Image-Guided Technique in Neurotology

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If they haven’t already, systems for image-guided surgery (IGS) are coming to an operating room near you. IGS systems are already commonplace for sinus surgery and neurosurgery. The appeal of IGS systems is that they allow real-time tracking of current anatomic position on preoperative CT or MRI scans. (Note: IGS systems differ from real-time intraoperative imaging, such as CT/OR or MRI/OR suites, where surgically induced anatomic changes are visible.) Although IGS systems do not replace detailed anatomic knowledge, they have been shown to improve outcomes with inexperienced [1] and experienced surgeons [2,3].

The transition of IGS from sinus surgery and neurosurgery to otology/neurotology has been stalled by the need for a compact system that has accuracy at a level suitable for the skull base—on the order of ≤ 1 mm. Commercially available systems do not achieve this level of accuracy without bone-implanted fiducial markers. Once this level of accuracy is achieved, however, the use of IGS in skull base surgery will have profound implications, including safety control (eg, turning off the drill when a critical boundary is reached), robotic surgery (eg, robotic milling of the mastoid), and minimally invasive surgery (eg, percutaneous cochlear implantation).

Before presenting these exciting applications of IGS in otology/neurotology, we first must understand the basics of IGS systems. This understanding is crucial in being able to appreciate the strengths and weaknesses of IGS. Contained herein is (1) a description of IGS systems focusing on the
“accuracy” of such systems, (2) a review of the current commercially available systems, and (3) an overview of future applications of IGS in otology/neurotology.

**How image-guided surgery systems work**

IGS systems are analogous to global positioning systems but on a much smaller, local scale. The typical set-up is depicted schematically in Fig. 1. The systems consist of (1) a set of markers on a patient (called “fiducial markers” or simply “fiducials”), which are present during preoperative CT or MRI scanning, (2) a computer tracking system used in the operating room that aligns the markers in the CT or MRI to the current anatomy and tracks a patient’s fiducial markers within the operating room. For tracking, most systems (eg, BrainLAB, Feldkirchen, Germany; Medtronic, Minneapolis, Minnesota; and Stryker, Stryker Leibinger, Inc., Kalamazoo, Michigan) use infrared technology, whereas one system (GE Medical Systems, Lawrence, Massachusetts) uses electromagnetic field distortion technology. Infrared systems are limited by line of sight, whereas electromagnetic systems are distorted by metal instruments within the surgical field.

![Fig. 1. Typical IGS set-up.](image-url)
Fiducial markers

The key to IGS systems are the fiducial markers. The familiar computer axiom that holds that “garbage in equals garbage out” is applicable to IGS systems because the only items visible to the IGS system are the fiducials. Tracking of unknown anatomy depends on actively matching fiducial markers in the preoperative scan to those within the operating room. This matching requires an accurate determination of the position of each fiducial, a process that is termed fiducial “localization.” Without excellent fiducial localization, all anatomic point localization is compromised. Fiducial markers range from neurosurgical N-frames (rarely used given less cumbersome choices), bone-implanted screws, proprietary head-frames (eg, GE Instatrack head frame), skin-affixed adhesive markers, contours of surfaces obtained by laser scanning, and dental-affixed mouthpieces. The requirements for excellent fiducials are that (1) they are repeatedly positioned in exactly the same location relative to patient anatomy during radiographic imaging and in the operating room (a flaw for all non–bone-affixed systems), (2) they surround the anatomic region of interest, (3) a sizeable number of markers is used, and (4) they can be accurately localized.

Why are fiducial markers the key? Fiducial markers are the only things visible to the IGS system. Everything else depends on them. Once a CT or MRI scan is loaded into the IGS computer, the operator finds the same fiducial markers on the patient in the operating room, and the computer’s job is to align/superimpose the fiducial markers from the CT or MRI scan to those found in the operating room. To the extent that the anatomy is rigid, fiducial alignment ensures that the anatomy, including surgical targets, is also aligned. This process is called “registration.” This important process deserves a precise definition: Registration is the alignment of anatomic points from the radiographic scan (eg, CT or MRI) with their true positions in the operating room. This process is schematically illustrated in Figs. 2–4.

Error within image-guided surgery systems

As one can imagine, error is inherent to the process. Although not often discussed in brochures or advertisements, an engineering standard does exist in analysis of IGS. This analysis assigns error to each step of the process, as shown in Fig. 4. First is “fiducial localization error” (FLE), which is the error in identifying the positions of the fiducial markers in the radiographic images (FLE_rad) and in the operating room (FLE_OR). Contributions to FLE_rad include the resolution of the CT or MRI scan, image distortion of the scan, and noise in the scan. Components of FLE_OR include human error in identifying the fiducial markers and error inherent in the tracking system. Overall, FLE represents the error in finding the fiducial markers. In an ideal world, the location of fiducial markers could be determined perfectly; given the imperfections of the real world, however, this rarely happens. Thus FLE is rarely zero. When fiducial locations are imperfectly determined, alignment of the markers...
from the radiographic study to the operating room is also imperfect. The resultant error in aligning fiducial markers is termed “fiducial registration error” (FRE) and is graphically depicted in Fig. 4. To minimize this error, a mathematical best-fit algorithm is used to minimize the differences between the corresponding image and patient fiducials. (Most systems use a strategy that minimizes the sum of the squares of the distances between fiducial markers). The FRE or a derivative of it is the number typically displayed on IGS systems after registration as an indication of the goodness of fit.

Only after registration is done can IGS tracking begin. Once tracking is initiated, the surgeon identifies a point of anatomic interest. The difference
between where the IGS system says the anatomy is located and its true position is termed “target registration error” (TRE)—the accuracy of the system. TRE and FRE each statistically depend on FLE via relationships that are beyond the scope of this article. (The interested reader is directed to Fitzpatrick and colleagues [4].) An important point to remember is that TRE for a system is not well described by a single number but rather a statistical distribution. When one states that the accuracy of a system is 1 mm, what is actually being implied is that the average accuracy of the system is 1 mm, but the accuracy may in fact be higher or lower at any particular time. (The statistical distribution is a chi-squared distribution with 3 degrees of freedom [Fig. 5]). When comparing systems, the TRE within the anatomic region of interest should be compared.

A common misconception is that lower FRE means a more accurate registration, which is not necessarily true. Although most systems have a threshold below which FRE must fall to proceed with IGS, lowering FRE further below this threshold does not mean higher registration accuracy. Some authors have called for removal of fiducial points from the registration to lower FRE [5]. This approach is dangerously flawed. Although FRE tends statistically to decrease with fewer fiducials, error in target alignment (TRE) tends to increase [6]. Because FRE can be observed directly, it is tempting to removal fiducials to see a reassuringly smaller error value displayed on the IGS screen, but the chances are great that removing them will increase the error that counts—the error in hitting the target (ie, TRE). Many examples can be given to illustrate this effect, but the simplest is the case of one fiducial. When only one fiducial is used, FRE may be easily reduced to zero, but as is depicted in Fig. 6, a zero fiducial registration error

Fig. 4. Error analysis for IGS. Error occurs when identifying fiducials in the radiographic image (FLE\text{rad}) and when identifying fiducials in the operating room (FLE\text{OR}). Error also occurs when aligning the fiducials (FRE). The accuracy of the system is the error in finding surgical targets (TRE). TRE and FRE depend on FLE. The keys to IGS are the fiducial markers.
clearly does not mean a more accurate registration. When more markers are used, because of the uncertainty in their localization (FLE), FRE tends to rise but TRE likely decreases, which results in better accuracy. For clinical use, more fiducial markers are better, even if it means a larger FRE.

For laser scanning systems, the analysis described in the preceding paragraphs is as follows:

- A three-dimensional surface model is constructed from the radiographic data, and multiple points are captured from the surface of the patient in the operating room using a scanning laser.
- The collection of these anatomic points (fiducials) is compared with the surface generated from the radiographic data and aligned such that the distance from the collection of points to the surface is minimized. This concept is similar to using multiple fiducial markers.
- A larger FRE may result from more anatomic points captured during laser scanning. This larger FRE does not mean that the TRE would be higher; rather the TRE would be expected to be lower. More laser scans are better even if it means a larger FRE.

**Commercially available image-guided surgery systems**

Although no IGS systems are marketed for lateral skull base surgery, many are approved by the US Food and Drug Administration (FDA) and currently are used for sinus surgery and neurosurgery. An in-depth
review of the accuracy of such systems was performed for a prior publication [7] and is repeated in this article with permission from the publisher.

The four leading commercial IGS systems used for sinus surgery are (in alphabetical order):

- BrainLAB system (BrainLAB, Feldkirchen, Germany)
- InstaTrak System (GE Medical Systems, Lawrence, Massachusetts)
- LandmarX and StealthStation system (Medtronic, Minneapolis, Minnesota)
- StrykerImage Guidance System (Stryker Leibinger, Kalamazoo, Michigan)

For each of these systems, the literature was reviewed to find the most relevant article reporting accuracy of the system. Each company was contacted to determine whether the cited study was the most up-to-date regarding error analysis.

**BrainLAB**

For the BrainLAB system, no error studies could be identified specifically for sinus surgery, but such work has been done for neurosurgical applications, which use similar fiducials and registration methods. In a study performed at the University of Regensburg, Germany, error analysis for 36 patients undergoing intracranial surgery was performed [8]. FRE using skin-affixed fiducial
markers was reported as 1.10 ± 0.53 mm; using laser skin contouring, FRE was reported as 1.36 ± 0.34 mm. TRE was calculated by comparing a skin-affixed marker on the patient with that location in the corresponding radiographic image; for the skin-affixed marker registration, TRE was reported as 1.31 ± 0.87, and for laser skin contouring, TRE was reported as 2.77 ± 1.64 mm.

**InstaTrak**

For the InstaTrak System, a multicenter, multisurgeon study was performed and published in *Laryngoscope* in 1997 [9]. In this study, registration was performed either with six skin-affixed markers or a proprietary headset. TRE was measured using two skin-affixed targets placed on the lateral right and left supraorbital rims. FRE was not reported. For the skin-affixed fiducial registration, a TRE of 1.97 mm with a 95% CI, of 1.75 to 2.23 and a maximum value of 6.09 mm was reported. For the headset registration, a TRE of 2.28 mm with a 95% CI, of 2.02 to 2.53 and a maximum value of 5.08 mm was reported.

**LandmarX**

For the LandmarX system, Metson and colleagues [10] performed a prospective study of 34 physicians performing 754 sinus cases over a 2.5-year period. Using five anatomic key points as fiducials (these points are undefined), they reported “mean accuracy of anatomical localization at the start of surgery was 1.69 ± 0.38 mm (range, 1.53 ± 0.41 mm to 1.79 ± 0.53 mm).” Although the specific methods are not given, this study seems to report FLE—the error associated with repeated identification of the fiducials—and not TRE. Hence the question mark in Table 1.

**Stryker**

The Stryker Image Guidance System was evaluated prospectively on 50 patients undergoing anterior cranial base surgery by Snyderman and colleagues [5]. Each patient had ten skin-affixed fiducials placed over the scalp, lateral face, and mastoid. TRE was not measured in this study. Rather, the authors reported the error within zone of accuracy, which is an estimate of TRE based on FRE performed by an algorithm proprietary to Stryker. They reported for their clinical applications that the Stryker system estimates that in a zone of accuracy, which it demarcates in image space, it has achieved a TRE < 2 mm. The authors visually validated the registrations, but they reported no independent error measurements to check these estimates.

**Applications of image-guided surgery in otology/neurotology**

Within our literature there are limited references to the clinical use of IGS. (Excluded from the current discussion is the use of IGS for virtual training; eg, virtual temporal bone trainers.) Use of IGS clinically has been limited to

It is surprising to the authors that IGS has not been exploited more by otologists/neurotologists given (1) the extensive use by neurosurgeons that shows more complete disease resection in less operative time [2,3] and minimally invasive surgery for placement of deep brain stimulators [14], (2) the large numbers—upwards of 100,000 mastoidectomies per year—of otologic procedures performed annually in the United States [15], (3) projections that IGS will be a part of operating rooms of the future [16], and (4) predictions that IGS offers an area of advancement of our field [17]. Areas in which IGS may have large impact on otology/neurotology include (1) safety constraints regarding surgical tool control, (2) robotic surgery, and (3) minimally invasive surgery, such as percutaneous cochlear implant placement.

Safety controls

Perhaps the most practical application of IGS is increased safety control. In otology/neurotology, in which the surgical field is encased in rigid bone, the use of IGS to define boundaries and prevent transgressions has great appeal. Two groups have been working on this, including the authors [18] and a group from Germany [19].
The concept is simple: define the boundaries of the surgical field (eg, tegmen, sigmoid, external auditory canal, facial nerve, labyrinth), track the position of the drill, and turn it off when the drill approaches vital anatomy. Although both groups have limited experimentation in nonhuman models, volumetric speed of drilling is increased using such IGS-controlled drill cut-off, especially for inexperienced surgeons.

Robotic mastoidectomy

Robots have been used in operating theaters for more than 20 years. Their advantages are many, including reliability, repeatability, and lack of tremor. Probably best known is the da Vinci Surgical System (Intuitive Surgical, Sunnyvale, California), which has been cleared by the US FDA for laparoscopic procedures [20]. The daVinci system is considered a “master–slave” system, meaning that the robot mimics the surgeon’s motions, eliminating tremor and miniaturizing motions. It acts as an extension of the surgeon and depends on the surgeon performing the procedure. In contrast to master–slave robots, autonomously acting robots offer the potential of replacing the surgeon for at least portions of surgical procedures. Autonomous robots have use in several surgical applications in which the procedure can be planned a priori. The FDA-approved ROBODOC (Integrated Surgical Systems, Davis, California) is an example of an autonomous robot used to perform a component of total hip replacement surgery [21,22]. (Note: Novatrix Biomedical Inc., San Clemente, California, has an agreement of purchase for Integrated Surgical Systems at the time of this writing.) To use this system, the surgeon first locates fiducial markers attached to the femur and visible in the CT scan. The ROBODOC system then registers the preoperative CT scan with the surgical anatomy and plans an optimal milling of the femur for placement of a prosthetic shaft. The robot aligns itself to the optimal trajectory and drills a cylinder of specified diameter and depth.

In otologic surgery, autonomous robots have been used to surface mill the temporal bone to a depth of 4.5 mm to create a receiving well for the internal processor of a cochlear implant device [23]. Recently, our group extended this work with the goal of performing a robotic mastoidectomy. To accomplish such a task we have built an open-architecture, autonomous robot and incorporated it with an IGS system. Preliminary studies with this system show that it can drill the volume of a mastoid cavity repeatedly in approximately 4 minutes. Given the “x-ray vision” afforded by IGS, the typical strategy of visual identification of mastoid boundaries may be replaceable by more effective edge routing techniques, which remove the mastoid en bloc. Note that such a system is not intended to replace the surgeon. Rather it is intended to carry out low-level milling and allow the surgeon to concentrate on the high-level tasks of fine drilling on vital structures (eg, facial nerve, internal auditory canal).
Minimally invasive surgery: percutaneous cochlear implantation

Perhaps the most powerful aspect of IGS applied to otology/neurotology is the concept of truly minimally invasive surgery. The authors from Vanderbilt have been working on the concept of minimally invasive surgery as applied to cochlear implantation for the past 5 years [24,25]. The author from the University of Hanover also has been performing similar work [26].

The concept (Fig. 7) is to use radiographic guidance to drill directly from the surface of the skull to the cochlea without injuring vital structures. To achieve the necessary accuracy in avoiding the facial nerve, bone-implanted fiducials are placed around the temporal bone. Initial efforts were performed free-hand, analogous to the way functional endoscopic sinus surgery is currently performed [24]. Majdani and colleagues [26] reported a similar approach using robots. Extensions of this work include automated paths constrained by drill guides [25]. After CT scanning, a proposed drill path is predicted using a computer program. If the surgeon accepts the proposed path, an electronic plan is sent for rapid prototyping of a drill guide, which mounts on the bone-implanted fiducials and constricts the motion of the drill to pass through the facial recess and intersect the basal turn of the cochlea.

Fig. 7. The concept of percutaneous cochlear implant. With IGS, a path from the lateral cortex of the mastoid to the cochlea avoiding vital structures (eg, the facial nerve) can be planned. (From Labadie RF, Choudhury P, Cetinkaya E, et al. Minimally-invasive, image-guided, facial recess approach to the middle ear. Otology Neurotology 2005;26:560; with permission.)
cochlea. We recently completed our first validation on a human patient (Fig. 8) via funding from the Triological Society and are embarking on a multicenter trial funded by the National Institutes of Health. This concept is not limited to cochlear access; it includes access to any structure within the temporal bone (eg, endolymphatic sac, semicircular canals).

Summary

IGS systems enhance surgical navigation by linking preoperative radiographic scans to intraoperative scans, and they are coming to otology/neurotology. The keys to IGS systems are fiducials markers (also known as “fiducials” or “markers”). The positions of these markers, which are attached to the patient before imaging, are determined in the image and on the intraoperative scan and are used to align the two. Determination of fiducial position is never perfect, which results in FLE. Ideal fiducial markers are repeatedly mounted around the anatomy of interest, with the most accurate being bone-implanted markers. Alignment is never perfect, and as a result there is inevitable error in the alignment of the fiducials, termed FRE, and in the alignment of surgical targets, termed TRE. The latter alignment represents the accuracy of the guidance system.

Typical IGS systems display FRE intraoperatively and specify that it fall below a set threshold for reliable navigation. Using more fiducial markers results in a higher FRE but is likely to provide better guidance accuracy.

Fig. 8. Clinical validation of percutaneous cochlear implantation. The drill guide attached after traditional right cochlear implant surgery (top left). A magnified view showing the drill bit passing through the facial recess (bottom right).
Current FDA-approved IGS systems for otolaryngology-head and neck surgery have accuracies (TREs) on the order of 2 mm with noninvasive fiducials (ie, skin-affixed markers, proprietary headsets, laser scanning of facial features).

To date, clinical application of IGS otology/neurotology has been limited, but a large potential market and numerous applications support its use. Such applications include control of surgical instruments (eg, turning off a drill when close to an anatomic boundary), robotic surgery (eg, robotic mastoidectomy), and minimally invasive surgery (eg, percutaneous cochlear implantation).

References


