Validation of a Simulated Virtual Reality Model of Lumbar Laminectomy as a Surgical Educational Tool

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Abstract

Objective: Simulation training allows surgical trainees to deliberately and repetitively practice a given skill, in a safe and stress-free environment. The aim of this case series study was to investigate face, content and construct validity of a lumbar laminectomy scenario on the TSYM^{TM} simulator platform.

Methods: Neurosurgery and orthopedic surgery consultants, fellows, and residents, participated in the study. Participants were grouped a priori into two categories: skilled including residents in post-graduate year (PGY) 6, fellows, and neurosurgeons and orthopedic surgeons and less skilled (residents PGY1 to 5).The skilled group evaluated the lumbar laminectomy's face and content validity using a 7-point Likert scale questionnaire. Construct validity assessment was based on performance and tools metrics data collected from the simulator during each interactive step of the procedure.

Results: Nineteen skilled and 22 less skilled participants were included in this study. All the steps of the simulated laminectomy scenario achieved the face and content validity threshold with a median score ≥ 4. Significant difference was found between the skilled and less skilled group in simulation-derived performance metrics (lamina removal, detachment of ligamentum flavum and decompression verification) and tools metrics (average force on high-speed burr, Kerrisson and Woodson tools; average force on nerve root and dura; 3D force applied on haptic arm, time in contact with dura ($p<0.05$).

Conclusion: This study provides arguments of validity for the laminectomy scenario on the TSYM simulator, supporting its potential utility as a formative educational tool.

Résumé

Objectif : La simulation permet aux résidents des spécialités chirurgicales de pratiquer délibérément et de façon répétitive leurs compétences chirurgicales dans un environnement sécuritaire et sans risque. TSYM (Symgery, Montréal) est un simulateur de réalité virtuelle de chirurgie spinale. Le but de cette étude de série de cas est l'investigation de la validité de face, contenu et construit de la laminectomie lombaire simulée sur cette plateforme.

Méthodes : Des consultants, des fellows et des résidents en neurochirurgie et chirurgie orthopédique ont participé à l'étude. Les participants ont été regroupés a priori en deux catégories : stagiaires (résidents en troisième cycle de la première à la cinquième année) et experts (résidents en sixième année, fellows et chirurgiens neurologiques ou orthopédiques). Le groupe expert a évalué la validité de la laminectomie lombaire, tant sur le plan visuel que sur le plan du contenu, à l'aide d'un questionnaire sur une échelle de Likert en 7 points. L'évaluation de la validité de construit reposait sur les mesures de performance et d'évaluation d'outils collectées par le simulateur à chaque étape interactive de la procédure.

Résultats: 19 experts et 22 stagiaires ont été inclus dans cette étude. Toutes les étapes du scénario simulé ont atteint le seuil de validité apparente et de contenu avec un score médian ≥ 4. Une différence significative a été constatée entre le groupe d'experts et le groupe stagiaire concernant les indicateurs de performance dérivés de la simulation (résection de la lame, décollement du ligament jaune et vérification de la décompression) et les indicateurs d'outils (force moyenne sur la fraise à grande vitesse, outils de Kerrisson et Woodson ; force moyenne sur la racine nerveuse et la dure-mère ; force 3D appliquée sur le bras haptique, temps de contact avec la dure-mère), $p < 0,05$.

Conclusion : Cette étude fournit des arguments de validité pour le scénario de laminectomie lombaire dans le simulateur TSYM, soutenant son utilité potentielle comme outil pédagogique dans les programmes de chirurgie neurochirurgicale et orthopédique.

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Authors Contribution

The authors' contribution in the manuscript upon which this thesis is based is stated following the Contributor Roles Taxonomy (CrediT).

Bilal Tarabay: Contributed to conceptualization and methodology, formal analysis, data collection, investigation, participant recruitment, and writing.

Trisha Tee: Contributed to conceptualization, methodology, data collection, formal analysis, and writing– review & editing.

Puja Pachchigar: Contributed to conceptualization and methodology, formal analysis, data collection and processing, and participant recruitment.

Recai Yilmaz: Contributed to conceptualization and methodology, formal analysis, and writing – review & editing.

Rolando Del Maestro: Contributed to project creation, conceptualization, methodology, resources, and investigation, project funding, guidance, and supervision of this research, interpreting results, writing - original drafts and writing – review & editing.

Background

Challenges in surgical education

Surgical education is a lifelong and complex process requiring the acquisition of diverse set of skills, both technical and non-technical[1]. This process is essential to attain a level of competency insuring the delivery of optimal care for patients[2]. Trainees need to develop their non-technical abilities as well, in communication, leadership, decision making, formulating treatment plans, gathering important information, working in teams alongside their theoretical and procedural knowledge. Developing these technical and non-technical skills may be challenging, given the high-stakes and highly stressful surgical environment[3].

Traditionally, surgical training follows an apprenticeship model, developed 1890 by William Halsted[4]. In this model, a skilled mentor provides trainees with instructions, demonstrations, tutoring and feedback to deepen their understanding and knowledge in a particular field. When the trainees acquire the required competency level in a given skill, they can progressively obtain the opportunity to actively participate in patients' care[5]. Although this model suffers from major flaws[6,7], including the subjective definition of competence, it remained the cornerstone of surgical education. However, new regulations limiting residents working hours to prevent burnout[8–10], concerns about patients' safety and its medico-legal implications[,1,8–10], the financial challenges facing healthcare, as well as the shift towards minimally invasive techniques and the introduction of rapidly evolving new technologies requiring continuous adaptation of both expert tutors and trainees, limited the learning opportunities and added to the challenges facing surgical education following the apprenticeship model. With raising concerns about some surgical trainees graduating while lacking the essential qualifications and technical abilities to provide patient care[11], there is a shift towards competency-based training models[1] in modern residency programs. This model requires explicit and objective tasks, common across training programs, that the trainees need to complete to achieve competency[7,12]. To achieve this standardized approach for surgical education, residency programs need to ensure appropriate, equal and repetitive exposure to surgical procedures, independent of case availability and expert tutors experience in the operating room[13–15]. To address this challenge, surgical simulators have begun to play valuable role as educational tools in medical training.

Simulation training as educational tool

Simulation training in surgical education allows trainees to deliberately and repetitively practice a given skill, in a safe and stress-free environment[16]. When the learners achieve fluency of a complex surgical skill through simulation, trainees can then focus on successfully transferring these skills to performing real human surgical scenarios[17]. Cadaveric and animal models were traditionally used for simulation training[9,18–20], however, difficulties related to high cost, availability, reusability, and ethical considerations limited their utilization[9,18–20].

Technology-based simulators, such as virtual reality simulators, allows trainees unlimited repetition of a particular surgical skill or procedure, and provide objective and real-time feedback that enhances deliberate practice[18,21]. Another advantage of these simulators is that their usage is not dependent of instructor's availability[22,23]. Moreover, technology-based simulators allow the deconstruction of complex surgical procedures into separate steps, which permits appropriate skill acquisition depending on trainees' level of competency[24,25].

Computer-based simulators have the ability to track users' activities in the simulated environment and generate extensive datasets that can be used to analyze their performance and compare this information to other groups with different levels of expertise. As previous studies published by our group have shown[26,27], the recorded data can be used to generate performance metrics that differentiate skilled from less skilled participants which cannot be measured in an operating room setting, such as acceleration, force and tool tips distance[22]. Despite the advantages of simulation training in acquiring technical and non-technical skills, their utility as educational tools need to be assessed by validation studies, to ensure proper implementation in medical education programs[28].

Validation

Validation is an important step in the evaluation of the utility of a simulator as an educational tool[29]. Validation can be achieved using the traditional framework, assessing face, content and construct validity[30], or the contemporary framework, an important approach in the education field[30] that consists of gathering validity arguments to support the simulator's use for a particular goal and in a particular population[30].

In the traditional validation framework, validity can be separated into two categories: subjective and objective[29,31]. Subjective validity is based on the evaluation of an expert group and consists of face and content validity[29,30]. Face validity examines the resemblance of the simulated scenario to the real-life surgical procedure it is supposed to recreate[29–31]. In the case of surgical simulation, it examines the overall anatomical realism and the overall realism of the simulated procedure. Content validity addresses the question of how much the simulated tasks reflect the actual surgical tasks[29–31], by examining the realism of the simulated tools and surgical steps. Construct validity is an objective assessment based on datasets recorded on the simulator and investigates the ability of the simulator to distinguish skilled participants' performance from that of less skilled participants[31–33].The contemporary validity framework consists of providing evidence of validity of a given tool, used in a particular situation, by a particular group. It gives a particular emphasis to the real-word impact of an assessment tool, thus its role in meaningfully improving medical practice[30,34]. In fact, a major challenge to educational tools, including simulators, is whether the learned skills lead to actual improvement of surgical performance in the operating room[35]. This study will focus on investigating face, content and construct validity, while providing arguments of validity of the TSYM™ simulator as an educational tool, however, skill transferability to real life surgeries is out of the scope of this thesis.

Spine surgery simulators

Despite the important recent advancements in spine surgery techniques, simulators in this domain are still largely based on animal, cadaveric and sawbone models[36]. Most available computer-based spine simulators focus on pedicle screw insertion[19,37], but lack validity arguments for their regular use in surgical residents' education[8,19,36,38–40]. Developing a virtual reality spine simulator is a challenging task, because of the complexity of the different anatomical structures to replicate, including the soft tissue (fat, muscle, ligaments, dura matter, nerve roots), bone and cartilage, as well as the different forces needed to be applied on these structures and the resulting tissue deformities[24]. Another challenge of virtual reality simulators is to provide the accurate haptic feedback while performing bone drilling, a cornerstone step in spine surgery[23]. However, with the shift towards minimally invasive spine surgery, including microscopic and endoscopic surgery, trainees have more limited opportunities for hands-on practice, thus the need to develop validated spine surgery simulators becomes of major importance.

Lumbar Laminectomy

Lumbar laminectomy is one of the most common procedures performed by orthopedic surgeons and neurosurgeons, with an estimate average of 34 per 100,000 hospital admissions[41]. To perform this procedure using the classic open approach, the surgeon starts by exposing the spinous process and the lamina, then proceeds to thinning the lamina using a high-speed drill to allow for resection of the lamina using the Kerrison rongeur, then detaches and resects the ligamentum flavum. Verifying the medial and lateral resection of the ligamentum flavum is an important step to achieve satisfactory decompression. To safely perform this surgery, the operator needs to have a good knowledge of the surgical anatomy of the spine, to prevent important complications like hemorrhage, durotomy and nerve injury as well as long term complications such as spinal instability. The posterior spinal decompression achieved through lumbar laminectomy is considered in the scope of practice for both the involved specialties[42], thus its mastery is required for residents graduation[42] **.** However, exposure to spine cases varies widely among residents. In Canada, while neurosurgery residents are continuously exposed to spine surgery as early as in their first training year[43], orthopedic surgery residents have only three months of dedicated training in spine surgery, unless they choose to obtain an elective rotation in this field [44,45]. With added limitations related to restricted working hours, increased number of surgeries performed using minimally invasive microscopic or endoscopic techniques limiting the hands-on training opportunities, new educational surgical tools become a necessity to achieve mastery of this technique.

TSYM^{TM} Simulator

The TSYM^{TM} is a virtual reality simulator focusing specifically on spine procedures, developed by Cedarome Canada Inc. dba Symgery, Montreal, Canada. It is a stand-alone non immersive platform, consisting of a touch display, a single robotic arm and a footswitch.

The display allows a three-dimentional voxel-based representation of the simulated surgical environment. The robotic arm allows the attachment of three different handles that simulate the surgical tools (Kerrison, burr, curette, Woodson) frequently used during spine procedures. The different steps of the simulated surgeries can be standardized to allow comparison between different participants while minimizing confounding factors. This included what instrument is used to achieve each step, as well as the size of the instruments when applicable. Using the robotic arm, participants would reproduce the same movements used in real-life scenarios when manipulating the instruments. The footswitch is used to activate the virtual burr and to acquire fluoroscopic views during the procedures.

The simulator provides tactile feedback through the robotic arm, including vibrations when using the burr and resistance when in contact with bone structures or soft tissue including the dura matter, as well as audio and visual feedback. In this simulation platform, torque was not reproduced on the robotic arm. However, this feedback metric has no significant influence in the laminectomy procedure studied in this thesis. This limitation is important during the pedicle screw insertion simulation, another procedure examined by our group in a separate study using the same simulator. Bleeding and cerebrospinal fluid leaks were not reproduced on the simulator, however, lesions to major vessels and increased pressure on the dura matter produced tactile (vibration) and visual feedback (a warning message on the center of the screen).

Besides the simulated procedures, including the lumbar laminectomy and pedicle screw insertion, the simulator provides a lab simulation, where participants can get acquainted with the different tools and to the non-immersive 3D environment on non-anatomical objects. This standardized step is performed by all the participants before commencing trials involving this simulator. .

STUDY RATIONALE, HYPOTHESIS, AND OBJECTIVES

Rationale

Surgical skills can be acquired by repeatedly practicing a specific task for a certain period of time[46]. The development of eye-hand coordination, fine motor skills and spatial representation of anatomical structures are considered the basics of surgical training[47]. However, overcoming the learning curve involved in acquiring the technical skills necessary to successfully complete complex surgical procedures can be challenging and exposes patients to increased risk of complications and poor clinical outcomes[48].

Lumbar laminectomy and free-hand pedicle screw placement are common neurosurgical and orthopedic procedures with a steep learning curve. Recent publications showed that trainees need to place 60 to 80 pedicle screws under direct supervision before being able to independently perform accurate and safe pedicle screw placement[46,49].

Simulation training in surgical education allows trainees to deliberately and repetitively practice a given skill, in a safe and stress-free environment[16]. When the learners achieve fluency of a complex surgical skill through simulation, they can be focused on successfully performing in real surgical scenarios[17].

TSYM™ is a high-fidelity, high-haptic, non-immersive virtual reality simulator focusing on spine procedures, that allows measuring performance metrics in 2 simulated scenarios: lumbar laminectomy and pedicle screw placement. Its role as an educational tool is yet to be determined through a validation study.

Hypothesis

There will be statistically significant differences when comparing skilled and less skilled participants technical skills performance utilizing the lumbar laminectomy simulation on the TSYM^{TM} platform .

Primary Objective

To evaluate face, content and construct validity of the lumbar laminectomy simulation on the TSYM^{TM} platform .

Secondary Objective

To assess the difference in performance metrics between skilled and less skilled trainees during the lumbar laminectomy simulation on the TSYM^{TM} platform

Manuscript

Validation of a Simulated Virtual Reality Model of Lumbar Laminectomy as a Surgical Educational Tool

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Abstract

Objective: Simulation training allows surgical trainees to deliberately and repetitively practice a given skill, in a safe and stress-free environment. The aim of this case series study was to investigate face, content and construct validity of a lumbar laminectomy scenario on the TSYM simulator platform.

Methods: Neurosurgery and orthopedic surgery consultants, fellows, and residents, participated in the study. Participants were grouped a priori into two categories: skilled including residents in post-graduate year (PGY) 6, fellows, and neurosurgeons and orthopedic surgeons and less skilled (residents PGY1 to 5).The skilled group evaluated the lumbar laminectomy's face and content validity using a 7-point Likert scale questionnaire. Construct validity assessment was based on performance and tools metrics collected from the simulator during each interactive step of the procedure.

Results: Nineteen skilled and 22 less skilled participants were included in this study. All the steps of the simulated laminectomy scenario achieved the face and content validity threshold with a median score ≥ 4. Significant difference was found between the skilled and less skilled group in simulation-derived performance metrics (lamina removal, detachment of ligamentum flavum and decompression verification) and tools metrics (average force on high-speed burr, Kerrison and Woodson tools; average force on nerve root and dura; 3D force applied on haptic arm, time in contact with dura ($p<0.05$).

Conclusion: This study provides arguments of validity for the laminectomy scenario on the TSYM simulator, supporting its potential utility as a formative educational tool in neurosurgical and orthopedic surgery programs.

Running Title: Validation study of a laminectomy simulator

Keywords: lumbar spine surgery, surgical education, validation, virtual reality simulator

Introduction

Surgical training programs have the important task of creating comprehensive formative and summative curriculums which helps their trainees achieve adequate level of proficiency in core surgical competencies[51]. Advancements in surgical procedures using minimally invasive, laparoscopic and endoscopic techniques, work-hours restrictions, decreased hospital educational budgets, patient safety, along with medico-legal issues related to surgical complications, make achieving this goal challenging [51–54]. These concerns particularly apply to spine surgery, a high-risk field in the neurosurgical and orthopedic specialties which deal with complex anatomical structures and demanding technical abilities[36,55]. Because of the limited exposure to hands-on training in complex procedures, the classic apprenticeship model in surgical instruction may fail to help residents obtain the critical educational requirements needed in a field like complex spine surgery[56,57].

Simulation training in surgical education is becoming an important technology which allows trainees to deliberately and repetitively practice a given skill, in a safe and stress-free environment[16,58,59]. When the learners achieve competency in performing complex surgical skills through simulation, these skills can be successfully transferred to human operative environments[17]. Virtual reality simulator platforms can achieve these goals and allow a standardized approach for training with quantitative and competency-based evaluation of trainees [16,60].

Lumbar laminectomy is a common spine intervention, and its mastery is critical for both neurosurgical and orthopedic surgical trainees. Many spine surgery simulation technologies have been developed and evaluated, including physical three-dimensional models, cadaveric models (animal or human) and computer-based models [36,61,62]. Virtual reality spine simulator platforms have the advantage of recreating realistic surgical simulations that allow deliberate practice and provide immediate and personalized feedback decreasing the necessity for supervisor availability[27,60–62].

TSYM (Cedarome Canada Inc. dba Symgery. Montreal, Canada), is a high-fidelity, high-haptic, non-immersive virtual reality simulator focusing on spine procedures, that allows measuring performance metrics in 2 simulated scenarios: lumbar laminectomy and pedicle screw placement. This simulator can provide real-time and personalized feedback to the users depending on their performance. Its role as an educational tool is yet to be determined through a validation study.

The goal of this study is to evaluate the lumbar laminectomy procedure on the TSYM simulator for face, content and construct validity. Face validity examines the realism of the simulator in replicating the actual surgical procedure while content validity addresses the accuracy of the simulator in measuring the metrics it is supposed to measure[31,32]. These types of validity are subjective since they are achieved through surveys[31] . Construct validity is an objective measure of the ability of the simulator to distinguish between different levels of proficiency (skilled vs less skilled) of the participants in performing a given task[27,32]. The studies of Gallagher and co-researchers have reviewed and evaluated the principles fundamental to the traditional validation framework as outlined above. In a contemporary framework proposed by Messick, validity is an argument supported by an ongoing process consisting of accumulating quality arguments of how the results supports a tool’s use for a particular purpose and population of learners[63]. The contemporary framework may help to provide a more holistic evaluation of the TSYM simulator’s capacity to evaluate and train learners in the laminectomy simulation assessed in this investigation. This study was designed using both validity methods, with the goal of gathering arguments of validity of the lumbar laminectomy scenario on the TSYM spine simulator as a potential educational tool that can be implemented in neurosurgical and orthopedic surgical curriculum.

Methods

Participants

Neurosurgeons and orthopedic surgeons, fellows, and residents, participated in the study. An exclusion criterion was prior experience with the TSYM simulator. The included participants were grouped a priori into two categories: skilled (residents in post-graduate year (PGY) 6, fellows, and neurosurgeons and orthopedic surgeons) and less skilled (residents PGY1 to 5). Participants first signed an informed consent approved by the Neurosciences-Psychiatry McGill University Health Center Research Ethics Board. A demographic questionnaire was then completed by the participants. All participants received the same standardized verbal and written instructions describing the steps and tools required to complete the simulated laminectomy. Each participant then performed a standardized dry lab to get acquainted with the three-dimensional environment of the simulator screen and the haptic arm and tools used during the simulation. Participants then performed the lumbar laminectomy simulated procedure on the TSYM simulator. There was no time limit to complete the steps or the procedure, however, each step was dependent and required participants' confirmation of completion before proceeding to the next step.

VR Simulator Platform

The study utilized the TSYM virtual reality simulator platform, developed by Cedarome Canada Inc. dba Symgery (Montreal, Canada). It is a voxel-based[27], non-immersive simulator, that uses a single haptic arm that provides continuous feedback and replicates common tools used during spine surgery. Users receive haptic and auditory feedback while using different instruments. The system is capable of tracking the participants' performance during the simulation by capturing different performance metrics. The laminectomy simulation consisted of four interactive steps: laminae thinning, ligamentum flavum detachment, decompression, and decompression verification (Table 1). Participants were restricted to specific instruments and instrument sizes to standardize the evaluation of the simulated procedure. Participants were informed they had unlimited time for completion of the trial.

Face, Content, Construct Validity

The skilled group evaluated the lumbar laminectomy's face and content validity using a 7-point Likert scale questionnaire. They scored the steps, tools, and simulated scenario from 1 to 7, 1 being completely unrealistic and 7 being completely realistic[27,64]. In the absence of consensus on an acceptable median for appropriate face and content validity, the overall procedure and specific tasks were deemed valid if they achieved a median >= 4.0 on the 7-point Likert scale, consistent with previously published studies of our center[27,64].

Construct validity assessment was based on metrics collected from the simulator during each interactive step of the procedure. These metrics were categorized into performance metrics and tool metrics for the high-speed burr, Kerrison, angled curette and Woodson. Performance metrics includes percentage of lamina removed, percentage of facet removed, percentage of area covered under laminae to detach the ligamentum flavum, percentage of area covered for final laminectomy verification and time to completion for every step. Forty eight metrics were evaluated for the tool metrics, including the position of the tools in the simulated environment (3D velocity and 3D acceleration), their contact with the anatomical structures (Tool Contact Voxels bone, Tool Contact Voxel Dura, Tool Contact Voxel nerve root right/left) and the force exerted on the haptic arm and the simulated anatomical structures (3D force and maximum force).

Statistical Analysis

We used Python to generate tool metrics from the collected data. Statistical analysis was performed using SPSS (version 29.0; IBM, Armonk, New York). The data did not follow a normal distribution as assessed by Shapiro-Wilk's test ($P < .05$). Statistical differences between groups were assessed using Mann-Whitney tests for each performance metric.

RESULTS

Participants

Demographic data concerning the two groups (skilled and less skilled) were collected before the beginning of the simulation (Table 2). A total of 43 participants from neurosurgical and orthopedic surgery backgrounds were included in this study. Due to technical difficulties during the simulation, two participants were excluded from the study. Of the remaining 41 participants, the skilled group reported a mean of 123 (SD=192) lumbar laminectomy procedures performed independently while the trainees group reported a mean of 0.8 (SD=1.5) lumbar laminectomies performed independently. The difference between the two groups was statistically significant ($P<0.001$).

Face and content validity

The median and ranges for face and content validity of the simulated laminectomy scenario and instruments were calculated based on the evaluation of the skilled group. The results are shown in Table 3. The skilled group rated the overall realism of the procedure and anatomical structures with a median score of 5 (range 3-7), supporting the argument for face validity.

Since all the steps of the simulated scenario achieved a threshold with a median score ≥ 4 this supported the argument for content validity. The skilled group recommended integrating the simulator for technical skills training for residents with a median of 6 (range 1-7). In the less skilled group, participants thought that they would use the simulator if it was available in there training program, with a median of 7 (range 2-7).

Construct validity

Significant differences between the two groups were found in both performance and tool metrics.

Simulation-derived performance metrics (Table 4): The skilled group removed significantly more lamina than the less skilled group (89.9%, 95% CI [85.6,93.7] vs 73.7%, 95% CI [66.5,81.2]; p=0.004) and covered a significantly larger area while verifying the extent of the decompression (67.3%, 95%CI [53.9, 79.0] vs 49%, 95%CI [38.4,59.7]; p=0.022). The skilled group covered a significantly larger area under the lamina to detach the ligamentum flavum as compared to the less skilled group (67.3%, 95%CI [54.0, 79.0] vs 45.5%, 95%CI [29.4,61.5]; p=0.006 (Figure 1). There was no statistically significant difference between the groups during the thinning of the lamina, removal of the ligamentum flavum or the time to completion of each of the 4 interactive steps.

Simulation-derived tool metrics (Table 5): During lamina thinning using the high-speed burr, the skilled group exerted more average force of the lamina than the less skilled group, but this was not statistically significant (p=0.071). An increase in average force on anatomical structures in the skilled group was also seen in the Kerrison and Woodson tool metrics, where the average force on the dura and on the nerve root were significantly higher compared to the less skilled group (p=0.011 and p=0.001 respectively). The 3D force applied on the haptic arm while using the simulated Kerrison and Woodson was significantly higher in the skilled group compared to the less skilled group, (p=0.013 and 0.025 respectively). The time spent in contact with the dura while using the Kerrison was higher as well in the skilled group (p=0.007). Figures 2 and 3 outline the significant metrics.

DISCUSSION

In this case series, we used the traditional validity framework to assess the face, content and construct validity, while gathering validity arguments to support the use of this simulator for a particular goal and in a particular population, as outlined by the contemporary validity framework[32]. Thus, the simulated procedure showed face, content and construct validity and presented subjective and objective validity arguments for the potential utility of the platform as an educational tool in performing lumbar spine laminectomies during training of neurosurgical and orthopedic surgery residents.

Face and content validity

The laminectomy simulation consisted in five interactive steps: lamina thinning, detachment of the ligamentum flavum, lamina removal, ligamentum flavum removal and laminectomy verification. Participants from the skilled group attributed a score to these steps using the 7-point Likert scale. Each step achieved a median score >=4, which was used by our group in previous publications as a cutoff of evidence of face and content validity [27,64]. The skilled group had a range of scores from 1 (completely unrealistic), to 7 (completely realistic). This divergence may be explained by a variation among the skilled group of the appreciation of the added value of simulation in surgical training, and its ability to replace the traditional apprenticeship model[65].

The overall anatomical realism and the overall realism of the simulated procedure had a median score of 5. When compared to animal or sawbones simulation models, virtual reality simulation presents the advantage of replicating the anatomy and creating a three-dimensional representation of the surgical field with high fidelity[66]. This may help the less skilled participants conceptualizing the complex spinal three-dimensional surgical anatomy. With the shift towards minimally invasive surgery with its limited surgical exposures and the opportunities to visualize anatomical landmarks less skilled residents may feel that they may gain more from opportunities to use virtual reality platforms for technical skills learning [67–69]. It has also been demonstrated that active participation in simulation-based training can result in a better understanding of complex tasks or anatomical nuances when compared to didactic teaching[66,70].

Construct validity

Of the five interactive laminectomy steps, the skilled group significantly outperformed the trainee's group in three: lamina removal, ligamentum flavum detachment and decompression verification. There was no statistical difference in the time to complete these steps. Moreover, this study showed statistically significant difference in 8 of the simulation-derived tool metrics when using the Kerrison and Woodson tools. When using the Kerrison tool, skilled participants exerted more 3D force on the haptic arm and the dura during lamina removal. When using the Woodson tool, skilled group used more 3D force on the haptic arm and more average force on the right and left nerve root during the verification of decompression. These findings contradict previously published studies where force exerted on instruments during tools manipulation was lower in the skilled group[50,71,72]. The data in this study demonstrated that the less skilled group did not verify the extent of the decompression laterally, at the level of the nerve roots, as shown by the absence of the Woodson tool contact on the right and left nerve root in this group. This pattern of force application demonstrates the capabilities of skilled participants to adapt the force they apply on anatomical structures and safely manipulate the neurological elements (central dura and nerve roots) to efficiently perform the key steps of the procedure (lamina removal, ligamentum flavum detachment and decompression verification).

TSYM in surgical education

Although there is a growing interest in developing spine surgery simulators for pedicle screw insertion and instrumentation[19,36], there is a scarcity of simulators dedicated to teaching the basics of lumbar laminectomy [39].This study provides arguments of validity of the lumbar laminectomy simulation on the TSYM simulator as a training and evaluation tool for surgical trainees. Feedback provided by the simulator for performance and tools derived metrics can help learners understanding crucial steps in performing this procedure. It may also help enhance procedural and cognitive performance as well as tool manipulation capabilities which would be essential during real-life surgeries[39,66,73,74].

Most of the participants from both the skilled and less skilled groups stated that they would use the simulator if it was available in their programs, consistent with previously published reports involving VR simulation[39,75,76]. The benefit of a technical skills training platform with readily available surgical spine simulations, along with immediate feedback without the need of direct supervision, is an advantage of VR simulators compared to other simulation modalities[77]. Junior trainees showed the highest interest in using the TSYM as a learning tool, and could particularly benefit from the implementation of a simulator in their training program[39,78].

A major advantage of VR simulators is the large amount of data generated that can be used in better understanding technical differences between skilled and less skilled trainees, allowing the enhancement of skills acquisition by surgical residents. As previously shown , artificial neural networks can be used to generate new metrics, not recognizable by instructors or supervising surgeons in an operating room setting, guiding trainees into focusing on a particular set of skills that can improve their performance[50,71,79,80]. Achieving this goal certainly requires input from expert educators to develop programs that accurately incorporate artificial-intelligence in their curriculum[81,82].

Limitations

The TSYM simulator has inherent limitations. Although the platform notifies the user when major vascular or nervous structures are compromised during the simulation, it does not provide real-time feedback on the steps to take to prevent errors. The simulated procedures were represented as a series of consecutive steps, where advancing to the next sequence requires finalizing the previous step, which does not replicate the dynamic opportunities for the surgeon during human procedures. The simulator utilized in this study uses a single haptic feedback arm which does not allow the use of different surgical instruments together, which limits its utility in developing bimanual technical skills.

Finally, despite the accurate representation of the three-dimensional surgical spine anatomy, cerebrospinal fluid leak and bleeding, common intraoperative complications of laminectomy surgery, were not simulated. Such simulations could be added to target more advanced surgical skills and complication management capabilities.

The participants were recruited from 3 different universities and were grouped based on their training year, without taking into consideration their proficiency in performing the lumbar laminectomy procedure. A future study considering the level of competency of participants in performing this type of surgery can reduce this selection bias. Although the study included participants from both neurosurgical and orthopedic surgery backgrounds, and from different levels of expertise, the sample size remains small which impacts the ability to generalize these results.

Conclusion

This study provides arguments of validity for the laminectomy scenario on the TSYM simulator, supporting its potential utility as an educational tool in neurosurgical and orthopedic surgery programs.

Thesis Discussion

Contributions to Original Knowledge

This study contributes to the surgical education literature by gathering evidence of validity of a novel virtual reality spine simulator. With the increased complexity of spine surgery cases, and the shift towards minimally invasive techniques, the need of such an educational tool exists for trainees to gain a better understanding of surgical anatomy, surgical tools and steps to perform a lumbar laminectomy.

Validity Evidence

This validation study combines the traditional and contemporary validity framework. While evaluating face, content and construct validity, we collected arguments supporting the educational utility of the TSYM simulator when used to perform lumbar laminectomy scenario.

Based on Mesick's contemporary validation framework, evidence of validity can be accumulated from five sources[32] : test content, response process, internal structure, relations to other variables and consequences. The test content was assessed by the skilled group consisting of PGY6 residents, fellows, neurosurgeons and orthopedic surgeons. All simulated tasks were deemed reflective of the real surgical procedure and anatomy, as shown by the median score >= 4 on the 7-point Likert scale. To reduce the bias in the assessment, we used standardized instructions (written, verbal and dry lab performance), as well as standardized tools and simulated steps. Although this is not consistent with what happens in a real surgical scenario, where operators get to choose the step to perform in a non-linear fashion, as well as the type of tools to use, this standardization allowed for gathering evidence of the "response process". Concerning the internal structure evidence, ensuring that the assessment is measuring what it is intended to measure, the performance metrics and tools metrics data generated by the simulator showed significant difference between the skilled and less skilled group in 3 performance metrics (Percentage of Lamina removed, Percentage of Ligamentum flavum detachment and Percentage of Decompression verification) and in 8 tools metrics (3D force applied to the Woodson and Kerrisson, average force applied to the dura when using the Kerrisson, average force applied to the nerves while using the Woodson and Kerrisson contact with the dura). Future studies will be needed to assess the relations to other variables and consequences of the simulated scenario by examining the skills transferability of the performance of operators during the simulated scenario to real life laminectomy surgery.

Future Directions

The results of this study provide arguments in favor of the potential utility of the TSYM simulator as an educational tool in neurosurgical and orthopedic surgery residency program, by establishing face, content and construct validity. The results and data outlined in this study will be provided to the manufacturer to serve as useful information to improve the simulator and its educational value. This may allow the manufacturer to continue to improve the realism of the anatomical structure and the haptic feedback from the simulator's tools. An area of significant improvement would be adding a second haptic feedback arm, allowing for bimanual training, an important surgical skill to acquire.

Moreover, further studies will be essential to evaluate skill development with deliberate use of the simulator by the trainees, the importance of real time feedback in developing the needed surgical skill, and most importantly, the clinical implications of using the simulator in improving patients' care and safety. A longitudinal study comparing learning curves in performing lumbar laminectomy between a group of trainees that used the simulator versus a group that did not can further establish the importance of simulation in gaining specific surgical skills.

One of the benefits of virtual reality simulators is their ability to gather large amount of data. This data can be assessed using artificial intelligence algorithms to identify important aspects of surgical performance that sometimes cannot be evaluated in a clinical setting.

Thesis summary

The shift of surgical education towards a competency-based framework requires tools that allow the generation of quantifiable data. Virtual reality simulators have the advantage of allowing safe and risk-free deliberate training, all while generating large amount of performance data. Validation studies allow gathering evidence of the utility of a simulator in training before the implementation of such a tool in surgical programs. The goal of this study was to evaluate a novel virtual reality spine simulator (TSYM) for face, content and construct validity while gathering arguments of validity aligning with the contemporary and traditional validation frameworks. The results of our study showed that the simulated lumbar laminectomy procedure showed face, content and construct validity and presented subjective and objective validity arguments for the potential utility of the platform as an educational tool in performing lumbar spine laminectomies during training of neurosurgical and orthopedic surgery residents.

The laminectomy simulation consisted of five interactive steps: lamina thinning, detachment of the ligamentum flavum, lamina removal, ligamentum flavum removal and laminectomy verification. Each step achieved a median score >=4, as rated by the skilled group on a 7-point Likert scale. However, there was an important variance within the skilled group responses ranging from 1 (completely unrealistic), to 7 (completely realistic). The skilled group significantly outperformed the trainee's group in three out of the five interactive steps: lamina removal, ligamentum flavum detachment and decompression verification. Moreover, this study showed statistically significant difference in 8 of the simulation-derived tool metrics when using the Kerrison and Woodson tools. The measured data failed to show any difference between the two groups while using the high-speed drill.

These findings suggest that improvements of the anatomical representation of the lumbar spine and the haptic arm feedback provided by the simulated tools might be needed in future

versions of the simulator to insure it reflects more accurately the real surgical scenarios. The study showed that more force was applied on the dura and the nerves by the skilled group as compared to the less skilled group. Although this finding might be explained by the lack of verification of decompression of the nerve roots by the less skilled group, thus the absence of any force applied on these structures, further studies to assess the distribution of force on neurological structure during different steps of a lumbar laminectomy and its possible value in differentiating expertise levels may be important in assessing expertise in this procedure. Artificial intelligence technologies such as artificial neural networks can be used to generate novel metrics which may aid in the assessment and training of this procedure.

In conclusion, this case series study suggests that the simulated lumbar laminectomy scenario on the TSYM has a potential value as an educational tool.

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Figures

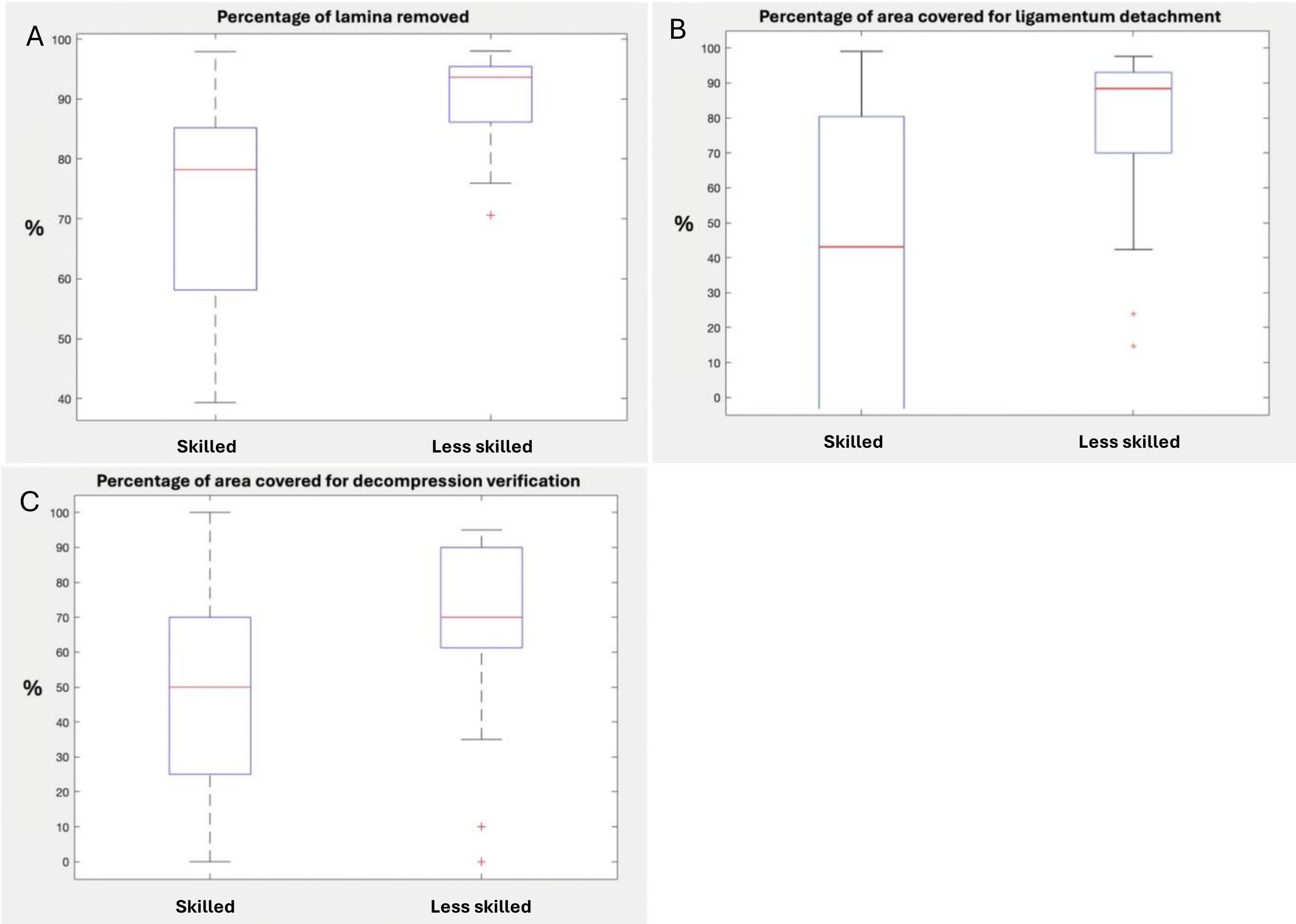

Figure1 Pairwise comparison of performance metrics showing statistically significant difference between groups after Mann-Whitney U test (p<0.05). The central (red) line indicates the mean value for each group. **A**. Percentage of lamina removed using the Kerrisson, **B.** Percentage of area covered by the Woodson to remove the ligamentum flavum, **C.** Percentage of area covered by the Woodson for decompression verification

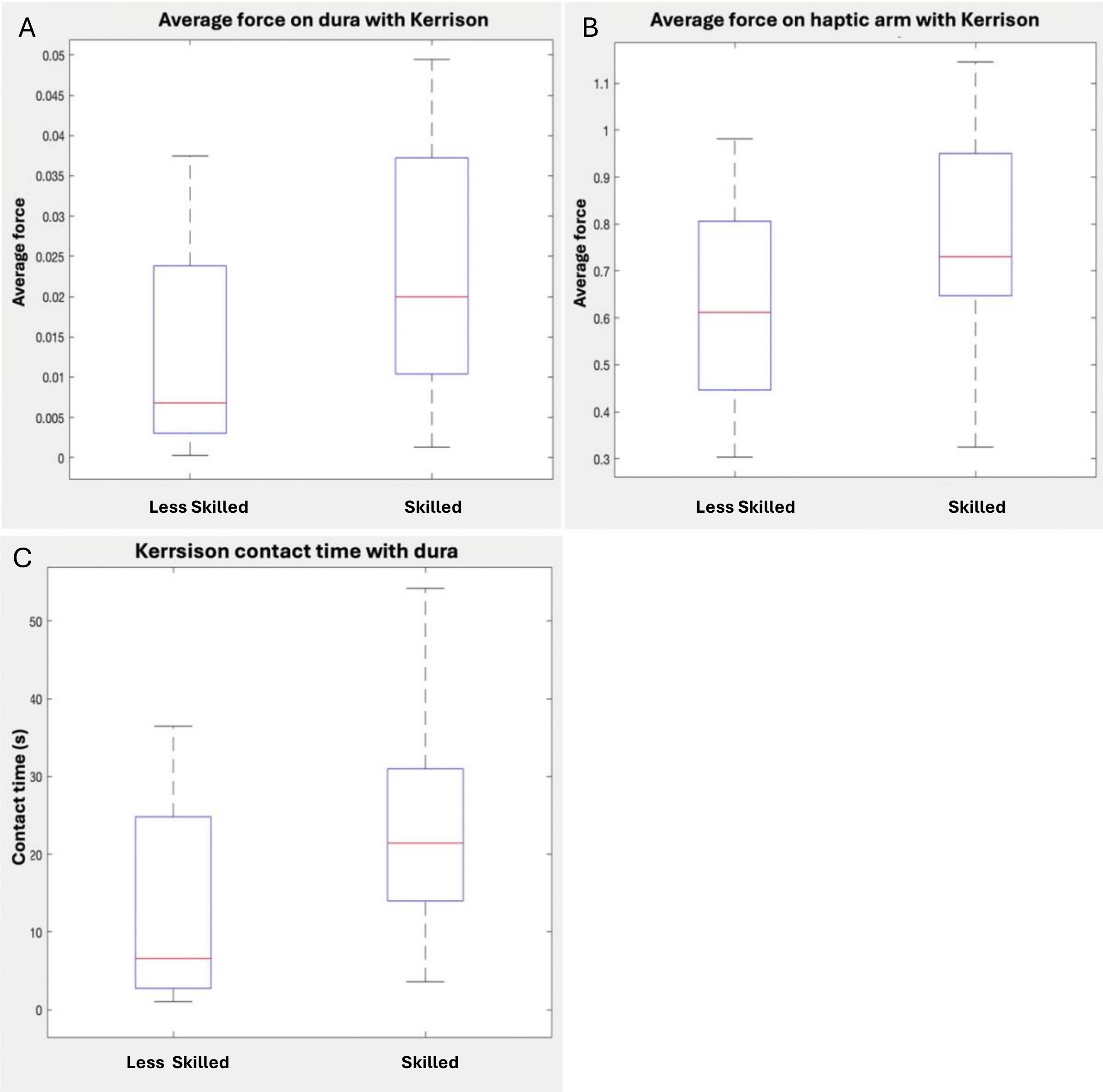

Figure 2 Pairwise comparison of simulation-generated tool metrics for the Kerrisson showing statistically significant difference between groups after Mann-Whitney U test ($p<0.05$). The central (red) line indicates the mean value for each group. **A.** Average force applied on the dura by the Kerrisson, **B.** Average force applied on the haptic arm while using Kerrisson, **C.** Kerrisson contact time with dura

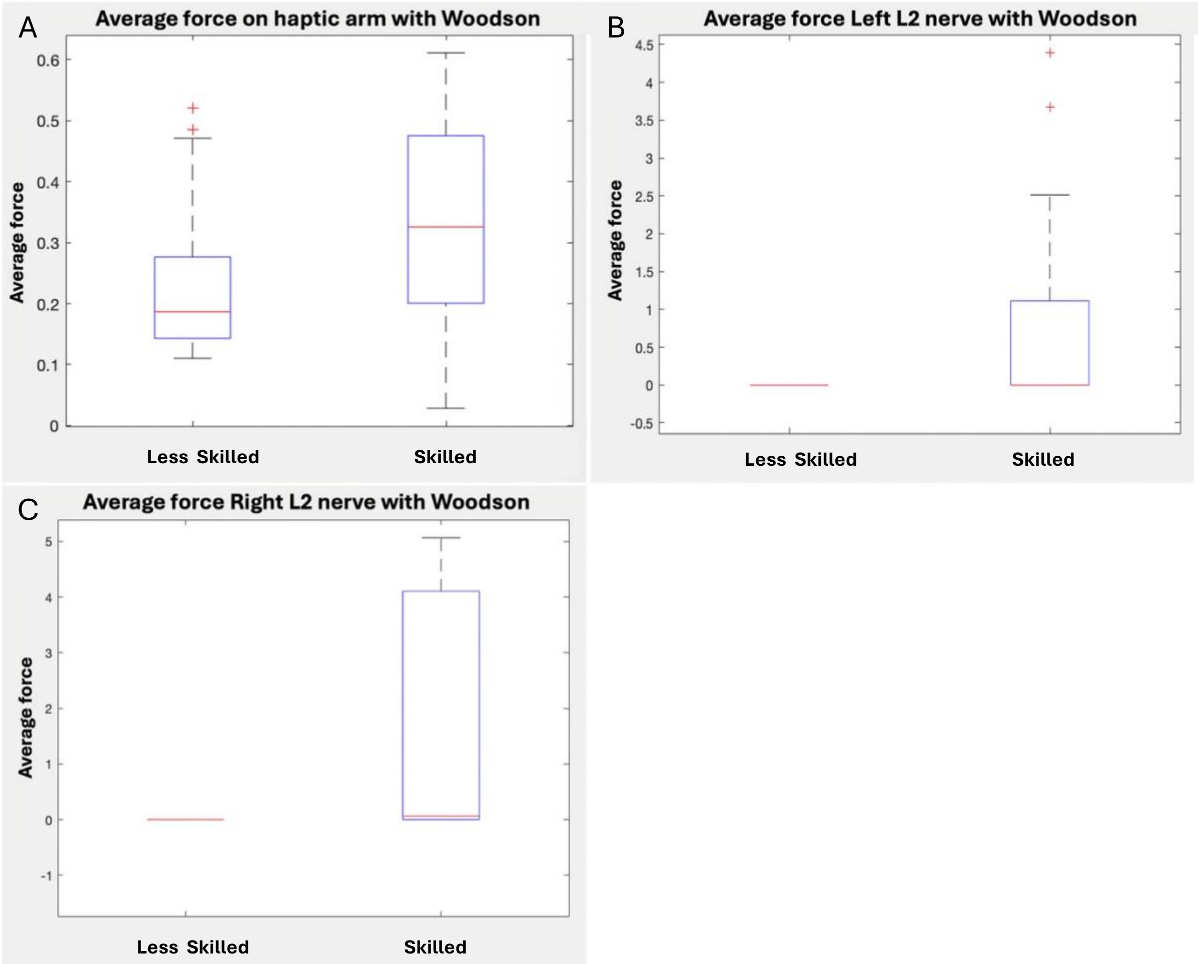

Figure 3 Pairwise comparison of simulation-generated tool metrics for the Woodson showing statistically significant difference between groups after Mann-Whitney U test ($p<0.05$). The central (red) line indicates the mean value for each group. **A.** Average force applied on haptic arm while using Woodson tool, **B.** Average force applied on the left nerve root while using Woodson tool, **C.** Average force applied on the right nerve root while using Woodson tool

Tables

Table 1 **Steps and tools used for laminectomy scenario in the TSYM Simulator**

Steps	**Objective**	**Tool used**
Step 1: Lamina thinning	Drill the lamina's external cortical and cancellous bone layers	High speed drill
Step 2 : Ligamentum flavum detachment	Separate the ligamentum flavum from its attachment to the lamina	Angled curette
Step 3A: Laminectomy	Remove the remaining lamina to expose the dura matter	Kerrison
Step 3B: Resection of ligamentum flavum	Remove the ligamentum flavum to expose the dura matter	Kerrison
Step 4 : Decompression verification	Verify the lateral extent to the decompression and the patency of the neurological foramens	Woodson

Table 2 **Demographic Data for the Participants Performing the Simulated Lumbar Laminectomy on the TSYM Simulator Platform**

	Less skilled group	**Skilled group**
Number of participants	22	19
Age (years)		
Mean (SD)	29 (1.8)	39 (7.2)
Gender		
Male	18 (82%)	18 (95%)
Female	4 (18%)	1 (5%)
Specialty		
Neurosurgery	16 (73%)	10 (53%)
PGY 1-3	10	-
PGY 4-5	6	-
PGY6	-	4
Fellow	-	4
Surgeon	-	2
Orthopedics	6 (27%)	9 (47%)
PGY 1-3	4	-
PGY 4-5	2	-
Spine Fellow	-	5
Spine Surgeon	-	4
Affiliation		
McGill	18 (82%)	13 (68%)
Université de Montréal	4 (18%)	6 (32%)
Number of laminectomies performed independently		
Mean (SD)	0.8 (1.5)	123 (192)
Prior Experience with any Virtual Reality Surgical Simulator		
Yes	6 (27%)	8 (42%)
No	16 (73%)	11 (58%)

PGY = Post Graduate Year

SD = Standard Deviation

Table 3 **Face and content validity for the skilled group after completing the simulated laminectomy using a 7-point Likert scale.**

Validity Type	**Validity statements**	**Median scores for skilled group**	**Range**
Content Validity	Using the high-speed drill to thin the lamina	5	2-7
	Using the angled curette to detach the ligamentum flavum	4	2-6
	Using the Kerrison to remove the lamina	4	3-7
	Using the Kerrison to remove the ligamentum flavum	4	1-7
	Using the Woodson to verify the decompression	5	2-7
Face Validity	Overall anatomical realism of the simulated spine.	5	2-6
	Overall realism of the simulated procedure	5	3-7
	You would use this simulator for technical skills training if it was available in your program	6	1-7

Table 4 **Performance metrics for the laminectomy simulation scenario and Mann-Whitney U Test p-values**

Performance metrics	p-value
Percentage Lamina Removed	**0.004**
Percentage Right Facet removed	1
Percentage Left Facet Removed	0.516
Percentage Ligamentum flavum detachment (area covered)	**0.006**
Percentage Decompression verification (area covered)	**0.022**
Time for lamina thinning	0.229
Time for lamina removal	0.734
Time for ligamentum flavum detachment	0.695
Time for decompression verification	0.619

Table 5 **Tools metrics for the laminectomy simulation scenario and Mann-Whitney U Test p-values**

Tools Metrics	**Drill**	**Kerrison**	**Woodson**
3D Force (haptic)	0.204	**0.013**	**0.027**
3D Velocity	0.161	0.187	0.214
Max force	0.521	0.113	0.573
3D acceleration	0.107	0.266	0.266
Average force on Bone	0.073	0.234	0.865
Average Force on Dura Mater	1	**0.011**	1
Average force on nerve root left	_	1	**0.001**
Average force on nerve root right	_	1	**0.0004**
Tool Contact Voxels Dura Mater	1	**0.007**	1
Tool Contact Voxels Bone	0.704	0.054	0.947
Tool Contact Voxels nerve root Left	_	1	**0.0001**
Tool Contact Voxels nerve root Right	_	1	**0.001**