COMPUTER-ASSISTED IMAGE-GUIDED SURGERY USING THE REGULUS™ NAVIGATOR

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The term "frameless image-guided surgery" has become as well-known to surgeons as computerized tomography or operating room microscope over the past several years. The technologies behind this new surgery option include robotic arms, infra-red camera arrays (1D and 2D), ultrasound, robotic microscopes and magnetic field digitizers. The authors have shown the magnetic field technology incorporated in the Regulus Navigator to be a viable, accurate surgeon's tool by first integrating a conventional framed device and magnetic field frameless device, then advancing to the frameless device alone.

During surgery a patient's anatomy is first registered to preoperatively acquired radiological data. Surgical instruments are tracked on interactive CT/MRI displays as the surgeon locates his point or volume-in-space within the surgical field and uses his own procedure/technique of choice for surgical treatment. A clinical trial of 221 patients showed an overall mean accuracy of 2.56mm with a standard deviation of 1.15mm for intraoperative registration. Major concerns of utilizing magnetic field technology in the operating room, such as interference from surrounding metallic objects and equipment, were proven manageable while maintaining acceptable accuracy.

1. *INTRODUCTION*

The concept of stereotaxis, the use of a mechanical device to position instruments - probes, electrodes, biopsy cannulas, etc. - in three-dimensional space, dates back to 1873 when Dittmar developed and reported guiding devices for the placement of probes into the medulla oblongata of animals.[1] The most definitive description of the principles of stereotaxis is usually credited to Robert Henry Clarke and Victor Horsley. In 1906, they wrote "by this means every cubic millimeter of the brain could be studied and recorded".[2]

Having the capability to localize a specific point or area during surgery is accomplished by a surgeon's ability to register the surgical three-dimensional area of interest (patient's anatomy) to previously acquired radiological images. Modern neurosurgical stereotaxy utilizes preoperative diagnostic images to provide localization information during surgery.[3] Typically, the radiological databases are computerized tomography (CT) and/or magnetic resonance imaging (MRI).

Over the past few years techniques have been developed to assist surgeons in locating relevant pathology. Clinical history, physical examinations and radiology provide the fundamental building blocks for determining the individual patient's anatomy. The advent of high speed computers, CT and MRI have revolutionized medical imaging.[4]

Stereotactic frame-based systems require an external localization system on a frame rigidly fixed to a patient's head during the data acquisition phase. Frame-less or free-hand navigation systems do not require this rigidly fixed, sometimes uncomfortable, headframe. They use various referencing techniques such as skull fixation markers placed into the skull or non-invasive external reference markers fixed to the skin. Anatomical landmarks may also be selected on the image database and referenced to the patient. Anatomical referencing technique is sometimes very difficult to perform.

All image-guided surgery systems, whether a frame-based reference system or a free-hand (frameless) image-guided system, can trace their principles and ideas to the above pioneers. Every new idea and innovation has been a stage of evolution to bring neurosurgery where it is today.

2. *PURPOSE*

A surgeon desiring to use a free-hand imaged-guided system has many options in digitizers to choose from: infra-red (1D or 2D) camera arrays, ultrasound, magnetic field and robotic arms. Each of the image-guided digitizers has its own advantages and disadvantages. This paper presents data collected using the Regulus Measurement Unit (RMU), a frame-based image-guided stereotactic system and the Regulus Navigator (RN), a free-hand image guided system. Both were validated during clinical trials at various universities, tertiary care facilities, and small rural community hospitals. Thirty one procedures were performed using the RMU and over two hundred intra/extracranial procedures were performed with the RN.

3. *METHOD*

The Regulus Navigator (RN) utilizes a commercially available 144 Hz pulsed DC Flock of Birds (Ascension Technology Corporation; Burlington, VT 05402) magnetic field transmitter as its digitizer which defines its three-dimensional coordinate system. We chose this magnetic field technology for these reasons: 1) the low cost of the digitizer, 2) ease-of-use, 3) DC magnetic fields are less susceptible to foreign metal than other AC magnetic field digitizers, and 4) it had accuracy comparable to other commercially available digitizers. The Regulus Measurement Unit (RMU), a predicate device of the Regulus Navigator (RN), works in conjunction with the proven frame-based COMPASS Stereotactic System (Fig. 1).

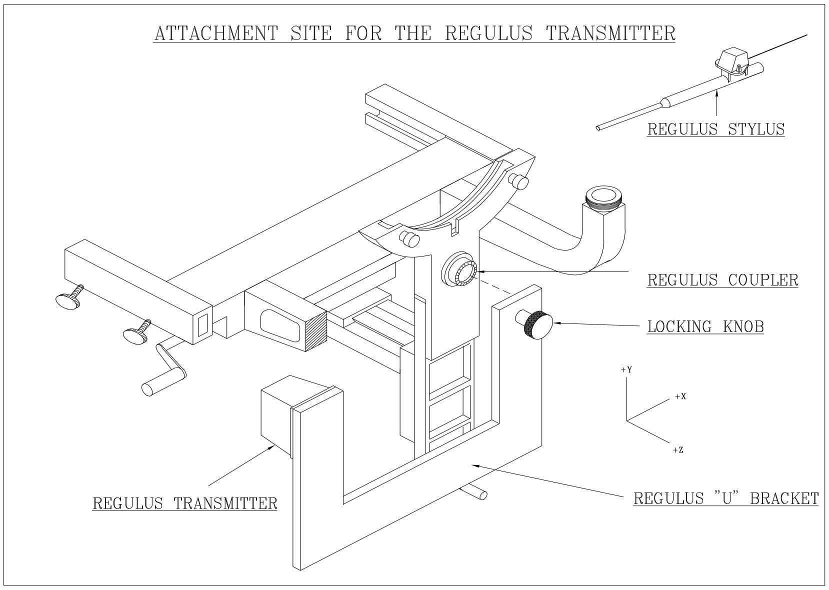

Figure 1. RMU attached to COMPASS stereotactic slide system.

A concern with magnetic field digitizers is they may be susceptible to outside distortion from foreign metals. In order to measure or confirm this, a magnetic field distortion test grid was developed and attached to the COMPASS headframe. When minor field distortions were discovered in the test grid, each individual unit could be corrected by software.[5] The accuracy of the system was analyzed by both visual comparison and quantitative measurement. Using a CT and MRI compatible test phantom secured to a rigid frame (headframe), we scanned the phantom in various CT and MRI scanner models. We then compared each test point with an x, y, z value from the frame-based system to the registered x, y, z value from the magnetic field digitizer. These results are shown in Table 1. A total of 31 patients underwent surgical navigation with the RMU.

Table 1. Average error over seven phantom tests at various rotations (22 pts. per test).

	X	Y	Z	3D
Average (mm)	-0.24	0.47	0.04	3.01

The results from the RMU study led to the Regulus Navigator, a free-hand neurosurgical navigation device. Whereas the RMU utilized reference points on a stereotactic headframe for calculations of a registration matrix, the RN utilizes corresponding points selected on radiological images and the patient's anatomy, without a headframe.

Test Phantom:

Today's scanners allow CT slice spacing of 1mm which means a single CT voxel can be up to 1mm away from its expected position. However, 1mm cuts throughout the entire skull are seldom performed because of the time, expenditure and increased radiation to the patient.[6] Therefore the authors utilized and recommend 3mm or less slice thickness in phantom and patient scans.

In-house bench testing with the RN was performed to determine the accuracy of the system without the headframe. Reference "stick-on" markers (I.Z.I. Medical Products, Owings Mills, MD) were placed on the outside of the acrylic phantom cover (Fig. 2). The phantom was scanned in various scanner models with various scanning parameters and was then placed in a three point pinion headholder on an operating room table.

CT Scanner Parameters
Field of View - 24cm
Scan thickness- 3mm or less
Kv levels- normal head

MRI Scanner Parameters
Field of View - 24 to 26 (headcoil)
Scan thickness- 3mm or less
Normal head scan setting
T1 or T2 spin echo series

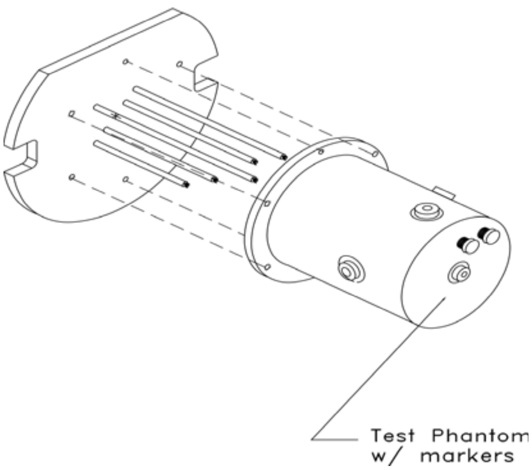

Figure 2. CT/MRI compatible phantom

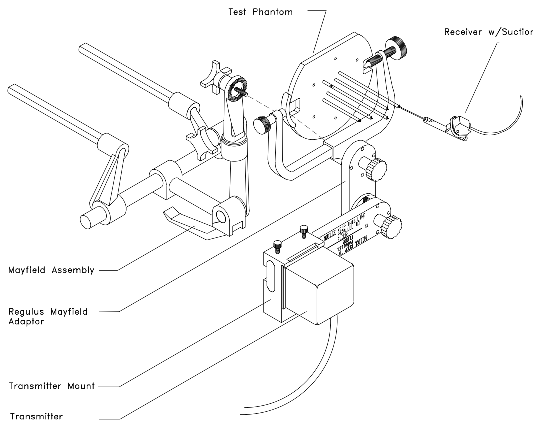

Figure 3. Phantom test set-up

Registration of the phantom was performed by selecting the reference markers on the radiological images and then placing the RN pointer/suction tip (attached to a magnetic field receiver) at the same corresponding reference marker on the phantom. After registration a root means square (RMS) error was calculated. The phantom cover was then removed. The RN pointer/suction tip was placed on the tip of each test point and an x, y, z value was determined (Fig. 3). The software allowed the measurement of errors in image data corresponding to pointer/suction tip location. This value was then compared to the actual tip location on image data.

The same phantom set-up was also used at each study site for system calibration during installations.

Hardware/Software:

As with the RMU, the RN operates on a Sun SPARCstation (Sun Microsystems, Inc., Mountain View, CA) and utilizes custom software. It also uses a color monitor with various peripheral devices. The radiological image data transfer can be performed via 4mm DAT tape, 8mm magnetic tape, 1/2” magnetic tape, or network. A potential problem for any company providing image-guided devices is importing radiological data into their planning system. Each scanner company, each model, and each software upgrade to the scanner seems to bring different proprietary image formats, all of which require custom software to be written. During the last few years, scanner companies have instituted a standard image format that can be utilized by everyone. This image format is called DICOM3.0. During the last 12 years, we have interfaced with 22 scanner models and have written 17 custom image transfers software programs on various CT, MRI, and Digital Subtraction Angiography (DSA) machines.

The RN utilized data from the Flock of Birds digitizer transmitted from the magnetic field (source) to its receiver. Various surgical instruments may be attached to the receiver with designated offsets to display the instrument tip over pre-operative radiological image data bases in the corresponding area.

The RN transmitter (source) is attached to a three-point pinion skull fixation device (i.e. Mayfield, Gardner) by the use of an adaptation bracket (Fig. 4). By attaching to the un-used starburst of the skull fixation, it can be positioned by the surgeon to be out of the way and positioned for increased accuracy. The current adaptation bracket allows over 200 degrees of freedom. All registration is performed in a non-sterile atmosphere in several steps:

1) Surgeon loads patient radiological images into the COMPASS database.

2) Reference markers are selected from the radiological database (non-invasive skin markers or anatomical landmarks). Three to eight registration points are selected.

3) The patient is secured into the skull fixation (Fig. 4) and RN hardware is attached.

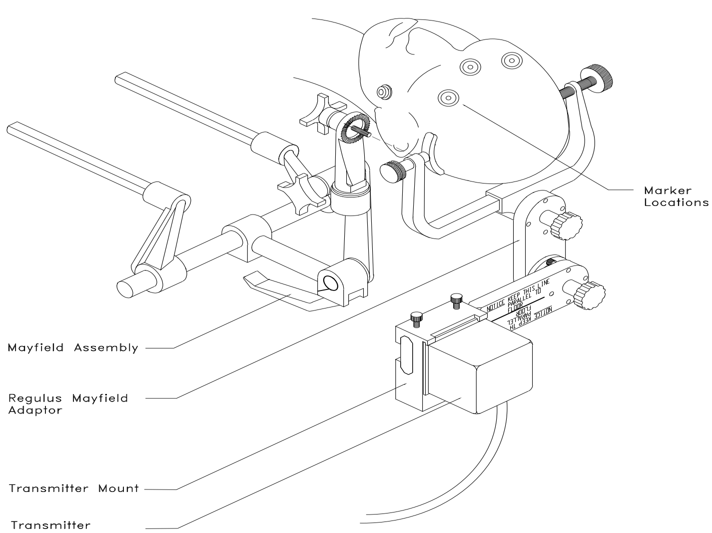

Figure 4. Patient set-up

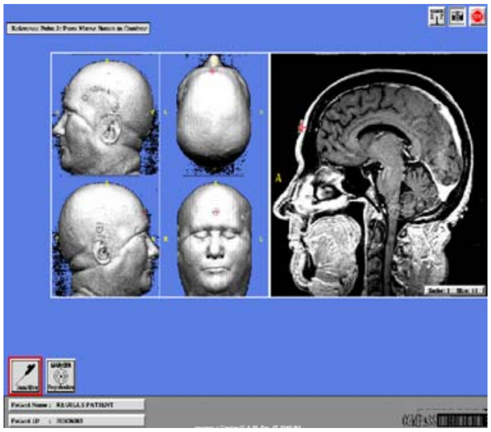

Figure 5. Reference marks as displayed on computer monitor.

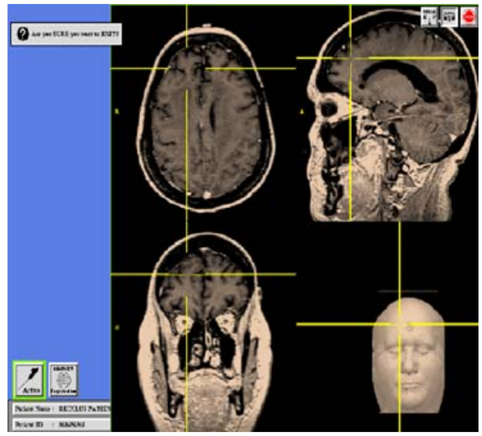

Figure 6. Image display mode showing tri-planar slices and volumetric rendering.

4) Registration is performed by placing the RN surgical tool (i.e. pointer/suction tip) at each reference mark corresponding to the selected point on the radiological image data displayed on the computer monitor (Fig. 5). From this the three-dimensional surgical field is correlated to the image data through a transformation matrix.

5) Upon completion of the patient registration, an RMS value is provided to the surgeon. This value corresponds in millimeters to how the software has registered the radiological database to the patient's anatomy in the operating room.

6) The surgeon can now proceed to interact between the pointer/suction tip and various image display options provided within the Regulus software (Fig. 6).

4. Results

As stated before, more than 221 procedures were performed during the RN clinical trial. 17% of the cases registered under anatomical references (Table 2) and 83% of the cases with external reference markers (Table 3)

Table 2. Anatomical Registration - 17% of Procedures

Overall Mean	2.49mm
Overall Min	0.49mm
Overall Max	4.14mm
Overall Stdv	0.91mm

Table 3. Reference Registration - 83% of Procedures

Overall Mean	2.58mm
Overall Min	0.21mm
Overall Max	7.61mm
Overall Stdv	1.18mm

Table 4. Overall Registration Analysis

Overall Mean	2.56mm
Overall Min	0.21mm
Overall Max	7.61mm
Overall Stdv	1.15mm

5. *Conclusion*

Almost all other image-guided systems require a dynamic reference frame (DRF) to be attached to the patient because there is no physical connection between the digitizer source and the patient. That is, the source (digitizer) is independent from the surgical field, sometimes several meters, and not linked to the surgical area. DRFs are utilized because the system needs to track both the patient and the fixation device used to immobilize the patient and the instrument in use. The RN does not require a DRF because its digitizer source is secured to the skull fixation clamp. This allows the surgeon to rotate the skull clamp or move the operating room table thereby moving the digitizer source with it.

The electro magnetic field technology accomplished our main goals by maintaining acceptable accuracy while doing so within a favorable price range. Other digitizer systems have reported accuracy of <5mm in 85% of cases for the stereotactic navigating microscope[7] and within 5mm in more than 90% of cases for the robotic arm[8]. The Regulus Navigator showed registration accuracy of 5mm or less in 97% of the cases.

Major concerns of utilizing magnetic field technologies, such as interference from surrounding metallic objects and its ability to obtain acceptable accuracy, were proven manageable. With little or no pre-operative concern for surrounding metal objects (i.e. C-Arm fluro unit, carts, etc.) accuracy was not affected. Electrically generated signals (i.e. bovie, lesion generator) placed into the field, but not in physical contact with the receiver, created no accuracy deficiencies. Ease-of-hardware set-up in the operating room was a major advantage taking an average of only a few minutes.

The Regulus Navigator has been shown to be an accurate, reliable and easy-to-use image-guided device during its clinical trials for any intra/extracranial procedure. The system has also been shown to be a cost effective alternative to significantly higher priced commercial image-guided systems.

Technological advancements have revolutionized many areas of medicine. Image guided instrumentation promises to play a substantial role in these advancements for years to come. As we have mentioned, there are many technologies currently being used, or investigated for image guided surgery. Many of these will continue to be refined adding new applications for use such as in breast biopsies, cardiovascular surgery, increased use in Orthopedics, ENT/Otolaryngology and many more areas of medicine. As the technology advances, so will the list of surgical instruments which can be attached to the image guided device, again allowing for further applications. The goal of developers is to interface virtually any and all instruments the surgeon may wish to use providing real-time visualization of the instrument tip in the actual surgical field.

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