ORIGINAL ARTICLE

Navigation with the StealthStation™ in Skull Base Surgery: An Otolaryngological Perspective

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ABSTRACT

The introduction of computer-assisted navigation systems has played a significant role in assuring the integration and consistent intraoperative use of radiological information. We used a frameless stereotactic navigation system to treat 62 patients with a variety of skull base pathologies. The optoelectric appliance uses digital imaging information to locate surgical instruments in the operative area. The aim of this study was to evaluate the clinical accuracy, practicality, and impact of this navigation system on otolaryngological procedures. In conjunction with rigid head fixation and bone-anchored registration markers, the precision of registration was 0.8 mm and the accuracy of clinical measurements was less than 2 mm. With conventional fiducials and flexible head positioning, deviations were as large as 4.5 mm. The additional use of surface registration increased the precision of registration. Preoperative preparations took 15 to 35 minutes, depending on the complexity of the planning. Intraoperative computer support is an important aid to a surgeon's orientation, especially when a patient's anatomy is atypical. Navigation systems will likely improve the quality of surgery and facilitate training.

KEYWORDS: Navigation, computer-assisted surgery, image-guided surgery, skull base surgery, frameless stereotaxy

During the last few decades, minimally invasive techniques have initiated far-reaching changes in ear, nose, and throat (ENT) surgery. Operative techniques have been developed for numerous indications. Smaller routes of access and use of the natural space in the head and neck area have made procedures less traumatic. However, restricted access often implies reduced visibility, thus

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impairing conventional orientation. Especially when tumors, malformations, trauma, or previous operations distort the anatomy and destroy common anatomical landmarks, unequivocal identification and orientation can be difficult to achieve.

Typically, surgeons convert two-dimensional (2D) images into a spatial perception, which they transfer to the surgical site. When anatomy is distorted, this perceptual task can be complex, even for experienced surgeons. Computer-assisted surgery (CAS) represents the link between preoperative imaging and the surgical site and has been introduced to different surgical disciplines in the last few years.[1–6] Frame-based stereotaxy has already been superseded by frameless navigation systems in many neurosurgical clinics, but the special demands of ENT surgery initially have prevented their extensive application.[7] Today, however, systems are available that enable their routine use in this area. This study therefore investigated the clinical scope, limitations, and benefits of frameless stereotactic navigation in head and neck surgery.

MATERIALS AND METHODS

The StealthStation™ (Medtronic-Sofamor Danek™, Memphis, Tenn, USA) was used in the surgical treatment of 62 patients (mean age, 49.3 ± 15.35 years; range, 29 to 74 years; 35 males, 27 females; Table 1).

The StealthStation (Fig. 1) is based on the location of instruments with infrared light-emitting diodes (LEDs). The impulses are detected by a charged-couple device camera system (Image Guided Technologies IGT™, Boulder, Colo, USA). Two cameras are located on a freely swivelling base. A workstation (processor R 10,000 MIPS; 192 MB RAM; 250 MHz, 4-GB hard drive, UNIX operating system) with a high-resolution 21-inch monitor is integrated into a rack with emergency power accumulators. The data can be transferred via network, magneto-optical disc

Table 1 Incidence of Pathology in 62 Patients

Disorder	Number of Patients
Ethmoiditis	8
Pansinusitis	7
Panpolyposis nasi	15
Polyposis nasi revision	21
Inverted papilloma	4
Adeno-Ca ethmoid bone	1
Endocrine ophthalmopathy	1
Acoustic neuroma	5

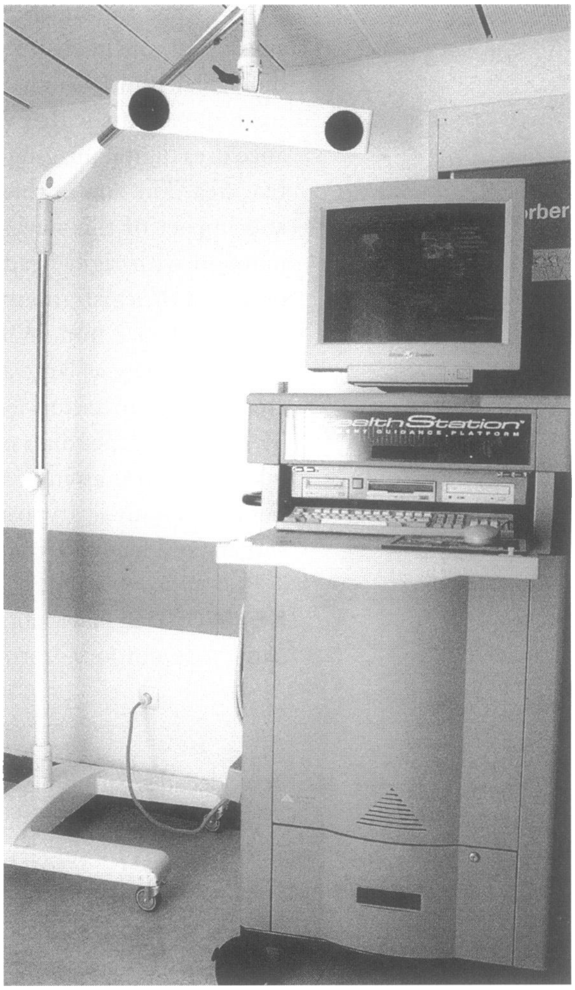

Figure 1 StealthStation™ navigation system: camera system, workstation, and monitor.

(MOD), or 4-mm digital audiotape (DAT). Instruments fitted with LEDs are available as pointers in various shapes and lengths (Fig. 2). A straight punch can be integrated into the system during surgery on the ethmoid bone (Fig. 3). The system is able to detect two instruments simultaneously. During the study, integration with a microscope was not yet possible. The camera system detects both passive instrument markers and LEDs. Infrared impulses are reflected by passive-marker spheres mounted on the surgical instrument. However, these spheres were unavailable during the study. For operations without head fixation (e.g., surgeries on the paranasal sinuses) an LED-fitted headset was used as a prototype (Fig. 4) to ensure dynamic head tracking. The system was able to calculate changes in the patient's position in almost real time and without the need for re-registration.

Diagnostic imaging is the starting point for preparing for a skull base operation. Registration markers must be fitted to patients before scans are obtained to allow registration of image data to the positioned patient in the operating room. Because of the elasticity of the skin, the use of fiducials is susceptible to substantial inaccuracies. For this reason, bone-anchored markers such as osteosynthetic screws (Microplus™, Leibinger™, Freiburg, Germany) were implanted for operations on the lateral skull base. For endonasal operations, only computer tomography (CT)-compatible fiducials (IZI Medical Products™, Baltimore, Md, USA) were used, placed in areas subjected to as little skin mobility as possible.

Figure 2 Pointer instrument with light-emitting diodes, head tracking, and attached to the Mayfield clamp.

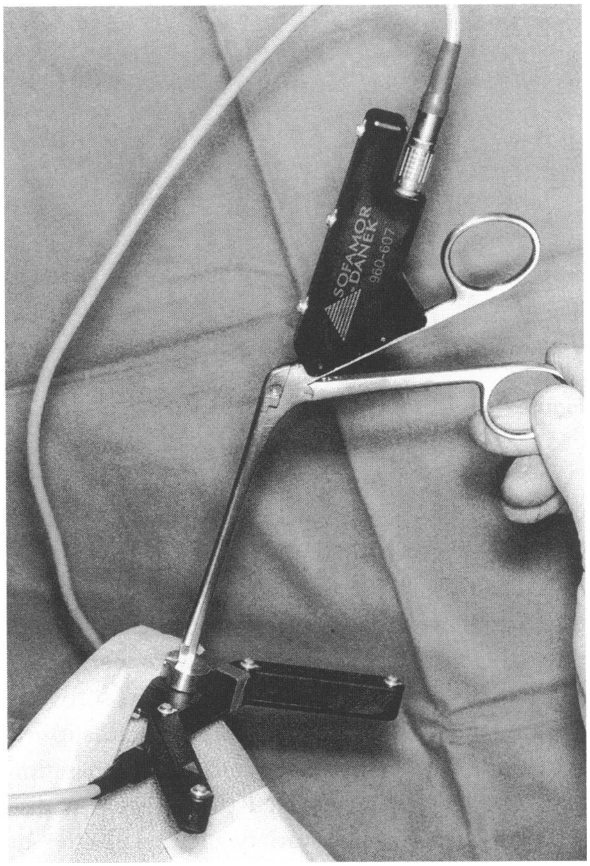

Figure 3 Calibration of ethmoid bone punch.

Imaging was performed after the registration markers were applied. Image data from CT, magnetic resonance imaging (MRI), or digital subtraction angiography can be transferred to the system. Data were transmitted by means of an MOD. The preferred imaging modality for osseous skull base navigation was spiral CT (General Electric™, Highspeed Advantage™, Milwaukee, Wis, USA); slice thickness was 1 mm; table projection, 2 mm; and reconstruction interval, 2 mm). The resulting pixel size of 0.49 mm enabled about 0.4 mm accuracy at an effective slice thickness of 1.8 mm. The use of low-dose scan protocols (25-cm field of

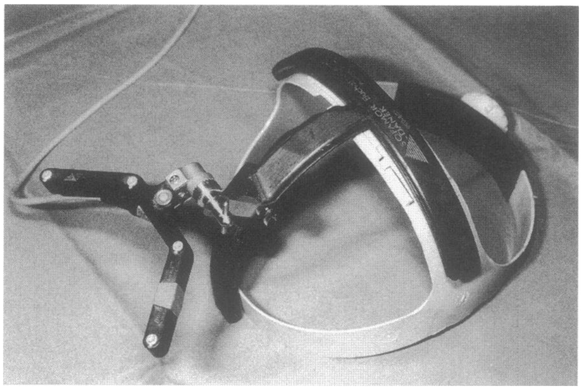

Figure 4 Headset for dynamic registration.

view, 140 kV, 40 mA, bone reconstruction interval, 180-degree reconstruction profile) involved a radiation load similar to that associated with conventional skull overview exposures.[8] Segmentation and three-dimensional (3D) editing were performed automatically by the navigational system's software. Subsequently registration points were identified and marked in layers. The automatic generation of a 3D data record enabled the surgeon to display the anatomy in a variety of ways. Different structures could be color-coded and desired sections could be generated preoperatively. It was possible to establish an entrance point and a target point to determine a trajectory. The virtual extension of the pointer tip permitted "predictive" preparation.

To use the imaging data for surgical navigation, the patient's registration markers must be correlated with those from the radiological data. This registration is achieved by means of the spatial relationship between the individual points. Changing the registration by displacing the head clamp or the headset must be avoided. When using fiducials, registration was performed against the sterile covering. The relative success of the registration procedure was indicated by the root mean square error (RMSE), which was automatically generated by the navigation system. This value represented a metric measure of the correlation between radiological and patient-specific data. Erroneous or inaccurate registration values are automatically displayed. In addition to this point-to-point registration (point merge), surface registration (surface merge) is possible.

After point registration was performed with reference to the placed markers or anatomical landmarks, 40 points on the skin surface were correlated with the corresponding points of the radiological data. After the comparison, navigation proceeded largely in real time. The locating procedure can be differentially displayed in the data records (Fig. 5). A trajectory can be displayed, in addition to axial, sagittal, and coronary incisions. Before the operation begins, a so-called plausibility test must be performed. This test involves making "stops" at anatomical landmarks (e.g., radix nasi, teeth, epicantus, tragus). These stops are correlated with the sectional display of the orientation system. The system is operated using a mouse, keyboard, and foot pedal.

Endonasal procedures were performed using a combination of microscopic and endoscopic techniques (OPMI 111® or ORL®, Carl Zeiss, Oberkochen, Germany; Hopkins® optics 0 degrees, 30 degrees, 70 degrees, Karl Storz, Tuttlingen, Germany). Lateral skull base procedures were performed with the aid of a surgical microscope (CSI®, Carl Zeiss, Oberkochen, Germany).

The additional time required to use the navigation system was determined. The accuracy of registration using a different marker system and various head positions was evaluated. The intraoperative precision of the navigation system was determined using anatomical landmarks. The deviations in localization caused by the navigation system were calculated at the workstation.

RESULTS

Initial trials with fiducials showed that the elasticity of skin caused a displacement as large as 3.5 mm. These accuracies were unacceptable,

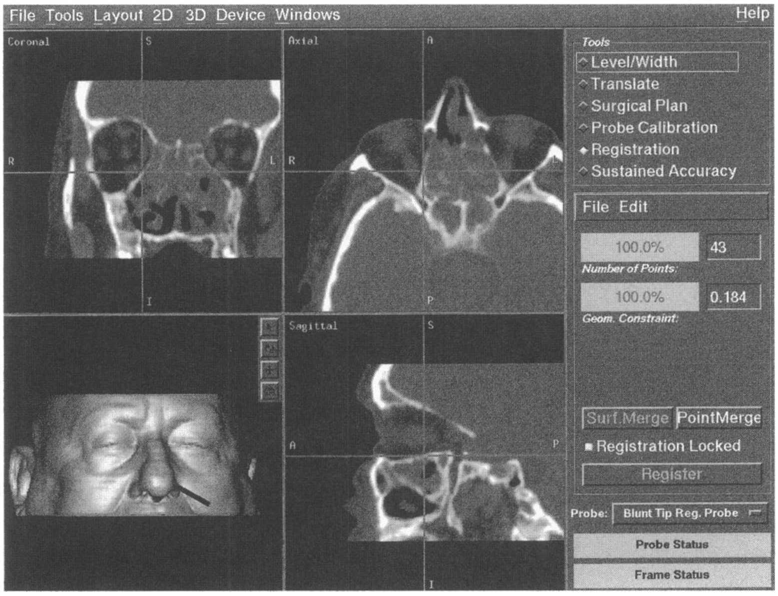

Figure 5 Monitor with three-dimensional and orthogonal section display.

showing that the application of noninvasive fiducials was inadequate. The bone-anchored markers, which were used during the preparation and imaging of patients with lesions in the lateral skull base area, improved accuracy. Under local anesthetic, five osteosynthetic screws were placed in the area of the planned incision. For patients with inflammatory disorders of the paranasal sinuses, no additional foreign material was implanted and noninvasive fiducials were used.

After an appropriate practice phase, the total length of time required to enter each patient's data into the workstation, to perform segmentation, and to plan surgery ranged from 15 to 35 minutes.

The navigation system must be positioned to the sight line of the camera system. Anesthesiology equipment, surgical team members, and the surgical microscope can obstruct this "line of sight" between the camera system and the LEDs on the instruments. Pre-emptive planning of the site and intraoperative alteration of the camera's position may be needed. The camera can be adjusted within a radius of about 1.2 m without the need for re-registration.

When a high-resolution CT scan of the temporal bone, bone-embedded registration markers, and head fixation with a Mayfield clamp (five patients) were used, registration was accurate to 0.76 mm (RMSE, Table 2). This purely arithmetical mean indicates the degree of correlation between the radiological and anatomical data. Intraoperative precision, determined from anatomical landmarks (e.g., "messenger's blue line," fallopian aqueduct, umbo, teeth, spina nasalis), was subject to deviations ranging from 0.7 to 1.4 mm. The use of eight to ten fiducials and head fixation (38 patients) yielded a RMSE of 1.72 mm. Intraoperative accuracy was between 1.4 and 2.3 mm.

Head fixation during endonasal operations proved inconvenient; therefore, 19 surgeries were performed with flexible head positioning, fiducials, and dynamic registration. It proved impossible to adjust the first prototype of the headset sufficiently when working with smaller head diameters. Further improvement and experience are required in terms of the degree of motility (caused by the synthetic material, which provided insufficient frictional resistance) and positioning of the back of the

Table 2 Registration Accuracy of the Frameless System during Navigation-Aided Surgeries

Registration	Number of Patients	RMSE	Std. Dev.
Screws + head fixation	5	0.76 mm	0.17 mm
Fiducials + head fixation	38	1.72 mm	0.27 mm
Fiducials + dynamic registration	19	1.76 mm	0.31 mm

RMSE, root mean square error; Std. Dev., standard deviation

head on the adjusting mechanism of the headset. Significant displacements followed alteration of the head position; observed deviations were as large as 4.5 mm.

Additional use of surface registration, in conjunction with the use of fiducials, increased registration accuracy a mean of 0.28 mm (± 0.16 mm) RMSE. This procedure should be performed with great care because considerable deviations can arise due to the motility of the skin. Integration of a foot pedal for the registration process proved to be very useful. However, the intraoperative control of the system was problematic. To dispense with an additional member of the surgical team to handle the mouse, a mouse was sterilized before use and placed on the instrument table. About 30 resterilizations were possible. No technical problems were associated with this procedure.

Integration of the ethmoid bone punch, an active instrument through which online navigation was possible, also proved problematic. The instrument had to be calibrated for each operation, which involved pivoting the point of the instrument for several seconds in a groove of the registration arc on the headset. The accuracy was comparable with that of conventional pointer instruments. The system automatically recognized individual instruments. It proved ergonomically useful to integrate the images from the microscope or endoscope via a video card and to implement this information onto the display of the navigation monitor. This strategy prevented the need for an additional monitor in the already cluttered operating theatre.

DISCUSSION

The aim of navigation technology is to provide a more efficient use of preoperative, high-resolution imaging and its direct integration into surgical procedures. More precise and better-controlled surgical procedures are made possible through the use of image-guided operating systems. It is important to conserve the functionality of the surgical region of interest and adjacent tissues. To do so necessitates maximizing resection while minimizing surgical invasiveness.[9]

Do current navigation systems meet these demands? Can CAS reduce operating times? An answer based on controlled, prospective, and randomized studies with an appropriate control group is not yet available. Because of the variety of pathologies, individual variations in anatomy, and unrelated intraoperative complications (e.g., bleeding tendencies), it is unrealistic to expect statistically significant results from the navigational studies.

Navigational systems are one of a variety of surgical adjuncts. In general, current systems lack robotic functions, rendering the importance of a surgeon's previous experience a parameter that is difficult to determine. However, the surgeon's experience considerably influences the outcome of navigation-assisted surgery. Neurosurgical reports[5,10,11] suggest that CAS represents a significant aid to surgeons, particularly in anatomically complex regions. Because of the anatomical complexity of the skull base with a large number of crucial structures near each other, each of which is only a few millimeters in size, navigation systems used for skull base surgery must be accurate to one millimeter or less.[12,13] The technical precision of currently available navigation systems ranges from 0.1 to 0.5 mm. Intraoperative accuracy, however, is dictated by additional parameters: imaging, registration, head tracking, and intraoperative transposition.

The basis of navigation should be accurate imaging data which, by minimizing the thickness and distance between slices, keep the interpolation error as low as possible during 3D segmentation.[8,14] In our opinion, registration (i.e., correlation of the radiological data with the patient's anatomy) represents the biggest problem. The need to identify precisely defined points in all three planes must be reconciled with the need to minimize costs and the strain placed on the patient.

As in other studies,[5,13,15] we could only achieve the required accuracy by using bone-anchored screw markers. The procedure is made more difficult by cosmetic concerns in exposed areas, the strain imposed on the patient during an operation under local anesthetic, and the additional logistical and financial expenditure. Because of skin motility, fiducials do not constitute an ideal basis for registration.[16,17,18] Our patients usually were imaged on the day before surgery. Consequently, an additional waterproof marking had to be applied to the registration markers to allow potential displacements to be detected and corrected. In addition to the attentive placement of markers in areas subjected to the lowest possible skin motility, markers were placed in regions near the surgical site to ensure identification in all three spatial planes. Surface registration is time-consuming but increases accuracy considerably when performed with care.[19,20]

Whereas operations in the middle cranial fossa are routinely performed at our clinic using fixation with Mayfield clamps, head fixation during endonasal surgeries is complicated. The prototype of a headset for head tracking provided inadequate stability. Systems that integrate the upper jaw as a stabilizing element would appear to be more useful for these indications. The VBH (Vogele-Bele-Hohner) mouthpiece[15,21] and so-called upper jaw splint have been studied.[18,22] Noninvasive head supports (i.e., according to Sandstrom[15]) that use the nasion, external auditory canal, vertex, and occiput as "stops" also appear better suited to attaining accuracies of 1 to 1.5 mm.[15] The adjustment of the upper jaw mold with a polyether paste, however, entails about 10 more minutes of preparation and the extra material costs about 40 U.S. dollars.

In our view, the bony skull base is the ideal site for applying CAS. Intraoperative changes, which through the action of "brainshift" can lead to considerable transposition of soft tissue structures,[5,10] rarely occur. The expensive and time-consuming integration of intraoperative imaging such as MRI, CT, or ultrasonography is seldom needed to recalculate the degree of transposition. No current navigational system is able to calculate the proportion of tissue already removed without re-imaging. New technical solutions will be required in the future.

Although more time was required for preoperative preparations, the use of intraoperative navigation benefited both experienced and inexperienced surgeons at our clinic. Three-dimensional visualization was most helpful during preoperative planning. Significantly altered anatomical conditions or heavy bleeding during the surgery made the efficacy of intraoperative navigation apparent to both attending surgeons and assistants. During surgery continued skepticism about the accuracy of the system and repeated validation of registration are necessary. The system alone cannot determine and enable intraoperative changes in the registration points. In this respect, current navigation systems cannot replace the experience of the surgeon; the visualization, however, improves the surgeon's 3D perception of the patient-specific anatomy and pathological anatomy in relation to the surgical instruments.[23–26]

The indications for the integration of CAS are malformations, enlarged tumors, and previous operations, because anatomical landmarks in these conditions cannot be recognized or can only be identified with great difficulty.[27–29] The opportunities presented by preoperative planning and intraoperative correlation with radiological cross-sections facilitate learning new operations and access routes.[12,14] The technology also could be applied to access routes with associated restricted visibility, biopsies, and surgical exploration for foreign bodies.[30-33]

The use of high-tech equipment implies additional expense, and navigation cannot be justified in these times of limited health resources if it also necessitates additional staffing. It should be possible for the system to be operated by the surgeon or scrub nurse.

The StealthStation™ requires the use of a mouse. Sterilization of the mouse for surgical procedures is far from an ideal solution. Voice control, remote control, or a touch pad (the last is recently available) are all preferable solutions.

At the time of this study, it was not yet possible to link the system to a microscope. For lateral skull base procedures, an autofocus would be useful as a locational instrument because conventional instruments could then be used. For paranasal sinus surgery, however, an autofocus would be a hindrance because the microscope would focus on the surface of the blood and not on the anatomical structure.[12] The use of the navigated ethmoid bone punch limited the use of other pointer instruments. Although it is possible to locate a structure with a pointer, such a procedure does not constitute navigated surgery. The location of "active instruments" that can potentially cause damage appears important if "online navigation" is to be of value. The need for universal integration of instruments should influence further developments in navigational systems. Since the beginning of 1999, the StealthStation has been developed and sold for use in the ENT field by Medtronic Xomed™ (Jacksonville, Fla, USA) as LandmarX™. A microscope link has now been successfully integrated.

CONCLUSION

Challenges for the smooth integration of frameless navigational systems into routine ENT surgeries still exist, and further development of the available navigation systems is obligatory. Encouraging results, as reported in this article and other studies,[1,6,13,19,20,24,27,31,34] suggest that the use of navigation will become standard practice in ENT surgery in a few years' time.

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