Title: Validating A Spinal Simulation Model Using NeuroVR

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Abstract

Introduction:

The NeuroTouch/NeuroVR simulator platform is a virtual reality simulator which has been used to compare the performance of expert surgeons to non-experts. Validation of NeuroTouch/NeuroVR is critical to the goal of using this simulator in neurosurgical training, evaluation and curriculum development.

Methods: This study was conducted to assess the performance of both neurosurgeon and resident groups performing a left lumbar one level hemilaminectomy using a simulated drill in the dominant hand and simulated suction in the non-dominant hand. Thirteen novel NeuroTouch/NeuroVR derived metrics for spinal simulation were assessed including simple metrics such as: blood loss (BL), percentage of L3 lamina removed (PLR), total tip path length for the drill and suction (TTPL), volume of ligamentum flavum removed (VLFR), sum of forces applied (SFA) of the simulated drill and suction and number of times the thecal sac was touched by an active drill. Other metrics including the suction efficiency index, drill path length index (DPLI) and coordination index (CI) were also assessed. A Likert scale was used to assess the face and content validity of the simulated tasks.

The hypotheses tested were: 1) that the novel performance metrics utilized would differentiate neurosurgical performance between neurosurgeon and resident groups and 2) that the simulated task assessed has face, content and construct validity.

Results: The simple metrics assessed did not show statistically significant differences in performance between neurosurgeon and resident groups except in the SFA by suction on the ligamentum flavum (neurosurgeons vs junior residents). Advanced metrics showed statistically significant differences in suction efficiency and drill path length indices between the neurosurgeon and senior resident groups. The metrics did not show any significant differences between resident groups. Likert scale evaluation showed the means of overall realism and satisfaction of 3 and 3.5 respectively, and 91.7 % of the participants recommended the use of the simulated task in the training program.

Conclusion: The NeuroTouch/NeuroVR platform utilizing the simulated spinal scenario and novel metrics differentiated the performance of expert and non-expert groups. The model demonstrated face and content validity. A number of limitations of the current model and the future improvements needed, are discussed.

Résumé

Introduction: La plateforme de réalité virtuelle en neurochirurgie NeuroTouch/NeuroVR est utilisée dans un contexte compétitif afin d'évaluer et de comparer la performance de neurochirurgiens experts à celle de non-experts. La validation du NeuroTouch/NeuroVR est essentielle afin d'utiliser la plateforme pour la formation, l'évaluation, ou le développement de cursus.

Méthodes: Cette étude a été conduite dans le but d'analyser la performance de groupes de consultants et de résidents effectuant une hémilaminectomie lombaire gauche avec, dans leur main dominante, un foret et dans leur main non-dominante, un aspirateur. Treize mesures inédites, en provenance du NeuroTouch, ont été analysées: perte de sang (BL), pourcentage de lame L3 retiré (PLR), longueur totale de la trajectoire du foret et de l'aspirateur (TTPL), volume du ligament jaune retiré (VLFR), somme des forces utilisées par la foret et l'aspirateur (SFA), nombre de fois où le sac thécal a été touché par le foret activé, indice d'efficacité de l'aspirateur, indice de longueur de la trajectoire du foret (DPLI), et indice de coordination (CI). Une échelle Likert a été utilisée pour évaluer la validité de l'opération simulée.

Hypothèses: les nouvelles mesures de performance peuvent-elles différencier la performance neurochirurgicale des experts de cieex qui n'nt pas cette expertise? L'opération simulée a-t-elle une validité apparente et de contenu?

Résultats: Nos analyses ont démontré que les mesures simples comparant la performance des experts aux autres n'étaient pas statistiquement significatives, sauf sans le cas de la somme des forces utilisées par l'aspirateur sur le ligament jaune (entre consultants et résidents juniors). Les

mesures complexes comparant les consultant's aux résidents seniors étaient significatives statistiquement dans le cas de l'indice d'efficacité de l'aspirateur, et de l'indice de longueur de la trajectoire du foret. Il n'y avait pas de différences significatives entre les résidents juniors et les résidents seniors, pour aucune des mesures. D'après l'échelle Likert, les sujets ont donné un note moyenne de 3 sur 5 pour le réalisme de la simulation, et de 3.5 sur 5 pour leur sentiment de satisfaction. 91.7% des participants recommandent l'utilisation de cette simulation dans un programme de formation.

Conclusion: Les mesures de performance, basées sur la simulation d'une opération chirurgicale sur les vertèbres de la plateforme NeuroTouch/NeuroVR, permet de différencier les experts des non-experts. La validité apparente et de contenu est confirmée, mais certaines lacunes du modèle actuel devront être corrigées dans les itérations futures.

Acknowledgements

This project has become a reality thanks to Dr. Rolando Del Maestro, my thesis supervisor and the Director of the Neurosurgical Simulation Research and Training Center at the Montreal Neurological Hospital and Institution and McGill University. Under his constant supervision and guidance, I was able to gain the knowledge to understand the NeuroTouch/NeuroVR simulation platform and other virtual reality simulators. His support started from the first day I considered doing a MSc. in surgical education in the Department of Experimental Surgery and has continued until the completion of the project.

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I would like to especially thank Dr. Fahad Al-Otaibi for his help in designing, gathering, analyzing and interpreting the data. His guidance helped me in all these aspects.

Doing a MSc degree while doing neurosurgery residence is not an easy decision. I do not think I could finish, or even begin, this research journey, without the support and understanding of my family and my treasured parents who taught me nothing is impossible if one truly believes in it. Special thanks to my beloved wife Hanan and my twins Ahmed and Mohammed, for their love and understanding.

Preface & Contribution of Authors

The structure of the thesis is manuscript-based, which is supported by the McGill University Faculty of Graduate Studies and research regulations for the "Guidelines for Thesis Preparation". The format of the manuscript-based thesis requires that the paper should have a cohesive, unitary character and a report of a single field of research.

The introduction of the manuscript has been expanded to help the reader appreciate the issues involved in expert performance.

The candidate functioned as the principal investigator for all aspects of study design, developing the algorisms for the simulation metrics utilized and extracting data from the simulator, interpretation of findings, and writing of this manuscript.

The co-authors of the manuscript were members of the Neurosurgical Simulation Research and Training Center at the Montreal Neurological Hospital and Institution.

Robin Sawaya helped in the development of the algorism utilized in obtaining the data from the NeuroVR platform.

Dr. Abdulgadir Bugdadi contributed through his neurosurgical knowledge and experience with the NeuroVR simulation platform.

Dr. Fahad Al-Otaibi having derived multiple metrics for the NeuroVR platform involving simulated brain tumor resection provided expertise in both designing metrics and in the analysis and interpretation of the data.

I am the candidate responsible for the scientific quality of the research, the accuracy of the data and the quality of reporting.

The information in this thesis includes all the data for submission of the manuscript for publication with possible consideration given to reducing the metric categories assessed.

Glossary

ACDF = Anterior Cervical Discectomy and Fusion

BL = Blood Loss

VR = Virtual Reality

NRC = National Research Council of Canada

OSCE = Objective Structured Clinical Examination

PLR = Percentage Lamina Removed

SFA = Sum of Forces Applied

VRLF = Volume Removed of Ligamentum Flavum

TTPL = Total Tip Path Length

EI = Efficiency Index

CI = Coordination Index.

PLI = Simulated Ultrasonic Aspirator Path-Length Index

L3 = Third Lumbar Spine

L4 = Fourth Lumbar Spine

LF = Ligamentum Flavum

N = Newtons

cc = cubic centimeters

mm = millimeters

Introduction

Simulation Historical Background

The roots of simulation training for complex tasks started in the commercial and military aviation industry. It was first utilized in 1910 when student pilots trained in land-borne aircraft with reduced wingspans. The first rudimentary simulator was available in 1929 and was known as the Links Trainer (Kelly et al., 1970). This simulator consisted of a wooden fuselage put on an air bellows, which was able to represent the movements involved in flight. Student pilots could train for extensive time periods without risk to personal safety or that of the aircraft. Following a series of aviation accidents, the US purchased six Links simulators in 1934. At the time it was recognized that the current training programs were inadequate and simulation was a step towards improving the training system. Simulation also was critical in World War II where many pilots had to be trained in short periods of time to high levels of proficiency. The factors of safety and time involved in reaching an adequate level of proficiency have pushed the development of multiple simulators for a variety of uses. The present highly sophisticated aeronautical systems of today can precisely replicate an aircraft environment and can duplicate a vast range of potential flight scenarios. The Federal Aviation Administration mandates that all certified pilots undergo ongoing annual training entitled "checking out" in order to ensure ongoing certification and for additional training to pilot other types of aircraft. Simulation is also an integral part of military and astronaut training.

Delp et al. (1990) created the first virtual reality (VR) surgical simulator. It was an orthopaedic lower limb model that simulated tendon transfer. Virtual reality technology has evolved to the point today where actual patient data and radiological images can be input into the simulator allowing for a complete simulated run-through before operating on the patient; a process known

as mission rehearsal. This technology has been embraced by many members of the surgical community who recognize the vast potential of simulation to revolutionize this field.

The Use of Simulators in Surgical Training

The introduction of virtual reality simulators has been one of the main innovations that has resulted in a change in training curricula in surgery. Virtual reality simulation in training programs was first recommended by Satava et al. (2006). Simulation in training surgical residents is growing in popularity and research applications. Several factors have favored the increasing use of surgical simulation, including mandated resident work-hour restrictions, growing demand for hospital efficiency, and a greater emphasis on patient-centered care with closer supervision by attending physicians. Additionally, there are concerns that the traditional Halstedian model of surgical mentorship may limit the efficiency of surgical skill acquisition in an era that residents are expected to master an unprecedented amount of knowledge (Bambakidis et al., 2013; Clarke et al., 2013; Parker at al., 2015). Simulation allows residents to gain skills in a risk-free environment. With surgical tasks that require the use of unique instrumentation, visualization methods, and ergonomics, simulation training should be beneficial in terms of improving resident operative performance. Furthermore, simulation affords an environment without time constraints and repercussions of error relating to surgical performance (Wiet et al., 2009). Haptic technology enhances virtual reality simulation by allowing for tactile sensation and feedback, which are critical elements in all surgical procedures (Cohen et al., 2013).

Assessment Tools of Surgical Technical Skills

Ericsson and co-workers defined expert performance as a laboratory technique, used to assess expertise in a simulated environment, which should mimic the real task as closely as possible (Ericsson et al., 1993). This implies, to mimic real life tasks, the simulated skill should be carried out under a controlled setting. Performing any technical skills in the real operating room under

specific conditions is a stressful and complex experience which can result in variable responses based on the operative situation that is being addressed. The ongoing introduction of new surgical technologies into the operating room makes it difficult to assess technical skills. Novel instruments are continually being introduced and operative procedures are constantly being modified (Reijnen et al.2005). This variability mandates that surgical educators need to develop and use more objective assessment tools that are reliable, reproducible and valid to assess trainee surgical skill acquisition and progress.

In the last two decades a number of tools have been created and validated to assess technical and cognitive skills.

In 1995 the Objective Structured Clinical Examination (OSCE) was introduced, followed by the Objective Structured Assessment of Technical Skills (OSATS), a global rating scale, McGill Inanimate System for Laparoscopic Skills, and the Imperial College Surgical Assessment Device (ICSAD) (Jansen et al., 1995; Martin et al., 1997; Regehr et al., 1998; Fried el al., 2004).

The broad criteria within each scale and rater subjectivity made the test-retest reliability very poor for these assessment tools. Dr. Gélinas-Phaneuf and Dr. Del Maestro (personal communication) failed to provide validity of a new global assessment scale for intraoperative neurosurgical skills (GOALS). This may have been due to variation in the type of neurosurgical procedures and the nature of the skills performed.

Reliability and validity are two important measures of a training and assessment tool. Reliability relates to the extent of reproducibility and consistency of an assessment tool when evaluating the same individual on different occasions in the same task and with no intervening learning. Validity is whether or not the tool measures what it intends to measure (Moorthy et al., 2004).

This concept is more complex since it includes face, content, construct, concurrent and predictive validities. Face validity is defined as the extent to which assessment conditions resemble a real life situation. Content validity is defined as the extent to which certain attributes being measured are measured by an assessment tool. Both face and content validity are usually measured by expert opinions using a questionnaire (Moorthy et al., 2003). Using face and content validity in the context of developing a new technology for training neurosurgical skill, presumes the technology is realistic and measures skills required for the specific activity or skill being assessed (Moorthy et al., 2003). Construct validity should establish correlation with operative experience and be able to discriminate between novice and expert performance. Concurrent validity is established when the scores from a new measurement procedure are directly related to the scores from a well-established measurement procedure for the same construct, that is, there is a consistent relationship between the scores from the two measurement procedures (Moorthy et al., 2003).

Spinal Surgery Education and Simulation

Spinal surgery education involving simulation can be conducted either by the method of simulation used (cadaveric, physical, VR, etc.) or by the specific procedure being simulated (pedicle screw fixation, laminectomy, dural repair, etc.).

Cadaveric Simulation

Cadaveric dissection has been used for spinal surgery education. Although over 80% of responding program directors reported using cadavers for teaching spinal approaches and instrumentation, descriptions of specific methods, procedures, and validation using cadavers in teaching spinal neurosurgery has not been commonly reported in the literature. Sheep, calf, and deer spines have been extensively used in simulation and resident education in spinal

neurosurgery (Anderson, 2011; Kalayci et al., 2005; Sheng et al., 2010; Suslu et al., 2012). A novel simulator for minimally invasive spine surgery (MISS) was reported by Walker et al. (2009). It was designed to teach residents important skills before application in the operating room. For this model residents reported increased mean confidence ratings for both minimally invasive laminectomy and pedicle screw placement after working with the simulator. Anderson et al, (2011), from the University of Wisconsin developed two spine simulation models: dural repair and laminoplasty. In the dural repair simulation, two Foley catheters are placed into the dural space and infused with saline to 90 mmHg pressure. After a resident performs a laminectomy, a midline durotomy is made which the resident must repair, with the quality of repair being assessed by the degree of water-tight closure. This is one of the fundamentals of spine surgery skills because failure to properly close an incidental durotomy may lead to prolonged bed rest and increased hospital costs. Residents may receive little intraoperative practice with this procedure before they themselves may deal with a dural tear in practice. The use of sheep spines for training in pedicle screw fixation, lumbar microdiscectomy, and percutaneous lumbar transforaminal epidural injection was reported recently by Suslu et al. (2012, 2014).

Physical (Synthetic) Simulation

There are several physical or synthetic methods used for skills training. The use of manikins was one of the first methods used to teach cardiopulmonary resuscitation and airway management (Singh et al., 2013). Synthetic spinal surgery simulators involving advanced three-dimensional utilizing computed tomography (CT) scans (3D) printing have been introduced. One of these synthetic simulators has been developed by the Department of Neurosurgery at the University of Illinois where it is used for pediatric lumbar spine pathologies like tethered cord syndrome and

open neural tube defects. The simulator is designed to incorporate different types of material that mimic the tensile properties of actual tissue. In addition, the simulator is modular in nature to allow for the replacement of certain layers that are eventually disrupted and destroyed with repetition (Mattei et al., 2013).

Anterior cervical discectomy and fusion (ACDF) is a common neurosurgical operation and simulating this procedure would be very useful. At the Congress of Neurological Surgeons (CNS) meeting in 2012, an ACDF simulator was shown (Ray et al., 2013). This simulator is comprised of a mix of silicone compounds to emulate the tissue in the anterior cervical region, and a polyurethane mix for vertebrae, ligaments, and discs. Actual cervical screws and plates are used to perform the procedure, and the spine portion of the simulator can be removed and replaced after each use.

Virtual Reality Simulation:

Virtual reality (VR) simulators have the potential to become a central component of resident education and have the possibility to transform the training of future surgeons. One of the earliest VR spine simulators was developed by Kockro et al. (2000). An ImmersiveTouch® spinal simulator developed by the University of Chicago (Gasco et al., 2014; Luciano et al., 2011; Luciano et al., 2013) is one of the most studied spine simulators. Several spinal procedure scenarios are simulated by this platform including: percutaneous lumbar puncture, Jamshidi needle biopsy, thoracic and lumbar pedicle screw placement, percutaneous spinal fixation, and vertebroplasty. The manufacturer has also reported that several other procedures are under development, including anterior cervical discectomy, lateral mass fixation, lumbar laminectomy, lumbar microdiscectomy, C1-2 transarticular screw fixation, pelvic fixation, and minimally invasive direct lateral interbody fusion. Another simulator called the Dextroscope has been

developed in Singapore in 2013 (Ferroli et al., 2013; Gu et al., 2011; Kockro et al., 2013). This simulator focuses on preoperative planning, allowing surgeons to visualize patient-specific anatomy in a 3D environment through the creation of a virtual surgical field. At the Mayfield Village in Ohio the Surgical Rehearsal Platform (SRP) was developed for spinal neurosurgery simulation. This model also assists in pre-operative planning through an interactive 3D setting (Bohm and Arnold, 2015).

Pedicle screw placement is a crucial step in spine surgery as misplacement can cause damage to neighboring neural and vascular structures, and a working knowledge of complex 3D anatomy is necessary for proper screw alignment and trajectory. Wang et al. (2010), reported a 15% misplacement rate among neurosurgical residents inserting freehand thoracic pedicle screws. Simulated pedicle screw placement can aid residents in mastering this complex procedure. Rush et al. (2008) described a computerized simulator for sacroiliac screw insertion. The visualization of the 3D reconstruction of the pelvis aids in the use of the appropriate screw size and its trajectory. Liu et al. (2011) utilized 3D reconstruction model technology for the craniocervical junction, which helped to simulate and better understand the trans-oral and posterior-lateral approaches to the superior cervical spine. Malone et al., authors of a 2010 review of VR simulation in neurosurgery, have begun to develop a simulator for instrumented lumbar fixation, which includes pedicle cannulation, internal pedicle fixation, and screw insertion.

Combined (Mixed) Simulation:

Combinations of the aforementioned methods of simulation have been described in the literature (Halic et al., 2010; Bova et al., 2013; Chitale et al., 2013; Harrop et al., 2013). These simulators combine at least two models of simulation in order to take advantage of the respective strength of

each. Bova et al. (2010) describe their experience with mixed simulation and spinal instrumentation. They described the development of the simulator and stress the importance of taking steps to emulate the environment of the operating room during simulation, including surgical drapes, C-arm footswitches, and overlying soft tissues in the physical model. At the 2012 CNS annual meeting, a novel cervical spine simulator for teaching both posterior foraminotomy and laminectomy was presented by Harrop et al. (2013). Collaborating with Phacon Corporation (Leipzig, Germany) the authors, using 3D printed cervical spines, special tools that could be tracked via a standard webcam for intraoperative navigation, and pressure sensors, created their simulator platform. Chitale et al. (2013) reported a simulator for minimally invasive percutaneous pedicle screw placement that utilized both fluoroscopic and CT-navigated components.

Simulated Bone Drilling

Bone drilling procedures are essential in many surgical specialties such as neurosurgery, orthopedic, dental, maxillofacial and ear, nose and throat (ENT) surgery. Accurate control of the drilling force is a crucial step to bone drilling success. The training of novices in bone drilling skills is an important step in acquiring this technical expertise. Synthetic bone and animal bones have been primarily used for teaching these skills (Sheng et al., 2010). These methods have many of the same limitations as cadaveric systems.

Bone drilling using virtual reality simulators can provide tactile, visual and audio sensations which recreate realistic training scenarios (Coles et al., 2011; Hamza-Lup et al., 2011; Wan et al., 2010; Zirkle et al., 2007).

A number of virtual reality simulators have been developed for different surgical procedures. ENT trainers have been validated for use in the simulation of temporal bone dissection (Wiet et

al., 2009; Wan et al., 2010). Their studies demonstrated that virtual representations were capable of providing introductory training equivalent to cadaveric models. This simulator is currently being used to conduct a multiple institution, randomized, controlled trial to evaluate its efficacy for use in training, specifically in the integration of standardized metrics and automated assessment of performance. Another group has validated virtual reality simulators used for skull base visualization, functional endoscopic sinus surgery and temporal bone surgical simulation, more specifically, for drilling a complete mastoidectomy using a facial recess approach. Prevedello et al. (2011) developed a virtual reality simulator for skull base approaches such as pterional, pre- and retrosigmoid. The future plans are to expand to more complex approaches like the orbitozygomatic and far lateral craniotomies (Prevedello et al., 2011; Stredney et al., 2013; Thawani et al., 2006).

Bone drilling in spine surgery is a fundamental step in most spine surgical approaches. Performing a laminectomy is a common drilling procedures done daily in spinal surgery and it is the gate of entry for most of the approaches for spinal procedures such as discectomy, spinal decompression with/without fusion and also for spinal tumor resections. In this study we are testing laminectomy skills using the virtual reality simulator (NeuroVR) platform.

Manuscript: *Validating A Spinal Simulation Model Using NeuroVR*

Introduction

The scientific description of 'experts' was first elucidated when Francis Galton, in his book called *Hereditary Genius,* described extraordinary innate abilities (Ericsson et al., 2009). Recent research

suggests that expert superior performance is acquired through learning and adaptation being impacted by goal oriented practice with only a limited role for hereditary abilities (Ericsson et al., 1993). Innovation in surgical procedures and technology combined with the need to enhance patient safety, limited operating room resources and decreased resident work hours has mandated the development of simulation technology to improve the surgical education experience (Fried et al., 2004, Gelinas-Phaneuf and Del Maestro, 2013).

The expert-performance model developed by Ericsson and colleagues comprises three crucial stages and strives to identify the mechanisms mediating expert-performance (Ericsson et al., 2009). Their goal was to aid in curriculum design to ultimately improve the ability to produce and maintain expert performance. The first stage requires the identification of representative tasks of expert-performance and their replication within a controlled laboratory setting. The second stage describes the empirical analysis to identify the mechanisms underlying an expert's superior performance. The last stage examines the effect of a specific practice activity to elucidate factors that may influence the acquisition of these expert-performance mechanisms.

Since perceptual-motor tasks can be designed to capture the essence of specific surgical tasks (Ericsson et al., 2003), simulators lend themselves well to applying Ericsson's expert-performance approach for they allow measurement and empirical analysis of representative tasks in a controlled setting (Ericsson et al., 2009; Reznick and MacRae., 2006). Simulation in surgical training offers low-stakes, learner-centered education, with task-based simulation allowing beginners to acquire the fundamental skills prior to their clinical experience through practice in a safe environment. Simulator practice allows repetition of a task that can be interrupted as needed, providing an opportunity for immediate feedback. Through retrospective analyses of recorded performance, simulator-based assessments may reveal performance aspects that need more training to be improved (Ericsson et al., 2003). In this sense, simulation also provides an opportunity for objective skills assessment

(Kneebone et al., 2004) through validated performance metrics (Fraser et al., 2003). Performance in certain simulators correlates with intraoperative performance (Fried et al., 2004; Dawe et al., 2014) and simulator training can improve both initial technical performance (Park et al. 2007) and its maintenance (Seymour et al. 2002). Simulators thus provide a good platform for both implementing deliberate practice, potentially improving clinical performance and measuring this impact.

Research from the surgical literature relies upon expert and novice performance analysis utilizing a variety of different simulators. The National Research Council of Canada (NRC) in collaboration with different universities across Canada has developed the NeuroTouch, now called NeuroVR, which is a virtual reality simulation platform with haptic feedback used for neurosurgery and ENT surgical residency and training assessment. (Alotaibi et al., 2015; AlZhrani et al., 2015; Azarnoush et al., 2015; Azarnoush et al., 2016; Bajunaid et al., 2016; Choudhury et al., 2013; Delorme et al., 2012; Gélinas-Phaneuf et al., 2014; Rosseau et al., 2013; Varshney et al., 2014).

The simulator (Figure 1) consists of a microscope and handles which use different surgical tools required to perform the surgical task. The realism of the simulator is derived from its accurate 3D anatomical display of the tissue and its haptic feedback. This gives the operator sensorial cues as to the targeted tissue and feedback on how to manipulate these tissues and how much can be removed. A number of studies have been carried out to validate the NeuroTouch/NeuroVR simulator platform (Gélinas-Phaneuf et al., 2014; Alotaibi et al., 2015; Azarnoush et al., 2015). The assessment metrics used to measure user performance were categorized into three tiers: tier 1, tier 2 and advanced tier 2. Each metric was also categorized based on safety, quality and efficiency (Alotaibi et al., 2015; Azarnoush et al., 2015).

The hypotheses tested in this study are:

(1) that the simulated spinal operative task differentiates 'expert' (neurosurgeon) from 'non-expert' (resident) performance, and

(2) that the simulated task assessed has face, content and construct validity.

Methods

The study was conducted at the Neurosurgical Simulation Research and Training Centre at McGill University. The previously described NeuroVR (formerly NeuroTouch) platform was used to conduct the study. (Alotaibi et al., 2015; AlZhrani et al., 2015; Azarnoush et al., 2015; Azarnoush et al., 2016; Bajunaid et al., 2016; Choudhury et al., 2013; Delorme et al., 2012; Gélinas-Phaneuf et al., 2014; Rosseau et al., 2013; Varshney et al., 2014; Winkler-Schwartz et al. 2016). Laminectomy was performed using a simulated drill held in the dominant hand and suction in non-dominant hand (Figure.1).

All participants in the study signed an approved McGill University Ethics Review Board Consent (Appendix A).

Subjects

Nineteen individuals, 7 Board Certified spine surgeons, 6 senior (5-neurosurgey and 1 orthopedic, PGY 4-6) and 6 junior residents (PGY 1-3) participated. Demographic data included age, sex, handedness, number of spine (lumbar-cervical) cases assisted or performed, use of drill or up biter while doing a laminectomy and surgical simulator experience (Appendix B).

After the completion of the virtual reality tasks, each participant evaluated face and content validity on five criteria using a Likert scale questionnaire (1 indicates strongly disagree, and 5 indicates strongly agree). The criteria included: task difficulty, visual realism, sensory realism, overall satisfaction, and use of NeuroTouch/NeuroVR as a training tool (see Appendix C).

Simulation Scenarios

The goal for the participants was to use a simulated drill tool in the dominant hand to drill away the L3 left lamina without removing the spinous process, the facet, or injuring the surrounding tissue. A simulated suction was used in the non-dominant hand to control simulated bleeding. Instrument intensities were controlled and set at constant values. The participants were given 5 minutes to complete the task since in a number of preliminary trials this amount of time allowed all participants despite their level of training to finish the trial. Standardized instructions regarding the aim of the operative task and how to start the scenario were given to each participant at the beginning of the trial (see Appendix D). To start the simulation, the participant touched a virtual START button with the tips of both the virtual reality drill and suction. On completing the drilling, the participant would touch the virtual STOP button using the tips of both instruments. The participants were not aware of the metrics to be used to assess their performance.

Metrics:

Alotaibi et al. (2015) validated multiple performance assessment metrics using the NeuroVR platform to resect virtual reality brain tumors. We redeveloped these metrics to be used in the current model. The metrics were divided into 3 tiers: tier 1, tier 2 and advanced tier 2. Each one of the metrics in the 3 tiers was further categorised to assess the quality, safety and efficiency components of the procedure (Figure 2).

Tier 1

Amount of Blood Loss (BL): This metric provides a volume measurement in cubic centimeters (cc) of blood loss during the drilling of the lamina. The goal for the participant is to remove

simulated lamina with minimum blood loss. Increased amount of blood loss is an unwanted outcome and an inverse measure of patient safety.

Percentage of Lamina Removed (PLR): This metric provides a measurement of the percentage of the simulated lamina which has been removed by drilling. The goal for the participant is to use the drill in the dominant hand and only remove the left L3 lamina.

Sum of Forces Applied (SFA): The sum of all applied force (in Newtons) during the simulated operation is used as a measure of overall applied force employed by each instrument (drill and suction). The goal for the operator is to use the most appropriate and safe applied forces during the drilling.

Volume Removed of Ligamentum Flavum (VRLF): This metric provides a volume measurement in cubic centimeters (cc) of simulated ligamentum flavum removed during drilling. The goal for the operator is to remove no ligamentum flavum during the procedure. This metric is therefore a direct measure of potential tissue injury and thus an inverse measure relating to patient safety.

Tier 2 Metrics

This category of metrics is divided into two subgroups: tier 2 and advanced tier 2. Both of these tier 2 metrics focus on the safety and efficiency of the operator. Advanced tier 2 tests complex psychomotor and cognitive neurosurgical skills such as the operator decision-making ability as related to surgical judgment and its execution efficiency, two hands coordination interaction and the efficiency in using the simulated instrument.

Tier 2

Number of Times Thecal Sac Touched by Simulated Active Drill or Suction: This metric assesses the safety of using the two simulated instruments while working close to the simulated thecal sac.

Total Tip (Simulated Drill and Suction Instrument) Path Length (TTPL): The length of the path traversed by the tip of the instrument tool measured in millimeters (mm) is used as a metric to assess the efficiency of the tool usage. The goal for the operator is to carry out the drilling using the most efficient and safe path trajectory.

Advanced Tier 2

Efficiency Index (EI): Efficiency index is defined as the percentage of time an operator spends actively drilling the lamina divided by the total time for the task. The goal for the operator is to use the tool as efficiently as possible without any unnecessary pauses. This metric focuses on the cognitive–motors skills interaction, concerned with decisions related to next step planning while carrying out the current step.

Coordination Index (CI): The goal of this metric is to measure how efficient the operator is in introducing the simulated suction in the surgical field while performing the drilling using the simulated drill. It is calculated as percentage of time the suction instrument is used simultaneously with the drill divided by the time the suction instrument is used overall.

Simulated Ultrasonic Aspirator Path-Length Index (PLI): This is defined as the percentage of the simulated drill TTPL spent in the simulated surgical field divided by the overall ultrasonic aspirator TTPL assessing efficiency of instrument use.

Method of Statistical Analysis

All statistical analyses were performed using JMP version 13. Non parametric multiple comparisons were carried out using Dunn's Test with control for joint ranks. Values are represented as means ± SEM and p values < 0.05 were considered significant.

Results

Demographics

The demographic data of the 19 participants, 7 spine surgeons, 6 senior (PGY4-6) and 6 junior residents (PGY1-3), involved in this study from 3 institutions can be seen in Table 1. Fifteen participants (79%) were males. Mean age for all participants was 36.8 (neurosurgeons (47), residents (31). All the neurosurgeons were right handed, 56% commonly use a drill in performing a laminectomy and 85.7 % had used the NeuroVR simulator previously. Nine (75%) of the residents were right handed, 2 (16.7 %) left handed and 1 (8.3 %) ambidextrous. Eight (66.7 %) residents had used the NeuroVR simulator previously and 41% had experience using the drill during laminectomy procedures. The Likert questionnaire measured NeuroVR experience satisfaction, NeuroVR as a training tool, and task visual and tactile realism (Table 2). All the participants completed the post simulation assessment with above-average scores for each item and 91.7% of the all participants strongly felt the NeuroVR system would be useful for training spine surgical skills.

Metrics Analysis Assessment and Differentiation of the Performance Between Participant Groups

Tier 1 Analysis

There was no statistical difference in the performance between the neurosurgeons and the senior resident group. Neurosurgeons applied more sum of forces by the suction on the ligamentum flavum than both resident groups but this was only statistically significantly for the junior residents (Figure 3D).

Blood Loss: The mean blood loss by neurosurgeons was 0.11 cc ± 0.06 which was more than that seen in the senior 0.08 cc ±0.08 and junior residents 0.04 cc ± 0.01 (Figure 3A).

Percentage of L3 lamina removed*:* Figure 3B shows the mean percentage removed of L3 lamina 35 ± 5% by neurosurgeons and 24 ± 4% and 33 ± 4% by senior and junior residents respectively.

Volume of ligamentum flavum removed (VLFR) between L3-L4: Figure 3C shows that neurosurgeons removed 0.21 ± 0.08 cc and junior residents 0.14 ± 0.03 cc of ligamentum flavum while senior residents removed the lowest amount 0.08 ± 0.02 cc.

Sum of forces (SFA) applied: Figure 3D shows the mean SFA by the suction on the ligamentum flavum by neurosurgeons was 167.4 ± 35.0 N. This was more than senior residents 65.3 ± 18.3 N and statistically significantly higher than the junior resident group, 56.2 ± 21.8 N. The SFA when using the drill on the L3 lamina and ligamentum flavum by the neurosurgeons (26.9 ± 5.0 N and 133.9 ± 12.6 N) and junior residents (23.6 ± 4.2 N and 126.8 ± 7.8) was more than the SFA by the senior residents (18.0 ± 4.9 N, 112 and 4.0 ± 23.4) as showed in figure 3 E-F respectively.

Tier 2 Analysis

One of the important safety metrics, the mean number of times the thecal sac was touched by an active drill, was higher in the resident groups (senior 47.3 ± 24.0, junior 44.2 ± 11.8) compared to the neurosurgeon group (31.6 ± 17.9). The mean number of contacts with the thecal sac by the suction was higher in the neurosurgeon group (39.1± 16.3) compared to senior (21.8 ± 9.6) and junior resident (22.8 ± 1.0) groups. (Figure 4 A-B). Figure 4C shows that the TTPL for the simulated drill of senior residents was the shortest (2764.7 ± 657.0 mm) compared to the neurosurgeon (3571.5 ± 512.5 mm) and junior resident (3366 ± 974.2 mm) groups. The TTPL of the suction was longer in the resident groups (seniors 1712.0 ± 457.2 mm) and (juniors 1738.5 ± 473.2 mm) compared to the neurosurgeon group (1571.0 ± 304.2 mm) as seen in Figure 4D.

Advanced Tier 2 Analysis

A number of the advanced tier 2 metrics (efficiency index, drill path length index and coordination index) were measured and showed that neurosurgeon group was on average more efficient compared to the resident groups (Figure 5A-C). Efficiency and drill path length indices showed statistically significant differences between the neurosurgeon group (71.5 ± 3.0 % and 69.0 ±3.1 mm) and the senior resident group (50.3 ± 3.8% and 43.6 ±7.6 mm) (Figure 5A-B). There were no statistically significant differences in the coordination index (Figure 5C) but a similar trend was seen. There were no statistically significant differences in any of the advanced tier 2 metrics measured between the two resident groups.

Discussion

Summary

Our group has developed and assessed several metrics to define expert surgical psychomotor performance during virtual reality tumor resections utilizing the NeuroVR platform (Alotaibi et al.,

2015; Azarnoush et al., 2015). Based on these studies a number of new novel metrics have been developed to assess the use of a virtual drill and sucker while performing L3 hemilaminectomy. Our results demonstrate face, content and construct validity of the spinal simulation model assessed. Our findings also demonstrate that for some advanced tier 2 metrics including efficiency index and drill path length index, we can differentiate the performance of 'expert' (neurosurgeon) from non-expert (senior and junior resident groups). As was shown in a series of studies involving the simulated resection of virtual reality tumors advanced tier 2 metrics are most useful in assessing 'expert' performance (Alotaibi et al., 2015; AlZhrani et al., 2015; Azarnoush et al., 2015; Azarnoush et al., 2016; Bajunaid et al., 2016). Our results support these findings.

Spine Surgery and Current View of Spinal Surgery Simulation

Lumbar laminectomy is a common operation performed for decompression or arthrodesis for a variety of indications and it is one of the demanding spinal procedures utilized in the daily practice of neurosurgeons. Lumbar laminectomy requires the trainee to gain proficiency in multiple areas, including understanding natural tissue planes, appreciating the variable tolerance of structures to manipulation and retraction, achieving hemostasis, and protection of the neural elements. All trainees are required to acquire these skills. Laminectomy exposure is a relatively simple surgical technique that will aid in developing the requisite skill to perform the more advanced types of spinal procedures such as those with and without fusion. Laminectomy involves many posterior approaches for spinal procedures. Being safe and efficient in performing this procedure is an important acquired skill for the neurosurgical or orthopedic trainee. Implementation of neurosurgical simulation in residency training is in an early stage. Multiple reports on neurosurgical simulation models have provided evidence that repetitive exposure and learned psychomotor skills reliably transfer to improve the workflow in real surgical procedures. These studies have demonstrated good construct and concurrent validity (Chan et al., 2013;

Ganju et al., 2013; Seymour et al., 2002; Thawani et al., 2016; Stredney et al., 2013). Previous spine surgical simulators have focused largely on techniques for posterior thoracolumbar spinal instrumentation while this study focuses on the basic posterior approach of spine surgery

Face and content validity help to establish an empirical foundation for a concept instrument, e.g., the NeuroVR simulator. Many studies have been conducted to validate different virtual reality systems as tools for training surgeons in different specialities (Bova et al*.,* 2010; Harrop et al., 2013). These studies also demonstrated face and content validity for these systems. In the NeuroVR spine model we assessed thirteen metrics used to demonstrate face and content validity.

Current NeuroVR spine model and its limitations

This study demonstrates that the NeuroVR virtual reality simulator discriminates among participants in this simulated spinal procedure utilizing some advanced tier 2 metrics such as efficiency and drill path length indices but not the other tier 1 and tier 2 metrics assessed. This establishes construct validity for the spine scenario model assessed.

There was a trend for neurosurgeons to touch the thecal sac less frequently with the drill (Figure 4A), However, neurosurgeons contacted the thecal sac more frequently with the suction (Figure 4B) and applied significantly greater sum of forces on the ligamentum flavum with the suction than the junior residents (Figure 3D). Although these results were not statistically significant for the frequency of touching the thecal sac by the drill it does suggest that neurosurgeons are more aware of the risks of interaction of the thecal sac by the drill while contact with the sucker with the thecal sac and ligamentum flavum may be less of a concern.

The NeuroVR virtual reality neurosurgical platform does not represent the multifaceted situations encountered in the operating room during complex spinal procedure as elucidated below:

First, to help assess the participants' surgical performance, a series of variables including instrument intensities and instruments used were held constant. Participants were not allowed to change microscope positions or the operative view. The model studied did not account for the range of adjustments available to a neurosurgeon during a spinal operative procedure. The participants commented that the differentiation between the lower portion of the lamina and ligamentum flavum was not fully represented in the model. This deficiency compromised the ability of operators to assess the depth of the field and may have impacted their ability to differentiate different structures. The five-minute time allotment only represents a small portion of the time involved in a real spinal operative drilling task. Although the majority of the participants had been exposed to the NeuroVR platform, some had not, and this may have led to the large amount of variability found within and obscured any statistically significant differences between the junior and senior residents. Even though neurosurgeons and residents from three institutions were assessed, the small number of participants may be another reason for the inability to find more significant differences between groups. The small sample size makes it difficult to extrapolate our results to other populations. These concerns are presently being addressed in a study that includes a greater sample size and with participants from multiple institutes.

This study did not test the full range of skills and knowledge required to perform this specific task as suggested by some participants about increasing the haptic feedback of both the lamina and the ligamentum flavum, adding the possibility of a cerebral spinal fluid leak if the thecal sac was damaged. The ability to change instruments from a drill to a Kerrison rongeur and to use micro dissecting instruments were felt to be important additions to further spine scenario development. Despite these limitations, the initial experience with this model was positive with

overall satisfaction of the simulated task and 91.7% of the participants recommended the incorporation of the simulator into the neurosurgical training.

Overall Conclusions and Future Directions

Conclusions

The tier 1 and tier 2 metrics assessed in this study did not show statistically significant differences in the performance between neurosurgeon and residents groups, except the SFA by suction on the ligamentum flavum (neurosurgeons vs junior residents). Statistically significant differences in suction efficiency and drill path length indices were demonstrated between the neurosurgeon and senior resident groups. Between resident groups, metrics assessed did not show any statistically significant differences. Likert scale summary showed the means of overall realism and satisfaction of 3, 3.5 respectively and 91.7 % of the participants recommended the use of the simulated task in the training program.

Future Directions

Working in conjunction with both National Research Council (NRC) of Canada and the AO Foundation, we are developing a virtual reality scenario for teaching transforaminal lumbar interbody fusion (TLIF). In association with this scenario, our group is developing a series of new metrics to better assess a hemilaminectomy, facet drilling, discectomy and insertion of an interbody graft. Care is being taken to incorporate the comments of all the participants in this study including the development of the different instruments with improved anatomical and haptic feedback with the scenario of cerebrospinal fluid leak.

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Figures

Figure 1

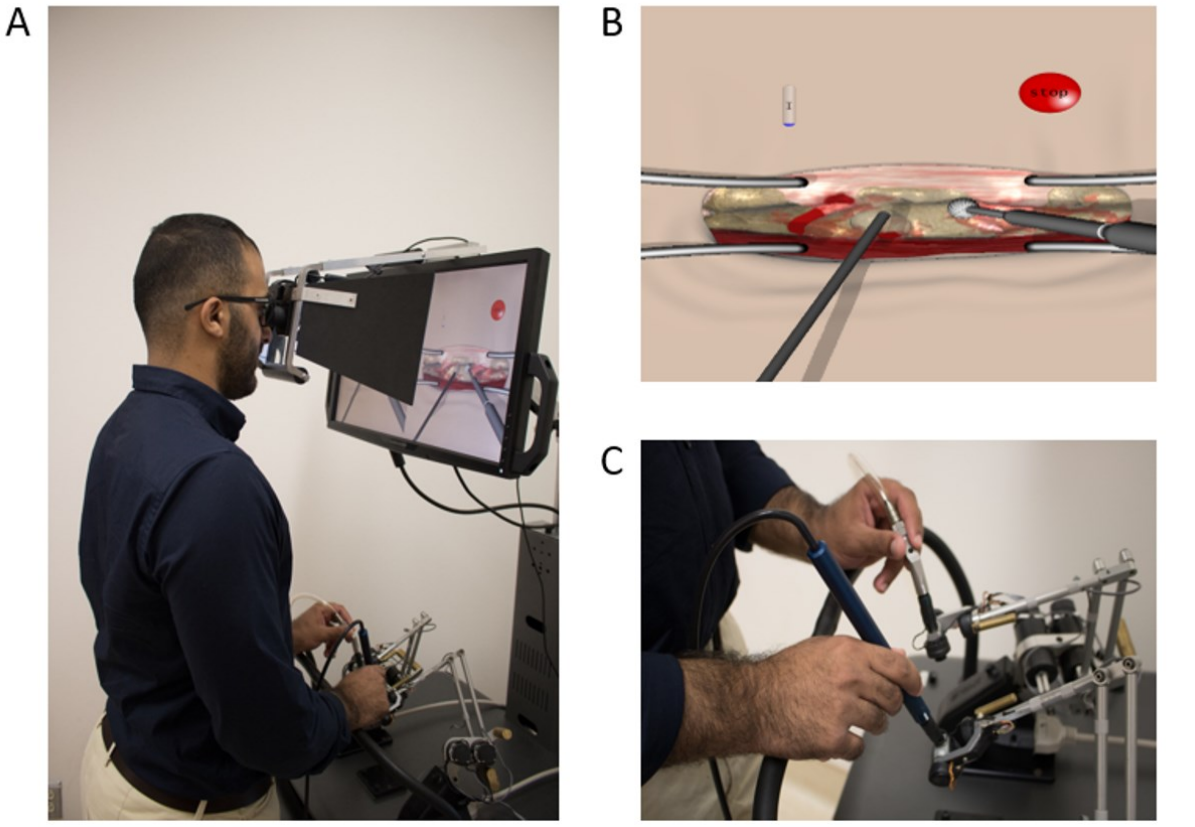


Figure 1: (A) The NeuroVR Simulation Platform. B) View of the operating scene. (C) Participant hand positions using a simulated drill in the right hand and sucker in the left.

Figure 2. Organization of the metrics based on their safety, quality and efficiency

Tier 1	Tier 2	Advance Tier 2
Percentage Removed of L3 lamina	Total Tip Path Length – Suction	Efficiency index (EI)
Sum of forces applied by drill on L3 lamina		
Volume Removed Flavum Ligament between L4 and L3	Total Tip Path Length – Drill	Coordination Index (CI)
Sum of forces applied by suction on Ligamantum Flavum		
Sum of forces applied by drill on Ligamantum flavum	Number of times thecal sac touched by active drill	Drill Path Length index (PLI)
Total Blood Loss	Number of times thecal sac touched by suction	

Safety	*Quality*	*Efficiency*
Sum of forces applied by drill on L3 lamina	Percentage Removed of L3 lamina	Efficiency index (EI)
Volume Removed Flavum Ligament between L4 and L3		Coordination Index (CI)
Sum of forces applied by suction on Ligamantum Flavum		Drill Path Length index (PLI)
Sum of forces applied by drill on Ligamantum Flavum		Total Tip Path Length – Suction
Total Blood Loss		
Number of times thecal sac touched by active drill		Total Tip Path Length –Drill
Number of times thecal sac touched by suction		

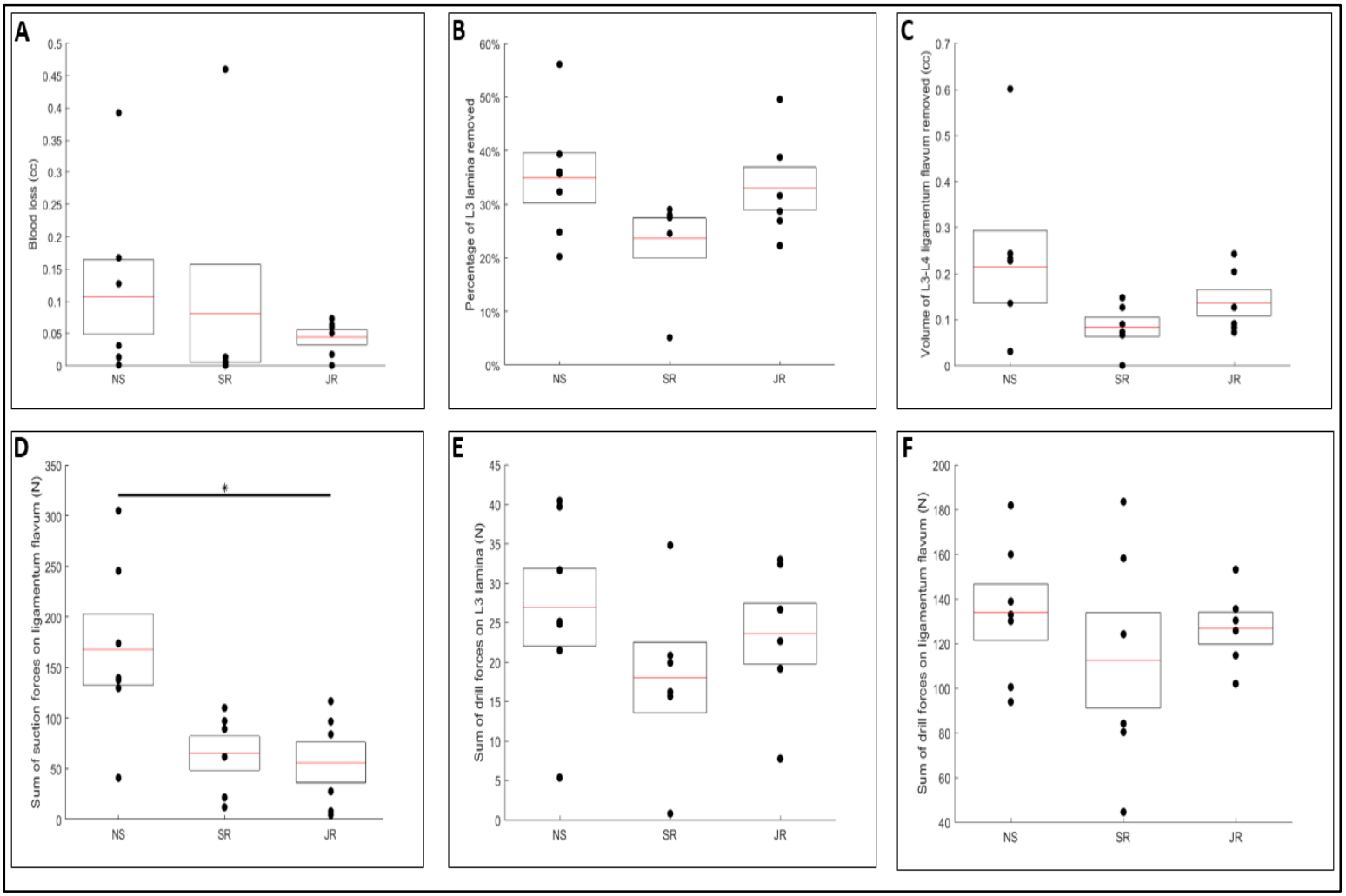


Figure 3. Tier 1 metrics. **A**: Blood loss (cc). **B**: Percentage of L3 lamina removed. **C**: Volume removed of the ligamentum flavum between L3 and L4 (cc). **D**: Sum of forces applied by suction on ligamentum flavum (N). **E**: Sum of forces applied by drill on L3 lamina (N). **F**: Sum of forces applied by drill on ligamentum flavum (N). Neurosurgeons n=7 (NS), senior residents n=6 (SR), junior residents n=6 (JR). **Red lines**: means ± SEM. **Black Line**: *** p < 0.05**

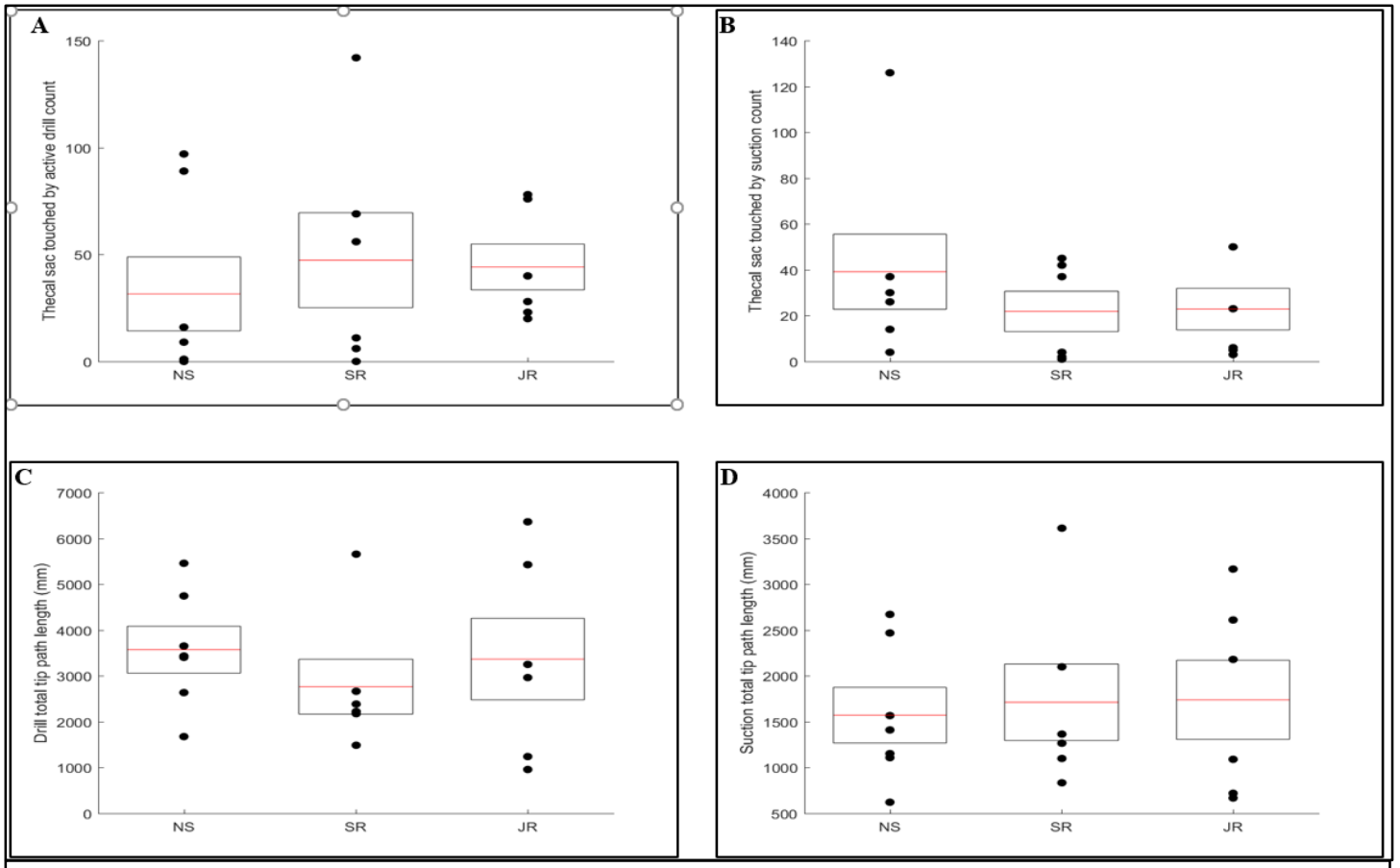


Figure 4. Tier 2 metrics. **A**: Number of times thecal sac touched by active drill. **B**: Number of times thecal sac touched by suction, **C**: Drill total tip path length. **D**: Suction total tip path length. Neurosurgeons n=7 (NS), senior residents n=6 (SR), junior residents n=6 (JR). **Red lines**: means ± SEM. **Black Line**: * **p < 0.05**

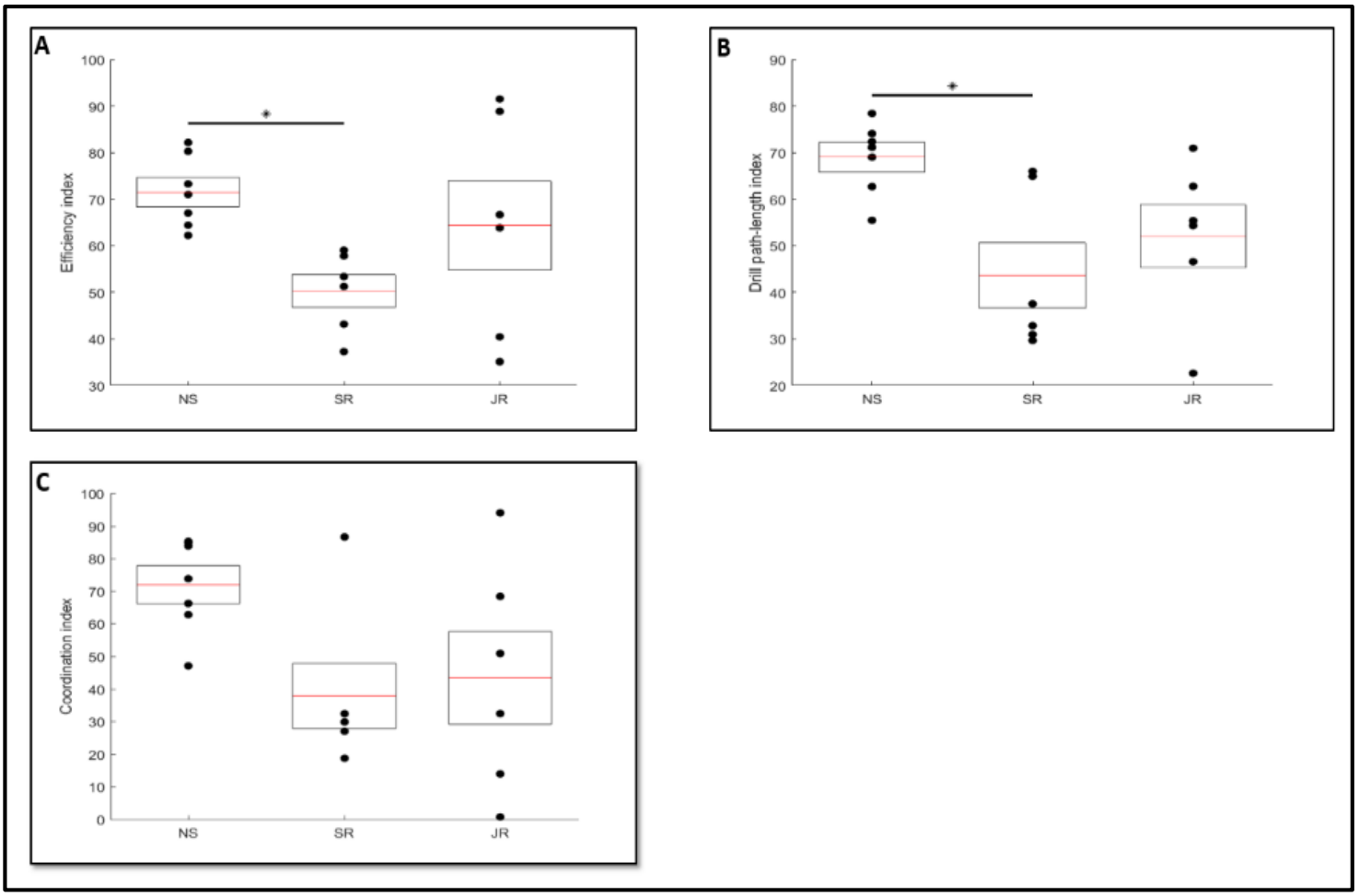


Figure 5. Advance tier 2 metrics A-Efficiency index. **B**-Drill Path Length index. **C**- Coordination Index. Neurosurgeon n=7 (NS) senior resident n=6 (SR), junior resident n=6 (JR). **Red lines**: means ± SEM. **Black Line**: *** p < 0.05**

Table 1

Table 1. Demographic data	
Group	**n(%)**
Neurosurgeons	**n=7**
Age (mean)	47
Gender	
Male	6(85.7)
Female	1(14.3)
Handedness	
Right	7(100)
Left	0(0%)
Ambidextrous	0(0%)
Used VR simulator	6(85.7)
Use drill in laminectomy	56%
Residents	**n=12**
Age (mean)	31
Gender	
Male	9(75)
Female	3(25)
Handedness	
Right	9(75)
Left	2(16.7)
Ambidextrous	1(8.3)
Used VR simulator	8(66.7)
Use drill in laminectomy	41%
Level of training	
PGY-1	3(25)
PGY-2	2(16.7)
PGY-3	1(8.3)
PGY-4	3(25)
PGY-5	2(16.7)
PGY-6	1(8.3)

*VR: Virtual reality

Table 2

TABLE 2. Evaluation of the NeuroVR Simulator on a 5-Point Likert Scale				
Statement	***Scale***			
	Junior resident	**Senior resident**	**consultants**	**all Groups**
Difficulty of the scenario (1-very easy, 5-very difficult)	2.3	2.7	1.8	2.3
Overall sensory realism (1-completely unrealistic, 5-completely realistic)	3	2.8	3.1	3
Overall task satisfaction (1-completely unsatisfied, 5-completely satisfied)	3	3.7	3.7	3.5
Overall performance (1 very poor- 5 excellent)	3	3.7	3.6	3.4
Recommended to use the simulator in the training Program (Yes/No)		Yes (91.7 %)	No (8.3)%	

Appendix A
Evaluation Form

INFORMED CONSENT FORM

Study: *Neurosurgical virtual reality simulator validation*

Principal Investigator: Rolando Del Maestro

Study Site: Montreal Neurological Hospital
3801 University Street
Montreal, Qc, H3A 2B4

We are asking if you would be willing to participate in a research study. This document describes the rationale, nature, and your potential role in the study. Please read it carefully. Should you decide to participate, please identify and have answered any questions that you may have prior to signing the attached consent form.

Purpose of the Research

The main objective of this study is to develop a valid virtual reality neurosurgical simulator. This simulator will eventually be used in the training and evaluation of neurosurgical residents and staff performances. Currently, there is no virtual reality neurosurgical simulator available commercially. This project represents a first step in the development of such a simulator. The objectives of this study are to develop valid metrics (measurements) of performance as well as improving both the simulator itself and what it measures. If you were a participant in a previous study called *Global Assessment Tool for the Evaluation of Intraoperative Neurosurgical Skills,* you will be asked to allow the data from this previous study to be used to analyze the similarity of your performance in the operating room and on the simulator. The second purpose of this research is to assess physiologic responses (heart rate, body temperature, breathing and other measures) **and biochemical parameters measured by salivary cortisol levels** during the resection of virtual reality simulated tumors to understand these physiologic changes during the simulated tumor resection.

Description of Research Methodology

Participants will be recruited to participate in the development of the neurosurgical simulator. A participant from the MNH can be any staff, resident or medical student who has the possibility of using the simulator. Also, anybody who can have access to the simulator is a potential participant (engineer, gamer, etc.) Subjects will be asked for their consent to participate in the study by allowing recordings of the data produced while using the simulator. These data

include the metrics of the performance (measurement), the virtual video recording of the virtual surgery and the various feedbacks the participants will provide to improve the simulator. The virtual videos will then be assessed by two blinded raters. These evaluators will assess the technical skills of the surgeon performing the surgical manipulations on the videos according to the tool developed by the researchers. This tool is a 5-point Likert scale based on the Global Rating Scale introduced by Reznick et al. for open surgery. It is modified to include items that capture important technical skills in neurosurgery. The evaluations will be done blindly, i.e. the evaluator will not have a priori knowledge of the level of experience of the surgeon to be evaluated. The identity and training level of the surgeon (including both resident and staff) are masked from the evaluators. For the participants where data from the *Global Assessment Tool for the Evaluation of Intraoperative Neurosurgical Skills* study are available, a comparison between their performance in the operating room and on the simulator will be done with the permission of the participant.

If you consent to have physiological monitoring during your resection of virtual reality simulated tumors a number of sensors will be attached to your person. These may include one or all of the following sensors. To measure body temperature a temperature sensor is attached to the second finger of your left hand (for right hand participants). A electrodermal response sensor which measures the electrical activity of the skin will be attached to the first and third fingers of your left hand using a Velcro band. A blood volume sensor will be attached to your left thumb using surgical tape or a Velcro band. To measure your electrocardiogram electrodes will be attached to both wrists using non-latex medical straps. Your respiratory pattern will be measured using a spring gauge positioned around your abdomen. Surface electromyography will be measured using special adhesive electrodes placed on both trapezius muscles (two muscles in the neck). Electroencephalography will be assessed using scalp electrodes.
If you consent to biochemical parameter monitoring, you will be asked to provide a salivary sample before and after the resection of the simulated tumor.

Potential Benefits

Any participants in this study can benefit by having access to practice material in the field of neurosurgery. This could theoretically improve their performance and technical skills, although no formal studies have shown that point with this particular simulator.

As a participant, you can be provided with some useful feedback upon assessment of your skills. This may help you identify areas of weakness that may require further practice or training. Although this assessment will have no implication on your formal academic skills assessment, it may aid you in improving areas of weakness prior to such evaluations. The feedback will be given to you by one of the researcher as well as by simulator itself through messages on the screen. If you are currently a trainee in neurosurgery, we will ensure that your performance will not be reported to your academic supervisor and will not have any effect on your academic record.

Potential Harms, Injuries, Discomforts or Inconvenience

A potential risk is that you may be identified by the study evaluators. Careful measures will be taken to blind the evaluators to prevent this from occurring, but on the chance that it should occur, we assure you that your technical performance will have no bearing on your academic evaluations or on your professional relationships with the study evaluators/investigators. As well, your willingness/unwillingness to participate in the study will have no bearing on academic evaluations or professional relationships. If you consent to have physiologic monitoring during your virtual reality simulated operation(s) a number of sensors will be placed on your person. A series of monitors are placed using Velcro bands surgical tape and non-latex medical straps and there is a small risk that these could cause some skin irritation To place the surface electromyography electrodes on your two trapezius muscles (two muscles on the side of your neck) the skin is cleaned with isopropyl alcohol beforehand. There is a small risk that this cleaning may cause some skin irritation. When the EEG monitors are applied an NuPrep gel is used to remove dead skin, sweat and other contaminants on a very small area of the scalp and a small amount of conductive paste is used to attach the electrode. There is a small risk that this cleaning and/or the material to attach the electrode could cause scalp irritation. **No potential harm would be expected by providing two salivary specimens**.

Confidentiality

We request your signed consent for participating in the study. Your name is required in order to keep track of your level of training, handedness and your anonymous code/subject number on a separate "*Participant Data Collection Form"*. For data analysis purposes you will be assigned a code number known only to the principal investigator and all data collected will be identified using only this code. Again, care will be taken to mask your identity and level of training by using virtual videos bearing no identifying data. Identifying information will be kept in a locked file in the Division of Neurosurgery offices at the Montreal Neurological Hospital. Confidentiality will be respected and no information that discloses your identity will be released or published without your consent. The study data will be kept until full analyses have been performed and research has been published. All electronic files will be erased and hard copies will be shredded no longer than seven years after the completion of the study.

A Research Ethics Board or Quality Assurance Officers duly authorized by it may access study data for audit purposes.

Participation

Your participation is voluntary. You are free to withdraw from this study at any point without any penalty. Upon withdrawal, your data would be erased and not used for research purposes.

Compensation

No monetary compensation for loss of time and inconvenience will be provided for your participation in this study.

Legal Rights

By accepting to participate in this study, you are not waiving any of your legal rights nor discharging the researchers or the institution, of their civil and professional responsibility.

Contact Information

You will be given a copy of the consent form to keep. If you have any questions or concerns regarding the research or your participation in it, either now or at any time in the future, please feel free to ask Dr. Rolando Del Maestro, Dr. Khalid Bajunaid or Dr. Alexander Winkler-Schwartz and they will be happy to answer any questions you may have. You can also communicate with the investigators at this address:

Dr. Rolando Del Maestro
Montreal Neurological Institute and Hospital McGill University
3801 University St., Room 438m
Montreal, Quebec Canada H3A 2B4
rolando.delmaestro@mcgill.ca
Telephone : 514 398 1569

If you have any questions regarding your rights as a research subject and you wish to discuss them with someone not conducting the study, you may contact the Montreal Neurological Hospital Patient Ombudsman at (514) 934-1934 Ext 48306.

Summary of Research Results

Any published results of these studies can be mailed to you in reprint form if you are interested in knowing the findings.

Conflict of Interest

We have no known actual, apparent, potential or perceived conflicts of interest in conducting this study.

PARTICIPANT'S STATEMENT AND SIGNATURE

- By my signature to this consent form, I declare that this consent is given voluntarily under my own free will after sufficient time for consideration, and that I have

completely understood the information regarding my participation in the study and have agreed to participate in the study.

- My signature to this Consent Form does not constitute a waiver of my legal rights or release the investigators, sponsor, or medical institutions connected with the study from their respective legal and professional responsibilities.
- I am free to withdraw from the study at any time with no penalty or loss of benefit to which I am otherwise entitled. During my continued participation I am entitled to request clarification or new information throughout the study, and the study neurosurgeon will make every effort to respond to my request.
- I agree to be contacted by a member of the Research Ethics Board of this hospital or the Quality Assurance Officer duly authorized by it, at their discretion.
- If I withdraw my consent, all my data will be erased and not used in the analysis.
- I will be given a copy of this document.

☐ Check here if you consent to physiologic monitoring during your virtual reality simulated operation(s).

☐ **Check here if you consent to salivary cortisol assessment during your virtual reality simulated operation(s).**

☐ Check here if you allow the data from the *Global Assessment Tool for the Evaluation of Intraoperative Neurosurgical Skills* study to be used in this study.

I, _____, (name of the participant), agree to participate in this study.

_____	_____	_____
Printed name of Participant (BLOCK CAPITALS)	Signature of the Participant	Date

INVESTIGATOR'S (OR DESIGNEE) STATEMENT AND SIGNATURE

I _____ (name of physician or designee) received from the hospital's Research Ethics Board an approval to perform the clinical trial on human subjects in accordance with the accepted research ethics guideline. I hereby declare that I have fully explained the Consent Form to the participant.

_____	_____	_____

Name of the Investigator or Designee	Signature of the Investigator or Designee	Date

Appendix B

Personal Data form

First we would like to thank you for your co-operation.

This information will remain confidential and will not be made available to any individuals not involved in this study. The data entered here will serve for group stratification during analysis of the data and no individual data will be used.

Name: _____ Age_____

Sex: M □ F □ Handedness: Left □ right □ ambidextrous □

1) You are a:

□ **Medical Student**

a. Year in medical school □ 1 □ 2 □ 3 □ 4
b. What university are you attending? _____
c. Have you done surgical rotation before? □ yes □ No
d. How many times you have observed or assisted spine surgery? Observed _____ assisted _____

□ **Resident or Fellow**

a) Please provide residency program: _____
b) Level of training: PGY _____
c) Are you a Fellow? Yes No
d) What Fellowship Program _____
e) What University: _____
f)

> Procedures you **performed** in during your residency + fellowship if applicable _____

How many:

Lumbar discectomies _____ + fusion _____
Cervical discectomies _____ + fusion _____
Lumbar laminectomies_____+ fusion _____
If you do lumbar laminectomies
In what percentage do you use a drill _____
In what percentage do you use up biter _____

Any other instruments used _____

> Procedures have you **assisted** at during in your residency + fellowship if applicable:

How many:

Lumbar discectomies _____+ fusion _____
Cervical discectomies _____ + fusion _____
Lumbar laminectomies_____+ fusion _____
If you do lumbar laminectomies
In what percentage do you use a drill _____
In what percentage do you use up biter _____
Any other instruments used _____

 Consultant Staff:

Δ Neurosurgery Δ **Orthopedic Surgery**

a) Years in practice: _____
b) Please provide university: _____

If you are a **neurosurgeon** is your practice focused on:

General Neurosurgery Pediatrics Spine Oncology Other_____

If you are an **orthopedic surgeon** is your practice is focused on:

General Orthopedics Pediatrics Spine Other_____

How many spine procedures do you average per year _____

Lumbar discectomies _____ +fusion _____
Cervical discectomies _____ + fusion _____
Lumbar laminectomies _____ + fusion _____
If you do lumbar laminectomies
In what percentage do you use a drill for the laminectomy _____
In what percentage do you use up biter for the laminectomy ____
Any other instruments used _____

2) Have you used a surgical simulator in the past? Yes/ No
   a. If so which one:
      Neuro Touch Number if >1
      Immersive Touch Number if > 1
      Surgical Theatre Number if > 1

If other which one (s):

_____

_____

_____

Any other comments that may help us understand your surgical area of interest

_____

_____

DATE: _____

Appendix C
Evaluation Form

OBJECTIVE: Using drilling technique perform a lumbar hemilaminectomy

1) On a scale from 1-5, please rate the difficulty of this scenario.
(1- very easy, 5- very hard):

1 2 3 4 5

2) On a scale from 1-5, please rate the overall sensory realism (the feel of the different tissues) of this simulation task. (1-completely unrealistic, 5-completely realistic):

1 2 3 4 5

3) On a scale from 1-5, please rate your overall satisfaction with this simulation task. (1-completely unsatisfied, 5-completely satisfied):

1 2 3 4 5

4) How do you think you performed on a scale of 5 (1 very poor- 5 excellent)?

1 2 3 4 5

5) If this simulator was available in my program, I would use this simulation scenario for training of the technical skills simulated.
(1-completely disagree, 5-completely agree):

1 2 3 4 5

6) Would you recommend integrating simulation training (using virtual reality operative simulation) into a curriculum during neurosurgery training program as a mandatory block?

YES NO

7) How would you improve this simulation task? Please explain:

_____
_____
_____
_____

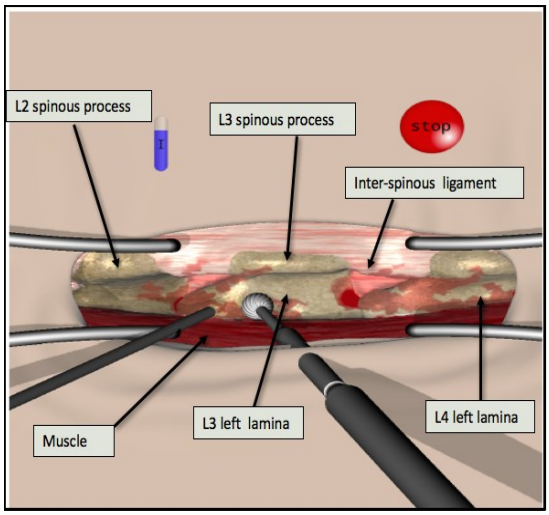
8) Other comments concerning the trial

_____
_____
_____
_____

Thank you for your participation

Appendix D
Evaluation Form

Simulation scenario: Laminectomy is a procedure which can be done using either high speed drill or up-biter while mindful of surrounding structures.



1- **The purpose of this scenario is to perform a left hemi-laminectomy using high speed drill without damaging the surrounding structures** (cauda equine facet joints, pars interarticularis, ligamentum flavum)
2- To accomplish this task, you need to utilize a high speed drill in the dominant hand and suction in the non-dominant hand.
3- You will be allowed five minutes to complete the procedure, but you can terminate the procedure any time you feel you finished.

In order to start the procedure, first with the tips of both instruments (Drill and suction) touch the green **START** button on the upper left of the screen. When you have completed the trial again with both tips touch the red **STOP** button on the upper right of the screen. Please be careful not to touch the red **STOP** accidentally before you complete the procedure as this will exit the program without achieving the desired results. The procedure should be done carefully as possible with minimal damage to surrounding structures.

If you have any questions concerning the test, please ask before starting.

Thank you for your participation