

**ELECTROMAGNETIC STEREOTACTIC COMPUTER-ASSISTED NAVIGATION IN
MINIMALLY INVASIVE SURGERY**

Dr. Ronald von Jako

Advisor:

Professor Gyorgy Weber

PhD Leader:

Professor Erzsebet Roth



University of Pécs, Faculty of Medicine
Department of Surgical Research and Techniques

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1. INTRODUCTION

Stereotactic surgery also known as surgical navigation or image guided surgery (IGS) with computer assistance, is a technique utilizing imaging to guide surgery which was first developed for neurosurgery nearly two decades ago. It has continued to evolve and expand into additional applications such as endoscopic sinus surgery for procedures involving the paranasal sinuses, minimally invasive spine and orthopedic procedures. Surgery in these regions is particularly suited for navigation applications because of the proximity to the orbit and cranial cavities in rhinological procedures and neurovascular structures in spine and orthopedic surgeries that require higher degrees of anatomical precision. The key issue regarding navigation in paranasal sinus surgery is the inability to update preoperative CT images during dissection. An issue in pedicle screw instrumentation for spinal stabilization, is the accurate placement to avoid neurological or vascular injury. In spine, many techniques exist to aid in the accurate placement of pedicle screws, including blunt pedicle probes, ball-tipped feelers, intra-operative fluoroscopy, and more recently computer assisted image-guidance systems.

Additionally, the use of intra-operative fluoroscopy for placement of pedicle screws or other modes of internal fixation has resulted in prolonged fluoroscopy time and radiation exposure to the surgical personnel and patient. Based on existing technology and principles used in stereotactic neurosurgery computer navigation and image-guided surgery were developed to minimize radiation exposure to OR personnel and improve the surgeon's orientation to unexposed anatomy.

2. OVERALL AIM OF THE EXPERIMENTS

In earlier investigations we split our experiments into two bench tests to evaluate the technology for cadaver and human investigations. First, we evaluated various optical trackers in comparison to ours to assess individual static and dynamic performance characteristics. Second, we bench-tested the overall system accuracy in which the EM tracker performance was tested to ensure that the transmitter, receiver and tracker components are operating within our specifications. When we were satisfied, we proceeded with a series of different open and minimally invasive experimental investigations described in the Thesis.

In the first and second parts of our investigation, we built on our previously improved accuracy algorithm and combined it preclinically and then clinically in a feasibility experiment with a new 3D intraoperative fluoroscopic imaging method to enhance the real-time precision of endoscopic sinus surgery (ESS) and to compare differences in x-dose exposure between 3D fluoroscopy and CT. At two multi-center, high-volume tertiary care and academic hospitals, we applied and tested new software that allows the reconstruction of several 2D fluoroscopic images into a reconstructed CT-like volume intraoperatively for near real-time imaging and instrument navigation for the nasal cavity and paranasal sinuses. Our aim was to demonstrate that intraoperative updates of altering sinus anatomy

during surgical dissection could be updated using a real-time 3D rotational C-arm enabled by custom software we created and that the image quality is sufficient to safely apply this method as a future alternative to preoperative CT scans following additional improvement tests.

In the third part of our experimental investigations, we focused on the key component of enhancing a new surgical navigation technology using EM guidance for spinal applications by measuring and improving the performance of a new beta software algorithm we developed in comparison to our current navigation software version. We used two fully intact human cadaver torsos with a simulated OR set-up. Our aim was to use a fluoroscopically guided image platform with improved beta software called Platinum tracking to percutaneously place Kirshner wires (K-wires) into a biopsy needle and through vertebral pedicles in the regions of the thoracic and lumbar-sacral spine. We used the newer Platinum tracking software on one side of the spine and the current Gold tracking software on the contralateral segment of the same vertebrae to assess tracking accuracy and stability between these two different versions of tracking algorithms.

In our fourth preclinical investigation, we concentrated on spinal decompression and stabilization techniques in open thoracic pedicle screw fusion using EM-based fluoroscopic navigation. Previous results in an open lumbar navigation experiment, showed that the use of EM navigation for insertion of pedicle screws gives accuracy equal to that of conventional techniques while significantly decreasing the fluoroscopic time. Our aim was to compare the accuracy of EM navigation-guided thoracic pedicle screw insertion to conventional techniques using anatomic landmarks and fluoroscopy and secondarily to measure insertion time and C-arm x-ray times.

In the fifth part of our experiments, we moved from open pedicle screw placements to a percutaneous approach to demonstrate the feasibility and safety of placing navigated guidewires (K-wires) through the thoracic and lumbar-sacral pedicles in comparison to the standard free-hand fluoroscopic technique. Advances have reduced surgical approach related trauma and morbidity as compared with standard open surgery. As a result, minimally invasive (MIS) procedures designed to treat various spinal conditions are rapidly growing in popularity. We integrated navigation with MIS procedures requiring the placements of K-wires to see whether we can provide an ideal environment for accurate and safe placement of a variety of implants to follow (such as pedicle screws and cement injection for kyphoplasty), before future experiments could be initiated. Our aim was to demonstrate the safe and accurate placement of K-wires in cadavers with a custom-navigated trocar to simulate the key operative steps and to measure the reduction of x-ray time.

In the sixth set of experiments, we continued with a minimally invasive approach built upon the previous cadaver study findings to assess the safe placement of specific transcutaneous spinal instrumentation and implants. Our aim was to build a prototype set of cannulated pedicle screw instruments and implants to evaluate the feasibility, accuracy, and time efficiency of an EM Navigation system compared with a conventional freehand and 2D fluoroscopic image-guided technique for

percutaneous transpedicular instrument insertion. This experimental approach compared navigation to freehand implant placements side by side at the same vertebral segments with a standalone navigation platform and separate C-arm fluoroscope.

In our seventh experiment, we modified the previous percutaneous cadaver experiments by randomly assigning the levels rather than alternating the technique from side to side using a different set of instrumentation and measurement methods for ionizing radiation. Our aim was to perform a comparison by level in which one technique is performed bilaterally because it was thought to reduce the potential bias for a reduction in time and improved accuracy based on knowledge gained from placement of the first screw when placing the contralateral screw vs. our previous experimental method. Comparison by level is also more consistent with the manner in which some surgery is performed with sequential placement of screws bilaterally before moving to the next level. In addition, we tested different customized MIS instruments on an integrated navigation platform vs a standalone separate platform used previously. Also, to demonstrate that different brand instruments can be used with EM navigation technology. We also measured ionizing radiation to the hands and thyroid using special thermoluminescent dosimeter rings and badges for each technique vs. timing the number of x-ray shots as done in previous experiments.

The eighth investigation expanded the use of computer-assisted image guidance from 2D fluoroscopic use to a CT approach with 3D images to target the complex anatomy of the intervertebral disc space with a navigated trocar for laser surgery not yet found in the literature. A percutaneous approach to the intervertebral disc in the treatment of disease can be a challenging pathway to embark for the spinal surgeon in an effort to circumvent sensitive neurovascular tissues using a spinal trocar. Endoscopic and x-ray C-arm fluoroscopy provide visualization, but not in the transverse view. Our aim was to apply preoperative CT scans to provide axial images of the lumbar segments to demonstrate precise targeting when navigating the safe triangle zone with a tracked trocar and laser fiber to the disc obviating the need for repetitive C-arm fluoroscopy.

The ninth investigation included the use of a nonisocentric C-arm with software we created to generate a CT-like image of the spine with a series of 2D fluoroscopic images rotated around the vertebrae to assess accuracy of percutaneous pedicle screw placement compared with placement by 2D fluoro navigation and conventional non-navigated fluoroscopy. We used human cadavers to place percutaneous pedicle screws first in the lumbar spine with the aim to test feasibility of prototype MIS instruments and to check the accuracy and x-ray times as compared with the 2D conventional technique.

Our tenth final investigation transitioned to exploration of extremity-based fracture reduction in the field of orthopedics focusing on percutaneous approaches to femoral and intertrochanteric fractures of the pelvic region using EM surgical guidance. Approximately 300,000 hip fractures occur annually in the United States, the vast majority requiring operative stabilization. The technique for

operative stabilization depends on the fracture pattern, but usually involves placement of one large compression hip screw (CHS) or three to four cannulated lag screws (CLS). Both procedures require frequent use of intraoperative fluoroscopy for placement of the guide wire, drilling, reaming, and insertion of the implant. Our aim was to evaluate the feasibility to use computer navigation to determine if it would significantly decrease the radiation exposure secondary to fluoroscopy use and provide the necessary accuracy to track a power drill to place guidewires and cannulated lag screws.

3. PHANTOM STUDY FOR 3D C-ARM X-DOSE EXPOSURE AND CLINICAL FEASIBILITY STUDY OF IMAGE QUALITY IN SINUS SURGERY

3.1 MATERIALS AND METHODS

In the first part of our study, a CT head phantom was used along with a CT ion chamber to measure radiation exposure. FluoroCT scans were performed using our GE C-arm. Scans were performed using each of the three fluoroscopic scanning modes on the GE C-arm; normal fluoro, high level fluoro, and digital Ciné at 15 pulses per second (pps). In the second phase of our experimental study for sinus surgery, we obtained approval from the hospital's institutional review board to utilize the navigation and 3D C-arm software for patients. We applied our key learnings from the first phase phantom experiments. Fourteen consecutive patients undergoing navigation were then recruited to participate in the study. All patients had preoperative CT scans completed with the electromagnetic (EM) navigation protocol. These were loaded onto the EM navigation system preoperatively.

The patients' navigation reference headsets were modified preoperatively by gluing a special fluoroscope reference transmitter to the back of the headset. This consisted of spinning the C-arm 190 degrees while the machine automatically took up to 190 images. The data acquired were then loaded onto the EM navigation unit using the FluoroCT program and reconstructed into CT-like images. Instruments were then calibrated. Standard CT images were then loaded into the EM Nav system and used for the patients.

3.2 RESULTS

The first study with the phantom utilized the GE C-arm to reconstruct triplanar views and found to be similar to those of a traditional CT. The accuracy of the image registration were also similar on the phantom. With TLD badges we found significantly less surface dose compared with a CT. In a more sophisticated set up, the highest radiation dose was measured using Digital Ciné 15pps. The dose measured at the center of the head phantom was 4.1 Gy while the maximum surface dose was 10.7 mGy. The center and surface radiation dose recorded from the CTDIvol reading on the control panel of a GE CT Lightspeed® Plus during a scan for the navigation unit was 85 mGy. Comparing these two radiation doses demonstrates that the C-arm FluoroCT scan used substantially less radiation vs. an equivalent standard CT scan. The experiments estimated that the FluoroCT for sinus surgery produced approximately 10-12% of the radiation of a standard image-guided navigation CT.

The second study portion for clinical use obtained fluoroscopic images from all patients using previously described methods. Initial images were deemed poor secondary to inadequate penetration and image scatter and followed up by image quality improvements through learned adjustments. Variables became apparent during the patient study that were not evident in the laboratory. These included the weight of the patient on the modified operating table, the need to work around drapes to change Nav sensor transmitters, the interference of the CT transmitter affecting scanning and navigation, and the effect of blood and nasal packing on image scatter. The final six patients had images that were deemed adequate for evaluation of disease and delineation of anatomy and had similar navigation accuracy to CT images (accuracy to less than 2mm). Bony anatomy was clearly shown on the preoperative images and extent of disease easily detected, but the images were still determined to be inferior to standard CT images, particularly in the axial plane.

4. SPINE CADAVER EXPERIMENTS FOR TWO NAVIGATION TRACKING ALGORITHMS

4.1 MATERIALS AND METHODS

In this experiment, we undertook cadaveric comparison testing between two software algorithms for spinal tracking developed by our team. We set out to evaluate a new prototype version of tracking software called Platinum Accuracy we developed. The prototype was tested for accuracy against the current version of software used on our EM navigation platform. This current tracking algorithm is called Gold Accuracy. In a statistically balanced experiment using human cadavera and a simulated surgical environment, we aimed to measure the differences in accuracy and stability between the two tracking algorithms (Gold vs. Platinum).

Two fresh-frozen human cadavers were used for the test and were noted to have good bone quality and no deformity. A 9-inch (23cm) surgical C-arm was positioned at the tableside to capture x-ray images for the electromagnetic (EM) surgical navigation platform (running both software versions, Gold vs. Platinum). The EM navigation unit has a 20-inch (51-cm) touchscreen monitor for the x-ray images and juxtaposed navigation features (i.e., virtual instrument trajectories).

Surgical procedure, An electromagnetic reference dynamic frame (RDF) was attached to the spinous processes of the thoracic and lumbar levels. This was accomplished by a small 1-cm stab incision followed by blunt finger dissection to the appropriate thoracic and lumbar spinous processes to attach the reference transmitter. A 2-mm Casper-like bone pin was driven securely into the plateau of the spinous processes (we measured them to be between 5 and 8mm in diameter) and checked each for a rigid purchase placement. The EM transmitter was then applied to this, and the process of image acquisition and registration was done.

Experimental protocol. We next performed the step of instrument calibration and verification with an orthopaedic surgeon's assistance by navigating a bone biopsy needle transcutaneously through each pedicle between the thoracic and lumbar spine levels. The Gold and Platinum software modes were alternated such that each vertebra was operated in both modes: one mode/side. The surgeon was unaware of the mode he's operating in. The spine was divided into three segments, each with 3 vertebrae (the EM transmitter is affixed on the spinous process of the middle vertebra). In each segment, the mode was switched once (Gold ↔ Platinum), and the NAV access Needle was recalibrated after each mode switch. AP and lateral images were used for navigation. For each pedicle, accuracy verification was measured at the entry point (AP, lateral) and at the vertebral body exit point (lateral) yielding 3 accuracy numbers. Control shots were taken to further assess placement accuracy between the two modes). In addition, the surgeon noted whether he would use the placed K-wires on a real patient (YES/NO) and assessed the helpfulness of the system (LOW/MED/HIGH).

K-wires were next placed through this trocar to simulate a MIS Kyphoplasty or cannulated pedicle screw procedure relying solely on navigational guidance. Three accuracy measurements were performed on each navigated pedicle entry point on an anterior/posterior image, pedicle entry point on a lateral image, and vertebral body final point on a lateral image.

4.2 RESULTS

The surgeon successfully navigated 34/36 pedicles on two cadavers in the lower thoracic and lumbar-sacral spine between T10-S1. The surgeon accepted 100% of the placements with the Platinum tracking software (17/17) vs. 88% (15/17) with the Gold tracking software. One of the Gold failures can be linked to multiple issues: a) system inaccuracy of 3.9 mm, 2) usage of the system in the frontier of the "too close to transmitter" area (as detected by the navigation system, meaning that the receiver-sensor in the surgeon's hand was too close to the transmitter reference frame in the spinous process, which creates distortion in the EM-field within a 7.5-cm proximity to each other), and 3) navigating on a collapsed vertebral body. The other failure was due to the surgeon's inability to drill the ideal pilot hole in the bony structure with the available instrument.

The surgeon ranked the navigation system highly useful for 100% of the pedicles navigated with Platinum (17/17) vs. 94% (16/17) considered highly useful and 6% considered somehow useful (1/17) with Gold. The user never ranked the system low.

On the average, the Platinum configuration was 40% more accurate than Gold (combining all the measurements, mean and standard deviations that are [1.87, 1.00] mm for Gold and [1.12, 0.78] mm for Platinum). The Platinum system resulted in better placement of the K-wires. The three critical to quality (CTQ) measurements were: 1) Entry point, posterior image (mm, 95%ile): 1.50 Platinum vs. 2.94 Gold; 2) Entry point, lateral image (mm, 95%ile): 3.14 Platinum vs. 3.18 Gold; and: 3) vertebra body point, lateral image (mm, 95%ile): 2.36 Platinum vs. 3.42 Gold.

5. CADAVER OPEN THORACIC INVESTIGATIONS

5.1 MATERIALS AND METHODS

Four fresh-frozen human cadavers were thawed and randomly allocated into one of two groups. We applied screws bilaterally at each level from T1 to T12 in all specimens. An awl was used to perforate the posterior cortex, and then a blunt pedicle finder was used to locate the pedicle. Five-millimeter USS pedicle screws were used in all cases.

Fluoroscopic C-arm method. In the cadavers in Group one, thoracic pedicle screws were inserted with conventional fluoroscopic C-arm technique using AP, lateral, and oblique views as necessary. There were two specimens in this group, and two screws were inserted at each thoracic level for a total of 48 screws.

Navigation Method. In the cadavers in Group two, thoracic pedicle screws were inserted using the EM-navigation system alone. There were two specimens in this group, and two screws were placed at each level for a total of 48 screws. The set-up for navigation included the rigid placement of a bone pin or clamp to each spinous process. To these, a dynamic reference frame is attached (in this case, our EM transmitter to a bone pin). We moved the transmitter to each bone pin or clamp and updated our C-arm x-ray images. After the transmitter was securely placed at each level with saved images, our Nav spine T-handle was used with various attachments (awl, bone probe, and implant driver) after they were calibrated for each tip offset. The transmitter attached to the spinous process is used to track the C-arm's position.

Procedural protocol, The time to insert thoracic pedicle screws, as well as the total c-arm exposure time, was recorded for each specimen in each group. In addition, the time required for set-up of the navigation system (placement of transmitter) as well as time for the computer to capture an appropriate image for navigation was recorded in group two. This was later factored into pedicle screw insertion time for this group.

Once all pedicle screws were placed, we dissected all the specimens' en bloc. We then analyzed the data to compare accuracy, insertion time, and fluoroscopic time between each of the groups. Statistical analysis was performed using one-way ANOVA and chi squared analysis. Data was considered significant at $p < 0.05$.

5.2 RESULTS

We placed a total of 48 screws in each of groups one and two. The average insertion time per pedicle screw differed significantly between the two groups. Group 1 averaged 261 seconds per pedicle screw and group 2 averaged 179 seconds per pedicle screw ($p=0.04$). However, when image acquisition and

set-up time (i.e., application of bone pin and transmitter) was factored in, insertion time averaged 293 seconds per pedicle screw for group 2. This difference was no longer statistically significant.

Total fluoroscopic time for group 1 was 270 seconds, and for group 2 it was 162 seconds. The average amount of fluoroscopic time per pedicle screw was 5.9 seconds for group 1, and 3.6 seconds for group 2. This difference was statistically significant ($p=0.04$). We anticipated higher fluoroscopic times as we placed a reference transmitter at each level and acquired new AP and lateral images. Our next studies will demonstrate how we learned from this study and lowered the overall need for x-ray use.

The accuracy of groups one and two were 90 and 92%, respectively. This difference was not statistically significant. This was due in part to the more difficult anatomy. This results in greater focus on multiple fluoroscopic views as this area of the spine can tend to be smaller and more challenging to the surgeon's general comfort level compared with the lumbar spine where the tendency to rely less on intraoperative C-arm fluoroscopy and more on general feel when EM navigation is used.

In addition, when a misplaced pedicle screw occurred, the degree of misplacement was reduced with the EM navigation. Critical perforations were seen in 10% in group 1 and 8% in group 2. This difference was not statistically significant. The average extent of break through or perforation was 2.36 mm for group 1 and 1.71 mm for group 2 ($p=0.055$).

6. MINIMALLY INVASIVE SPINAL SURGERY CADAVER INVESTIGATIONS

6.1 MATERIALS AND METHODS

Four fresh-frozen human cadavera were obtained, thawed, and randomly allocated (two in each group) to be instrumented navigation (EM group) or without navigation (Fluoroscopy Group). An experienced spine surgeon performed the procedures. K-wires were applied bilaterally at each level from T10 to S11 in two specimens (one in each group) and T8 to S1 in two specimens (one in each group) for a total of 80 wire placements (20 levels).

In the Fluoroscopy Group the K-wires were inserted via conventional biplanar fluoroscopic technique using a C-arm. Anteroposterior and lateral projection views were utilized in combination to locate and navigate the pedicle and place the wire at all points during the procedure. In the other specimen, K-wires were inserted using the EM based navigation system. Of 40 possible pedicles, all were instrumented. Time for set up, placement and fluoroscopy was recorded. Post insertion, the accuracy for each level was assessed for the presence and location of facet joint, pedicle or vertebral cortical perforation using computed tomography imaging with multiplanar reconstructions. Comparison to an idealized trajectory was performed. The "ideal trajectory" was considered to be a convergence of the wires at the ventral aspect of the vertebral body in addition to staying within the pedicle. This was graded on a 4-point scale as follows: Ideal (grade 0), minimally displaced by 1-3 mm (grade 1), moderately displaced by greater

than 3 mm but less than 5 mm (grade 2) and markedly displaced by greater than 5mm (grade 3). Comparison between these dichotomous variables was performed using a chi square test.

6.2 RESULTS

The EM group had an average setup time of 9 minutes 35 seconds. The Fluoroscopy group had an average setup time of 3 minutes 38 seconds. Placement Time: EM group average time per level was 381 seconds (6 minutes 20 seconds), range 90-780 seconds. Fluoroscopy group average time per level was 579 seconds (9 minutes 39 seconds), range 258-960 seconds. This difference was significant ($p=0.005$, t-test). Fluoroscopy Time: EM group average time per level was 11 seconds (range 1-53). Fluoroscopy group average time per level was 48 seconds (range 15-86). This difference was significant ($p<0.0001$, t-test).

For each specimen, the number of successful K-wire placements was 100% (40/40) for both the EM group and the Fluoroscopy group. For pedicle breaches, the EM group had 10.0% (4/40) and the Fluoroscopy group had 15.0% (6/40) breaches. This difference was not significant ($p=0.50$, chi square). For vertebral body breaches, the EM group had 0.03% (1/40) and the Fluoroscopy group had no (0/40) breaches. This difference was not significant ($p=0.31$, chi square). For facet joint breaches, the EM group had 15% (6/40) and the Fluoroscopy group had 12.5% (5/40) transgressions. This difference was not significant ($p=0.75$, chi square). There were no critical cortical breaches in either group. Trajectories results were as follows. The EM group trajectories were: ideal 62.5% (25/40), minimally displaced 22.5% (9/40), moderately displaced 10.0% (4/40) and markedly displaced 5.0% (2/40). The Fluoroscopy trajectories were: ideal 40.0% (16/40), minimally displaced 27.5% (11/40), moderately displaced 25.0% (10/40) and markedly displaced 7.5% (3/40). This was a significant difference between idealized trajectories ($p=0.04$, chi-square) but not for the entire distribution ($p=0.17$, chi square test for trend).

7. PERCUTANEOUS PEDICLE SCREWS INSERTED IN CADAVERS USING TWO METHODS PER LEVEL

7.1 MATERIALS AND METHODS

Experiment I.

In the first experiments five human cadaveric specimens were used. Each cadaver was subject to screw placements from L1 to S1 (inclusive); K-wires were applied bilaterally at each level. For comparative analysis, screws were placed on one side of each cadaver using conventional fluoroscopic technique alone and on the opposite side using the EM-based navigational system.

For the conventional fluoroscopy group, K-wires were inserted via a conventional Jamshidi needle using multiple AP and lateral views to localize the pedicle at each level. For the EM group (EM), a custom designed minimally invasive instrumentation kit was created by RVJ and used for these experiments. In

this EM group, K-wires were inserted using the EM Navigation system. An EM transmitter was attached rigidly to a spinous process to produce three orthogonal EM fields encompassing the anatomical field. AP and lateral views were acquired of each target spinal segment. Surgical instruments that require tracking were each fitted with an EM receiver and calibrated to the EM transmitter. With calibration, instruments could be tracked in real time simultaneously on AP lateral and oblique image displays.

Using this tracking method on the EM-side and 'free-hand' fluoroscopic placement on the control side, a navigated Needle (Jamshidi style) was placed, and a custom cannulated NAV Spine T-handle built by RVJ with custom-attached Taps (J&J - Depuy Spine) were used. Finally, Depuy Spine Expedium style (Viper) cannulated lumbar pedicle screws were placed using custom screwdrivers.

Intraoperative variables for analysis included total fluoroscopic time and mean fluoroscopic side per screw by dividing the number of screws placed and taking approximately 3 AP shots and 3 lateral shots per specimen in order to place the 12 screws. Each specimen underwent a postoperative CT with reconstructions by an independent, blinded radiologist to rate screw placement for pedicle breach, defined as penetration through the cortical edge of the pedicle breach, vertebral body breach, and critical breach. The ideal trajectory was defined as screw placement precision toward medial ventral aspect of the vertebral body such that bilateral screws would converge while remaining entirely within the pedicles. The trajectory was rated accordingly: 0 (ideal), 1 (1–3mm off ideal), 2 (>3 but < 5 mm off ideal), 3 (≥ 5 mm off ideal). In comparing trajectories, overall number of pedicle breaches, vertebrae breaches, and critical breaches were evaluated for EM-guidance compared with conventional fluoroscopy. Additionally, lumbar spine segment (L1-L5) breaches were evaluated in a separate comparison to specifically study the breach rates for lumbar pedicle screw placement.

Statistical analysis was conducted using Wilcoxon Matched-Pairs Signed-Ranks Tests for total fluoroscopy time, mean fluoroscopy time/screw, and trajectory. Fisher Exact tests were used to compare rates of pedicle breach, vertebrae breach, and critical breach. P-value < 0.05 was considered significant.

Experiment II.

In the second set of cadavers, Eight fresh-frozen human cadaveric torsos were used. Pedicles from T8 to S1 were individually randomized to minimally invasive screw placement with the aid of navigation or by a C-arm. A key addition over the previous experiment was how the radiation exposure was measured using thermoluminescent dosimeter rings and badges. Set-up, insertion, and fluoroscopic times, radiation exposure, and accuracy (measured with post-procedural computed tomography) were analyzed in each group. Two operative stations were used to compare two additional different minimally invasive pedicle screw systems that had been modified for use in an EM environment. Here, the difference over the previous experiment method that went side to side for comparison of fluoro vs. Nav was instead performed based on screw placement per level rather than alternating the technique from side to side. A

comparison by level, in which one technique is performed bilaterally, was thought to reduce a potential bias for a reduction in time and improved accuracy based on knowledge gained from placement of the first screw when placing the contralateral screw. A comparison by level is also more consistent with the manner in which some surgery is performed with sequential placement of screws bilaterally before moving to the next level. The S1 level was allocated to either the Nav or C-arm group on an alternate basis to ensure the numbers for this level were even between groups. All other levels were randomly allocated starting at L5 and moving upward based on a coin flip.

Post-procedural CT scans were performed on each specimen and each screw was assessed for pedicle breach, vertebral breach, critical breach, and ideal trajectory. The ideal trajectory is considered to be a convergence of the pedicle screws at the ventral aspect of the vertebral body that stays within the pedicle. This is graded on a 4-point scale:

- Grade 0 (Ideal) – accurate screw with no perforation through any cortex
- Grade 1 (Minimally displaced) – safe screw with perforation of <3 mm
- Grade 2 (Moderately displaced) – displaced by ≥ 3 mm but ≤ 5 mm
- Grade 3 (Critical perforation) – displaced by >5mm

The accuracy of each technique over each spinal zone (thoracic, lumbar, and sacral) was statistically analyzed using a chi-square test with $p = 0.05$ considered significant.

7.2 RESULTS MIS EXPERIMENT

Results Experiment I.

Overall, the average total fluoroscopy times/specimen were 383.3 ± 255.6 sec for c-arm fluoro (CF) and 160.5 ± 79.6 sec for EM, which was an insignificant difference. The overall mean fluoroscopy time per screw was 58.9 ± 44.7 sec for CF and 27.4 ± 13.5 sec for EM ($p = 0.0003$). Data for total fluoroscopy time was excluded for one specimen (Spine 5); L1 was not instrumented in Spine 5 due to a previous kyphoplasty, and S1 was not instrumented due to an abnormal anatomic relationship with the pelvis that confounded screw placement. As such, a total fluoroscopy time for that specimen would be confounded by the exclusion of two levels.

Trajectory and breach were analyzed on postoperative CT. The difference in the mean trajectory rating was 1.1 ± 1.1 for CF and 1.4 ± 0.2 for EM, which was not significant. Overall, the EM screws demonstrated 3 more pedicle breaches, but 3 fewer critical breaches than the CF screws (not significant). When lumbar screws were evaluated alone, EM-guided screws demonstrated one more vertebrae breach, but 6 fewer critical breaches ($p = 0.02$).

Results Experiment II.

In total, 122 pedicle screws were placed, 62 under fluoroscopic guidance and 60 under EM guidance. Seventy-eight of these were lumbar pedicle, 28 were thoracic, and 16 were sacral. Accuracy of placement over all segments, as assessed by pedicle and vertebral body breaches, was better in the EM group than in the NAV group, but this difference was not statistically significant: Pedicle breaches were seen in 17% of EM-placed screws and 29% of fluoroscopically placed screws ($p=0.12$) while vertebral body breaches were seen in 1.7% of the EM-placed screws and 4.8% of the fluoroscopically placed screws ($p=0.33$). Accuracy of placement of lumbar pedicle screws was significantly improved with the use of EM (16.2% pedicle breach vs. 42.5% with fluoroscopic; $p=0.01$), but there was no significant decrease in cortical breaches with the use of EM in the thoracic or sacral regions.

Ideal trajectories were achieved more often with EM guidance over all spinal segments (62.7% vs. 40%; $p=0.01$). This effect was most pronounced in the lumbar segments, where 64.9% of screws placed with EM guidance achieved ideal trajectory versus 40% placed with fluoroscopy ($p=0.03$). There was no significant difference between the two techniques over other segments. Insertions times, including set-up time, between the two techniques did not significantly differ overall for the two groups (923 seconds with EM vs. 952 seconds with NAV; $p=0.6911$), and this was also true for any spinal segment analyzed separately. Radiation time, however, was significantly reduced over all segments (5 seconds with EM vs. 22 seconds with Fluoro; $p<0.0001$). Highly significant reductions in radiation time were seen over all spinal segments upon individual analysis.

Total body and hand radiation doses seen by the operating surgeons were decreased with the use of EM, although these results were just less than significant (13.8 vs. 20.2 mrem, $p=0.073$, and 15.0 vs. 37.5 mrem; $p=0.058$, for body and hand, respectively). Of note, all surgeons tended to take a step away from the fluoroscope during image acquisition for both the Nav and Fluoro groups, and this is a reflection of their experience using fluoroscopy.

8. NAVIGATED 3D FLUORO VERSUS 2D NAVIGATED FLUORO VERSUS NON-NAVIGATED FLUORO

8.1 MATERIALS AND METHODS

At the Cedars Sinai University Hospital in Los Angeles, forty-eight pedicles (T11-S1) in three intact unenbalm human cadavers were randomly assigned to undergo paired percutaneous pedicle instrumentation using a lighted dilating bivalved endoscopic assembly (based off the Jakoscope concepts first applied in spine by Howard-Jako-Weber in 1992) via conventional fluoroscopy, virtual fluoroscopy, or our 3D C-arm fluoroscopy method. After attaching our EM transmitter to the spinous process, fluoroscopic images were obtained, calibrated, and saved. Paired insertions of two adjacent pedicle screws for a single-level fusion were compared side to side from T11 to S1 using the three imaging techniques. Side-to-side comparisons were made between standard fluoroscopic technique on one side and either virtual fluoroscopy or the 3D fluoroscopy technique on the other side. Operative

time from skin incision to completion of pedicle screw insertion was measured as well as fluoroscopic time. The 3D fluoroscopy images were also obtained after pedicle insertion and compared with virtual CT images. The specimens were subsequently checked for accuracy by comparing dissecting specimens under 2X magnification to evaluate for pedicle wall perforation.

8.2 RESULTS

The operative time using standard fluoroscopy was 40 minutes (30–65 minutes); virtual fluoroscopy was 35 minutes (15–66 minutes), and 3D fluoroscopy was 38 minutes (29–50 minutes). Radiation time was 90 seconds (36 seconds–3 minutes) for standard fluoroscopy, 11 seconds (2–30 seconds) for virtual fluoroscopy, and 30 seconds for the 3D fluoroscopy group. The 3D fluoroscopy group takes 30 seconds to sweep through a 180-degree arc and takes approximately 90–120 seconds to render reconstructed axial, sagittal, and coronal images, down from the original 3–4 minutes with our version 1.0 algorithm. The poor images due to image scatter from vibration or artifacts are automatically ejected by the computer's 3D image quality software. This time was not counted toward the operating time, as this would occur while the patient was being anatomically prepared for surgery. The 3D fluoroscopy had to be recalibrated once during our experiments as a result of a loosening transmitter pin from the osteoporotic spinous process. We had the option to use transmitter clamp for the spinous process, but wanted to keep the incision length to a minimum. The mean trajectory angle difference between virtual and fluoroscopic displayed probes was 3.1 degrees \pm 0.9 degrees. The mean probe tip error was 0.99 \pm 0.55. There were no pedicle wall perforations using standard fluoroscopy, the 2D fluoroscopic navigation, or the 3D fluoroscopic navigation.

9. STEREOTACTIC CT SURGICAL NAVIGATION EXPERIMENTS FOR LASER DISCECTOMY

9.1 MATERIALS AND METHODS

Two ex-vivo porcine lumbar spines were obtained and used according to the policies of the University of Kaposvar Medical Center's Institutional Review Board. The fresh specimens were from two 80-kg swine and were prepared with intact soft tissues, paraspinous muscles, and skin. The porcine spine has six lumbar vertebrae; we experimented on six intervertebral discs for each of the two specimens for a total of 12 discs.

High-intensity, small-size clinical laser equipment with fiberoptic guides manufactured by Biolitec AG (Jena, Germany) was used for this study. The Ceralas D 25 model delivers up to 25 W of laser power. Its wavelength is 980 \pm 10 nm, which is close to the wavelength of the Nd:YAG, and its water absorption is also similar. The manufacturer provides 200-, 400-, and 600- μ m diameter quartz fiber waveguides. For the delivery we used the 400- μ m guide. The fiber was inserted into a custom-made 17-gauge, 300 series stainless steel trocar (laser fiber tube) designed by the authors. This was subsequently introduced

into the navigation trocar (Nav Trocar) designed by the author (RVJ) and integrated with an electromagnetic (EM) tracking receiver. The laser fiber trocar tube has a side connector, which is attached to an aspirator to eliminate evaporation plumes produced by the laser irradiation.

We used the EM stereotactic navigation system with its accessories and preoperative computer tomographic (CT) scans.

Each swine specimen was placed into a plastic basket in the prone position and scanned using both CT and magnetic resonance (MR) imaging to obtain the preoperative scans for registration and comparisons. The navigation computer compiles the anatomical image data from the CT scan through an Ethernet connection between the CT suite and the operating room and renders three orthogonal planes (axial, sagittal, and coronal views), as well as a 3D reconstructed model of the spinal segments and an optional endoscopic view. Surface markers were used for the registration process and a percutaneous mounted transmitter to the porcine spinous for the tracking.

The navigation computer then plotted and saved the measured optimal trajectory through the triangular safe working zone between the traversing and exiting nerve roots of the foraminal annular window. The calculated path centered within the mediolateral aspects of the pedicle and intervertebral disc space. This was represented as a dotted color trajectory on the navigation display monitor. The EM navigated needle was guided over the predetermined length of the target path at a 30- to 60-degree angle depending on anatomy. This was displayed on the workstation as traversing Kambin's triangle toward the dorsolateral aspect of the intervertebral disc. Once in the disc a work path was created through the trocar tube that laser was inserted through and used to debulk the disc at various levels of energy per level. Post procedure the porcine spine were followed up with a second MR for comparisonal changes. The spines were then harvested for macro and micro-histological studies.

9.2 RESULTS

Monitoring of a needle trocar is essential during percutaneous laser discectomy and the use of CT in this experimental study provided superior spatial and soft tissue resolution to that of the single-plane C-arm views. The additional spatial configuration data provided by CT navigation facilitated the puncture position of the navigated trocar tip on axial and sagittal images, enabling for precision laser ablation of the intervertebral disc. We determined that the Nav Trocar was inserted into the intervertebral disc accurately with the aid of the navigation system with 1.0–1.5 mm total system tip-tracking accuracy confirmed by spot x-ray fluoroscopy and further measured by the “distance from trocar” feature available on the navigation system.

The navigation computer also provided a registration root mean square (RMS) error of 0.50 mm and 0.80 mm in the two specimens using external fiducials. The postoperative MR study showed changes in the disc compared with images obtained before laser irradiation. Post-dissection macroscopic examination demonstrated that the insertion of the Nav Trocar was in the intended target area of the disc

as planned by the computer software and correlated with low-dose pulse x-ray shots. Under magnification, visual dissection of the lumbar vertebrae showed no evidence of disruption to the adjacent nerve root and visceral or vascular structures. Furthermore, the microscopic examination revealed tissue coagulation changes in the uniformly and in the gradually irradiated discs. Total scout x-ray control time averaged less than 9 seconds. In this experimental study, our intention was not to evaluate quantitatively the effects of the disc irradiation, only the precision of the laser trocar insertion.

10. FEMORAL/HIP FRACTURE FIXATION IN CADAVERS AND CLINICAL FIXATION WITH NAVIGATION

10.1 MATERIALS AND METHODS

Pre-clinical experiment. At the Moritz Kaposi Medical Center in Kaposvar, Hungary, we organized an investigational study in which EM-navigation was compared for the placement of 7.3 mm cannulated lag screws (CLS) in the proximal femora of five human cadavers against the use of the standard fluoroscopic technique. Screws were placed on one side with standard technique using biplanar fluoroscopy and on the other side using EM navigation. The set-up time, total overall times, x-ray times, insertion times per method and side, and follow-up X-ray fluoroscopy accuracy assessments were all recorded as outcome measures.

The screws were implanted bilaterally in each of the five cadavers for a total of 30 screws. We used a Synthes compact pneumatic drill for which we created a special adaptor for the navigational sensor to calibrate the drill for the cannulation of the femurs. With the drill, we used 2.8-mm guidewires. A Caspar-style bone pin was attached to the proximal femurs to which the reference transmitter was attached for automatic registration. In both x-ray planes, the virtual trajectory is juxtaposed over the x-rays. A red trajectory line simulates the real-time position of the navigated instruments and/or implant. An extended green trajectory demonstrates a projection line forward into the bony anatomy.

Clinical experiment. With an experienced surgeon, we investigated an L5-to-iliac bi-lateral spinal-to-pelvic fixation procedure using titanium the Universal Spine System Schanz screws (7.3 x 100 mm) and surgical EM navigation with sacral laminectomy for sacral nerve root decompression. The patient was a 40-year-old man who was injured in a motor vehicle accident, sustaining a S2 U-shaped sacral fracture dislocation and spinal pelvic dislocation with cauda equina syndrome. The construct that was used allows for immediate bilateral weight bearing for the lower extremities.

10.2 RESULTS

Preclinical. We found that the transmitter is best located on the tip of the lesser trochanter and that minimal EM distortion from the drill occurs. All 30 cannulated lag screws were safely placed through the proximal femurs. Twenty-seven screws were accurately placed within 5 mm of the subchondral bone of the femoral head and 3 screws were within less than 5 mm of the subchondral bone but not

intraarticular. All of the fracture lag screws were accurately placed. The C-arm Fluoroscopy time decreased from 53 seconds per side to 6 seconds per side.

Clinical. The transmitter was placed at the caudal end of the L4 spinous process in approximately 5 seconds. Six images were captured for a total of 12 seconds of C-arm time. Previous scout shots for C-arm positioning totaled 26 seconds. Five minutes were required to place two bilateral Schanz pedicle screws on the left side and nearly 10 minutes were required on the right side because of a slight deformity. It was estimated that the standard fluoroscopic technique here could have required 5–10 minutes of dose time. Total fluoroscopy time was 73 seconds.

12. SUMMARY CONCLUSION

We developed and tested an electromagnetic (EM) tracking system as an alternative to optical navigation systems. This avoids the line of site issues that are associated with the optical tracking. We improved our EM system to minimize the potential for magnetic interference. The objectives of these preclinical and clinical experiments were to demonstrate that navigation coupled with a C-arm X-ray system intraoperatively can be integrated to record 2D images (where surgical anatomy is not entirely visualized without the axial plane, the most critical plane for ensuring spatial accuracy in geometrically challenging anatomy) and with 3D anatomical images to be saved for real-time surgical uses. Our aim was to also minimize X-ray exposure of the patient and staff while improving surgical precision through added visual dimensions, new tracking software and in the first uses of new percutaneous instrumentation.

Using a C-arm navigational platform for paranasal sinus surgery has the intraoperative advantage of updating anatomical structural changes beyond endoscopic views. Our investigations on preclinical specimens and in patients performed by clinicians showed that the image quality was sufficient, but should be improved. We have planned protocols for future improvements.

For spine surgery we looked at the conventional fluoroscopic approach to pedicle screw fusion and instrumentation. We applied and tested our next generation electromagnetic tracking technology as an alternative to the previous generation of optical line of site navigation systems to determine clinically relevant tracking accuracy.

Under my direction, we designed and built custom instruments for the use in open and percutaneous spinal procedures. Through my experimental study with my collaborative team, new instruments were designed for navigation to improve the insertion of a fiber optics trocar for percutaneous laser discectomy and for pedicle fusion. We conducted 2D and 3D comparison studies between EM tracking and conventional C-arm placements for open and MIS pedicle screw approaches. Our results noted a substantial improvement in navigated mean accuracy vs. non-navigated spinal instruments and

significantly lower critical perforation rates in comparison to conventional fluoroscopic implant placements.

We also measured the difference in x-ray exposure times and doses and found the results to be significantly less than with conventional fluoroscopy. In cases of placement of percutaneous pedicle screws, we noted that the surgeon is required to extrapolate the third dimension based on an interpretation of available images and knowledge of the pertinent anatomy. In our findings, we realized computer-assisted surgical navigation could be used as the link between visualized and non-visualized anatomical relationships, thereby minimizing guesswork associated with spinal surgery.

We also determined that the use of electromagnetic tracking in various open and transcutaneous thoracolumbar spinal procedures is feasible, safe and effective and therefore can add value in enhancing surgical precision while minimizing the need for additional use of ionizing radiation. More technical and clinical experiments with larger sample sizes, refined instruments, and software algorithms using the various experimental approaches described in this Thesis, may further improve stereotactic navigation in minimally invasive spine surgery. For this, we have created a spinal protocol for a future prospective minimally invasive multicenter randomized clinical trial to compare surgical navigation data with traditional C-arm fluoroscopy: in the accurate and expedient placement of thoracic and lumbar MIS instrumentation.

In orthopedic minimally invasive surgery of the femur, we designed and built electromagnetic compatible instruments to address the precision targeting and calculations of bony entry points. To accomplish this, we designed software for trajectories to measure the length and positioning of necessary guidewires and implants. During our experimentation we discovered materials for the instruments, which can be used to avoid electromagnetic field distortion (EMF). We also established the least invasive placement positions of a reference transmitter suitable for intraoperative registration and tracking. Our preclinical comparison studies resulted in substantial reductions of the overall need for fluoroscopy. We concluded through our experimental work and clinical evaluations that EM navigation technology can be used to enhance future emerging minimally invasive techniques.

13. ARTICLES IN REFEREED JOURNALS RELATED TO NAVIGATION

- 1) *"Percutaneous Laser Discectomy with Stereotactic Computer-Assisted Surgical Navigation."* von **Jako, RA**; Cselik, Z; J. Lasers in Surgery and Medicine, 41: 42-51, 2009. IF: 2.771

- 2) *"Image Guided Spine Surgery for Percutaneous Transpedicular Needle Insertion in Thoracolumbar Sacral Spine Using an Electromagnetic Tracking System; Accuracy and Efficiency Compared to Conventional Fluoroscopy Technique."* von **Jako R**; Carrino JA; Yonemura KS; Noda GA; Zhu W; Blaskiewicz D; Raju M; Groszmann D; Weber G; J. NeuroImage; Accepted.2009. IF:5.565

- 3) *"Electromagnetic Navigation in Minimally Invasive Spine Surgery: Results of a Cadaveric Study to Evaluate Percutaneous Pedicle Screw Insertion"*, Fraser J; von **Jako R**; Hartl R. J. Of Spine Arthroplasty Society,2:43-47, 2008.

- 4) *"Method for evaluating compatibility of commercial electromagnetic tracking systems with surgical imaging tables"*. Nafis C, Jensen V, von **Jako R**, SPIE Medical Imaging, 6918:Visualization, Image-Guided Procedures and Modeling, Bellingham WA. 2008. IF: 3.084

- 5) *"Feasibility of Real-Time Image Guided Sinus Surgery Using Intra-operative Fluoroscopic Computed Axial Tomography"*, Brown SM; Sadoughi B; Cuellar H; Brook A; **Von Jako R**; Fried MP; Cover Page. Journal of Otolaryngology – Head and Neck Surgery.136:268–73,2007. IF: 1.339

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- 2) *"The Evolution of Image-Guided and Computer-Aided Orthopaedic Surgery"*. Sagi HC, von **Jako R**, Yuan HA. Submitted to Journal of American Academy of Orthopaedic Surgeons,2009.

13.1 ABSTRACTS RELATED TO NAVIGATION

- 1) *"Electromagnetic navigation and radiation exposure in the placement of percutaneous pediclescrews"*. Finn MA, Yonemura KS, Araghi A, Khoo LT, Perez-Cruet M, Carrino JA, **von Jako R**. Abstract; 35th Annual Lende Snowbird Neurosurgery Conference. Jan30-Feb 4th, 2009.
- 2) *"Surgical Electromagnetic Navigation in Musculoskeletal Procedures"* IEEE Engineering in Medicine and Biology Society (EMBS). **Von Jako, RA**; Abstract IEEE. MIT Nov 2008.
- 3) *"An Invitro Study Comparing Minimally Invasive Spine Fusion between the Conventional FluoroscopicTechnique and Surgical Navigation, Results for Accuracy, Insertion Time, X-ray Time and Dose Reduction"*.
Yoneumra KS, Carrino JA; **von Jako R**; Perez-Cruet M; Araghi A; Khoo L University of Utah, Johns Hopkins University School of Medicine, Baltimore, MD, Providence Hosp, Detroit, MI, Texas Back Institute, Phoenix, AZ, UCLA Medical Center, Los Angeles, CA. Abstract; North American Spine Society, Austin, Texas. 2007.
- 4) *"Navigation Surgery in Cochlear Implantation"*. Repassy G, Kustel M, Hrabak K, Fent Z, **von Jako R**. Semmelweis University Medical Faculty of Medicine, Dept of ORL and HNS, Budapest, Hungary and GE Healthcare Surgery, Lawrence, MA., 8th International Conference of the European Society of Pediatric Otorhinolaryngology, ESPO 2008. June 8-11th. Presented abstract published 2008.
- 5) *"Percutaneous Pedicle Screw Insertion via Electromagnetic Navigation"*. Fraser J; **von Jako R**; Carrino J, Hartl R, Weill Medical College of Cornell University, NYNY; Johns Hopkins University School of Medicine, Baltimore, MD; Cornell University, NYNY. Abstract; North American Spine Society, Austin, Texas. 2007.
- 6) *"Electromagnetic Surgical Navigation for the Placement of Transcutaneous Pedicle Screws into theThoracolumbar Spine, A comparison to Freehand Fluoroscopy"*. Perez-Cruet M; Yonemura KS; Carrino JA; Araghi A; Khoo L; **von Jako R**. Abstract/Poster; Congress of Neurological Surgeons, San Diego. CA. 2007.
- 7) *"Method for evaluating compatibility of commercial Electromagnetic (EM) catheter tracking systems with surgical and imaging tables"*, Nafis C, Jensen V, **von Jako R**, abstract. SPIE, 2007, Bellingham WA.
- 8) *"Navigation Surgery in Cochlear Implantation"*. Kustel M, Hrabak K, Fent Z, von Jako R, Abstract 50. Collegium Oto-Rhino-Laryngologicum Amicitiae Sacrum 27-30 August 2006, Moscow, Russia.

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10) *"Feasibility of Real-Time Image-Guided Sinus Surgery using Intraoperative Fluoroscopy"*, Brown SM; Sadoughi B; Cuellar H; Brook A; **Von Jako R**; Fried MP; Montefiore Medical Center. American Rhinological Society, 2005 Abstract.

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13.2 BOOK CHAPTERS RELATED TO NAVIGATION

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2) Hormoz, S, Eichholz, KM, Nioguy, S, Samartzis, D, **von Jako, R**, Perez-Cruet, M: *"Image Guidance in Minimally Invasive Spinal Surgery"*, Chapter 52 In *Neurosurgical Operative Atlas*, by Wolfa and Resnick., 2nd Edition: Thieme Medical Publishers, Inc and American Association of Neurological Surgeons, 2007.

3) Eichholz, K, Nioguy, S, Samartzis, D, **von Jako, R**, Perez-Cruet, M: *"Applications of Image Guidance in Minimally Invasive Spine Surgery"*, Chapter 10 In *An Anatomical Approach to Minimal Access Spine Surgery*, by Perez-Cruet, Khoo, and Fessler, Quality Medical Publishing, Inc., 2006.

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