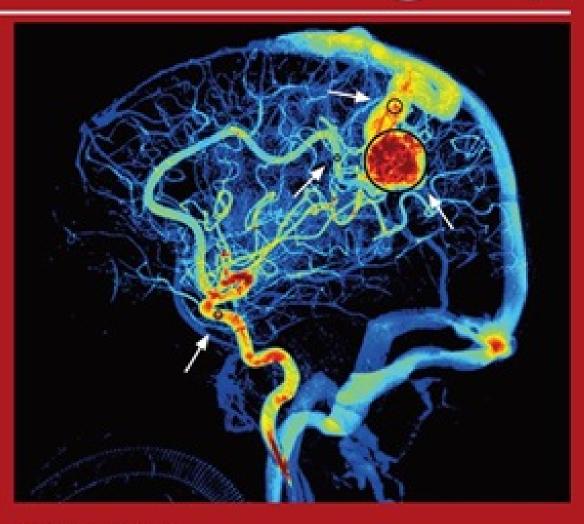
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In Vivo Accuracy Testing and Clinical Experience with the ISG Viewing Wand

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Abstract

A frameless stereotactic system (the Viewing Wand; Elekta Instruments, Atlanta, GA) has been developed for use with preoperative computed tomography, magnetic resonance imaging, and positron emission tomography as an adjunct for surgical planning and intraoperative navigation. This clinical study was designed to evaluate the safety, efficacy, and accuracy of the Viewing Wand in a variety of intracranial procedures.

We used this system in 250 patients undergoing a wide range of neurosurgical procedures from July 1990 to July 1994, to assess its clinical usefulness and safety. In a subset of 45 neurosurgical patients studied between March 1993 and March 1994, a battery of objective accuracy measurements was obtained before and during surgery.

In this series, there were no instances of adverse outcomes attributable to the use of this system. A comparison of two alternative patient-image registration techniques established that the fiducial-fit method was slightly more accurate than the surface-fit method (geometric means = 2.51 and 3.03 mm, respectively). The clinical accuracy achieved with magnetic resonance imaging was nearly equivalent to that with computed tomography.

On the basis of this clinical series, recommendations are made regarding preoperative scanning parameters, registration techniques, and methods for reestablishing registration if needed during the course of surgery. The primary clinical benefits of the wand in this series were improved intraoperative navigation and surgical safety. For most cases, the wand was also useful in planning the location and size of the scalp incision, craniotomy, or corticotomy, as well as the extent of surgical resection.

The advances in radiographic imaging techniques that have occurred within the past 2 decades have revolutionized our abilities to visualize the central nervous system and adjacent structures noninvasively. Although image acquisition commonly generates three-dimensional data sets, limitations in user interfaces generally require that this information be presented clinically as a series of two-dimensional images. Consequently, during preoperative planning and intraoperative navigation, surgeons are required to transform this wealth of two-dimensional information qualitatively into a mental three-dimensional understanding of individual patient anatomy. "Frameless stereotactic" systems have been developed to improve intraoperative access to three-dimensional imaging data by using interfaces that facilitate neurosurgical navigation without obstructing the surgical field (1-3, 5-7, 9, 11-15). In this report, we present our surgical experience with use of a navigational system in a clinical series of 273 procedures performed between July 1990 and July 1994. We also report the results of objective correlational accuracy testing performed prospectively in a subset of 45 neurosurgical patients within the larger series, including comparative accuracy data for two alternative patient-image registration methods as well as preoperative computed tomography and magnetic resonance imaging (MRI).

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MATERIALS AND METHODS

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Stereotactic system

The stereotactic software, created by ISG Technologies, Inc. (Mississauga, Ontario, Canado), is implemented on a Hewlett-Packard Apollo Series 700 UNIX workstation. This workstation is interfaced with the FARO Surgicom (FARO Medical Technologies, Orlando, FL), a passive, articulated mechanical arm that is used to make the stereotactic spatial measurements (Fig. 1). The arm was constructed with 2 d.f. at each of three joints. A short(7.5 cm) or long (15 cm) metallic probe is attached to the arm at the last joint. Sensors at each of the six rotational axes pass information about the relative angles of the arm segments to the computer via an analog-todigital conversion board. These data are used in conjunction with known geometric information about the arm and the probe to solve for the spatial position and orientation of the device trigonometrically. The probe tip(Fig. 1) is used as the point of interest for stereotactic localization. This combined system, with a high-resolution monitor, is available commercially from Elekta Instruments under the product name The Viewing Wand (Fig. <u>2)</u>.

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Data presentation

Stereotactic data may be displayed on the computer monitor in a number of ways. A three-dimensional view of the probe can be displayed on the screen along with reconstructed computed tomographic (CT), MRI, or positron emission tomographic (PET) imaging data, thus presenting the actual position and orientation of the real probe in relation to the head of the patient. For optimal visibility, the probe image is displayed with a blunt tip on the computer screen.

The CT, MRI, or PET imaging data can also be displayed in three orthogonal planes intersecting at a single voxel that represents the current location of the probe tip. In this mode, crosshairs represent the position of the probe tip on axial, coronal, and sagittal views. Additionally, an oblique projection can be displayed along the trajectory of the probe, providing a plane of view analogous to that achieved with intraoperative ultrasonography.

Multiple images can be superimposed to permit simultaneous display of data from different imaging modalities. This permits inspection of a precise point in the brain intraoperatively through the concurrent use of computed tomography, MRI, and PET data.

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Patient selection

Approval for this clinical investigation was obtained from our local Institutional Review Board before proceeding with patient enrollment. Patient selection was at the discretion of participating surgeons; however, patients known or suspected to have Creutzfeldt-Jakob disease were excluded from the study. Informed consent was obtained from each patient before preoperative image acquisition.

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Preoperative data acquisition

Each patient was evaluated with a CT or MRI examination after placement of seven to nine hydrogel multimodality markers (IZI Medical, Baltimore, MD) on the face and/or scalp. The CT scans were performed using 3-mm slice thickness, 3-mm table incrementation, 125 kVp, 450 mAs, and 4-second scan time. The MRI examinations were performed using a standard spoiled gradient recalled acquisition at steady-state three-dimensional scan with a TE of 5 ms, a TR of 35 ms, a 45-degree flip angle, one excitation, a 24-cm field of view, a slice thickness of 1.5 mm, and a matrix of 256 × 128. After reconstruction of the relevant structures, the data were then

transferred to the stereotactic workstation. For image reconstruction and presentation, the Viewing Wand software uses a combination of preprocess and on-the-fly data interpolation to achieve an optimal balance of image quality and computation time.

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Intraoperative positioning

The computer system, including its three-dimensional data, display screen, and the mechanical arm, was then moved to the operating room. Patients were routinely immobilized in a Mayfield headholder, and the mechanical arm was attached to the operating table close to the head so that the probe tip could easily reach the operative site. A rigid, mechanical connection was established between the Mayfield head frame and the base of the FARO arm, such that any adjustments in the position of the operative table or movements of the head during the course of surgery would be communicated to the arm, thus maintaining the head of the patient and the mechanical arm in the same relative positions.

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Patient-image registration

Once the patient was positioned appropriately for the planned surgical procedure, patient-image registration was performed to convey to the computer the precise three-dimensional location and orientation of the subject with respect to the probe tip in real space, thus permitting the position of the probe tip to be displayed on the computer monitor along with the corresponding anatomic data obtained with the preoperative scans. Two related registration methods were evaluated.

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Fiducial-fit registration method

In the first method tested, each registration fiducial marker on the subject was touched with the tip of the probe (Fig. 3). At the same time, the corresponding representation by the marker on the computer image was identified by a mouse-driven cursor on the screen. This resulted in a point-pair file that contained the real-space and image-space locations of each of the markers. By using rigid body translational and rotational motions and isotropic scaling, a least squares fit was performed between these groups of corresponding point pairs, resulting in a linear transformation matrix that was used to transfer the real-space coordinates from the arm into the data-space coordinates of the reconstructed imaging data. The actual algorithm used is an adaptation of a singular value decomposition process (10).

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Surface-fit registration method

The second registration process also began with a point-by-point correlation of corresponding locations. In this case, however, instead of markers, the points used were anatomic locations that could be identified both on the patient and on the three-dimensional reconstruction. Any distinct anatomic surface landmark, such as the medial and lateral canthi, nasion, and tragus, can be used for this purpose. Because there are inherent ambiguities involved in using facial features for registration (the process often involves choosing areas instead of specific points), a further refinement of this registration was needed. This was achieved by performing a surface fit between the surface anatomy of the patient and the outer surface of the reconstructed data. A large number of points (i.e., 80-120 points) along the contours of the patient's head were digitized and stored in the computer. The locations of points used in this technique were constrained only by the requirement that they had to be on the surface of the head of the patient within the slice stack. The entire registered data set thus consisted of a few selected anatomic landmarks and many surface points. The computer was then used to obtain an initial rough registration from the digitized anatomic landmarks by the same procedure as already described. With this initial registration, the surface points were transformed into the data space coordinates of the reconstructed patient image. The computer then performed the same set of rotation, translation, and scale operations by

using a singular-value decom-position algorithm as in the previous registration procedure but this time with the objective of minimizing the average least squares distance between each individual point and the location on the surface of the model that was closest to the transformed point. This process is analogous to fitting a skintight, custom-made hat back onto the patient's head. The result is a much better fit than could be obtained by fitting anatomic features alone.

Several measures were implemented to ensure that the algorithm functioned even with suboptimal data. At each iteration, points that were >4.0 mm (a user-configured parameter) from the surface of the model were discarded. This ensured that false measurements and measurements in areas in which patient anatomy had been distorted did not skew the final fit. In addition, the computer was programmed to ignore points that were outside the slice stack or too near the edge. In this way, the algorithm avoided fitting points to artificial edges or surfaces that were formed at the boundaries of the reconstruction when the slice stack did not encompass the entire object to be fitted. The fitting procedure also ignored the scale factor derived by the algorithm in favor of that given by the CT or magnetic resonance (MR) scanner. This was done to avoid the "shrinking sphere" effect in which a surface that is traced too firmly causes the scale to shrink to fit the data better. Surface fitting is particularly prone to this effect because of difficulty in obtaining points exactly on the surface of soft tissues that yield to pressure. For both of the registration methods, a visual check of the registration was made by touching widely separated identifiable anatomic points on the surface of the head of the patient with the probe tip and confirming the accuracy of positions indicated on the computer screen.

The registration process was performed by the same trained technician for all cases in this series; it was usually accomplished within 15 minutes while other members of the surgical and anesthetic teams established vascular access, set up monitoring devices, and performed other requisite preoperative tasks. Thus, this process contributed little to the duration of anesthesia and was minimally disruptive.

Accuracy testing

A random subset of five to seven fiducials was used for patient-image registration. Once this was accomplished, the other available fiducials were used to assess correlation accuracy, a measure of how well the imaging data set can be matched to the anatomy of the patient in the operating room. The tip of the probe was placed in the center of the fiducial, and the spatial coordinates, with respect to the mechanical arm, were recorded. The probe was then manipulated while the screen was observed until the crosshairs indicating the position of the tip were located in the center of the fiducial on the CT or MR data set. This new position was digitized also. The distance between the real center of the fiducial and the indicated center was computed from these two coordinates. In some cases, it was not possible to position the crosshairs correctly on the screen for every test fiducial because it would have involved moving the probe inside the head of the patient. The data for the problematic test fiducial were discarded in these cases. Correlation accuracy measurements were obtained by use of this procedure with the same fiducials for both of the registration methods described, and the better of the two registration data sets was selected for use during the operation. Two points were then marked on the Mayfield head frame, and their positions in space relative to the mechanical arm were digitized.

After registration and initial accuracy measurements, the probe was detached from the mechanical arm and was steam-sterilized. The operative field was established, and a sterile plastic drape was placed over the mechanical arm. Once sterilized, the probe was attached to the draped mechanical arm.

After a skin incision was made and the calvarium was exposed, three or four small holes were made through the outer table of the cranium of the patient with the aid of the surgical drill. The probe tip was placed on these marks, and their positions, with respect to the mechanical arm, were digitized. During the course of the surgery, the use of the wand was preceded by placing the tip of the probe on one of these marks. The apparent distance from the original position at the beginning of surgery was calculated and recorded. Had this distance exceeded the limits of accuracy deemed necessary by the surgeon(generally 2.0-5.0 mm), registration could

have been quickly reestablished by touching and digitizing the new positions of the cranial marks. The computer then could have recalculated the transformation matrix to compensate for the measured positional drift of the head of the patient. It was not necessary to perform this adjustment during this investigation in any of the patients for whom accuracy measurements had been obtained. At the end of the procedure, just before the skin flap was closed, the probe was once again placed in all four holes and the distance from the original location was calculated and recorded as a measure of the stability of the methods used for fixation of the head and the mechanical arm. Similarly, immediately before the patient was removed from pins, the probe tip was again placed on the two marks previously made on the Mayfield headholder, and distances from their original positions in space were calculated and recorded.

In summary, at least four types of accuracy data were recorded for each surgical procedure: 1) initial registration accuracy of the fiducial marker registration method, 2) initial registration accuracy of the surface-fit registration method, 3) positional drift of the head of the patient with respect to the stereotactic probe during the course of surgery, and 4) positional drift of the Mayfield headholder with respect to the stereotactic probe during the course of surgery. All of these measurements were made with respect to points defined on the basis of the mechanical arm coordinate system and were therefore independent of any registration or reconstruction procedures. These accuracy data were recorded prospectively for 45 patients between March 3, 1993, and March 2, 1994.

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Statistical method

The distributions of the accuracy measurement data were positively skewed(i.e., lognormal distributions). A logarithmic transform was therefore used to normalize the distributions. The geometric means and their confidence intervals are used to present these data.

Subjective assessments

To supplement the objective measurements of total system accuracy, questionnaires evaluating the potential benefits or adverse outcomes from use of this frameless stereotactic system were completed by the attending surgeon on the day of surgery for the cases in this series. The form comprised 29 questions by which the surgeon rated the impact of use of the system on a variety of surgical variables. Additionally, after patient discharge, the attending surgeons were asked whether any postoperative data had become available (e.g., postoperative scans) to modify their initial impressions about use of this system.

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RESULTS

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Patient population and surgical cases

During the 4 years from July 1990 to July 1994, the Viewing Wand was used in 273 surgical procedures for 250 patients ranging in age from 4.5 months to 73.2 years. Because of recurrent disease or planned staged procedures for extensive or multiple lesions, 19 patients each underwent two operations and 2 patients each underwent three procedures. There were 135 male and 115 female patients (ratio, 1.17). The frameless stereotaxy system was used by 23 surgeons at the Johns Hopkins Hospital; however, 75% of the procedures were performed by 3 of these surgeons.

Neurosurgeons performed 94% of the procedures, and the remaining 6% were performed by otolaryngologists, plastic surgeons, or ophthalmology surgeons. Table 1 and 2 summarize the cases in this series according to pathological diagnosis and operative site, respectively. In these patients, there were no potentially harmful effects or adverse outcomes attributable to the use of the wand.

Objective assessments of system accuracy

With the two registration methods, 86 sets of accuracy measurements were performed in 45 patients. For the fiducial-fit and surface-fit methods, the initial registration accuracy was 2.51 and 3.03 mm, respectively (geometric means; upper limit of 95% confidence bounds = 3.67 and 4.16 mm, respectively). The positional drift of the head of the patient with respect to the stereotactic probe during the course of surgery was 2.21 mm (geometric mean of 119 measurements in 45 consecutive patients; upper 95% confidence limit = 3.34 mm). Similarly, the geometric mean positional drift of the Mayfield headholder with respect to the stereotactic probe during the course of surgery was 2.14 mm (upper 95% confidence limit = 3.28 mm). The accuracy measurements for frameless stereotaxy based on computed tomography and MRI were comparable. These data are summarized in Table 3.

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Subjective assessments

Forty-two of 45 postoperative questionnaires were completed and returned by the attending surgeons. There were no adverse outcomes attributed to the use of this frameless stereotactic system in this series. The device was deemed helpful or very helpful in 93% of the cases evaluated by this method. Some illustrative benefits reported in this series are listed in Table 4. In no case did postoperative data change the initial impressions reported on the questionnaire. In one case, the use of the wand was discontinued at the outset of the surgical procedure because the head of the patient slipped in the Mayfield headholder after registration was complete. Although this problem was correctable, the surgeon chose not to delay the start of the procedure to repeat the registration process.

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Illustrative patients

Patient 1

A meningioma arising from the cribiform plate in a 72-year-old woman was electively approached through a right frontal craniotomy. The wand was used to identify precisely the location and extent of the frontal air sinus and therefore to avoid it during surgery while optimizing the exposure to the tumor (Fig. 4).

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Patient 2

One year after surgical resection of a right parietotemporal glioblastoma multiforme and then radiation and systemic chemotherapy, this 65-year-old woman developed a large, enhancing mass lesion. Use of the wand for intraoperative navigation based on coregistration of MRI and PET data(Fig. 5) facilitated surgical debulking of the mass in two ways. First, it was helpful in ensuring that no major extension of the tumor was missed. Second, on the basis of the PET imaging data, it helped the surgeon precisely obtain metabolically active specimens from within the enhancing region of the tumor for pathological analysis.

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Patient 3

The navigational arm was useful in the resection of the posterior portion of this suprasellar meningioma (Fig. 6), because it helped demonstrate that the thickened arachnoid around the basilar artery was separate from the tumor.

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DISCUSSION

Techniques such as intraoperative ultrasound and conventional, framebased stereotactic methods, which have become standard navigational tools for a

variety of neurosurgical procedures, have important benefits and limitations. Ultrasound provides real-time feedback during surgery, an important advantage over any of the stereotactic systems that rely on preoperative images and thus cannot account for tissue movement or removal without repeated scanning. Ultrasound, however, requires that target lesions have echogenic interfaces with surrounding brain. It is of no value until after the dura has been exposed, and is difficult to use in surgery for deep-seated lesions, such as cranial-base tumors. By contrast, stereotactic methods are of value for planning surgical trajectories and targeting deep-seated or small lesions either with minimally invasive procedures through burr holes or as an adjunct to open craniotomies. Stereotactic frames, however, require an immediate preoperative scan and can be uncomfortable for patients and unwieldy for surgeons, restricting access to the surgical field and interfering with the use of other instruments or devices. These limitations are eliminated by the use of frameless stereotactic systems that can serve as valuable adjuncts for surgical planning and intraoperative navigation during open intracranial procedures.

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Preoperative imaging

This clinical series demonstrates that satisfactory accuracy can be achieved with frameless stereotaxy based on either CT or MR data sets(<u>Table 3</u>). Therefore, the choice of imaging format may be made purely on clinical grounds.

Standard radiographic scan parameters suffice for three-dimensional data collection, with only a few additional considerations. To provide improved out-of-plane resolution for the three-dimensional reconstructed objects and the two-dimensional reconstructed views, the slice thickness must be smaller than that typically used for diagnostic scans. Also, to provide a proper three-dimensional data set, adjacent slices must be contiguous, meaning that the table position or slice position increments must be equal to or smaller than the slice thicknesses. Clinical experience has led us to use a standard CT protocol of 4-mm slice thicknesses with 3-mm table incrementation and a standard MR protocol of 1.5-mm slice thicknesses and

1.5-mm slice incrementation. Attention must also be paid to the placement of the registration fiducial markers to ensure that the slice stack encompasses the entire marker set. Consequently, the slice stack will usually be larger than that of ordinary clinical scans. Although in most cases the scan parameters used in this series made it necessary to obtain a data set specifically for use with the frameless stereotactic system, standard clinical scan parameters may also be used with this system.

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Clinical accuracy

In preclinical testing with plexiglas phantoms and a plastic replica of the human cranium, the accuracy of this frameless stereotactic system(15) compared favorably with measurements previously (4) and subsequently (8)reported for four commonly used conventional stereotaxy sytems (Brown-Roberts-Wells and Cosman-Roberts-Wells; Radionics, Burlington, MA) (Leksell; Elekta Instruments)(Kelly-Goerss; Stereotactic Medical Systems, Rochester, MN). The measurements reported in these studies, however, overestimate the clinical accuracy, because they do not account for sources of error such as patient motion during preoperative scanning, inaccuracies in the registration process unique to the clinical setting (e.g., limitations in placement of fiducial markers and compression or distortion of soft-tissue structures), and intraoperative positional shifts after registration. Therefore, this clinical trial was conducted to assess the intraoperative accuracy of the wand more definitively. As expected, the clinical accuracy is not as good as was achieved in preclinical testing; however, these results validate the use of this system in many neurosurgical settings.

This clinical trial permitted us to compare the accuracy of the wand by using both the fiducial-fit and the surface-fit registration methods. As is evident from the data presented in <u>Table 3</u>, the fiducial-fit registration method was slightly more accurate than the surface-fit method for CT- and MR-based localization. By using both techniques plus a comparison of visual checks of the registration processes, the more accurate registration data set can be selected for each patient at the beginning of surgery.

The measurements of positional drift performed in this surgical series provide information regarding the mechanical stability of the methods used for fixation of the head, the headholder, and the navigational arm and probe. Movements of the head with respect to the navigational arm and probe during the course of a surgical procedure will result in incremental reductions in accuracy of the Viewing Wand that are not assessed with measurements of the initial registration accuracy. Because the positional drift of the Mayfield headholder with respect to the probe is nearly as great as the positional drift of the cranium with respect to the probe, we may reasonably conclude that most of the intraoperative movement we measured with this system occurred between the Mayfield and the probe rather than between the Mayfield and the head (as would occur if the head slipped in the cranial fixation pins, for example).

Shift of intracranial contents, as might occur during the resection of large intraparenchymal or cystic structures, provides one additional intraoperative source of error that cannot be measured by the techniques used in this study. As is true of any other frameless or conventional stereotactic system presently available, the Viewing Wand uses preoperative imaging data for intraoperative localization and thus cannot compensate for intracranial shifts during surgery. However, this limitation was easily overcome by using the wand for intraoperative navigation before draining cystic lesions or significantly debulking large intraparenchymal lesions. In such cases, intraoperative ultrasound provides a valuable adjunct to the use of the wand because it permits real-time assessments of the extent of surgical resection.

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Clinical safety and usefulness

The use of the Viewing Wand was safe in all 273 cases in this series. There were no adverse or potentially harmful events attributable to the use of this navigational system.

The subjective impressions of attending neurosurgeons using the Viewing Wand were also obtained to help validate the clinical use of this system. The wand was generally deemed helpful or very helpful (<u>Table 4</u>). These

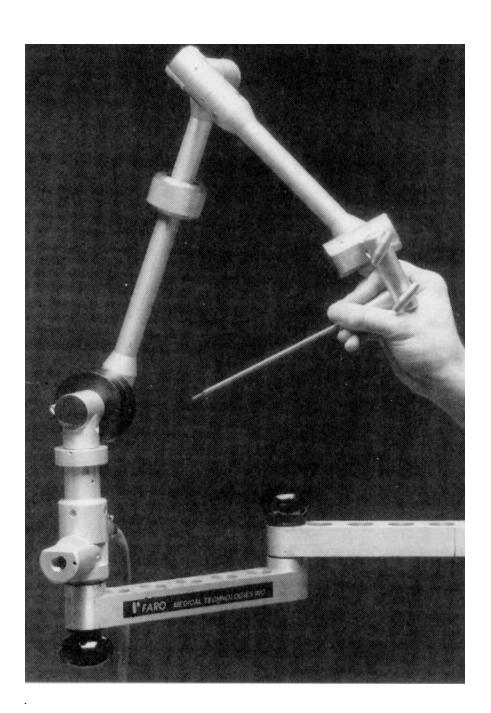
subjective data are important to consider, because they reflect the clinical usefulness of this system in ways that are not quantifiable by objective accuracy data. Furthermore, negative subjective impressions could have precluded the use of the wand despite its great accuracy.

In this series, the primary clinical benefits of the wand were intraoperative navigation and improved surgical safety. The use of this navigational system generally improved the understanding of anatomic details, facilitated the identification of structures, and permitted the appropriate adjustments to be made in the surgical trajectory leading to exposure of deeper neurosurgical lesions. These benefits often resulted in smaller, better-centered craniotomies with less brain manipulation. In addition to its use for planning the location and size of the scalp incision, craniotomy, and corticotomy, the Viewing Wand was often helpful for evaluating the extent of surgical resection. For these reasons, the surgeons had an improved sense of intraoperative safety in 86% of the procedures in this series.

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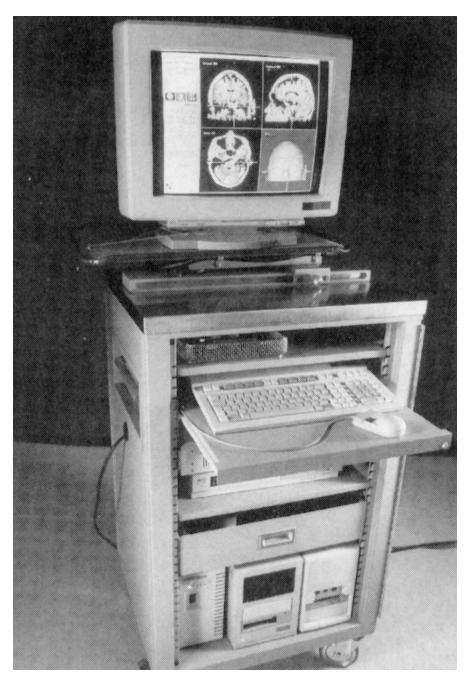
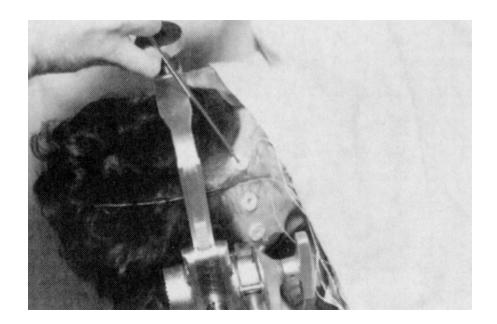


Figure 1. Because this equipment is mobile, it can be rolled into the surgical suite and positioned wherever convenient during surgery.



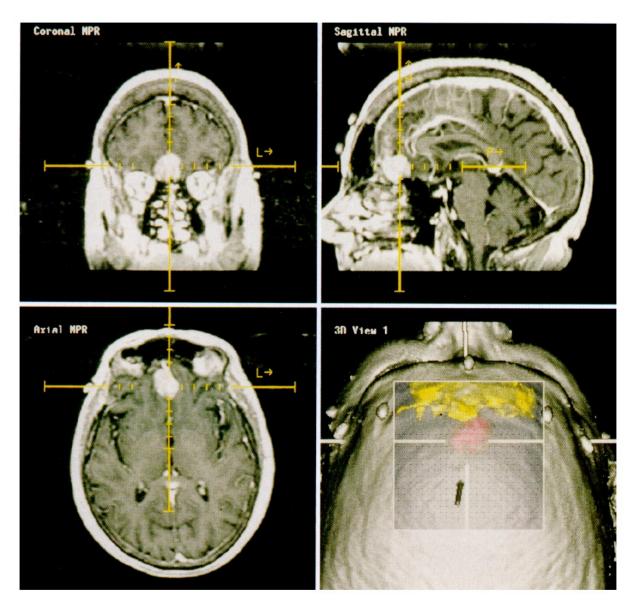
Diagnoses	Accuracy Series	Totals
Intracranial tumors	4	
Gliomas		114
Glioblastoma multiforme	12	54
Anaplastic astrocytoma	1	14
Astrocytoma	1	9
Oligodendroglioma	4	25
Pilocytic astrocytoma	3	10
Gliosarcoma	1	2
Other intracranial malignancies		20
Metastasis	3	12
Lymphoma		4
Chordoma		4
"Benign" intracraníal neoplasms		83
Meningioma	17	62
Schwannoma	1	7
Dermoid/epidermoid	1	2
Pituitary adenoma		1
Craniopharyngioma Craniopharyngioma		1
Rathke's cleft cyst		1
Teratoma		1
Fibro-osseous mass		3
Fibrous dysplasia		5
Vascular disease		8
Arteriovenous malformation		5
Cavernous angioma		1
Intraventricular aneurysm		1
Orbital hemangioma '		1
Seizure surgery		21
With tumor	4	9
Without tumor		12
Craniofacial reconstruction		13
For trauma		5
For developmental anomalies		8
Miscellaneous		23
Brain biopsy		6
Cerebrospinal fluid leak		2
Encephalocele		3
Nasopharyngeal carcinoma		3
Ameloblastoma		2
Sinusitis		2 2 3
Intraorbital procedures		3
Vestibular neurectomy		1
Radiation necrosis	1	1

^a Because patients with tumors who underwent seizure surgery are listed in both the tumor and the seizure categories, the apparent totals in this table exceed the actual number of procedures performed.

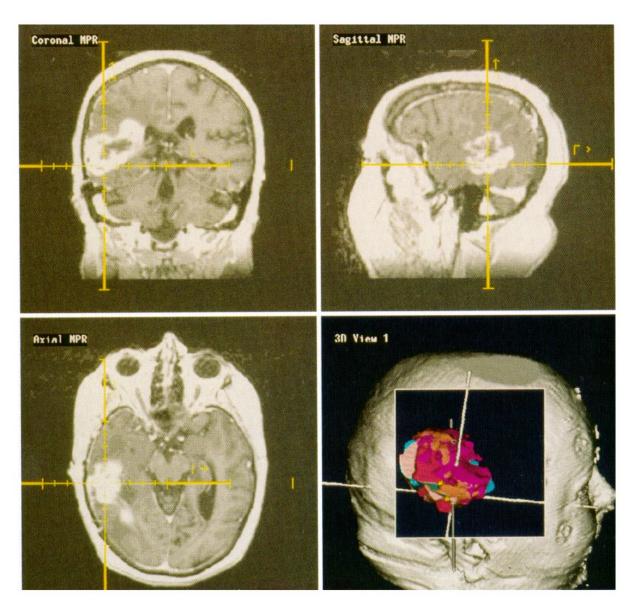
Operative Site	Accuracy Series	All Patients	
Intracranial		244	
Intraparenchymal			
Supratentorial	21	136	
Infratentorial		5	
Convexity	8	19	
Falcine/parasagittal	4	1 <i>7</i>	
Intraventricular	1	3	
Cranial base			
Anterior cranial base	4	10	
Sellar/parasellar	3	19	
Sphenoid wing/middle fossa	2	8	
Clivus	1	9	
Tentorial		4	
Cerebellopontine angle	1	11	
Multi-compartment		3	
Calvarial or extracranial		29	
Craniofacial		12	
Orbital		4	
Nasopharyngeal		5	
Sinuses		6	
Ear		2	

Measurement	Number of Measurements	Geometric Mean (mm)	95% Confidence Upper Limit
Fiducial-fit initial registration accuracy			
All trials	64	2.51	3.67
Computed tomography trials	33	2.26	3.54
Magnetic resonance imaging trials	31	2.81	3.99
Surface-fit initial registration accuracy			
All trials	66	3.03	4.16
Computed tomography trials	34	3.10	4.29
Magnetic resonance imaging trials	32	2.96	4.14
Positional drift			
Head versus probe	107	2.11	3.25
Mayfield versus probe	70	2.14	3.28

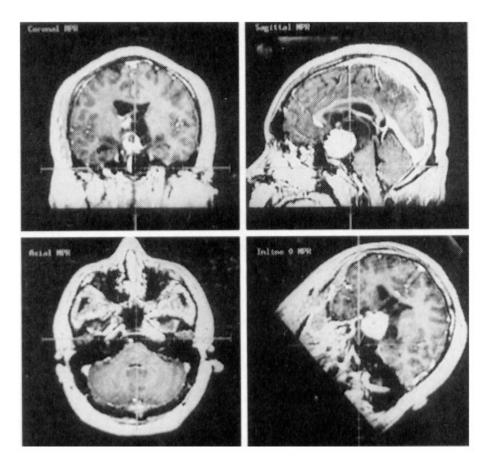
Utility Parameter	Helpful or Very Helpful (%)	No Effect (%)	Harmful or Very Harmful (%)	Not Applicable (%)
Intraoperative navigation		9		
Overall effect	93	2	0	3
Understanding of anatomy	93	5	0	0
Identification of structures	86	10	0	2
Adjusting surgical trajectory	50	38	0	10
Planning				
Scalp incision	52	29	0	17
Craniotomy position	57	26	0	15
Craniotomy size	57	29	0	12
Parenchyma incision	45	31	0	22
Extent of resection	69	21	0	8
Surgical safety				
Surgeon's sense of safety	86	12	0	0
Better-centered craniotomy	36	45	0	17
Smaller craniotomy	31	50	0	17
Less brain manipulation	60	26	0	12
Surgical invasiveness	57	31	0	10



yellow crosshairs. In the three-dimensional (3D) view, reconstructed images of the frontal sinus (yellow) and the tumor(red) are shown, with the position of the probe tip indicated by the intersection of the white lines (within the tumor). MPR, multiplanar reformat.



3D) reconstruction of data from the thymidine PET scan. In this reconstructed image, different colors represent different levels of thymidine uptake. MPR, multiplanar reformat.



O) projection (lower right image) is displayed along the trajectory of the probe. MPR, multiplanar reformat.

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COMMENTS

In this article, Sipos et al. present the application, accuracy, and clinical experience with the ISG Viewing Wand in a series of 273 surgical procedures for 250 patients. The construction of the device, registration techniques, and display features of the system are briefly reviewed.

Many of the observations and findings of this group using the ISG device mirror those of our own using a different surgical navigation system in>400 patients (2, 3). The vast majority of these patients underwent neurosurgical procedures, and most of the surgical experience was obtained by a small number of surgeons. Similarly, although virtually all of our neurosurgeons have used this device, it is routinely used by only a few. Those of us who use the device routinely think it is important to gain experience and confidence using these navigation systems rather than to first use the device in a patient in whom it is really needed. Surprisingly, even in such patients, these systems generally prove useful, although the user may not be getting the full benefit afforded by these systems.

Much of the article is devoted to measurements of accuracy using several different measures. Galloway et al. (4) have performed a great deal of work exploring the application accuracy of various frame systems. The stated errors in these articles are comparable with those that we find. I suspect that much of this is because of inherent limitations of scalp-mounted fiducials and that cranium-fixated fiducials should improve accuracy even with the image-limitations noted within the article. Nonetheless, these measurements compare very favorably with those obtained in recent reports of application accuracy of stereotactic frames. In our experience, the accuracies obtainable with these systems using scalp fiducials is sufficient for virtually any open neurosurgical procedure and even most intracranial biopsies.

The authors' findings that the use of fiducials and contour matching produced nearly identical accuracy measurements have some important practical implications. Although a vast improvement over the application of traditional stereotactic frames, scalp fiducial application remains somewhat tedious and uncomfortable for the patient. The use of surface contours as a

registration technique could potentially eliminate this step, thereby streamlining the procedure and cutting costs.

Although most of the article seems to be devoted to the discussion of accuracy, its points regarding the clinical usefulness of the system merit reemphasis. This system is clearly useful for preoperative planning by allowing the surgeon to examine the orthogonal image sets and to define the location of the lesions with respect to vascular structures and cortical anatomy. At surgery, these techniques allow optimization of craniotomy by means of avoiding air sinuses (their Patient 1), encompassing dural tails of meningiomas, or fashioning a minimal-access craniotomy. To gain full intraoperative use may require surgeons to modify their standard approaches to performing surgery. The use of standard scalp retraction techniques may move the head of the patient in the Mayfield or may move the Mayfield itself before placement of reference holes in the calvarium. In such cases, registration can be irrecoverably lost. When removing intraparenchymal tumor, such as primary gliomas, we concur with Dr. Patrick Kelly's observations that these lesions are best resected en bloc to minimize tissue shifts that occur after a typical centripetal resection (5).

As we enter the last half of this decade, I anticipate that framed stereotaxy will fall into relative disuse except, perhaps, for some functional procedures, and even that application may fall into disuse. We have had satisfactory results in using frameless techniques for more than 30 stereotactic brain biopsies to date, and Adler (1) has made great progress toward practical, frameless, stereotactic radiosurgery(1). I anticipate that in the near future, use of these surgical navigation systems in neurosurgery (and likely other specialties) will be as common as use of the operating microscope and, perhaps, as common as use of bipolar cautery.

Gene H. Barnett

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As the technology of interactive image-guided neurosurgery becomes more widespread, it is being rapidly integrated into standard neurosurgical practice. This clinical series of 45 patients, set against the backdrop of a broader experience of 250 patients, represents one example of an emerging

new standard in clinical intracranial neurosurgery. Although many first-generation systems seem to have somewhat less application accuracy than is optimally achievable with stereotactic frames, the flexibility of frameless systems allows them to be used for a far more extensive spectrum of operations. Improved techniques of image registration and more accurate intraoperative localization devices promise to further tilt the balance in favor of the new.

It is encouraging to read of the successful incorporation of navigation technology into routine neurosurgical practice. It is even more exciting to consider the time when universal availability of this technology leads us to test less invasive approaches and to devise entirely new surgical procedures.

Robert J. Maciunas

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This article deals with the accuracy of a popular, commercially available system for frameless stereotaxy. However, clinical accuracy is different from bench accuracy. The authors recognize this and try to provide information for readers to assess the accuracy of the ISG device when used in human surgery.

The problem with frameless stereotactic procedures, as opposed to frame-based procedures, is registration. In frame-based stereotactic procedures, registration is accurate, simple, and straightforward. In frameless stereotaxy, registration can be a major problem. To establish a frameless coordinate system, small, well-defined fiducials that are easily recognizable on the patient and on the imaging study are required. Slight errors in selecting fiducials or corresponding parts of fiducials between the imaging study and the actual patient can result in significant transformation errors, especially for points distant from the origin of that coordinate system.

We have performed similar studies using the Regulus (COMPASS International, Inc., Cascade Business Park, Rochester, MN) magnetic field digitizer. In our experience, in contrast to the findings of this article, a surface-fit registration program can help reduce this error. We found that accuracy was poorer with corresponding anatomic points and with scalp-

mounted fiducials than with the surface-matching algorithm. However, it must be realized that few neurosurgeons will be willing to select many points on the scalp of a patient (80-120 points, as in this article) for the execution of a surface-fit registration algorithm. Most neurosurgeons want something quick, touching three or four anatomic points or placing three or four fiducial markers before imaging.

The problem with scalp-based fiducials is that the scalp can move. Some have talked about imbedding craniummounted fiducials before imaging. The advantage of this over simply applying a stereotactic head frame for database acquisition escapes me. We have found excellent registration accuracy and reproducibility if we obtain a database in a stereotactic head frame and register the frameless device on the base ring of the stereotactic head frame, which then attaches to a Mayfield adapter, similar to the three-point fixation device currently in use. Nonetheless, some may think that this defeats the purpose of "frameless" stereotaxy; in my opinion, it does not. Frameless stereotaxy frees the surgeon from using a cumbersome quadrant assembly and allows on-line, real-time interaction with the imaging database.

Neurosurgeons have been subjected to claims from instrument manufacturers about the accuracies of these systems. I have no doubt that the mechanical bench accuracy of the ISG device is on the order of 1 to 2 mm. Claims such as "submillimeter accuracy" and "within 2 mm" are now common sales phrases heard in the exhibit areas of our national meetings. This article provides very optimistic results on the accuracy of this device. However, I doubt that the practical clinical accuracy, taking into consideration registration errors, is nearly as good. The 95% upper confidence limit figures (and not the mean accuracy) reported in this article are more to the point clinically and must be considered when using this or similar devices on any individual patient. A surgeon will never know prospectively the accuracy of the frameless device and should always consider the worst-case scenario. If 1- to 2-mm accuracy is required, I would use a stereotactic frame.

Patrick J. Kelly

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This article presents a sizable clinical experience with the ISG Viewing Wand and a prospective study of the accuracy achieved with two registration methods. It makes a contribution first for the subjective responses elicited from a large number of surgeons. These are positive, primarily for the navigational assistance provided in finding selected structures and in assuring appreciation of their extent. A common summary statement from users of similar navigational systems has been that such guidance increases the confidence of the surgeon, and the responses reported here seem to reflect that.

The second contribution concerns the level of accuracy achieved in clinical use, and the data reported confirm that accuracy sufficient for most applications can be reasonably achieved. Independent of this, the amount of movement noted between the Mayfield headholder and the mechanical arm over the course of an operation is surprising. This would seem to be remediable, but in any event, the most crucial use of such a system is generally early in surgery, and as with the error that may arise from intraoperative soft-tissue movement and deformation, this may not prove to be the practical problem that theoretical considerations might suggest.

Fiducial methods of registration have served a valuable role in the transition to frameless technology. They are relatively straightforward to implement and have enabled the concept and feasibility of interactive, image-guided surgery to be demonstrated. However, as such systems become an integral part of the operating room, their use will require eventual elimination of such steps as additional, prospective imaging, which fiducial methods require. For this reason alone, registration algorithms using natural features will become dominant. In addition, such methods can become fully automated, furthering the desired transparency of navigational systems. The level of accuracy achieved without fiducials in this series confirms that that transition is further along than many realize.

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Keywords:

Brain neoplasms; Computed tomography; Instrumentation; Magnetic resonance imaging; Operative technique; Positron emission tomography; Stereotaxy

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