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Accuracy of Image-guided Surgical Systems at the Lateral Skull Base as Clinically Assessed Using Bone-Anchored Hearing Aid Posts as Surgical Targets

Ramya Balachandran, PhD,

Department of Otolaryngology-Head and Neck Surgery, Vanderbilt University Medical Center, Nashville, TN, ramya.balachandran@vanderbilt.edu

J. Michael Fitzpatrick, PhD [Professor of Computer Science], and

Department of Electrical Engineering and Computer Science, Vanderbilt University, Nashville, TN, j.michael.fitzpatrick@vanderbilt.edu

Robert F. Labadie, MD, PhD [Associate Professor of Otolaryngology-Head and Neck Surgery]

Department of Otolaryngology-Head and Neck Surgery, Vanderbilt University Medical Center, Nashville, TN, robert.labadie@vanderbilt.edu

Abstract

Objective—Image-guided surgical (IGS) technology has been clinically available for over a decade. To date, no acceptable standard exists for reporting the accuracy of IGS systems, especially for lateral skull base applications. We present a validation method that uses the post from bone anchored hearing aid (BAHA) patients as a target. We then compare the accuracy of two IGS systems—one using laser skin-surface scanning (LSSS) and another using a non-invasive fiducial frame (FF) attached to patient via dental bite-block (DBB) for registration.

Study design—Prospective.

Setting—Tertiary referral center.

Patients—Six BAHA patients who had adequate dentition for creation of a DBB.

Intervention(s)—For each patient, a dental impression was obtained, and a customized DBB was made to hold a FF. Temporal bone CT scans were obtained with the patient wearing the DBB, FF, and a customized marker on the BAHA post. In a mock OR, CT scans were registered to operative anatomy using two methods: (a) LSSS, (b) FF.

Main outcome measure(s)—For each patient and each system, the position of the BAHA marker in the CT scan and in the mock OR (using optical measurement technology) were compared and the distances between them are reported to demonstrate accuracy.

Results—Accuracy (mean $\pm$ standard deviation) was 1.54 ± 0.63 mm for DBB registration and 3.21 ± 1.02 mm for LSSS registration.

Conclusions—An IGS system using FF registration is more accurate than one using LSSS ($p = 0.03$, two-sided Student's t-test). BAHA patients provide a unique patient population upon which IGS systems may be validated.

Introduction

Within the field of Otolaryngology-Head and Neck Surgery, image-guided surgical (IGS) systems have been used with increasing frequency since 1997 [1]. This technology is akin to global positioning systems (GPS) albeit on a much smaller scale. IGS systems take pre-operative radiographic images, superimpose them on intra-operative anatomy, and allow real-time tracking of position during surgery. While it is not standard of care yet, IGS is used routinely for difficult sinus cases as well as for complex and/or revision surgery. The use of IGS systems in other areas, for example skull base surgery, is emerging.

The usefulness of properly functioning IGS systems is quickly apparent. Studies have shown that inexperienced surgeons using IGS make fewer anatomical errors [2]. Such systems are also useful for experienced surgeons, who remove more diseased tissue with less collateral damage to healthy tissue [3], [4]. Critics argue that surgeons will become too dependent upon such technology, and our literature is replete with caveats about using IGS systems as an adjunct to detailed surgical knowledge. This concern is real as IGS systems have become more commonplace in operating theaters [5]. Surgeons must understand how IGS systems work as well as their limitations, notably the inherent inaccuracy of the systems.

Accuracy of IGS systems has been the topic of numerous recent review articles [6], [7]. A central theme in these articles is the need for standardization in reporting accuracy of IGS systems. Such a standard does exist in the engineering literature [8], [9], [10] but has yet to be adopted in the clinical world, where clinical advertisements tout the accuracy of IGS systems without sufficient supporting data.

To the credit of IGS system manufacturers, clinical testing of IGS systems is difficult. What is required is a repeatably identifiable anatomic landmark that can serve as a target. The IGS system is then used to identify this point and the difference between the true position and that predicted by the IGS system is the error of the system. Certain anatomic points have been suggested, including the nasion, infraorbital foramen, and manubrium of the malleus [11]. However, there is inherent inaccuracy in repeatably measuring such anatomic landmarks at a level that encroaches upon the level of accuracy that is trying to be demonstrated.

An ideal target would consist of a bone-implanted marker that can be precisely localized in the radiographic image as well as on the patient. Studies based on such targets have been carried out in neurosurgery, where bone-implanted pins and markers are tolerated by patients with severe, often life-threatening, diseases [12]. In otolaryngologic applications of IGS—mainly rhinology—such bone-implanted markers are poorly tolerated. However, within the discipline of otology, there exists a unique patient population for whom bone-implanted markers are commonplace. This population comprises patients with bone-anchored hearing aids (BAHAs), for whom a titanium screw is tapped into the skull behind the auricle onto which a vibratory sound processor is attached. The surgery to implant a BAHA is FDA-approved for patients with fixed conductive losses as well for those with unilateral sensorineural hearing loss. As of this writing, 35,000 BAHA surgeries have taken place worldwide, approximately 15,000 of which are within the United States (source: Cochlear Corporation literature).

Presented herein is a new method of clinical validation of IGS systems. A target marker is introduced at the BAHA abutment post, which acts as the surgical target. By capitalizing on this unique set of patients, we have devised a method for testing the accuracy of IGS systems and present data comparing two systems. The first of these systems is an experimental system—the EarMark™ system—that was developed by the authors. The system uses for registration a lightweight fiducial frame attached to the patient via a dental bite-block. The EarMark™ system is not commercially available and is used for research only. The second of these is the FDA-approved BrainLab VectorVision® system that uses laser-skin surface registration.

Methods

The concept of using BAHA posts as targets for IGS testing was first introduced to validate the fiducial frame system [13], [14]. The current study was undertaken as described below following Institutional Review Board (IRB) approval to find the accuracy of different IGS systems for clinical use.

Surgical Target

A customized post was created which snaps directly onto the BAHA abutment. Onto this post a 4.76 mm stainless steel ball was concentrically affixed, the center of which acts as the surgical target for our study. A customized probe consisting of a hollow tube, which fits over the ball, was used to locate the center of the ball (Figure 1). With the BAHA sound processor removed and this target affixed, a highly reliable, accurately localizable target was created, thus allowing us to measure the error of the IGS system at this location.

IGS System 1 – EarMark™ System

We have previously reported on an IGS system developed for research called the EarMark™ system, which uses a dental bite-block for registration [15], [16], [17]. In practice, a patient gets a dental impression from which a customized bite block, formally called a Locking Acrylic Dental Stent [18], is constructed. Before CT scanning, the bite block is attached to the patient, and a lightweight frame with 12 fiducial markers (six fiducial markers surrounding each ear) is snapped onto the bite block (Figure 2). The patient then undergoes clinically applicable CT scanning. The fiducial markers are 4.76 mm titanium spherical balls whose centers can be localized both in CT space and physical space. Registration in the procedural room (operating room or laboratory) is accomplished by comparing the location of corresponding fiducial markers in the CT space and physical space. A best fit is created by minimizing the sum of the squares of the distances between markers in the two spaces, in a registration process called “point-based registration”. At the time of intervention, the fiducial frame is replaced with an abbreviated frame, termed a Coordinate Reference Frame (CRF), which also snaps onto the bite block. The use of the CRF is likely to result in a slight reduction in the accuracy of the system, but its use is necessary to allow unencumbered access to the patient's temporal bone anatomy. The purpose of the present work is to measure overall error of each IGS system, as opposed to error contributed by its individual components, which is considerably more difficult to assess. However, by applying previously published methods for assessing such errors [8], [19], we estimate that the contribution from the CRF to the overall measured error is approximately 0.25 mm. Active tracking then occurs either through the use of (a) an infrared (IR) tracking system (Hybrid Polaris from Northern Digital Inc; Waterloo, Ontario, Canada) or (b) an optical tracking system (MicronTracker from Claron Technology Inc; Toronto, Ontario, Canada). Using IR tracking, the EarMark™ system has been previously reported as having submillimetric accuracy (0.733 ± 0.25 mm) within the region of cadaveric temporal bones [16], [17]. The current study evolved from the need to validate the system in clinical use.

IGS System 2 – BrainLab VectorVision®

At our institution, the BrainLab system is used for functional endoscopic sinus surgery and thus serves as the ideal comparative IGS system. This system uses laser scanning of facial features to register a pre-operative CT or MRI scan to the patient's anatomy. To accomplish this registration, multiple skin-surface points are acquired using a hand-held scanning laser, which bounces a signal from the skin to two infrared detectors of a hybrid Polaris tracking system, relative to a CRF on a headband (Figure 3). Via triangulation, the points can be localized, and a constellation of points on the surface of the skin are then compared to the surface generated from the pre-operative CT or MRI. The best fit, defined as the minimum of

the sum of squares of the distances from the points to the radiographic surface, is determined, in a registration process called “surface-based registration”. Following the registration, infrared tracking of surgical tools commences. The accuracy of this system has been previously reported as 2.77 ± 1.64 mm [20].

Experimental Protocol

Prior to, and independent of, these experiments, each component of each IGS system was calibrated for accuracy as per the manufacturer's recommendations. Six patients from the author's clinical practice were recruited who were at least three months out from BAHA implant surgery and had good dentition. IRB approved informed consent was obtained. Dental impressions were made, and a customized bite block was created. Within fourteen days of manufacturing of the bite block, clinically applicable CT scans were obtained (slice thickness of 0.8 mm with 0.4 mm overlap). During scanning, patients wore both the bite block with affixed fiducial frame and the customized surgical target affixed to their BAHA abutment (Figure 2). With the marker still attached to the abutment but with the dental bite-block and fiducial frame removed, patients traveled back to the laboratory for physical data acquisition. The CRF was attached to the fiducial frame of IGS System 1, and the locations of all the fiducial markers on the frame were obtained relative to the CRF using calibrated hollow-tube probes (Figure 1) for the IR acquisition system and the optical tracking system—a process called “fiducial localization”.

The fiducial frame was removed, and the CRF was then attached to the patient via the bite-block. The idea is that the fiducial frame, when it is attached to the CRF during fiducial localization, will be at the same position relative to the patient as it was during the CT scan. Thus, after fiducial localization we need not reattach the fiducial frame to the patient. All the measurements were obtained relative to the CRF, thus allowing movement of tracking camera relative to the patient during the physical tracking. The location of the surgical target was identified three times relative to the CRF for each of the tracking systems using the hollow-tube probes (Figure 4). Next, the headband CRF for the IGS System 2 was affixed to the forehead of the patient (Figure 3), following which laser scanning was performed to register the physical space to the BrainLab image space. Following verification of a satisfactory registration as per the software installed on the IGS System 2, IR reflective balls were attached to the hollow-tube probe to build a surgical tool as per the specified protocols. The probe was calibrated, and the surgical target was localized three times.

During data collection, the display of the current location of the tracked probe on the pre-operative CT scan was monitored to ensure that each IGS system was functioning within acceptable visual tolerance. In particular, the physical location and radiographic location were compared visually to assure that they were roughly in agreement.

Data analysis

The registration between the physical space and CT space for the IGS System 1 was obtained by performing point-based registration [9] using the fiducial markers on the fiducial frame, whereas for the IGS System 2 it was obtained by performing surface-based registration. The physical location of the surgical target was then directly compared to the corresponding location in the CT space. The distance between the two points is by definition the navigational error, known more formally as the “target registration error” (TRE) of the system, as applied to this point in space. It is customary to refer to this measure also as the “accuracy” of the system. This measure is thus the accuracy at the BAHA.

Two-tailed t-tests with Bonferroni correction was used to compare the various systems. P-values of these comparisons are reported.

Results

Table 1 reports the results from the data collected from the six patients tested with the two IGS systems. Note that for IGS System 1, physical data was collected using two methods of tracking—infrared tracking (IR) and optical tracking. Results for all three tracking methods (two for IGS System 1 and one for IGS System 2) are listed in the table. The mean and standard deviation of TRE listed for each patient and each tracking method were computed based on the three physical acquisitions of the surgical target (marker at the BAHA).

Comparison between the groups using t-tests with Bonferroni correction shows that the EarMark system with IR tracking ($p = 0.033$) and with optical tracking ($p = 0.033$) performed significantly better than the BrainLab system. No significant difference was observed between the EarMark system with IR tracking and the EarMark system with optical tracking ($p > 0.7$).

Discussion

Presented herein is a novel method for comparing IGS systems based on bone-implanted targets. These targets, bone-anchored hearing aids (BAHAs), are implanted for aural rehabilitation. The novel concept of utilizing BAHAs as surgical targets for IGS validation was initially tested on skulls [13] and used on patients to determine the accuracy of the EarMark system [14]. The difficulty involved in the validation of an IGS system is identifying anatomical landmarks precisely and repeatably. In order to overcome this problem, we attached a post with a marker to the bone-anchored screw of BAHA patients. This marker lets us measure error at a certain location using different systems and compare the results without any discrepancy.

We have found that, in the region of the temporal bone, the accuracy of the Earmark system, which is approximately 1.6 mm, is significantly better ($p = 0.033$) than that of the BrainLab system, which is approximately 3.2 mm. This finding is not surprising given that the BrainLab system was designed for sinus surgery, while the EarMark system was designed for lateral skull-base work. As has been previously documented, accuracy is increased when fiducial systems (1) are stably affixed to the patient, (2) are not placed collinearly, (3) are spread far apart, and (4) surround the field of interest [21]. Given these guidelines, perhaps it is more surprising that the BrainLab fared as well as it did as applied to the lateral skull base.

Regarding tracking with the EarMark, no significant difference was found between infrared tracking (1.54 ± 0.63 mm) and optical tracking (1.61 ± 0.49 mm). In the vast majority of commercially available IGS systems, infrared tracking is utilized. The core infrared tracking technology used in most of the common IGS systems is obtained from Northern Digital Inc. (NDI, www.ndigital.com) and retails for approximately \$20,000. As such, it is the most expensive hardware component of an IGS system. The advantages of the NDI infrared tracking systems are its accuracy (tracking error as low as 0.25 mm) and the large volume over which it supports tracking (its field of view can encompass an entire operating room table and patient). The optical tracking system used in this study, which is the MicronTracker from Claron Technology Inc. (www.clarontech.com), utilizes ambient light detected by two digital cameras coupled with proprietary software that detects the intersecting lines of checkered patterns mounted on the patient and on the surgical instrument (visible in Figure 4). This technology is cheaper than comparable infrared systems, retailing for approximately \$10,000. While it achieves accuracy on the order of the infrared system (tracking error as low as 0.25 mm), the volume of tracking is smaller (approximately half that of the infrared systems). However, for lateral skull base work, the smaller volume of tracking does not represent a limitation, and the cost-savings may prove significant. Furthermore, the optical camera is smaller and lighter than those employed by infrared systems, enabling it to be positioned closer to the operative field, thereby reducing the problem of obstruction of its view by the surgeon.

A limitation of the study is that it provides a measure of error in only one very specific area, namely at the position of a BAHA placed on the surface of the lateral skull base. Because error at only one position is known, exact extrapolation to other locations is not possible. However, insight into the spatial pattern of error can be gained from an analysis of the error into its translational and rotational components. Error from each IGS system can be decomposed into translational shift and rotation relative to the central point of contact of the fiducial marker system with the patient's anatomy. For the EarMark system, this point is just anterior to the central incisors; for the BrainLab, it is approximately the nasion. While translation error is difficult to assess, it is independent of target position. Rotational error, which can be expected to be largely independent of translation error, is, however, directly proportional to the distance from the axis of rotation to the target, which can be expected to be near the central point of contact. Thus, targets (e.g., the cochlea) that are closer to the central point of contact can be expected to exhibit smaller error. While we cannot explicitly pinpoint error at other locations within the temporal bone, we can expect their values to be statistically smaller than the values we report for the BAHA.

The technique proposed herein is the first report of direct comparison among IGS systems using a reliable, bone-implanted target. The technique involved has multi-fold value. First, it allows testing outside the confines of the operating room, where time is extremely expensive. Second, it allows head to head comparison between IGS systems (e.g. the EarMark and BrainLab systems described herein) as well as between various subtleties of each system (e.g. infrared tracking versus optical tracking, laser-skin surface registration versus dental-affixed fiducial frame registration). Third, given the large number of BAHA patients both within the United States (over 15,000) and worldwide (over 35,000), this technique provides an accessible “gold standard” for the reporting of the clinical accuracy of IGS systems, potentially replacing the varied techniques currently reported in the literature. Such a method may prove invaluable in allowing surgeons to know the true accuracy of IGS systems in the area of planned surgical dissection.

In conclusion, bone-anchored hearing aid (BAHA) patients are a unique group of patients with externally-accessible, bone-implanted hardware on which a fiducial marker may be accurately relocated. This allows a new, clinical approach to testing of accuracy of image-guided surgical systems outside of the constraints of the operating room.

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Figure 1. Surgical target. (a) Customized post with the ball affixed, (b) The post attached on to the BAHA abutment, (c) Hollow-tube probe tip used to localize the center of the ball.

Figure 2. Patient wearing the fiducial frame and customized surgical target (not visible in this figure) just before the CT scan.

Figure 3.
Headband CRF attached to the patient for the physical data localization with the BrainLab system.

Figure 4.
Physical localization of the target marker at the BAHA with respect to the coordinate reference system (CRF).

Table 1

Mean $\pm$ standard deviation of the error values at the surgical target (BAHA). Errors are given for EarMark system for both infrared tracking (IR) and Optical tracking. (Only IR tracking is employed by the BrainLab system). All values are in mm.

Patient	IGS 1 (EarMark)		IGS 2 (BrainLab)
	IR tracking	Optical tracking	
1	0.67 $\pm$ 0.18	1.62 $\pm$ 0.18	2.77 $\pm$ 0.41
2	1.36 $\pm$ 0.05	1.81 $\pm$ 0.34	4.42 $\pm$ 0.19
3	2.44 $\pm$ 0.04	2.00 $\pm$ 0.40	1.85 $\pm$ 0.04
4	2.09 $\pm$ 0.35	1.54 $\pm$ 0.34	4.59 $\pm$ 0.19
5	1.18 $\pm$ 0.16	0.81 $\pm$ 0.46	2.70 $\pm$ 0.01
6	1.50 $\pm$ 0.38	1.89 $\pm$ 0.17	2.90 $\pm$ 0.14
Mean $\pm$ St Dev	1.54 $\pm$ 0.63	1.61 $\pm$ 0.49	3.21 $\pm$ 1.02