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Validation of a Sensorized Instrument-Based Training System for Minimally Invasive Surgery

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Validation of a Sensorized Instrument-Based Training System for Minimally Invasive Surgery

(Spine title: Validation of a Sensorized Laparoscopic Surgery System)

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ABSTRACT

Minimally invasive surgery training is complicated by the restraints imposed by the surgical environment. A sensorized laparoscopic instrument capable of sensing force in 5 degrees of freedom and position in 6 degrees of freedom was evaluated. Novice and Expert laparoscopists performed a complex minimally invasive surgical task – suturing - using the novel instruments. Their force and position profiles were compared. The novel minimally invasive surgical instrument is construct-valid and capable of detecting differences between novices and experts in a laparoscopic suturing task with respect to force and position. It is also concurrently valid with an existing standard: the Fundamentals of Laparoscopic Skills. Further evaluation is mandated to better understand the ability to predict performance based on force and position as well as the potential for new metrics in minimally invasive surgical education.

Key words: Minimally Invasive Surgery, force, position, surgical technology, surgical education

ACKNOWLEDGEMENTS

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ACS	American College of Surgeons
DOF	Degrees of Freedom
FLS	Fundamentals of Laparoscopic Skills
ICSAD	Imperial College Surgical Assessment Device
IQ range	Interquartile range
MIS	Minimally Invasive Surgery
MISTELS	McGill Inanimate System for Training and Evaluation of Laparoscopic Skills
SAGES	Society of American Gastrointestinal Endoscopic Surgeons
SD	Standard Deviation
SIMIS	Sensorized Instrument-Based Minimally Invasive Surgery

Chapter 1: Evolution of Minimally Invasive Surgical Training

1.1. Introduction

Professor Erich Mühe of Germany performed the world's first laparoscopic cholecystectomy in 1985 [1]. At the time, this was a shock to the surgical establishment and The German Surgical Society rejected Mühe in 1986 after he reported that he had performed this innovative operation. The advantage of the laparoscopic, or minimally invasive approach, was that patients did not have a large incision to recover from. Instead of large, open incisions, laparoscopic techniques use long, slender instruments that are held by an operating surgeon. They are introduced into a patient's body through access trocars ranging from 5-12 mm. Though this novel approach resulted in better cosmesis and faster recovery after gallbladder surgery, new serious complications that had rarely been seen with open surgery occurred due to the new procedure. Therefore, the new technique introduced new challenges in surgical training. Much time has passed since the introduction of Minimally Invasive Surgery (MIS) and the time of Mühe; however, the educational challenges of laparoscopy persist even today.

Minimally invasive surgery (MIS) has been applied to virtually every organ system with success. Compared to open surgery, MIS reduces tissue trauma, post-operative pain, and recovery time which allows patients to return to normal activities more rapidly [2]. Moreover there is new evidence to suggest that minimally invasive approaches may result in lower in-hospital mortality rates for some patients undergoing elective surgery [3]. Similarly, it is well established that serious long term complications such as bowel obstruction and incisional

hernias are less likely to occur in patients who have MIS as opposed to open operations [4]. Despite these benefits to patients, the widespread application of MIS is hindered by the lack of appropriate educational and training tools.

MIS poses educational challenges due to the nature of the surgery itself. The use of access ports and long instruments instead of large incisions and hands results in a fulcrum effect generated at the entry site resulting in a reduction in dexterity and reversal of hand motion (Figure 1.1). In other words, in order to make an instrument's tip go "up" on the operating room monitor, the surgeon must make their hand, which is holding the instrument, go down. Similarly, higher manipulation forces may be necessary to overcome instrument drag, and there is also a considerable decline in sense of touch. These limitations result in new perceptual-motor relationships that are unfamiliar to new users and require additional training [5, 6]. Furthermore, the operative field is typically on a 2-dimensional monitor which may further confound spatial orientation [5, 7].
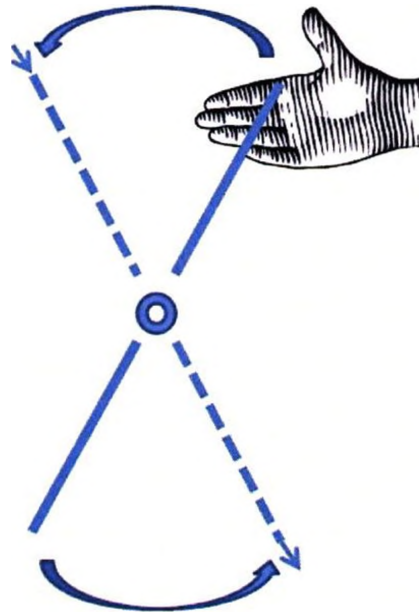
Figure 1.1. Fulcrum effect in MIS resulting in reversal of hand motion and tip movement

The modern paradigm of surgical education is based on the Halstedian approach developed in the 1920s. After a period of graduated clinical responsibility, trainees are gradually introduced to open operative skills [8]. During such conventional surgical training, a trainee first watches an experienced surgeon perform various operations. After starting with basic tasks like skin suturing, the trainee progresses to more and more complicated tasks until they finally perform entire operations under a mentor's guidance [9]. This mode of training is inefficient and in many cases the required skills for laparoscopic surgery take

longer to master than open techniques [10]. This poses a serious challenge to surgeons interested in acquiring these skills. In addition, when trainees finally become primary surgeons this generally has occurred without an objective assessment of their skills. Since the skill and the level of experience of the surgeons are not exactly known, the current method of training is potentially unsafe for the patient [11]. The constraints of MIS further complicate this process. Conventional surgical specialty training takes place over five years after the completion of medical school. As a result, many surgical trainees seek further specialized training in order to properly develop MIS skills [10, 12], thus further delaying independent patient care. Indeed, most General Surgeons in Canada feel their MIS training is inadequate for advanced operations and that additional training is essential [13]. Similarly, most practicing General Surgeons in Canada are forced to acquire MIS skills through brief mentorship experiences which do not allow efficient practice; thus, a need exists for efficiency, effective methods of training and re-training surgeons in MIS techniques [14, 15].

It has been recognized that the education and training of clinicians in MIS is falling short of meeting health care needs [16]. Simulation has been recognized as a method of teaching minimally invasive surgical techniques to trainees; thus, allowing repetition and errors in inanimate systems prior to real patient contact. Simulation is defined as the act of imitating the behaviour of some situation or some process by means of something suitably analogous (especially for the purpose of study or personnel training). It is further defined in computer science as the technique of representing the real world by a computer program by

imitating the internal processes and not merely the results of the thing being simulated [17].

Simulators as instruments to measure performance of trainees must be validated. A valid instrument measures what it was intended to measure [18]. There are several methods of describing aspects of validity. These include subjective and objective approaches to the determination of validity. Subjective approaches include face and content validity, which describes the degree to which the instrument seems reasonable to experts. For face validity, an expert is asked to judge whether, on the face of it, the instrument seems to assess the desired qualities. Content validity is a judgment about whether the instrument encompasses all the relevant domains [18].

There is a variety of terms used to describe objective aspects of validity. If other scales of the same attribute exist, one compares results from the new instrument with that of the old to see the degree of correlation (criterion validity). There are two types of criterion validity: concurrent validity, in which the new and old measures are administered at the same time, and predictive validity, which is the extent to which the measurement tool predicts future performance. In the absence of an available gold standard, evidence for construct validity is sought. This is an ongoing process, in which the skill measured by the instrument is linked to some other attribute by a hypothesis or construct. This is usually done by measuring performance in 2 groups who are hypothesized to differ in the skill being measured by the instrument. For example, in assessing a new laparoscopic simulator, that expert practicing laparoscopic surgeons outperform junior residents provides evidence for construct validity. Another experiment

might track performance of trainees over time to see if simulator performance increases with increasing clinical experience. A series of converging experiments of this nature is accrued over time to provide construct validity [18].

The public is increasingly finding it unacceptable for trainees to practice surgery on patients without some form of simulator based experiences first [19]. To address this, research has been recently directed to develop methods for effectively assessing the level of expertise of surgeons and trainees using inanimate models. There is a variety of simulation methods available for assessing the proficiency of trainees in MIS. These can be broadly categorized as simple inanimate models; position sensors; force sensors; and computer-based virtual reality simulators.

1.2 Simple Inanimate Simulators

The McGill Inanimate System for Training and Evaluation of Laparoscopic Skills (MISTELS) is the current standard by which laparoscopic skills are evaluated. It was specifically developed for the evaluation of laparoscopic skills [20-22]. MISTELS, after initial studies confirming its validity [22, 23] has become the cornerstone of the skills component of the Fundamentals of Laparoscopic Surgery (FLS) program adopted by the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) and the American College of Surgeons (ACS). It consists of five tasks performed in a laparoscopic trainer box using inanimate materials (Figure 1.2). Scores are generated from the tasks that incorporate the

time needed to complete the task in addition to penalties for errors. Pass/Fail scores to distinguish competent from non-competent surgeons have been standardized [24]. The FLS program and MISTELS have also been shown to have consistency and reliability [25, 26]. MISTELS scoring has also shown that surgeons who achieve pass scores on the program are more likely to successfully transfer this skill to the real operating room environment [27]. Despite the validity and wide-spread adoption of the FLS program, it has a major flaw: a trained evaluator must be present to record and assess each performance. Moreover, the system lacks the ability to provide real time feedback as the trainees must wait for their overall performance to be scored before receiving feedback they can learn from. In addition, the success on FLS is for the most part defined by the speed with which the surgeon performs the task. While penalties are applied for errors, these can be overcome by rapid completion of the task. Essentially, the qualitative aspects of the tasks are not incorporated into the score. Surgical education research has demonstrated that surgical learning is most likely to occur if feedback is given in a timely fashion [28]. To be specific, if feedback is given concurrently and summatively, trainees are most likely to improve their performance [29].
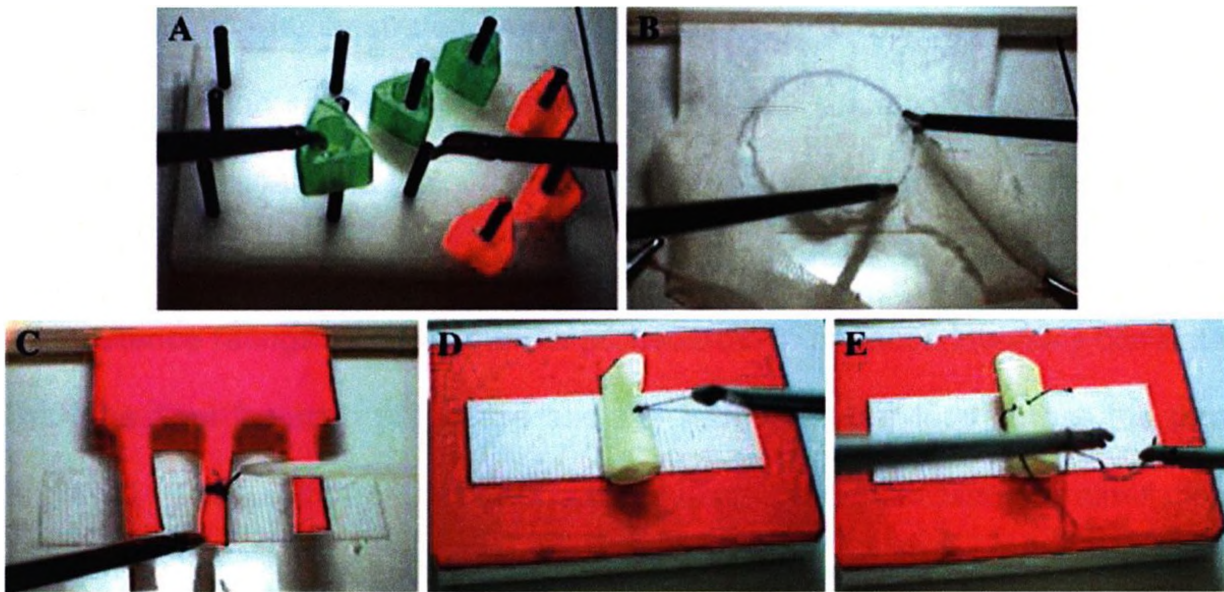
Figure 1.2. FLS/MISTELS tasks 1-5. (A) Peg Transfer, (B) Pattern Cutting, (C) Endoloop application, (D) Extracorporeal Suture, (E) Intracorporeal Suture (from Scott et al. [30]

Recognizing the need for safe training in MIS and the need to prepare surgeons for real operations, there have been attempts to create simple, inexpensive inanimate models that mimic actual surgery. One group developed three renewable models that represent difficult or challenging segments of laparoscopic procedures; laparoscopic appendectomy, laparoscopic cholecystectomy, and laparoscopic inguinal hernia [31]. They videotaped subjects with different experience levels on each of the models and again during a post-training evaluation session. Five expert MIS surgeons then assessed the evaluation session performance. For each simulation, the surgeons were asked to rate overall competence and four skills: clinical judgment (respect for tissue), dexterity (economy of movement), serial/simultaneous complexity, and spatial orientation.

This research demonstrated very high reliability of performance ratings for competence and surgical skills using a mechanical simulator [31]. Moreover, in research to validate the tasks as teaching tools, the amount of experience of the subjects in years directly correlated with the skills ratings and with the competence ratings across the three procedures. Experience inversely correlated with the time for each procedure and the technical error total across the three models. The authors thus concluded that the laparoscopic simulations demonstrated both face and construct validity. More importantly, the quality of performance increased with experience, as shown by the improvement in the skills assessments by expert laparoscopic surgeons [32]. However, unlike FLS, this series of tasks has not yet been shown to translate into improved proficiency in the real operating room.

At the University of Texas, another simple inanimate model for laparoscopic simulation has been developed. Using rudimentary materials to simulate real surgical tasks, they have shown that a curriculum using simple, inanimate and inexpensive materials, like FLS, can result in better performance in the real operating room for trainees learning MIS [33]. All of these examples demonstrate that using readily available materials and laparoscopic box-trainers (Figure 1.3), expensive, limited operating room time can be spent learning more advanced skills, thus allowing basic skills to be acquired in the dry-lab setting.

1.3 Position and Path-Length

Another means by which laparoscopic skills may be assessed is the Imperial College Surgical Assessment Device (ICSAD). It is a motion analysis system and

has undergone extensive validation studies and is very sensitive in discriminating surgeons according to their experience [34-39]. It consists of a signal generator that creates an electromagnetic field in which sensors placed on the surgeon's hands can be detected using special software. These positional data can be converted to data reflecting the surgeon's dexterity. It is a useful adjunct to training as trainees can be expected to achieve a certain level of proficiency prior to progress. They can also be provided with an objective feedback of their performance [37, 38]. As an assessment method it can be used for credentialing in laparoscopic surgery. MISTELS, and the FLS program have been shown to demonstrate concurrent validity with ICSAD [40]. One of the advantages of the ICSAD system over FLS is that its metrics are potentially less labour intensive due to the instant and fully automated computerized scoring that it provides; hence, trainees are able to achieve immediate feedback on their performance. Like MISTELS, the ICSAD system is relatively inexpensive; however, several systems are required including hardware if many trainees are to be evaluated.

Despite the ICSAD findings that movement and path length are inversely related with performance, one study has shown that there is no fixed relationship between the number of movements and the time needed for performance of surgical tasks. In other words, when surgeons attempted to complete tasks as quickly as possible they produced more movements per minute than doing the same task, taking their time and using maximum precision [41].

In general, modalities such as FLS and ICSAD use parameters that could be used for feedback and assessment like operative time and errors or extra

movements. But time and error measurement are not sufficient and have to be seen in conjunction with other parameters.

Sokollik et al. [42] endeavoured to analyze the trajectories and the speed profile of MIS tasks more closely and attempt to deduce assessment parameters that are relevant for MIS skills evaluation. To study this, they developed an inanimate model with interchangeable training modules. The module and the instruments were connected to a microprocessor which permitted the recording of errors during the tasks. The tasks performed ranged from touching randomly lit lights, as well as sequential suturing tasks. With the aid of the ultrasound system they recorded the *x, y,* and *z* coordinates and the rotation in space. This information was calculated from the travel time differences of three ultrasound transmitters. The ultrasound probes were attached to conventional laparoscopic instruments which allowed real-time tracking of the tasks. These researchers found that the standardized times, as well as the error times as precision indicators, in addition to parameters for spatial perception could significantly differentiate experts from novices. Furthermore, these parameters improved over the course of a training program [42]. This study, was limited by a small sample size and a cumbersome experimental set-up; however, it did successfully show that feedback regarding position of the operating tip of an MIS instrument may be an adjunct to MIS training.

In the ADEPT system (Advanced Dundee Endoscopic Psychomotor Tester), laparoscopic graspers are equipped with sensors to measure angular deviations, and a target plate can also measure errors like excessive contact. Various tasks, involving manipulation of switches and dials, can be performed under videoscopic

guidance. In a study of 10 senior registrars, performance in ADEPT (number of tasks successfully completed, total time, and errors) was compared with clinical assessment of the trainees by consultant surgeons [43]. When the first run was excluded, there was little improvement with practice, leading the authors to suggest that the system identifies some aspects of performance better described as "innate ability." Subsequent study demonstrated that master surgeons committed fewer errors helping to establish the validity of the construct [44].

This instrument was assessed using simple object manipulations, however, it is versatile and may be used to assess more complex skills, such as suturing, and its employment of real instruments and imaging systems is beneficial. Problems include the complexity of the system and the need for specialized equipment including a special dome and target system.

The ProMIS augmented reality laparoscopic simulator was designed to retain the benefit of a traditional box trainer by using original laparoscopic instruments and tactile tasks. However, it also generates objective measures of performance. It has been through rigorous face and construct validations [45-47]. The ProMIS hybrid simulator also consists of a personal computer. The laparoscopic interface consists of a plastic mannequin a black Neoprene® cover. The mannequin contains 3 camera tracking systems arranged to identify any instrument inside the simulator from 3 angles. The surgeon works through two 12 mm ports. Camera tracking captures instrument motion in the x, y and z coordinate planes at a rate of 30 frames per second. The distal end of the laparoscopic instrument shaft is covered with electrical tape to serve as a camera tracking reference point. Precise measures of time, instrument path length and instrument

smoothness, as detected by changes in instrument velocity, are recorded for each instrument ambidextrously during all simulated tasks [48]. It has recently demonstrated concurrent validity with FLS and MISTELS [48].

1.4 Force Sensors

Another approach to the objective assessment of technical ability is to measure the forces and torques applied at the hand/tool interface during laparoscopic surgery using sensors and video analysis.

One approach to force sensing involved the sensing of forces at the level of the instrument's grasper handles [49-51]. Another approach has been to attempt to sense forces on the shaft of the minimally invasive instrument as an estimate for forces acting at the tip [52]. There are several other examples of force-sensing instruments that have predominantly been assessed in the dry lab setting. Most have not undergone construct validation studies. However, many of these instruments have elegant designs that have demonstrated promise in force and position sensing [53-55].

Force sensing technology has also been developed and evaluated during animal-model simulations of actual General Surgical operations: laparoscopic cholecystectomy and Nissen fundoplication in a pig model. Although the analysis was complex because each step of the operation was analyzed separately, it appeared that the forces and torques applied by experts and novices differed, as did the time to complete the procedures [56]. This study was influenced by a small sample size. Another example of force measurement included a hybrid

device that incorporates a motion-tracking device and software package which generates a final score [57]. This system's score is obtained by incorporating time, various kinematic properties, and the outcome of the task. This metric can discriminate between expert and novice surgeons with kinematic properties accounting for most of the observed differences.

Hwang et al. have designed a tool that is capable of tracking force/torque at the instrument handle and derivatives of tool tip position (velocity, acceleration, and jerk) as measures of motor performance in MIS [58]. They endeavoured to evaluate motor performance during MIS on humans during laparoscopic cholecystectomy. They found that novice surgeons had a significantly greater mean velocity compared to expert surgeons. However, force, position, and jerk were similar between groups. They concluded that differences may not have been apparent due to a small sample size.

The BlueDRAGON system was designed with integrated force and position sensing [59]. The system uses two four-bar linkages equipped with position and force sensors that acquire the kinematics and dynamics of two laparoscopic instruments. Force measures are taken outside the MIS access trocar. Use in actual MIS operations is hindered due to its large manipulator that may not appropriately move real laparoscopic instruments. Nonetheless, efforts have been made to understand the relationship of force and surgical skill [56]. These force/torque measurements have gone through evaluations that establish construct validity and attempt to relate surgical skill to force application in MIS [54, 60]. The next generation of the BlueDRAGON, the redDRAGON has undergone design modifications but incorporates many of the same features.

Construct validity has not yet been established; however, it has undergone preliminary face validation with performance of the FLS tasks by expert surgeons [61].

Generally, all of these examples illustrate that the favoured approach to force measurement has been assessment at the instrument handle. The problem with this approach is that forces are substantially dampened in MIS due to the length of the instruments as well as the fulcrum effect. Thus, the forces being measured are only a surrogate marker of the actual forces at the tissue level. So, for training and skills evaluation analysis, the forces acting on the tissue should be measured [62].

1.5 Computer-Based Virtual Reality Simulators

Virtual reality refers to a computer generated representation of an environment that allows sensory interaction which gives the impression of actually being in the simulated environment [63]. One of the advantages of virtual reality is that it allows for continuous tracking of the actions of the user in real-time, allowing for objective measurement such as accuracy of hand placement, amount of pressure used, and others, to be continuously fed back to the user [64]. Although the field has enormous potential, limitations include high start-up costs and the need for ongoing upgrade purchasing. In addition, most virtual systems currently available do not have tactile feedback (haptics) and use computer-generated algorithms to artificially represent tissue deformity. Since tissue deformity is one of the cues

used by laparoscopists to determine instrument tissue interaction, the fidelity of this appearance on the monitor is very important [65].

The MIST-VR system is commercially available (Mentice Medical Simulation AB, Gothenburg, Sweden) and has been studied by several groups in Europe and North America. The tasks were chosen after ergonomic evaluation of the psychomotor skills required for laparoscopic cholecystectomy [66]. The interface is based on two virtual reality MIS instruments designed to for 6 degrees of freedom. The system runs on a desktop computer. A 3D operative field on the computer screen represents the operating space. Targets appear and can be manipulated by the user according to the task selected. Each of the tasks can be recorded for later analysis that can include accuracy and errors, time to complete tasks, right or left hand performance, and economy of motion [66]. Interestingly in a study comparing MIST-VR to a standard laparoscopic box trainer, 77% of the participating surgical residents preferred the physical trainer because it was "more realistic" [67]. The construct validity of the MIST-VR system has been established in a number of studies from various institutions. Nonetheless, the system has shown construct validity [39, 68-70].

The LapSim trainer has been developed by Surgical Science Ltd (Gothenburg, Sweden) and is another example of a commercially available device that can run off of a personal computer. The system consists of a generic platform to which modules can be attached, each containing specific skills that are performed using virtual instruments. Face and content validity were achieved by discussions with experienced laparoscopic surgeons, and efforts have focused on the graphic design, including shadows, light, and background movement [71, 72]. Tissue will

even simulate bleeding and rupture. Like other computer based systems, the basic skills modules include camera navigation, instrument navigation, coordination, grasping, cutting, clip applying, and suturing tasks. Since initial validation studies [73] it has subsequently demonstrated validity and reliability as a construct with consistent improvement in surgical skills [71, 72, 74-77].

Recently, the LTS 2000-ISM60 device (LTS; Realsim Systems, Alburquerque, NM, USA), a computer enhanced video-laparoscopic training system, has been developed [78]. It was evaluated in a study designed to validate the LTS and to correlate its scoring performance with that of MISTELS. This was done using 124 participants from 3 Canadian universities divided into 4 groups based on laparoscopic experience: novice, intermediate, competent, and expert. Based on laparoscopic experience and academic level, the LTS showed a comparable discriminating capability for level of performance with that of the FLS [78]. However, the incremental benefit over FLS alone is not apparent. Furthermore, the system is computer-based for dry lab use only and cannot be used in a wet-lab or real operating theatre environment.

Another example of a commercially available system for surgical skills assessment and training is LAP Mentor™ (Simbionix). Like other computer based virtual reality simulations, the main limitation is that there is no real force or haptic feedback. In other words no real or simulated tissue is actually handled and the platforms rely upon simulated haptic feedback. In the case of LAP Mentor, there is no haptic feedback at all. Like other virtual reality systems another problem with these systems is that they are very expensive. Each new teaching module

has an additional expense. While LAP Mentor has been shown to demonstrate face and construct validity [79-82] the incremental benefit over low-fidelity simulations like FLS has never been demonstrated.

While many of the described educational developments are promising, none have shown superior ability over FLS in the ability to discriminate between training levels. Moreover, these novel technologies are expensive and lack the low-tech reproducibility of FLS. Also, these expensive simulation units do not use the same instruments as are used in the real-life operating theatre, confounding the translation of these skills into practice. In view of the above, it is clear that the need remains for a surgical education system that can be used in any training scenario (laparoscopic trainer, animal labs or real surgery) for the purpose of skills assessment and training.

1.6 Objectives

The purpose of this research was to demonstrate construct validity of novel surgical instrument designed to sense forces and position at its tip as an educational tool in surgery. The specific aim was to demonstrate differences in force as well as position measures between novices and experts. Another objective was to demonstrate concurrent validity with the existing "gold standard."

1.7 Contributions of the Thesis

The novel contribution of this thesis is the construct and concurrent validation of a novel MIS instrument designed to detect force and position at its tip. Validation of the instrument in this manner determines the instrument's potential as a teaching

adjunct in surgical training and skills assessment. It will also help identify future directions of research in the development of technology for surgical education. This research has demonstrated:

- Construct validity of SIMIS forces

- Construct validity of SIMIS positions

- Concurrent validity of SIMIS measures with FLS score for suturing

1.7 Thesis Outline

The ensuing chapters of this thesis will detail the initial construct and concurrent validation of the novel instrument. This begins in Chapter 2 with an introduction and summary of the novel instrument's design and specifications. Chapter 3 details the methodological and statistical approach to the construct validation and concurrent validation. This includes a description of the recruitment and sorting of subjects based on surgical expertise. Chapter 4 contains the experimental work that was done as part of this thesis research and discusses the analyses that were performed on the experimental data. Chapter 5 states the conclusions of this research and identifies potential future areas of research for this novel technology.

Chapter 2: Development of SIMIS

2.1 Introduction

In view of some of the limitations of the FLS model and other available surgical simulation platforms a sensorized MIS instrument was developed [62]. Specifically, this instrument was designed to sense forces in five degrees of freedom (DOF) at its tip including the forces in three dimensions, the torque about the instrument axis and the gripping or cutting force which depends on the type of tip attached to the instrument. If different tasks need to be performed, the instrument was designed to permit interchangeable tips and handles depending on what is required. For example, all of the FLS tasks that require conventional tips can be performed with the novel instrument (grasping, cutting, suturing). It is also capable of sensing position in six degrees of freedom at the tip. Furthermore, the instruments were specifically tailored to the constraints of MIS as they fit through a standard MIS access port with a maximum outer shaft diameter of 10 mm. The novel MIS instrument was also specially tailored such that its appearance and weight were consistent with existing standards in MIS. In other words, the design was fashioned to ensure that the instrument mimicked actual MIS instruments used by surgeons in real operating theatres. Finally, a software interface was designed that allowed force and position data to be recorded while trainees perform a series of standardized tasks. The novel instrument and software package were named the Sensorized Instrument-Based Minimally Invasive Surgery (SIMIS).

2.2 Instrument Design

Design of the SIMIS instruments is based on work done by Trejos et al [62, 83]. The design of the instruments occurred prior to this thesis and the author of this thesis did not contribute to their design. Details regarding the technical aspects and design characteristics are included for the sake of completeness and to ensure this thesis is considered in the proper perspective.

Face and content validity of SIMIS were ensured by including a surgeon specializing in Minimally Invasive Surgery in the consultations for instrument design. Three concentric shafts form the long-axis, or main shaft of the SIMIS instruments. The inner shaft controls the opening and closing of the tip and is directly connected to the handle. A middle shaft provides rigidity. The outer shaft encases the middle shaft and provides a seal for the sensors. Figure 2.1 shows the overall design of the instrument in two different configurations: a scissor handle with a gripper attachment and a needle driver with corresponding handle. The sensors are strain gauges which are all attached to the middle and inner sections of the instrument. This permits the sensorized elements to be used to perform virtually any task depending on the configuration of the instrument handles and tips.
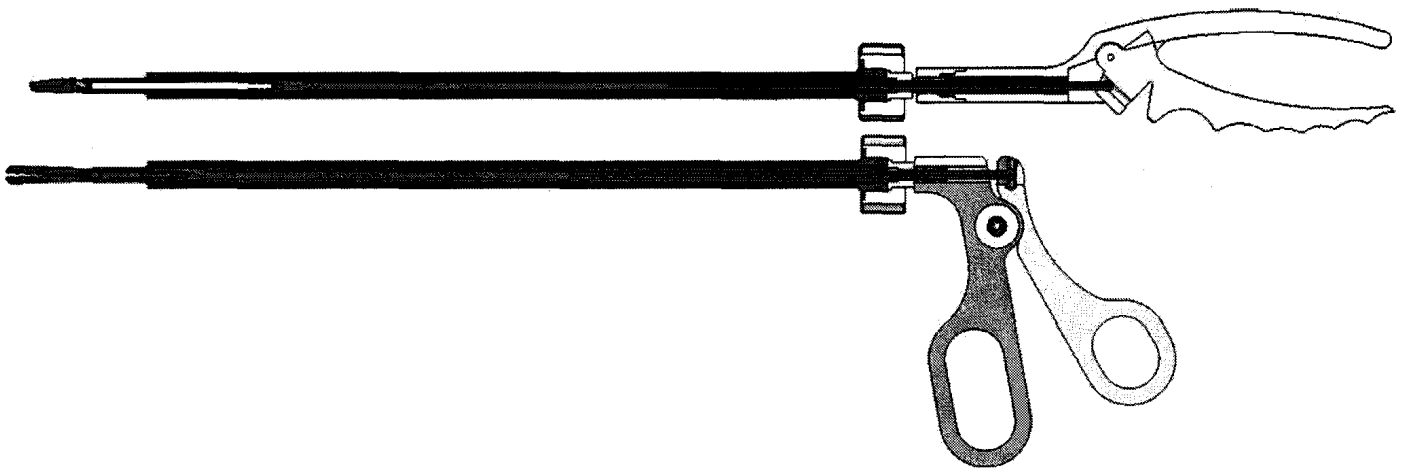
Figure 2.1. Instrument design with traditional handle and gripper attachment (*top*) and with needle driver handle and tip (*bottom*). (from Trejos et al.[83])

Once the system is set up to measure strain on the instrument shaft, it is possible to determine the magnitude of the forces and torques acting in all 5 DOF available during MIS. Figure 2.2 depicts the four degrees of freedom aside from actuation. Before experiments are performed the instrument is calibrated in all degrees of freedom using standardized weights.

For the purpose of tracking instrument tip position, the microBIRD™ electromagnetic tracking system (EMTS) (Ascension Technology Corp.) was used. Two sensors allow the instrument position to be tracked in 6 DOF.

2.3 Instrument Prototype

Two identical prototypes of the instruments were constructed from stainless steel. The scissor handles were constructed of ABS plastic. The needle driver handles used were obtained from commercially available laparoscopic needle drivers

(models 8393.941 and 8393.0005, R. Wolf, Inc.). The instrument tips include the Raptor Grasper tip (ML-3291-E), the Endocut Scissor tip (ML-3141E) and the Super-Atrau Raptor Grasper (ML-3632, Microline Pentax, Inc.). The needle driver tips were fashioned from stainless steel. Figure 2.3. shows the prototype with examples of the tips and handles available. Figure 2.4 shows the strain gauges mounted on the inner and middle shafts. The experimental platform and set-up is shown in Figure 2.5. The system includes a personal computer, the position sensing system, and the force sensing elements.
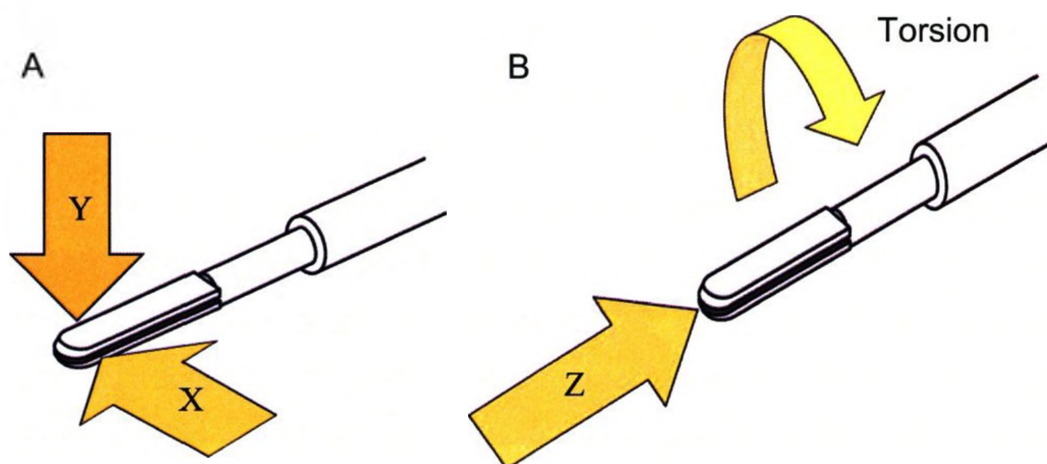
Figure 2.2. Schema of 4 of 5 DOFs for forces available with SIMIS excluding actuation. (A) X and Y axes (B) Z axis and Torsion (credit: Michael D. Naish).
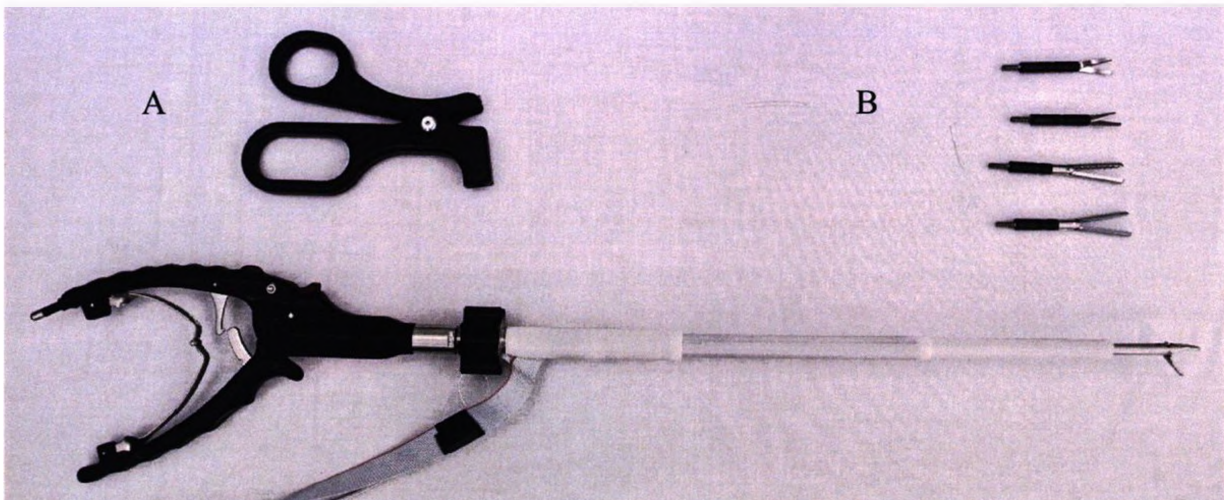
Figure 2.3. SIMIS instrument prototype with examples of exchangeable (A) handles and (B) tips that can be attached to the instrument. (photo credit: Michael D. Naish)
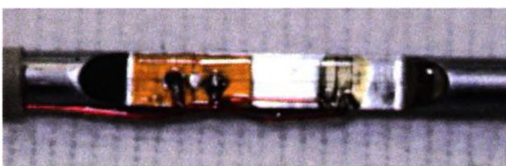
Figure 2.4. Placement of gauges on the middle (top) and inner (bottom) shafts.(from Trejos et al. [83])
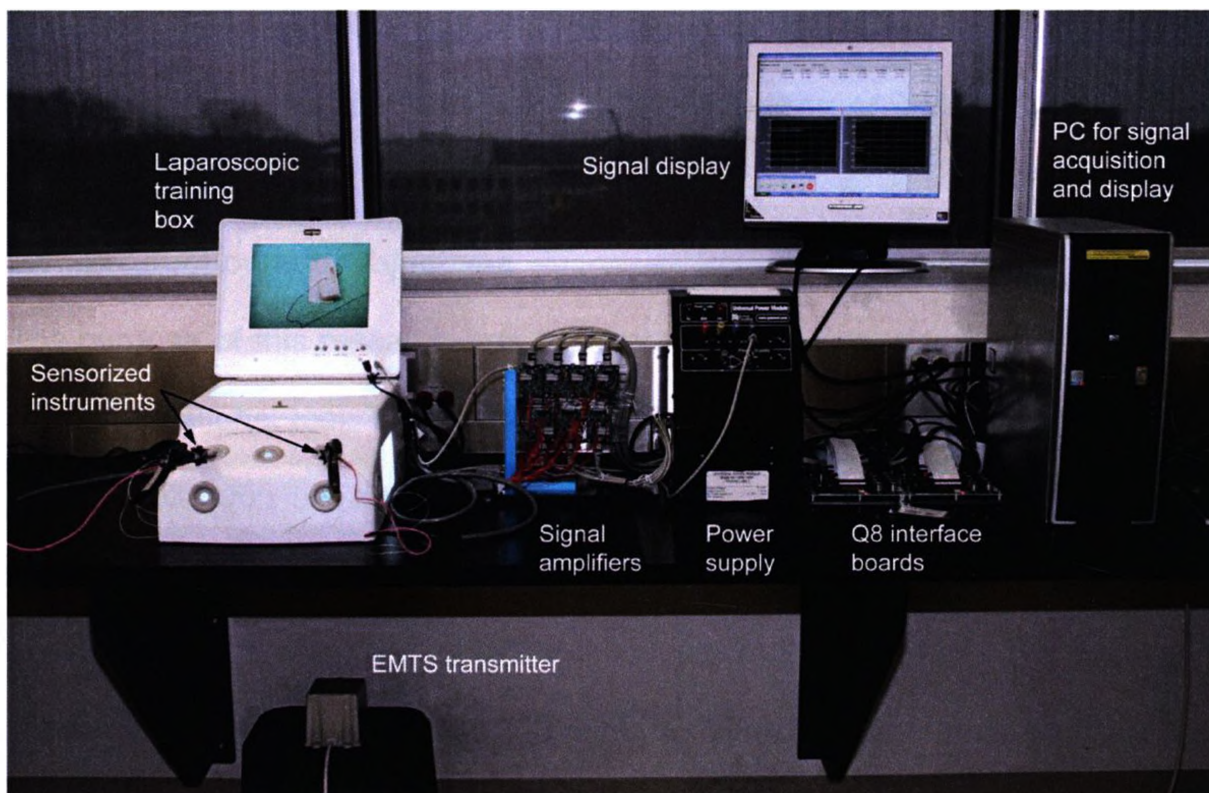
Figure 2.5. Experimental setup.(from Trejos et al. [83])

Chapter 3: Experimental Evaluation of SIMIS

3.1 Introduction and Objectives

The purpose of this research was to demonstrate the construct validity of SIMIS as an educational tool. To achieve this, the goal was to demonstrate differences in the application of force as well as position measures between novices and experts. Another objective was to demonstrate concurrent validity of SIMIS with the existing "gold standard" of MIS training: the FLS. Specifically, the aim was to show concurrent validity with FLS task 5: intracorporeal suturing. This task involves a simple suture with three knots to secure a small incision in a latex drain in an inanimate box trainer. It was selected as it is generally accepted as the most complicated MIS task [84].

In order to evaluate SIMIS, we recruited 20 volunteer participants from a single educational institution including surgeons, surgical trainees as well as graduate engineering students. Participants were stratified according to their level of training into four groups: non-trained novices (engineering students), trained novices (PGY 1 residents), experienced (PGY 4-5), and experts (staff surgeons). The groups are demonstrated in Table 2.1. A cohort of engineering graduate students was included due to the PGY1 residents having recently completed a laparoscopic surgery training program. All participants read and signed an informed consent form prior to participation in the experiments. Experiments were performed in an official FLS laparoscopic box trainer (Figure 2.1). After recruitment, the participants viewed the SAGES FLS instructional video

demonstrating task 5 from MISTELS: intracorporeal suturing. The suturing task involves grasping a 2-0 silk suture with an attached needle that is cut to a predetermined length of 12 cm. After grasping the needle, the participant must then drive the needle through dots spaced at a controlled distance from a slit in a Penrose drain.
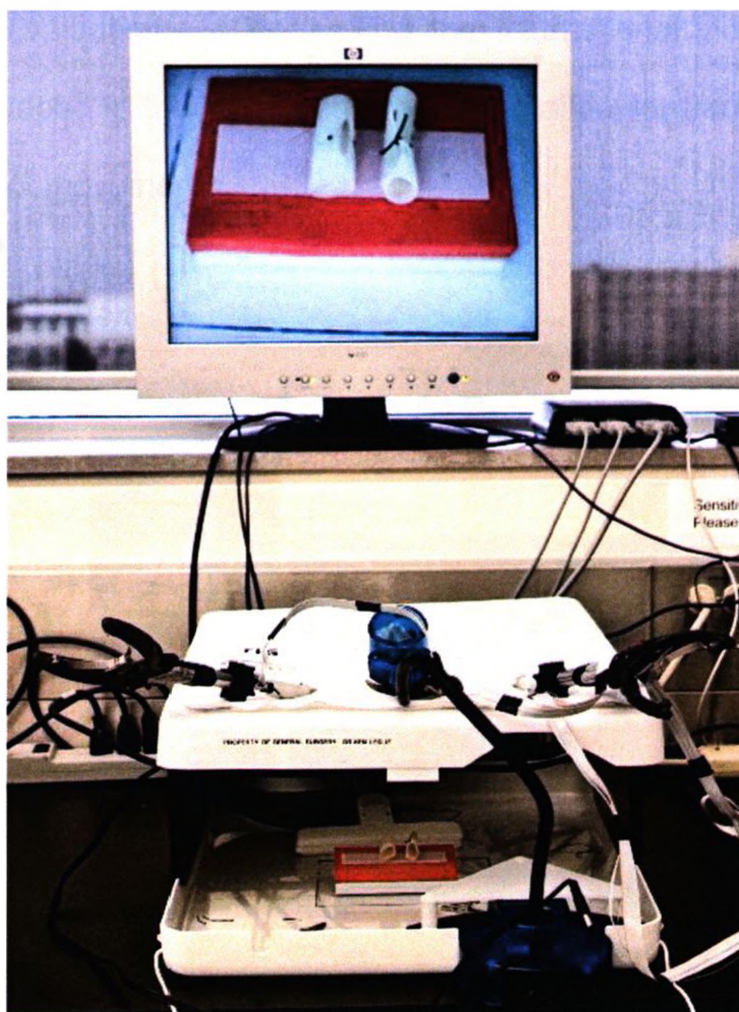

Figure 3.1. Close-up of FLS box trainer test-bed with SIMIS instruments in trocar access sites (photo credit: Meg Woodhouse)

After driving the needle, the participant must then tie a double knot (surgeon's knot), followed by two further single knots before cutting both suture strands with

scissors (Figure 3.2). This video briefly gives instruction as to how to perform a simple suturing task in an inanimate model. Participants were given the opportunity to view the instructional video as many times as they wanted prior to performing the task. The needle drivers used for the suturing task were equipped with the SIMIS sensors and were connected to a single computer for SIMIS evaluation. After viewing the instructional video, ICSAD hand sensors were taped to the participants' hands to allow for tracking of path length and numbers of movements.
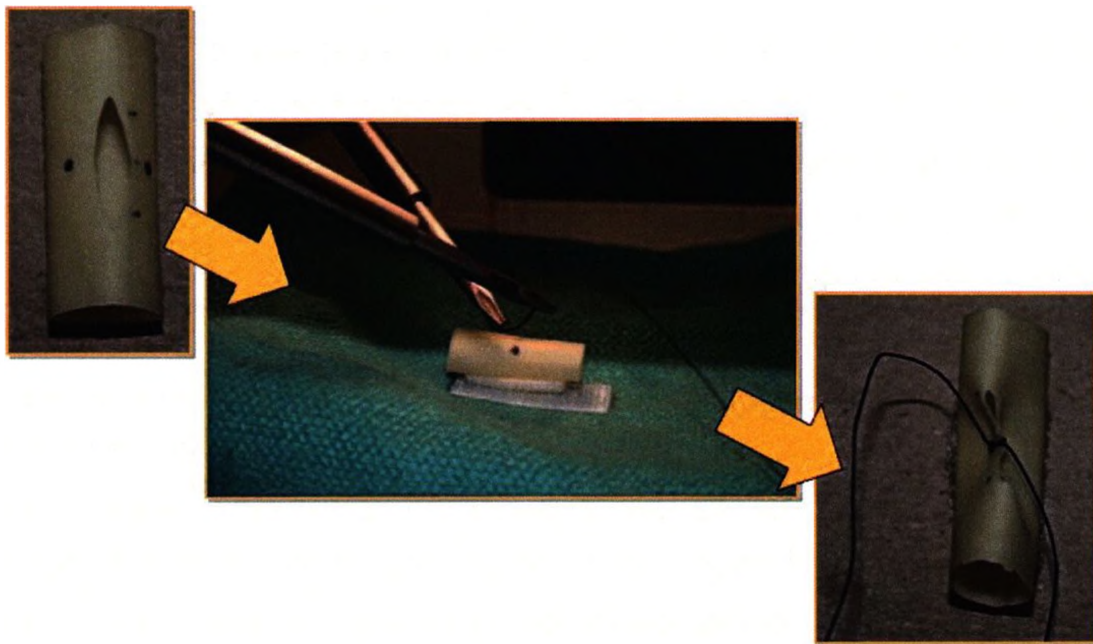
Figure 3.2. Suturing task

In the experiments described in this section, we have only used the SIMIS-enabled laparoscopic needle drivers. SIMIS also has laparoscopic graspers and scissors for the completion of other FLS tasks including peg-transfer, and pattern cutting. These experiments only evaluate Task 5 (intracorporeal suturing) as it is recognized as the most challenging, and thus, the most likely to demonstrate differences. Moreover, the logistics of changing the instrument head to allow for grasping and cutting require mid-experiment calibrations that may limit feasibility.

Table 3.1: Experimental Groups

Group	Number of Participants
E (Engineering Graduate Students)	5
A (1st Year Surgery Residents)	5
B (4th-5th Year Surgery Residents)	5
C (Staff Surgeons)	5

FLS task five is a simple suturing task. A simple suture 12 cm in length must be placed through two pre-marked points in a longitudinally slit Penrose drain. The suture then is tied using an intracorporeal knot-tying technique. The cut-off time is 600 seconds. An individual's score is derived by subtracting the total time to perform the task in seconds from 600. The penalty score is the sum of the distance in millimeters that the suture placement misses the premarked points, plus the gap in millimeters if the suture failed to approximate the edges of the slit.

An additional penalty is assessed if the knot is loose (10 points) or insecure (20 points).

An *a priori* hypothesis is that despite training for junior surgical residents and a lack of training for engineering graduate students, it would be possible for there to be overlap in ability irrespective of discipline or MIS training. Indeed current MIS training is still very inconsistent. It is possible that a final year resident may have had little exposure to an advanced MIS teaching service and that experienced MIS surgeons may actually do little suturing in practice making "experience level" less reliable than other objective means of assessing skill level [24]. Therefore, as the currently accepted standard is satisfactory completion of the FLS program [85], the participants' FLS scores were used to stratify the subjects into two groups: Novices and Experts. To perform this stratification, FLS score was used as a test to distinguish novices and experts by finding the optimal range under a receiver-operator characteristic (ROC) curve using the participants from Groups A, B, and C as controls for "surgeons" and the Engineers (Group E) as subjects.

3.2 Objective 1: Face-Validity of SIMIS for Forces and Positions

As previously described, SIMIS is capable of generating force data in five degrees of freedom as well as position data in six degrees of freedom (describe) at a frequency of 500 Hz. This allows the ability to descriptively evaluate the qualitative differences between the participants of different levels of experience. Matlab version R2009a (The Mathworks, Natick, MA) was used to graph the force and position data for every participant over time. The force and position plots of

all trainees were qualitatively examined to determine congruence within groups as well as to identify differences between groups. The first hypothesis was that the force and position plots for participants within the same group would be similar, while the plots of participants in different groups would not be similar.

Hypothesis 1:

H_0 – There will be no congruence within groups in the qualitative assessment of plots of force and position over time using SIMIS with a suturing task.

H_1 - There will be congruence within groups in the qualitative assessment of plots of force and position over time using SIMIS with a suturing task.

Hypothesis 2:

H_0 – There will be no difference between groups in the qualitative assessment of plots of force and position over time using SIMIS with a suturing task.

H_2 – There will be differences between groups in the qualitative assessment of plots of force and position over time using SIMIS with a suturing task.

3.3 Objective 2: Construct-Validity of SIMIS for Force

In order to determine if a construct is valid as an educational tool, it is imperative to demonstrate that it is capable of detecting objective differences in performance between people with different skills and experience. SIMIS allows an incredible degree of precision in evaluating performance of a surgical technique. As such, if there are differences in performance between groups, SIMIS also allows the

opportunity to understand why those differences occur. The software package for SIMIS includes video playback. This allows for the breakdown of a task into smaller sub-tasks. Table 2.2 demonstrates the individual components of a simple suturing task.

Table 3.2: Components of suturing task.

Component	Description of sub-task
1	Preparing needle
2	Driving needle through tissue
3	Tying first knot (double-knot)
4	Tying second knot (single-knot)
5	Tying third knot (single-knot)

Videos of the performance of each participant were viewed and times were generated for each of the five components of the suturing task. The mean forces exerted over each time period were extracted from the data using Matlab. Similarly, the mean forces for each sub-task for all participants in each of the groups were averaged. This allowed comparison of how each group performed each task differently from a force perspective.

If force application is a metric for performance, then experts at laparoscopic suturing should not only perform well on the FLS grading of intracorporeal suturing, but they should also exert a force profile that suggests purpose and

proficiency. Conversely, novices should score lower on the FLS scheme and display force patterns that suggest a lack of purpose and refinement.

Hypothesis 3:

H_0 – Mean forces between novices and experts for the entire suturing task will not be different

H_3 – Mean forces between novices and expert for the entire suturing task will be different

Hypothesis 4:

H_0 – Mean forces between novices and experts for suture sub-tasks will not be different

H_4 – Mean forces between novices and experts for suture sub-tasks will be different

Statistical Analysis for Objective 2:

Data were assessed for normality with the D'Agostino & Pearson omnibus normality test. Normally distributed data between groups were analysed using the one-tailed, unpaired t-test while non-normal data between groups were analysed using the Mann-Whitney U-test. Linear regression was used to understand the relationship between FLS scores and Force performance for statistically significant findings. Normal data were analysed using the Pearson correlation to compare FLS and SIMIS force scores. If data were not normal,

Spearman correlation was utilized. In all cases *p* values less than 0.05 were considered statistically significant.

3.4 Objective 3: Construct–Validity of SIMIS Position Sensing

The ability of SIMIS to track the position of the tip of the instruments in six degrees-of-freedom may also be used as a surrogate marker for performance. In addition to generating charts to qualitatively demonstrate the impact of position and performance, the data generated by SIMIS permit the calculation of a "work-sphere" calculated from the volume of an ellipsoid depicting the 95% confidence intervals of position with each instrument for each research participant during the entire task. As such, the volume of each ellipsoid can be calculated and compared. Expert surgeons are hypothesized to have a smaller work-sphere than less experienced trainees. Moreover, the work spheres of subjects within groups should also be similar. Similar predictions regarding the size of the work spheres for the aforementioned sub-tasks one through five were also anticipated.

Hypothesis 5:

H_0 – Mean work spheres between groups will not be different

H_5 – Mean work spheres between groups will be different

Hypothesis 6:

H_0 – Mean work spheres between groups for each subtask will not differ

H_6 – Mean work spheres between groups for each subtask will differ

Statistical Analysis for Objective 3:

Data were assessed for normality with the D'Agostino & Pearson omnibus normality test. Normally distributed data between groups were analysed using the one-tailed, unpaired t-test while non-normal data between groups were analysed using the Mann-Whitney U-test. Linear regression was used to understand the relationship between FLS score and SIMIS position data in the form of the mean work-sphere volumes. Normal data were analysed using the Pearson correlation to compare FLS and SIMIS force scores. If data were not normal, Spearman correlation was utilized. In all cases p values less than 0.05 were considered statistically significant.

3.5 Objective 4: Comparison of SIMIS Position Sensing with ICSAD

Not only does SIMIS have the ability to sense forces in five degrees of freedom at the tip of a laparoscopic instrument, it also senses position in six degrees of freedom. Therefore, there are two aspects of the system requiring validation: force sensing and position sensing. The ICSAD system is the current standard for measuring path-length and numbers of movements in education for both open and laparoscopic surgery. Thus, this system is ideally suited for validating SIMIS's position sensing. ICSAD is capable of providing data on path-length and numbers of movements with both the right and left hand. This affords the opportunity of more precise validation of SIMIS as the left (Instrument A) and

right (Instrument B) needle drivers are sensed separately. Likewise, if numbers of movements and path lengths are metrics for performance, then force profiles demonstrating improved proficiency should be matched with shorter path-lengths and fewer movements.

Hypothesis 7:

H_0 – SIMIS work sphere differences will not correlate with ICSAD differences between groups.

H_7 – SIMIS work sphere differences will correlate with ICSAD differences between groups

Statistical Analysis for Objective 4:

Pearson or Spearman correlation coefficient analyses were employed after assessing the data for normality using the D'Agostino & Pearson omnibus normality test. Correlation was also assessed using the linear regression analysis.

3.6 Other Statistical Notes

Data are presented as means ± standard deviation. Similarly, when data were not normal, results are presented as median ± interquartile range. Descriptions of all the statistical tests used in this thesis are given in Appendix 1. Statistical analysis was performed using GraphPad Prism 5 (GraphPad Software Inc. La Jolla, CA).

Chapter 4: Experimental Results

4.1 Group Assignment

Twenty study subjects were recruited from the aforementioned disciplines: surgery and engineering. Of the participants, five were expert minimally invasive surgeons, five were senior General Surgery residents (2 fourth year, 3 fifth year), and five were first year General Surgery residents. The remaining five participants were engineering graduate students with no laparoscopic experience.

After viewing the FLS instructional material as many times as necessary, each participant was given the opportunity for one practice attempt of the intracorporeal suturing task. Upon completion of the suturing task, FLS scores for all the participants were obtained. They are shown in Table 4.1.

Table 4.1: FLS Task 5 scores for study participants

Engineers	Surgeons		
Group E	Group A	Group B	Group C
0	72	337	465
70	85	434	440
85	0	357	413
30	226	285	467
0	324	378	484

FLS scores for surgeons tended to increase with experience level with the best scores predominantly being obtained by expert surgeons. The mean FLS scores for subjects with more MIS experience were higher than those from lower

experience levels. Group E had the worst mean FLS scores (37± 39.3). Some improvement in the mean FLS score was noted in Group A (141.4 ± 130.9). Group B (358.2 ± 54.6) and Group C (453.8 ± 27.7) similarly demonstrated improved scores. This is demonstrated in Figure 4.1. The D'Agostino & Pearson omnibus normality test was employed to determine if the FLS scores were normal. Due to the small size of each group, normality could not be assessed. Therefore, the Kruskal-Wallis test was employed to compare the groups. The differences in FLS scores were statistically significant (p=0.0011). The Dunn's multiple comparison test was used to see which differences accounted for the overall differences that were observed. The FLS scores which accounted for the difference were due to the difference in mean scores between Group C and Group E and Group C and Group A.
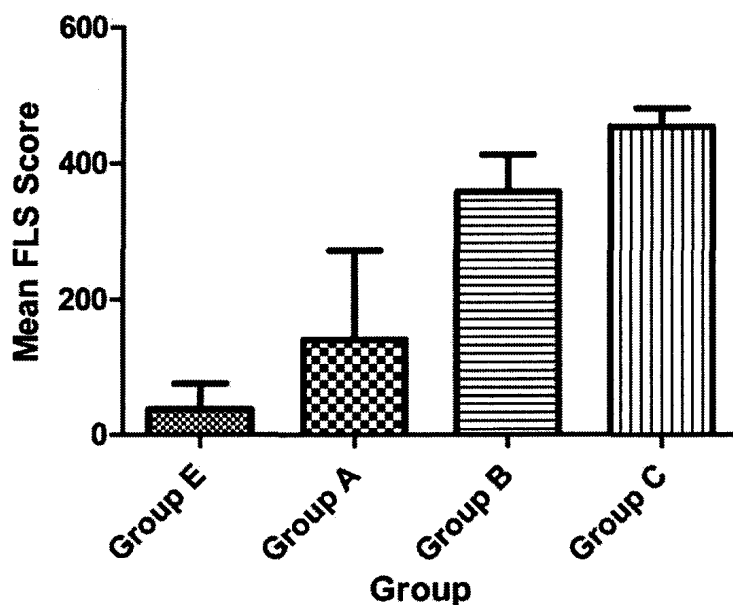
Figure 4.1. FLS scores between groups

A priori it had been decided to group the subjects based on FLS scores. The data demonstrate that despite not having any formal laparoscopic surgical training, or any education in the principles of surgery, some engineers obtained FLS task 5 scores as high or higher than first year surgery residents. Therefore, the Receiver-Operator Characteristic (ROC) was used to identify threshold of FLS score that optimizes the sensitivity and specificity of FLS task 5 score in defining who is indeed a surgeon. If being a "surgeon" is considered a "disease" in this concept, then the 15 surgeons in the study function as a control group in this technique with the "treatment" group being the 5 engineers. The purpose of an ROC curve is to help decide where to draw the line between "normal" and "not normal". This can be an easy decision if all the control values are higher (or lower) than all the "treatment" values. Usually, the two distributions overlap as is the case in this series. If the threshold is made too high, it is unlikely that one could mistakenly diagnose a disease in those who don't have it; however, there is a risk of missing some who have the disease. If the threshold is low, there is a higher likelihood of correctly identifying almost all of the people with the disease, but there is a risk of diagnosing the disease in more people who don't have it. Sensitivity is the fraction of people with the disease that the test correctly identifies as positive. Specificity is the fraction of people without the disease that the test correctly identifies as negative. In this case, the disease is "being a surgeon" and the test is FLS. The ROC curve is demonstrated in Figure 4.2.
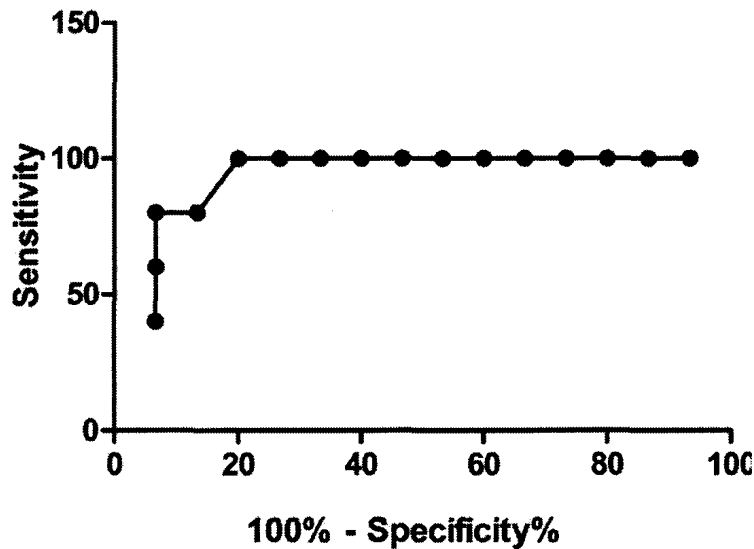
Figure 4.2. ROC curve

The area under an ROC curve quantifies the overall ability of the test to discriminate between those individuals with the disease and those without the disease. A test that is no better at identifying true positives than flipping a coin has an area of 0.5. A perfect test is one that has zero false positives and zero false negatives and has an area of 1.00. The area of the ROC curve depicted in Figure 4.2 is 0.9267 suggesting that the FLS task 5 score is, as expected, an excellent test for proficiency. If patients have higher test values than controls, then the area represents the probability that a randomly selected patient will have a higher test result than a randomly selected control. If patients tend to have lower test results than controls, then the area represents the probability that a randomly selected patient will have a lower test result than a randomly selected control. In this case, "patients" tend to have a lower result than controls; therefore, the threshold in FLS score selected should determine who is least

likely to be a true surgeon. Table 4.2 demonstrates the optimal ranges of FLS scoring in relation to sensitivity and specificity. Using this technique we see that scores less than 155.5 are the least likely to be consistent with being a surgeon.

Table 4.2. Sensitivity and Specificity of FLS score

FLS score	Sensitivity (%)	Specificity (%)
< 15.00	40	93.33
< 50.00	60	93.33
< 71.00	80	93.33
< 78.50	80	86.67
< 155.5	100	80
< 255.5	100	73.33
< 304.5	100	66.67
< 330.5	100	60
< 347.0	100	53.33
< 367.5	100	46.67
< 395.5	100	40
< 423.5	100	33.33
< 437.0	100	26.67
< 452.5	100	20
< 466.0	100	13.33
< 475.5	100	6.667

Thus, using the ROC curve technique the study participants were categorized as Novices if their FLS score was less than 155.5 (n=8) and as Experts if their FLS score was greater than or equal to 155.5 (n=12). Subject groupings and designations as novices and experts are given in Appendix 2.

4.2 Results for Objective 1: Face-Validity of SIMIS for Forces and Positions

Force Sensing:

Qualitative review of the force data graphically illustrated using Matlab suggested that there were differences in force exertion between the groups: Novices and Experts. In general, novices tended to be more erratic in their use of force in all 5 DOFs while experts generally tended to use little to no force for the bulk of the task until suddenly dramatically increasing their force exertion - especially in the x-plane and the grasp readings – when cinching down the three knots. Figures 4.3 and 4.4 demonstrate the qualitative differences in performance between a Novice and Expert surgeon performing the suturing task. Recall, the task was subdivided into five smaller sub-tasks: preparing the needle (Task 1); driving the needle (Task 2); tying first knot (Task 3); tying second knot (Task 4); tying third knot (Task 5). The same tendency to demonstrate noisy force distribution was similarly demonstrated in the sub-tasks in novices as compared to experts. Within the two groups, there was a general tendency for force profiles to appear similar qualitatively. While there was some variation within the groups, they generally showed congruent force profiles subjectively. All force profiles for all subjects are given in Appendix 3.

Position Sensing

Qualitative review of the data regarding position of the left and right hand instruments was performed after graphically depicting the raw data using Matlab. Using the raw plots, it was apparent that there was a greater tendency for direction changes and a more noisy position profile for novices. The position data suggested differences between novices and experts and also suggested congruence within experience groups. Figures 4.5 and 4.6 show the plots of position data for a novice and expert respectively. All position plots are given in Appendix 4.

In view of the above qualitative assessments, the null hypotheses for Hypothesis 1 and Hypothesis 2 were rejected. There is congruence within groups in the qualitative assessment of plots of force and position over time using SIMIS with a suturing task and there are differences between groups in the qualitative assessment of plots of force and position over time using SIMIS for a suturing task.
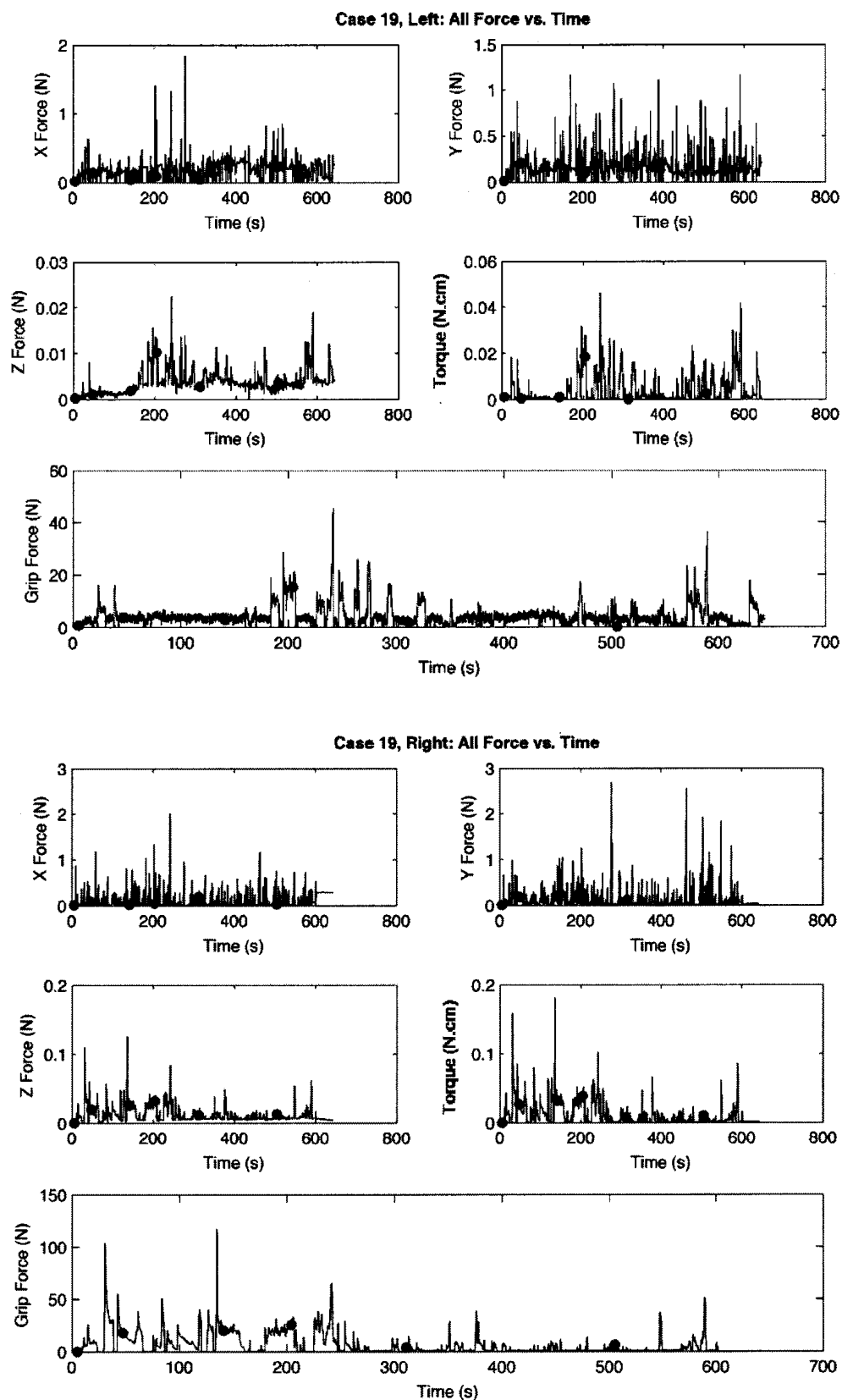
Figure 4.3. Raw data plot of force versus time in all 5 DOF in a Novice with left and right hand
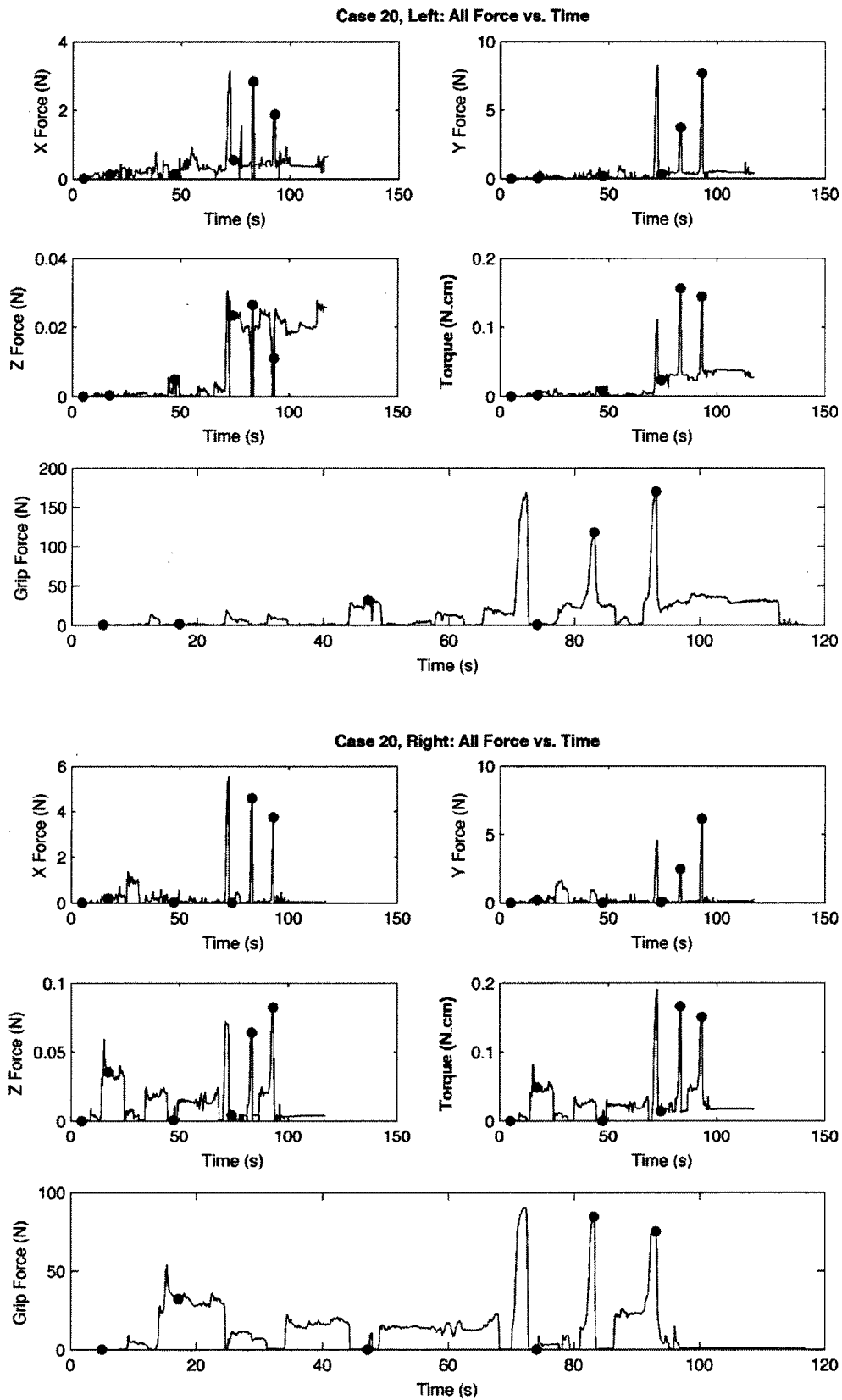
Figure 4.4. Raw data plot of force versus time in all 5 DOF in an Expert with left and right hand
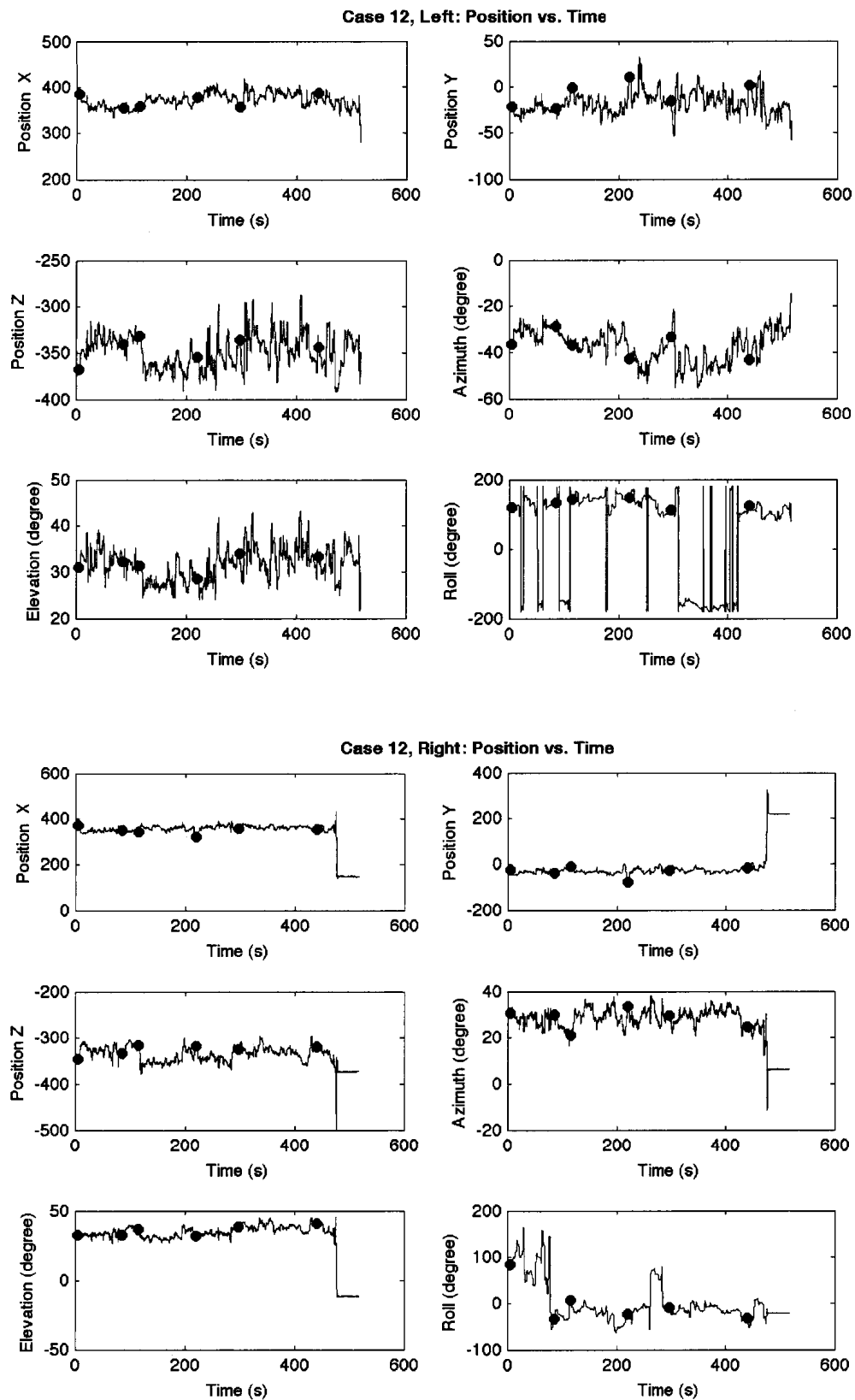
Figure 4.5. Raw data plot of position versus time in a Novice in all 6 DOF with left and right hand
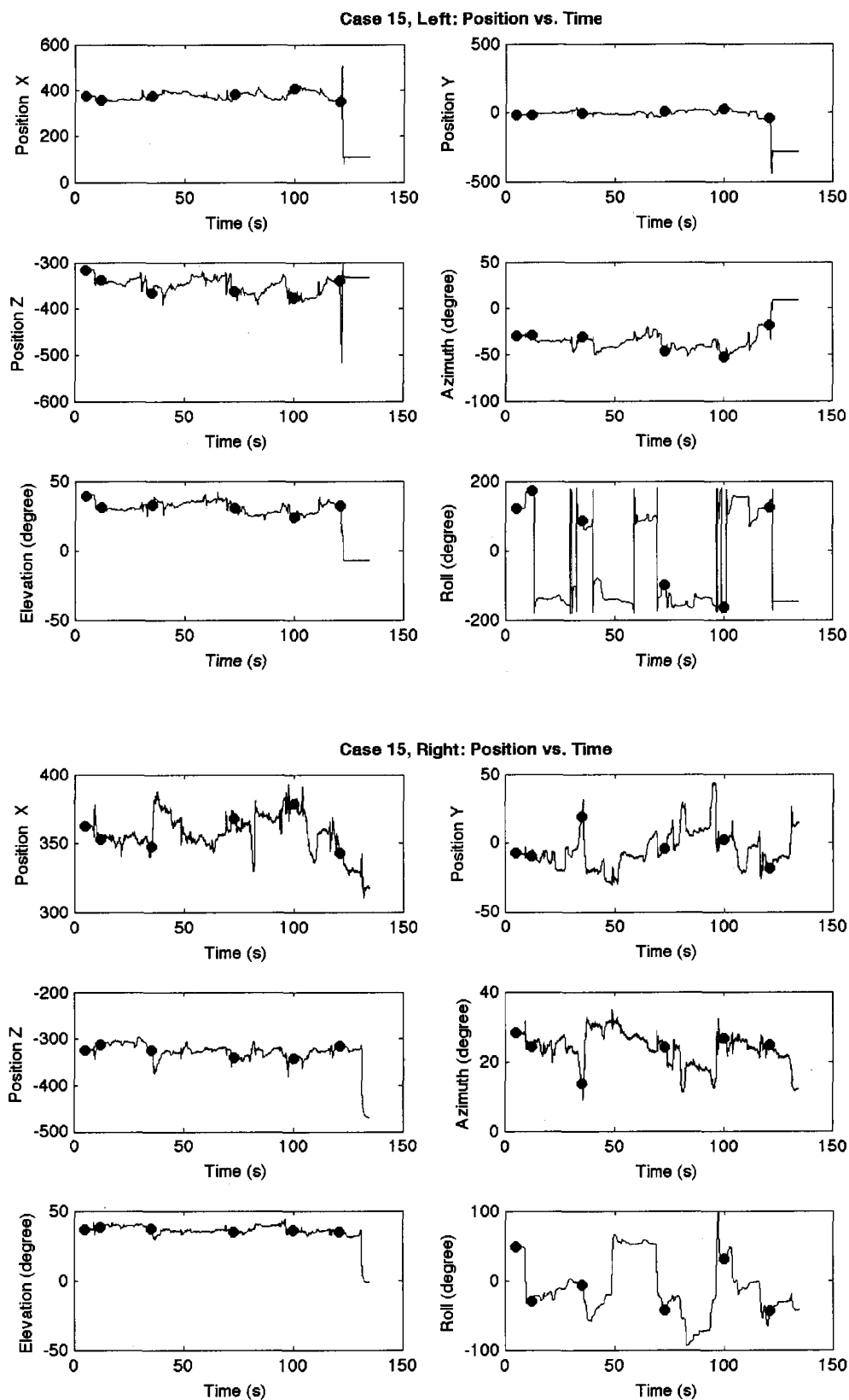
Figure 4.6. Raw data plot of position versus time in all 6 DOF in an Expert with left and right hand

4.3 Results for Objective 2: Construct-Validity of SIMIS for Force

As previously mentioned, using the FLS scores, the subjects were divided into two groups: Novices and Experts. To examine Hypothesis 3, the mean forces between the groups were compared using the forces exerted over the entire suturing task. The forces were considered in three ways: Total Force (magnitude of sum of forces in x, y, and z planes), Grasp Force, and Torsion Force.

Evaluation of the raw data regarding force revealed that a cohort of the novices had improper zeroing of the left-handed instrument for forces in the x-plane. These subjects' scores were corrected by re-zeroing their forces in the x-plane for the left instrument by subtract 12.3 N from all of their scores as this was the zero value in the raw data for all of the affected participants. The performance of this correction decreased the magnitude of their forces substantially. However, the morphology of their raw data performance and the amplitude of the variation in their force exertion mimicked that of the right handed instrument in their own trials. Also, it appeared grossly similar to the performance of the other 3 novices in the group. In addition, the amplitude of forces about the re-zeroed level of 12.3 N was similar in morphology to data from the right-handed instrument as well as other research subjects.

Total force data were found to have a Gaussian distribution. Therefore, mean total forces were compared. There was a trend for novices to exert a higher mean force over the course of the procedure than experts (0.7314 N ± 0.2999 vs. 0.9148 N ± 0.3169); however, this was not statistically significant (Figure 4.7).
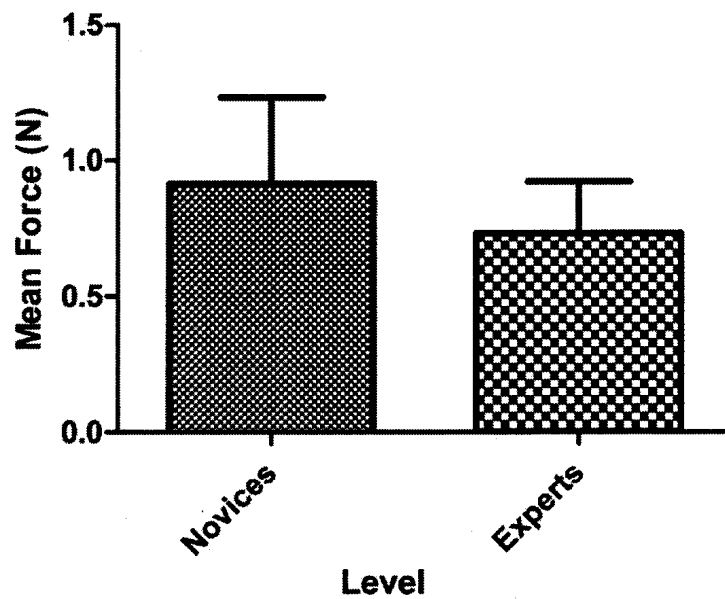
Figure 4.7. Total force for entire suturing task

Grasp force data were found to have a Gaussian distribution. Therefore, mean grasp forces were compared. Experts exerted a significantly higher mean grasp force over the course of the procedure than novices (21.84 N ± 6.873 vs. 15.14 N ± 7.171, $p=0.025$). These results are shown in Figure 4.8.
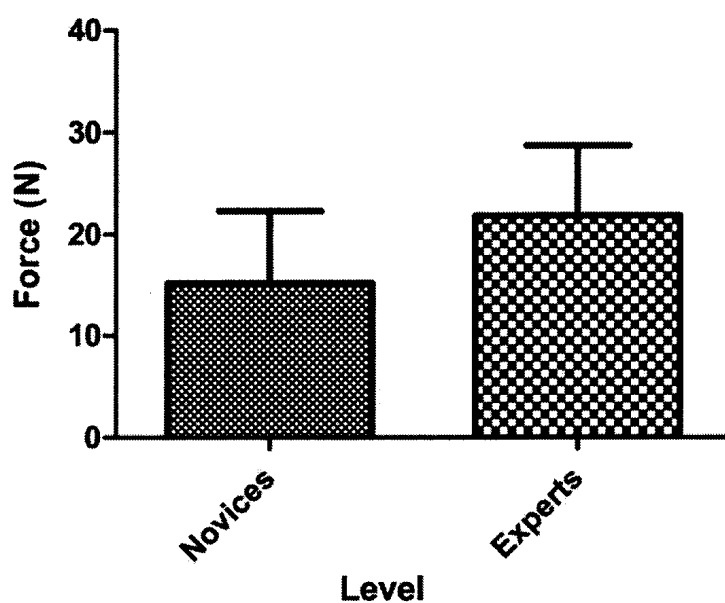
Figure 4.8. Grasp force for entire suturing task

Torsion force data were found to not have a Gaussian distribution. Therefore, median torques were compared. There were no differences between novices and experts for median torsion force over the course of the procedure (0.03134 N.cm, 0.01714-0.07697 vs. 0.02814 N.cm, 0.01670- 0.05039, p= 0.3080). These results are shown in Figure 4.9.
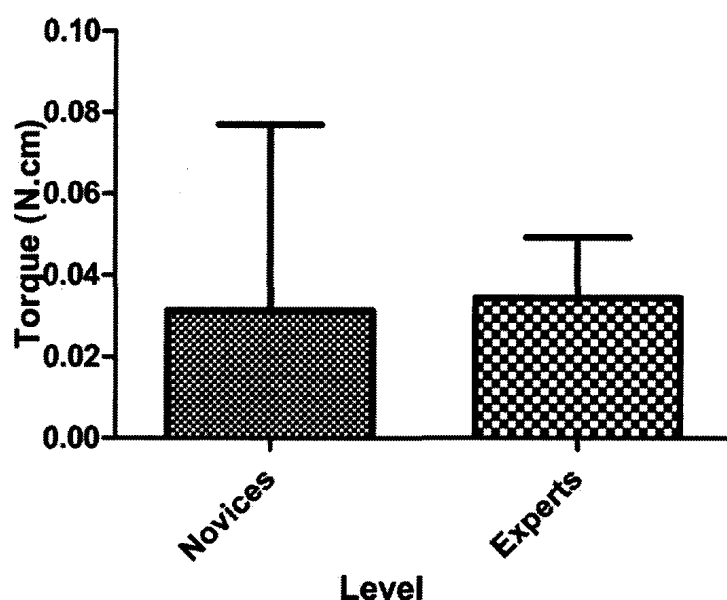
Figure 4.9. Torques for entire suturing task

The differences in force patterns exerted over the entire suturing task were predominantly explained by the differences between novices and experts in grasp forces. Linear regression was used to understand the relationship between grasp force and FLS score. Linear regression is a form of regression analysis in which the relationship between one or more independent variable and a dependent variable is modelled by a least squares equation. This allows the construction of a simple formula – in the form of a slope of a straight line – that will allow prediction of the value of a variable when given the value of another variable. It

also allows how one variable is related to another. In the case of this experiment, the independent variable is the FLS score of the subject, and the dependent variable is the SIMIS derived data. If significant relationships are found using linear regression, there is the possibility of developing new metrics to predict proficiency based on SIMIS data. There was a positive relationship between FLS score and grasp forces with higher FLS scores being significantly associated with higher mean grasp forces (F=6.525, p=0.0199). The regression is shown in Figure 4.10. Grasp force data for all subjects over the entire task were normal; therefore, correlation was assessed using Pearson's test. There was a significant correlation between the FLS scores and the grasp forces for the entire task (r=0.5158, p=0.0199).
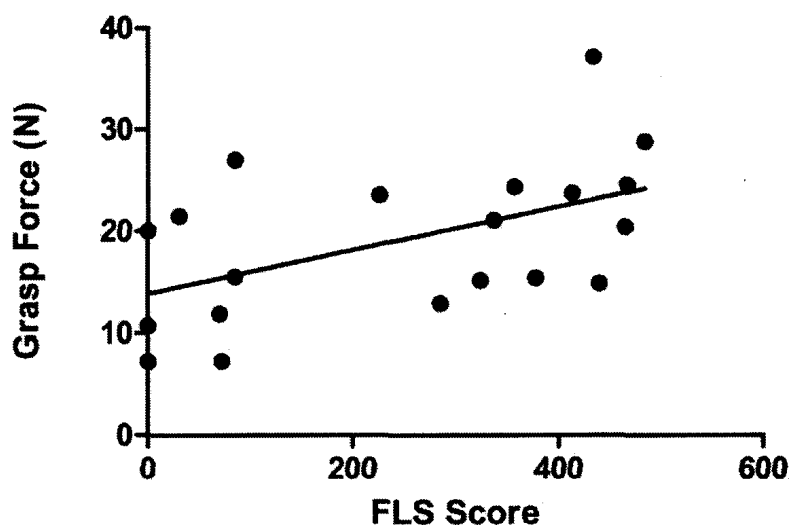
Figure 4.10. FLS correlation with grasp force

In view of the above findings, the null hypothesis for Hypothesis 3 was rejected. Forces for the entire suturing task between novices and experts are different.

Data for the subtasks were analysed in the same fashion. Total force data for each task was found to be non-Gaussian. Therefore medians were compared. Significant differences were demonstrated for Task 1 (preparing needle) and Task 2 (driving needle) with novices exerting more total force than experts (Table 4.3). Non significant trends demonstrating greater force exertion by novices for Tasks 3 to 5 were also demonstrated. These final three tasks represent knot tying tasks. When results from these three tasks were pooled, novices demonstrated significantly greater forces than experts. Subtasks for total force are depicted in Figure 4.11.

Table 4.3. Total force for each subtask. Data are presented as median with interquartile range

Total Force (N)			
Task	Novices	Experts	p
1	0.9986 (0.0482-1.092)	0.281 (0.2130-0.5024)	0.0031
2	1.121 (0.6862-1.194)	0.7037 (0.4803-0.8844)	0.0294
3	1.046 (0.7368-1.149)	0.6952 (0.4847-1.067)	0.1316
4	1.046 (0.5418-1.281)	0.6818 (0.5280-1.010)	0.2318
5	1.001 (0.6362-1.222)	0.5851 (0.5329-0.7825)	0.1015
All Knots	1.046 (0.5899-1.219)	0.6517(0.5302-0.8097)	0.0263

Grasp force data for Tasks 1 to 3 were Gaussian while grasp force data for Tasks 4 and 5 and for all knots were non-Gaussian. The results of subtask analysis for grasp force demonstrated non significant trends with experts exerting greater force than novices for Tasks 1 to 3. Experts were also found to exert significantly more force than novices for Tasks 4 and 5. Considering all knots tied, again

expert surgeons used significantly more force than novices. These findings are summarized in Table 4.4 and Figure 4.12.
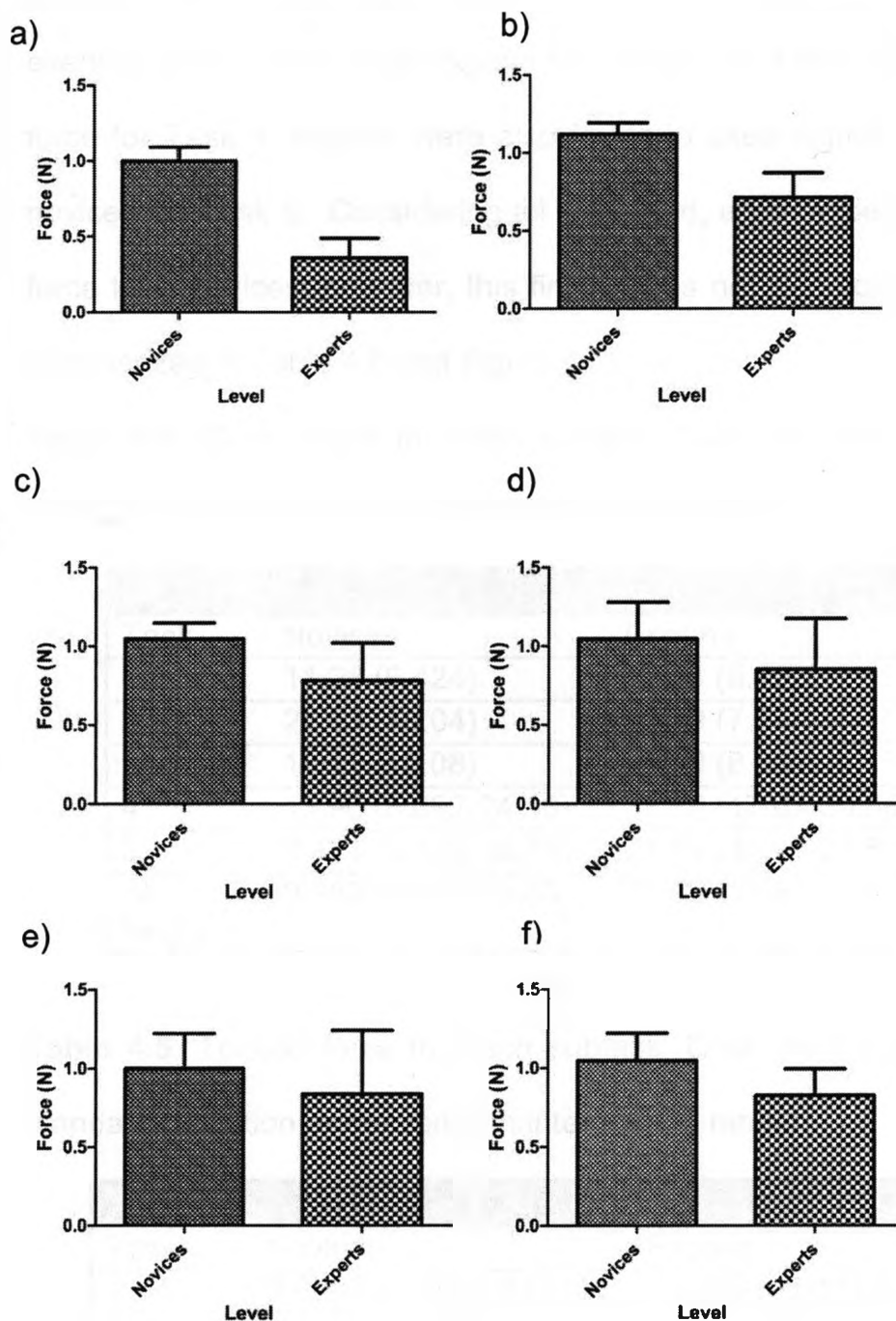
Figure 4.11. Total forces for subtasks 1(a), 2(b), 3(c), 4(d), 5(e), and all knots (f)

Torsion force data for Tasks 1 to 3 were Gaussian while torsion force data for Tasks 4 and 5 and for all knots were not Gaussian. The results of subtask analysis for torsion force demonstrated non significant trends with novices exerting greater force than experts for Tasks 1 to 3 and experts exerting greater force for Task 4. Experts were also found to exert significantly more force than novices for Task 5. Considering all knots tied, again expert surgeons used more force than novices; however, this finding was not significant. These findings are summarized in Table 4.5 and Figure 4.13.

Table 4.4. Grasp force for each subtask. Data are presented as means with standard deviation or median with interquartile range

Grasp Force (N)			
Task	Novices	Experts	*p*
1	11.28 (6.424)	12.14 (5.402)	0.376
2	21.63 (15.04)	20.19 (7.344)	0.3887
3	19.29 (10.08)	27.09 (8.084)	0.0357
4	13.96 (5.692-24.16)	22.62 (17.07-30.86)	0.0413
5	7.421 (5.126-16.75)	21.04 (15.47-24.81)	0.0075
All Knots	9.982 (5.575-19.83)	22.62 (17.81-32.07)	< 0.0001

Table 4.5. Torsion force for each subtask. Data are presented as means with standard deviation or median with interquartile range

Torsional Force (N.cm)			
Task	Novices	Experts	*p*
1	0.0203 (0.0143-0.0267)	0.0180 (0.0111-0.0288)	0.308
2	0.05028 (0.03881)	0.03513 (0.01883)	0.1283
3	0.05042 (0.03628)	0.04631 (0.02748)	0.388
4	0.0261 (0.0122-0.0559)	0.0336 (0.0176-0.0541)	0.308
5	0.0196 (0.0091-0.0388)	0.0384 (0.0231-0.0482)	0.0486
All Knots	0.0232 (0.0181-0.0559)	0.0371 (0.0209-0.0534)	0.2245

In view of the above finding the null hypothesis for Hypothesis 4 was rejected. Mean forces between novices and experts for suture sub-tasks are different.
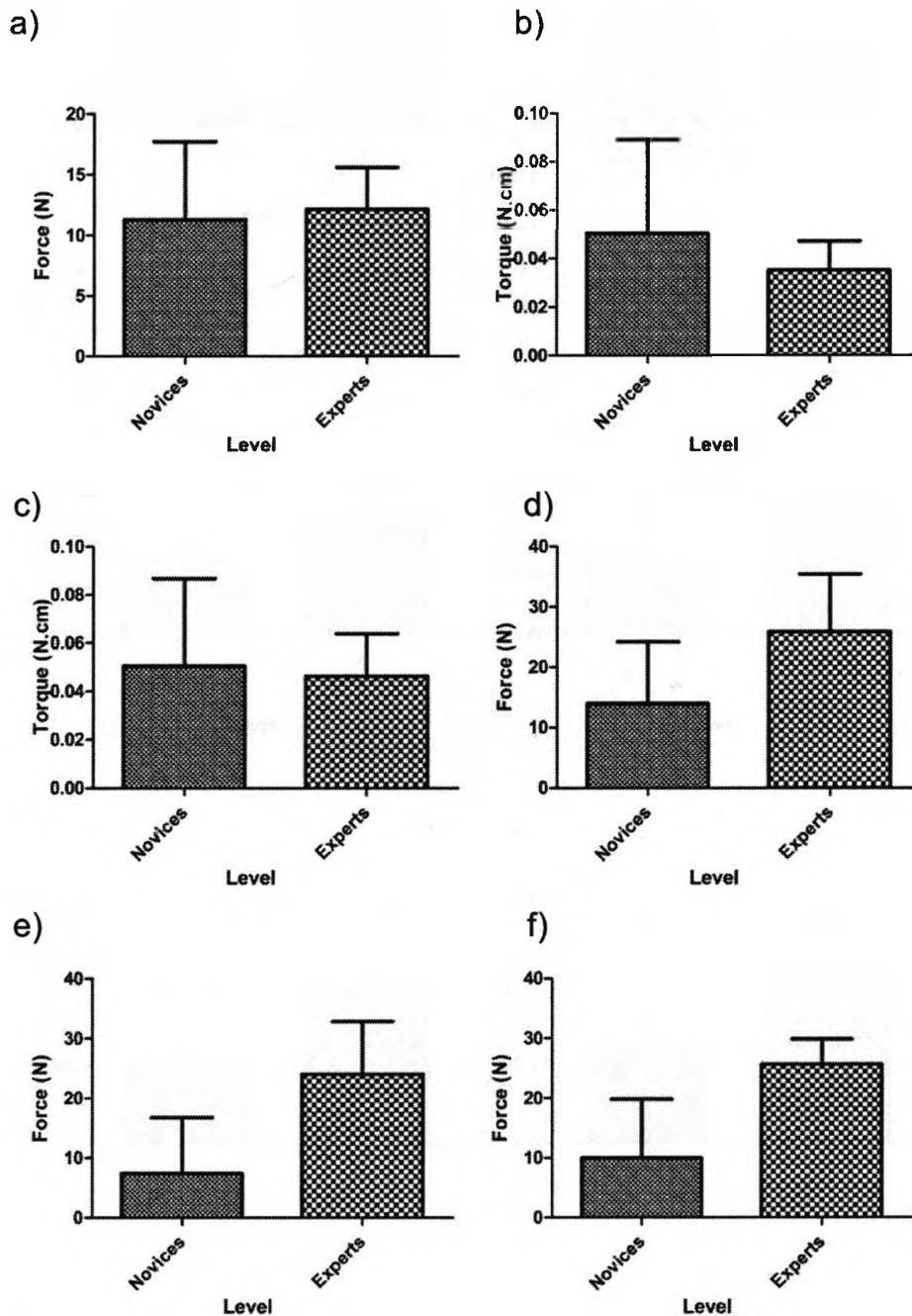
Figure 4.12. Grasp forces for subtasks 1(a), 2(b), 3(c), 4(d), 5(e), and all knots (f)
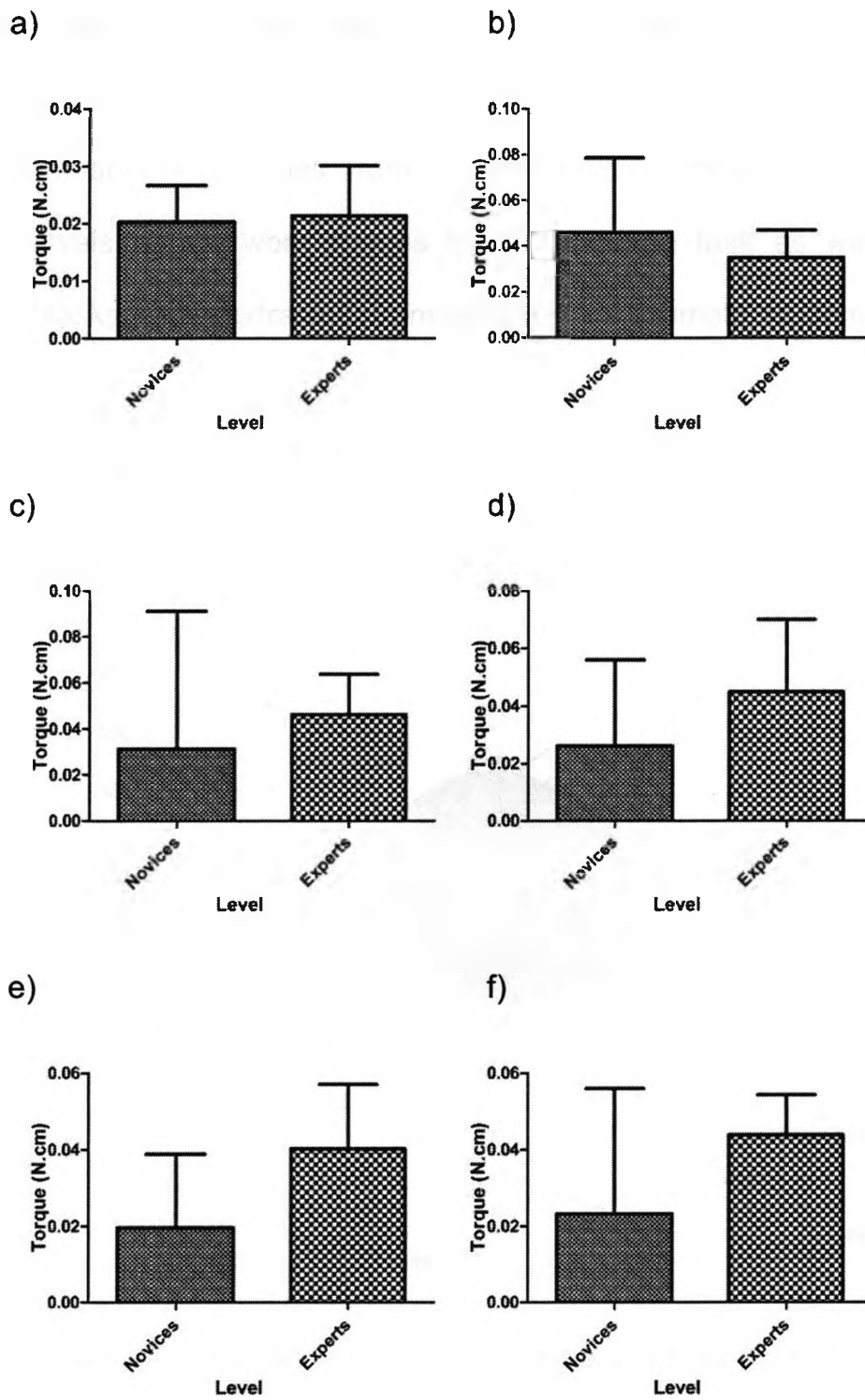
Figure 4.13. Torsion forces for subtasks 1(a), 2(b), 3(c), 4(d), 5(e), and all knots (f)

4.4 Results for Objective 3: Construct–Validity of SIMIS Position Sensing

Work sphere volumes from the ellipsoids representing the 95% confidence intervals of the work spaces for the suturing task as well as the individual subtasks were extracted from Matlab. An example is demonstrated in Figure 4.14.
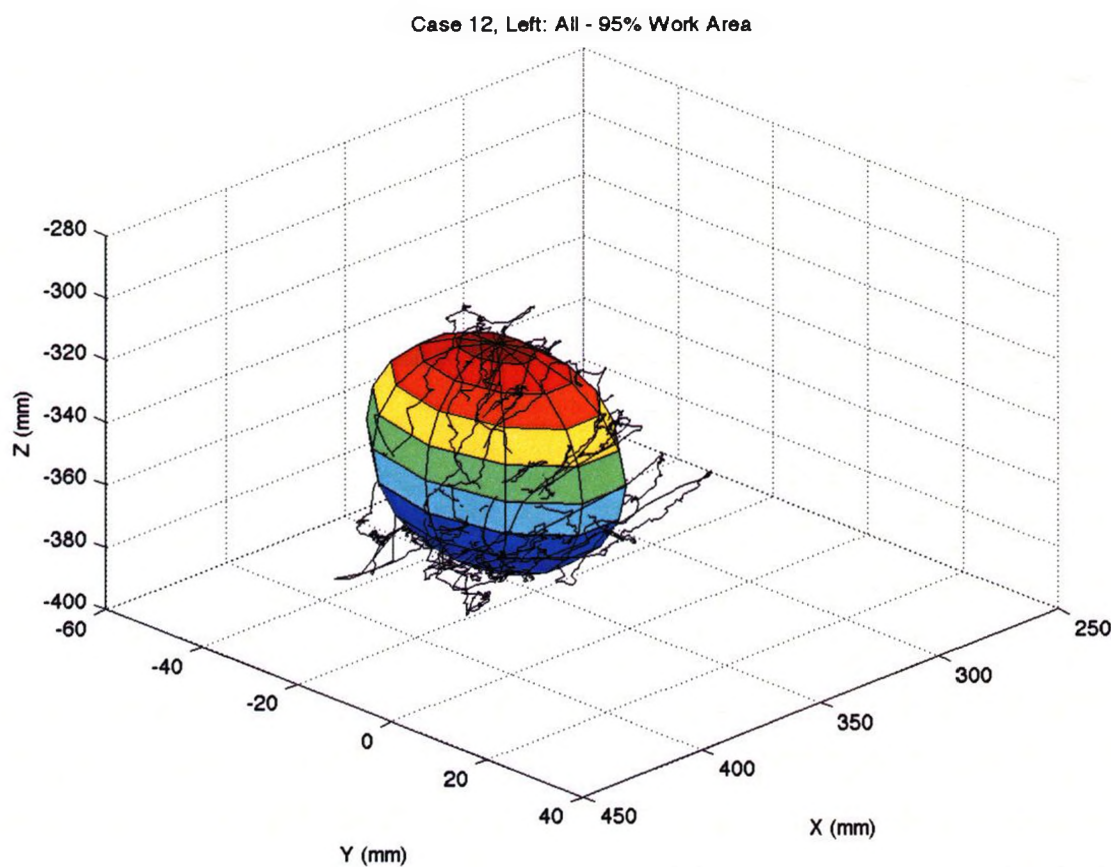
Figure 4.14. Example of work sphere for entire suturing task for a novice

Work sphere data for the entire suturing task were Gaussian. Mean work spheres between groups were significantly different with Experts using a greater work area than novices (2.609 $\times 10^6$ mm^3 ± 1.592 $\times 10^6$ vs. 1.009 $\times 10^6$ mm^3 ± 624687, p= 0.0075). This difference is illustrated in Figure 4.15.
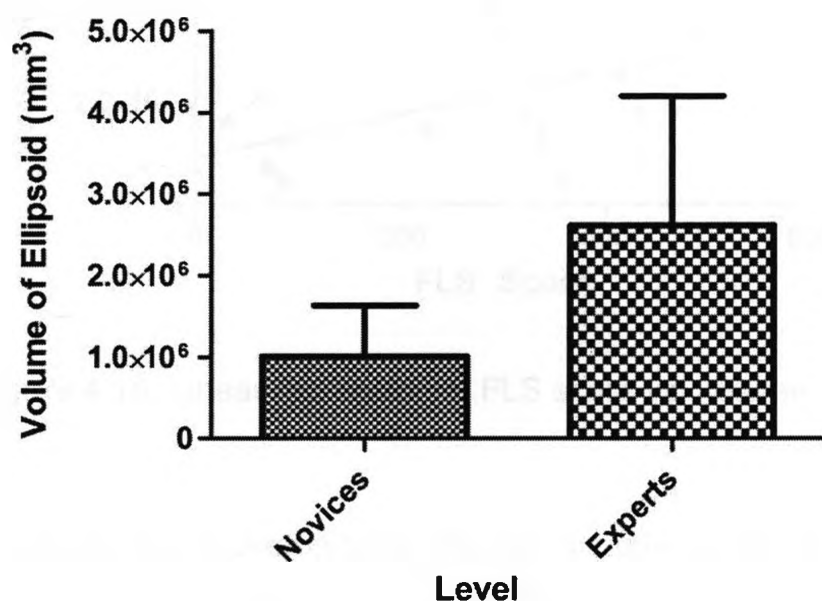
Figure 4.15. Mean volumes with standard deviation for entire suturing task

For the same rationale as described for Objective 2, linear regression was used to understand the relationship between work sphere volumes and FLS score. There was a positive relationship between FLS score and work sphere volumes with higher FLS scores being significantly associated with larger mean work spheres (F= 6.673, p= 0.0187). The regression is shown in Figure 4.16. Work sphere volume data for all subjects over the entire task were non-Gaussian; therefore, correlation was assessed using Spearman's test. There was a

significant correlation between the FLS score and the work volume for the entire

task (r= 0.5815, p= 0.0072).
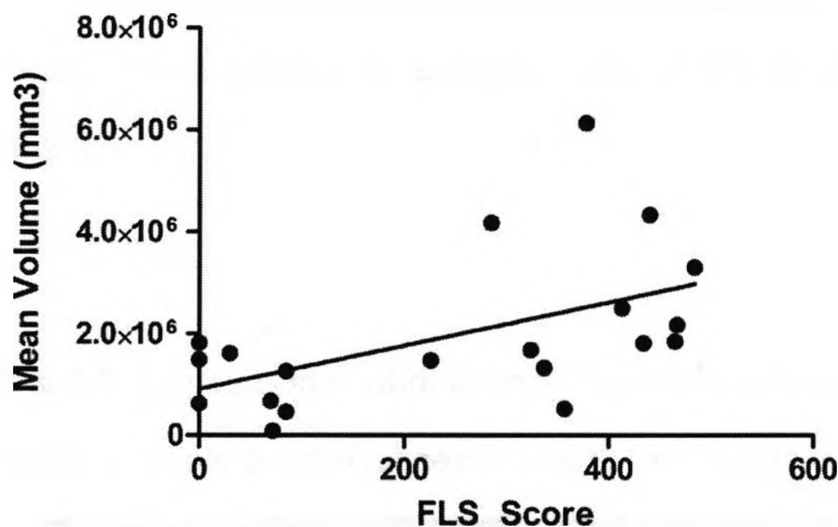
Figure 4.16. Linear regression of FLS score vs. volume

In view of the above findings, the null hypothesis for Hypothesis 5 was rejected.

Work spheres between groups are different.

Individual subtasks were evaluated in the same fashion. Figure 4.17 shows an

example of work spheres for all subtasks with the left instrument in an Expert. All

subtask graphics are given in Appendix 5. Data were assessed for normality.

None of the subtask volume data sets were Gaussian; therefore, medians were

compared. In contrast to the overall task volumes, non-significant trends showing

smaller work space volumes for the individual subtasks were demonstrated for

experts (Table 14.5). When all tasks were considered, the mean task volumes

were smaller for experts than novices; however, this finding was not statistically significant. These findings are shown in Figures 4.18 to 4.23.

In view of the above findings the null hypothesis for Hypothesis 6 was not rejected. Work spheres for subtasks between the groups are not substantially different.

Table 4.6. Comparison of work volumes for each subtask. Data are presented as medians with interquartile ranges or means with standard deviation

Work Sphere Volume (mm^3)			
Task	Novices	Experts	p
1	24314 (17225-32952)	19647 (8853-56347)	0.3642
2	16118 (10137-26626)	11790 (10924-24559)	0.3357
3	107479 (62303-275504)	68485 (49897-90994)	0.0767
4	66357 (60197-97880)	57215 (54671-98582)	0.3210
5	121064 (58684-189595)	78128 (53351-125883)	0.2363
All	127523 (359691)	75298 (140842)	0.0738

Case 8, Left: Task 1 - 95% Work Area
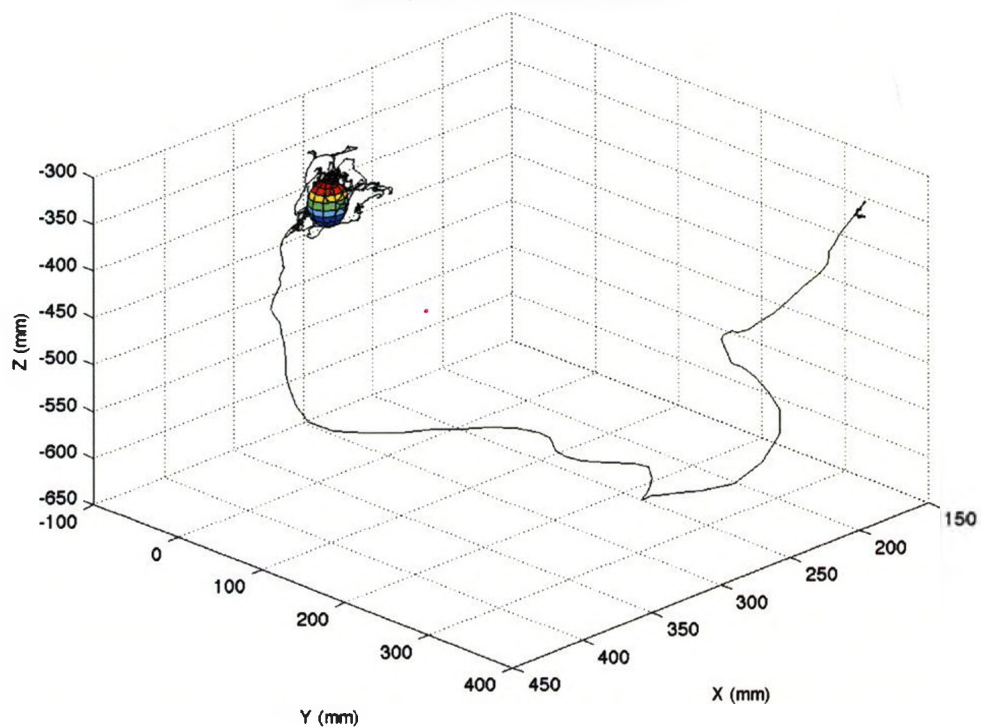
Case 8, Left: Task 2 - 95% Work Area
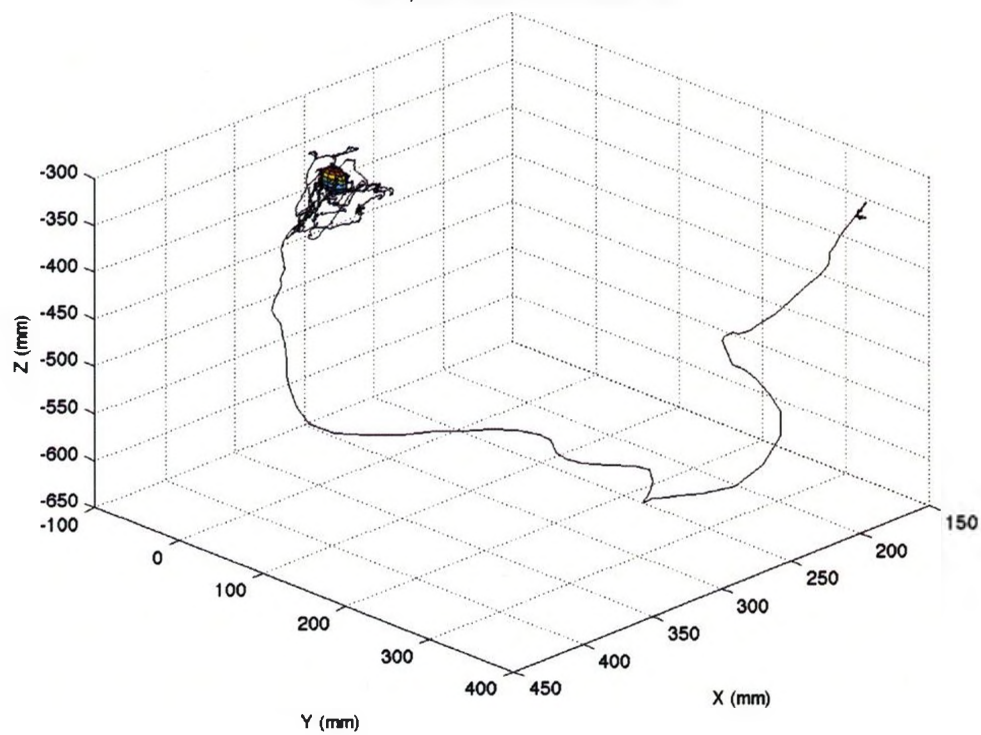
Case 8, Left: Task 3 - 95% Work Area
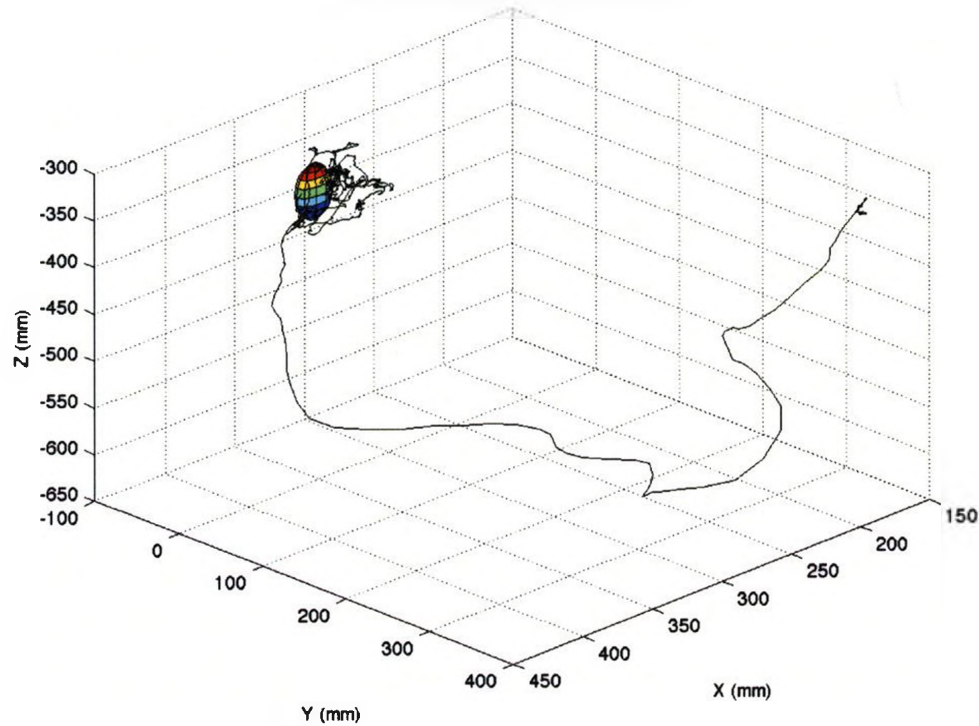
Case 8, Left: Task 4 - 95% Work Area

Case 8, Left: Task 5 - 95% Work Area
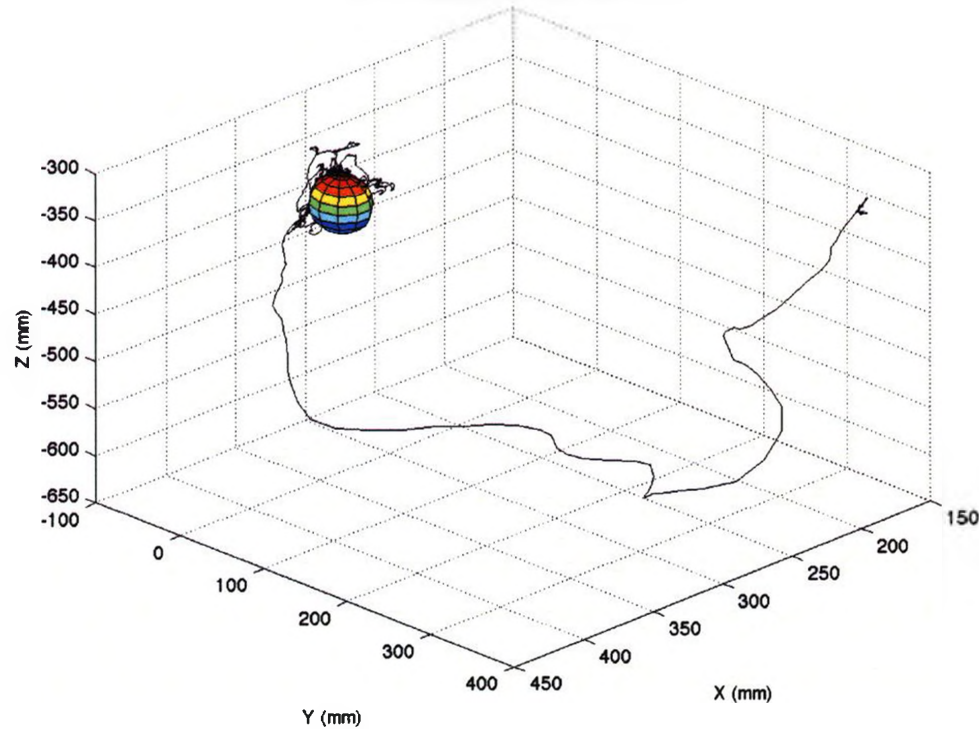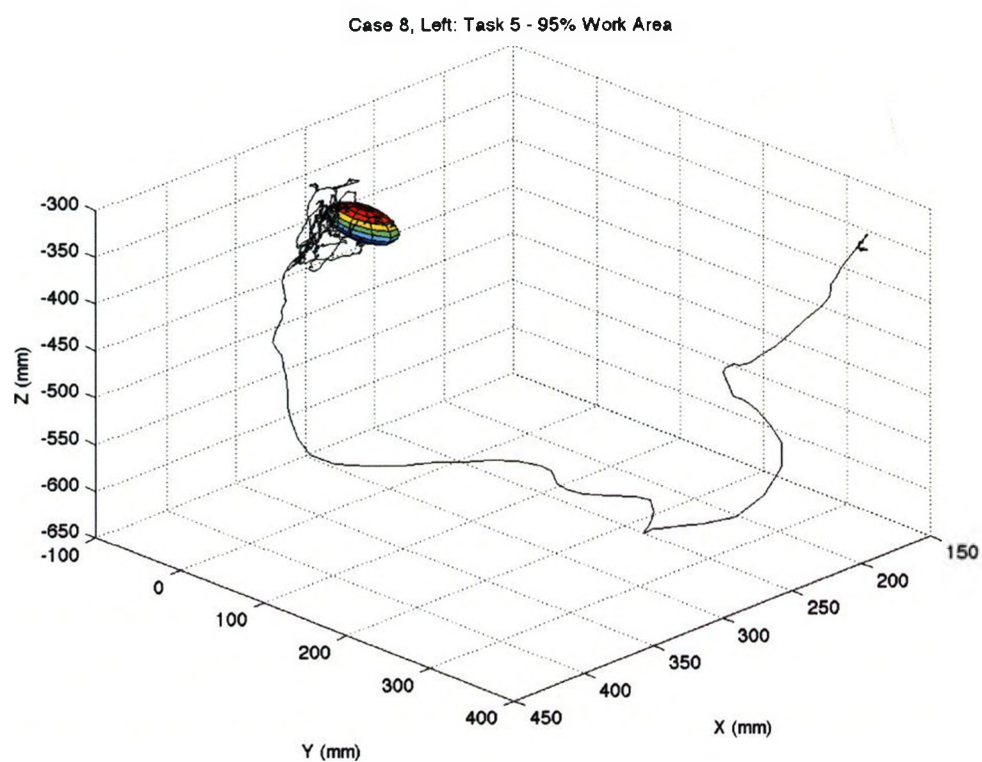
Figure 4.17. Ellipsoids in an expert surgeon for all subtasks
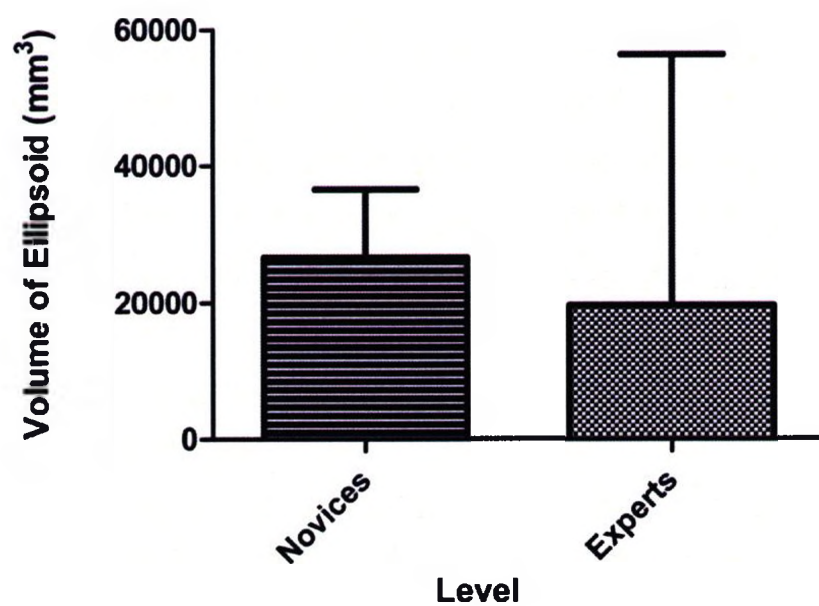
Figure 4.18. Median volume of ellipsoid with interquartile range for task 1
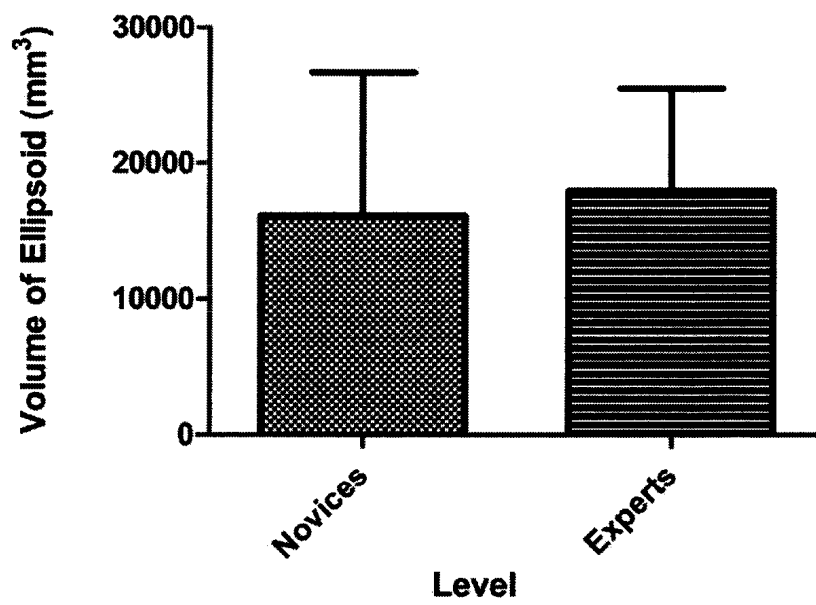
Figure 4.19. Median volume of ellipsoid with interquartile range for task 2
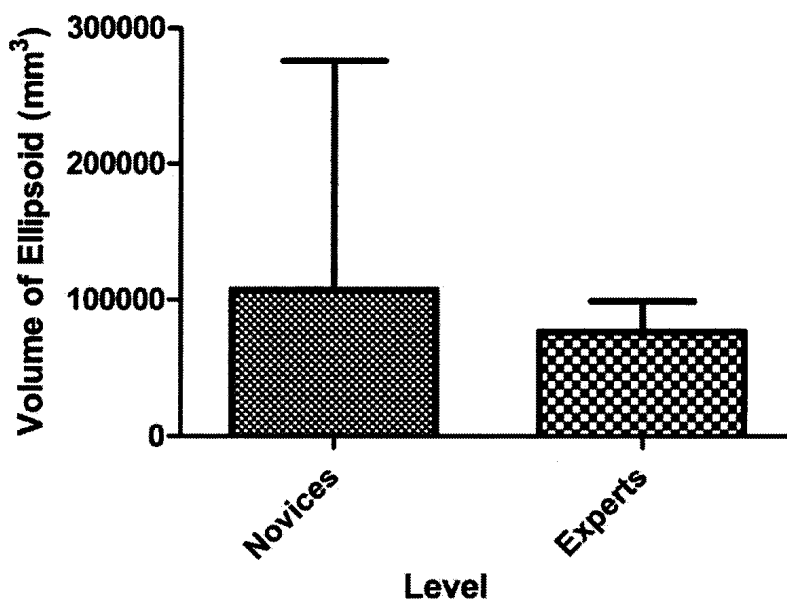
Figure 4.20. Median volume of ellipsoid with interquartile range for task 3
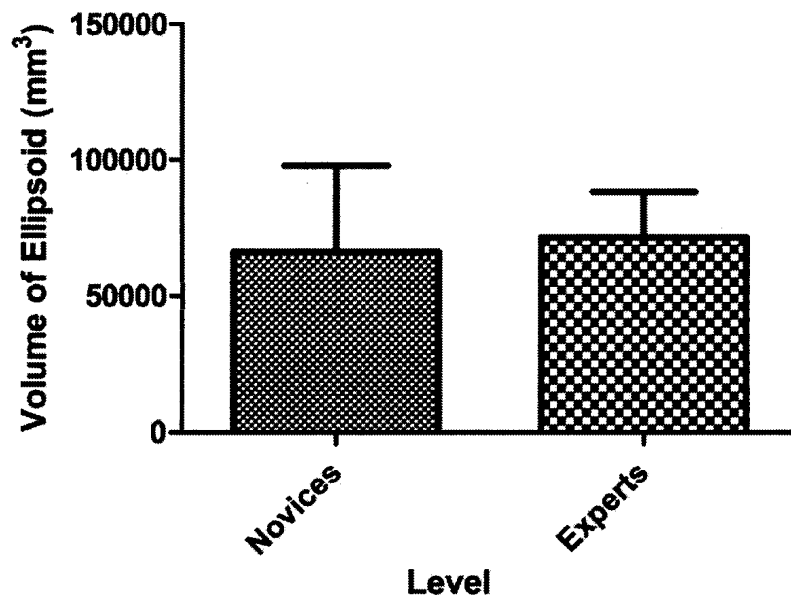
Figure 4.21. Median volume of ellipsoid with interquartile range for task 4
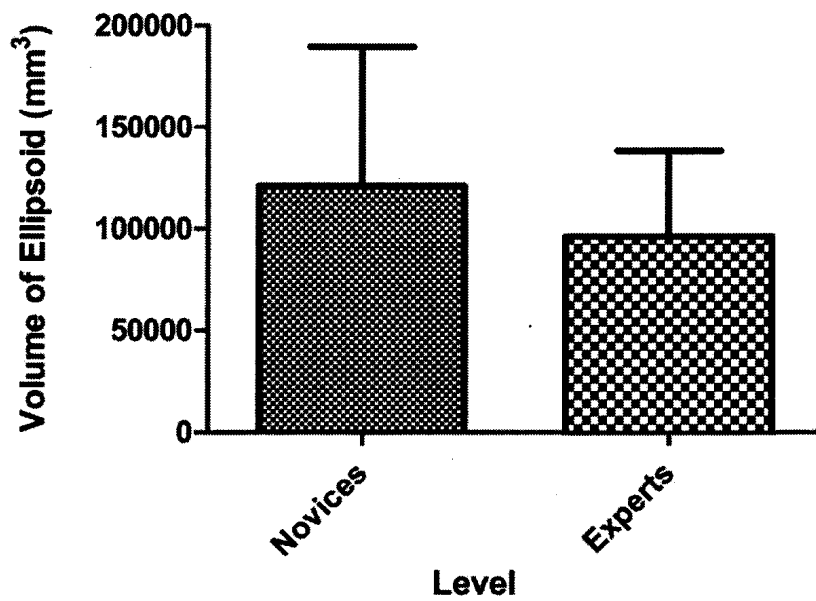
Figure 4.22. Median volume of ellipsoid with interquartile range for task 5
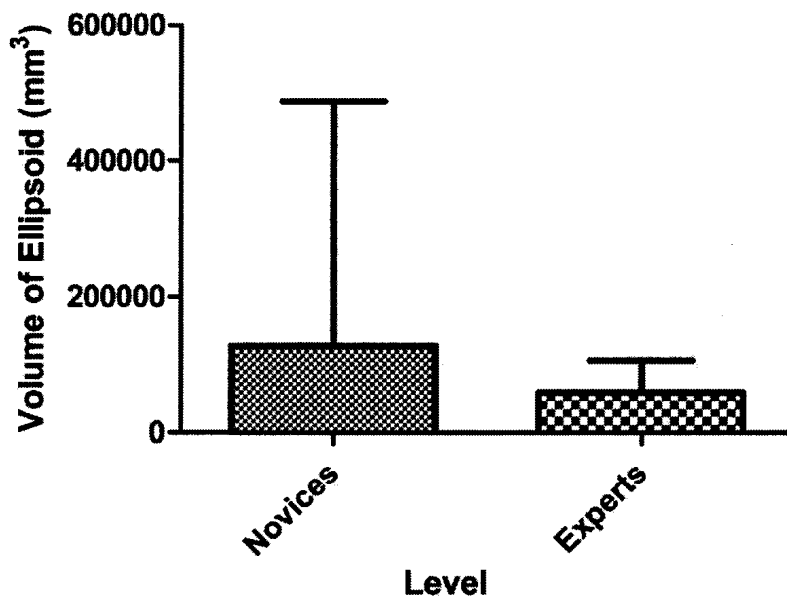
Figure 4.23. Mean volume with standard deviation of ellipsoid for all individual tasks

4.5 Results for Objective 4: Comparison of SIMIS Position Sensing with ICSAD

ICSAD data for all subjects were extracted from the ROVIMAS software (Imperial College, London). Path lengths and numbers of movements by subjects in the novice and expert categories were assessed for normality. Both data sets were Gaussian. Novices had a significantly larger mean path length than experts (47.82m ± 9.443 vs. 18.90m ± 6.044, $p<0.0001$). Similarly, novices used significantly more movements than experts (148.8 ± 72.45 vs. 65.33 ± 28.43, $p=0.001$). These findings are summarized in Figures 4.24 and 4.23.
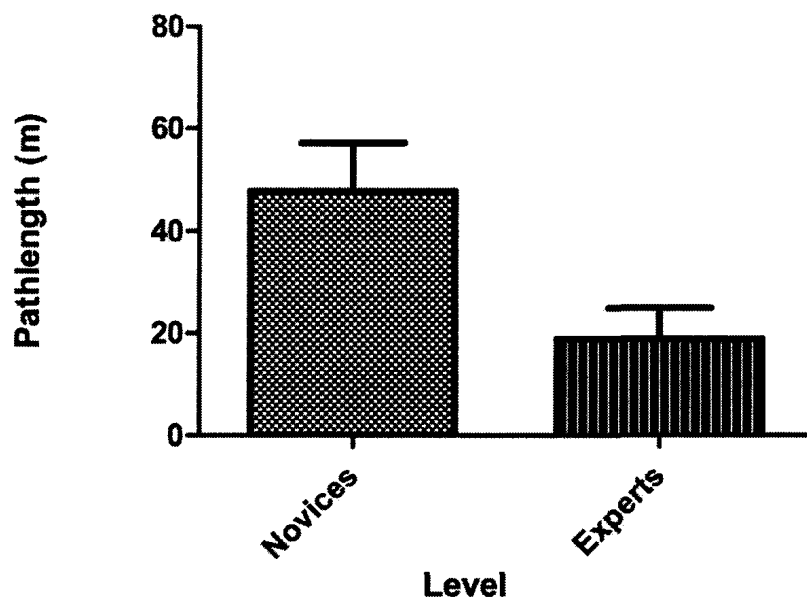
Figure 4.24. ICSAD pathlength
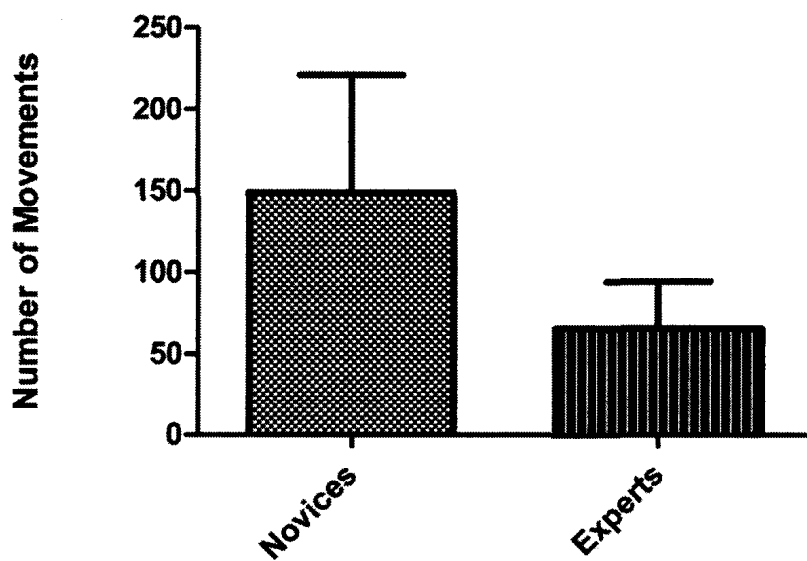
Figure 4.25. ICSAD movements

Linear regression demonstrated that there was a significant inverse relationship between ICSAD path length and work sphere volumes (F=5.741, p=0.0182, Figure 4.26). Spearman correlation also confirmed correlation between ICSAD path length and work sphere volumes (r= -0.5895, p=0.0062). Linear regression for numbers of movements also demonstrated an inverse relationship between ICSAD movement counts and work sphere volumes; however this finding was not statistically significant (F=2.394, p= 0.1392, Figure 4.27). Spearman correlation was similarly non-significant (r = -0.2775, p= 0.2361).

In view of these findings, the null hypothesis for hypothesis 7 was rejected. There is correlation between SIMIS work sphere data and ICSAD data.
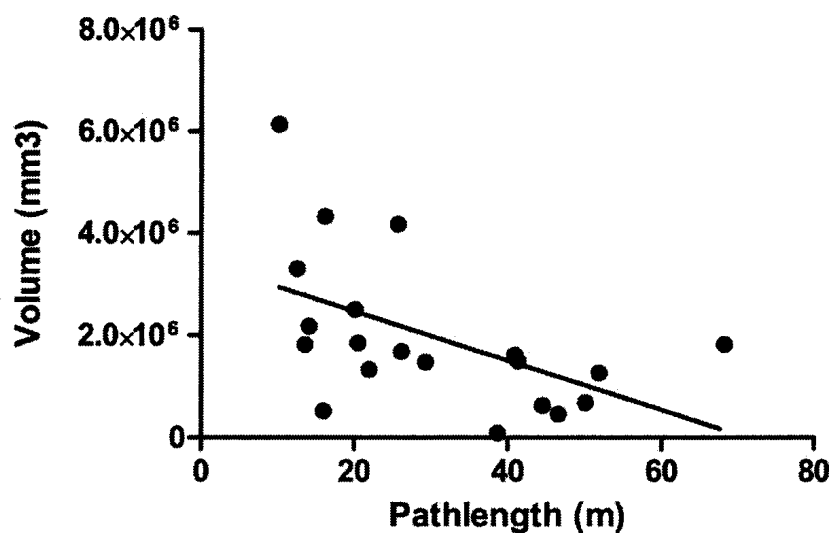
Figure 4.26. ICSAD pathlength vs. volume
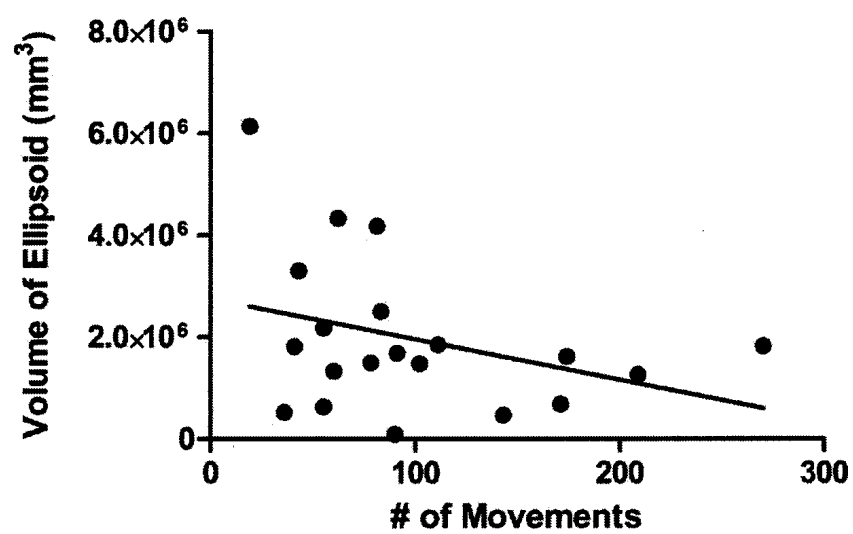
Figure 4.27. ICSAD movements vs. volume

Chapter 5: Conclusions and Future Work

5.1 Summary

Surgical education is in a period of flux and it has only recently been established that surgical simulation is a valid tool for training of laparoscopic psychomotor skills and should be incorporated into surgical training programs [6, 10, 86, 87]. Existing simulations vary in the skills that are evaluated and the fidelity of the systems. Modern simulators have a tendency to be more expensive and more elaborate technologically than the low-fidelity standards such as MISTELS; however, new metrics to evaluate surgical skills and provide real-time feedback to trainees have not yet been developed. Indeed, the finer aspects of proficiency that distinguish surgeons of different levels of expertise as well as experts of varying proficiency have yet to be elucidated. In the evaluations detailed in this research, SIMIS, a novel force and position sensing laparoscopic instrument, has demonstrated construct validity as a teaching tool as it can detect differences in performance of an MIS task between experts and novices. Furthermore, it has also demonstrated concurrent validity with the current laparoscopic training "gold-standard" FLS.

Our hypotheses regarding the ability of SIMIS to distinguish experts and novices on the basis of force measurements were correct. Most of the differences in force exertion were explained by the grasp force as well as the total force (force magnitude in x, y, and z directions summed). Interestingly, the knot tying component accounted for much of the observed difference. This is not surprising

as an increase in amplitude with the cinching-down of knots is likely done to ensure the knot does not come unravelled. Interestingly, while a significant increase in grasp force was demonstrated by Experts, they also demonstrated significantly lower total force while tying knots. This finding, while somewhat paradoxical, may suggest that the more important component of knot tying is the grasp force on the suture and that the 3D forces are not as important. The tendency for Experts to exert lower total force may suggest proficiency and economy of force application gained through experience. Regarding the torque readings for all of the tasks, there was essentially no difference between groups of expertise over the whole suturing task and the individual subtasks. This is likely due to the FLS suturing model which is made from pliable latex Penrose surgical drains. This material offers almost no resistance. Perhaps different findings would have been seen if a different model had been used.

With respect to the position data for the overall task, the null hypothesis was rejected; however, it was rejected for a different reason than was expected. The *a priori* hypothesis was that experts would use a smaller work volume area. This prediction was based on research with other instrument tracking systems that demonstrate that expert surgeons make fewer movements and use shorter over-all path lengths than novices when performing surgery [38, 40, 41, 88, 89]. Interestingly, expert surgeons used a larger overall work volume, but made fewer hand movements as measured using ICSAD and also used an overall smaller path length. Moreover, though the work volume for the overall suturing task was larger than that for novices, the volumes for the subtasks were smaller for experts. This finding suggests that experts make better use of the operative field

and efficiently perform tasks in different areas using a minimal amount of space, whereas novices may attempt to "work in a small hole" for the entire task. Additionally, experts may accentuate their moves laparoscopically for safety purposes. This notion has been supported in research done by Chmarra et al. [90] who found that experts make accentuated goal-oriented movements in MIS. They also proposed that such goal-oriented approaches can be split into two phases: retracting and seeking. Novices are less effective than experts in the seeking phase which is the portion of the operation that accounts for touching an object of interest or performing a surgical task. Therefore, the seeking phase is characteristic of performance differences. Furthermore, the retracting phase improves safety by avoiding intermediate tissue contact. Perhaps the small expert subtask volumes observed in these experiments are an analogue to the seeking components observed by Chmarra and colleagues. Therefore, the shortest path length, as presently used during the assessment of basic MIS skills, may be not a proper concept for analyzing optimal movements. To be more specific, path length alone may not be the optimal metric as the "work-sphere" or work area may a more important determinant of expertise. The differences observed in these experiments using SIMIS in a FLS training scenario provide more insight into the relationship between experience and instrument positioning. The aforementioned findings regarding force and position differences between experts and novices establish that both of these constructs within SIMIS are valid.

It is possible that bias could have been introduced through the training and exposure of the subjects to minimally invasive surgery. As the degree of

variation in FLS scores to categorize the expertise of the participants was minimal, this was not a factor for any group except the group of first year residents: Group A. This group had very wide variance in performance and accounted for all the sorting of subjects. Coincidentally, this group had recently been trained in MIS in a formal curriculum. Their performance suggests this experience was not retained as many performed inferiorly to untrained engineering students. This finding suggests that bias was likely not an issue in the study cohort.

After first ensuring face and content validity, construct validation is the first important step in developing new metrics for MIS simulations and educational tools [18, 26, 70, 91, 92]. SIMIS force and position information may allow the prediction of a subject's expertise based on the profile of their forces and work space. This research has generated regression curves for the force and position data that may be used in future experiments to predict a research subject's level of training in MIS.

Concurrent validity with FLS is an important finding as FLS is the current standard. Training of complex skills should include multiple performance objectives [11]. FLS scoring is dependent exclusively on time and error metrics which are the current paradigm in surgical skills assessment [93-95]; however, if force and work-space data from SIMIS can be translated into a system for real-time feedback the opportunity to improve upon the FLS and MISTELS metrics may exist. For SIMIS to be an effective teaching tool, trainees given instruction and feedback using the SIMIS metrics will have to show improvement in objective performance. It is possible that force measures as an instrument for feedback

might be confusing to trainees [96]. Thus, further study of the impact of force feedback on performance is necessary.

5.2 Future Work

Before further experiments are initiated, the stability of the SIMIS platform needs to be improved. This should involve rapid, reliable calibration and a more robust design. Work has already begun on the successor prototype that should address the stated concerns. Similarly, these results were derived from the raw data generated by SIMIS. Future projects could use the existing data or new data to examine the role of using measures of energy, frequency domains, and time-frequency evaluations as another means of examining the data.

Previous published research exploring force and position data as tools to distinguish experts from novices have shown construct validity as well. However, this research analyses the combined effect of these parameters in a more detailed fashion than the previous literature. There are various ways that these findings can be explored. While validity as a construct has been demonstrated, it has only been accomplished by distinguishing novices from experts. Future research should be directed at distinguishing surgeons to a greater extent based on expertise and, if possible, help distinguish mastery of surgery from mere competence.

Force patterns of exertion and the differences between subjects of different expertise needs to be studied for all of the MISTELS/FLS tasks. While laparoscopic intracorporeal suturing is the most complex MIS task in FLS, it is

possible that the other four MISTELS tasks will demonstrate different force and position profiles. The first step in further establishing the SIMIS construct is for it to be validated for all of the components of the FLS curriculum. It is possible that the force and position profiles we have demonstrated that distinguish experts from novices will not be seen or may differ for the other four tasks (peg transfer, pattern cutting, application of loop, extracorporeal suture).

Concurrent validity with the FLS curriculum as it currently exists (the MISTELS tasks) is not enough for SIMIS to be deemed beneficial as a surgical education adjunct. Some additional benefit must be demonstrated for it to achieve acceptance as teaching tool. This could be done by devising experiments to understand how SIMIS derived data change as a trainee progresses through a MIS curriculum. This research constitutes a pilot series from which we have generated linear regressions that may be used to predict a larger cohort's level of experience based on SIMIS data. As the sample size of this pilot experience was small so, these regressions may be inaccurate; therefore confirmation with a larger cohort of subjects is appropriate. This series can appropriately be used to generate hypotheses and sample size calculation for future work. For example, the linear regressions can be used to hypothesize how subjects will perform in MISTELS/FLS tasks as they progress through training. Moreover, if a large enough sample is examined and the validity of the SIMIS construct is further established, a scoring metric may be devised to give trainees on the spot, real-time feedback that is currently lacking. All relevant parameters relating SIMIS with performance can be synthesized to generate a multiple regression curve as well as receiver-operator-characteristic (ROC) curves for SIMIS scores to

distinguish experts from novices. Indeed, this was how the MISTELS tasks and scoring system were established [22, 23]. Ideally, this information should be used to not only grade the performance of trainees, rather, it should also afford he opportunity for immediate feedback. More experimentation and a better understanding of the distinguishing features of experts and novices is required.

The difference in torques applied by experts and novices was not informative in this series. As previously mentioned, this is likely due to the limitations of the MISTELS Suturing Task materials: latex Penrose drains. The SIMIS instruments are portable and can be introduced through any standard laparoscopic trocar. Therefore, experiments that examine differences in the pattern of force application with different tissues or models can be explored. In addition to using different materials, different tasks such as tissue handling, dissection, and retraction should be performed. Such experiments may provide insight into SIMIS' ability to predict performance at more complex task and could involve more evaluation in inanimate box-trainers, or alternatively, experiments during simulated in vivo operations could be performed as well. The latter has the opportunity to provide more opportunities to explore our findings regarding SIMIS position data. Specifically, the findings of larger overall task volumes with smaller subtask volumes for experts can be studied to see if these findings occur during actual operations.

Another interesting area for the potential application of SIMIS is haptic feedback in robotic surgery. As previously described, in MIS, the surgeon operates directly on the patient by using an endoscopic interface. In robot-assisted surgery a computer-instrumented interface (surgical robot) is positioned between the

surgeon and patient and the surgeon controls the robot from a console. Reduced haptic feedback, as experienced while performing laparoscopy, or a total lack of it, as experienced while performing robotic surgery, may be a missing feature for the endoscopic surgeon [97]. No clear consensus within the MIS performing community exists on the importance of reduced haptic feedback in MIS, related to MIS surgical outcome, and therefore in MIS training. There is a feeling that haptics will be beneficial in the advancement of computer-based virtual reality simulators [97]; however, the role in improving robotic surgical platforms is not understood. While instruments designed to understand the force characteristics of tissues handled by experts and novices for translation into robotic haptics have been developed [98, 99], no firm consensus exists on the clinical and pedagogical importance of haptic feedback in performing minimally invasive surgery. SIMIS may be beneficial in this area and should be evaluated.

Natural Orifice Translumenal Endoscopic Surgery (NOTES) is an emerging branch of surgery and endoscopy that uses conventional intralumenal endoscopes as instruments for intra abdominal surgery using the stomach, vagina, or rectum as access points to the abdominal cavity [100]. Several issues have been raised regarding the safety of this approach; nonetheless, human series of real operations have been initiated and successful operations have been reported [101]. The constraints of the MIS paradigm are heightened with NOTES since instruments must be long-enough to fit down an endoscope (minimum 110 cm) and must be very narrow in diameter (2.8-3.2 mm). Instruments conforming to these strict specifications must be able to manipulate tissue and perform surgical tasks in the NOTES environment. As these forces -

particularly in the context of NOTES - are not understood, SIMIS sensorized endoscopic instruments could help in the development of novel NOTES technologies.

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Appendix 1: Descriptions of Statistical Tests

Pearson D'Agostino normality test: This test computes the skewness and kurtosis to quantify how far from Gaussian the distribution is in terms of asymmetry and shape. It then calculates how far each of these values differs from the value expected with a Gaussian distribution, and computes a single P value from the sum of these discrepancies. It is a versatile and powerful normality test, and is recommended for most biostatistics.

Unpaired t-test: The unpaired t test compares the means of two unmatched groups, assuming that the values follow a Gaussian distribution.

Mann-Whitney test: The Mann-Whitney test is a nonparametric test that compares the distributions of two unmatched groups.

Correlations and Regressions:

Correlation quantifies the degree to which two variables are related. Correlation does not find a best-fit line (as in regression). The purpose is to compute a correlation coefficient (r) that tells you how much one variable tends to change when the other one does. Unlike regression, correlation does not consider cause and effect. Essentially they quantify how well two variables relate to each other. With regression, cause and effect is critical as the regression line is determined as the best way to predict Y from X. With correlation there need not be dependent and independent variables; any variable will do.

Linear Regression: The goal of linear regression is to adjust the values of slope and intercept to find the line that best predicts Y from X. More precisely, the goal of regression is to minimize the sum of the squares of the vertical distances of the points from the line.

Pearson correlation calculations are based on the assumption that both X and Y values are sampled from populations that follow a Gaussian distribution, at least approximately.

Spearman correlation makes no assumption about the distribution of the values, as the calculations are based on ranks, not the actual values.

Appendix 2: Subject Grouping and Designations

Group A	Group B	Group C	Group E
case 12	case 7	case 1	case 2
case 13	case 8	case 9	case 3
case 17	case 10	case 14	case 4
case 18	case 11	case 15	case 5
case 19	case 16	case 20	case 6

Novices	Experts
case 2	case 1
case 3	case 7
case 4	case 8
case 5	case 9
case 6	case 10
case 12	case 11
case 13	case 14
case 19	case 15
	case 16
	case 17
	case 18
	case 20

Appendix 3: Raw Force Plots

Case 1, Left: All Force vs. Time

Case 1, Right: All Force vs. Time
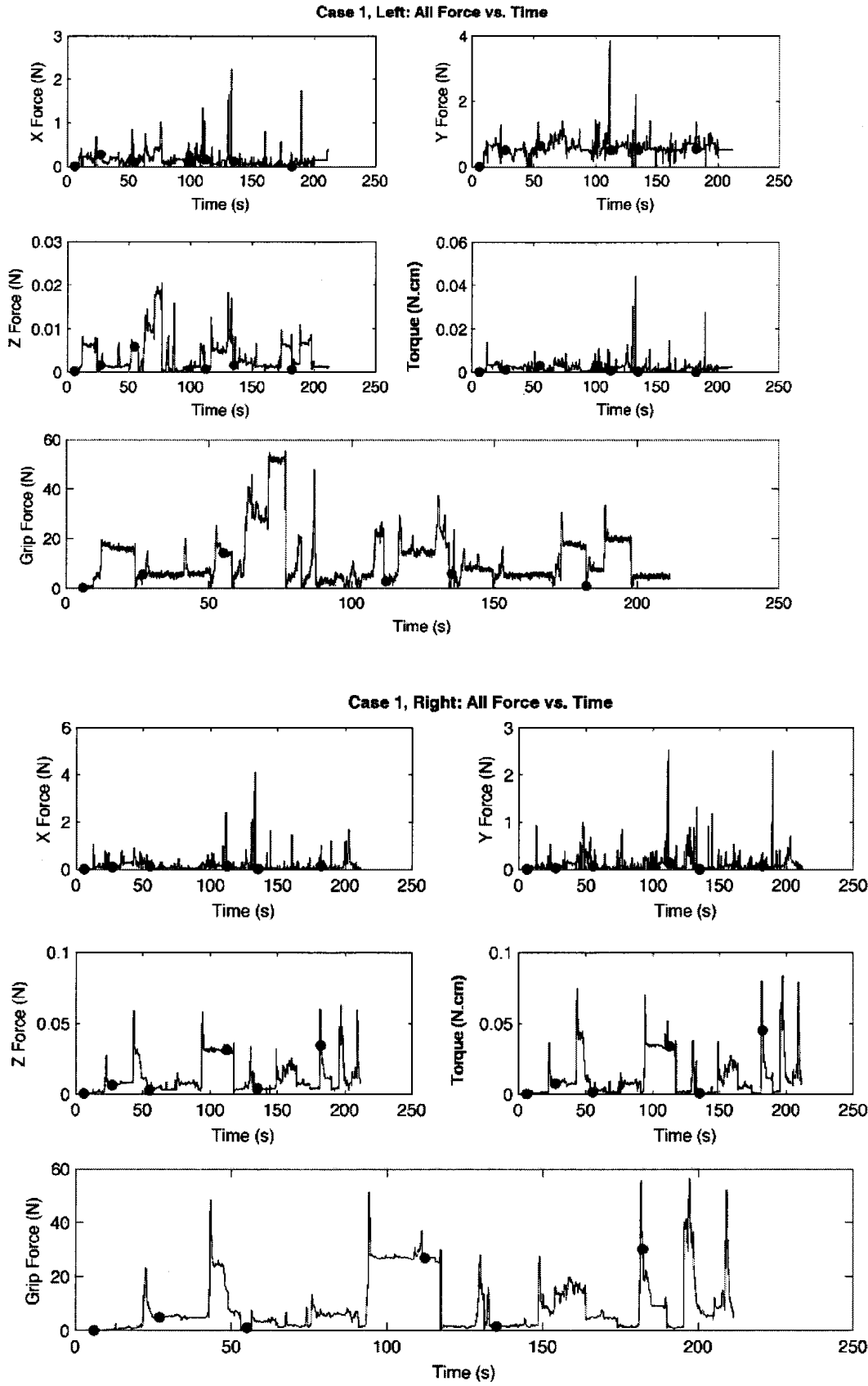
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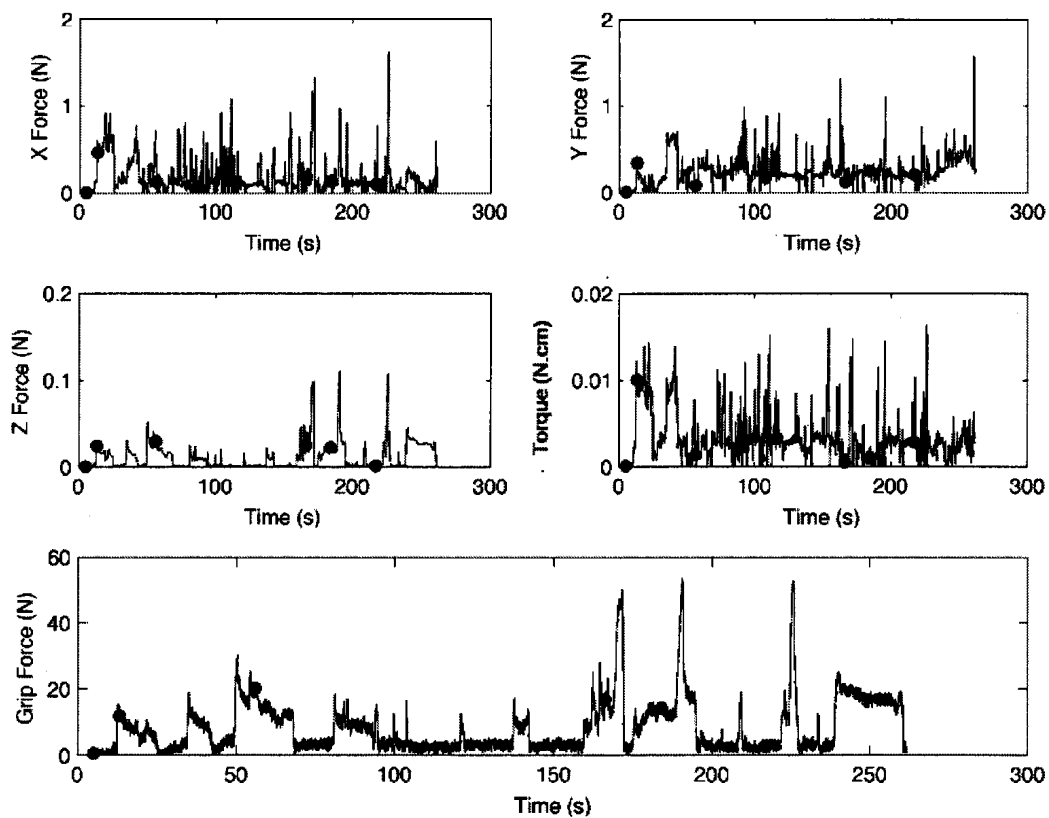
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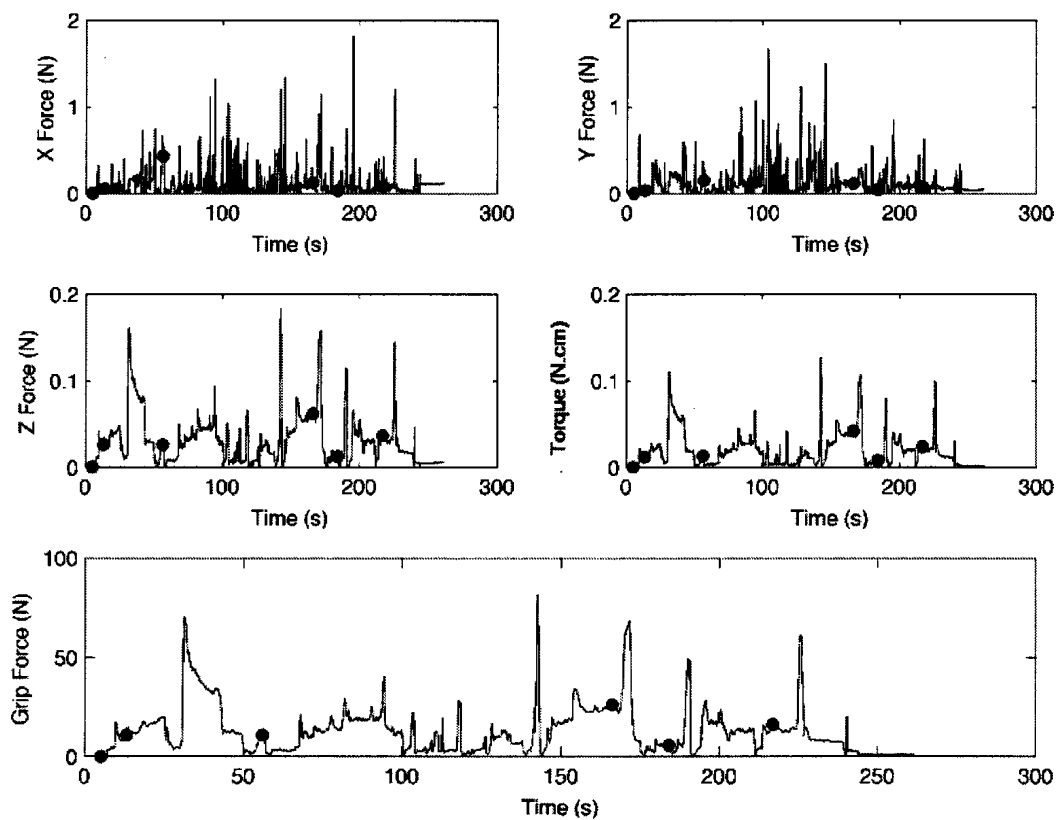
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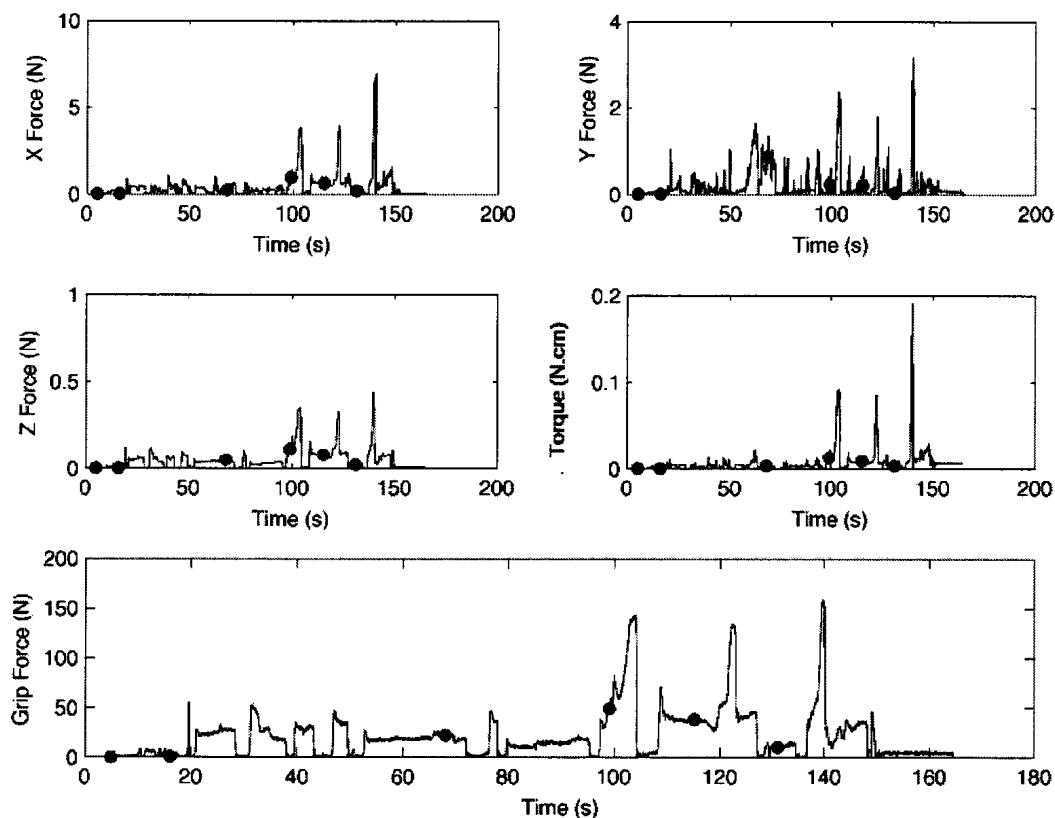
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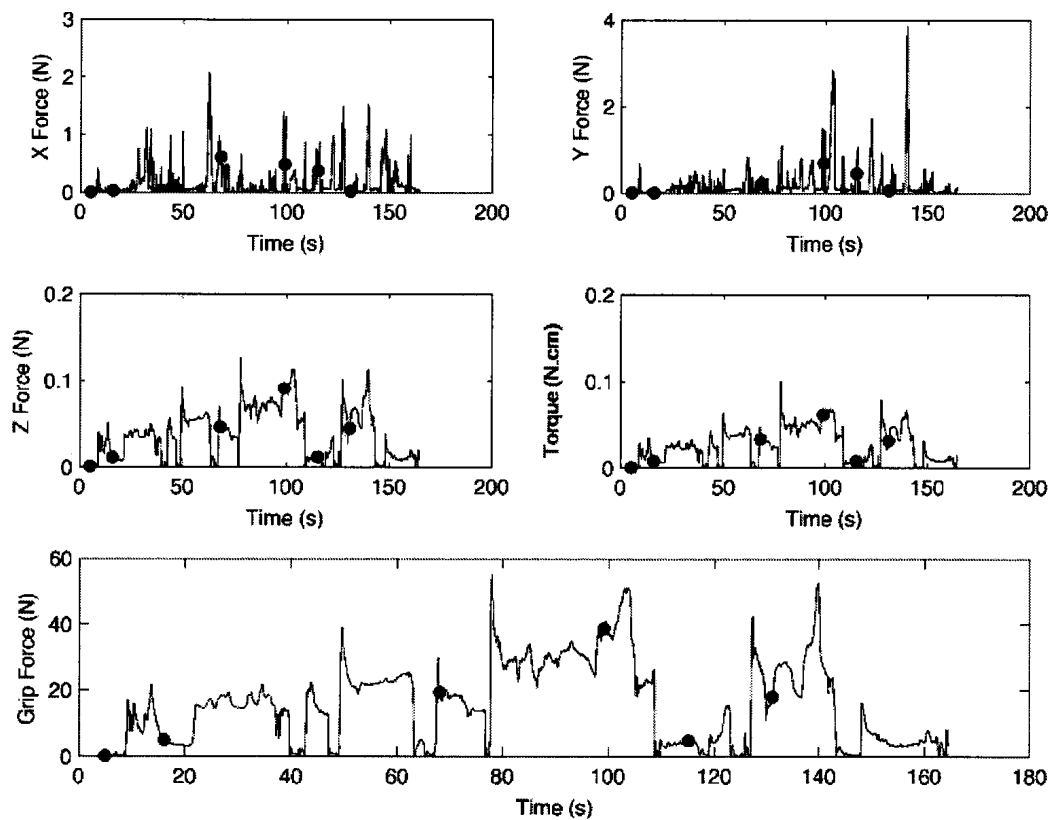
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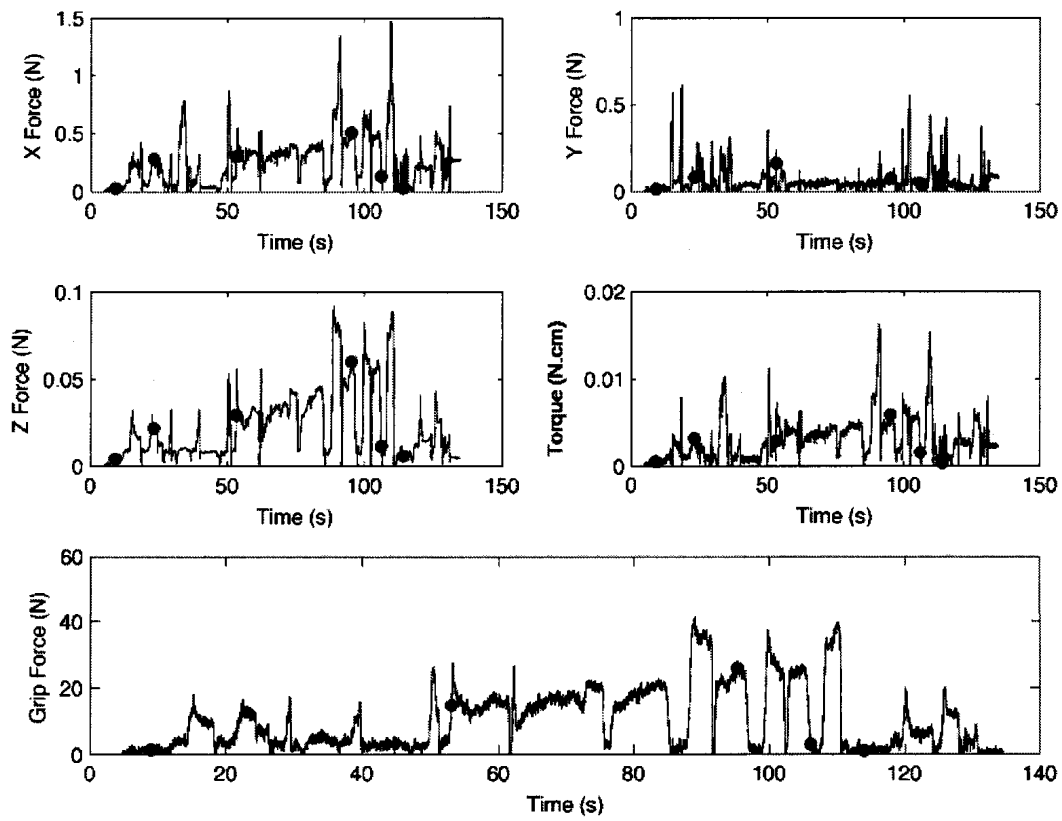
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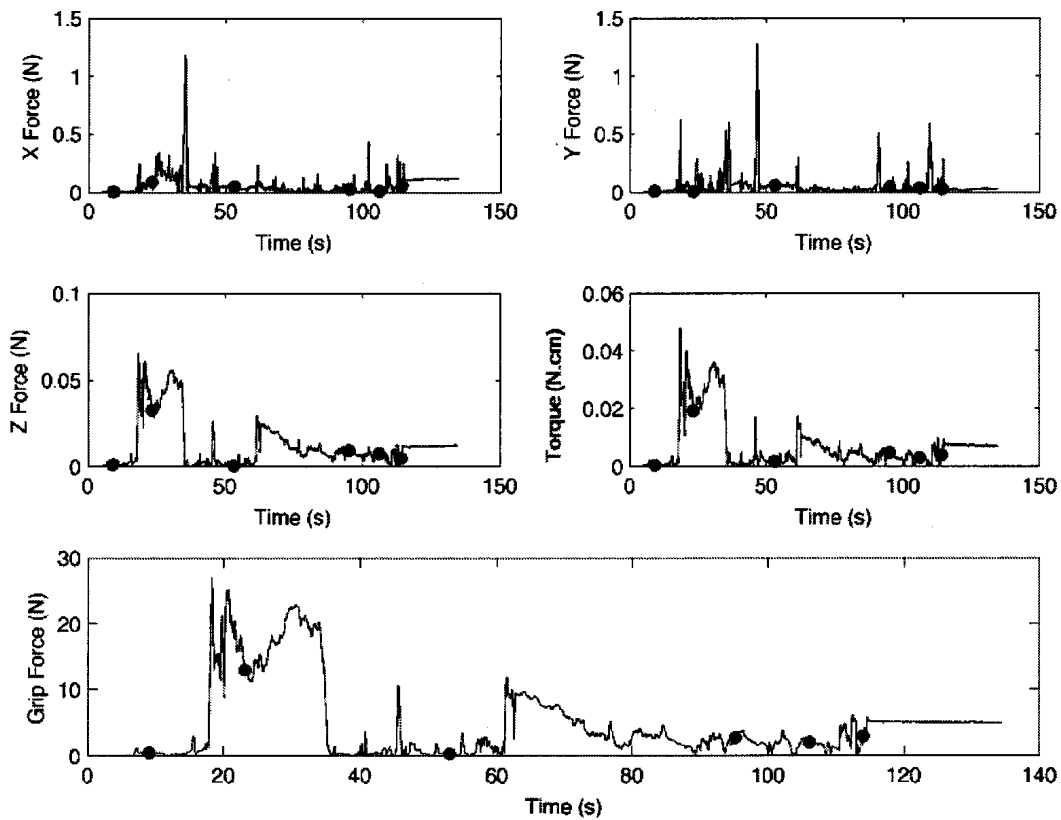
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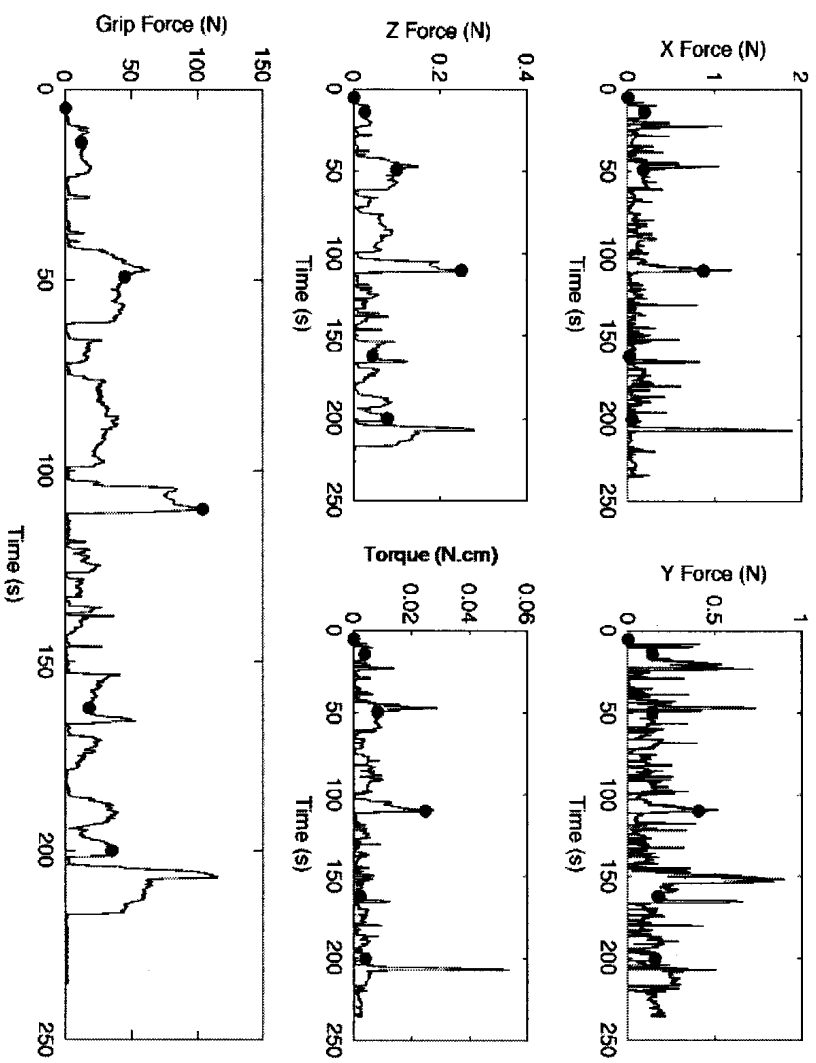
Case 10, Right: All Force vs. Time

93
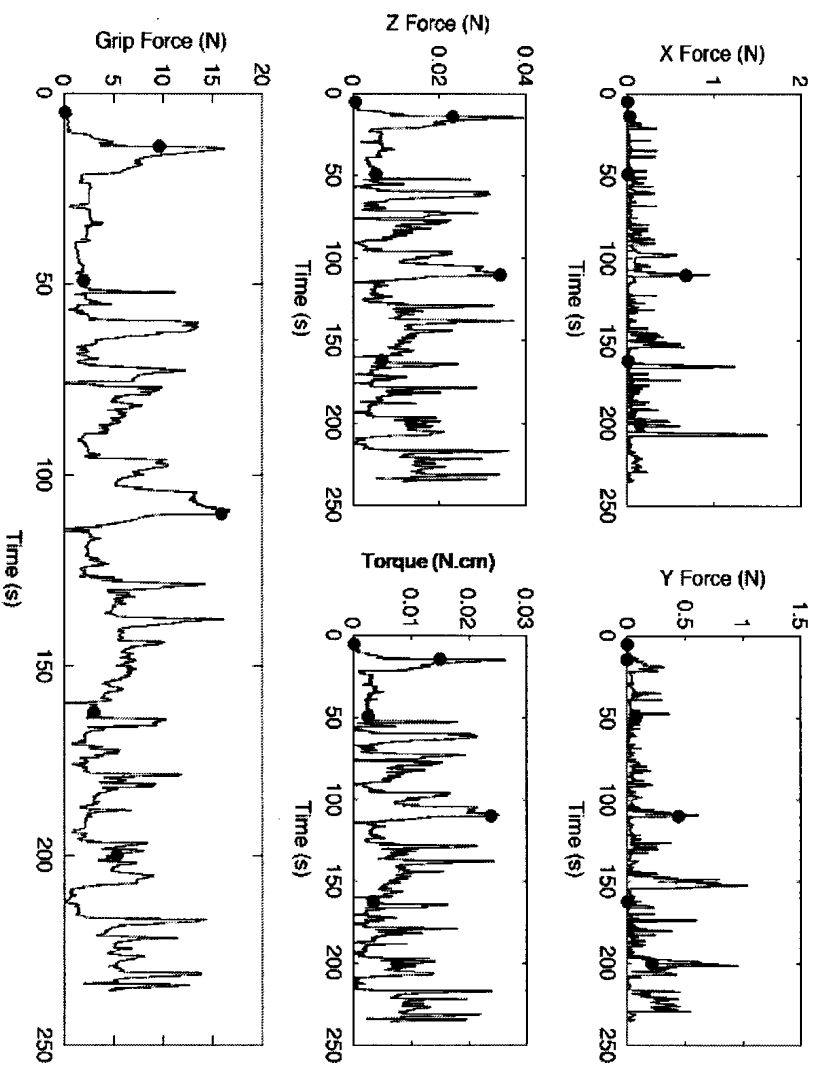
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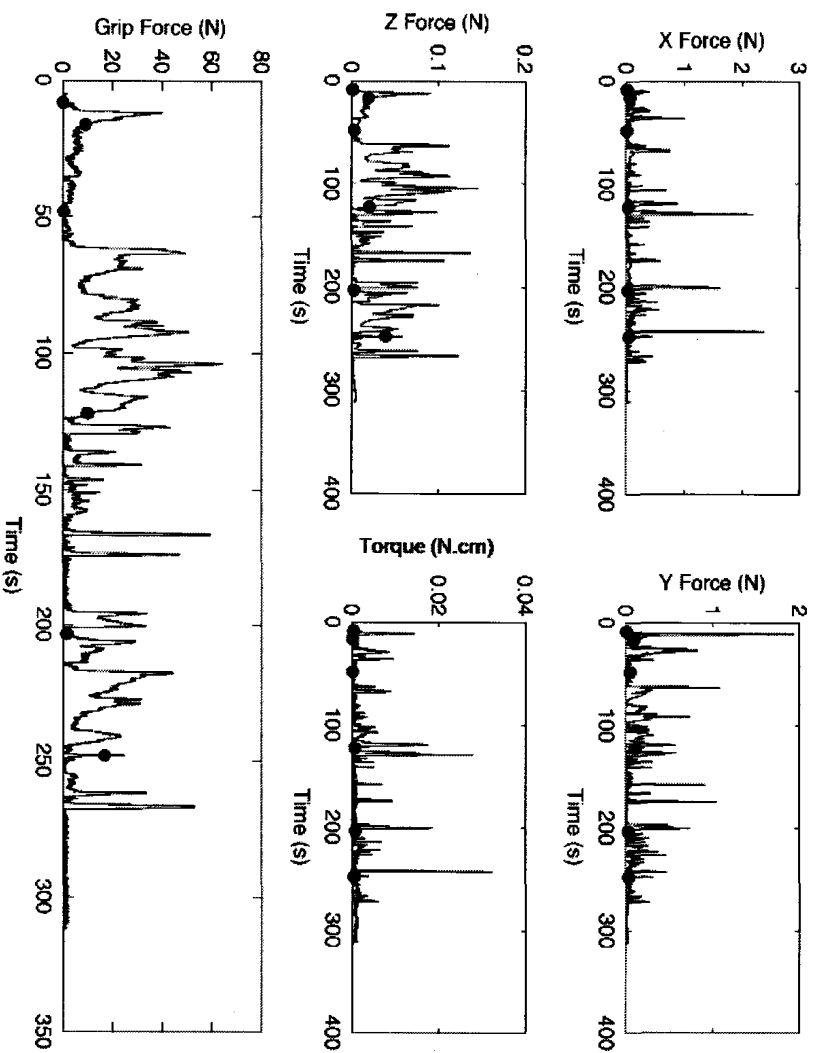
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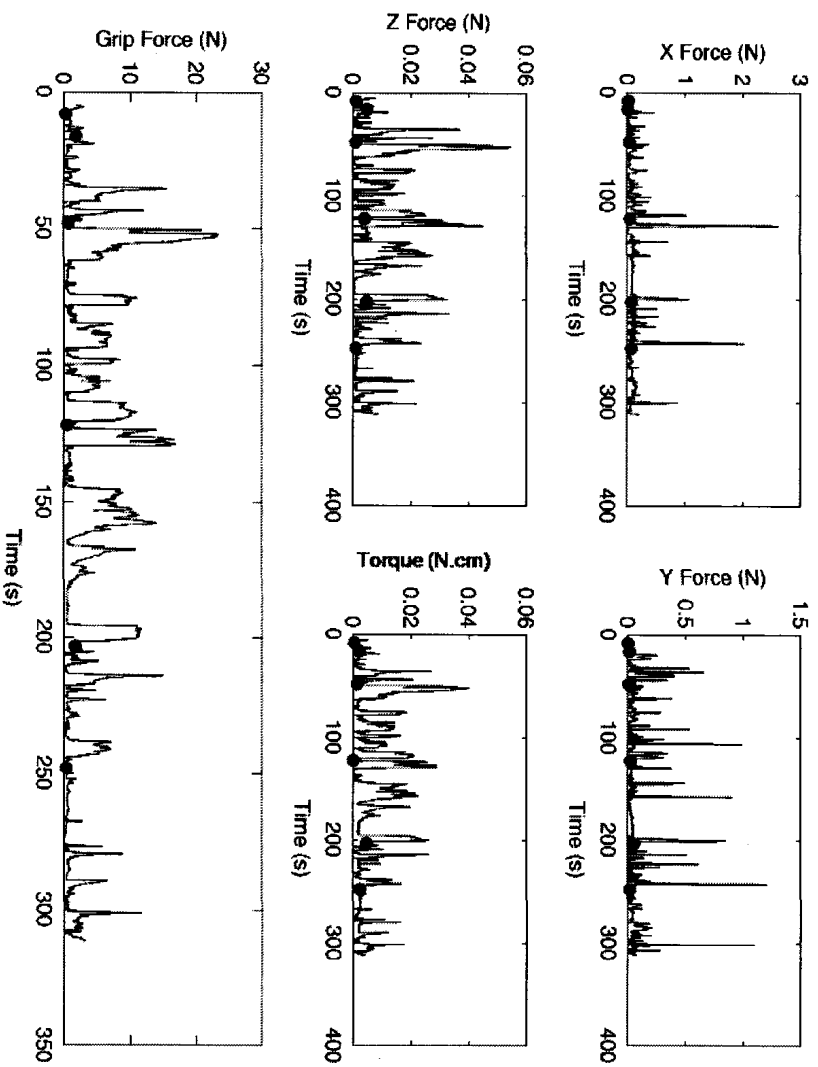
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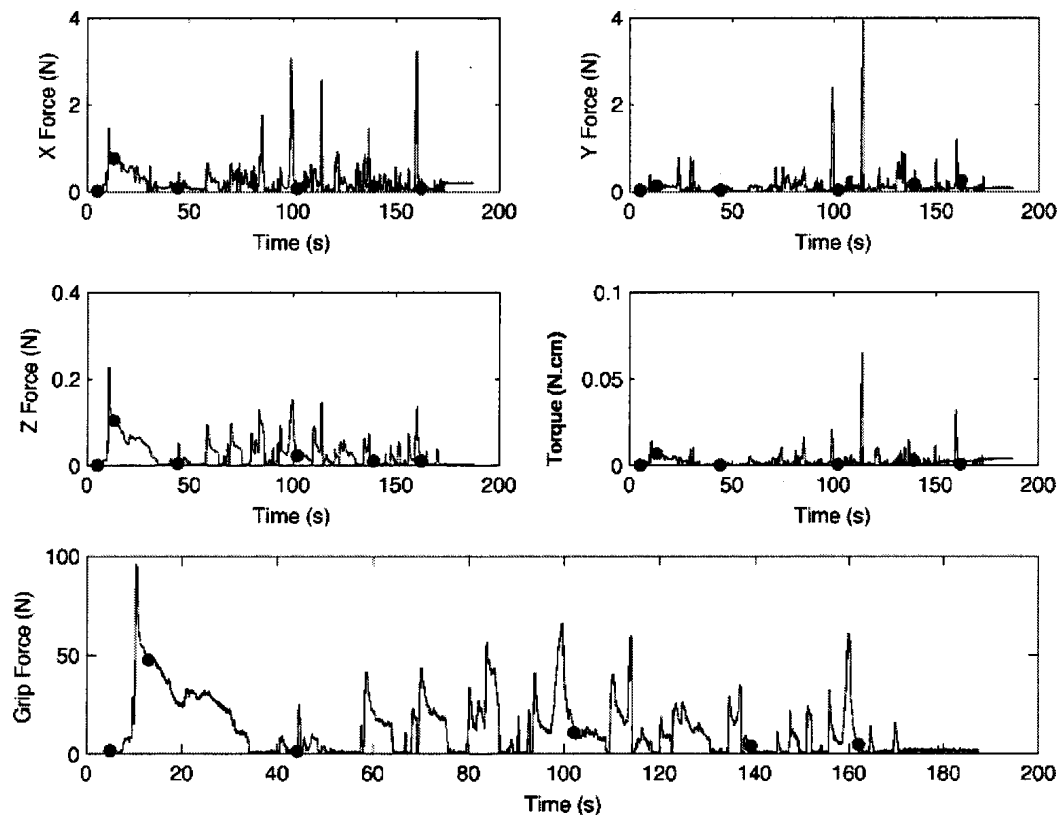
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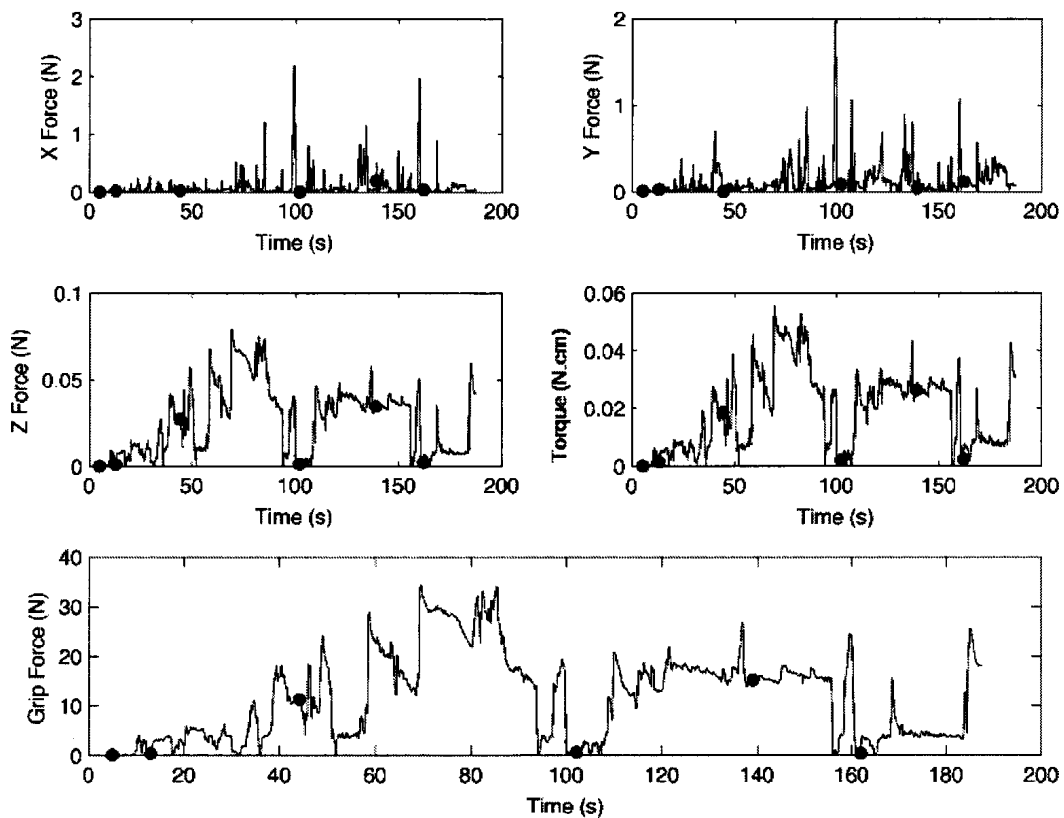
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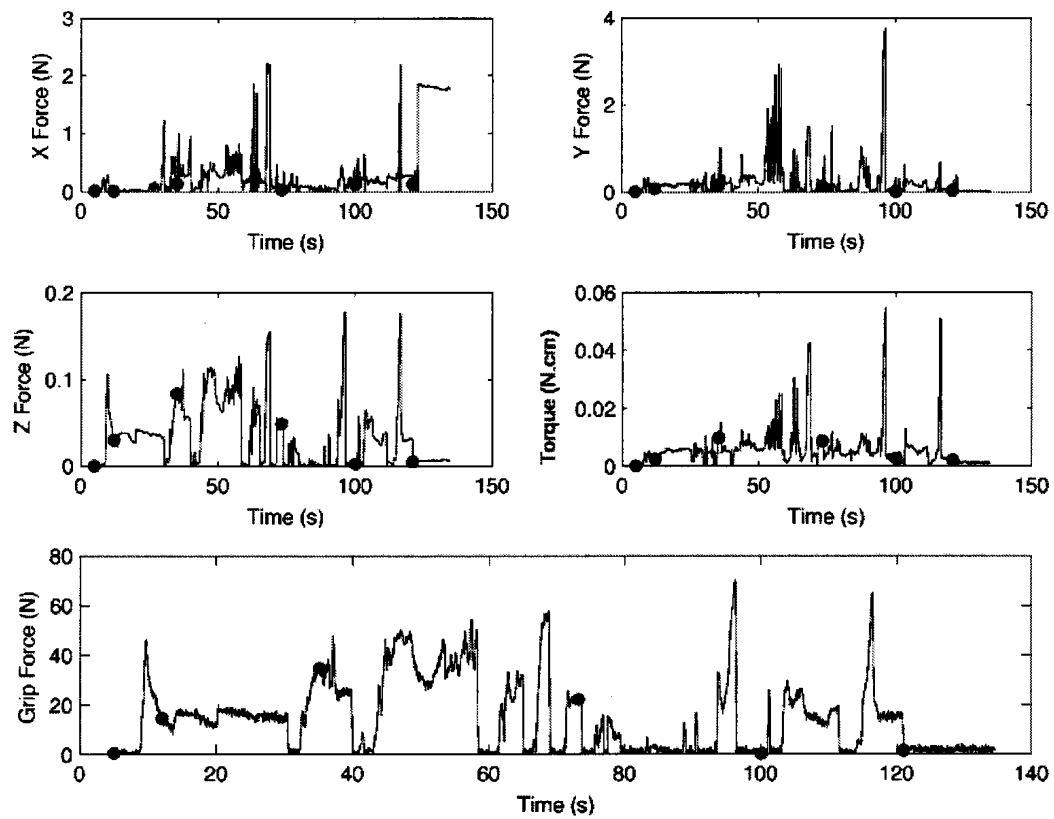
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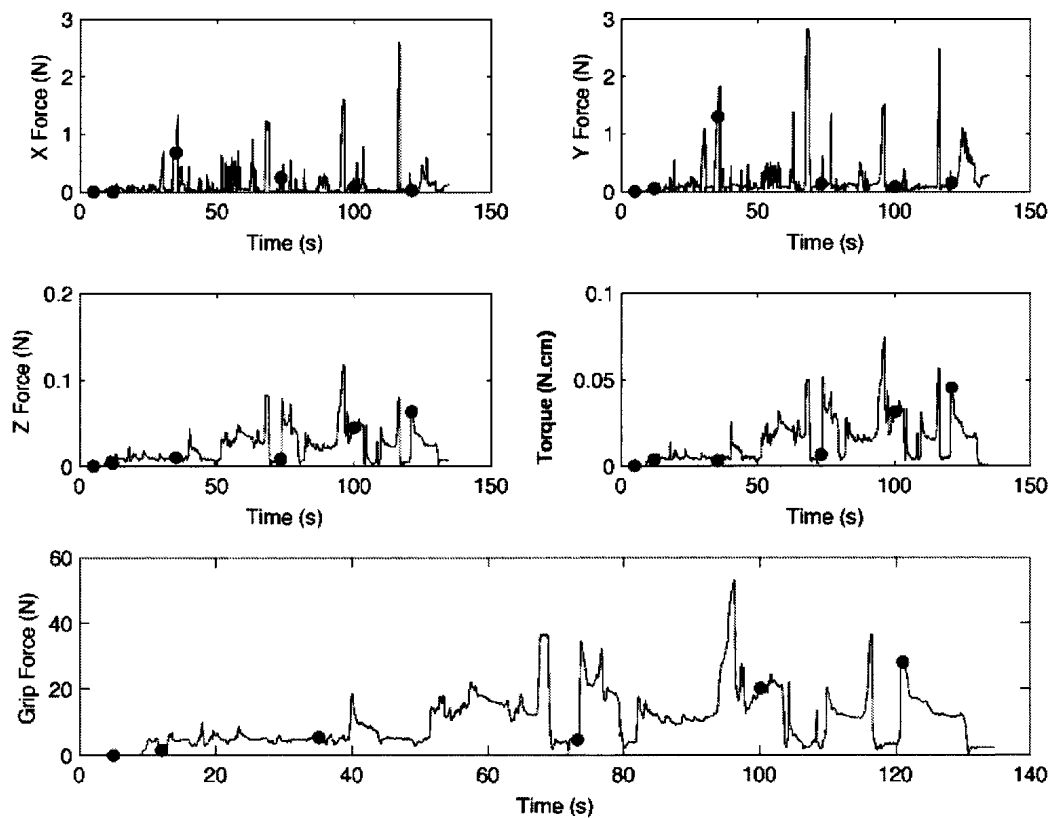
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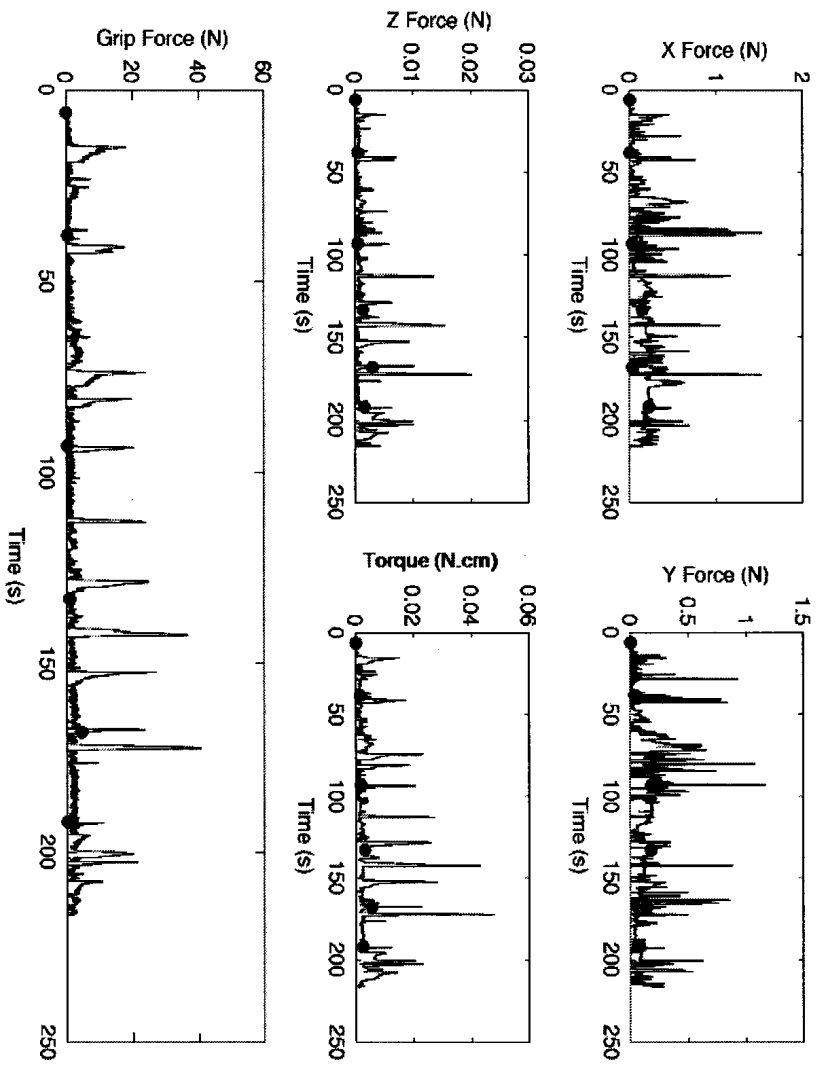
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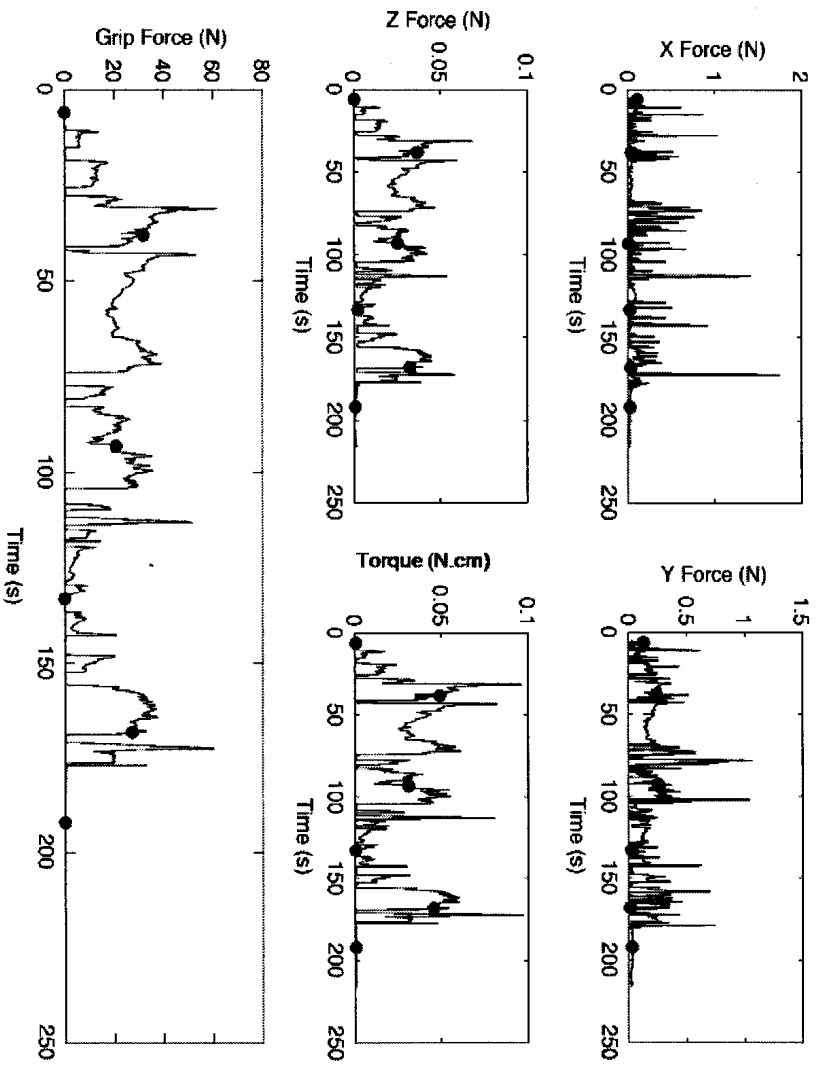
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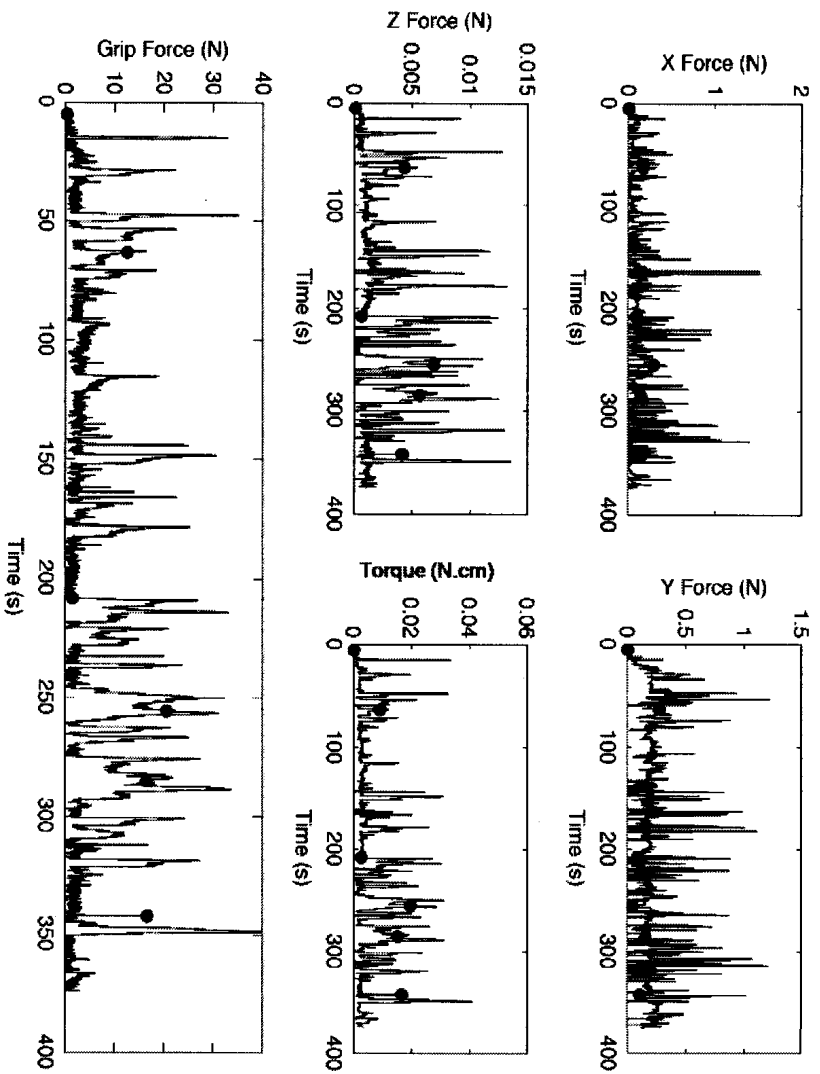
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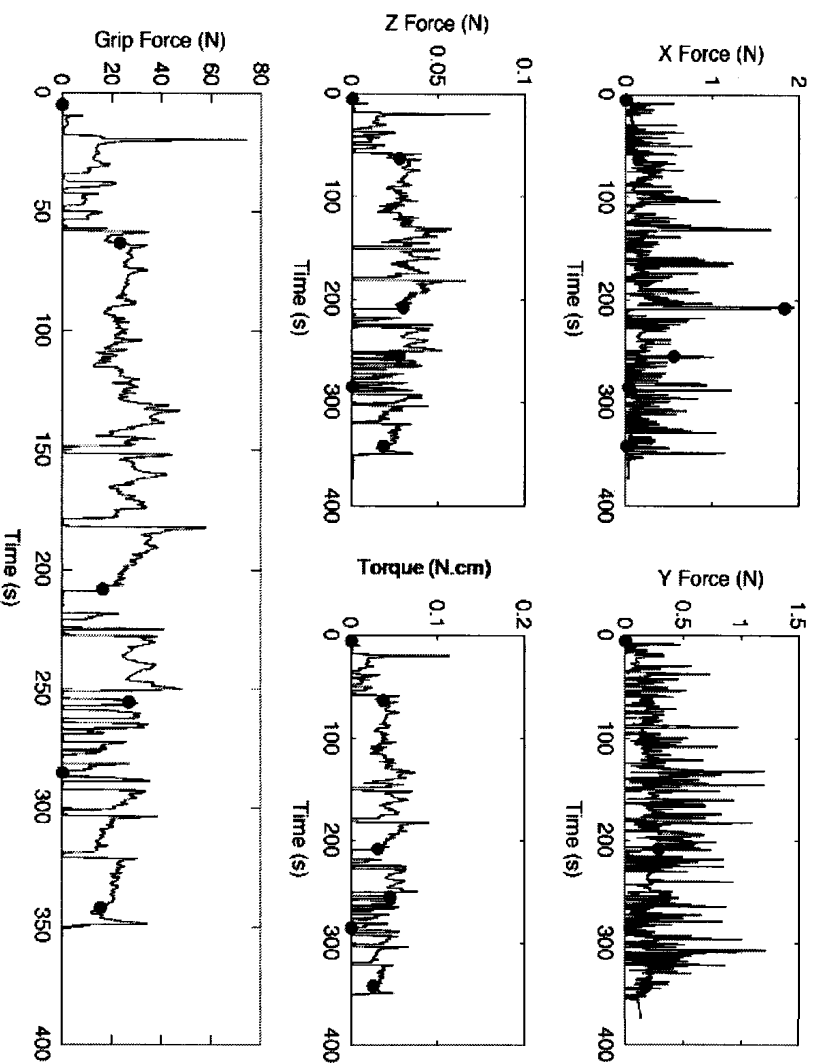
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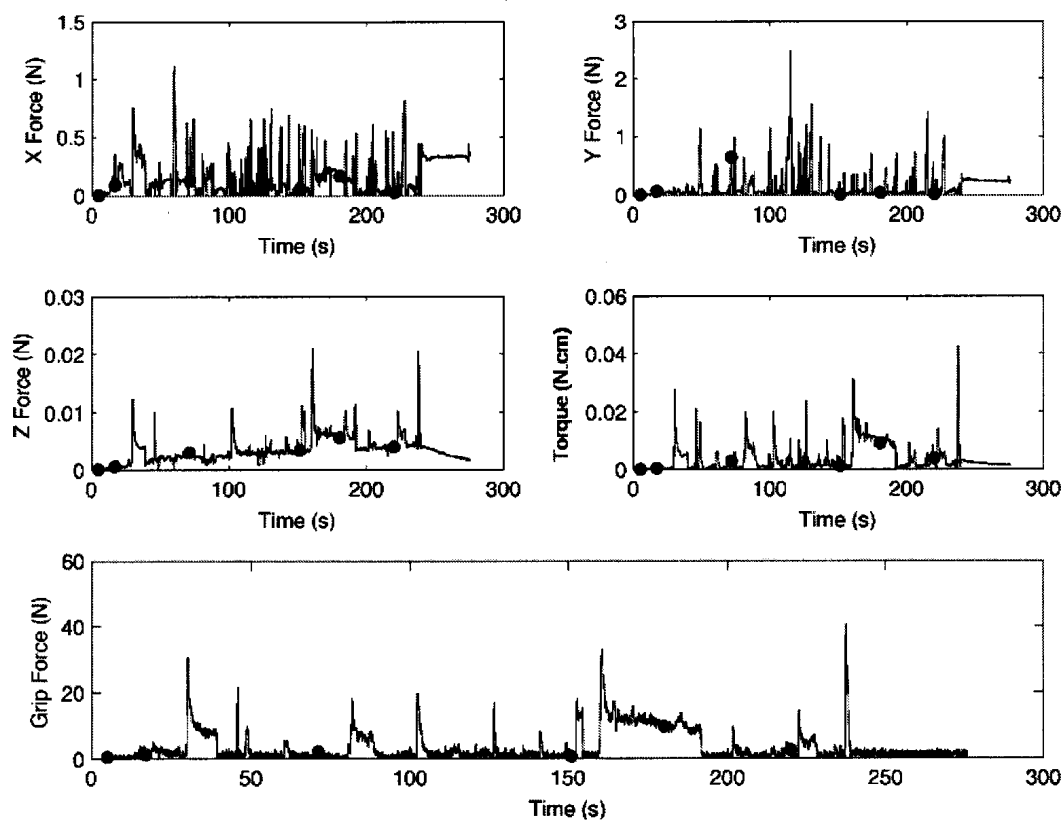
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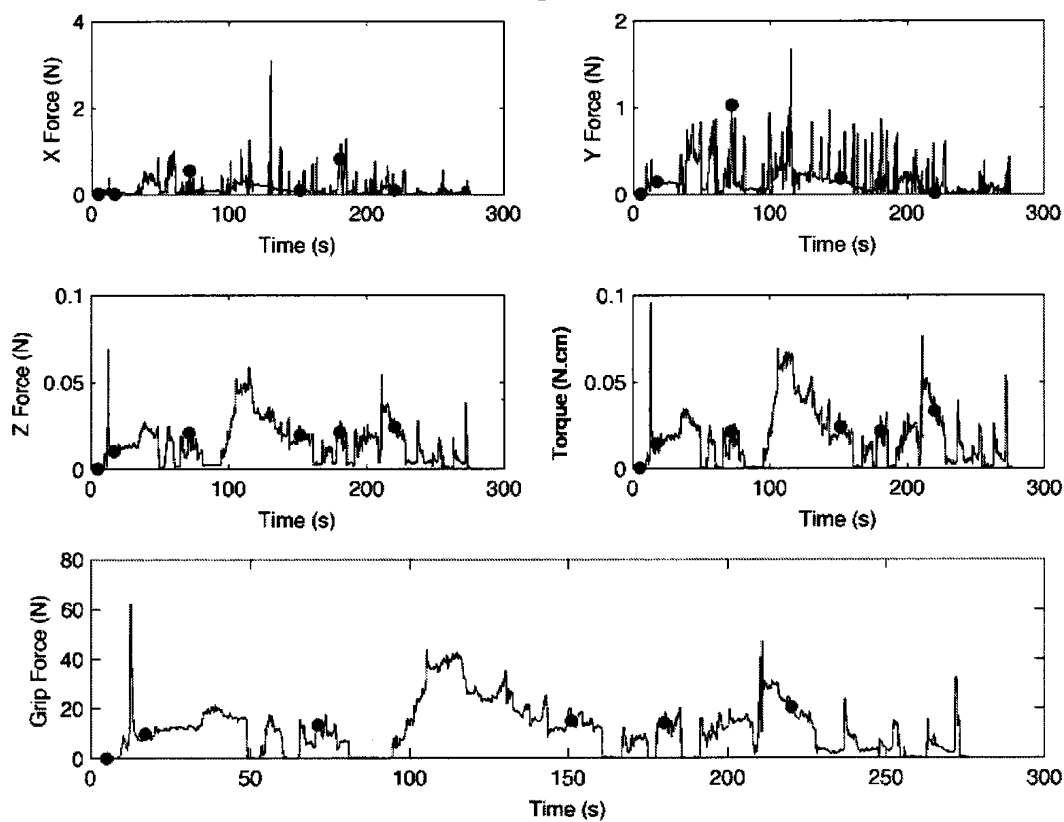
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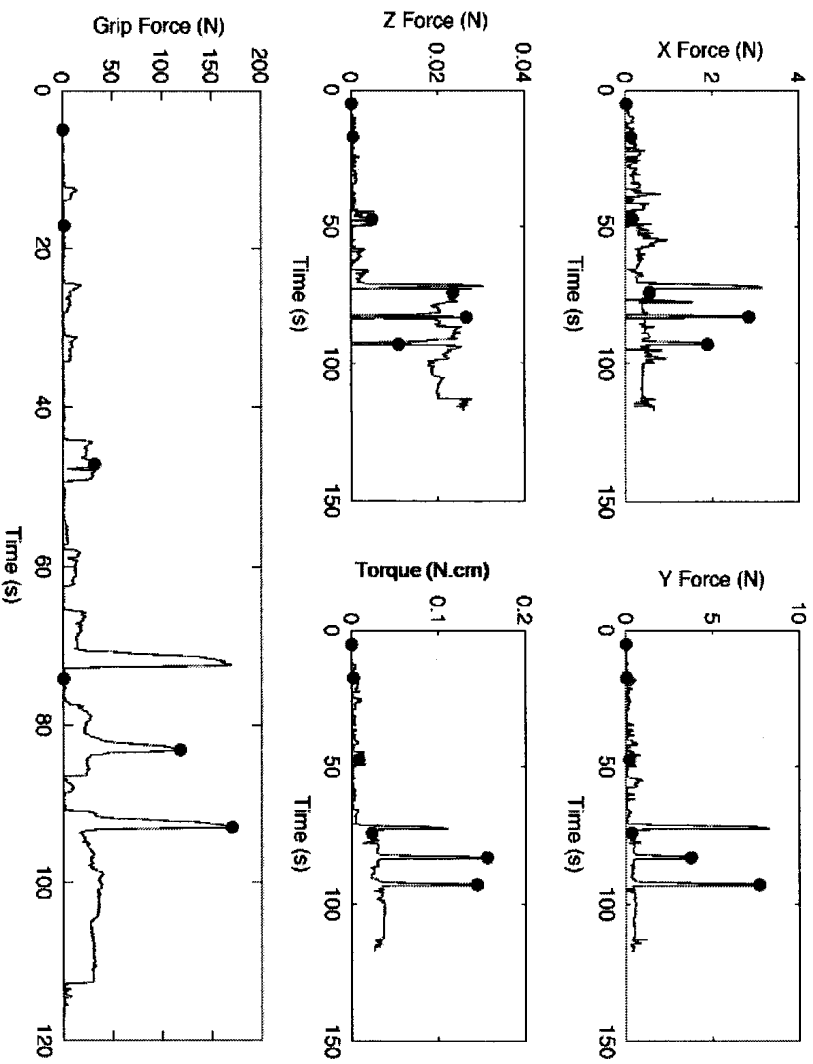
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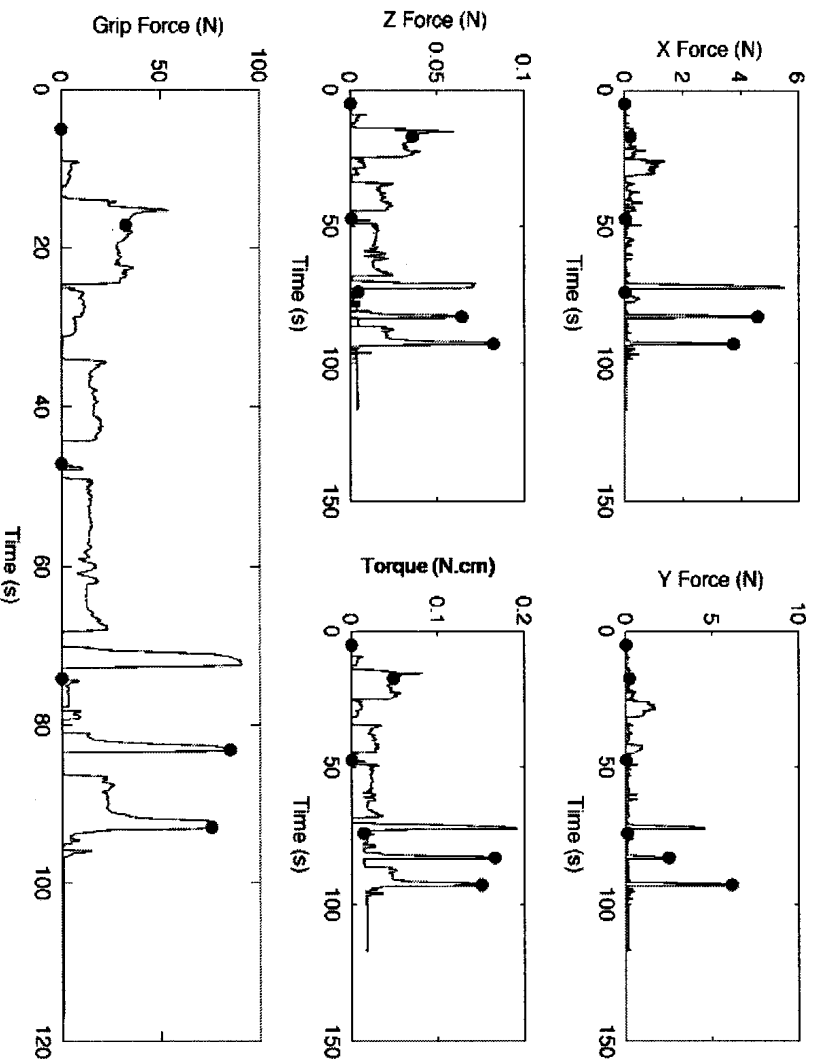
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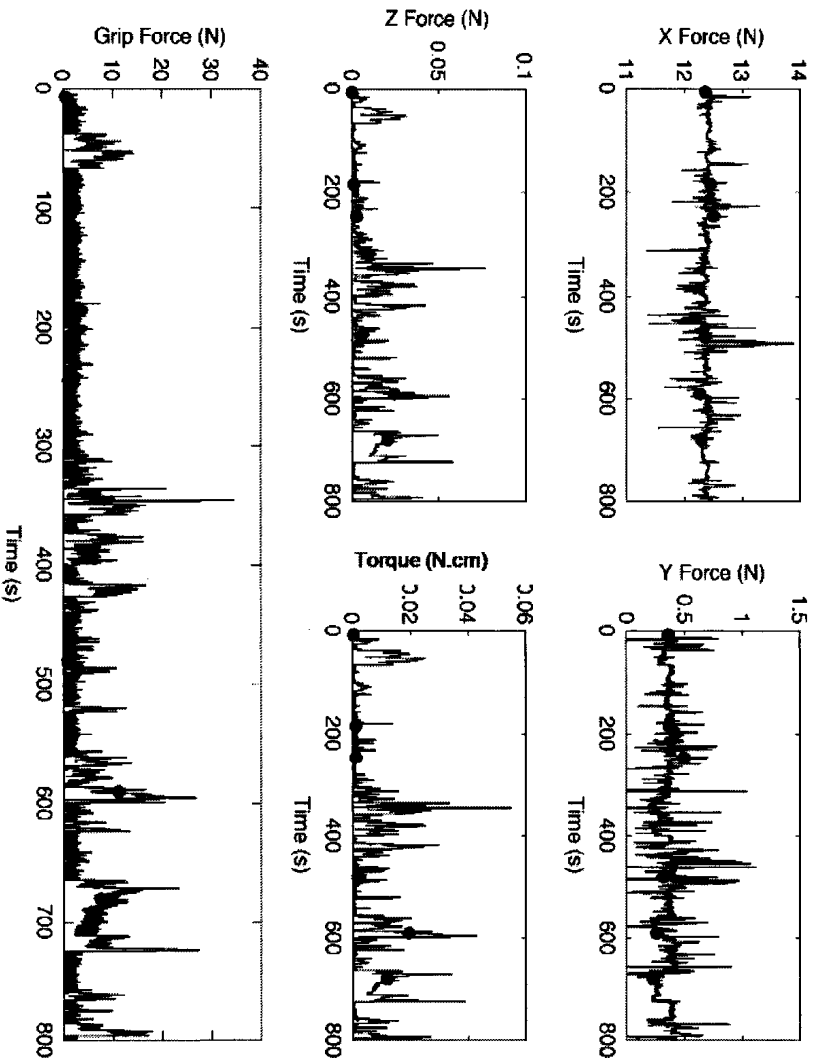
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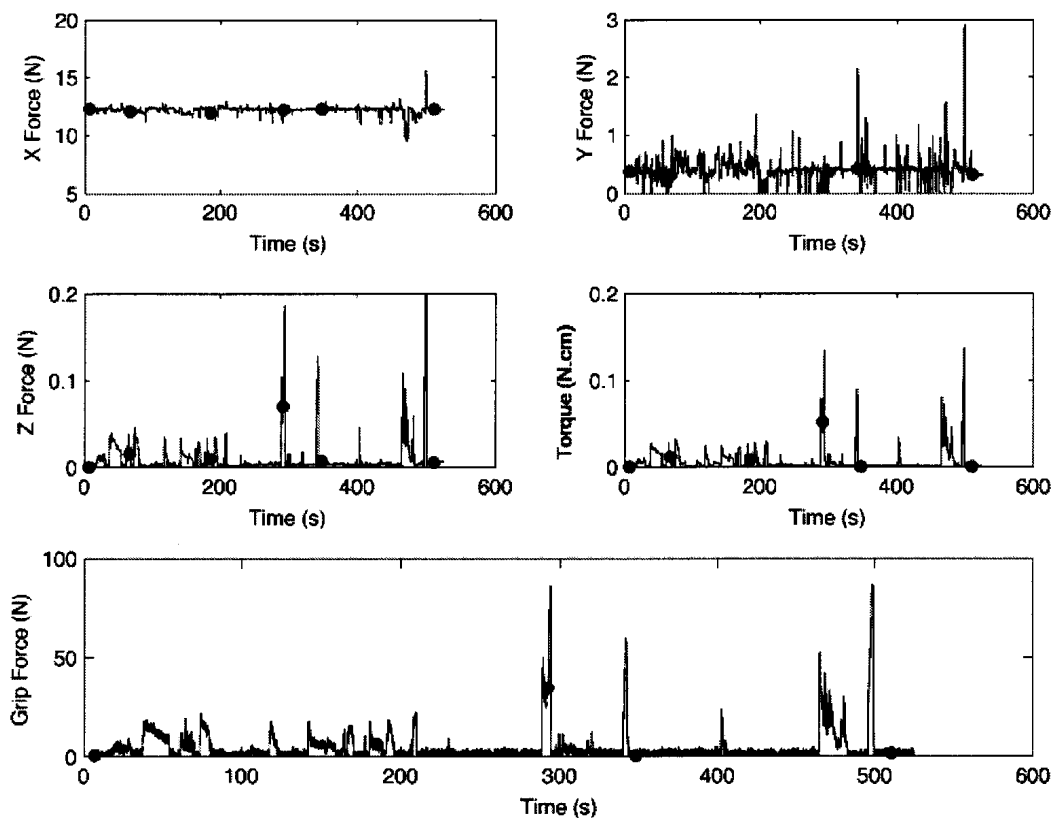
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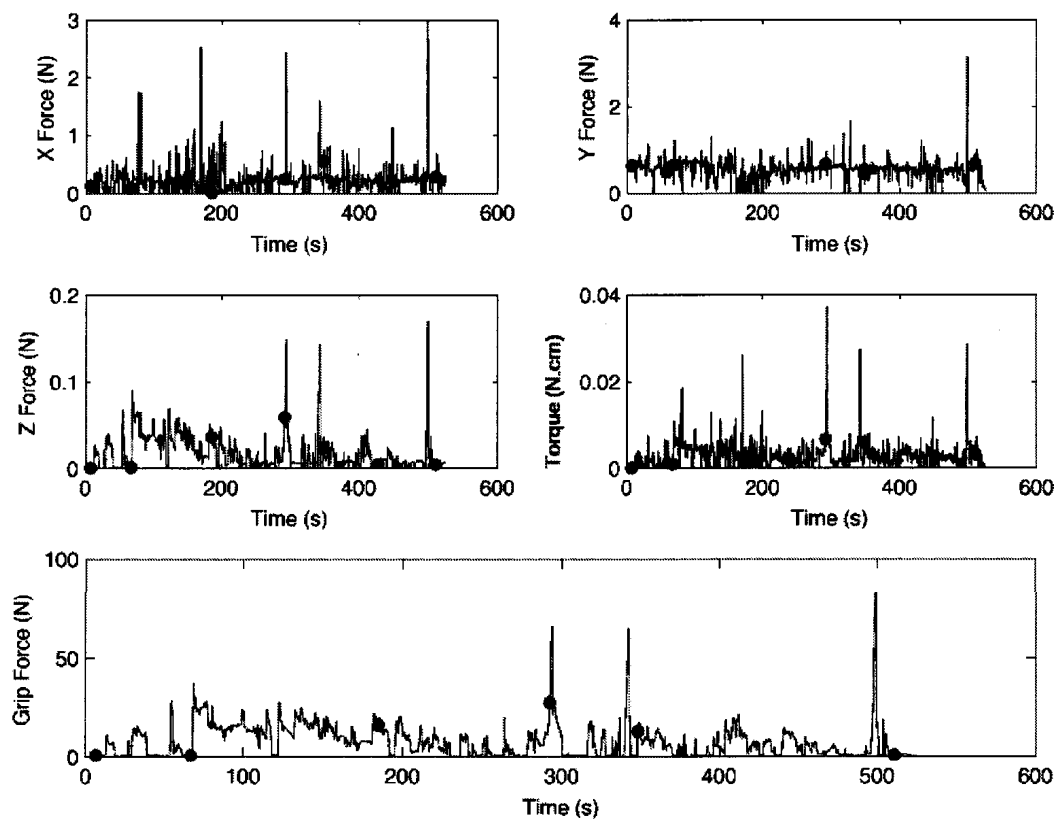
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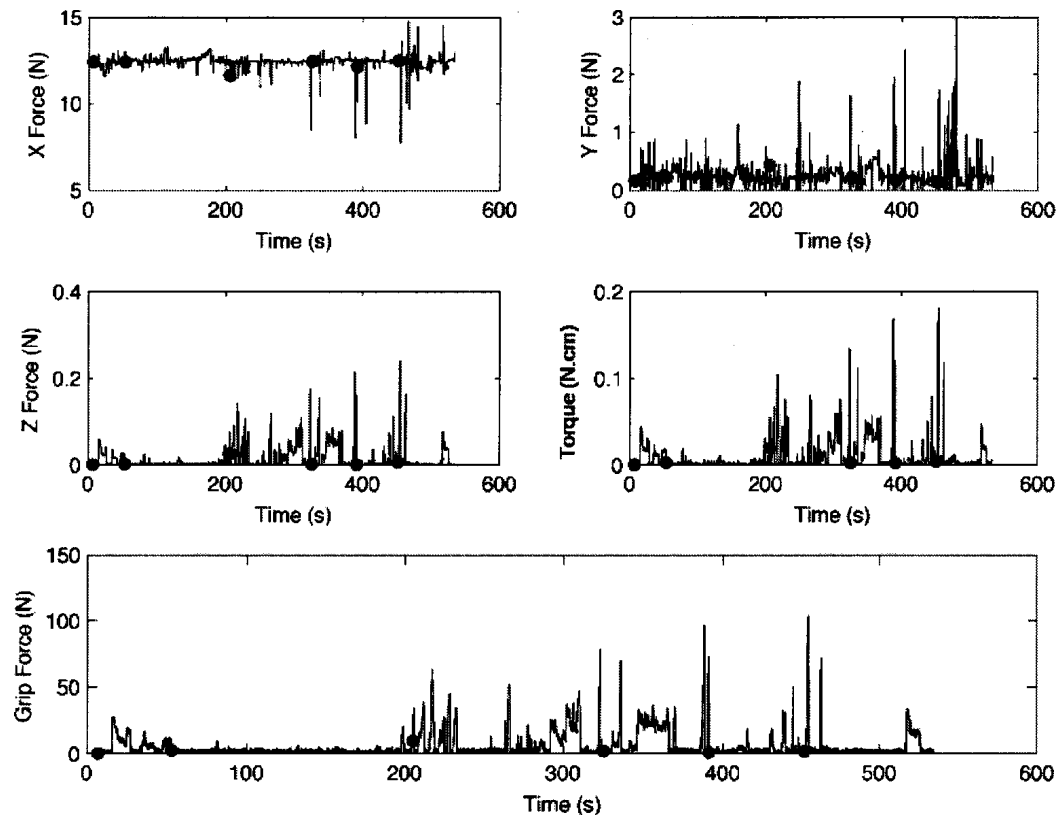
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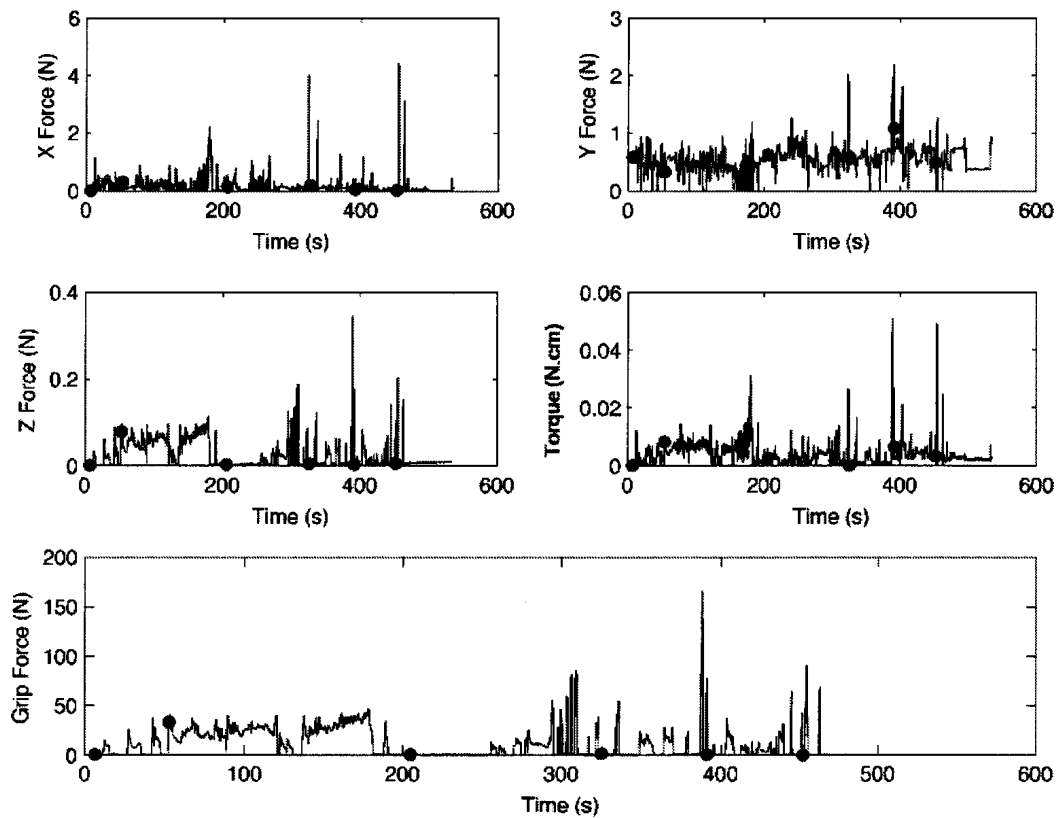
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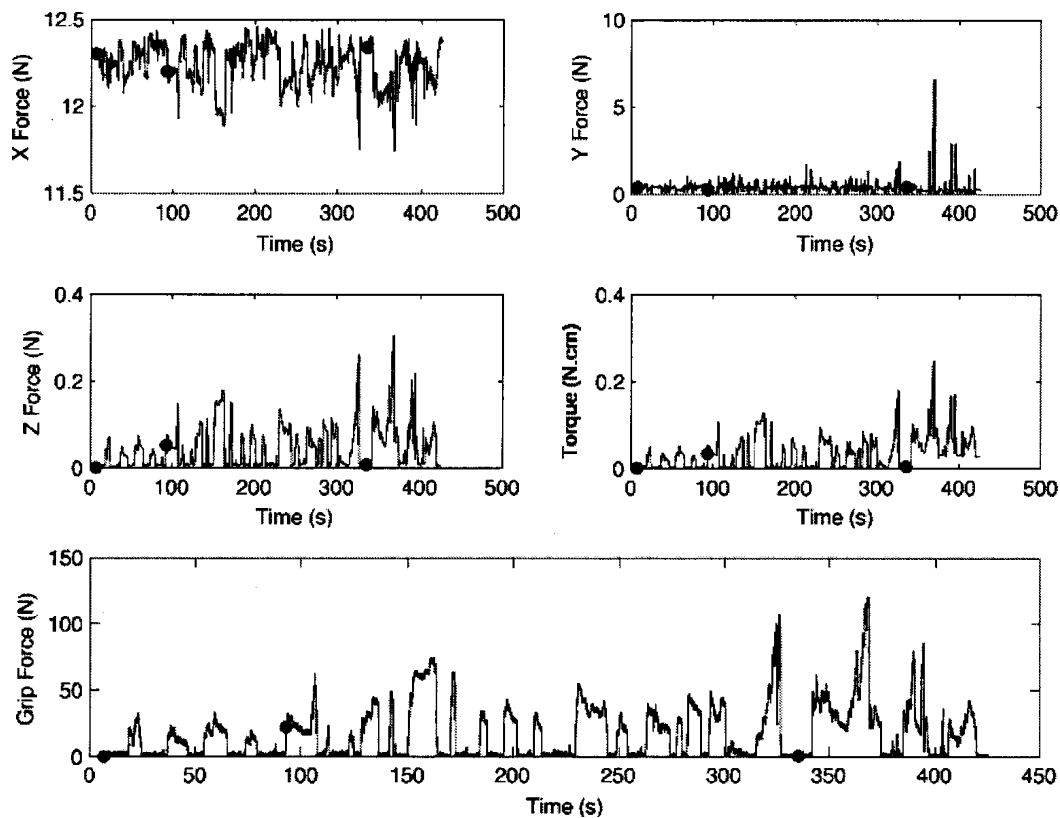
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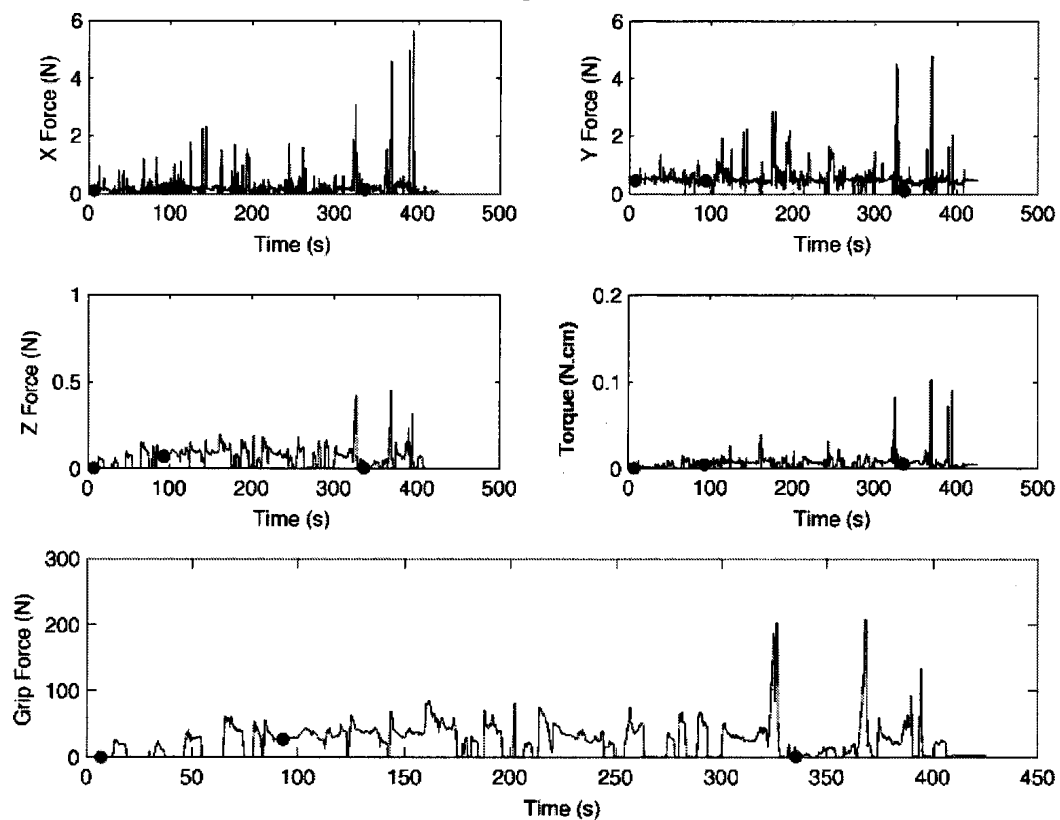
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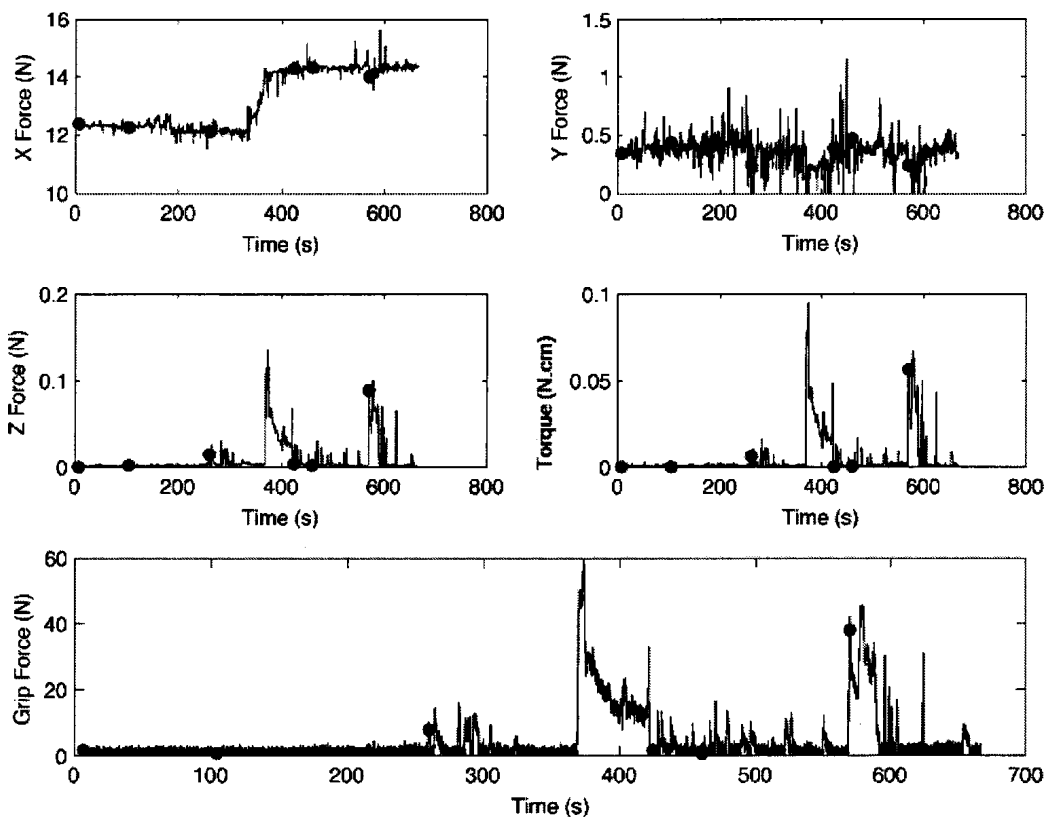
Case 6, Right: All Force vs. Time
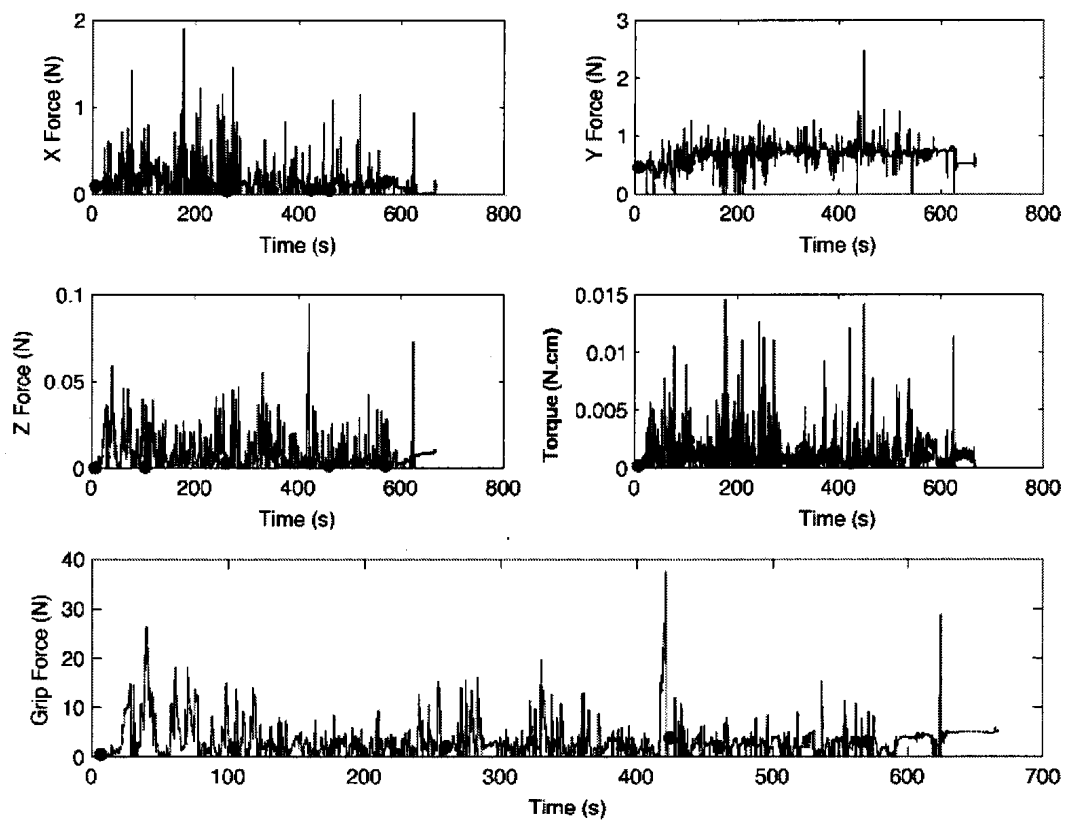
Case 12, Left: All Force vs. Time
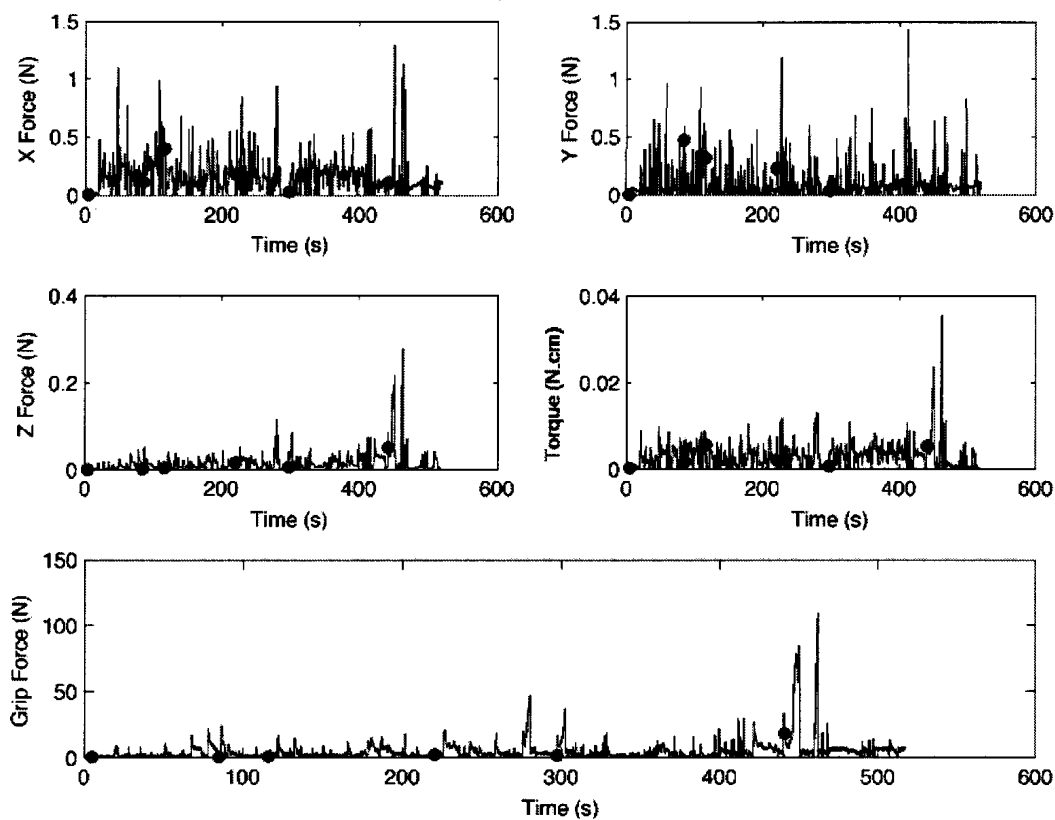
Case 12, Right: All Force vs. Time
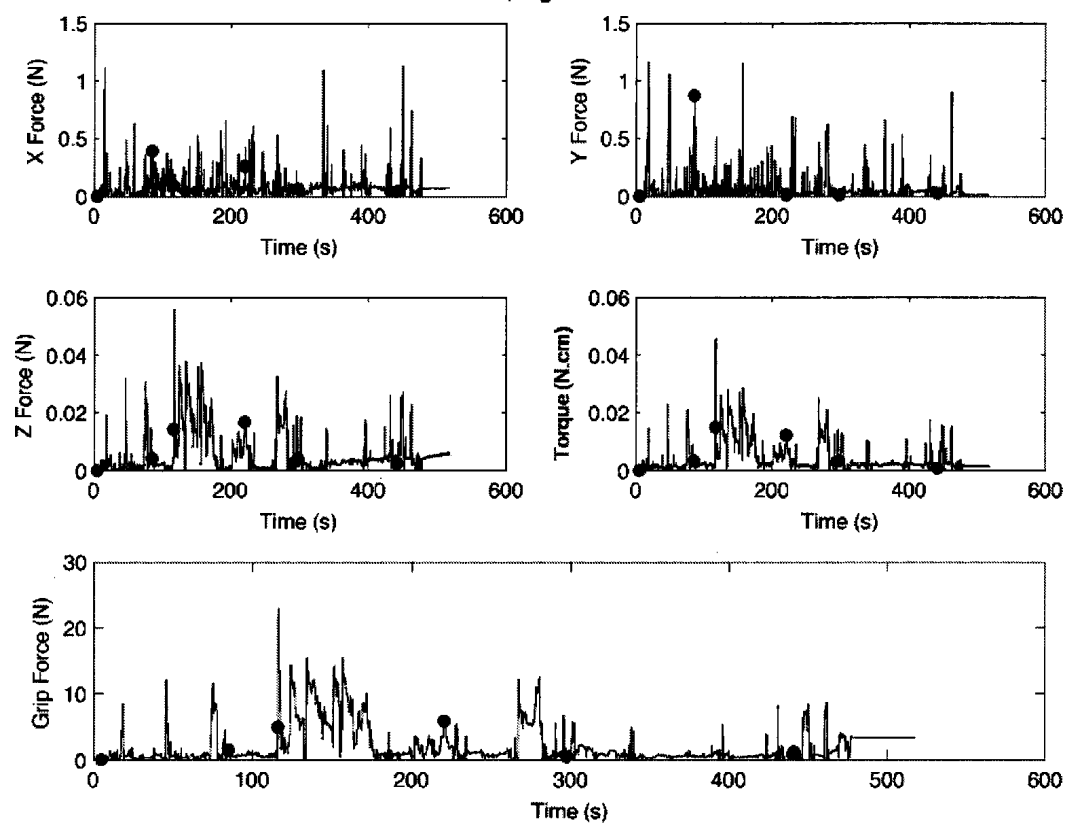
Case 13, Left: All Force vs. Time
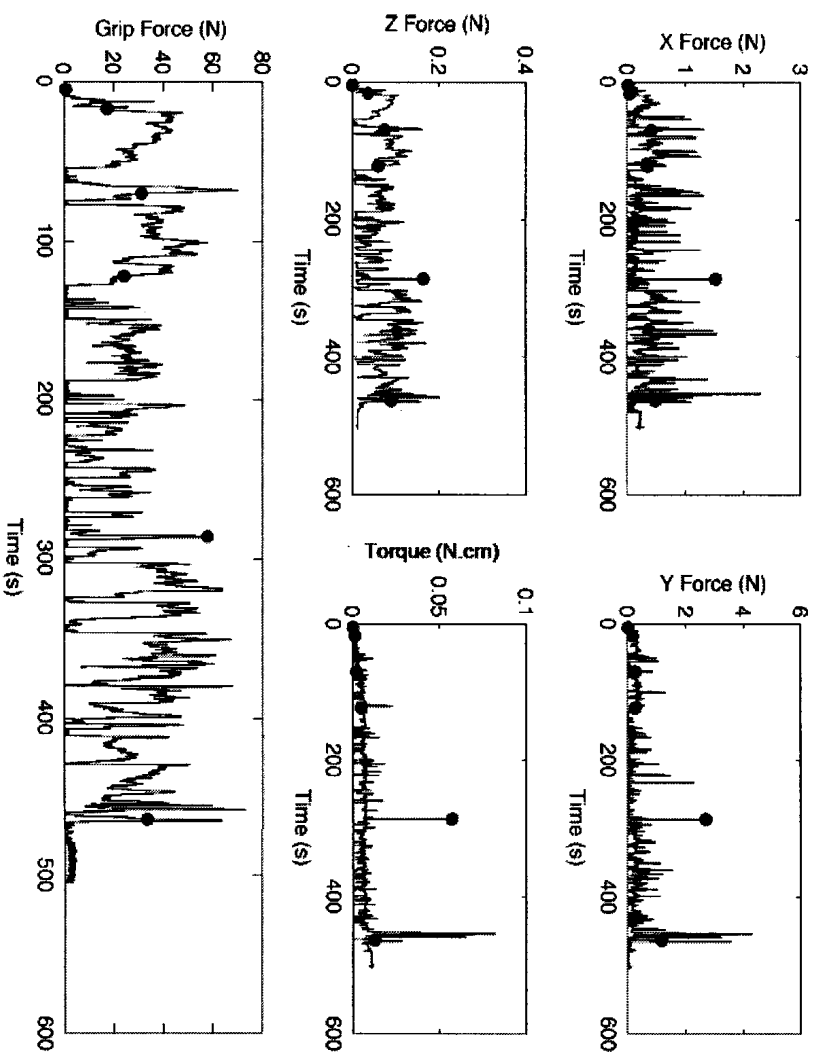
Case 13, Right: All Force vs. Time
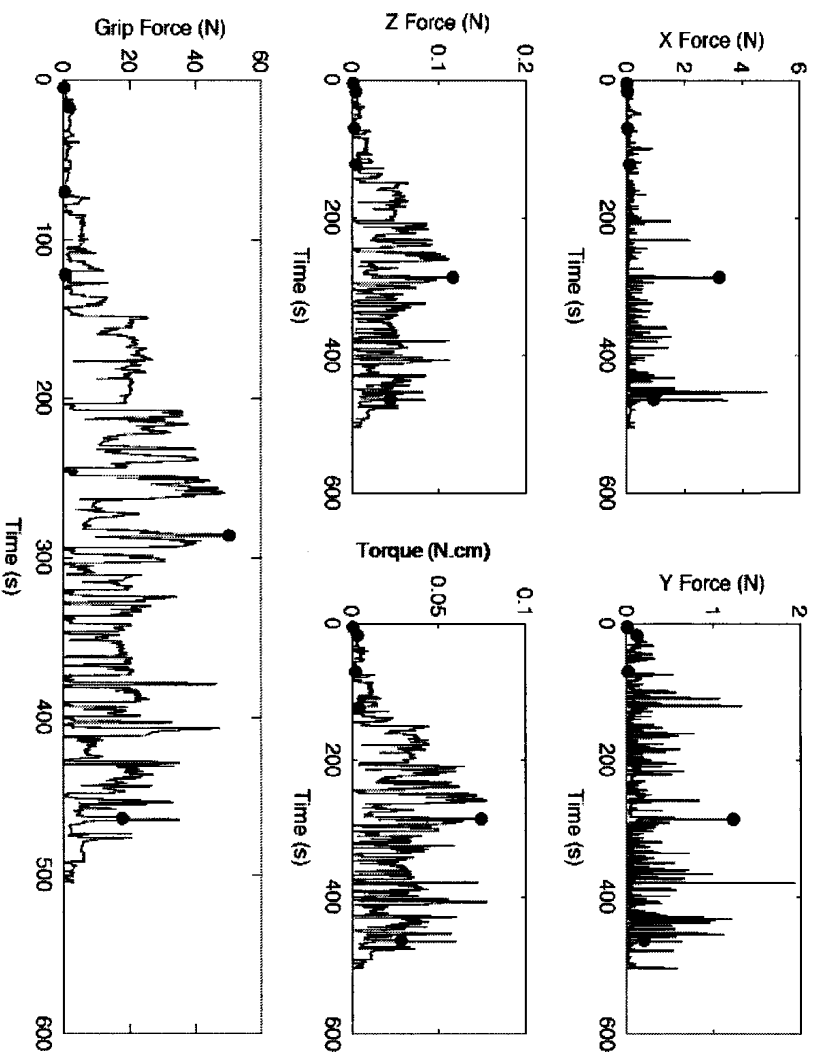
Case 19, Left: All Force vs. Time
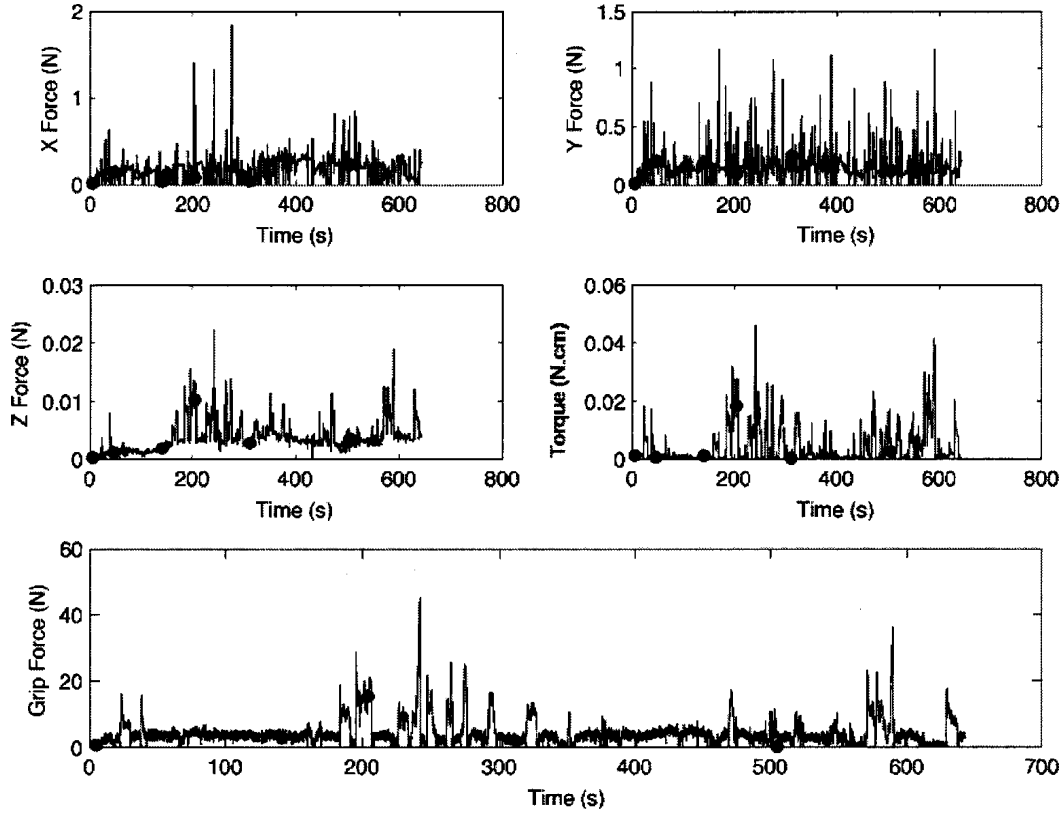
Case 19, Right: All Force vs. Time
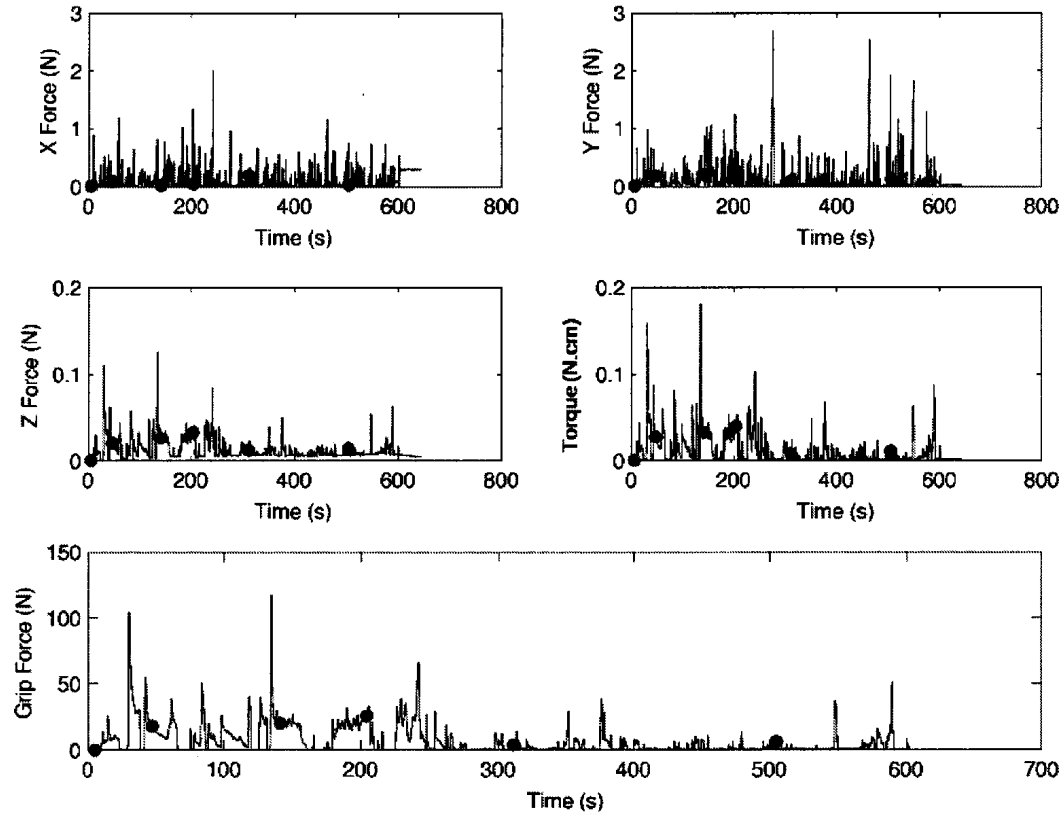
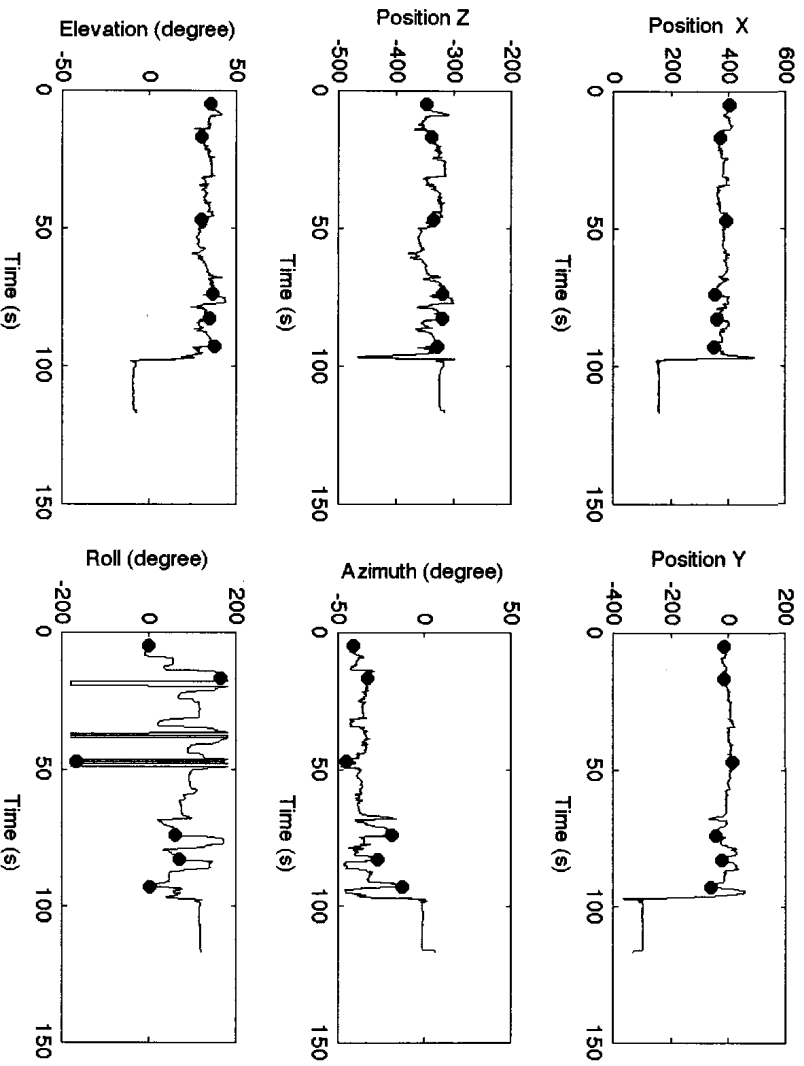Case 1, Left: Position vs. Time

Position X

Position Y

Position Z

Azimuth (degree)

Elevation (degree)

Roll (degree)

Case 1, Right: Position vs. Time

Position X

Position Y

Position Z

Azimuth (degree)

Elevation (degree)

Roll (degree)
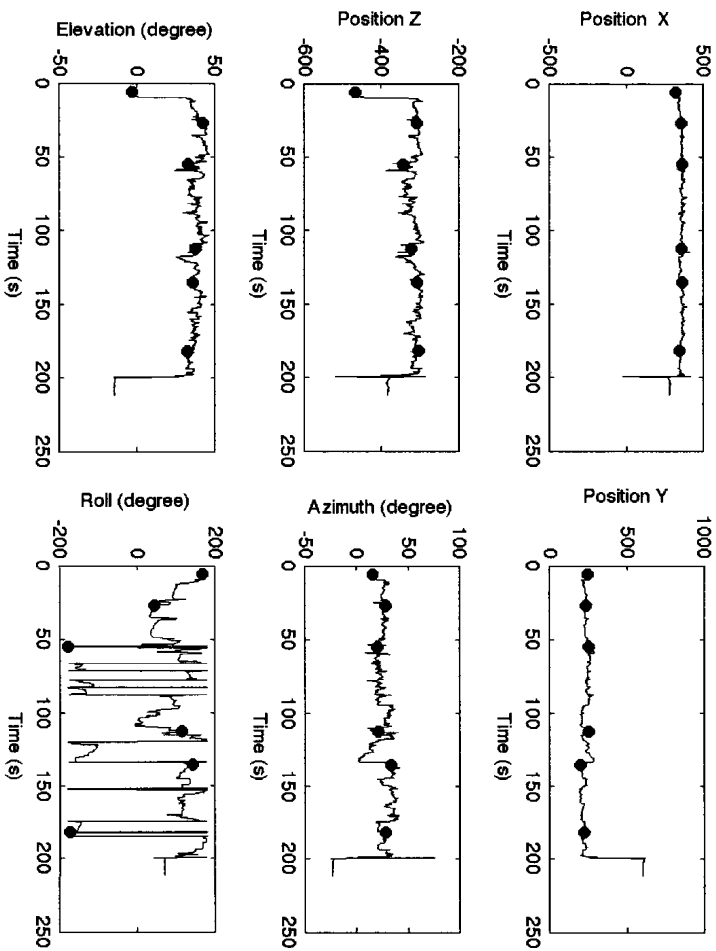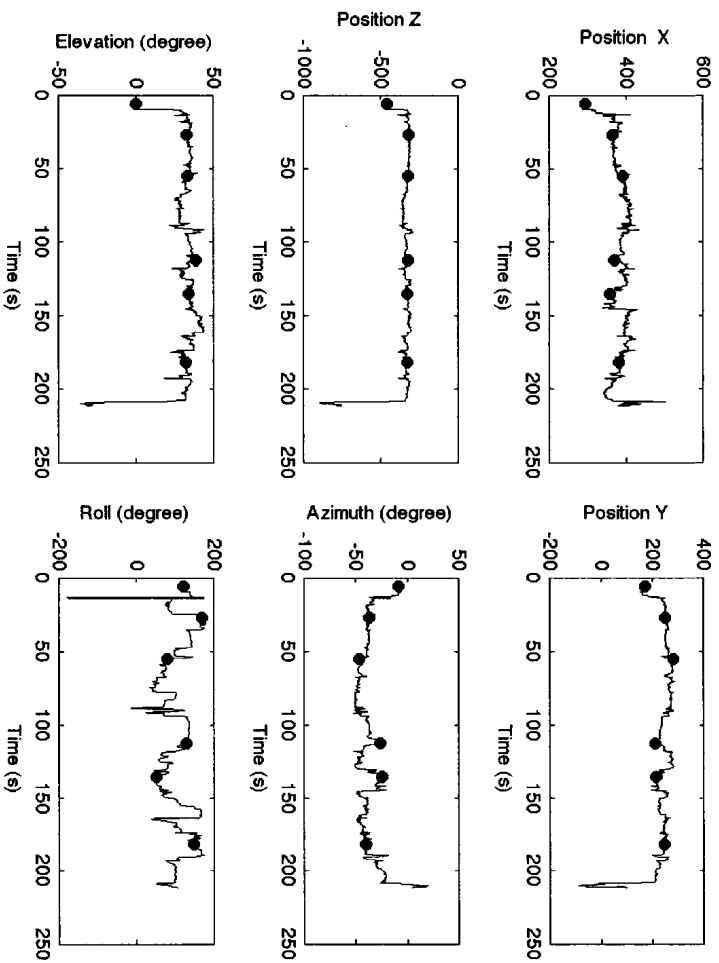
Case 7, Left: Position vs. Time
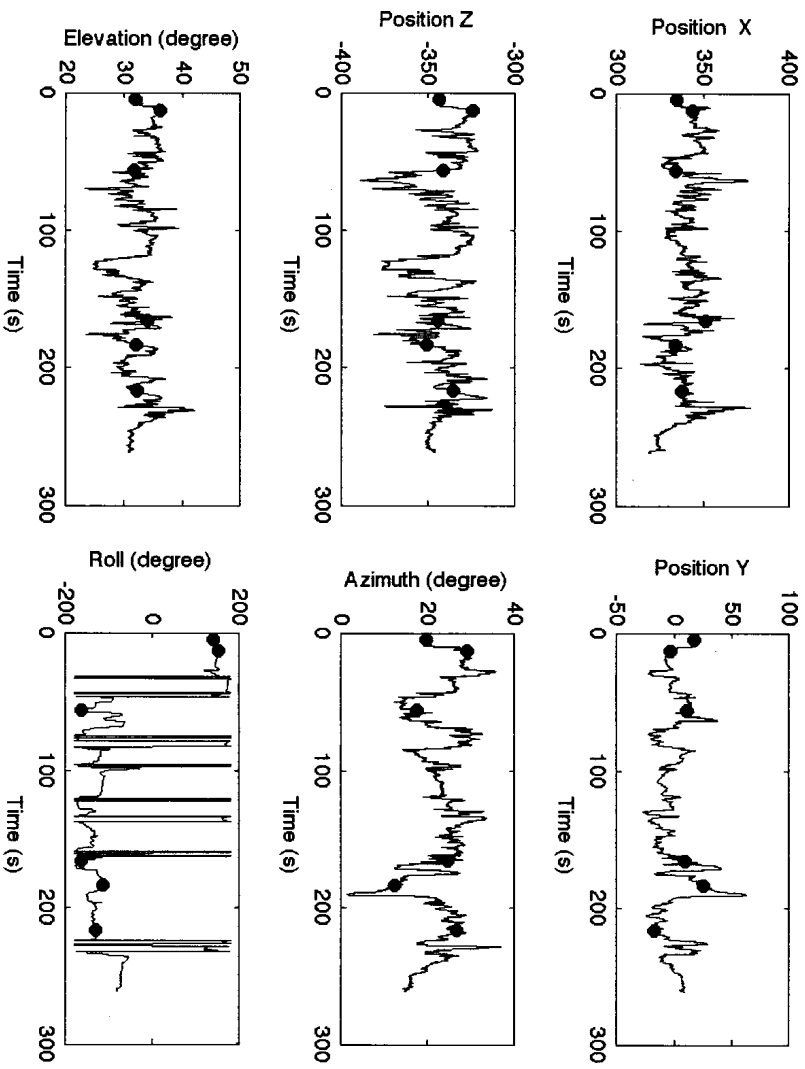
Case 7, Right: Position vs. Time
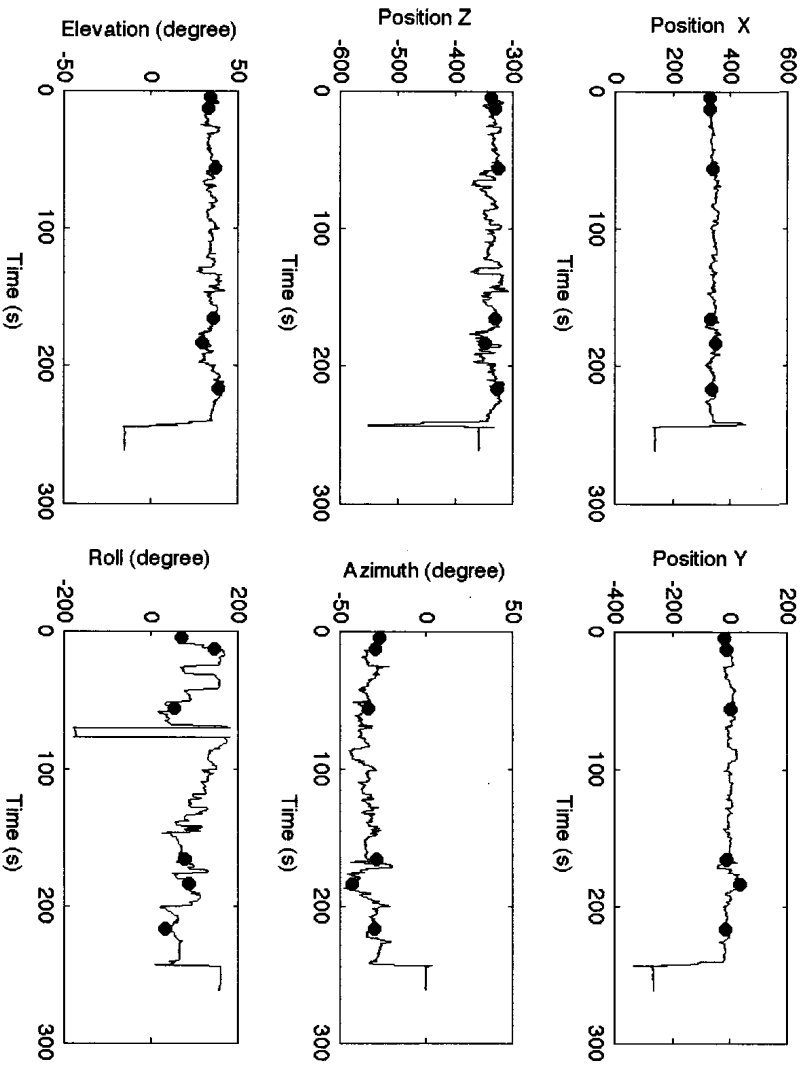
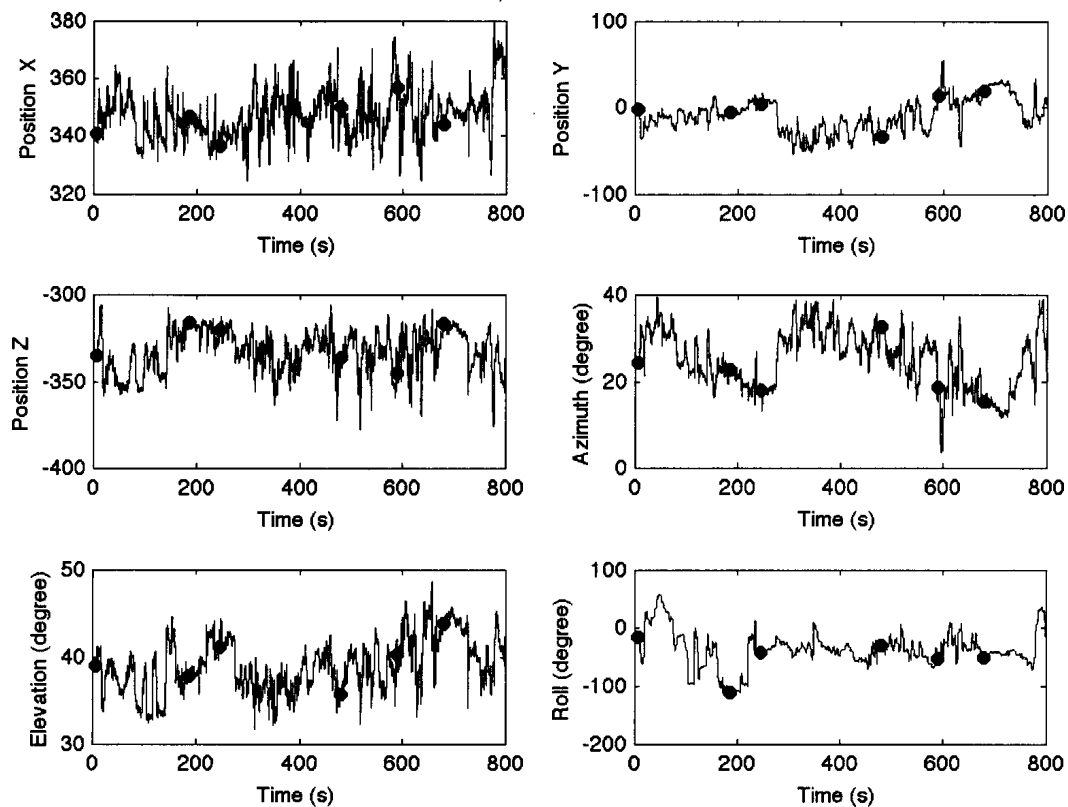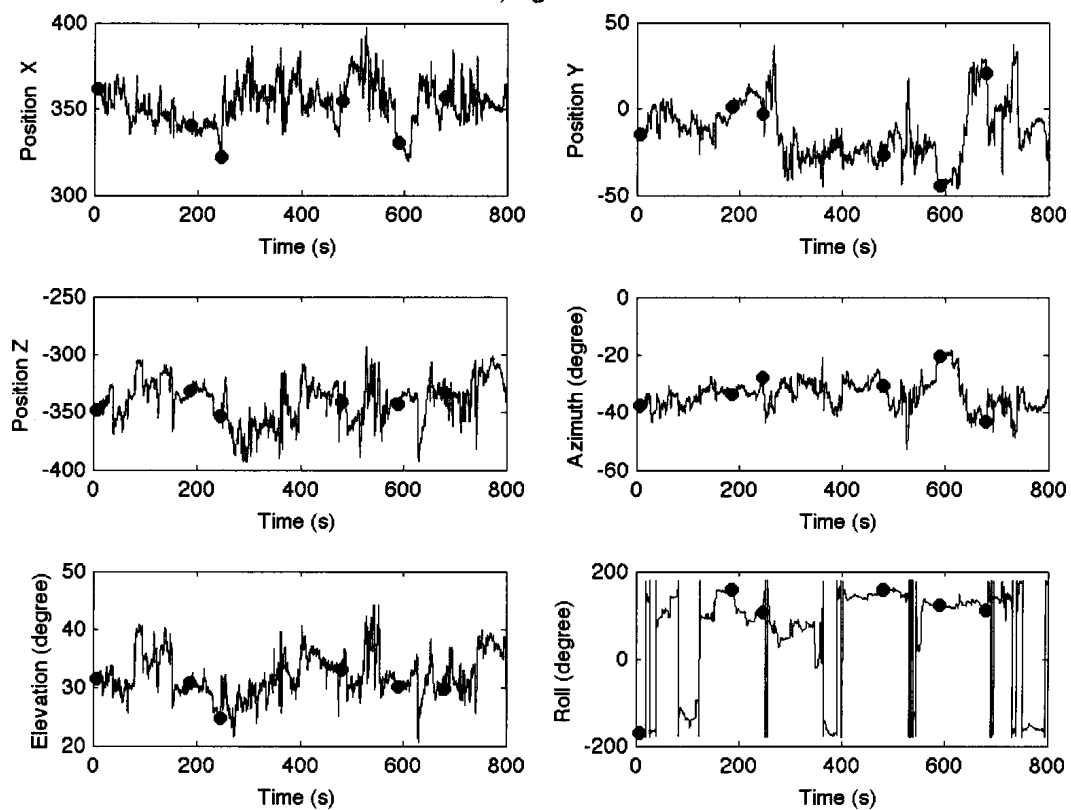Case 8, Left: Position vs. Time
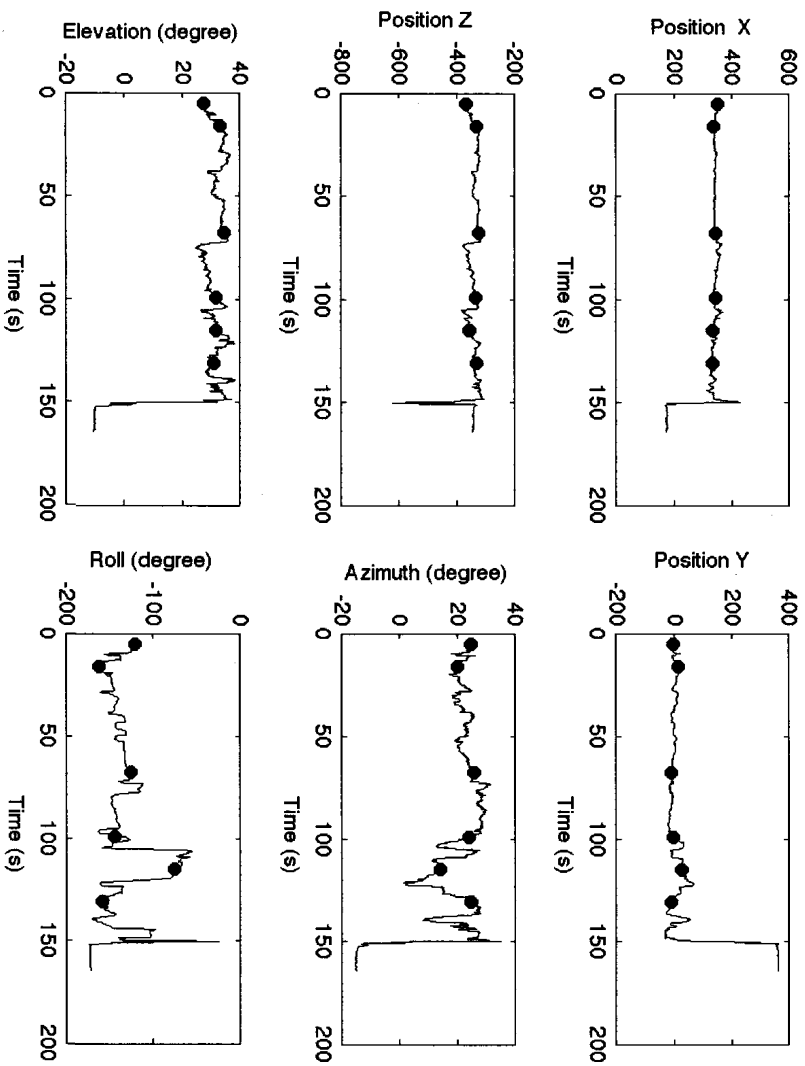
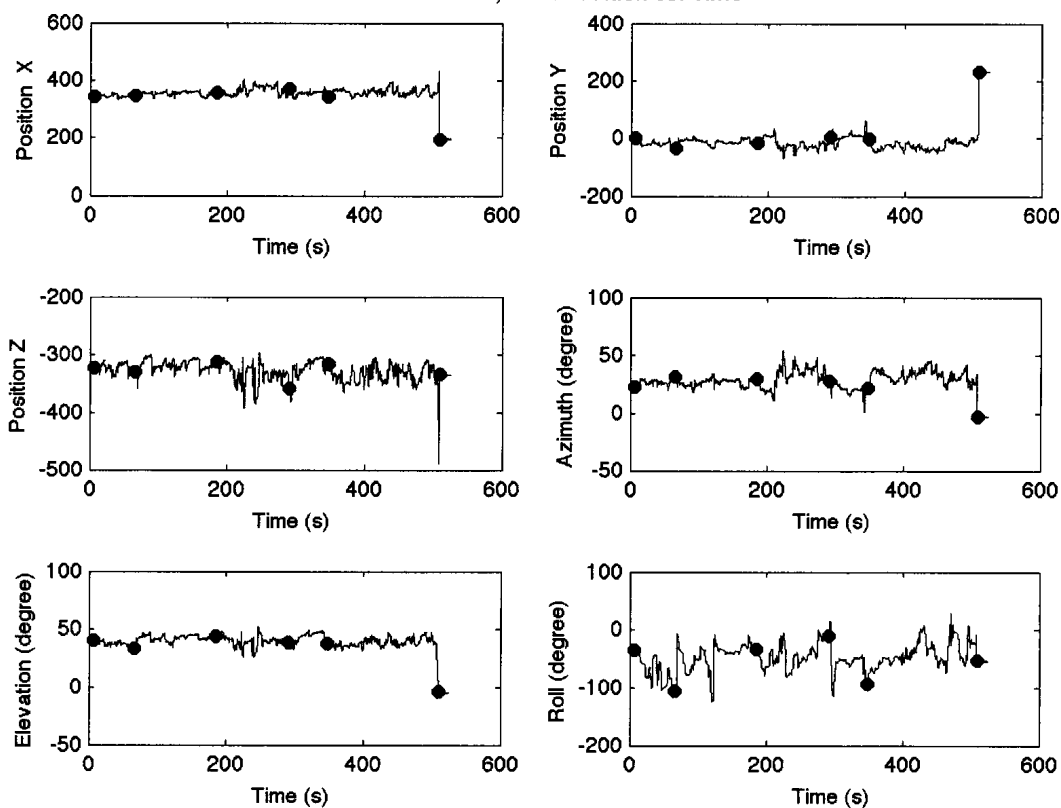Case 8, Right: Position vs. Time
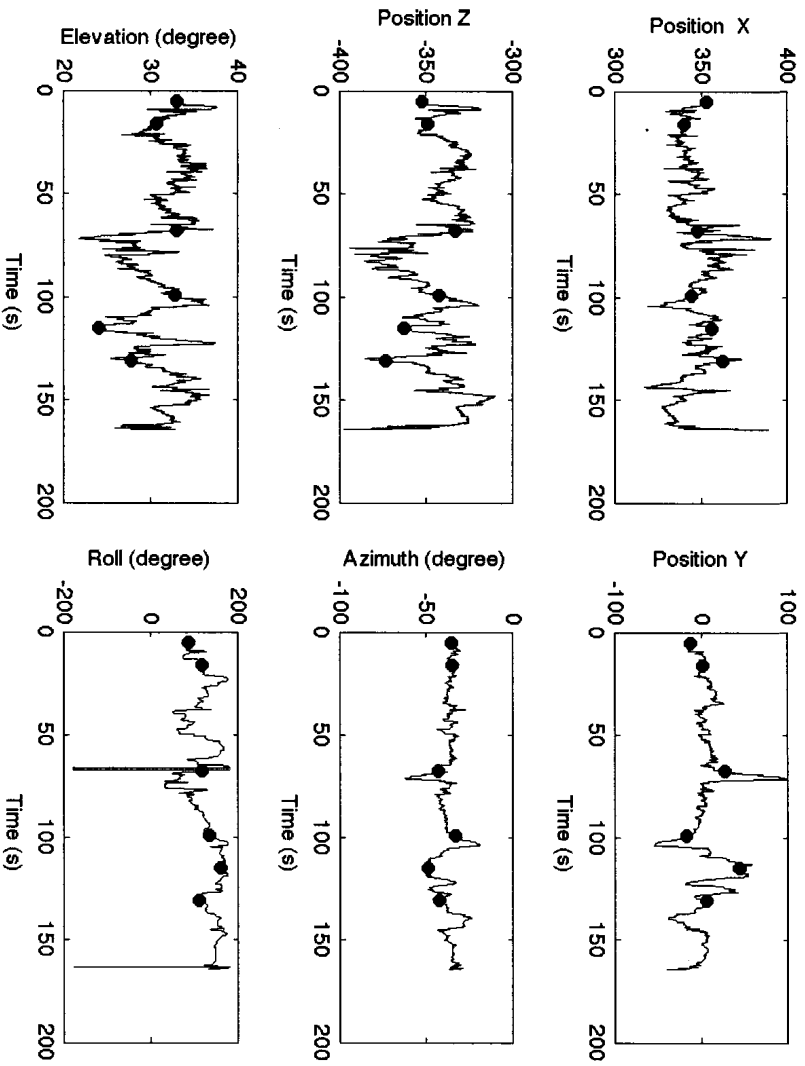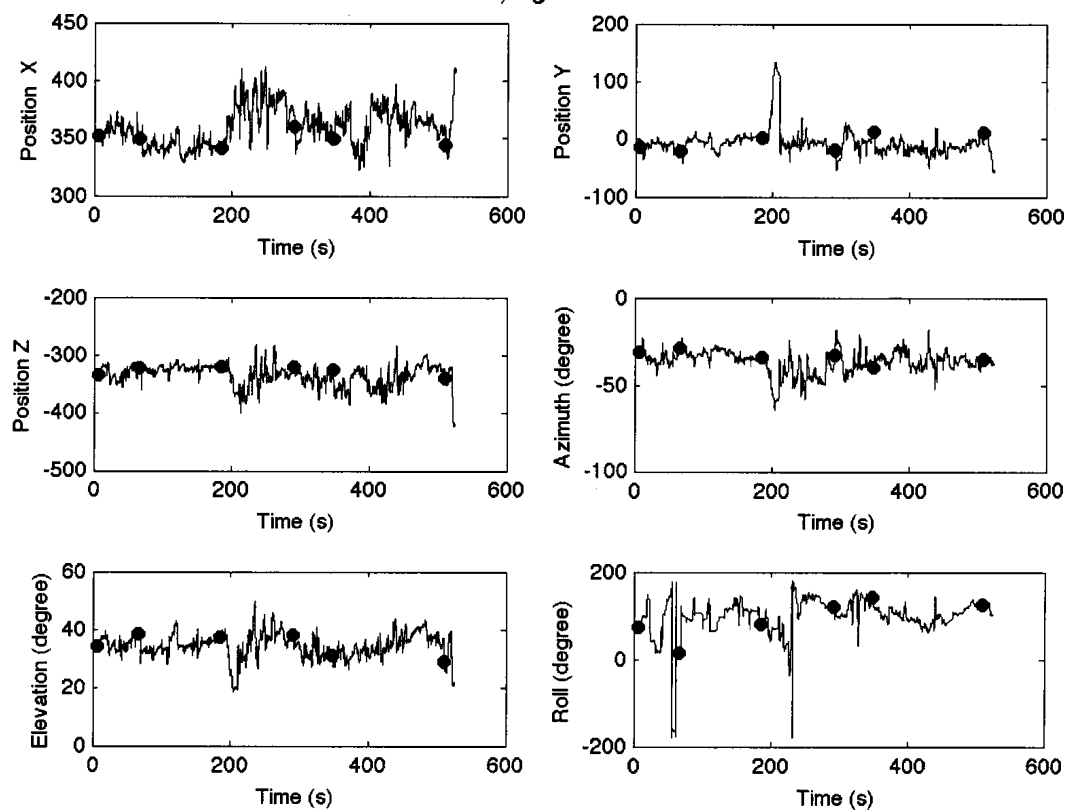
Case 9, Left: Position vs. Time
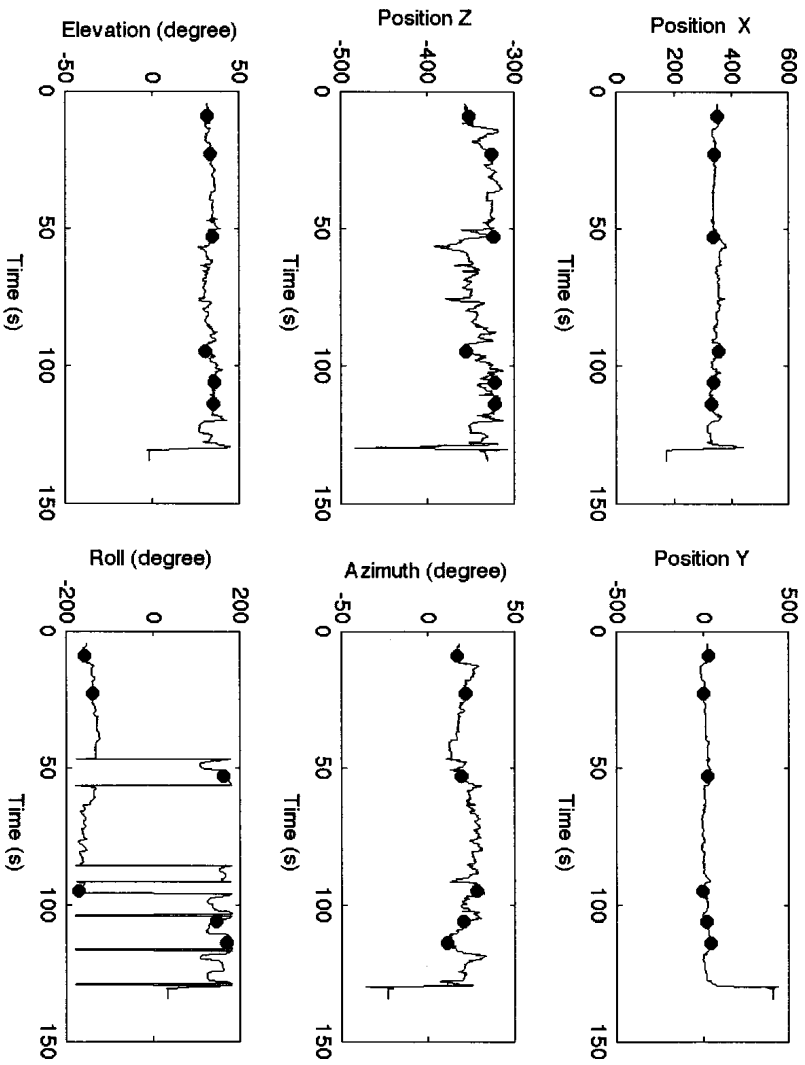
Case 9, Right: Position vs. Time

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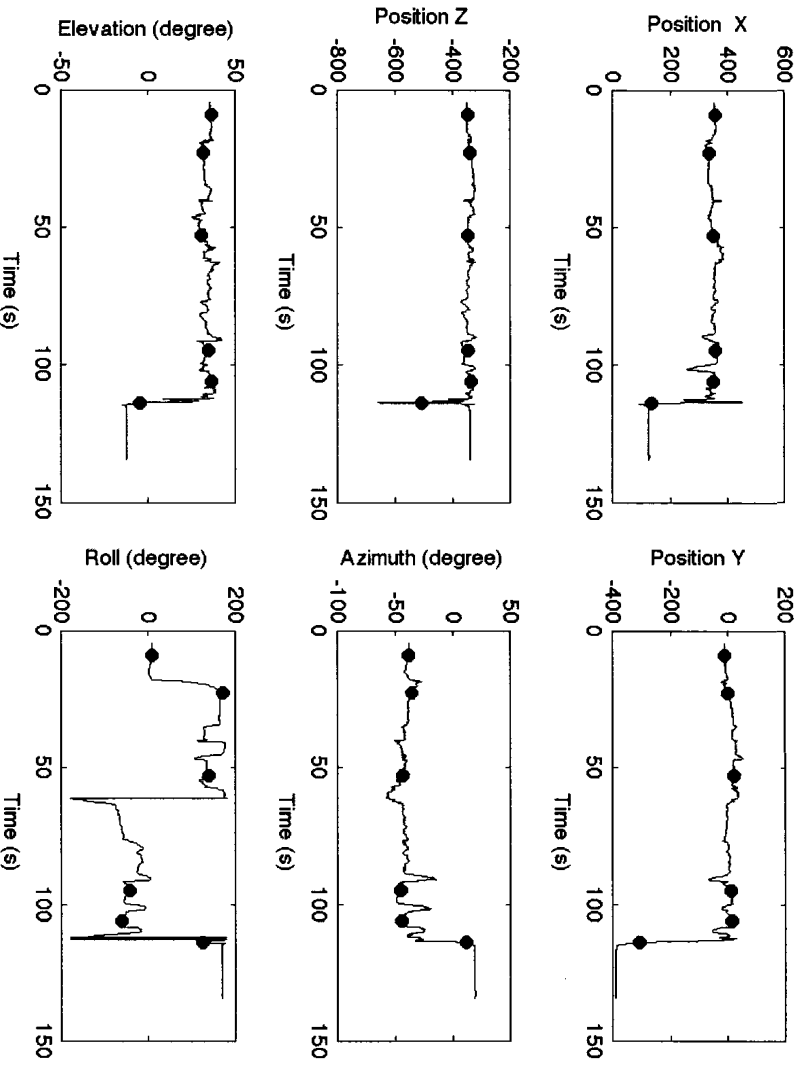
Case 10, Left: Position vs. Time

Case 10, Right: Position vs. Time

Position X

Position Z

Elevation (degree)

Position Y

Azimuth (degree)

Roll (degree)

Time (s)

Case 11, Left: Position vs. Time

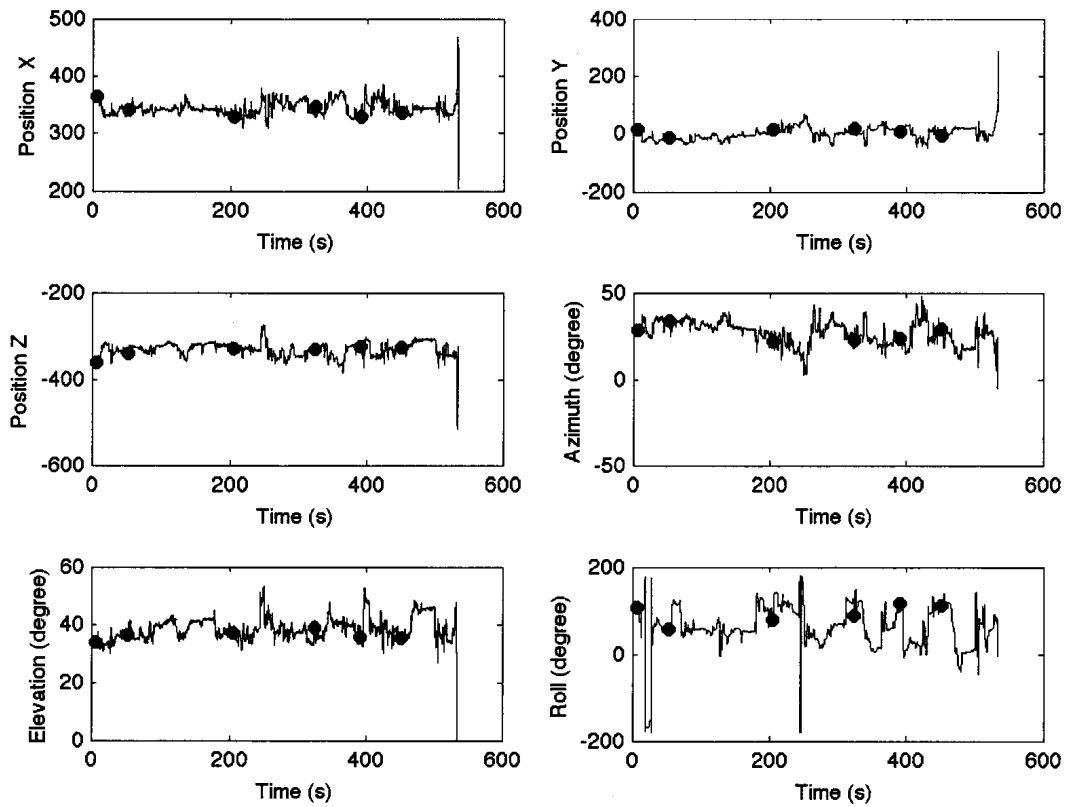Position X

Position Z

Elevation (degree)

Position Y

Azimuth (degree)

Roll (degree)

Time (s)
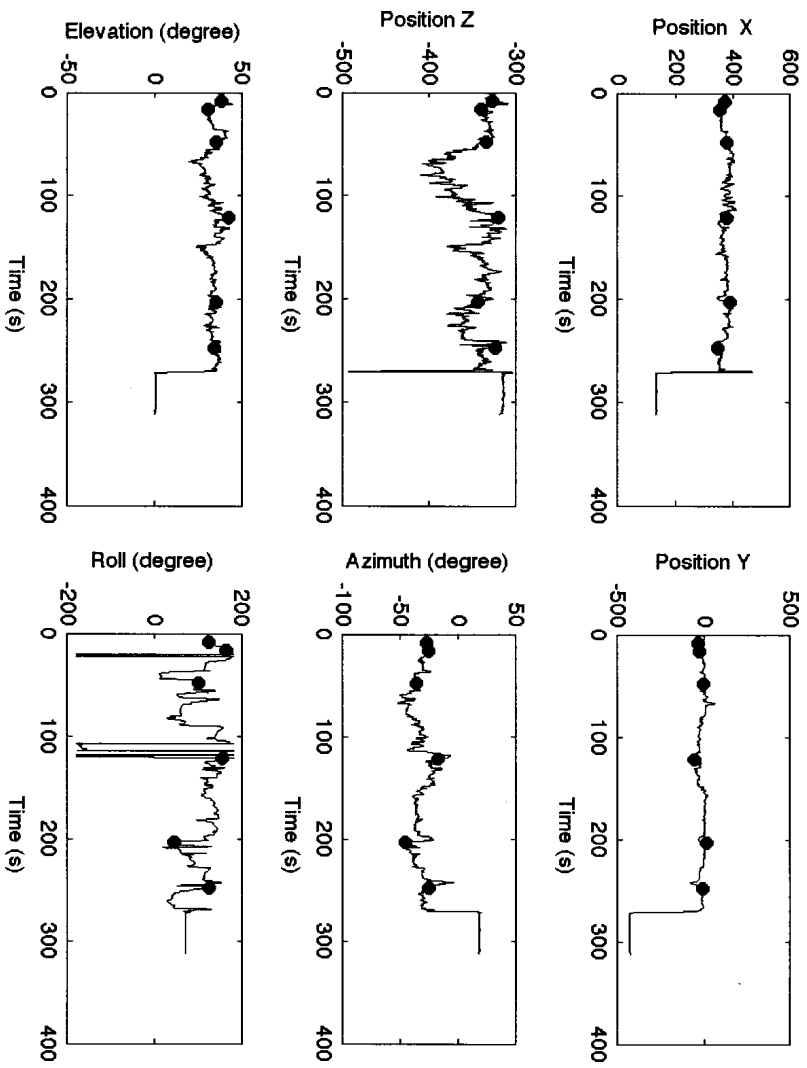
Case 11, Right: Position vs. Time
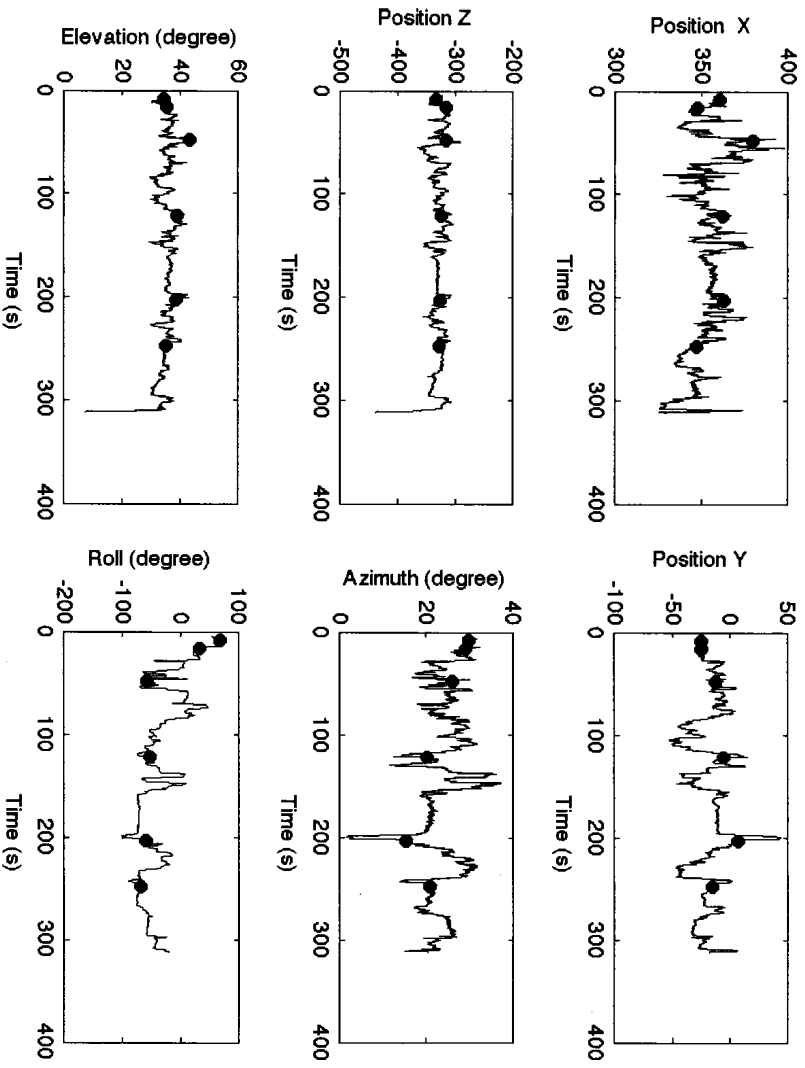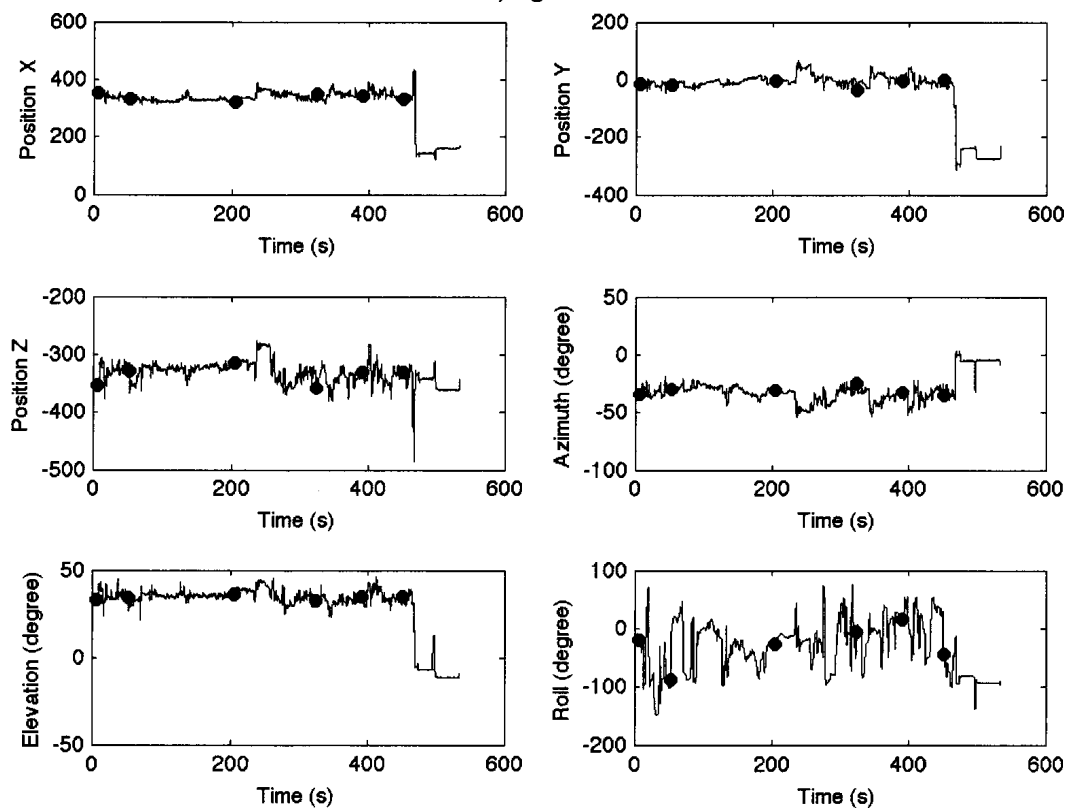
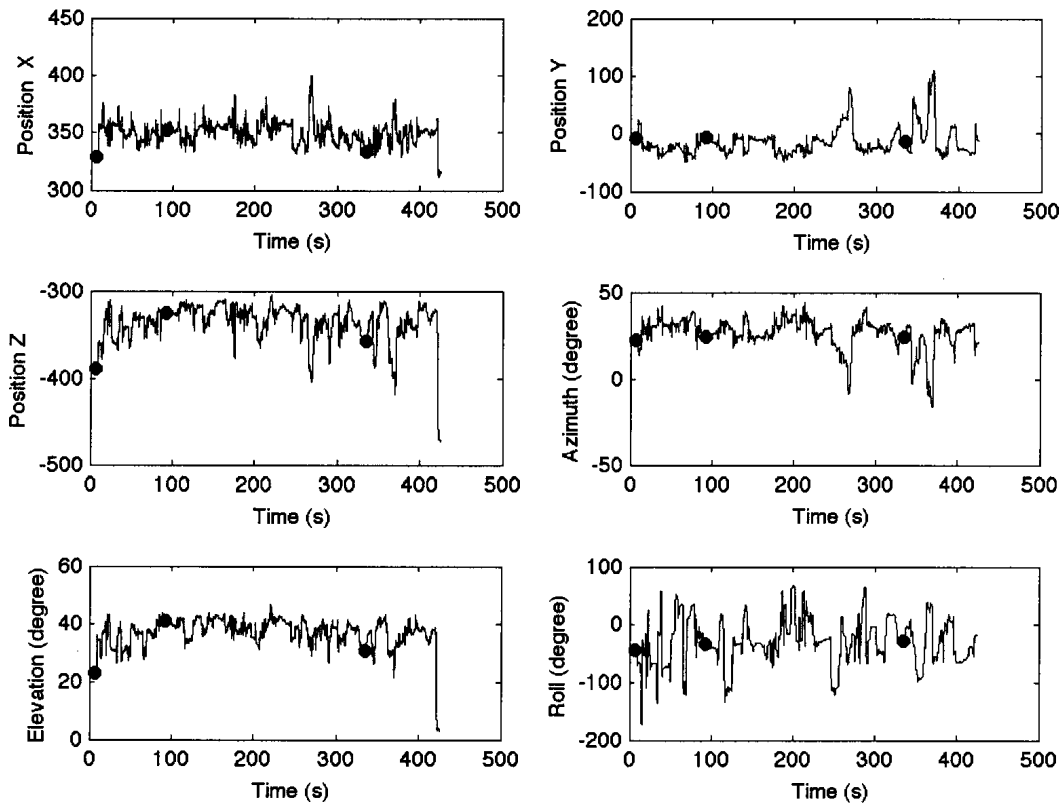**Case 14, Left: Position vs. Time**
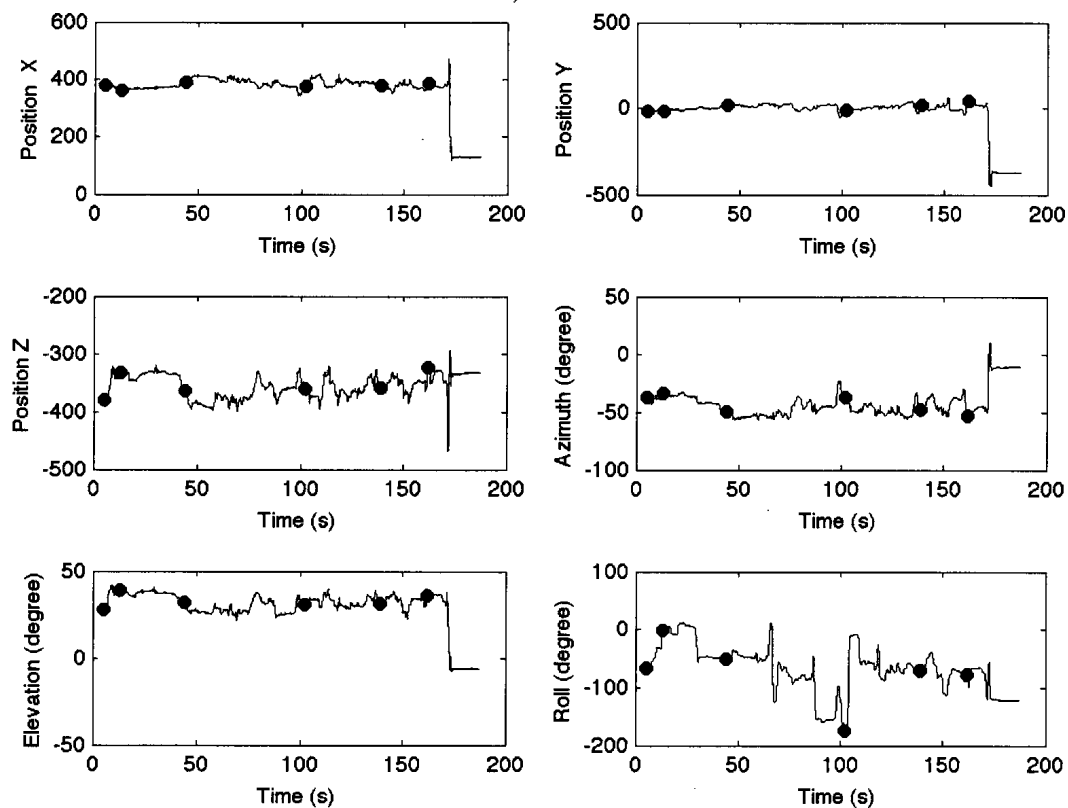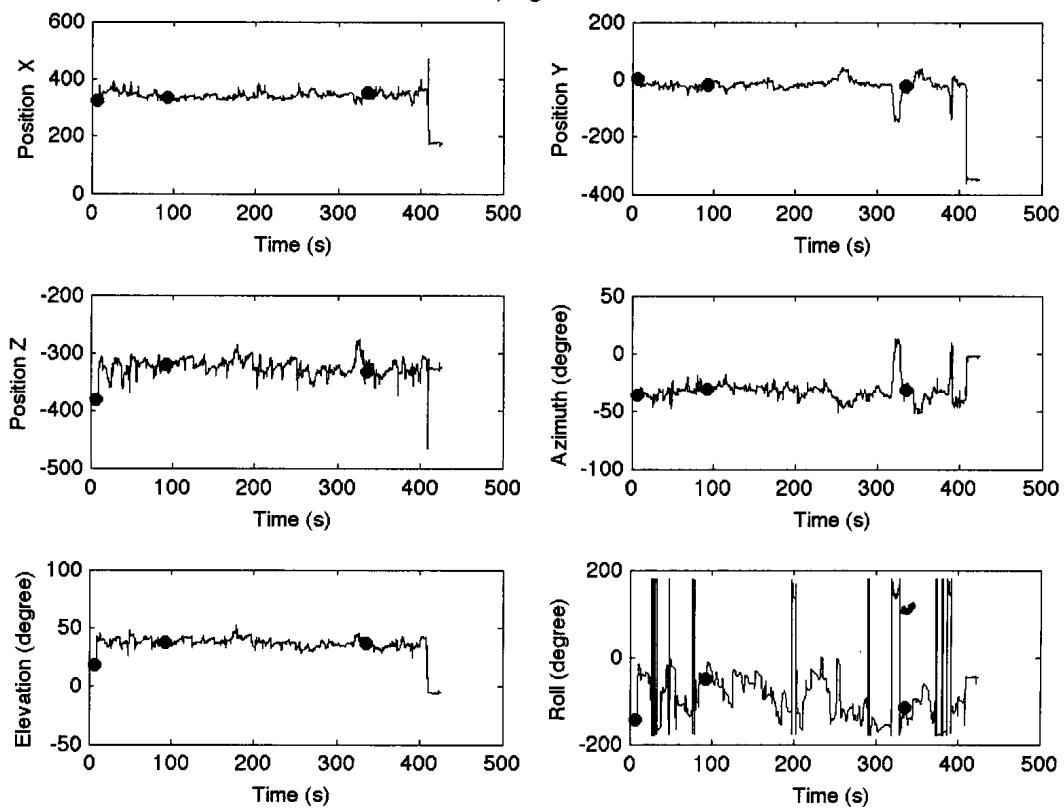

Case 14, Right: Position vs. Time
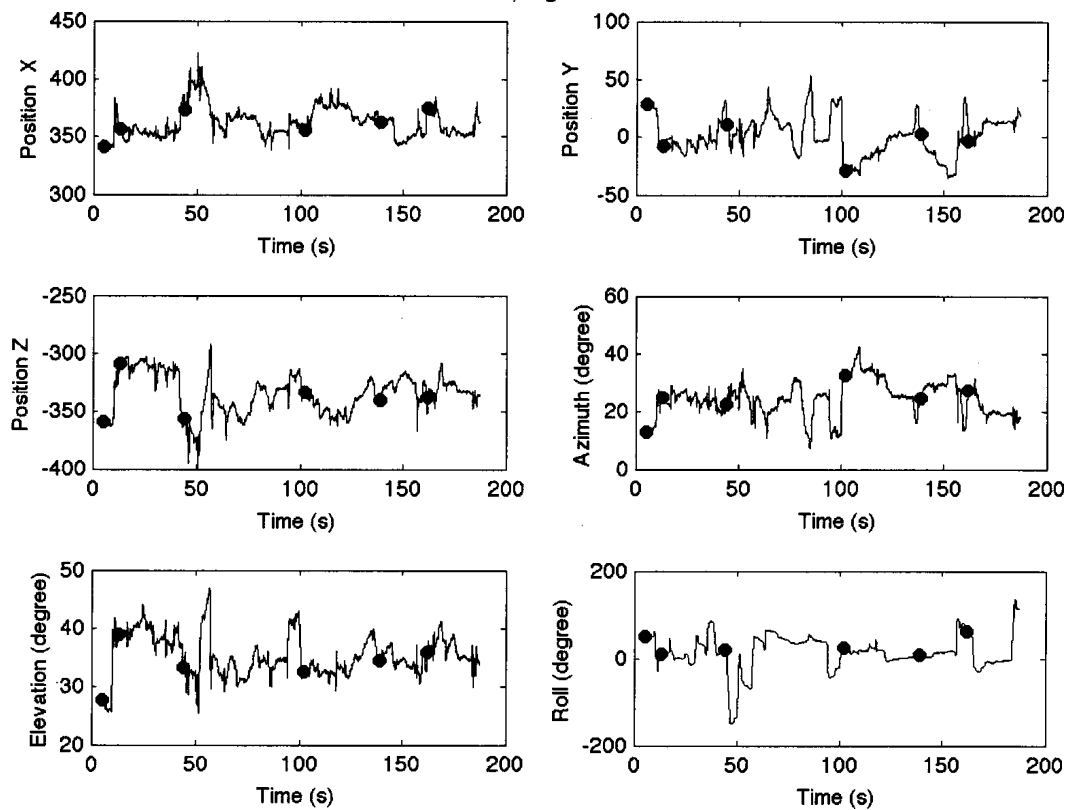
Case 15, Left: Position vs. Time
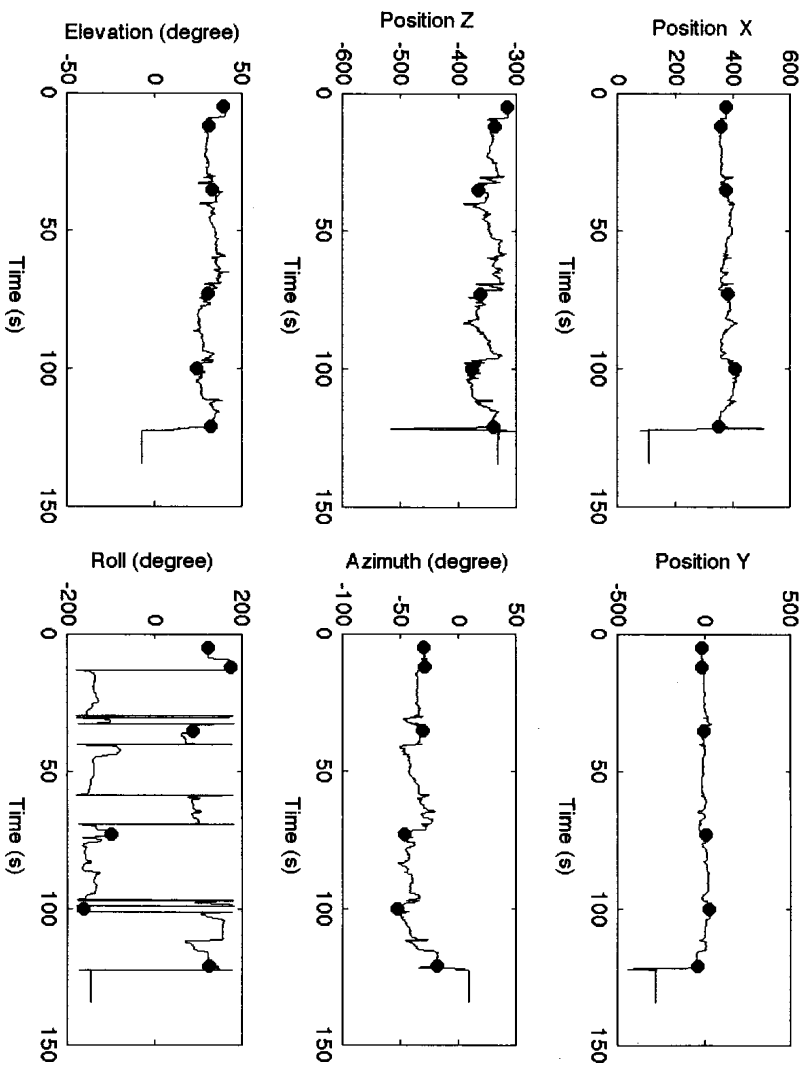
Case 15, Right: Position vs. Time
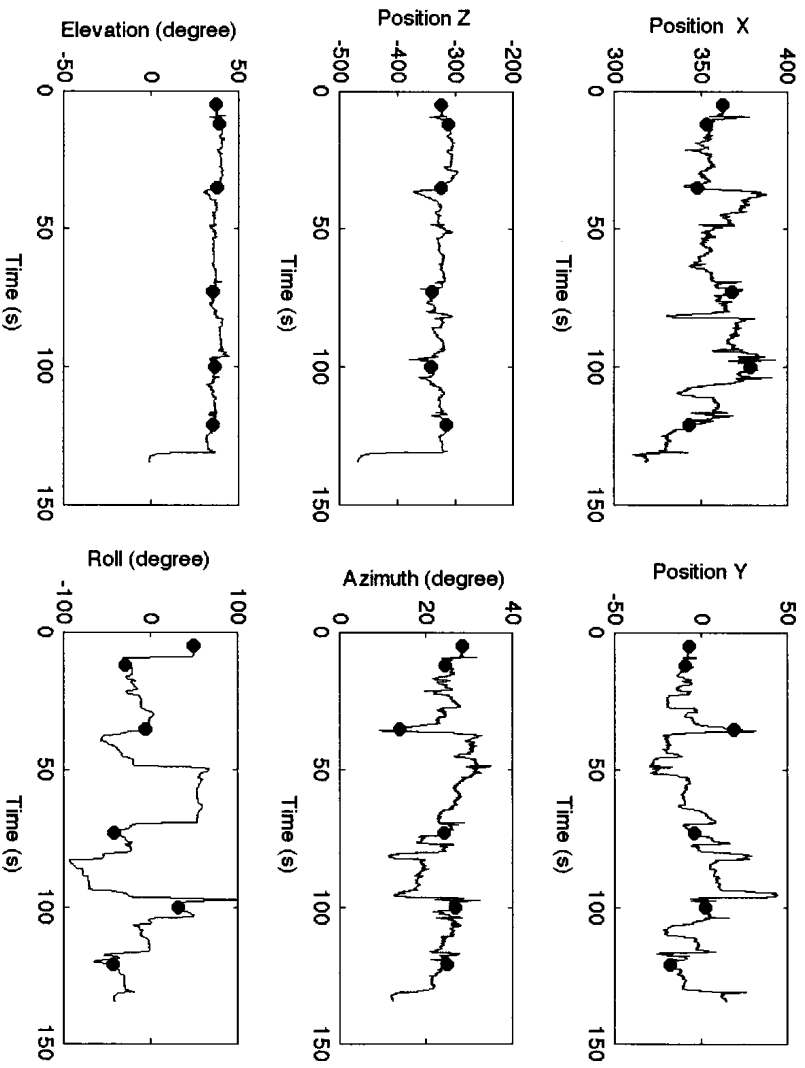
Case 16, Left: Position vs. Time

Case 16, Right: Position vs. Time

Position X

Position Z

Elevation (degree)

Position Y

Azimuth (degree)

Roll (degree)

Time (s)

Case 17, Right: Position vs. Time

Position X

Position Z

Elevation (degree)

Position Y

Azimuth (degree)

Roll (degree)

Time (s)
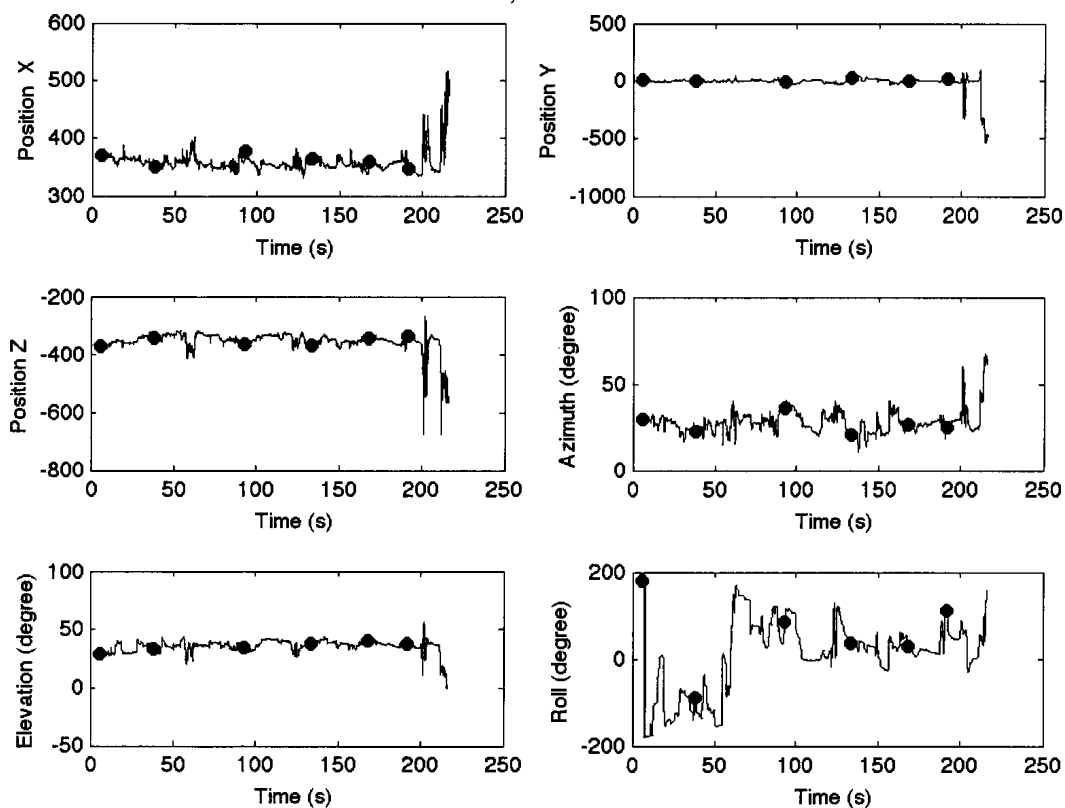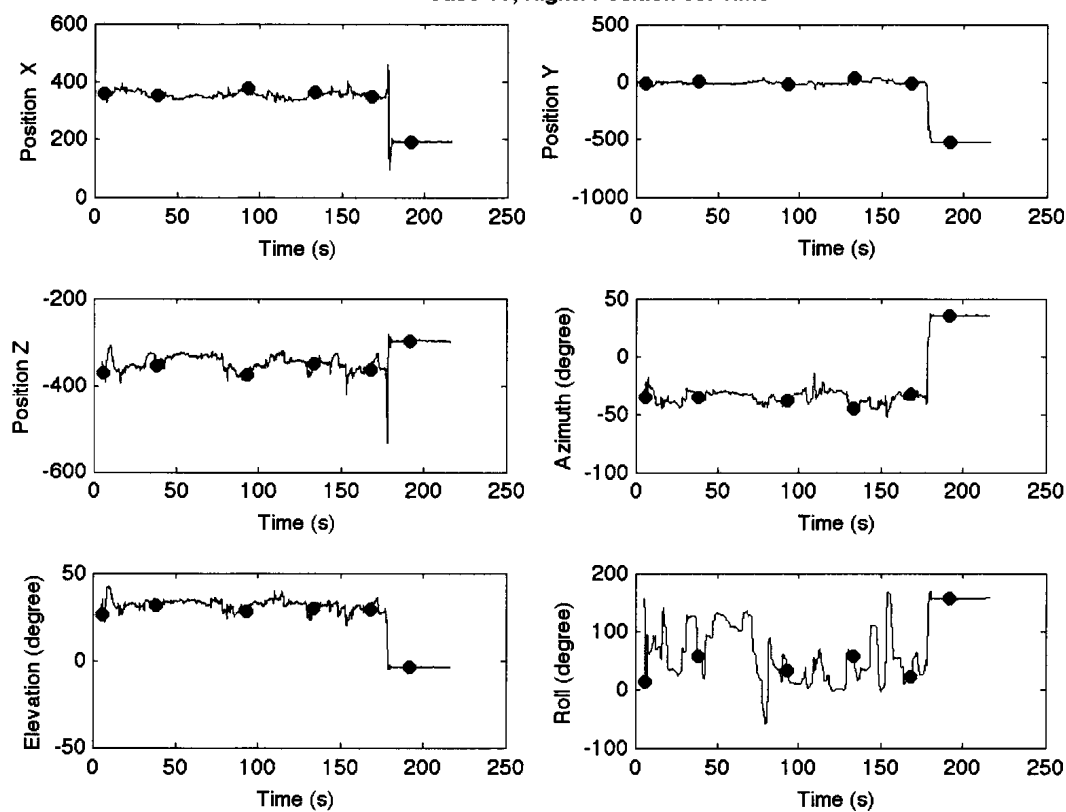
Case 17, Left: Position vs. Time

118
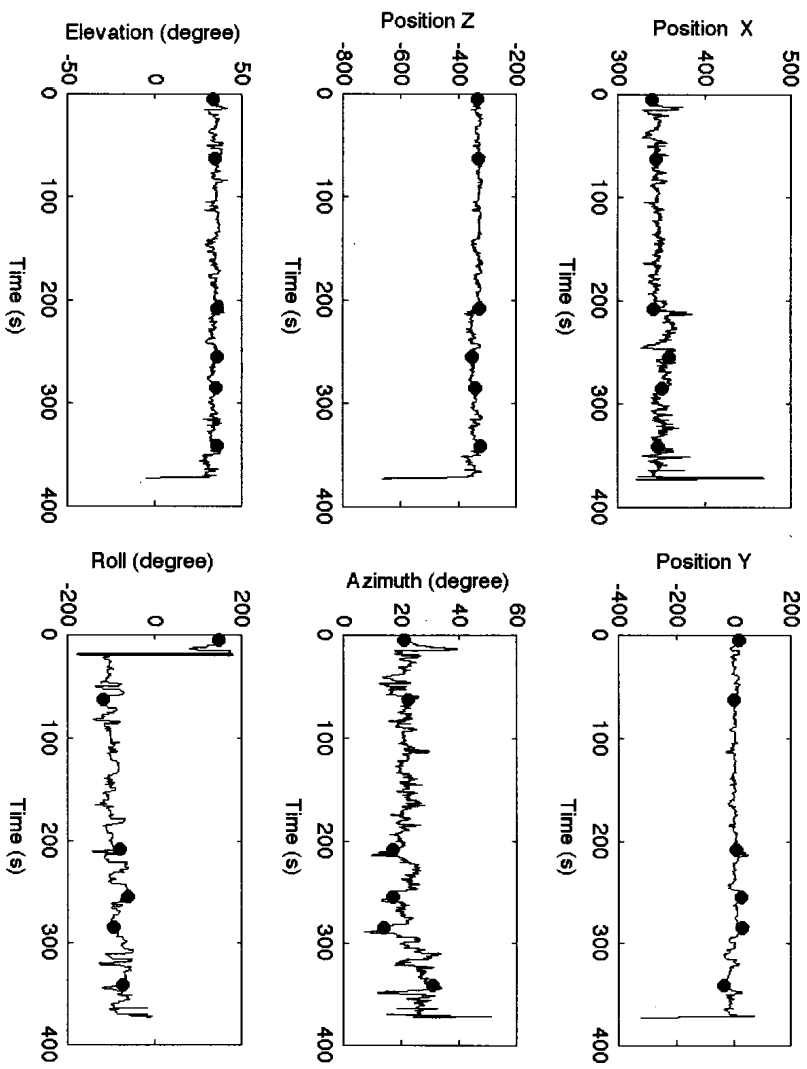
Case 18, Left: Position vs. Time

Case 18, Right: Position vs. Time
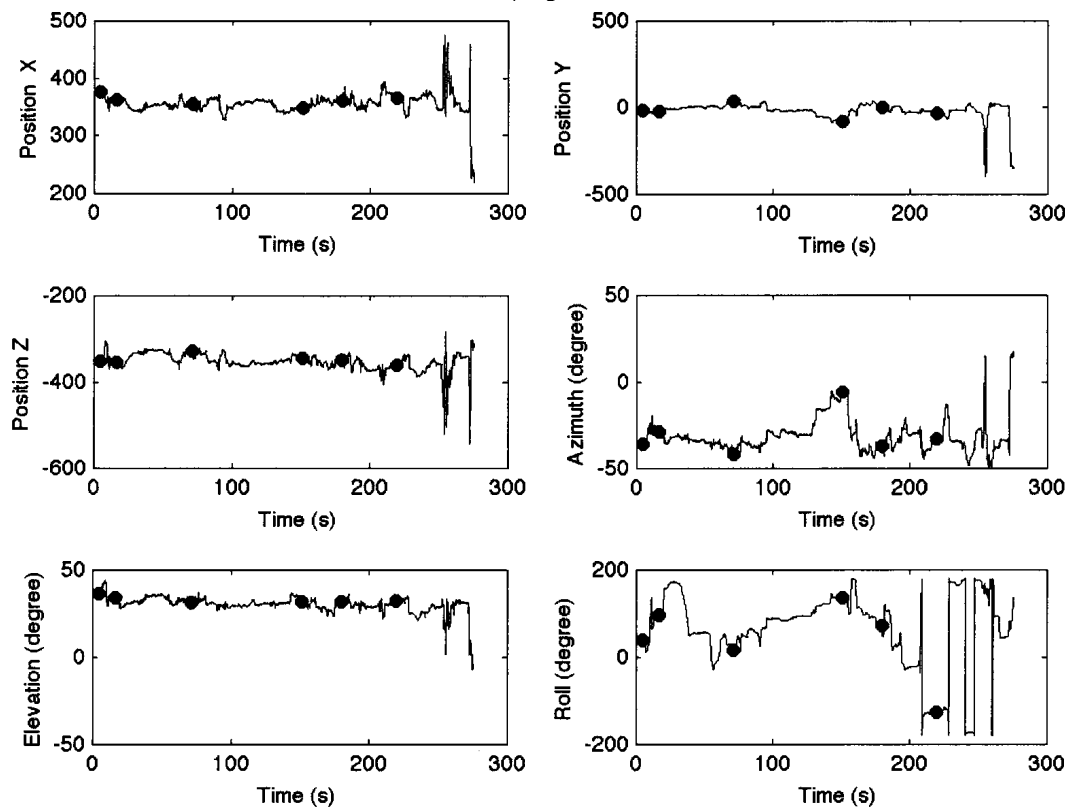
Case 20, Left: Position vs. Time
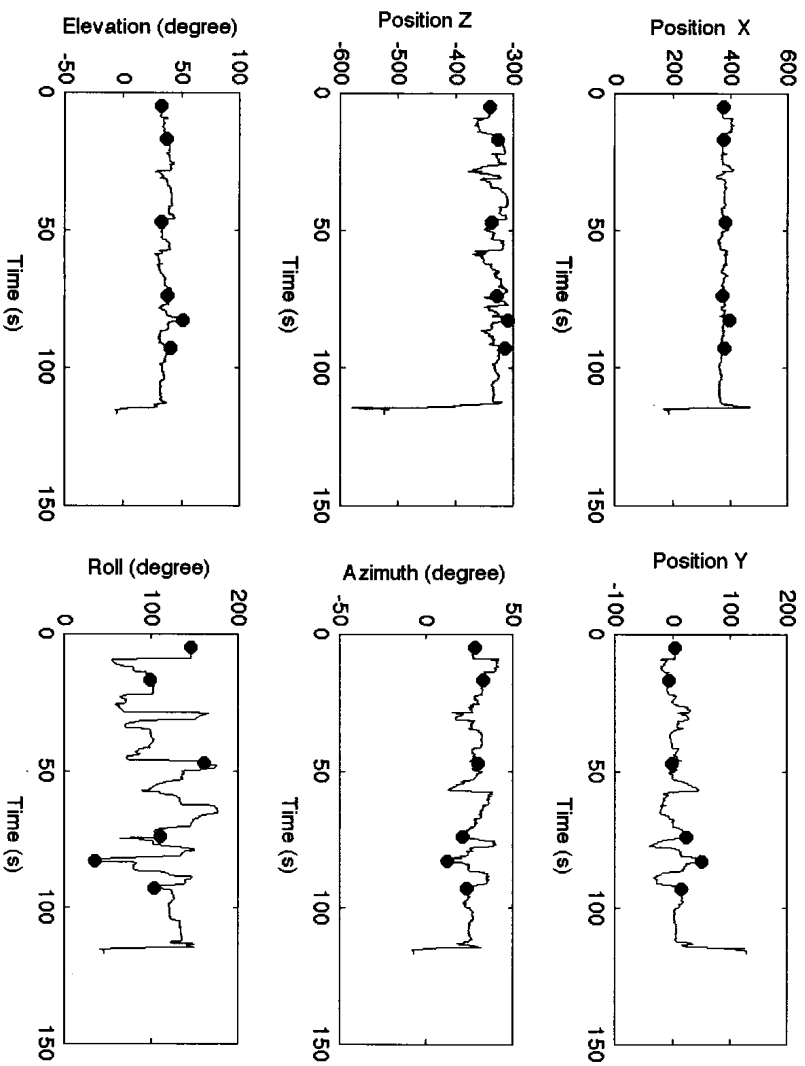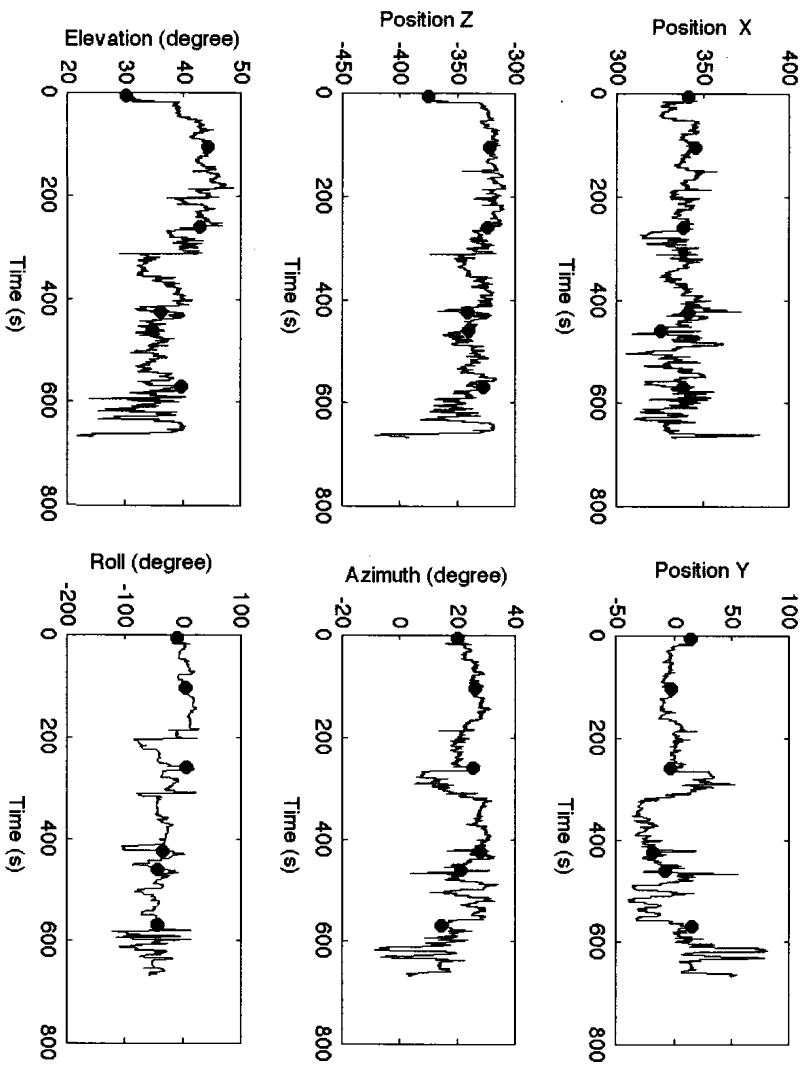
Case 20, Right: Position vs. Time

120

Case 2, Left: Position vs. Time

Case 2, Right: Position vs. Time

Case 3, Left: Position vs. Time

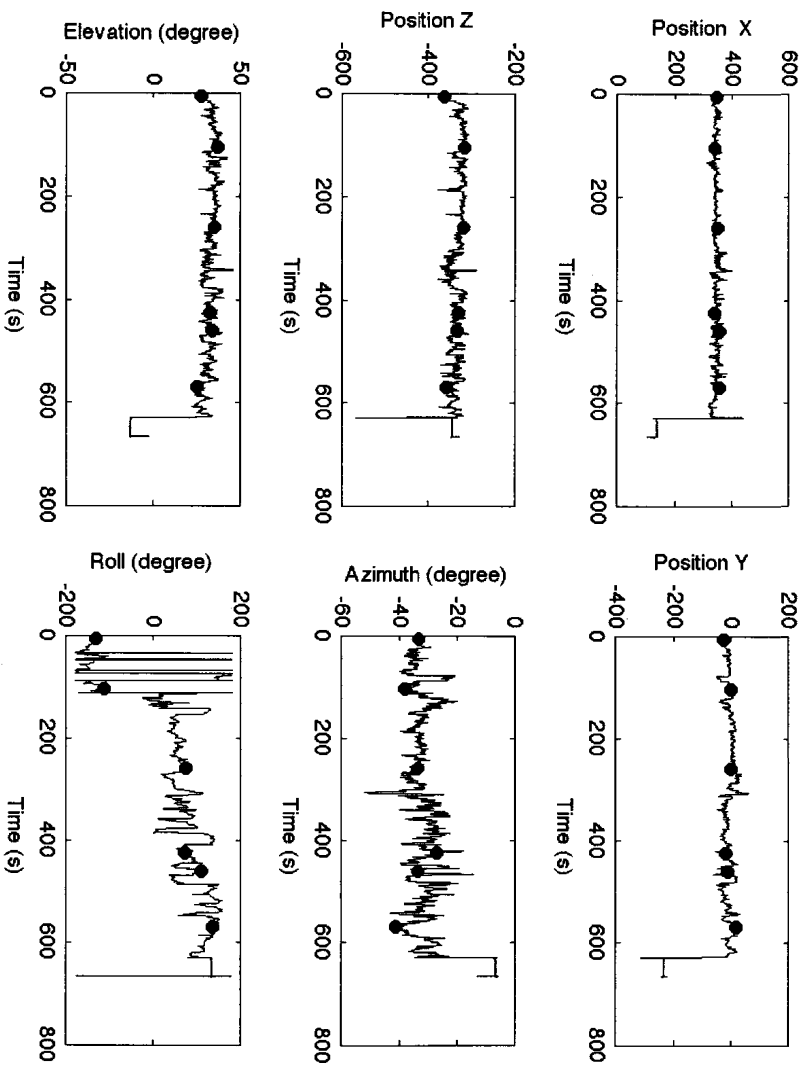**Case 3, Right: Position vs. Time**

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Case 4, Left: Position vs. Time

Case 4, Right: Position vs. Time

Case 5, Left: Position vs. Time
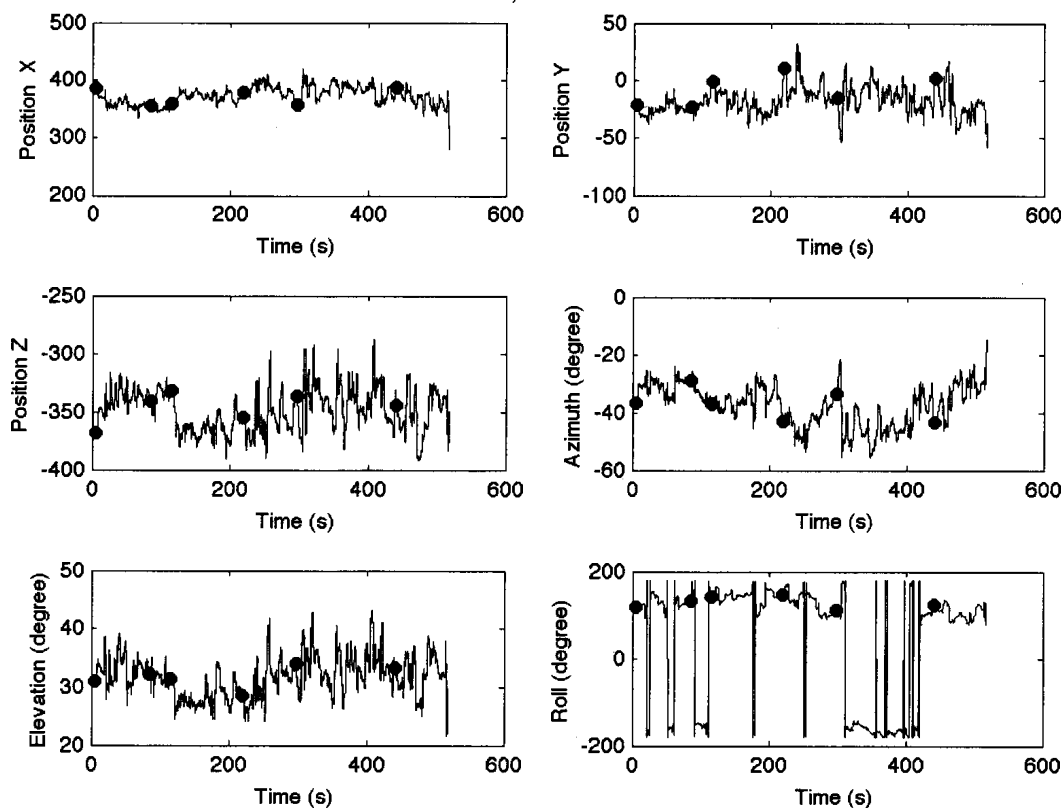

Case 5, Right: Position vs. Time
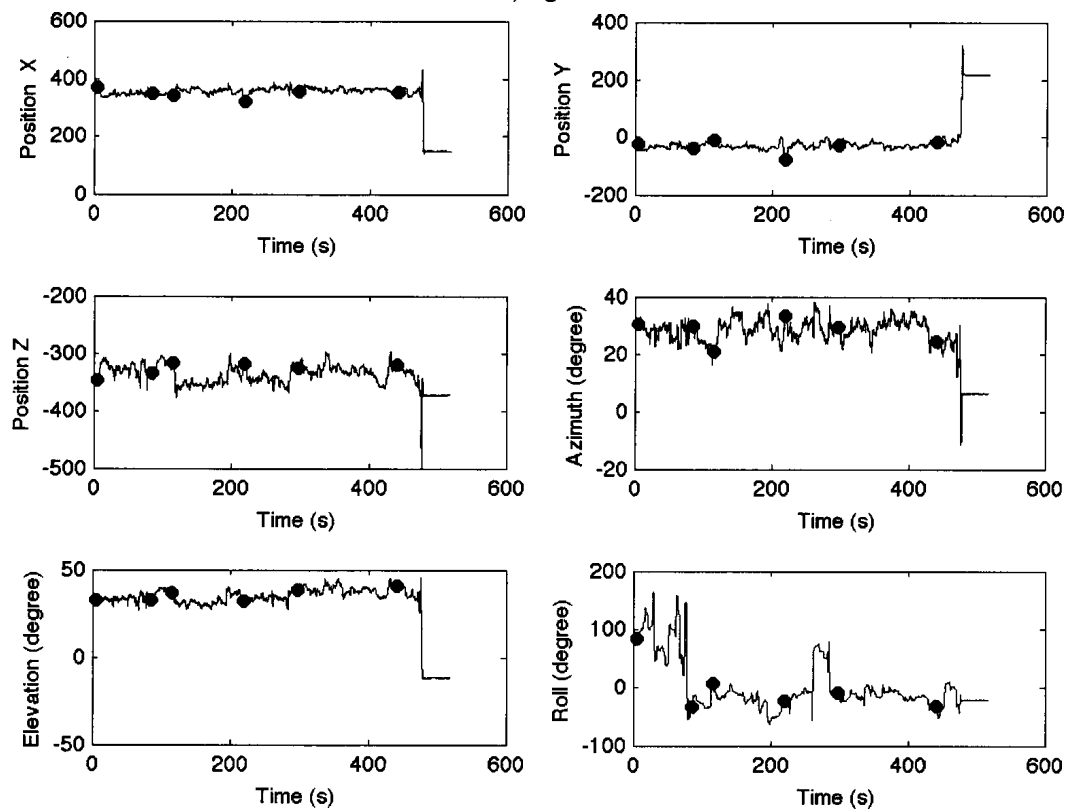
Case 6, Left: Position vs. Time

Position X

Position Y

Position Z

Azimuth (degree)

Elevation (degree)

Roll (degree)

Case 6, Right: Position vs. Time

Position X

Position Y

Position Z
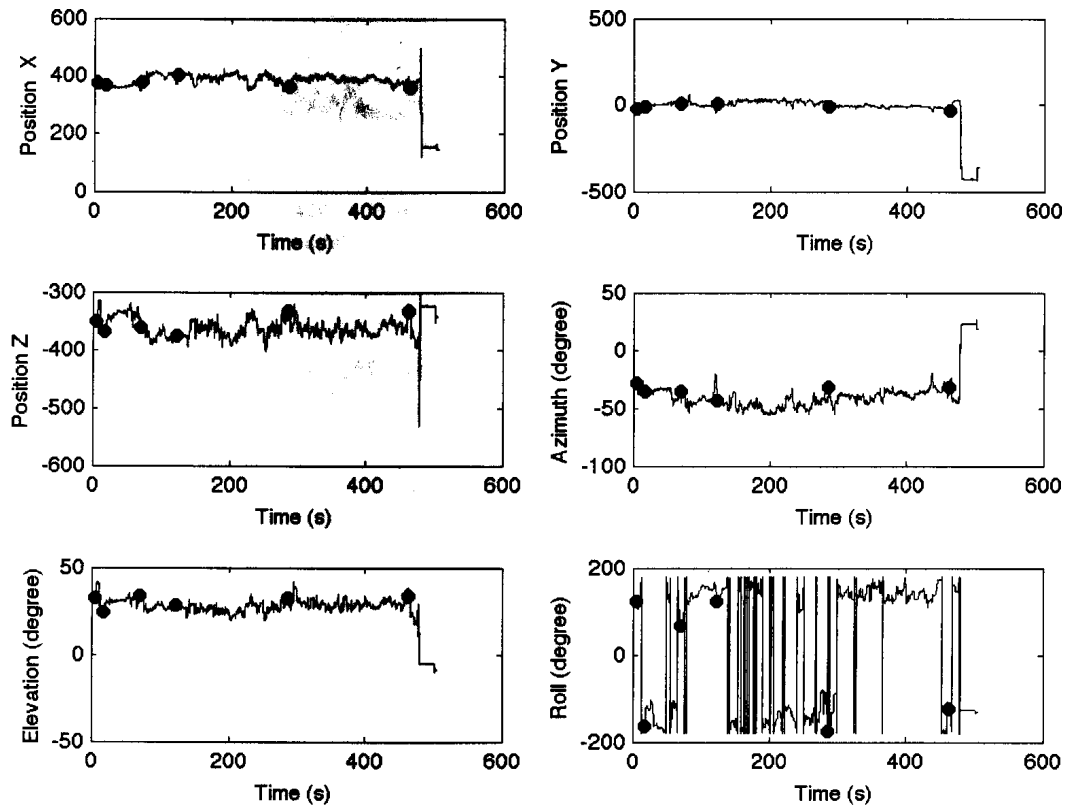
Azimuth (degree)

Elevation (degree)
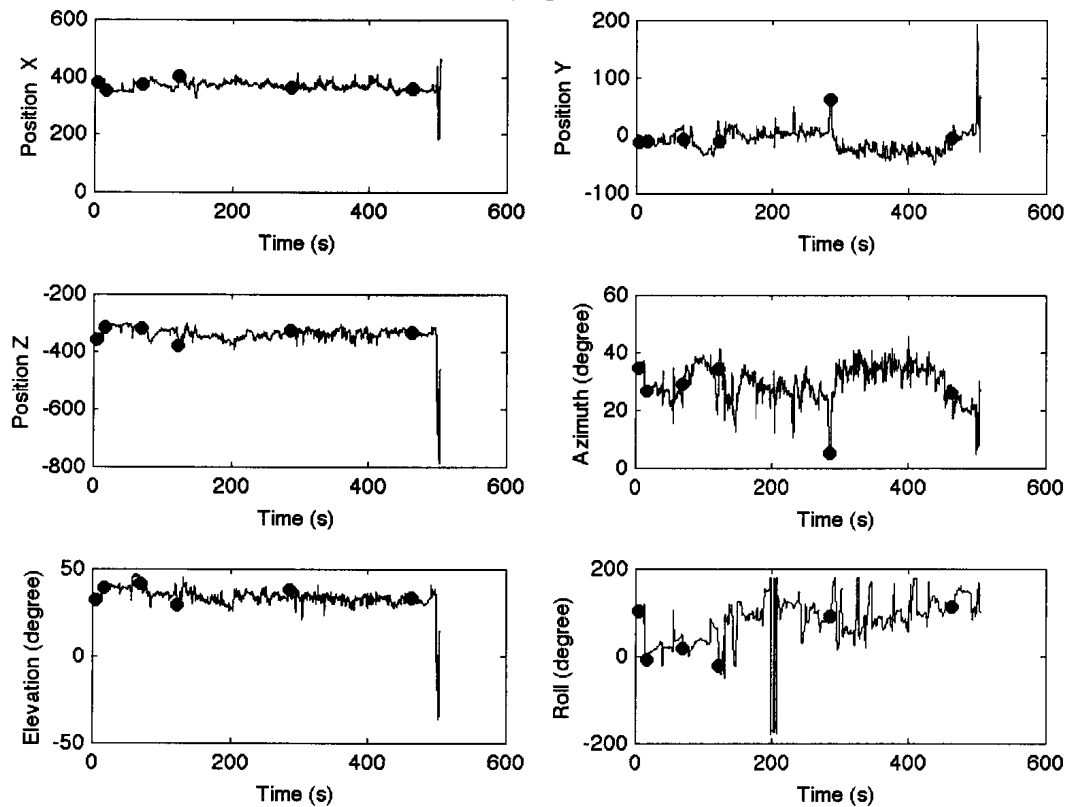
Roll (degree)

Case 12, Left: Position vs. Time
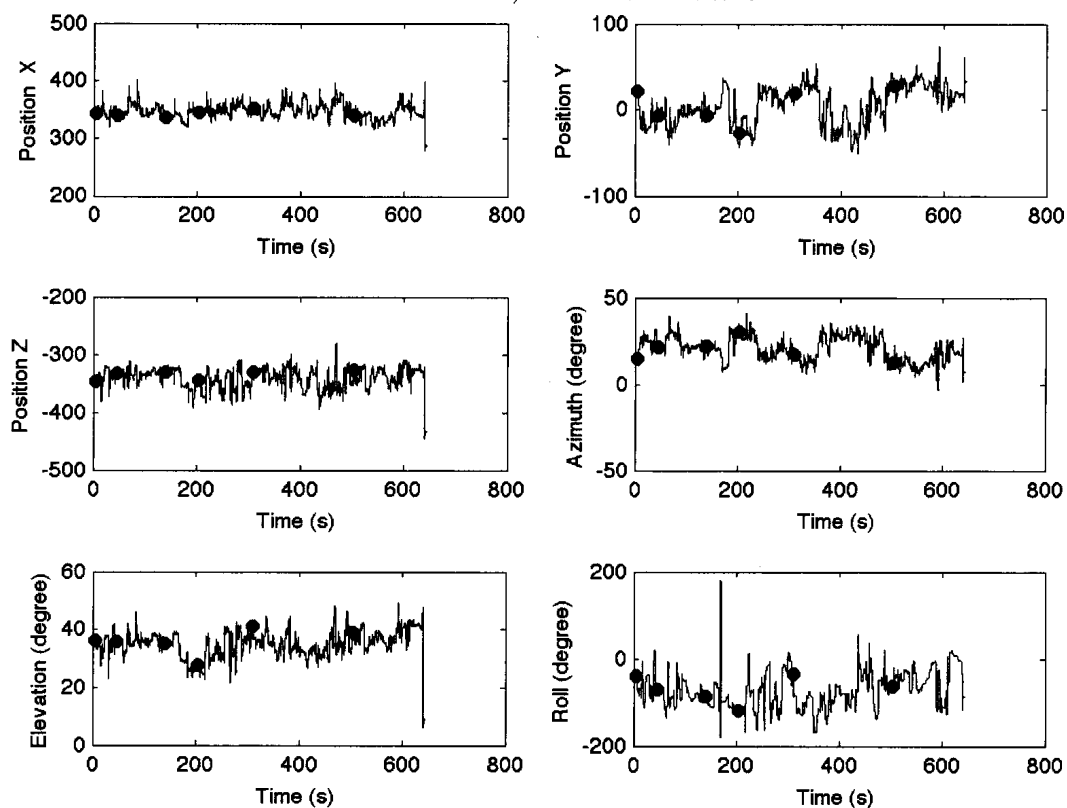

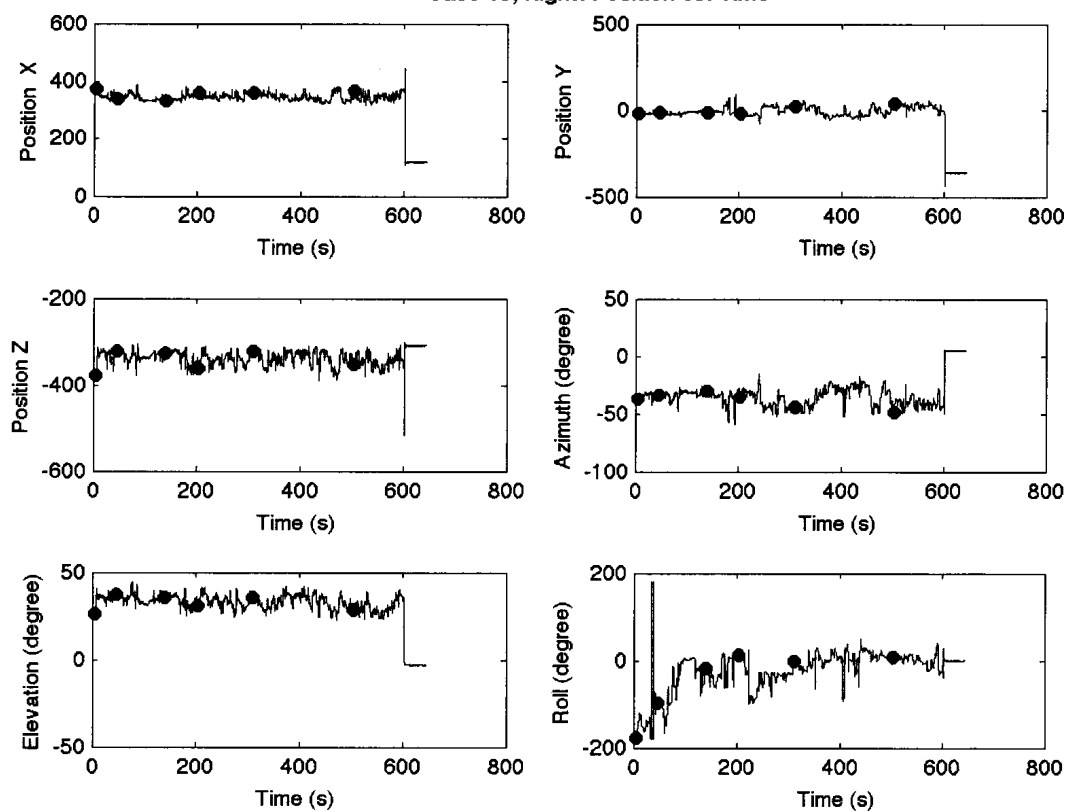**Case 12, Right: Position vs. Time**

Case 13, Left: Position vs. Time

Case 13, Right: Position vs. Time

Case 19, Left: Position vs. Time

Case 19, Right: Position vs. Time

Appendix 5: R.E.B. Approval

Office of Research Ethics

The University of Western Ontario
Room 00045 Dental Sciences Building, London, ON, Canada N6A 5C1
Telephone: (519) 661-3036 Fax: (519) 850-2466 Email: ethics@uwo.ca
Website: www.uwo.ca/research/ethics

Use of Human Subjects - Ethics Approval Notice

Principal Investigator:	Dr. R.V. Patel
Review Number:	15163E **Review Level:** Expedited
Review Date:	May 15, 2008
Protocol Title:	A Sensorized Instrument-Based Skills Assessment and Training System for Minimally Invasive Surgery
Department and Institution:	Electrical & Computer Engineering, University of Western Ontario
Sponsor:	NSERC-NATURAL SCIENCES ENGINEERING RSRCH COU
Ethics Approval Date:	May 30, 2008 **Expiry Date:** May 31, 2009
Documents Reviewed and Approved:	UWO Protocol, Letter of Information and Consent, Email Script
Documents Received for Information:	

This is to notify you that The University of Western Ontario Research Ethics Board for Health Sciences Research Involving Human Subjects (HSREB) which is organized and operates according to the Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans and the Health Canada/ICH Good Clinical Practice Practices: Consolidated Guidelines; and the applicable laws and regulations of Ontario has reviewed and granted approval to the above referenced study on the approval date noted above. The membership of this REB also complies with the membership requirements for REB's as defined in Division 5 of the Food and Drug Regulations.

The ethics approval for this study shall remain valid until the expiry date noted above assuming timely and acceptable responses to the HSREB's periodic requests for surveillance and monitoring information. If you require an updated approval notice prior to that time you must request it using the UWO Updated Approval Request Form.

During the course of the research, no deviations from, or changes to, the protocol or consent form may be initiated without prior written approval from the HSREB except when necessary to eliminate immediate hazards to the subject or when the change(s) involve only logistical or administrative aspects of the study (e.g. change of monitor, telephone number). Expedited review of minor change(s) in ongoing studies will be considered. Subjects must receive a copy of the signed information/consent documentation.

Investigators must promptly also report to the HSREB:
   a) changes increasing the risk to the participant(s) and/or affecting significantly the conduct of the study;
   b) all adverse and unexpected experiences or events that are both serious and unexpected;
   c) new information that may adversely affect the safety of the subjects or the conduct of the study.

If these changes/adverse events require a change to the information/consent documentation, and/or recruitment advertisement, the newly revised information/consent documentation, and/or advertisement, must be submitted to this office for approval.

Members of the HSREB who are named as investigators in research studies, or declare a conflict of interest, do not participate in discussion related to, nor vote on, such studies when they are presented to the HSREB.

Chair of HSREB: Dr. John W. McDonald

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