Evaluation of External Ventricular Drain Complications and the Use of a Procedure-Targeted Image-Guidance System

by

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For my Mother, Father, and three Sisters. Thank you for your loving inspiration.
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by

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ABSTRACT

Access to the cerebral ventricle (e.g. ventriculostomy) is required to manage multiple life-threatening ailments. It can be done either in the operating room or at the bedside to relieve increased intracranial pressure or deliver medication. At the bedside, the procedure is normally performed freehand, with the occasional use of a Ghajar guide for guidance support. In the operating room, ventriculostomy may be performed with an image-guidance system, whether optical or electromagnetic.

The most common complications of ventriculostomy are hemorrhage and infection. It is unclear whether catheter placement accuracy and the number of passes of the catheter for each placement are correlated with ventriculostomy complications. Our goals are 1) to evaluate the current state of practice, including complications of ventriculostomy, and 2) to evaluate a targeted image guidance system for use with ventriculostomy – the Smart Stylet.

To address these goals, an Institutional Review Board-approved retrospective cross-sectional study was conducted at the Brigham and Women’s Hospital (BWH) to characterize the practice of external ventricular drain placements using data from the patient electronic medical record. Post-procedure catheter location was measured on post-procedure CT and MRI imaging studies. Most cases were performed in the operating room and the operative reports provided all procedure-related information. Microbiology reports were collected within a four-week interval following catheter placements to evaluate presence of invading pathogens. All imaging studies, microbiology reports, and operative reports were reviewed manually. The rest of the medical records were not reviewed and, therefore, cerebrospinal fluid leak and shunt malfunction were not evaluated. Catheter placement accuracy and the numbers of passes for each placement were assessed. We evaluated whether these metrics were associated with the occurrence of procedure complications.

A procedure-targeted image guidance system in development stage, the Smart Stylet, was implemented for use on a ventricular phantom model with a right-sided midline shift. Smart Stylet consists of an electromagnetic tracking system and ventriculostomy catheter connected to a PC and display. The operator of the Smart Stylet can interface with the system via a custom designed module in BWH’s 3DSlicer software system. The system was tested for accuracy by calculating targeting error and reporting
the precision of catheter placement. Precision was measured using pair-wise distances among experimental groups. The system was reviewed and commented on by three novices and two neurosurgical residents from the Massachusetts General Hospital by using the NASA-TLX grading scale questionnaire and a targeted survey. The phantom model was designed to gauge whether further tests in animals and cadavers are warranted using Smart Stylet.

Patients with trauma were more likely to have catheters misplaced (OR = 9.13±2.31; p<0.05). It seems there is an opportunity to improve patient care if catheter placement is made more accurate and reliable.

Use of the Smart Stylet system in a phantom study provided improvements in mean pair-wise distance and accuracy for catheter placement at the sub-centimeter level. A blinded operator achieved statistically significant improvement in targeting error using the right frontal approach (p<0.05). The operator also significantly improved mean pair-wise distances using left and right frontal approaches (p<0.05). Novice operators and neurosurgical residents both showed improvements in targeting accuracy for catheter placement when using the system for the first time. However, the improvements were not statistically significant. Novices’ pair-wise distances were significantly better with Smart Stylet guidance using the left frontal approach (p<0.05).

Improved guidance techniques, such as the Smart Stylet approach, can potentially decrease ventriculostomy complications if they can be easily integrated into clinical use at low cost.

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INTRODUCTION

Cerebral ventricle access is required for a wide variety of pediatric and adult patients; it is one of the most common neurosurgical procedures performed (1). This life-saving procedure can be done at the bedside or in the operating room (OR) under difficult and time-sensitive conditions. Candidate patients may suffer from hydrocephalus, infection, vascular incident, malignancy, or trauma. Ventriculostomy is then used to accomplish cerebrospinal fluid (CSF) diversion and/or deliver medication.

When performing a ventriculostomy, the catheter may be guided to an undesirable location. Reported rates of inaccuracy range from less than fifteen to greater than fifty percent (2-11). Misplaced catheters appear correlated with a higher risk of malfunction (9). A malfunctioning drain necessitates an adjustment or replacement of the catheter. Infection may be associated with increased rates of adjustment and replacement (12-16). Fluid stasis in malfunctioning drains has also been shown to contribute to infection rates. Depending on the timing of malfunction, the implications of additional passes may correlate with hemorrhagic and infectious outcomes due to drain replacement. A relevant grading scale has been presented, described in Chapter One (2).

This thesis describes three studies to (1) evaluate the current state of ventricular access practices at one institution, (2) evaluate precision and accuracy of a novel procedure-targeted display using EM technology on a phantom model, and (3) report the relevance of the system as deemed by a cohort of novice and experienced or resident neurosurgical physician practitioners.

Ventriculostomy Complications

The catheter may not show free flow of CSF on first pass through the parenchyma. In such an instance, the catheter is withdrawn and an additional attempt to cannulate the ventricle is performed. Twenty passes of the ventricular catheter have been reported by neurosurgical residents in the United States, with the majority of attempts reported between one and ten (1). The implications of multiple passes have not been described adequately (3; 7; 17). However, the potential for damage to neuronal tissue is
obvious. Additionally, multiple modifications of trajectory with a difficult target location may inadvertently cause hemorrhagic outcomes (17).

Hemorrhage has been reported at rates ranging from one percent in needle ventriculostomies to forty-one percent in external ventricular drainage (12; 18-23). Studies with higher reported rates of hemorrhage demonstrated that large gauge catheters and patients with vascular diagnoses are more likely to have hemorrhagic outcomes (20). A recent meta-analysis showed the potential for significant hemorrhage to be less than one percent, indicating the overall rare occurrence of hemorrhagic outcomes (24).

The infection rate is normally reported at around ten percent (11-14; 16; 18; 19; 22; 25-27). Most recent scientific publications describe the efficacy of antibiotic impregnated catheters and the effect on serology (28; 29). A wide range of factors have been postulated to lead to infectious outcomes, including catheter manipulations and catheter leaks (14).

Differing patient populations and physician practices will undoubtedly result in differing outcomes. Chapter one reports the current state of practice at the Brigham and Women’s Hospital as a retrospective cross-sectional study for frontal external ventricular drainage. It measures procedure accuracy, number of catheter passes and reports hemorrhagic and infectious complications. The procedure is usually performed in response to patient diagnoses that are imminently life-threatening without timely intervention, underlying the necessity of the procedure. Yet, the question remains; why don’t neurosurgeons use guidance technology all the time?

Ventriculostomy Approaches

Ventriculostomy is usually performed freehand using visually estimated geometrical guides (a combination of plane intersections and anatomical points) to plan catheter entry and trajectory (30). When done from the frontal approach, the sagittal plane defined by the ipsilateral medial canthus is visualized and outlined with the coronal plane defined by the ipsilateral tragus – the plane intersection defines the trajectory from Kocher’s point.
It is unclear whether surgeon seniority and experience are related to accuracy in placement – both sides of the argument have been reported (2; 12; 31). If experience is a factor in defining operator ability, then simulators and guidance systems are critical for training (31-39). The question has been posed whether the community should be comfortable with current error rates in catheter placement (17).

In 1985, Ghajar presented an easily used guidance fixture. It consists of a tripod with the center placed over the burr hole. The tool ensures a ninety degree trajectory from the plane tangential to the burr hole. There is no real-time feedback or confirmation of catheter placement. A prospective study placing EVD’s with and without the guide showed a significant improvement in targeting error when using the guide (3.7 ± 5.7 mm Ghajar versus 9.7 ± 6.3 mm freehand; \( p = 0.001 \)). No significant difference was found in the ability to cannulate the ventricle (40). The guide is not useful in cases where anatomical variation renders the ninety-degree angle approximation inaccurate, such as brain shift.

Pre-procedure imaging studies were therefore investigated to improve on guidance approaches by implementing image-guidance systems (37; 38). Pre-procedure imaging studies are registered to the patient anatomy and trajectories are planned using tracking technology. Using this method, aberrant ventricular anatomy is addressed and the neurosurgeon can be more confident that a planned trajectory could improve on the predefined perpendicular trajectory. In these systems, real-time feedback is available; however, confirmation of placement is not. Ultrasound based systems were developed simultaneously to address real-time confirmation of catheter location (35). Statistically significant differences have not been reported between the freehand method and use of the ultrasound based systems (41).

Interestingly, a robotic system was presented in 2008 that was able to successfully cannulate ventricles in sixteen patients on first pass (36). This system uses pre-procedure images and holds the same drawbacks as conventional image-registration methods with one major difference – a robot is the operator. Replacing the physician operator with a robotic counterpart has been attempted in other fields for operations such as prostate resection with the DaVinci machine (42). Criticisms of robotic systems include the lack of tactile feedback to the operating physician. In effect, tissue resistance and the “pop”
that is felt upon entering the ventricle would no longer be conveyed to the operator. Indeed, it may take large numbers of patients to present a powerful and significant difference in outcomes that would result in widespread adoption. In practice, a portable and inexpensive solution will be necessary for bedside application. Above all, time consuming registration methods would need to be addressed with a system as complex as a robot.

**Smart Stylet**

Chapter Two of this thesis describes the accuracy of a direct current (DC) electromagnetic (EM) tracking system for bedside and OR-based catheter placement using Smart Stylet. EM was chosen for multiple reasons. First, portable, flat plate EM transmitters can easily be positioned under the patient’s head in a bedside application. Alternate solutions for mountable transmitters can be used in the OR when the patient’s head is in a clamp. Recent advances in tracking technology have made it possible for sensors to be as small as 0.3 mm in diameter. Therefore, these sensors can be placed on the tip of the instrument, providing the operator with a more accurate measurement.

An alternative tracking system currently in use is based on optical systems, which are large and expensive. They hold similar levels of accuracy to current EM systems. However, optical systems suffer from the constraint of the cameras’ lines of sight (43; 44). EM fields are vulnerable to interference from ferromagnetic materials. Therefore, novel metal-immune transmitters that shield the EM field from any interference below the transmitter have been developed.

Chapter Three presents initial measurements of performance and user acceptability for Smart Stylet. A recent poll of neurosurgeons nationwide found that greater than fifty percent of respondents would use an image-guidance system that guarantees placement one hundred percent of the time if it can be implemented within ten minutes (1). A portable and inexpensive solution will be necessary for bedside implementation. There have been preliminary reports of EM technology use in the OR for procedures such as EVD placement, Ommaya reservoirs, ventriculoperitoneal shunts,
endoscopy, craniotomy, and others (37; 38). Larger numbers of patients are needed to accurately assess the potential for improvement.
CHAPTER 1
Evaluating External Ventricular Drain (EVD) Practices –
An Electronic Medical Record (EMR) Based Study

Introduction
The Health Information Technology for Economic and Clinical Health (HITECH) Act encourages widespread adoption of EMR’s for storing and accessing patient data to support care management and delivery. In addition, the EMR enables the development of analytical data that can be used for research purposes (45). Clinical history can then be successfully organized using temporal relationships (46). Procedure related data can also be extracted based on physician coding (47). This study takes advantage of clinical procedure history using temporal relationships based on physician coding practices to create a cohort of records for analyzing EVD complications.

The rates of accuracy, hemorrhage and infection have been reported in varying numbers throughout the literature (2-29). However, clinical studies looking at the number of catheter passes are still lacking (3; 17).

A goal of this thesis is to assess complication rates of EVD and its association with catheter placement accuracy and number of passes, while validating the ability to successfully extract procedure related clinical history and outcomes from EMR-based data stores.
Materials and Methods

The BWH Institutional Review Board approved a study of patients who underwent a ventriculostomy from 2000-2010 at BWH. Medical records of all patients who had an ICD-9 code of 02.2 (for ventriculostomy) were obtained from the Research Patient Data Repository (RPDR), a database of medical records derived from the EMR. The data was available in Microsoft Access database format (Figure 1).

Feature Extraction

Statement Query Language (SQL) was used to query the RPDR database and retrieve the specified cohort of patients (See Appendix A-1). Each tuple within the final relation was composed of an individual patient’s operative report with an associated post-procedure radiology report completed within twenty-four hours and a microbiology exam within a four-week period, if available. In addition, each tuple contained patient
demographics. Only patients with primary catheter placements were considered in this dataset.

Features selected from the database included patient age, sex, preoperative diagnosis, number of passes of the catheter, post-procedure catheter location, guidance status, hemorrhage, and infection (including causative organism, if specified). Relevant clinical data sources included clinical data, operative reports, radiology imaging studies, and radiology reports.

**Data Analysis**

A modified grading scale was used to grade catheter placements (Table 1) (2). An additional grade (IV) was added for failed procedures. The location of each catheter was measured using the imaging study.

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Appropriately placed catheter in the ipsilateral frontal horn including tip of the 3rd ventricle</td>
</tr>
<tr>
<td>II</td>
<td>Suboptimal placement in noneloquent tissue including the contralateral frontal horn, corpus callosum or interhemispheric fissure</td>
</tr>
<tr>
<td>III</td>
<td>Suboptimal placement in eloquent tissue including the brainstem, cerebellum, internal capsule, basal ganglia, thalamus, occipital cortex, and basal cisterns</td>
</tr>
<tr>
<td>IV</td>
<td>Failed procedure</td>
</tr>
</tbody>
</table>

*Table 1. Kakarla et al. 2008 catheter location grading scale modified to include failed procedures.*

Number of passes of the ventriculostomy catheter was recorded as reported in the operative reports based on manual review. Cases were then categorized as a binary feature, “one pass” versus “greater than one pass” of the catheter.

The presence of hemorrhage was noted, defined as bleeding along the catheter tract as observed on the CT image. Trace and questionable hemorrhages were excluded. Questionable hemorrhages were defined as those causing slight increase in density
around the catheter on CT or slight enhancement on MRI that were indistinguishable from that caused by the catheter. All hemorrhages were confirmed using the radiology report.

**Statistical Analysis**

All statistical analysis was performed using R Statistical Software (The R Foundation for Statistical Computing, Vienna, Austria). (See Appendix A-2) Multiple logistic regression models were developed to identify features associated with hemorrhagic and infectious outcomes. Separate models for each outcome were developed. Independent variables included patient age, sex preoperative diagnosis, catheter placement grade, and the number of passes to accomplish ventricular cannulation. Univariate analysis was performed to select features to include in the models, excluding features with $p>0.25$. Using the remaining features, backward elimination was used to select variables for inclusion in the final model.

A model to determine variables associated with misplaced catheters was built. Grades 2, 3, and 4 were grouped to form a category representative of misplaced catheters. Independent variables included patient age, sex, preoperative diagnosis, number of passes and the types of guidance support. The model was built in a similar fashion to that of the hemorrhage and infection models.

All models were evaluated using ten-fold cross-validation. To test the ability of each model to distinguish hemorrhagic, infectious, and catheter placement outcomes, the areas under the receiver operating characteristic curves (AUC) were calculated for each fold of cross-validation and the values were averaged. To test model calibration, the Hosmer-Lemeshow (H-L) statistic p-value was calculated for the models on each fold and averaged.
Results

Clinical Results

110 patients who had 112 frontal EVD placements were identified in the RPDR database from 2003-2010 at the BWH. CT images prior to 2003 were not available in BWH’s PACS system. The average patient age was 55 (range 16 – 96) years of age. 51.8% were female and 48.2% were male. Diagnoses were separated into four categories – vascular (62.5%), tumor (21.4%), trauma (14.9%), or cyst (1.79%).

Procedures were performed freehand during 91 (80.5%) catheter placements. The Ghajar guide was used during 17 (15%) and image-guidance was used during 4 (3.54%) placements. Post-procedure hemorrhage was noted in 3 (2.68%) placements on imaging study. Infection was noted in 7 (6.25%) procedures. All infections occurred within 10 days of the procedure (range 3 – 10). Based on Table 1, there were 89 (79.5%) Grade I, 16 (14.3%) Grade 2, 5 (4.46%) Grade 3, and 2 (2.68%) Grade 4 catheter placements. Multiple passes were attempted in 6 (5.36%) procedures.

Procedure notes at BWH are not stored in EMR. Three operative reports analyzed provided data on Intensive Care Unit catheter placements. These were included in the final dataset.

Cross-Validated Model Results for Hemorrhage and Infection

The cross-validated model for hemorrhage was unreliable due to the low number of patients with hemorrhagic outcomes.

On univariate analysis, grade of catheter placements was identified to be associated with infection (Table 2). After adjusting the model for age and sex, the model no longer displayed a significant association between Grade 4 and infectious outcomes (Table 3).

<table>
<thead>
<tr>
<th>Variable</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 4</td>
<td>0.0578</td>
</tr>
</tbody>
</table>

*Table 2. Univariate analysis with infection as the outcome*
Table 3. Multiple regression model with infection as the outcome.

**Guidance Results**

On univariate analysis, three variables were found to be significantly associated with misplaced catheters; male sex, trauma-based diagnoses and the number of catheter passes (Table 4).

<table>
<thead>
<tr>
<th>Variable</th>
<th>P-value</th>
<th>OR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>0.514</td>
<td>1.64 ± 0.0108</td>
</tr>
<tr>
<td>Sex</td>
<td>0.742</td>
<td>1.02 ± 0.114</td>
</tr>
<tr>
<td>Grade (2, 3, 4)</td>
<td>0.597</td>
<td>1.67 ± 0.565</td>
</tr>
</tbody>
</table>

Table 3. Multiple regression model with infection as the outcome.

After backwards elimination, patient sex, diagnosis and number of passes were included in the final model. After ten-fold cross-validation, trauma-based diagnoses were significantly associated with misplaced catheters (p<0.05) (Table 5).

<table>
<thead>
<tr>
<th>Variable</th>
<th>P-value</th>
<th>OR</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male sex</td>
<td>0.0718</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diagnosis Code (Trauma)</td>
<td>7.91 x 10^{-4}</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;1 pass</td>
<td>0.0141</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 4. Univariate analysis of variables to include in the multivariate guidance model

The average AUC was 0.740 ± 0.130 (95% CI 0.639 - 0.842). The model seemed adequately calibrated with an average H-L statistic p-value of 0.304.
Discussion

Three patients had hemorrhagic outcomes and one failed procedure had an infectious outcome. All four cases were performed intraoperatively.

Case 1 - Hemorrhage

A 52 year-old male with cerebellar hemorrhage, intracranial hypertension, and brainstem compression underwent a freehand grade 2 EVD placement intraoperatively on first pass (Figure 2). Hemorrhage was found postoperatively along the catheter tract. There were no infectious outcomes.

Figure 2. Hemorrhage along the catheter tract in a Grade 2 placement that does not go through the ipsilateral ventricle.
Case 2 - Hemorrhage

57 year-old male with an arteriovenous malformation received a freehand grade 1 EVD placement on first pass. Hemorrhage was found postoperatively along the catheter tract. There were no infectious outcomes.

Case 3 - Hemorrhage

A 44 year-old female with a metastatic tumor underwent a freehand grade 1 EVD placement intraoperatively on first pass. Hemorrhage was found postoperatively along the catheter tract. There were no infectious outcomes.

Case 4 - Infection

A 29 year-old female involved in a motor vehicle accident presented with a large acute frontotemporoparietal subdural hemorrhage with midline shift. Three attempts to cannulate the ventricle were made. CSF did not express from the catheter and it was thus removed. A subdural catheter was placed. Positive bacterial culture developed within three days of the operation. There were no hemorrhagic outcomes.

Accuracy

EVD catheters were appropriately placed at satisfactory levels within BWH. Misplaced catheters may cause increased rates of malfunction (9). This pediatric study described the local environment of the catheter tip to have an effect on shunt failure. The article explicitly defined the catheter location as in the frontal horn, occipital horn, body of the lateral ventricle, third ventricle, embedded in brain, or unknown. The tip location was described as surrounded by CSF, touching brain, or surrounded by brain parenchyma within the ventricle (slit ventricle). The study determined the ideal location for the catheter tip to be in a pool of CSF away from brain structures. The current study used a comparably general grading scale and did not follow the EVDs for malfunction. A chart review would be necessary to determine the incidence of replacement and this information was not readily available in the EMR. Reviewing catheter tip location may result in more definitive results.

This is one of the first studies to report a percentage of cases that required more than one pass of the EVD catheter (3; 6).
Hemorrhage and Infection

EVD placement has most often been associated with hemorrhagic and infectious complications. Hemorrhagic outcomes have been associated with catheter gauge and vascular diagnoses (20). The presented dataset had 62.5% vascular diagnoses and was unable to reproduce this result, suggesting there may be additional factors involved.

Infection rates at this institution were in accordance with those reported in published studies. Grade 4 was significantly associated with infection on univariate analysis. After the model was adjusted to include age and sex, none of the variables were significantly associated with infectious outcomes. This may have been due to the low number of patients classified as Grade 4. One of two patients with a Grade 4 catheter placement developed an infection. It is unclear what caused the rapid development of infection. A thorough case review is necessary to gauge patient and procedure-related complications.

Grade

Patients with trauma were significantly associated with misplaced catheters. A previous study outlined trauma cases to be associated with increased rates of suboptimal EVD catheter placement. The study suggested that aberrant anatomy may be the cause (2). It may be necessary to encourage the use of guidance technology in cases with shifted anatomy. Shifted anatomy may be a technically difficult scenario using conventional landmarks.

The usage of a guidance support system, whether it was a Ghajar guide or an image-guidance solution, was not associated with catheter placement grade. The Ghajar guide is only useful in situations where ventricular anatomy is not shifted. Studies have shown that comfort levels with image-guidance systems may take time to develop. The systems are complex and a learning curve is evident (36).

Limitations

A limitation of this study included the lack of paper chart review to obtain data from handwritten notes. In addition, collecting more data to increase the number of patients with the outcomes of interest would improve the statistical power to detect associations between patient and procedural variables and infectious and hemorrhagic
outcomes. A future direction for this work could include the use of neural networks, the utilization of a rare events model in predicting hemorrhagic outcomes, or bootstrapping.
Conclusion

The RPDR, an EMR-based data repository, can be utilized in conjunction with temporal queries to evaluate EVD placement complications. EVD placement is found to be effective at a rate of 79.5% appropriate placement. More than one pass was attempted in 5.36% of procedures. The rate of observed negative outcomes, including hemorrhage and infection, was 8.93%. Patients with trauma are more likely to have catheters misplaced.
Chapter 2

Smart Stylet: Implementation of a ventriculostomy-targeted image-guidance system

Introduction

Image-guidance has been used effectively for multiple neurosurgical procedures (38). However, the difficulty associated with using it for ventriculostomy may be attributed primarily to time constraints. Further, some believe that a change in practice is necessary while others do not.

Varying levels of catheter placement accuracy have been reported (2-11). Chapter one of this thesis suggests that misplaced catheters lead to higher rates of complications. However, no method of guidance has been proven to significantly improve over the freehand method at this time. The development of an image-guidance solution that increases placement accuracy and is easy to use is warranted based on the rates of misplacement and the possibility of increased complication rates.

This thesis evaluates accuracy and mean pair-wise distance of a ventriculostomy-targeted EM image-guidance system under development, the Smart Stylet.
Materials and Methods

Clinical System Components

An EM system designed by Ascension Technologies (Burlington, VT), a conventional ventriculostomy stylet and catheter, and a personal computer (PC) with display were used to assemble Smart Stylet. The idea was formulated by Dr. Rajiv Gupta and Dr. Arnold Cheung of Massachusetts General Hospital's Department of Radiology. All components were commercially available for under $20,000 USD. Smart Stylet's software module was implemented in 3D Slicer 2.7 (www.slicer.org) and consisted of a three-dimensional display with two reformatted CT displays. Within the 3D display, two trajectories were defined – one along the path of the stylet and the other an ideal trajectory from the tip of the catheter to the target. A target can be a point with any desired radius. Alternatively, a target can be defined as the centroid of any visualization toolkit (VTK) model. One reformatted display was constructed in the plane of the target with an axial priority. The other reformatted display was constructed along the trajectory of the stylet with a coronal priority (see Figure 1). All displays were dynamic and viewed "live" using transmitted coordinates from the EM system thus allowing the operator to visualize the stylet in relation to all models at thirty frames per second.

One 0.3mm 5 degrees of freedom (DOF) sensor was used to measure the stylet position and orientation, excluding roll from transmitted coordinates. Another 1.8mm 6-DOF EM sensor was used to register the phantom to the 3D model. The 0.3 mm sensor was used to guide the catheter because it was small enough to be at the tip of the stylet within the catheter's lumen. The sensor was affixed to the side of the stylet using bone wax and was guided as far down the catheter as possible. Then, the stylet was calibrated to define the distance from the sensor location to the tip of the catheter (48). This process allowed the operator to accurately define the catheter tip location in relation to the segmented models and reformatted displays.
Figure 1. Smart Stylet display
**Phantom Model**

A phantom model was built using a plastic skull replica housing a shifted ventricle model. A patient DICOM data set with a significant midline shift was stripped of all identifying information. The image was segmented using thresholding techniques and a 3D VTK model was created. This image was converted to stereolithography (.stl) format for interpretation in computer aided design (CAD) software. The image was interpreted by a three-dimensional printer and a physical model was created. The model was placed within the plastic skull's cranial vault using anatomical landmarks and rigidly fixed.

Three frontal burr holes were created on the skull replica, two left frontal and one right frontal. Ten centimeters were measured posterior to the nasion along the midline. Three centimeters lateral from the midline were measured in both directions and two burr holes were drilled using a hand crank drill – one left and one right. Once it was determined that the left frontal horn was difficult to access from the traditional burr hole coordinates, two more centimeters were measured lateral from the left burr hole and an additional left frontal burr hole was placed. In all instances, the hand crank drill bit was positioned perpendicular to the plane tangential to the entry point while placing the burr hole. It was ensured that the target ventricle could be reached from all burr holes.

**Alpha Experiment**

**Model Building**

The skull phantom was imaged in a Siemens Somatom Flash CT scanner using 1.25 mm slice thickness. The DICOM images were segmented using a combination of thresholding and manual outlining for ambiguous boundaries using a Slicer 2.7 module. The ventricles were manually separated into right and left models. The skull surface model was also segmented for use in registration. The resultant VTK models were used during all experiments.

**Calibration and Registration**

First, the stylet was calibrated using the pivot method. The tip is fixed in space and the catheter is swiveled in a circular motion to acquire as many coordinates as
possible. The constraint problem is solved to define the location of the catheter tip in relation to the 0.3 mm sensor. Then, the 1.8 mm sensor was used to collect a surface map of points by tracing the dome of the cranium with adequate coverage of frontal, temporal and occipital areas. The iterative closest point algorithm was used to register the coordinate axes of the skull phantom to the segmented model (49).

**EVD Placement**

Each stylet insertion was carried out ten times without image guidance and ten times with image guidance by one operator. Each pass of the catheter was made to a maximum depth of 7 cm or if a solid structure within the phantom was encountered. The EM tracking system was used to acquire spatial coordinates of the catheter tip upon completion of each pass. On each attempt, the operator was blinded to success or failure in targeting the ventricle. Each attempt was separated by at least an hour to minimize visuospatial learning.

**Data Analysis**

All data analysis was carried out using Matlab 7.4.0 (The Mathworks, Inc., Natick, MA, USA). (Appendix B-1) Targeting error was calculated by measuring the distance from each point representative of the catheter tip to the centroid of each predefined target area on the superior aspect of each frontal horn. Means were compared with and without guidance for each approach using a t-test.

Targeting variability was measured using catheter tip point pair-wise distances. The distance between every permutation of pair-wise points in each category was measured. Mean pair-wise distances were compared using a t-test.

Trajectories from the burr holes of catheter entry to the points acquired from the catheter tip were calculated for a three-dimensional visualization of targeting ability and spread. Each figure was made from a bird’s eye view looking through or at an angle from the burr hole.
Results

The distance from the left burr hole to the left frontal ventricular target point was 60.9 mm. Right burr hole to right ventricular target area was measured at 40.5 mm.

The left frontal approach without guidance resulted in a 9.48±1.36 mm average targeting error. With guidance, the average target error was 10.2±1.97 mm (p = 0.323). The average target error using the right frontal approach without image guidance was 9.01±1.23 mm. The error improved to 6.38±1.10 mm using Smart Stylet (p = 0.0017) (Figure 2).

Pair-wise distances among the left frontal points without guidance averaged to 6.33±3.51 mm. Those with guidance presented a mean of 4.78±2.15 mm (p = 0.0121). The distances among the right frontal approach without guidance averaged to 8.38±5.16 mm. With Smart Stylet guidance, pair-wise distances improved to 5.75±2.76 mm (p = 0.0042) using the right frontal approach (Figure 3).
Figure 2. Targeting error measured from the centroid of each target area.
Figure 3. Pairwise distances by approach and guidance status.
Figures 4-7 display three-dimensional overlays of trajectories onto the ventricular models. Figure 4 shows a majority of trajectories missing the ventricle without Smart Stylet guidance. Figure 5 shows how most/all trajectories would intersect with the ventricle if continued past the surface. Figure 6 displays an example of encountering the contralateral ventricle on missed passes. Figure 7 shows how image-guidance can correct the technique of overshooting the ipsilateral ventricle.

Figure 4. Left Frontal without image guidance at an angled bird’s eye view from the burr hole. Most trajectories seem to miss the ventricle.
Figure 5. Left frontal with image-guidance viewed at an angle from the burr hole. All trajectories seem to encounter the ventricle.
Figure 6. Right frontal without image-guidance. Trajectories splay across both ventricles.
Figure 7. Right frontal with image-guidance. Trajectories focus on right ventricle.
Discussion

Image guidance may provide an advantage when the physician desires guidance or navigation support by providing real-time feedback. This series of experiments provided data to bridge the gap from navigation to targeting. Smart Stylet allowed for a lower amount of variability in the final catheter location as demonstrated by pair-wise distances. However, the differing levels of accuracy between left and right approaches raised questions.

The ventricular model in the phantom was shifted from left to right. Therefore, the pass from the left burr hole to the left ventricular target area was longer than the corresponding distance on the right. A potential reason for the decreased accuracy may have been the longer pass required and the resultant loss of control at the tip of the catheter. The proximal pivot point at the burr hole made small motions at the base resulting in large translations at the distal tip. This may have resulted in lower accuracy with long trajectory targeting. It is notable that the targeting variability significantly improved with Smart Stylet guidance. Further, according to the three-dimensional plots, the ventricle seemed more likely to be encountered with guidance despite comparable accuracy with the group that had no guidance. The large size of the target area or ventricle may have been partially responsible for the visual discrepancy.

Most current image-guidance systems require pre-procedure imaging to obtain registration and navigate effectively. Ultrasound-based systems are the only methods available to provide real-time feedback and confirmation of placement simultaneously. It may seem relevant to use a mixture of displays and technology to create the ideal image-guidance system for ventriculostomy.

For example, recent techniques have made it possible to transmit ultrasound waves through the skull (50). While the images are not of high resolution, they may provide rough estimates of targets as large as the ventricles. Current ventriculostomy-targeted ultrasound systems require enlarged burr holes to place the transducer on the dura (35). Smart Stylet’s unique display provides reslicing and three-dimensional capabilities that may make targeting easier. Therefore, three-dimensional plane reconstruction (51) using tracked transcranial ultrasound planes merged with Smart
Stylet’s slice reformatting capabilities may allow for real-time feedback, confirmation of placement, and a time-sensitive solution given removal of the registration process.
Conclusion

Smart Stylet provided an advantage in targeting the ventricles over the freehand technique in a phantom experiment representative of aberrant neuroanatomy using the frontal approach.
Chapter 3

Operator Performance and Perspective when using Smart Stylet

Introduction

There is limited objective data on how experience coincides with ventricular targeting ability. The topic is unique among targeting studies given the size of the target and its potential ambiguity in location given the presenting illnesses. The American Association of Neurological Surgeons held a Top Gun event in the past where residents were given the opportunity to evaluate their performance when placing ventricular catheters. In this study, post-graduate year level was not indicative of ability (31). Yet, recent data suggests that it may be a factor (12). Although increased experience often leads to improved ability, different people learn at different rates, potentially acting as a confounding variable.

Laparoscopic surgeons and gastroenterologists have recently published data with metrics such as instrument tip path length, velocity, acceleration, and jerk to assess procedure performance (52-54). Sophisticated methods have been developed assessing curvature of instruments (55). Task assessment was then used to gauge mental, physical and temporal demand. Performance, effort and frustration were also used to quantify an operator’s experience with a task (53; 54). These parameters provide objective metrics for evaluating an operator’s experience in performing a task. For example, if a surgeon is working too rapidly with jerky movements, it may be possible that his or her frustration is higher than usual or that he/she is a novice at the procedure.

This thesis utilizes a method to evaluate operator targeting performance in conjunction with evaluating the usability of Smart Stylet for placing ventricular catheters.
Materials and Methods

Performance Measures

This study was approved by the Massachusetts General Hospital Institutional Review Board. Two resident physicians from the neurosurgical service, one research fellow in image-guided therapy, and two fellows of differing medical disciplines were recruited to test Smart Stylet for ease of use in performing a ventriculostomy.

The Smart Stylet system was implemented as described in Chapter 2 of this thesis. A plastic skull replica housing a shifted ventricle was used. The same registration and calibration matrices utilized in Chapter 2 were maintained in this series of experiments for ease of comparison. Each operator was given an opportunity to pass the catheter once with and once without guidance per frontal approach. Data acquisition with and without Smart Stylet guidance were separated by a minimum of one hour to prevent visuospatial learning in the study subjects. The operators were requested to pass the catheter to a maximum depth of 7 cm or until solid was encountered within the cranial vault.

Once targeting point coordinates were obtained, targeting error was calculated as in Chapter 2 of this thesis. Three-dimensional plots of trajectories from the burr holes were also created to assess performance when utilizing Smart Stylet for the first time (Appendix C).

Display Evaluation

The NASA Task Load Index (TLX) questionnaire (NASA Ames Research Center, Moffett Field, CA, USA) was given to each study subject upon completion of the task with and without guidance (http://human-factors.arc.nasa.gov/groups/TLX/). (Table 1)
Parameter | Description
--- | ---
Mental Demand | How mentally demanding was the task?
Physical Demand | How physically demanding was the task?
Temporal Demand | How hurried or rushed was the pace of the task?
Performance | How successful were you in accomplishing what you were asked to do?
Effort | How hard did you have to work to accomplish your level of performance?
Frustration | How insecure, discouraged, irritated stressed and annoyed were you?

Table 1. NASA TLX measured parameters.

The six parameters measured were rated on an interval from 0-20. Weights for each parameter were collected once. Every permutation of paired parameters is presented and the operator selected one as more contributory to the workload involved in performing the task (Appendix C-1). For each parameter, the number of times it was selected on the weights survey was tallied and assigned as the parameter’s weight.

To calculate an overall workload score for an individual on completion of a task, each rating was multiplied by its corresponding weight given by that subject. The sum of the weighted rankings was divided by 15, or the sum of the weights to determine the final metric.

A visual analog scale (VAS) and questionnaire was used to provide test subjects with an opportunity to gauge his/her overall experience (53) (Appendix C-2). The scale was converted to a metric by measuring from the margins on a 15 point scale (fifteen cm grids).
Results

Novices

Test subjects were classified as novices if they were not neurosurgical residents. The mean targeting error for novices (n=3) using the left frontal approach was 16.7±3.42 mm using Smart Stylet guidance. Without guidance, the mean targeting error increased to 20.7±4.84 mm (p = 0.325). The mean targeting error for the right frontal approach using Smart Stylet was 9.47±3.34 mm. Targeting error increased to 13.6±3.55 mm without guidance (p=0.0934).

Mean pairwise distance among the left frontal approaches with guidance was 9.37±1.34 mm. The average distance among those without Smart Stylet guidance was 28.7±6.85 mm (p=0.0298). Among the right frontal approaches, the mean pair-wise distance was 9.69±4.51 mm with image-guidance. Without guidance, the mean error was 20.4±9.30 mm (p=0.0671). See Figure 1.
Figure 1. Pair-wise distance calculations among practitioners who have never placed a ventriculostomy.
Right frontal approach diagrams are shown in Figure 2.

Figure 2. Right frontal approach with guidance (red) and without guidance (green) in novice operators. Left frontal approach diagrams are shown in Figure 3.
Residents

Two residents evaluated the system for relevance and ease of use. Average targeting error was 10.9±0.283 mm from the left frontal approach using guidance support. Mean targeting error was 17.8±2.74 mm (p = 0.191) without guidance. From
the right frontal approach, the mean targeting error was 15.9±3.25 mm without guidance. With guidance, the average targeting error was 14.3±1.80 mm (p = 0.362).

Given that there were two points per approach, the distance between each pair of points was calculated. Left frontal with guidance showed a distance of 14.5 mm apart. Points taken from the left frontal approach without guidance showed a distance of 28.2 mm apart. From the right frontal approach, the two points taken with guidance were 28.2 mm apart. Without guidance, the distance was 15.1 mm.

Right frontal approach diagram is shown in Figure 4.

---

Figure 4. Resident operators using right frontal with (red) and without (green) guidance on first pass. The results of the left frontal approach are shown in Figure 5.
Figure 5. Resident operators using left frontal with (red) and without (green) guidance showing only the left ventricle.

Display Evaluation

The average task load index without image guidance for novice operators was 5.10 (range 6.67 - 8.63). With Smart Stylet image-guidance, the average improved to 3.00 (range 1.73 - 4.37). In resident operators, the task load index without Smart Stylet averaged to 5.85 (range 4.93 - 6.77). With Smart Stylet, the TLX averaged to 8.67 (range 6.23 - 11.1). See Table 2.
Novice operators’ VAS scale results are in Table 3. All three participants attested that Smart Stylet provided better orientation and better targeting ability than conventional ventriculostomy.

<table>
<thead>
<tr>
<th>Visual Analog Metric</th>
<th>Score</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall Experience with SS</td>
<td>13.0</td>
<td>(10.0 – 15.0)</td>
</tr>
<tr>
<td>Overall Experience with CV</td>
<td>3.5</td>
<td>(3.00 – 4.00)</td>
</tr>
<tr>
<td>Advantage provided by SS</td>
<td>12.2</td>
<td>(7.50 – 15.0)</td>
</tr>
<tr>
<td>Ease of use of SS</td>
<td>2.83</td>
<td>(0.50 – 7.50)</td>
</tr>
<tr>
<td>Ease of use of CV</td>
<td>9.67</td>
<td>(9.00 – 12.0)</td>
</tr>
<tr>
<td>Overall comfort using SS</td>
<td>7.00</td>
<td>(0.00 – 13.0)</td>
</tr>
<tr>
<td>Overall comfort using CV</td>
<td>2.75</td>
<td>(0.50 – 6.25)</td>
</tr>
</tbody>
</table>

Table 2. TLX Values

Table 3. VAS grades from novices (SS – Smart Stylet, CV – Conventional Ventriculostomy)

The residents’ VAS scale results are presented in Table 4. Using the questionnaire, both residents attested that the Smart Stylet system provided better orientation and better targeting ability than conventional ventriculostomy. One resident had performed five ventriculostomies during training, while the other performed 300. Both would use Smart Stylet in daily practice if the set up time was rapid in an emergency.
<table>
<thead>
<tr>
<th>Visual Analog Metric</th>
<th>Score</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall Experience with SS</td>
<td>10.0</td>
<td>(9.50 – 10.50)</td>
</tr>
<tr>
<td>Overall Experience with CV</td>
<td>10.75</td>
<td>(9.50 – 12.0)</td>
</tr>
<tr>
<td>Advantage provided by SS</td>
<td>8.75</td>
<td>(8.00 – 9.50)</td>
</tr>
<tr>
<td>Ease of use of SS</td>
<td>6.00</td>
<td>(2.50 – 9.50)</td>
</tr>
<tr>
<td>Ease of use of CV</td>
<td>7.25</td>
<td>(7.00 – 7.50)</td>
</tr>
<tr>
<td>Overall comfort using SS</td>
<td>6.25</td>
<td>(3.00 – 9.50)</td>
</tr>
<tr>
<td>Overall comfort using CV</td>
<td>6.50</td>
<td>(6.00 – 7.00)</td>
</tr>
</tbody>
</table>

*Table 4. VAS grades from residents (SS – Smart Stylet, CV – Conventional Ventriculostomy)*
Discussion

Preliminary results presented in this chapter indicate that systems like Smart Stylet may have a place in neurosurgical training and practice. All participants performed one pass with guidance and one without to prevent any level of visuo-spatial learning.

Targeting error of novices improved with usage of the Smart Stylet system on both approaches, although the differences were not statistically significant. Mean pair-wise distance improved significantly when using the right frontal approach. Targeting errors and mean pair-wise distance were not significantly different between unguided and guided approaches for the two residents. This may reflect learned practices that experienced operators have developed over time. On the other hand, novices might have depended more heavily on Smart Stylet to guide the catheter.

A novice’s dependence on imaging support suggests that Smart Stylet might have a role as a teaching tool and, eventually, a permanent aid in carrying out difficult procedures. The TLX scale shows marked differences in responses between novices and residents. Most notably, residents regarded the use of the Smart Stylet display as providing a heavier workload. This further supports the hypothesis that experienced operators have already developed techniques for performing procedures, and changes are perceived as imposing an added workload. The display may serve as an encumbrance rather than an aid.

This is further supported by the VAS scores, wherein the Smart Stylet was viewed as slightly more difficult to use by both groups of participants. Learning curves have been reported in the literature with using image guidance systems (36). However, the reports are of experienced surgeons using newly developed systems. Novices reported that Smart Stylet provided an advantage while residents found little difference. This was evident, as illustrated in Figures 2 to 5. Figures 2 to 5 likewise show that novices improve significantly when using the system while an experienced operator may be disturbed by the presence of an image-guidance system.
Conclusion

Although the Smart Stylet shows a trend towards improving targeting error, and was well-received by novices, the low number of participants provide inconclusive results and do not demonstrate a significant advantage over conventional methods. Smart Stylet may provide more advantage for novices than experienced practitioners.
CONCLUSION

Ventricular cannulation has been used reliably for almost a century to accomplish CSF diversion and deliver medication. Patients with traumatic diagnoses are more likely to have catheters misplaced. To improve on factors within the physician’s control, namely catheter placement and number of passes, the implementation of an image-guidance system was evaluated.

Smart Stylet provides an advantage in the hands of an operator that is comfortable using the EM system and display. Targeting error significantly decreased when using the right frontal approach.

Further evaluation with five operators, three novices and two experts (i.e. neurosurgical residents) demonstrate varied responses to using Smart Stylet for the first time. Novices attest to an advantage with use of Smart Stylet while resident neurosurgeons did not perceive any added advantage, which might reflect an already learned set of skills. Smart Stylet shows a trend towards improving targeting error. However, it did not provide a significant advantage over conventional methods. A larger number of test subjects are needed to conclusively evaluate operator performance and perspective at differing levels of expertise.

Optimal placement of EVD catheters may be necessary to decrease the incidence of complications. A procedure targeted image-guidance system is necessary for patients with aberrant anatomy. Smart Stylet may provide the operator with an advantage in the case of shifted ventricular anatomy.
REFERENCES


24. Bauer DF, Razdan SN, Bartolucci AA, Markert JM. Meta-Analysis of hemorrhagic complications from Ventriculostomy Placement by Neurosurgeons [Internet].


APPENDIX A-1

RPDR database queries (SQL)

1) Select all ventricular catheterization procedures

```sql
Ventriculostomy_Only
SELECT *
FROM Procedures
WHERE
(Code_Type='ICD9' AND Code='02.2')
ORDER BY MRN;
```

2) Select relevant Radiology report subset

```sql
Rad_reports
SELECT Radiology.MRN, Radiology.Report_Number,
Radiology.Report_Description, Format(Radiology.Report_Date_Time,
'mm/dd/yyyy') AS Report_Date, Radiology.Report_Date_Time,
Radiology.Report_Text
FROM Radiology
WHERE
((Radiology.Report_Description) Like 'HEAD' Or
(Radiology.Report_Description) Like 'BRAIN') AND
((Radiology.Report_Status)='Canceled' AND
((Radiology.Report_Status)='Scheduled');
```

3) Join Rad_reports and Ventriculostomy_Only into a single table based on MRN and
select those scans that are dictated within a one week period with ventriculostomy
date of service at the beginning of the interval

```sql
Ventriculostomies Reports
SELECT Ventriculostomy_Only.Date, Rad_reports.Report_Date,
Rad_reports.Report_Date_Time, Ventriculostomy_Only.MRN,
Rad_Reports.MRN, Ventriculostomy_Only.EMPI, Rad_Reports.EMPI,
Ventriculostomy_Only.Procedure_Name, Rad_reports.Report_Number,
Ventriculostomy_Only.Procedure_Flag, Ventriculostomy_Only.Inpatient_Outpatient
FROM Rad_reports, Ventriculostomy_Only
WHERE
(Rad_reports.EMPI=Ventriculostomy_Only.EMPI) AND
(DateDiff('d',Ventriculostomy_Only.Date,Rad_reports.Report_Date) <= 14)
AND
(DateDiff('d',Ventriculostomy_Only.Date,Rad_reports.Report_Date) >= 0)
ORDER BY Ventriculostomy_Only.EMPI, Date, Report_Date;
```
4) Pull the scans that have the words "catheter" or "shunt" or "ventriculostomy" in the report text. Create a column DIFF that shows the difference between the ventriculostomy billing date and when the radiology report was generated.

\[
\text{SELECT} \quad \text{Date, Report\_Date, Format(Report\_Date\_Time, 'hh:mm:ss') AS Report\_Time, DATEDIFF('d', Date, Report\_Date) AS DIFF, Ventriculostomy\_Only.MRN AS MRN, Ventriculostomy\_Only.EMPI AS EMPI, Report\_Number, Report\_Description, Report\_Text FROM Ventriculostomy\_Reports WHERE Report\_Text Like "%catheter%" or Report\_Text Like "%shunt%" or Report\_Text Like "%ventriculostomy%";}
\]

5) Pull the first scan chronologically

\[
\]

6) Create a count column that shows how many ventriculostomies were performed per patient

\[
\text{SELECT} \quad \text{Key, Date, Report\_Date, Report\_Time, DIFF, EMPI, MRN, Report\_Number, Report\_Description, Report\_Text (SELECT Count(Key) FROM Nested\_Post\_proc\_2 AS A WHERE A.EMPI = Nested\_Post\_proc\_2.EMPI) AS Key\_Count FROM Nested\_Post\_proc\_2;}
\]
APPENDIX A-1

7) Select only those patients who have had one ventriculostomy in his/her lifetime and order chronologically –

```
Primary_Ventric_2
SELECT *
FROM [Count]
WHERE Key_Count = 1
ORDER BY Report Number;
```

8) Select all CSF cultures**

```
SPINAL_FLUID
SELECT Microbiology.EMPI, Microbiology.MRN,
Microbiology.Microbiology_Number,
Format(Microbiology.Microbiology_Date_Time, 'mm/dd/yyyy') AS Micro_Date,
Format(Microbiology.Microbiology_Date_Time, 'hh:mm:ss') AS Micro_Time,
Microbiology.Name, Microbiology.Comments,
Microbiology.Status, Microbiology.Group_Type,
Microbiology.Specimen_Type, Microbiology.Organism_Code,
Microbiology.Organism_Comment, Microbiology.Microbiology_Text
FROM Microbiology
WHERE Specimen_Type='SPINAL FLUID (CSF)' AND Name<>'GRAM STAIN' AND Name<>'AEROBIC CULTURE' AND Name<>'THIS IS A CORRECTED REPORT!';
```

***"Aerobic Culture" and "This is a Corrected Report" labels were addendum tuples with no additional information in the textual portion of the report.

9) Create distinct pairs for results in Lookup table**

```
Micro_Names
SELECT DISTINCT Name, Organism_Comment
FROM Post_Spinal
GROUP BY Name, Organism_Comment;
```

**Label each (Name, Comment) pair as a 0 if not relevant data or the organism name if it is positive. Turn into a table
10) Select those CSF cultures that occurred within four weeks of the ventriculostomy

```
APPENDIX A-2

10) Select those CSF cultures that occurred within four weeks of the ventriculostomy

<table>
<thead>
<tr>
<th>Post_Spinal</th>
</tr>
</thead>
<tbody>
<tr>
<td>SELECT Primary_Ventric_2.Key, Primary_Ventric_2.Date, Primary_Ventric_2.Report_Date, Primary_Ventric_2.Report_Time, Primary_Ventric_2.DIFF, Primary_Ventric_2.EMPI, Primary_Ventric_2.MRN, Primary_Ventric_2.Report_Number, Primary_Ventric_2.Report_Description, Primary_Ventric_2.Report_Text, SPINAL_FLUID.Microbiology_Number, SPINAL_FLUID.Micro_Date, SPINAL_FLUID.Micro_Time, SPINAL_FLUID.Name, SPINAL_FLUID.Organism_Comment, SPINAL_FLUID.Microbiology_Text, DateDiff('d', Primary_Ventric_2.Date, SPINAL_FLUID.Micro_Date) AS MDIFF FROM Primary_Ventric_2, SPINAL_FLUID WHERE (Primary_Ventric_2.EMPI = SPINAL_FLUID.EMPI) AND (DateDiff('d', Primary_Ventric_2.Date, SPINAL_FLUID.Micro_Date) &lt;= 28) AND (DateDiff('d', Primary_Ventric_2.Date, SPINAL_FLUID.Micro_Date) &gt;= 0) ORDER BY Primary_Ventric_2.EMPI, Microbiology_Number;</td>
</tr>
</tbody>
</table>

11) Label each Record based on the lookup table

<table>
<thead>
<tr>
<th>Micro_Label</th>
</tr>
</thead>
</table>

12) Transpose the Label column

<table>
<thead>
<tr>
<th>Micro_Transform</th>
</tr>
</thead>
<tbody>
<tr>
<td>TRANSFORM Label</td>
</tr>
<tr>
<td>SELECT Key, Label FROM Micro_Label GROUP BY Key PIVOT Label;</td>
</tr>
</tbody>
</table>
```
APPENDIX A-1

13) Select only the infectious agent names and place them in one column

<table>
<thead>
<tr>
<th>Micro_0</th>
</tr>
</thead>
<tbody>
<tr>
<td>SELECT Key,</td>
</tr>
<tr>
<td>(IIF([ACINETOBACTER CALCOACETICUS-BAUMANNII COMPLEX] IS NULL,'',[ACINETOBACTER CALCOACETICUS-BAUMANNII COMPLEX] &amp; ' +')) &amp;</td>
</tr>
<tr>
<td>(IIF([ALPHA HEMOLYTIC STREPTOCOCCI (VIRIDANS)] IS NULL,'',[ALPHA HEMOLYTIC STREPTOCOCCI (VIRIDANS)] &amp; ' +')) &amp;</td>
</tr>
<tr>
<td>(IIF([CANDIDA DUBLINIENSIS] IS NULL,'',[CANDIDA DUBLINIENSIS] &amp; ' +')) &amp;</td>
</tr>
<tr>
<td>(IIF([CANDIDA GUILLIERMONDII] IS NULL,'',[CANDIDA GUILLIERMONDII] &amp; ' +')) &amp;</td>
</tr>
<tr>
<td>(IIF([CANDIDA PARAPSILOSIS] IS NULL,'',[CANDIDA PARAPSILOSIS] &amp; ' +')) &amp;</td>
</tr>
<tr>
<td>(IIF([CANDIDA TROPICALIS] IS NULL,'',[CANDIDA TROPICALIS] &amp; ' +')) &amp;</td>
</tr>
<tr>
<td>(IIF([CORYNEBACTERIUM JEIKEIUM (GROUP JK)] IS NULL,'',[CORYNEBACTERIUM JEIKEIUM (GROUP JK)] &amp; ' +')) &amp;</td>
</tr>
<tr>
<td>(IIF([CORYNEBACTERIUM SPECIES (DIPHTHEROIDS)] IS NULL,'',[CORYNEBACTERIUM SPECIES (DIPHTHEROIDS)] &amp; ' +')) &amp;</td>
</tr>
<tr>
<td>(IIF([CRYPTOCOCCUS] IS NULL,'',[CRYPTOCOCCUS] &amp; ' +')) &amp;</td>
</tr>
<tr>
<td>(IIF([ENTEROBACTER AEROGENES] IS NULL,'',[ENTEROBACTER AEROGENES] &amp; ' +')) &amp;</td>
</tr>
<tr>
<td>(IIF([ENTEROBACTER CLOACAE] IS NULL,'',[ENTEROBACTER CLOACAE] &amp; ' +')) &amp;</td>
</tr>
<tr>
<td>(IIF([ENTEROCOCCUS FAECALIS] IS NULL,'',[ENTEROCOCCUS FAECALIS] &amp; ' +')) &amp;</td>
</tr>
<tr>
<td>(IIF([ESCHERICHIA COLI] IS NULL,'',[ESCHERICHIA COLI] &amp; ' +')) &amp;</td>
</tr>
<tr>
<td>(IIF([KLEBSIELLA OXYTOCA] IS NULL,'',[KLEBSIELLA OXYTOCA] &amp; ' +')) &amp;</td>
</tr>
<tr>
<td>(IIF([KLEBSIELLA PNEUMONIAE] IS NULL,'',[KLEBSIELLA PNEUMONIAE] &amp; ' +')) &amp;</td>
</tr>
<tr>
<td>(IIF([PROPIONIBACTERIUM ACNES] IS NULL,'',[PROPIONIBACTERIUM ACNES] &amp; ' +')) &amp;</td>
</tr>
<tr>
<td>(IIF([SERRATIA MARCESCENS] IS NULL,'',[SERRATIA MARCESCENS] &amp; ' +')) &amp;</td>
</tr>
<tr>
<td>(IIF([STAPHYLOCOCCUS AUREUS] IS NULL,'',[STAPHYLOCOCCUS AUREUS] &amp; ' +')) &amp;</td>
</tr>
<tr>
<td>(IIF([STAPHYLOCOCCUS SACCHAROLYTICUS] IS NULL,'',[STAPHYLOCOCCUS SACCHAROLYTICUS] &amp; ' +')) &amp;</td>
</tr>
<tr>
<td>(IIF([STAPHYLOCOCCUS, COAGULASE NEGATIVE] IS NULL,'',[STAPHYLOCOCCUS, COAGULASE NEGATIVE] &amp; ' +')) &amp;</td>
</tr>
<tr>
<td>(IIF([STREPTOCOCCUS MITIS] IS NULL,'',[STREPTOCOCCUS MITIS] &amp; ' +')) &amp;</td>
</tr>
<tr>
<td>(IIF([STREPTOCOCCUS PNEUMONIAE] IS NULL,'',[STREPTOCOCCUS PNEUMONIAE] &amp; ' +')) &amp;</td>
</tr>
<tr>
<td>(IIF([STREPTOCOCCUS SALIVARIUS] IS NULL,'',[STREPTOCOCCUS SALIVARIUS] &amp; ' +')) &amp;</td>
</tr>
<tr>
<td>(IIF([STREPTOCOCCUS SANGUIS] IS NULL,'',[STREPTOCOCCUS SANGUIS]))</td>
</tr>
<tr>
<td>AS Infection</td>
</tr>
<tr>
<td>FROM Micro_Transform;</td>
</tr>
</tbody>
</table>
APPENDIX A-1

14) Select only those cases with infections

```sql
Micro_Infections
SELECT * FROM Micro_0 WHERE Infection<>'';
```

15) Assign a new column, “Infection,” where the infection is assigned to a ventriculostomy case

```sql
Rad_Micro
```

16) Select operative reports based on those for which we have a scan

```sql
Count_OP_Reports
```
APPENDIX A-1

17) Select those catheter placements for which the post-procedure images were within 1 day; add demographics.

```sql
EXPORT_OP_REPORTS
SELECT Count_OP_Reports.Date, Count_OP_Reports.Report_Date, Count_OP_Reports.EMPI, Count_OP_Reports.MRN, Count_OP_Reports.DIFF, Count_OP_Reports.Report_Number, Count_OP_Reports.Operative_Reports.Report_Text, Demographics.Gender, Demographics.Age
FROM Count_OP_Reports, Demographics
WHERE Count_OP_Reports.DIFF<=1 AND Count_OP_Reports.EMPI = Demographics.EMPI
ORDER BY Count_OP_Reports.Date;
```
Feature selection code

**Feature_s.r**

```r
rm(list = ls(all = TRUE))

D = read.csv("Frontal EVE.csv", header=T)
D$Sex.code <- 0
D$Sex.code[D$Sex=="Male"] <- 1

D$Inf.code[D$Infection_Code==2 | D$Infection_Code==0] <- 0
D$Inf.code[D$Infection_Code==1] <- 1

#group 2,3,4 as misplaced catheters for grading model
D$Grade.code[D$Grade==1] <- 0
D$Grade.code[D$Grade==2 | D$Grade==3 | D$Grade==4] <- 1

#univariate analysis for Hemorrhage model
J <- glm(Hemorrhage ~ Age^2, data=D, family="binomial")
L <- glm(Hemorrhage ~ as.factor(Sex.code), data=D, family="binomial")
M <- glm(Hemorrhage ~ as.factor(Diag_Code), data=D, family="binomial")
N <- glm(Hemorrhage ~ as.factor(Passes), data=D, family="binomial")
O <- glm(Hemorrhage ~ as.factor(Grade), data=D, family="binomial")

#univariate analysis for Infection model
P <- glm(Inf.code ~ Age, data=D, family="binomial")
Q <- glm(Inf.code ~ as.factor(Sex.code), data=D, family="binomial")
R <- glm(Inf.code ~ as.factor(Diag_Code), data=D, family="binomial")
S <- glm(Inf.code ~ as.factor(Passes), data=D, family="binomial")
T <- glm(Inf.code ~ as.factor(Grade), data=D, family="binomial")

#infection model after backwards elimination
F <- glm(formula = Inf.code ~ as.factor(Grade), family = binomial, data = D) #final model

#univariate analysis for grade of catheter placement
U <- glm(Grade.code ~ Age, data=D, family="binomial")
V <- glm(Grade.code ~ as.factor(Sex.code), data=D, family="binomial")
W <- glm(Grade.code ~ as.factor(Diag_Code), data=D, family="binomial")
X <- glm(Grade.code ~ as.factor(Passes), data=D, family="binomial")
Y <- glm(Grade.code ~ as.factor(Guidance), data=D, family="binomial")

#final model after backwards elimination
G <- glm(Grade.code ~ as.factor(Sex) + as.factor(Diag_Code) +
as.factor(Passes), data=D, family=binomial) #final model
```

APPENDIX A-2
Cross-validated and bootstrapped logistic regression models

Variables.r

```
rm(list = ls(all = TRUE))
#hw2a.r acquired from coursework lectures auc() and hl2()
source("hw2a.r")
library(MASS)
library(boot)

D = read.csv("Frontal_EVD.csv", header=T)
D$Sex.code <- 0
D$Sex.code[D$Sex="Male"] <- 1
D$Inf.code[D$Infection_Code==2 | D$Infection_Code==0] <- 0
D$Inf.code[D$Infection_Code==1] <- 1
D$Grade.code[D$Grade==1] <- 0
D$Grade.code[D$Grade==2 | D$Grade==3 | D$Grade==4] <- 1

ncrossval = 10
set.seed(1)
random_1 = D[sample(1:nrow(D)),]
random_1$group = rep(1:ncrossval,nrow(random_1)/1)[1:nrow(random_1)]

pred_lst <- matrix(1,1,113)
pred_d <- data.frame(pred_lst)

classes_lst <- matrix(1,1,113)
classes_d <- data.frame(classes_lst)

AUC <- c()
HL <- c()

AUC_i <- c()
HL_i <- c()
coeff_i <- c()
p_values <- c()

AUC_g <- c()
HL_g <- c()
```
for (group in 1:ncrossval)
{
  small_1 <- random_1[random_1$group==group,]
  big_1 <- random_1[random_1$group!=group,]
  classes_small <- subset(small_1, select=Hemorrhage)
  infection_classes <- subset(small_1, select=Inf.code)
  G <- glm(formula = Inf.code ~ as.factor(Grade), data=big_1,
           family="binomial")

  H <- predict(G, newdata=small_1, type='response',
               decision.values=FALSE, probability=FALSE)

  l <- auc(H, t(infection_classes))
  AUC_i <- append(AUC_i, l, length(AUC_i))
  n <- HL2(H, t(infection_classes))
  HL_i <- append(HL_i, n, length(HL_i))

  grade_classes <- subset(small_1, select=Grade.code)
  I <- glm(Grade.code ~ as.factor(Sex) + as.factor(Diag_Code) +
          as.factor(Passes), data=big_1, family=binomial)
  coeff_i <- append(coeff_i, I$coefficients, length(coeff_i))
  p_values <- append(p_values, summary(I)$coef[, "Pr(>|z|)"])

  J <- predict(I, newdata=small_1, type='response',
               decision.values=FALSE, probability=FALSE)

  o <- auc(J, t(grade_classes))
  AUC_g <- append(AUC_g, o, length(AUC_g))
  p <- HL2(J, t(grade_classes))
  HL_g <- append(HL_g, p, length(HL_g))
}
APPENDIX A-2

male <- c(coeff_i[[2]], coeff_i[[8]], coeff_i[[14]], coeff_i[[20]],
coeff_i[[26]], coeff_i[[32]], coeff_i[[38]], coeff_i[[44]],
coeff_i[[50]], coeff_i[[56]])
diag3 <- c(coeff_i[[4]], coeff_i[[10]], coeff_i[[16]], coeff_i[[22]],
coeff_i[[28]], coeff_i[[34]], coeff_i[[40]], coeff_i[[46]],
coeff_i[[52]], coeff_i[[58]])
passes <- c(coeff_i[[6]], coeff_i[[12]], coeff_i[[18]], coeff_i[[24]],
coeff_i[[30]], coeff_i[[36]], coeff_i[[42]], coeff_i[[48]],
coeff_i[[54]], coeff_i[[60]])

male_p <- c(p_values[[2]], p_values[[8]], p_values[[14]],
p_values[[20]], p_values[[26]], p_values[[32]], p_values[[38]],
p_values[[44]], p_values[[50]], p_values[[56]])
diag3_p <- c(p_values[[4]], p_values[[10]], p_values[[16]],
p_values[[22]], p_values[[28]], p_values[[34]], p_values[[40]],
p_values[[46]], p_values[[52]], p_values[[58]])
passes_p <- c(p_values[[6]], p_values[[12]], p_values[[18]],
p_values[[24]], p_values[[30]], p_values[[36]], p_values[[42]],
p_values[[48]], p_values[[54]], p_values[[60]])
APPENDIX B-1

%%Written by Vaibhav Patil
% credit for importVTK, readVTK to:
% Ramtin Shams

dir = 'C:/MIT/Thesis/Matlab/';

model_dir = 'MIT/Thesis/Models/';

%% Read Data
% Find data files
files_w = ls(['Tw_*_.vtk']);
files_wo = ls(['Two_*_.vtk']);

Theta_w = [];
% Read measured points in world coordinates and calculate Tras (Theta(i))
for i = 1:size(files_w,1)
    file = [dir files_w(i,:)];
    B = importVTK(file);
    SP = B.SensorPositions;
    Tc = B.Calibration;
    Tr = B.Registration;
    P = zeros(4,size(SP,3));
    for j = 1:size(SP,3)
        p = SP(:,:,j) * Tc * [0 0 0 1]';
        p = p(1:4);
        P(:,j) = p;
    end
    P = Tr * P;
    Theta_w(i) = P;
end

% Read measured points for without guidance
Theta_w0 = [];
for i = 1:size(files_w0,1)
    file = [dir files_w0(i,:)];
    B = importVTK(file);
    SP = B.SensorPositions;
    Tc = B.Calibration;
    Tr = B.Registration;
    P = zeros(4,size(SP,3));
    for j = 1:size(SP,3)
        p = SP(:,:,j) * Tc * [0 0 0 1]';
        p = p(1:4);
        P(:,j) = p;
    end
    P = Tr * P;
end
APPENDIX B-1

\[
\Theta_{\text{wo}}(i) = P;
\]
end

% compose final coordinate sets
Theta_final = [];
M1 = [];
for i = 1:numel(Theta_w)
    M1 = [M1 Theta_w{i}];
end

M2 = [];
for i = 1:numel(Theta_wo)
    M2 = [M2 Theta_wo{i}];
end

Theta_final{1} = M1;
Theta_final{2} = M2;

%% Load VTK Models
ventricles = ls(['Ventricles.vtk']);
L_Vent_T = ls(['LeftFrontalTarget.vtk']);
L_Vent = ls(['L_Vent.vtk']);
R_Vent_T = ls(['RightFrontalTarget.vtk']);
R_Vent = ls(['R_Vent.vtk']);
vents = readVTK(ventricles);
L_vent_t_data = readVTK(L_Vent_T);
L_vent_data = readVTK(L_Vent);
R_vent_t_data = readVTK(R_Vent_T);
R_vent_data = readVTK(R_Vent);
%drawVTK(ventricle)
vdct = vents.Points;
VPT = L_vent_t_data.Points;
VP_T = R_vent_t_data.Points;
VP = L_vent_data.Points;
VP_ = R_vent_data.Points;

VP(4,:) = 1;
VP_(4,:) = 1;
VPT(4,:) = 1;
VP_T(4,:) = 1;
%% 3D Visualizations

plot3(vdat(1,:),vdat(2,:),vdat(3,:), '.b', ...
Theta_final{1}(1,[2 4 6 8 10 12 14 16 18 20]),
Theta_final{1}(2,[2 4 6 8 10 12 14 16 18 20]),Theta_final{1}(3,[2 4 6 8 10 12 14 16 18 20]), '.r');

%Left without
%Theta_final{2}(1,[1 3 5 7 9 11 13 15 17 19]), Theta_final{2}(2,[1 3 5 7 9 11 13 15 17 19]),Theta_final{2}(3,[1 3 5 7 9 11 13 15 17 19]), '.g');
%Left with
%Theta_final{1}(1,[1 3 5 7 9 11 13 15 17 19]), Theta_final{1}(2,[1 3 5 7 9 11 13 15 17 19]),Theta_final{1}(3,[1 3 5 7 9 11 13 15 17 19]), '.r');
xlabel('Coronal'); ylabel('Sagittal'); zlabel('Axial');
grid on;
title 'Right Frontal With Guidance';

E = [-38 62 52]; %L Burr hole location
E = [28 59 57]; %R Burr hole location

%Grossly visualized Plane points
%Sagittal plane to the left of the right vent
P1 = [-8 75 69];
P2 = [-8 -30 -70];
P3 = [-8 32 -32];

%Sagittal plane to the right of the left vent
%P1 = [19 -8 89];
%P2 = [19 57 21];
%P3 = [19 -101 -72];

normal = cross(P1-P2, P1-P3);
syms x y z
P = [x, y, z];
planefunction = dot(normal, P-P1);

%VP = Tr * vent_data.Points

E_x = E(1,1);
E_y = E(1,2);
E_z = E(1,3);
for z = 1:size(Theta_final{1},2)
    if mod(z,2)==0
        TF1_x = Theta_final{1}(1,z);
        TF1_y = Theta_final{1}(2,z);
        TF1_z = Theta_final{1}(3,z);
        sym t
        tf = [TF1_x TF1_y TF1_z];
        draw = E + t*(tf - E);
        newfunction = subs(planefunction, P, draw);
        t0 = solve(newfunction);
        point = subs(draw, t, t0);
        new_point = int32(point)';
        new_x = new_point(1,1);
        new_y = new_point(2,1);
        new_z = new_point(3,1);
        line([new_x E_x], [new_y E_y], [new_z E_z],'Color','r')
    end
end

for z = 1:size(Theta_final{2},2)
    if mod(z,2)==0
        TF2_x = Theta_final{2}(1,z);
        TF2_y = Theta_final{2}(2,z);
        TF2_z = Theta_final{2}(3,z);
        sym t
        tf = [TF2_x TF2_y TF2_z];
        draw = E + t*(tf - E);
        newfunction = subs(planefunction, P, draw);
        t0 = solve(newfunction);
        point = subs(draw, t, t0);
        new_point = int32(point)';
        new_x = new_point(1,1);
        new_y = new_point(2,1);
        new_z = new_point(3,1);
        line([new_x E_x], [new_y E_y], [new_z E_z],'Color','g')
    end
end
APPENDIX B-1

%% Calculate Targeting Error

indices = [1:20];
shortest_d = inf;
err = [];
for j = 1:numel(Theta_final)
    P = Theta_final{j}(:, :);
    nP = size(P, 2);
    for k = 1:nP
        if mod(k, 2)~=0
            f = P(:, k)';
            shortest_d = [1.10138 19.31812 33.04042 1]';
            err{j}(1, k) = dist(f, shortest_d);
        elseif mod(k, 2)==0
            f = P(:, k)';
            shortest_d = [15.7785 21.7304 46.9315 1]';
            err{j}(1, k) = dist(f, shortest_d);
        end
    end
end
APPENDIX B-1

%% Calculate pairwise distances

it_odd = combk([1 3 5 7 9 11 13 15 17 19],2);
it_even = combk([2 4 6 8 10 12 14 16 18 20],2);

for k=1:size(it_odd,1)
  p1 = Theta_final(1)(:,it_odd(k,1));
  p2 = Theta_final(1)(:,it_odd(k,2));
  d(k) = dist(p1', p2);
end

for k=1:size(it_even,1)
  p3 = Theta_final(1)(:,it_even(k,1));
  p4 = Theta_final(1)(:,it_even(k,2));
  e(k) = dist(p3', p4);
end

for k=1:size(it_odd,1)
  p1 = Theta_final(2)(:,it_odd(k,1));
  p2 = Theta_final(2)(:,it_odd(k,2));
  f(k) = dist(p1', p2);
end

for k=1:size(it_even,1)
  p3 = Theta_final(2)(:,it_even(k,1));
  p4 = Theta_final(2)(:,it_even(k,2));
  g(k) = dist(p3', p4);
end

group_LW = ones(45,1);
group_LWO = ones(45,1)*2;
group_RW = ones(45,1)*3;
group_RWO = ones(45,1)*4;

group = [group_LW; group_LWO; group_RW; group_RWO];
group_1 = nominal(group, ["Left Frontal With", 'Left Frontal Without', 'Right Frontal With', 'Right Frontal Without']);
concat_1 = [d f e g];

figure;
t = sprintf('Frontal Ventricular Precision (Pairwise Distances)');
boxplot(concat_1, group_1);
title(t,'fontSize',12);
xlabel('Guidance Status'); ylabel('Distance Error (mm)');

[h, p] = ttest(d, f)
[h, p] = ttest(e, g)
%% Plot results
for i = 1:numel(err)
    err{i} = err{i}';
end

group_w = repmat([1 3]',size(err{1},1)/2,1);
group_wo = repmat([2 4]',size(err{2},1)/2,1);
group = [group_w; group_wo];
group_1 = nominal(group,{'Left Frontal With','Left Frontal Without','Right Frontal With','Right Frontal Without'});
concat_1 = [err{1}',err{2}']'
[p,h] = ttest(err{1}([1 3 5 7 9 11 13 15 17 19],1), err{2}([1 3 5 7 9 11 13 15 17 19],1))
[p,h] = ttest(err{1}([2 4 6 8 10 12 14 16 18 20],1), err{2}([2 4 6 8 10 12 14 16 18 20],1))

figure;
t=sprintf('Frontal Ventricular Targeting Error');
boxplot(concat_1, group_1);
title(t,'fontSize',12);
xlabel('Guidance Status'); ylabel('Distance Error (mm)');
**APPENDIX C-1**

**Figure 8.6**

**NASA Task Load Index**

Hart and Staveland's NASA Task Load Index (TLX) method assesses work load on five 7-point scales. Increments of high, medium and low estimates for each point result in 21 gradations on the scales.

<table>
<thead>
<tr>
<th>Name</th>
<th>Task</th>
<th>Date</th>
</tr>
</thead>
</table>

**Mental Demand**  
How mentally demanding was the task?

| Very Low | Very High |

**Physical Demand**  
How physically demanding was the task?

| Very Low | Very High |

**Temporal Demand**  
How hurried or rushed was the pace of the task?

| Very Low | Very High |

**Performance**  
How successful were you in accomplishing what you were asked to do?

| Perfect | Failure |

**Effort**  
How hard did you have to work to accomplish your level of performance?

| Very Low | Very High |

**Frustration**  
How insecure, discouraged, irritated, stressed, and annoyed were you?

<p>| Very Low | Very High |</p>
<table>
<thead>
<tr>
<th>Mental Demand Or Physical Demand</th>
<th>Mental Demand Or Temporal Demand</th>
<th>Mental Demand Or Performance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mental Demand Or Effort</td>
<td>Mental Demand Or Frustration</td>
<td>Physical Demand Or Temporal Demand</td>
</tr>
<tr>
<td>Physical Demand Or Performance</td>
<td>Physical Demand Or Effort</td>
<td>Physical Demand Or Frustration</td>
</tr>
<tr>
<td>Temporal Demand Or Performance</td>
<td>Temporal Demand Or Effort</td>
<td>Temporal Demand Or Frustration</td>
</tr>
<tr>
<td>Performance Or Effort</td>
<td>Performance Or Frustration</td>
<td>Effort Or Frustration</td>
</tr>
</tbody>
</table>
APPENDIX C-2

Evaluation of an Electromagnetic Tracking System for Cerebral Ventriculostomy by Physician Operators

KG Vosbutgh, PI

Thank you for using our Image-Registered Ventriculostomy (Smart Stylet) system. Please take a few extra minutes to answer the following questions. We greatly appreciate your time and feedback.

Please place an “X” on the line that corresponds to your response for each question.

Please rate your overall experience with the Smart Stylet system for the trials:

| Poor | Excellent |

Please rate your overall experience with conventional ventriculostomy for the trials:

| Poor | Excellent |

Did the Smart Stylet system provide an advantage when compared to conventional ventriculostomy for this case:

| No advantage | Superior Advantage |

Please rate the overall ease of use of the Smart Stylet system for this trial:

| Extremely easy to use | Difficult to use |
Please rate the overall ease of use of conventional ventriculostomy for this trial:

Extremely easy to use

Difficult to use

Please rate your overall comfort with using the Smart Stylet system for this trial:

Not comfortable

Extremely Comfortable

Please rate your overall comfort with using conventional ventriculostomy for this trial:

Not comfortable

Extremely Comfortable

For the following set of questions please place an “X” next to the statement(s) that most apply to this case:

- The Smart Stylet system provided better orientation than conventional ventriculostomy.
- Conventional ventriculostomy provided better orientation than the Smart Stylet system.

- The Smart Stylet system provided better targeting ability when compared to conventional ventriculostomy.
- Conventional ventriculostomy provided better targeting ability when compared to the Smart Stylet system.

Please answer the following questions:

Number of ventriculostomy procedures you have performed: __

If available, would you use the Smart Stylet system in your daily practice?

Yes ___ No ___

Why or why not?

How can we improve your experience with the Smart Stylet system?
ACKNOWLEDGEMENT

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