

## Published clinical evidence demonstrating accuracy when using Stryker's navigation systems for neurosurgical, ENT and craniomaxillofacial procedures

**Austin RE, Antonyshyn OM. Current applications of 3-D intraoperative navigation in craniomaxillofacial surgery: A retrospective clinical review. Ann Plast Surg 2012;69(3):271-8.**

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**Background:** Intraoperative navigation is a tool that provides surgeons with real-time, interactive access to their patient's diagnostic imaging studies while in the operating room. This modality allows for anatomic localization and facilitates intraoperative planning and diagnosis. The application of intraoperative navigation to neurosurgery, otolaryngology, and orthopedic surgery has been well documented; however, only isolated reports have analyzed its potential in the field of craniomaxillofacial surgery. Advancements in 3-dimensional navigational systems have greatly improved the accuracy of the technology, further broadening its scope.

**Methods:** In this article, we evaluate a series of 101 craniomaxillofacial cases in which intraoperative navigation was used. The most common application was for intraorbital cases, such as enophthalmos and acute orbital fracture repairs. Other applications included tumor resection, osteotomy design, pathology localization, and craniotomy design.

**Conclusion:** The major limitations of this technology have been its cost and the fact that it cannot reliably be used for soft-tissue reconstruction currently.

**Bergeron M, Leclerc JE. Is image guidance accurate in children sinus surgery? Int J Pediatr Otorhinolaryngol 2015;79(4):469-73.**

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**Objectives:** To compare the precision of the calibration of a 3D navigation system for endoscopic sinus surgery in children and adults. To compare the complication and calibration failure rates of the system in both populations.

**Methods:** The precision of the calibration of the Stryker navigation system (Stryker Neuronavigation ENT 2.0 Software) was found in the charts of children and adults operated on for various nasosinus procedures between May 2008 and February 2013 in a tertiary care center. Demographic characteristics and complication rates were also noted.

**Results:** Thirty-eight adults and 21 children were included in the study. No statistically significant difference was found between the two groups with an identical mean precision of 0.7 mm ( $p = 0.90$ ). The rate of precision unreliability and calibration failures was not statistically different between the two groups (14% children vs 5% adults). No major complications occurred in both groups ( $p = 1.00$ ). No demographic characteristic predicted a failed calibration (height, weight, BMI, age).

**Conclusion:** The Stryker image-guided system can provide a precision level that is equivalent in both children and adults. This study also demonstrated an absent/low complication rate respectively for children and adults post endoscopic surgery.

**Gui H, Yang H, Shen SGF, Bing X, Zhang S, Bautista JS. Image-Guided Surgical Navigation for Removal of Foreign Bodies in the Deep Maxillofacial Region. J Oral Maxillofac Surg 2013; 71:1563-1571.**

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**Background:** Most trauma surgeons encounter numerous penetrating injuries. Some foreign bodies can cause pain, infection, and discomfort to the patient. Serious functional disorders also are likely to occur. Foreign bodies in critical areas must be removed. This report describes the use of image-guided technology for the removal of foreign bodies deep in the maxillofacial region.

**Methods:** From 2008 through 2011, 5 patients with foreign bodies in the maxillofacial area underwent image-guided removal at the authors' department. The STN navigation system (Stryker-Leibinger, Freiburg, Germany) was used for surgical planning and intraoperative navigation. Preoperatively, computerized tomography and digital subtraction angiography were used to create 3-dimensional views of the region to aid surgeons in more accurately defining the spatial location of the foreign object. During surgery, the foreign objects and surgical instruments were visualized on the screen.

**Results:** In all 5 cases, the foreign bodies were removed by minimally invasive access without any complications. Surgical time was approximately 40% shorter compared with the conventional technique of not using image-guided navigation. A 1-year postoperative evaluation showed that the patients' complaints and symptoms had resolved, function was restored, and esthetics were remarkably improved.

**Conclusion:** Navigation-guided removal of foreign bodies in the complex, deep maxillofacial region in proximity to vital areas can be regarded an ideal and valuable option for these potentially complicated procedures.

**Kim YH, Jung D-W, Kim TG, Lee JH, Kim IK. Correction of Orbital Wall Fracture Close to the Optic Canal Using Computer-Assisted Navigation Surgery. J Craniofac Surg 2013; 24(4):1118-1122.**

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**Background:** Repairing orbital wall fractures can result in serious complications, including enophthalmos, diplopia, or even blindness. Especially, surgeons worry about damaging the optic nerve while dissecting the optic canal area. We avoid these complications by using a navigation system that was adapted to stereotactic concept based on three-dimensional imaging of the patient's anatomy. Here, we report 5 cases of orbital wall fracture that were repaired using a navigation system.

**Methods:** The Navigation System II (Stryker, Freiburg, Germany) and the iNtellect Cranial Navigation (version 1.1) platform were used for each operation. A computer-assisted navigation surgery was performed according to the following procedures: (1) image set, (2) planning, (3) apparatus setup, (4) registration, and (5) intraoperative navigation. Operations were performed under general anesthesia. Dissection was performed up to the periosteum immediately anterior to the optic canal, near the fracture. Vulnerable surrounding structures were identified with the intraoperative pointer. After navigation, we inserted an implant into the defect, successfully, avoiding damage to the optic canal and optic nerve.

**Results:** None of the patients had any surgical complications. Postoperative computed tomography scans demonstrated that the fractures were corrected, and continuity was maintained without displacement. The three-dimensional image allowed us to easily visualize intraoperative anatomical structure, allowing us to avoid unnecessary procedures and to correct the orbital wall. The mean volume of fractured orbital cavity was 29.2 cm(3) (range, 28.3-30.4 cm(3)) preoperatively and 27.0 cm(3) (range, 25.9-28.5 cm(3)) postoperatively; thus, the defects were corrected by 2.2 cm(3) (range, 1.3-2.8 cm(3)) on average.

**Conclusion:** We used a navigation system to perform accurate and safe surgery in patients with extensive orbital wall fractures, including around the optic canal. By using the functions to visualize the locations indicated by the pointer, we were able to perform successful dissections and implantations in areas adjacent to the optic canal. The good outcomes obtained here provide evidence that surgical correction of the orbital wall using a navigation system is useful in cases of deep, extensive orbital wall fracture.

**Markiewicz MR, Dierks EJ, Belll RB. Does intraoperative navigation restore orbital dimensions in traumatic and post-ablative defects? J Craniomaxillofac Surg 2012;40(2):142-8.**

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**Background:** The outcomes of the reconstruction of post-ablative and post-traumatic orbital defects are often unpredictable when considering the restoration of the orbital dimensions. Intraoperative navigation offers the surgeon visualization of bony landmarks via comparison to preoperative computed tomography, aiding in bony reduction and implant placement. The purpose of this study was to assess whether intraoperative navigation-guided orbital reconstruction re-establishes orbital volume and globe projection in subjects with post-ablative and post-traumatic orbital defects.

**Methods:** The investigators initiated a retrospective cohort study and enrolled a sample of subjects that underwent primary or secondary reconstruction for unilateral orbital deformities secondary to traumatic injury or tumor surgery. Pre- and post-operative orbital volume and globe projection were measured using Analyze (Mayo Clinic Biomedical Imaging Resource, Rochester, MN, USA). A matched pairs t-test was used to assess the difference in pre- and post-operative orbital volume and globe projection.

**Results:** Twenty-three subjects underwent intraoperative navigation-guided orbital reconstruction. The mean difference in orbital volume and globe projection between the non-operated orbit and operated orbit in the post-operative period was -1.3 cm<sup>3</sup> and 2.4mm respectively. Both final measurements were within the margin of error of clinically noticeable enophthalmos. The mean absolute difference in orbital volume and globe projection between the pre- and post-operative period was 5.1 cm<sup>3</sup> (p=<0.001) and 4.1mm (p=<0.001) respectively.

**Conclusion:** The results of this study suggest that orbital reconstruction using intraoperative navigation is effective in establishing normal orbital volume and globe projection in post-traumatic and post-ablative defects, therefore restoring the orbit and globe to pre-traumatic and pre-ablative conditions.

**McLaughlin N, Carrau RL, Kassam AB, Kelly DF. Neuronavigation in endonasal pituitary and skull base surgery using an autoregistration mask with head fixation: An assessment of accuracy and practicality. J Neurol Surg A Cent Eur Neurosurg 2012;73(6):351-7.**

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**Background:** Intraoperative navigation is an important tool used during endonasal surgery, which typically requires rigid head fixation. Herein we describe a navigational technique using an autoregistration mask without head fixation.

**Methods:** Prospective evaluation of a surface autoregistration mask used without rigid head fixation in 12 consecutive endonasal endoscopic skull base procedures was performed with patients positioned in a horseshoe head holder. We assessed the accuracy by recording the surface registration error (SRE) and target registration error (TRE). We also noted the time required for installation and the occurrence of system failure. The system's accuracy was validated using a deep target simultaneously viewed with endoscopic.

**Results:** In 12 consecutive endonasal cases performed by a neurosurgeon and ENT team, pathologies included pituitary macroadenomas (9), chordoma (1), craniopharyngioma (1), and sinonasal melanoma (1). Median time required for the registration and accuracy verification was 84 seconds (interval 64 to 129 seconds). The mask stayed on the patient throughout the procedure. The mean SRE was 0.8mm (interval 0.6 to 0.9 mm). The mean TRE was 0.9 ± 0.7 mm and 1.0 ± 0.8 mm measured respectively at the beginning and end of the case. In every case, the system was judged accurate by the surgical team using the sphenoid keel or an intrasphenoidal bony septation as a deep target for internal validation. No system failure occurred during these 12 cases.

**Conclusion:** A facial surface autoregistration mask maintained in place throughout surgery without rigid head fixation allows excellent operational accuracy in endonasal pituitary and skull base surgery. This navigation system is practical, reliable, and noninvasive.

**Weiner GM, Chivukula S, Chen CJ, Ding D, Engh JA, Amankulor N. Ommaya reservoir with ventricular catheter placement for chemotherapy with frameless and pinless electromagnetic surgical neuronavigation. Clin Neurol Neurosurg. 2015;130:61-6.**

**Background:** Accuracy in Ommaya reservoir catheter placement is critical to chemotherapy infusion. Most frameless image guidance is light emitting diode (LED) based, requiring a direct line of communication between instrument and tracker, limiting freedom of instrument movement within the surgical field. Electromagnetic neuronavigation may overcome this challenge.

**Objective:** To compare Ommaya reservoir ventricular catheter placement using electromagnetic neuronavigation to LED-based optical navigation, with emphasis on placement accuracy, operative time and complication rate.

**Methods:** Twenty-eight patients who underwent placement of Ommaya reservoirs at our institution between 2010 and 2014 with either electromagnetic (12 patients) or optical neuronavigation (16 patients) were retrospectively reviewed.

**Results:** Half of the patients were male. Their mean age was 56 years (range 28-87 years). Accuracy and precision in catheter tip placement at the target site (foramen of Monro) were both higher ( $p=0.038$  and  $p=0.043$ , respectively) with electromagnetic neuronavigation. Unintended placement of the distal catheter contralateral to the target site occurred more frequently with optical navigation, as did superior or inferior positioning by more than 5 mm. Mean operative times were shorter ( $p=0.027$ ) with electromagnetic neuronavigation (43.2 min) than with optical navigation (51.0 min). There were three complications (10.7%)--one case each of cytotoxic edema, post-operative wound infection, and urinary tract infection. The rate of complication did not differ between groups.

**Conclusion:** In contrast with optical neuronavigation, frameless and pinless electromagnetic image guidance allows the ability to track instrument depth in real-time. It may increase ventricular catheter placement accuracy and precision, and decrease operative times.

**Yu H, Shen SG, Wang X, Zhang L, Zhang S. The indication and application of computer-assisted navigation in oral and maxillofacial surgery - Shanghai's experience based on 104 cases. J Craniomaxillofac Surg 2013;41(8):770-4.**

**Objective:** To explore the indication and application of computer-assisted navigation in oral and maxillofacial surgery.

**Methods:** One hundred and four patients including 34 zygomatic-orbital-maxillary fractures, 27 unilateral TMJ ankylosis, 29 craniofacial fibrous dysplasia, 9 mandibular angle hypertrophy, 3 cartilage/bone tumours of jaw and 2 cases with facial foreign bodies were enrolled in this study. CT scans were performed and data was saved in DICOM (digital imaging and communications in medicine) format. The osteotomy lines, amount and range of resection, the reduction position of bony segments and the reconstruction morphology was determined and displayed by preoperative simulation with mirroring and superimposing procedures. All operations were performed under the guidance of navigation system. The accuracy of navigation was evaluated by comparing the postoperative CT 3-D model with preoperative surgical planning.

**Results:** Through registration, an accurate match between the intraoperative anatomy and the CT images was achieved. The systematic error checked by computer was within 1 mm. All operations were performed successfully with the guidance of real-time navigation. The mean error between virtual simulation and surgical results was  $1.46 \pm 0.24$  mm. All patients healed uneventfully and function and profile was improved significantly.

**Conclusion:** With the opportunity to perform preoperative planning, surgical simulation and postoperative prediction, computer-assisted navigation shows great value in improving the accuracy of maxillofacial surgery, reducing operation risk and postsurgical morbidity, and restoring facial symmetry. It is regarded as a valuable technique in these potentially complicated procedures.

Study title	Lead author	Device used	Published accuracy (mm)
Current applications of 3-D intraoperative navigation in craniomaxillofacial surgery: A retrospective clinical review	Austin RE	iNtellec; Stryker; Kalamazoo, MI	root-mean square error of alignment < 1 mm was required to proceed with the procedure
Is image guidance accurate in children sinus surgery?	Bergeron M	Stryker Neuronavigation System, ENT 2.0 Software	0.7 mm mean precision for both adults and children
Image-guided surgical navigation for removal of foreign bodies in the deep maxillofacial region	Gui H	Stryker Neuronavigation System; Stryker Leibinger, Germany	<0.8 mm accuracy
Correction of orbital wall fracture close to the optic canal using computer-assisted navigation surgery	Kim Y-H	Navigation System II; Stryker, Germany	0.7 mm mean error
Does intraoperative navigation restore orbital dimensions in traumatic and post-ablative defects?	Markiewicz MR	Intellect Cranial Navigation System; Stryker, Kalamazoo, MI	< 1 mm registration margin of error was considered acceptable to proceed with the procedure
Neuronavigation in endonasal pituitary and skull base surgery using an autoregistration mask with head fixation: An assessment of accuracy and practicality	McLaughlin N	Stryker Neuronavigation System; Stryker Instruments, Kalamazoo, MI	Target Registration Error (operational accuracy):  beginning of case mean $0.9 \pm 0.7$ mm median 1 mm (0.2 – 3 mm)  end of case mean $1.0 \pm 0.8$ mm median 0.5 mm (0.2 – 3 mm)
Ommaya reservoir with ventricular catheter placement for chemotherapy with frameless and pinless electromagnetic surgical neuronavigation	Weiner GM	iNtellec Cranial Navigation, Stryker Cranial Navigation, USA	$\leq 5$ mm of target site along x, y, and z axes in 62.5% of patients; $\leq 5$ mm of average position of the distal catheter along x, y, and z axes in 88.6% of patients
The indication and application of computer-assisted navigation in oral and maxillofacial surgery - Shanghai's experience based on 104 cases	Yu H	Stryker navigation system; Stryker Leibinger, Germany (7/104 patients)	"The navigation system error measured by computer was less than 1 mm after registration."

## Navigation

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