, vascular structures, and orbit. Anatomic distortion from chronically inflamed mucosa and absent anatomic landmarks from prior surgery further increase both potential risk of major and minor complications and operating time.

In a systematic review/meta-analysis of 13 studies (n = 1,274) of complications from endoscopic sinus surgery for chronic rhinosinusitis, the complication rate was 5.3% with enhanced recovery after surgery – a multimodal multi-disciplinary planning program – compared to the 19.1% rate using standard care (Wu, 2023). To optimize the visual surgical field and mitigate the risk of complications, stereotactic navigation has been proposed as an adjunct in endoscopic and external-approach sinus surgery.

The image guidance systems consist of a computer workstation, tracking system, and specially designed navigation instruments (Oakley, 2016). They require a compatible preoperative computed tomography scan of the sinuses using a special image guidance protocol, for example, a non-contrast axial image with 1 millimeter or thinner cuts. Image guidance systems digitally link the images and display them in axial, coronal, and sagittal planes. The image is coupled to the surgical instruments by an electromagnetic or optical tracking system. This gives the surgeon the ability to navigate the surgical instruments in real time within the diseased sinuses and improve the spatial orientation with vital structures while watching the monitor.

Findings

Guidelines

The American Academy of Otolaryngology — Head and Neck Surgery (2023) recommends stereotactic navigation based on consensus and current evidence, acknowledging that corroboration with Level 1 evidence would be impossible. They recommend the technology be used at the surgeon's discretion to clarify complex anatomy during sinus and skull base surgery. Specific indications include revision sinus surgery, distorted sinus anatomy of development, postoperative, or traumatic origin, and extensive sino-nasal polyposis. Additional indications encompass pathology involving the frontal, posterior ethmoid, or sphenoid sinuses; disease abutting the skull base, orbit, optic nerve, or carotid artery; cerebrospinal fluid rhinorrhea or conditions where there is a skull base defect; and benign and malignant sino-nasal neoplasms.

A guideline from the International Stereotactic Radiosurgery Society recommends stereotactic radiosurgery as a treatment for grade 1 meningioma (Marchetti, 2020).

Systematic Reviews

Two qualitative systematic reviews (Ramakrishnan, 2013; von Hofsten, 2013) failed to demonstrate a definitive reduction in complications or improvement in outcomes with stereotactic navigation. These conclusions may reflect the inability to conduct more definitive studies rather than a lack of efficacy. Individual primary studies lacked statistical power to identify a meaningful effect of stereotactic navigation in endoscopic sinus surgery.

A systematic review/meta-analysis of 27 studies found that stereotactic radiosurgery for benign intracranial meningiomas had a local control rate from 71% to 100% and progression-free-survival rate from 55% to 97% after 10 years, with a low toxicity rate (Marchetti, 2020).

A systematic review of 47 studies on endoscopic sinus surgery found the most commonly identified significant landmarks were maxillary sinus ostium; orbital wall; frontal recess; skull base; ground lamella; fovea posterior; and sphenoid sinus ostium. These landmarks may lead to systematic practice guidelines in navigated endoscopic sinus surgery (Baudoin, 2021).

A systematic review/meta-analysis of twenty-one studies (n = 705) of patients treated with stereotactic radiosurgery for dural arteriovenous fistulas found that non-cavernous sinus fistulas were associated with lower rates of complete obliteration (P = .03) and symptom cure rate (P = .001) (Singh, 2022).

A systematic review/meta-analysis of five studies (n = 208) of patients with pituitary adenomas who underwent endoscopic resection of the medial wall of the cavernous sinus showed the prevalence of medial wall invasion varied from 10.4% to 36.7% (de Macedo Filho, 2022).

Meta-Analyses

A meta-analysis (Dalgorf, 2013) of 14 comparative cohorts found both major complications (P = .007) and total complications (P = .02) were more common in the non-image guided group. However, there were no significant between-group differences in risk of orbital complications, intracranial complications, major hemorrhage, completion of operation, revision surgery, or patient-reported outcome measures.

Another meta-analysis (Vreugdenburg, 2016) of nine studies demonstrated a statistically significant decrease in the likelihood of total, major, and orbital complications in participants who had stereotactic navigation. However, a statistical benefit in reducing surgical revisions, major hemorrhage, or minor complications was not observed.

A meta-analysis of 21 studies (n = 199) of participants undergoing surgery for cavernous sinus hemangiomas found that 149 of the participants received standalone stereotactic radiosurgery, of whom 72.4% had greater than a 50% decrease in tumor volume, after being followed for an average of three years (Mishra, 2023).

Clinical Studies and Surveys

The perceived potential of increased safety and improved surgical outcomes with stereotactic navigation in endoscopic sinus surgery led to the introduction and diffusion of the technology in the early 2000s, despite the absence of clear benefit demonstrated in clinical research. A survey of American Rhinologic Society members showed growth in both the availability of stereotactic navigation to most practitioners and its use from 2005 to 2010 (P < .0001) (Justice, 2012).

American Rhinologic Society survey respondents identified primary anterior ethmoidectomy, revision anterior ethmoidectomy, primary total ethmoidectomy, Lothrop procedure, cerebrospinal fluid leak repair, tumor surgery, orbital decompression, and optic nerve decompression (all P < .05) as major indications for stereotactic navigation (Justice, 2012). These indications suggest stereotactic navigation is best reserved for situations with highest risk of major surgical complications or where suboptimal surgery may lead to poorer outcomes or revision procedures.

A cost-effectiveness study of pediatric patients who underwent sinus surgery with intraoperative navigation (n = 60) and without intraoperative navigation (n = 59) between 2003 and 2016 found that intraoperative navigation was associated with more complex surgeries with more sinuses opened (P = .008), increased presence of the attending surgeon and a trainee (P < .001 for both), and longer surgical time (P < .001). The study concluded that intraoperative navigation did not decrease complication rates or revision rates and was not cost-effective, being used primarily as an educational tool or to increase confidence in intraoperative landmark identification.

A randomized study (n = 200) of participants undergoing endoscopic sinus surgery with versus without an image-guided system in China found four re-hospitalizations and re-operations due to bleeding in the group without image guidance, compared with none for the image guidance group. Total costs were slightly greater for the group without image guidance due to re-hospitalizations (Wang, 2023).

In 2025, we reorganized the findings section thematically and by evidence type. No new studies were found or added and no policy changes were warranted.

References

On March 15, 2025, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “otorhinolaryngologic surgical procedures (MeSH),” “paranasal sinus diseases/surgery (MeSH),” and “Surgery, Computer-Assisted (MeSH),” and “endoscopic sinus surgery.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

American Academy of Otolaryngology — Head and Neck Surgery. Position statement: Intra-operative use of computer aided surgery. https://www.entnet.org/resource/position-statement-intra-operative-use-of-computer-aidedsurgery/#:~:text=Position%20Statement%3A%20Intra%2DOperative%20Use%20of%20Computer%20Aided%20Surgery,Position%20Statement%3A%20Intra&text=The%20American%20Academy%20of%20Otolaryngology,sinus%20and%20skull%20base%20surgery. Revised October 3, 2023.

American College of Radiology. ACR Appropriateness Criteria® sinonasal disease. https://acsearch.acr.org/docs/69502/Narrative/. Revised 2021.

Baudoin T, Greguric T, Bacan F, Jelavic B, Geber G, Kosec A. A systematic review of common landmarks in navigated endoscopic sinus surgery (NESS). *Comput Assist Surg (Abingdon)*. 2021;26(1):77-84. Doi: 10.1080/24699322.2021.1992504.

Dalgorf DM, Sacks R, Wormald P-J, et al. Image-guided surgery influences perioperative morbidity from endoscopic sinus surgery: A systematic review and meta-analysis. *Otolaryngol Head Neck Surg.* 2013;149(1):17-29. Doi: 10.1177/0194599813488519.

De Macedo Filho LJM, Diogenes AVG, Barreto EG, et al. Endoscopic endonasal resection of the medial wall of the cavernous sinus and its impact on outcomes of pituitary surgery: A systematic review and meta-analysis. *Brain Sci*. 2022;12(10):1354. Doi: 10.3390/brainsci12101354.

Gupta KK, Jolly K, Bhamra N, Osborne MS, Ahmed SK. The evolution of sinus surgery in England in the last decade – An observational study. *World J Otorhinolaryngol Head Neck Surg*. 2020;7(3):240-246. Doi: 10.1016/j.wjorl.2020.10.002.

Homsi MT, Gaffey MM. Sinus endoscopic surgery. In: *StatPearls* [Internet]. Treasure Island (FL): Stat Pearls Publishing; 2024 Jan. https://www.ncbi.nlm.nih.gov/books/NBK563202. Last updated September 12, 2022.
Justice JM, Orlandi RR. An update on attitudes and use of image-guided surgery. *Int Forum Allergy Rhinol.* 2012;2(2):155-159. Doi: 10.1002/alr.20107.

Marchetti M, Sahgal A, De Salles AA, et al. Stereotactic radiosurgery for intracranial noncavernous sinus benign meningioma: International Stereotactic Radiosurgery Society systematic review, meta-analysis and practice guidelines. *Neurosurgery*. 2020;87(5):879-890. Doi: 10.1093/neuros/nyaa169.

Mishra S, Kumar AG, Garg K, et al. Role of stereotactic radiosurgery for cavernous sinus hemangiomas – An individual patient data-based meta-analysis. *Neurol India*. 2023;71(Supplement):S21-S30. Doi: 10.4103/0028-3886.373654.

Oakley GM, Barham HP, Harvey RJ. Utility of image-guidance in frontal sinus surgery. *Otolaryngol Clin North Am.* 2016;49(4):975-988. Doi: 10.1016/j.otc.2016.03.021.

Ramakrishnan VR, Orlandi RR, Citardi MJ, et al. The use of image-guided surgery in endoscopic sinus surgery: An evidence-based review with recommendations. *Int Forum Allergy Rhinol.* 2013;3(3):236-241. Doi: 10.1002/alr.21094.

Singh R, Chen C-J, Didwania P, et al. Stereotactic radiosurgery for dural arteriovenous fistulas: A systematic review and meta-analysis and International Stereotactic Radiosurgery Society practice guidelines. *Neurosurgery*. 2022;91(1):43-58. Doi: 10.1227/neu.0000000000001953.

Von Hofsten P, Bark S, Blank S, et al. Navigationsutrustning som stöd vid endoskopisk sinuskirurgi. [Image-guided system for endoscopic sinus surgery]. Region Västra Götaland, Sahlgrenska University Hospital, HTA-centrum. Report number 2013:60. https://www.researchgate.net/publication/273761926_Navigationsutrustning_som_stod_vid_endoskopisk_sinuskirurgi_Image-guided_system_for_endoscopic_sinus_surgery. Published 2013.

Vreugdenburg TD, Lambert RS, Atukorale YN, Cameron AL. Stereotactic anatomical localization in complex sinus surgery: A systematic review and meta-analysis. *Laryngoscope.* 2016;126(1):51-59. Doi: 10.1002/lary.25323.

Wang Z, Liu C, Tan B, et al. Clinical and economic benefits of image-guided system in functional endoscopic sinus surgery: A retrospective chart review study in China. *Cost Eff Resour Alloc*. 2023;21(1):1. Doi: 10.1186/s12962-023-00414-2.

Wu Y, Fu Y, He Y, et al. The application of enhanced recovery after surgery (ERAS) in chronic rhinosinusitis patients undergoing endoscopic sinus surgery: A systematic review and meta-analysis. *PLoS One*. 2023;18(9):e0291835. Doi: 10.1371/journal.pone.0291835.

Policy updates

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