1	Face, Content, Construct, and Convergent Validity of a
2	Surgical Spine Simulator for Pedicle Screw Insertions
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84 85

- 86 ABSTRACT
- 87

88 **Objective**: Virtual reality spine simulators have the potential to become valuable educational 89 tools, offering learners a safe, risk-free environment to assess and train their psychomotor skills in challenging operative procedures like pedicle screw insertions. The TSYM Symgery simulator 90 platform is a virtual reality spine simulator capable of deconstructing and simulating complex 91 spine procedures, including pedicle screw insertions. This case series study aims to investigate 92 93 the face, content, construct, and convergent validity of an L4-L5 bilateral pedicle screw insertion 94 on the TSYM simulator platform. 95 Methods: Neurosurgical and orthopedic residents, fellows, and spine surgeons performed an L4-96 L5 bilateral pedicle screw insertion on the TSYM simulator. Participants were classified a priori into skilled groups (post-graduate year (PGY) 5-6, fellows, and consultant neurosurgeons or 97

98 orthopedic surgeons) or less skilled (PGY 1-4). Face and content validity were assessed utilizing

99 a Likert scale. Construct validity was determined by investigating group differences in

100 simulation-derived performance metrics and the Objective Structured Assessment of Technical

101 Skills (OSATS) ratings. Convergent validity was examined by correlating simulation-derived

102 performance metrics and OSATS ratings.

103 **Results**: Thirteen skilled and 14 less skilled participants were included in this study. The skilled

group rated all face and content validity statements with a median \geq 4. Significant differences

between the less skilled and skilled groups were found for 4 of 25 simulation-derived

106 performance metrics (P < .05) and all OSATS categories (P < .001). Two simulation-derived

107 performance metrics (maximum force and tool contact using the simulated screwdriver)

108 significantly correlated with OSATS ratings consistent with convergent validation.

Conclusion : The L4-L5 bilateral pedicle screw insertion simulation on the TSYM Symgery
simulation platform demonstrated mixed and variable evidence for face, content, construct, and
convergent validity, supporting some degree of educational potential for spine surgery training.
Improvements are needed to optimize the potential of the TSYM Symgery simulator platform.

132 RESUMÉ

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134 **Objectif**: Les simulateurs de colonne vertébrale en réalité virtuelle ont le potentiel de devenir des 135 outils éducatifs précieux offrant un environnement sûr et sans risque pour évaluer et former les 136 compétences psychomotrices des jeunes chirurgiens dans des procédures opératoires complexe comme les insertions de vis pédiculaires. Le simulateur TSYM Symgery propose une platforme 137 138 de réalité virtuelle capable de déconstruire et de simuler des procédures complexes en chirurgie 139 rachidienne, y compris les insertions de vis pédiculaires. Cette série de cas vise à examiner la 140 validité de face, contenu, construit et de convergence d'une insertion bilatérale de vis pédiculaires 141 L4-L5 sur la plateforme de simulateur TSYM.

142 Méthodes : Des résidents en neurochirurgie et en orthopédie, ainsi que des fellows et des 143 chirurgiens rachidiens ont effectué des insertions bilatérales de vis pédiculaires L4-L5 sur le 144 simulateur TSYM. Les participants ont été classés en groupes compétents (résidents en PGY 5-6, 145 fellows en chirurgie rachidien et neurochirurgiens consultants ou chirurgiens orthopédistes) ou moins compétents (résidents en PGY 1-4). La validité de face et contenu ont été évaluée en utilisant 146 147 une échelle de Likert. La validité de construit a été déterminée en examinant les différences de 148 métriques de performance dérivées de la simulation et l'Évaluation Structurée Objective des 149 Compétences Techniques (OSATS). La validité convergente a été examinée en corrélant les 150 métriques de performance dérivées de la simulation et les évaluations OSATS.

151 **Résultats**: Treize participants compétent et 14 moins compétents ont été inclus dans cette étude. Le groupe compétent a évalué toutes les déclarations de validité de face et de contenu avec une 152 153 médiane \geq 4. Des différences significatives entre les groupes moins compétent et compétent ont été 154 trouvées pour 4 des 25 métriques de performance dérivées de la simulation et toutes les catégories 155 OSATS, P<.05. Les métriques de performance dérivées de la simulation (accélération 3D et vitesse 156 3D en utilisant le robinet simulé et force maximale et contact avec l'outil en utilisant le tournevis 157 simulé) ont significativement corrélé avec les évaluations OSATS, cohérentes avec la validation 158 convergente.

159 Conclusion : La simulation de l'insertion bilatérale de vis pédiculaires L4-L5 sur la plateforme de 160 simulation TSYM Symgery a démontré des preuves de validité de face, de contenu, de construit et 161 convergente, soutenant son potentiel comme outil éducatif formateur dans la formation en 162 chirurgie de la colonne vertebrale.

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217 218	PREFACE AND CONTRIBUTION OF AUTHORS
219	The structure of this thesis follows a manuscript-based format, and the authors of the manuscript
220	have made substantial contributions to finalizing this work. The author's contributions are
221	detailed using the CRediT (Contributor Roles Taxonomy) format ^{1,2} . The following statements
222	outline the specific contributions to this research project made by each individual.
223	
224	Trisha Tee: Contributed to conceptualization, methodology, data collection, formal analysis,
225	investigation, and writing.
226	
227	Noel Abboud: Contributed to methodology, formal analysis, and writing.
228	
229	Bilal Tarabay: Contributed to conceptualization and methodology, formal analysis, data collection,
230	participant recruitment, and writing – review & editing.
231	
232	Abudlmajeed Abeloushi: Contributed to conceptualization and methodology, data collection, and
233	participant recruitment.
234	
235	Puja Pachchigar: Contributed to conceptualization and methodology, formal analysis, data
236	collection and processing, and participant recruitment.
237	
238	Mohamed Alhantoobi: Contributed to conceptualization and methodology, and formal analysis.
239	
240	Nour Abou Hamdan: Contributed to conceptualization and methodology and formal analysis.

review & editing. Ali Fazlohllahi: Contributed to conceptualization and methodology. 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. ABBREVIATIONS OSATS: Objective Structured Assessment of Technical Skills PGY: Post-Graduate Year 3D: Three Dimensional

Recai Yilmaz: Contributed to conceptualization and methodology, formal analysis, and writing -

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THESIS INTRODUCTION

Mastering technical skills is an essential learning objective in surgical training, as technical

errors can contribute to poor patient outcomes^{3,4}. Historically, acquiring technical skills follows

an apprenticeship model whereby surgical residents undergo a fixed-length residency learning

268 from a series of educators^{5,6}. However, surgical education is transitioning toward a competency-

269 based framework, valuing quantifiable measures of proficiency^{7,8}.

270 Tools capable of measuring meaningful performance metrics are a vital component of

271 competency-based training⁷. Virtual reality simulators for technical skill development may be a

valuable instrument in this framework⁹. To be implemented in surgical training, virtual reality

273 simulators must undergo a series of validation studies to elucidate their role in surgical

274 curricula¹⁰. The initial phases of validation involve investigating for face, content, construct, and

275 convergent validity¹⁰. Establishing these principles forms the groundwork for determining a

276 simulator's educational potential in surgical training 10,11 .

In neurosurgery and orthopedic surgery, the pedicle screw insertion is a fundamental technical
skill with a steep learning curve^{12,13}. Virtual reality simulators may be useful in learning pedicle
screw insertions, as it provides a controlled environment to focus on skill development¹⁴. A
limited number of virtual reality simulators for pedicle screw insertions exist, and they lack
comprehensive validation studies^{15,16,17,18,19}. This limits their ability to be implemented into
surgical training²⁰⁻²².

The TSYM simulator is a non-immersive, virtual reality platform capable of deconstructing an
L4-L5 bilateral pedicle screw insertion. It comprises a single robotic arm that provides haptic
feedback during the simulated operation. This new platform has the potential to be a valuable,
formative tool in surgical training, specifically for learning pedicle screw insertions, a technically

287	challenging and high-risk technique ^{9,12,13,10} . However, its potential in surgical training is yet to be
288	explored.
289	The following study investigates the educational potential of the TSYM simulator's L4-L5
290	bilateral pedicle screw insertion scenario for neurosurgical and orthopedic residents. This thesis
291	aims to establish the initial validation phases for the TSYM simulator's L4-L5 bilateral pedicle
292	screw insertion, laying the foundation for future studies that can further elucidate its role in
293	surgical education.
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310 BACKGROUND

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312 Surgical Education

Surgical education involves the simultaneous mastery of complex skills, experienced and taught knowledge, and composure in an unpredictable and, at times, highly stressful environment²³. It is defined as a life-long learning process that begins in residency and continues during the surgeon's career²³. Since its inception over 100 years ago, its founding principles remain, but its framework has begun to evolve in the last two decades.

318 The development of the modern surgical residency model can be traced back to the early 1890s 319 by Dr. William Halsted, who at the time was surgeon-in-chief and a Professor of Surgery at 320 Johns Hopkins University⁵. Inspired by the residency program created by his colleague and chief 321 of medicine at Hopkins, Sir William Osler, Dr. William Halsted introduced the Halstedian 322 training model, a pyramidal approach whereby trainees gained increasing responsibility after 323 each training year^{5,6}. The principles of this model included acquiring knowledge of surgical 324 disease, skills in patient management, and technical skills with increasing proficiency and independence through repetitive, supervised opportunities to take care of surgical patients^{5,6}. 325 326 Learning under the expert surgeon involved the "see one, do one, teach one" concept, where the 327 surgical trainee is expected to observe a skill, perform the procedure, and be able to consequently 328 teach it²⁴. Moreover, Dr. Halsted introduced a structured education with an overarching 329 apprenticeship principle for surgical training, which remains the foundation of surgical education to this day 5,6. 330

331 At the present time, surgical residency largely follows the principles it was founded upon.

332 Residents undergo a defined training period at university, university-affiliated, or community

333 hospitals with varying lengths, patient populations, and exposures³. Skill and knowledge

334 acquisition are still based on the apprenticeship model, whereby trainees learn under expert surgeons and progressively gain more patient care responsibilities and independence in the 335 336 operating room³. Surgical residency programs also continue to include grand rounds, educational 337 meetings where residents, surgeons, and healthcare providers discuss cases, recent advancements 338 in the field, and relevant research, as a vital component of the curriculum³. However, modern 339 surgical training has advanced in its educational framework, including but not limited to 340 protected education time for lectures and journal clubs to enhance critical analysis and appraisal as well as the incorporation of feedback, a critical component for trainee improvement³. While 341 342 this framework has produced many excellent surgeons and favorable outcomes for patients, the 343 current state of surgical education is not without many challenges.

344 Challenges in Surgical Education

In an era of rapid technological advancement and evolving healthcare landscapes, surgical
education is faced with a myriad of challenges that must be addressed to ensure the competence
and confidence of future surgeons while guaranteeing the safety of patients^{24,25}. Today, surgical
residents and educators must overcome challenges related to high-stress environments in and out
of the operating room, patient safety concerns, varying exposure and experience, and limited
feedback^{21,26,27,24}.

Given the high-stakes environment and technical skills involved in surgery, surgical training
fosters a high-stress environment²⁶. Unlike more common and less technically demanding
procedures, learning complex surgical operations becomes more challenging and stressful due to
the increased risk of patient harm.²⁶ Not only does this put the surgical educator in a difficult
position, balancing the responsibilities of teaching the surgical trainee and maintaining patient

safety, but it also makes acquiring the technical skills necessary for such procedures more
difficult for the trainee. ^{21,26}

Additionally, varying exposure poses an issue among surgical trainees^{28,29}. Exposure relies on the 358 surgical cases available, which can be unpredictable in terms of duration and frequency 28,29 . In 359 360 more specialized areas of training in both neurosurgical and orthopedic spine surgery, case 361 availability greatly varies depending on the residency program, resulting in limited opportunities for some surgical residents to acquire the appropriate technical skills^{28,29}. This limitation has led 362 363 trainees to work on days off in order to meet training requirements, leading to increased stress 364 and feelings of burnout; these phenomena indicate that inadequate training may contribute to concerns about career development and burnout²⁶. At the same time, the introduction of reduced 365 366 hours to address burnout issues has further decreased learning opportunities for surgical trainees³⁰. Moreover, varying exposure presents a complex issue in surgical education. 367 Finally, gaining feedback is another challenge in surgical education²⁷. Positive and negative 368 369 feedback is a critical component in surgical training and education, as it allows the learner to 370 understand the composites of expertise and how to acquire technical skill sets during their training³¹. While it is a requirement for surgical educators to provide feedback to their trainees, 371 meaningful, postoperative feedback tends to be given irregularly²⁷. However, this is largely due 372 to surgical instructors' demanding schedules and responsibilities^{21,27}. Solutions are needed to 373 374 accommodate the learning needs of surgical trainees and the demanding schedule and 375 responsibilities of surgical educators.

376 Such challenges in surgical education are well-documented, and measures are being taken

through research, educators, and policymakers to ensure the proper education of surgical

378 residents. Surgical education is shifting towards a competency-based quantitative training model
379 to address these complex issues^{7,8}.

380 Shift Towards Competency-Based Training

To address key challenges in surgical education and the evolving field of medicine, medical and 381 surgical education have shifted towards implementing a competency-based model into training^{7,8}. 382 383 This model's learning objectives are centered on competence, or how well learners can accomplish a task, rather than time⁷. As a result, this framework ensures the safety of patients 384 385 and uniform educational objectives and competence across training programs. Competency-386 based assessments have infiltrated surgical training in several ways. 387 A defining step towards a competency-based framework in surgical education is the introduction of Entrusted Professional Activities (EPAs) into surgical training³². EPAs are tasks or 388 389 responsibilities that can be entrusted to an unsupervised trainee after showing sufficient competence over several occasions^{32,33}. Such tasks and responsibilities range from technical to 390 391 interprofessional skills, covering all roles of the surgical profession. EPAs create structure within 392 the traditional apprenticeship model and enable key learning components, such as discussion, 393 assessment, and feedback to be easily incorporated into the curriculum³². Moreover, by 394 standardizing competency-based learning objectives in surgical training, EPAs ensure patient safety and quality outcomes³². However, while EPAs construct a buildable framework for 395 competency-based education, challenges related to its effective execution remain, including 396 397 uniform implementation across residency programs and the lack of science that guides the direction and implementation of EPAs³⁴. In Canada, post-graduate training is based on a 398 physician competency framework called CanMEDS³⁵. In this framework, a physician is 399 considered a medical expert with 6 intrinsic roles, communicator, collaborator, leader, advocate, 400

scholar, and professional³⁵. Further, in Canadian post-graduate training, EPAs are composed of 5
to 15 milestones that are associated with the CanMEDS roles³⁵.

403 The shift towards competency-based training has required a redefining of the focus of trainee assessment among surgical educators and researchers³⁶. A common and widely accepted 404 performance assessment tool in surgical education research, evaluation, and training is the 405 objective structured assessment of technical skills (OSATS)³⁷. This subjective Likert scale 406 407 assessment comprises several items reflecting technical surgical skills that surgical educators use to evaluate their trainees, including hemostasis, respect for tissue, instrument handling, economy 408 of movement, flow, knowledge of procedure, and an overall rating³⁷. The hemostasis item refers 409 410 to the ability to control bleeding while respect for tissue relates to the ability to avoid and minimize potential harm to surrounding anatomical structures³⁸. Instrument handling relates to 411 412 the surgeons' or trainees' ability to effectively use instruments, and the economy of movement refers to the extent to which repetitive, non-purposeful movements are made³⁸. Flow refers to the 413 414 forward planning of an operation, reflected by a seamless transition between steps and 415 movements of a procedure³⁸. Knowledge of procedure assesses the trainee's understanding of the entire procedure including the steps, instruments, and relevant anatomy³⁸. OSATS is considered 416 417 the gold standard in surgical evaluations and is often modified to meet the assessment goals of 418 the specialty and operation³⁷. While OSATS serves as a standardized assessment tool, studies have recently criticized its inability to oversee all aspects of surgical training^{39,40}. 419 Lastly, the current surgical curriculum requires surgical residents to enter their cases into the 420 Accreditation Council for Graduate Medical Education (ACGME) resident case log system. 421

Graduating surgical residents must enter 750 major operative cases with at least 150 entered

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423 during their final year^{5,41}. However, as requested by the ACGME, residents may only log an

operation when the individual has played a significant role in five competencies: diagnosis,
preoperative care, operation selection, operation, and postoperative care⁴². To be actively and
consistently involved in such aspects of an individual patient is highly unlikely given the limited
autonomy and condensed surgical rotations residents experience⁴². Such measures were put in
place to ensure surgical residents experience appropriate breadth and depth of surgical
operations⁴¹.

The movement toward competency-based training facilitates standardized competence across
surgical programs and their respective trainees⁷. Not only does this contribute to increased
patient safety, but it can also contribute to reduced burnout among surgical residents^{7,43,44}. The
latter can be explained by competency-based training's ability to offer equal training
opportunities, translating to an increased level of readiness⁴⁴. Through standardizing assessment
and creating milestones, surgical residents can feel more confident in their operative abilities, a
major component of reducing burnout^{43,44}.

437 While competency-based training strives for standardized opportunity and competence among 438 surgical trainees, case availability remains an issue in surgical education⁴⁵. Exposure to specific surgical cases varies per residency program^{39,40,46}. For example, spine operations are specialized 439 neurosurgical and orthopedic residency procedures^{39,40,46}. Moreover, depending on the hospital 440 and program, exposure and experience to spine surgery greatly varies among surgical 441 residents^{29,39,40,46}. While curricular measures can be put in place to ensure all residents gain 442 443 exposure to a specific operation, case availability is the limiting factor to this, which can make such a curricular objective difficult to achieve⁴⁵. Surgical simulation may be a valuable tool in 444 445 tackling this challenge and contribute to the shift toward competency-based training in surgical 446 education.

447 Surgical Education through Simulation Training

448 Modern surgical education is progressively incorporating simulation training, a method of learning by practicing clinical skills in a simulated environment⁹. Simulation can come in various 449 450 modes including virtual reality, which is primarily used for technical skills, and simulated 451 standardized patients, which is utilized for practicing skills like diagnostics⁹. Moreover, 452 simulation training could be useful for formative (focused on progress and learning) and 453 summative (focused on certifying competency) assessments in surgical education, which are integral components of competency-based training⁹. 454 455 Simulation training in surgical education has many advantages. In simulated environments, 456 surgical trainees can obtain knowledge and focus on specific skills, whether technical, 457 interprofessional, or behavioral⁹. Most notably, simulation provides a controlled, risk-free 458 environment where surgical trainees can devote themselves to learning essential clinical skills without putting patient safety and quality of care at risk¹⁴. Further, surgical trainees can master 459 460 skills and make errors without the stress and potential harm associated with learning in the operating room⁹. This translates to a better understanding of when errors can take place and 461 462 instigates the development of mitigation and prevention strategies for such errors; gaining this skill in a simulated environment enhances the surgical trainees' readiness as independent 463 surgeons while ensuring patient safety¹⁴. Simulation training also allows trainees to be exposed 464 465 to clinical variation, a typically difficult aspect to control for and include during clinical 466 rotations⁹. This aspect contributes to greater breadth and standardized competence across 467 surgical programs.

Scientific data supporting simulation training in surgical education continues to emerge,
highlighting its ability to develop diverse aspects of clinical skills for trainees⁴⁷. While
simulation training provides a valuable platform for surgical trainees to master and acquire

471 clinical skills, thorough research is essential to ensure its effective implementation and that

472 trainees fully benefit from the simulation experience⁴⁷. Specifically, validation studies are

473 essential for understanding the educational utility of simulators in surgical training.

474 Validation

As simulation gains traction in surgical education, validation emerges as a pivotal foundational phase in assessing the effectiveness of simulators for surgical training¹⁰. Validation studies aim to understand the appropriateness of a tool for a particular goal¹¹. For example, in the context of surgical simulation, a validation study for a surgical simulator would aim to understand its utility as a learning tool in surgical training. Currently, surgical simulation literature primarily follows a traditional framework while educational theorists accept a contemporary framework¹¹. Both

481 frameworks are outlined in Table 1.

Table 1: Validation Frameworks		
Framework	Approach	
Traditional	Establish concepts of validity.	Face: the extent to which the simulator replicates the real procedureContent: the extent to which the simulator measures the skills they were designed to simulateConstruct: the ability of the simulator to distinguish different operative skill levels and includes convergent validityPredictive: the extent to which the simulator can predict
		future performance, especially that of the operating room
Messick's Contemporary	Construct a validity argument by gathering evidence of validity from up to five sources.	Test Content: the relationship between a tool's content and the construct it aims to measureResponse Process: the integrity of the data collectionInternal Structure: the measures taken to determine the degree to which items of an instrument align with the underlying construct and are reported as statistical measuresRelationship to Other Variables: the degree of relatedness between assessment measures and external independent measuresConsequences: the potential and observed consequences of
		the tool of interest

483 The traditional framework of validation involves "types of validity", including face, content, construct, and transfer or concurrent validity¹¹. These types of validity can be divided into two 484 approaches: subjective and objective validation^{10,48}. Subjective validation utilizes expert opinion 485 486 to determine the value of the examined instrument, and it involves face and content validity^{10,11}. 487 In the context of surgical simulation, face validity refers to the extent to which the simulator 488 visually resembles the surgical task, while content validity refers to the extent to which the simulator's surgical task reflects that of the surgical task done in real life^{10,11,48}. These types of 489 validity require expert input, and while subjective questionnaires are typically administered for 490 assessing face and content validity, a universal consensus of evaluation does not exist^{10,11,48,49}. 491 492 Objective validation involves using experimental means to ascertain the extent to which the simulator's surgical task parallels the same task performed in the operating room^{10,48}. Notable 493 494 objective validation measures include construct validity and transfer or concurrent validity. Construct validity evaluates the simulator's ability to differentiate skill levels in the surgical 495 task^{10,11}. To assess this, experimental studies examine the performance of trainees compared to 496 497 that of expert surgeons on the simulator of interest. Convergent validity is a subset of construct validity that examines how closely measures of the same construct agree with another^{50,51}. This 498 499 is often evaluated by investigating the extent of agreement between a targeted measure and a well-known measure^{50,51}. Further, this validity is suggestive of the simulator's utility by relating 500 501 its performance assessment with that of what is used in surgical training. Transfer or concurrent 502 validity refers to the extent to which the simulator can predict future performance, especially that of the operating room^{10,48}. This type of validity typically involves longitudinal studies to 503 504 understand the transfer of skill from simulation to an accepted "testing" task like using ex vivo tissues or cadavers^{10,48}. Moreover, predictive validity is typically assessed after determining the 505

face, content, and construct validity of a simulator. This framework of validity is used
extensively in surgical simulation literature, although a contemporary framework is accepted in
the education community^{11,52}.

509 Messick's contemporary framework of validity proposes that validity is an argument consisting 510 of an accumulation of evidence that supports a tool's use for a particular purpose and population³⁷. It postulates that all evidence of validity relates to construct and comes from five 511 sources, content, response process, internal structure, relation to other variables³⁷, and 512 513 consequences. The "test content" dimension refers to the relationship between a tool's content and the construct it aims to measure^{11,52}. This source of evidence must be based on the input 514 from participants who are experts in the procedure of interest^{11,52}. "Response process" pertains to 515 the integrity of the data collection, including standardized instructions and blinded raters^{11,52}. 516 517 "Internal structure" relates to the measures taken to determine the degree to which items of an 518 instrument align with the underlying construct and are reported as statistical measures such as internal consistency and reliability^{11,52}. The "relationship to other variables" dimension refers to 519 520 the degree of relatedness between assessment measures and external independent measures such as proficiency level and experience^{11,52}. Finally, the "consequences" concept refers to evidence 521 522 relating to the potential and observed consequences of the tool of interest. 523 Messick's contemporary framework is the recommended approach in educational research, as

advocated by the American Educational Research Association (AERA), the American

525 Psychological Association (APA), and the National Council on Measurement in Education

526 (NCME), in *Standards for Educational and Psychological Testing*^{11,52}. However, the integration

527 of this approach into surgical education research has been $slow^{11,52,53}$. A study from 2018 found

that only 6.6% of validation studies for surgical simulation from 2008 to 2017 used the

529 contemporary framework⁵². This trend is speculated to occur to maintain consistency among past
530 literature¹¹.

531 The traditional and contemporary frameworks are formally distinct. Noticeably, the 532 contemporary framework focuses on gathering evidence compared to establishing validation as 533 in the traditional framework. The contemporary framework also values implementing research 534 methods to enhance the quality of validation studies, evident in the "response process" and 535 "internal structure" criteria. Nonetheless, a significant overlap exists between the two 536 approaches¹¹. Specifically, "face validity" and "content validity" in the traditional framework are 537 tightly related to the contemporary framework's "test content". In addition, the traditional 538 framework's "construct validity", including "convergent validity", is virtually the same as the 539 contemporary framework's "relationship to other variables" aspect. This trend follows the 540 traditional framework's "predictive validity" which relates to "consequences" in the 541 contemporary framework. Moreover, because establishing validity principles plays a critical step in evaluating the utility of simulation in surgical training, a compromise between the frameworks 542 543 involving clear definitions and justifications of validity methods may be the most practical way 544 forward in future simulation validation studies¹¹.

545 This study investigates the foundational steps involved in validation studies, namely establishing

546 face, content, construct, and convergent validity. Establishing such principles sets the

547 groundwork for future studies that outline a tool's role in surgical training.

548 Virtual Reality Spine Simulation

549 Surgical simulation is becoming an important tool in surgical training for technical skills, with 550 laparoscopic surgery being one of the most advanced areas⁵⁴. In the United States, surgical 551 simulation is implemented in laparoscopic training and assessment of performance⁵⁴. Virtual Reality simulation is an emerging tool in surgical education, although its application to spine surgery is minimal⁵⁵. In past years, studies have evaluated the utility of virtual reality spine simulators with many focusing on the pedicle screw insertion technique ^{15,55}. Nonetheless, only a limited number of spine surgery pedicle screw insertion simulation platforms exist; however, they lack comprehensive validity and high fidelity, highlighting the need for the development of more pertinent simulation training tools^{15,16,17,18,19}.

However, despite the growing number of virtual reality spine simulation studies, recent reviews 558 559 from Pfandler et al. and McCloskey et al. have determined that the majority of these platforms are 560 limited in quality based on scoring using the Medical Education Research Study Quality Instrument and the GRADE criteria, respectively^{15,55}. Further, although current literature points to 561 562 promising uses of virtual reality surgical simulation, the lack of robust literature on virtual reality spine simulation has limited its adoption in spine surgery training²⁰⁻²². Consequently, such reviews 563 advocate for future studies to assess how training on virtual reality spine simulators demonstrates 564 skill transfer to the operating room^{15,55}. Other notable suggestions for future virtual reality spine 565 566 simulator studies include justified, validated, and reliable metrics, and clinical expert ratings in their assessment^{15,55}. Considering these aspects in future virtual reality spine simulation studies 567 568 would increase the credibility of implementing virtual reality simulation in spine surgery training. Virtual reality simulation for spine surgery training may be an important advancement in surgical 569 570 education, as it addresses the challenges that residents face regarding restrictions and limitations in clinical hours²². Moreover, for virtual reality simulation to be implemented into spine surgery 571 training, comprehensive studies must be carried out with relevance to the operating room. 572

573 Pedicle Screw Insertion and Its Associated Risks

574 The pedicle screw insertion is a common, widely used technique in spine surgery. This is utilized in procedures like scoliosis, spine tumors, trauma, infection, and degenerative disease⁵⁶. The 575 576 procedure involves creating an entry point on the vertebral body using an awl followed by 577 preparing a channel using a cannulation probe, otherwise known as a pedicle finder, that advances through the vertebral cancellous bone⁵⁷. At this point, the surgeon largely depends on 578 tactile feedback and experience-based judgment to determine the location of the channel.⁵⁶ To 579 580 identify any errors in channel preparation, a ball tip probe is inserted into the channel, where the surgeon feels for any breaches that may have been made in the process⁵⁷. The channel is pre-581 582 threaded using a tap before further breach verification with a ball tip probe and insertion of the screw. Final X-Rays can be performed to ensure the proper positioning of the screw.⁵⁶ 583 584 While performing these steps, the surgeon must utilize the limited spinal anatomical landmarks, 585 which are subject to morphological variability, to make informed decisions on the accuracy and safety of the procedure⁵⁷. This aspect becomes crucial given this technique's limited margin of 586 error, as the pedicle is close to many vital neural and vascular structures^{56,57}. Today, image-587 588 guided techniques are employed in place to prevent the malplacement of screws, including fluoroscopy, intraoperative navigation, and robotic assistance⁵⁶. Despite the advancements in 589 590 navigational aid, mastering the pedicle screw insertion technique remains crucial, as resources at 591 hospitals vary and technical disruptions can make navigational aids unavailable. 592 Pedicle screw insertions pose risks for complication if not inserted correctly. For example, 593 although rare, malpositioned screws can put surrounding neural and vascular structures at serious 594 risk of damage, including complications like dysesthesia, hemorrhage, and neurological

595 injury.^{57,58} Suboptimal positioned screws can also lead to early construct failure or

pseudoarthrosis formation.⁵⁷ Moreover, the potential harm associated with the malplacement of 596 pedicle screws is well documented with an incidence ranging between 4.2-7.8%.^{58,59} 597 The pedicle screw insertion proves to be complex and demanding, necessitating a steep learning 598 curve.⁵⁶ Recent publications showed that trainees need to place 60 to 80 pedicle screws under 599 600 direct supervision before being able to independently perform accurate and safe pedicle screw insertions^{12,13}. With varying exposure, limited cases, and restricted hours,^{22,29,60} such a degree of 601 602 experience may be difficult to achieve for training neurosurgical and orthopedic residents and 603 spine fellows. Furthermore, tools for comprehensive surgical training could be valuable in 604 gaining the technical skills necessary for mastering the pedicle screw insertion technique.

605 TSYM Simulator

606 The TSYM simulator is a non-immersive virtual reality platform developed by Cedarome 607 Canada Inc. dba Symgery. (Montreal, Canada). This system provides various simulated surgical 608 scenarios, primarily focusing on spine interventions. The TSYM simulator is a stand-alone 609 system, consisting of a screen that displays the 3D surgical environment, a robotic arm attached 610 to the operative tool, and three tool handles for simulating an array of surgical instruments, as 611 seen in Figure 1. The simulator utilizes a voxel-based system to achieve a realistic intra-operative 612 user experience, enabling haptic feedback during the simulated operations. A previous study 613 examining the utility of virtual reality simulation in surgical training suggests that such 614 simulators with haptic feedback result in increased accuracy in cervical pedicle screw insertions 615 compared to training through traditional means⁶¹. Moreover, the simulator's tactile feedback 616 coupled with audio feedback enhances the fidelity of the simulator's surgical tasks. The TSYM 617 simulator creates a non-immersive operative environment, whereby the simulated procedure is limited to the screen, unlike immersive virtual reality platforms that provide a 360-degree virtual 618

619 environment. Although a non-immersive platform may possess lower fidelity compared to an 620 immersive platform, a recent study comparing the effectiveness of immersive and non-immersive virtual reality training for hip arthroscopy found similar outcomes related to skill and procedural 621 622 acquisition and skill transfer⁶². Further, such features of the TSYM simulator make it a more 623 promising tool for surgical training. The TSYM simulator offers an L4-L5 bilateral pedicle screw insertion scenario, an essential 624 625 technique in spine surgery with a steep learning curve^{12,13}. The following manuscript aims to establish the foundational principles of the L4-L5 bilateral pedicle screw insertion scenario, 626 investigating face, content, construct, and convergent validity. To our knowledge, this is the first 627 study to assess convergent validity for an L4-L5 bilateral pedicle screw insertion on a virtual 628 629 reality platform.

630

631 STUDY RATIONALE, HYPOTHESIS, AND OBJECTIVES

632 Rationale

Surgical training involves acquiring complex, bimanual skills while ensuring patient safety under 633 634 a stressful and high-stakes environment. Such challenges become heightened in spine surgery 635 training where mastering technical skills is critical, exposure in residency varies, and the need for comprehensive training is essential^{29,60,8}. Virtual reality simulators may be a valuable tool to 636 637 overcome such issues, as they provide residents with practical and accessible training in a safe, 638 stress-free environment. 639 However, simulation has not been implemented into training for spine surgery, as current 640 simulators lack comprehensive validation studies, preventing the uptake into surgical training. To 641 address the challenges in teaching spine surgery among neurosurgical and orthopedic residents, 642 we aimed to validate the utility of a virtual reality spine simulator's lumbar pedicle screw insertion scenario, a critical skill in spine surgery with a steep learning curve. In this study, a 643 644 consensus approach between the traditional and contemporary validation frameworks was used 645 to evaluate the simulator's educational potential, where components of the traditional framework

646 were evaluated to construct a validity argument.

647

648 Hypothesis

The TSYM virtual reality simulator's L4-L5 bilateral pedicle screw insertion scenario will
demonstrate face, content, construct, and convergent validity, contributing to evidence of validity
of the simulator's potential as a formative tool in spine surgery training.

652 **Objectives**

- 653 The objectives of this case series study are:
- 1. To evaluate face and content validity for an L4-L5 bilateral pedicle screw insertion
- simulation on the TSYM simulator platform.
- 656 2. To use simulation-derived metrics and the assessment of simulated pedicle screw insertion
- 657 operative performance utilizing OSATS to assess construct validity.
- 658 3. To establish convergent validity of the simulation's performance metrics by assessing the
- relationship between the simulation-derived metrics and simulated pedicle screw insertion
- 660 operative performance OSATS.
- 4. To attempt to use the results to construct an argument supporting the TSYM simulator's use
- 662 for training residents and fellows in the L4-L5 bilateral pedicle screw insertion.

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664

665 666	MANUSCRIPT
667	Face, Content, Construct, and Convergent Validity of a Surgical Spine Simulator for Pedicle
668	Screw Insertions
669	
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687	The preceding work has been augmented with additional information and materials to reflect the
688	requirements for thesis submission for a Master of Science.
689	Manuscript submitted for review to the Journal of Neurosurgery (June 18th, 2024).
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695 INTRODUCTION

Surgical training involves balancing the objectives of imparting complex skills and ensuring 696 697 patient safety²⁵. Intraoperative surgical teaching offers personalized instruction but may involve limited exposure to complex procedures with the potential for patient harm^{63,64}. This becomes 698 699 particularly relevant in spine surgery, where mastery of technical skills is essential, exposure in residency varies, and the need for comprehensive training is essential^{29,60,8}. Pedicle screw insertion 700 is a common but technically demanding spine surgical procedure^{8,57}. Mastering the pedicle screw 701 702 insertion involves a steep learning curve since trainees need to place many pedicle screws under direct supervision before being able to independently perform safe pedicle screw placement^{12,13}. 703 704 The potential harm associated with pedicle screw insertion malposition is well documented, and 705 in two large literature review articles, the incidence of pedicle screw malposition ranges between $4.2 - 7.8\%^{58,59}$. 706

707

708 The role of virtual reality simulation in enhancing surgical education and providing a risk-free environment for procedural learning and skill refinement continues to develop^{57,65,66}. There are a 709 710 limited number of spine surgery pedicle screw insertion simulation platforms. Many lack 711 comprehensive validity and high fidelity, highlighting the need for the development of more relevant simulation training tools^{15,16,17,18,19}. The need to shift towards quantitative competency-712 713 based surgical education is becoming increasingly clear⁸. This would standardize training methods, 714 focusing on the development and assessment of specific competencies rather than using time in 715 training as an indicator of experience⁶⁷. Such standardization is important in complex surgical 716 procedures like pedicle screw insertions, where competency of specific skills directly impacts patient outcomes^{58,59}. 717

718

719 The TSYM Symgery virtual reality platform allows for a realistic pedicle screw insertion 720 simulation and provides personalized feedback. This system provides an array of performance metrics useful to assess surgical techniques, offering an innovative approach to surgical training⁶⁸⁻ 721 722 ⁷⁰. The educational utility of the TSYM Simulator platform is yet to be established. This study 723 explores the simulator's training potential by gathering subjective and objective validity evidence, specifically face, content, construct, and convergent validity^{10,50,71}. Face validity refers to the 724 725 extent to which the simulator replicates the real procedure while content validity refers to the extent to which the simulator measures the skills they were designed to simulate^{10,48}. Face and content 726 validity can be determined through questionnaires⁴⁸. Construct validity is a type of objective 727 728 validity that describes the ability of the simulator to distinguish different operative skill levels and 729 can be investigated by comparing surgical performance between "less skilled" and "skilled" groups^{71,48,72}. Simulation-derived performance metrics on tool handling and the Objective 730 731 Structured Assessment of Technical Skills (OSATS) ratings, the gold standard for scoring 732 performance in surgical education in human operative procedures, were used to assess construct validity^{73,74}. Convergent validity, a subgroup of construct validity, explores the degree of 733 734 agreement between different measures of the same construct and is typically evaluated by correlating the measure of interest to a well-known measure ^{50,51}. We examine convergent validity 735 by investigating how well the simulation-derived performance metrics relate to OSATS^{50,51}. 736

737

Gallagher and co-workers have reviewed and outlined fundamental principles of the traditional
 framework of validation by applying scientific methods for the assessment of surgical education
 and training¹⁰. Messick's contemporary framework of validity proposes that validity is an

741 argument consisting of an accumulation of evidence that supports a tool's use for a particular 742 purpose and population³⁷. This study aims to utilize both methods to gather evidence of validity 743 for the utilization of the TSYM simulator platform in spine surgical training. This approach may 744 potentially provide a more holistic evaluation of the TSYM systems' capacity to assess and train learners in complex procedures like the pedicle screw insertion simulation^{10,48}. Therefore, the 745 746 objectives of this case series study were (1) to evaluate face and content validity for an L4-L5 bilateral pedicle screw insertion simulation on the TSYM simulator platform, (2) to use simulation-747 748 derived metrics and the assessment of simulated pedicle screw insertion operative performance 749 utilizing OSATS to assess construct validity, (3) to establish convergent validity employing 750 simulation-derived metrics and simulated pedicle screw insertion operative performance OSATS, 751 and (4) to attempt to use the results to construct an argument supporting the TSYM simulator's use 752 for training residents and fellows in the L4-L5 bilateral pedicle screw insertion.

753 METHODS

754 Participants

755 Neurosurgical and orthopedic residents, spine fellows, non-spine neurosurgical fellows who had 756 experience in pedicle screw insertion, and neurosurgical and orthopedic spine surgeons 757 participated in this case series study. An exclusion criterion was previous experience with the 758 TSYM simulator. Participants were categorized a priori into two groups, skilled participants (Post 759 Graduate Year (PGY) 5-6 residents, fellows, and spine surgeons) and less skilled residents in PGY 760 1 to 4. Participants signed an informed consent approved by the Neurosciences-Psychiatry McGill 761 University Health Center Research Ethics Board. After signing the consent, participants completed 762 a demographic questionnaire. Participants were then provided with standardized written and verbal

763 instructions regarding the steps and instruments available to complete the simulated L4-L5 764 bilateral pedicle screw insertion on the TSYM simulator. Verbal and written instructions were 765 administered in English; however, given the bilingualism presence in Ouebec, language-related 766 questions, specifically any French-related questions or issues, were welcomed and answered 767 appropriately by an on-site individual involved in running the trial. Participants then performed a 768 dry lab and an L2 simulated laminectomy procedure to become acquainted with the TSYM 769 simulator and simulated tools and their functions (see supplemental information). After completing 770 these tasks, participants performed a simulated L4-L5 bilateral pedicle screw insertion on the TSYM simulator. No time limit was imposed but each step was dependent, and once completed, 771 772 required participant confirmation before proceeding. This article follows the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting guidelines⁷⁵. 773

774 Virtual Reality Simulator Platform

775 The TSYM Symgery simulation platform, developed by Cedarome Canada Inc. dba Symgery. 776 (Montreal, Canada), was utilized in this study (Figure 1A). The three-dimensional (3D) 777 intraoperative spinal surgical procedures present in this simulator rely on a voxel-based system⁷² 778 (Figure 1B). The simulator consists of a single haptic arm that provides continuous tactile 779 feedback during operator manipulation of the surgical instruments employed to complete the task 780 (Figure 1C) and generates appropriate auditory and visual information for each tool used. This 781 system is equipped with a robust software platform including pre-programmed surgical tools and 782 captures multiple performance metrics, enabling a detailed analysis of surgical performance. The 783 pedicle screw insertion simulation task consists of 1 animated and 4 deconstructed interactive steps 784 described in Table 2. These steps were repeated for each screw. For standardization purposes, users 785 performed the pedicle screw insertions using constant magnification and inserted 6.5 x 45 mm
pedicle screws in a predetermined order left L5, left L4, right L5, right L4, (see supplemental
information). Participants had access to live X-rays to verify the entry point and angles for pedicle
cannulation and confirm inserted screw accuracy. Video 1 shows a skilled participant performing
a pedicle screw insertion on the simulator.

790 Face and Content Validity

791 The neurosurgical and orthopedic spine surgeons and spine fellows assessed the face and content 792 validity of the pedicle screw insertion simulation using questionnaires assessed with a 7-point 793 Likert scale with 1 being completely unrealistic and 7 being completely realistic ^{72,76}. A consensus on an acceptable median value for sufficient face and content validity has not been established^{72,76}. 794 795 Since no gold standard exists for face and content validity, in this study, the overall simulated 796 procedure and its deconstructed tasks were considered to have adequate evidence of face and 797 content validity if questionnaires achieved a median ≥ 4.0 on the 7-point Likert scale, consistent with our previous studies^{72,76}. 798

799 Construct Validity

To assess construct validity, the study assessed each pedicle screw insertion independently and employed performance metrics derived from the TSYM simulator and expert scoring using OSATS.

Simulation-Derived Tool Metrics: The TSYM simulator continuously assessed several features of performance during pedicle screw insertion. Data on each tool's 3D velocity, 3D force, maximum force, 3D acceleration, and tool tissue contact were collected for each screw. The 3D force and maximum force refer to the forces applied on the haptic arm while using the tool. The 3D velocity and 3D acceleration of each tool are derived from the position of the tool's tip in space. The tools that were assessed can be found in Table 2. The rationale to treat each pedicle screw insertion by
each participant independently was that each screw insertion involved a different simulated
vertebrae entry point, orientation, and angulation.

811 Blinded OSATS Assessment: In concert with the simulator-derived performance metrics, the study 812 utilized the validated methodology of learner operative performance assessment employed by surgical educators in human operative settings, OSATS ratings, to determine construct validity $\frac{29,30}{2}$. 813 Each participant's simulated L4-L5 bilateral pedicle screw insertion was recorded on-screen, 814 which was later subdivided into four videos, one for each pedicle screw insertion. Video recordings 815 816 of each lumbar pedicle screw insertion were randomized and blindly rated by two experts with 817 experience performing human pedicle screw insertions. The OSATS scale was adapted to the 818 simulator's capabilities, resulting in 5 items (respect for tissue, instrument handling, the economy 819 of movement, flow, and knowledge of procedure) and an overall rating. Each performance was 820 rated on a 7-point Likert scale. The OSATS scale demonstrated excellent internal consistency (a = .97 [95% CI, .96, .98]) and excellent inter-rater reliability ($\alpha = .97$ [95% CI, .97, .98]). 821

822 Convergent Validity

The simulation-derived tool metrics were correlated with the average OSATS ratings to assess convergent validity. A two-tailed Spearman Rank Order Correlation Coefficient was calculated between all collected data for each tool metric that achieved evidence of construct validity and each OSATS item.

827 Statistical Analysis

828 Collected data was imported into Python to develop tool metrics. Outliers in tool metrics were829 identified and imputed on MATLAB R2023b. All other statistical assessments were performed on

SPSS (version 29.0; IBM, Armonk, New York). The data was not normally distributed as assessed
by Shapiro-Wilk's test (P < .05). Mann-Whitney tests assessed statistical differences between
groups for each performance measure. A two-tailed Spearman Rank Order Correlation Coefficient
examined associations between performance metrics.

834 RESULTS

835 **Participants**

836 Demographic data and relevant information concerning the two groups in this case series study 837 are presented in Table 3. A total of 27 participants from two Ouebec universities were included in this investigation. The skilled group reported a mean of 452 pedicle screws (SD = 883.6) inserted 838 independently while the less skilled group reported a mean of 0.5 pedicle screws (SD = 1.4) 839 840 inserted independently. The difference between the two groups was statistically significant, (P <.001). Since each participant inserted 4 screws, a total of 108 simulated screws were inserted. 841 842 One screw was removed from the study due to a technical issue resulting in 107 screws available 843 for analysis. Therefore, 107 videos, one for each pedicle screw insertion, were evaluated using OSATS. 844

845 Face and Content Validity

The pedicle screw insertion simulation median ratings and ranges for face and content validity are outlined in Table 4. The 4 participating spine surgeons and 2 spine fellows assessed face and content validity. This group rated the simulated procedure's overall realism with a 5.0 median (range 3.0-6.0) rating, consistent with face validity. Related to content validity, all steps achieved adequate evidence of validity (median > 4.0) except the pre-threading step using the tap, which was rated a median of 3.5 (range 1.0-5.0). The skilled group rated the simulated procedure's overall
realism with a 5.0 median (3.0-6.0) rating.

853 Construct Validity

854 Simulation-Derived Tool Metrics: All simulation-derived tool metrics were assessed between the groups (Table 5). Significant differences were found between the two groups in 4 of 25 855 856 performance metrics. According to how convergent validity is assessed in studies in the literature, there is a documented anticipated result^{50,51}. We therefore anticipated observing group differences 857 858 between 3D velocity and 3D acceleration of the tap screw at step 3A and tool contact and maximum force of the screwdriver in step 4⁷⁷⁻⁷⁹. While pre-threading the channel with the tap, the skilled 859 group showed a significant increase in 3D velocity when compared to the less skilled group (.0014, 860 861 95% CI [.00119, .00153] vs .001, 95% CI [.0012, .0013]; P =.04). Using the tap, the less skilled 862 group showed a significantly higher 3D acceleration than the skilled group (4.36e-9, 95% CI [-7.26e-9, 16e-9] vs 5.43e-10, 95% CI [-5.19e-9, 6.28e-9]; P = .01). Although the 3D acceleration 863 864 values were small across both groups, statistical analysis confirmed a significant difference (P = .01). During the insertion of the screw with the screwdriver, the less skilled group applied 865 866 significantly more maximum force than the skilled group (10.14, 95% CI [7.34, 12.96] vs 7.52, 867 95% CI [5.07, 9.96]; P = .04) and spent significantly more time in contact with surrounding tissue than the skilled group (.22, 95% CI [.18, .25] vs .11, 95% CI [.09, .13]; P <.001). These group 868 differences are depicted in Figure 2. 869

Randomized, Blinded OSATS Ratings: An average rating for each OSATS item was calculated for
each screw video by blinded ratings provided by two experts. The skilled group achieved a
significantly higher mean overall OSATS rating compared to the less skilled group (5.02, 95% CI
[4.63, 5.41] vs 3.30, 95% CI [2.92, 3.69]; P <.001). In each OSATS item (instrument handling,

respect for tissue, economy of movement, flow, and knowledge of procedure), the skilled group significantly outperformed the less skilled group (P < .001 for each item). Group differences are outlined in Figure 3.

877 Convergent Validity

A two-tailed Spearman Rank Order Correlation Coefficient was calculated between each item of 878 879 the OSATS ratings and the four significant tool metrics (screwdriver maximum force, screwdriver 880 tool contact, 3D velocity using the tap, and 3D acceleration using the tap). As predicted, the maximum force using the screwdriver had significant negative correlations with all OSATS items: 881 respect for tissue, instrument handling, economy of movement, flow, knowledge of procedure, and 882 overall (Spearman's Coefficient = -.32, P < .01; Spearman's Coefficient = -.39, P < .01; Spearman's 883 Coefficient = -.37, P < .01; Spearman's Coefficient = -.38, P < .01; Spearman's Coefficient = -.29, 884 P < .01; Spearman's Coefficient = -.33, P < .01, respectively). As predicted tool contact using the 885 screwdriver significantly correlated with respect for tissue, instrument handling, economy of 886 movement, flow, knowledge of procedure, and overall. (Spearman's Coefficient = -.25, P < .01; 887 Spearman's Coefficient = -.34, P < .01; Spearman's Coefficient = -.42, P < .01; Spearman's 888 Coefficient = -.43, P < .01; Spearman's Coefficient = -.31, P < 0.01; Spearman's Coefficient = -.31, 889 890 P < .01, respectively). No significant correlations were found between the tap's 3D velocity and 891 3D acceleration and OSATS items. Table 6 outlines the associations between these performance 892 metrics.

894 DISCUSSION

The results of this case series study may be useful for surgical educators and researchers 895 896 interested in spine simulation for several reasons. First, the pedicle screw insertion simulation 897 employed in this investigation demonstrated varying degrees of validity: mixed and variable 898 levels of face and content, as well as mixed evidence of construct and convergent validity. These 899 subjective and objective results contribute to the evidence of validity as an argument for this 900 platform's potential as a formative educational tool in spine surgery training²⁵. Second, to our knowledge, this is the first study to correlate simulator-derived metrics with OSATS ratings to 901 902 assess the convergent validity of a simulated operative procedure on a virtual reality spine 903 surgery platform. Third, using OSATS ratings in simulator performance assessment and 904 simulator-derived metrics provides a more holistic understanding of learner operative 905 performance. This methodology may be useful to investigators interested in designing and 906 validating simulators focused on improving technical skills during surgical training.

907 Face, Content, and Construct Validity

The traditional validation framework investigates types of validity like face, content, and construct; 908 909 while, the contemporary framework gathers evidence from up to five sources (content, response 910 process, internal structure, relation to other variables, and consequences) to support a tool's use for a particular purpose and population³⁷. This study combines both frameworks, using traditional 911 types of validity to help construct a validity argument for the TSYM simulator's educational utility 912 913 in surgical training. This validity argument is primarily supported by the OSATS findings and 914 rather weakly by the other validity measures. Moreover, as elaborated below, the validity argument 915 lacks strength and would benefit from more robust findings.

916 The participating spine surgeons and fellows rated most face and content validity statements with 917 a median of 4.0 or greater, which is considered to provide adequate evidence of face and content validity^{72,76}. While these results are consistent with our definition of "adequate" face and content 918 919 validity, this evidence can be considered "mixed" for two reasons. First, we did not anticipate participants providing a rating of "totally realistic" (7) and our group has, accordingly, previously 920 considered a median of "4" as sufficient for providing evidence of face and content validity^{72,76}. 921 922 Second, the broad ranges of observed ratings of most items, some including "1" and "7", illustrate 923 meaningful variance within the experienced participants' perspectives. Participants were asked to 924 comment on the simulator's L4-L5 pedicle screw insertion scenario. Verbal feedback from this 925 group indicated that torque feedback utilizing the tap for pre-threading the inner pedicle canal 926 could be improved to enhance the realism of this step with the lowest median value. These results 927 are suggestive of borderline reasonable face validity and content validity; however, because of the 928 great variability, the results must be interpreted with care. The L4-L5 pedicle screw simulation will 929 need to be improved to enhance its realism.

930

931 The study demonstrated statistically significant differences between the two groups for four 932 simulation-derived tool metrics of 25 using two tools: 3D velocity and 3D acceleration of the simulated tap, and the maximum force and the tool contact of the simulated screwdriver (Figure 933 934 2). The skilled group had higher 3D velocity than the less skilled associated with tap screw use. The skilled group's familiarity with the procedural components⁷⁷ and operative technical skills 935 936 needed may allow this group to use increased velocity using the simulated tap. The less skilled 937 group being less experienced and more hesitant in the use of this instrument may have resulted in 938 lower tap velocity. The skilled group, conscious of the safety risk of high acceleration instrument 939 usage, may utilize lower tap acceleration consistent with previous studies highlighting that experience in pedicle screw fixation is an important factor distinguishing participant expertise^{12,13}. 940 941 The maximum force applied by the screwdriver was significantly higher for the less skilled group 942 than the skilled group consistent with previous virtual reality studies assessing instrument force application⁷⁷⁻⁷⁹. Studies using artificial neural networks (ANN) were able to assess junior and 943 944 senior residents, neurosurgeons, and orthopedic surgeons' performance and identify different patterns of force application, which is considered a safety metric⁷⁹⁻⁸¹. From a clinical standpoint, 945 946 increasing the force applied can result in breaches in the medial, lateral, and upper and lower 947 vertebral directions. This could place many neurological and vascular structures, such as the 948 adjacent nerve root, the dura, and arteries and veins at the anterior component of the vertebral 949 column, at risk of injury. Our results involving maximum force applied by the screwdriver are 950 consistent with a pattern of force application in which more skilled groups appreciate that using high forces during screwdriver use may impact patient safety and therefore moderate this metric 951 during their training and career⁷⁹. A different pattern may be the reason why the less skilled group 952 953 had higher screwdriver tool contact. The less skilled group may be more unsure concerning 954 appropriate screwdriver application and use on the pedicle screw due to lesser anatomical and 955 practical knowledge of the procedure, resulting in more inadvertent adjacent tissue contact.

956 Only four of 25 tool-related performance metrics provided evidence of construct validity. The 957 limited number of significant metrics identified could be related to the low number of participants 958 in the study. The possibility exists that less skilled individuals trained to modify these metrics to 959 more closely correspond to those of skilled participants may improve their operative performance. 960 However, the identification of these four metrics allowed further studies to assess the convergent 961 validity of the simulation platform. 962 The skilled group significantly outperformed the less skilled group in each OSATS component
963 (Figure 3). These OSATS studies support the evidence of simulator-derived instrument tool metrics
964 validation concerning the construct validity of the TSYM simulator for the L4-L5 pedicle screw
965 insertion simulation.

966 Correlating Simulation-Derived Performance Metrics and OSATS Ratings for Convergent 967 Validity

968 The ability to correlate novel simulation-derived metrics with OSATS scoring allowed an 969 assessment of the convergent validity of the TSYM platform^{29,30}. The finding that two of four 970 simulation-derived performance metrics correlated with all OSATS items provided evidence of 971 convergent validity for the TSYM simulator and has several implications. The OSATS ratings of 972 participant video pedicle screw insertion performance identified that screwdriver maximum force 973 application and screwdriver tool contact were negatively correlated with all OSATS items. The 974 less skilled groups' OSATS ratings for pedicle screw insertion were significantly lower, consistent 975 with their results on these two simulation-derived metrics discussed previously. Two of the four significant simulation-driven performance metrics, 3D velocity, and 3D acceleration using the tap, 976 977 did not significantly correlate with the OSATS ratings. This finding may suggest that these 978 performance features are not accurately captured in the items rated by OSATS. This may relate to 979 the expert evaluators scoring these videos' inability to visually accurately determine these specific 980 two composites of expertise, 3D velocity and 3D acceleration of tap instrument while in the bone channel^{79,82}. Although OSATS is a validated method to assess surgical performance, several studies 981 982 have questioned the ability of OSATS to fully measure the complexities of surgical operating room performance^{39,40}. This study suggests that the consideration of utilizing OSATS and other surgeon 983 984 educator assessments of surgical performance in combination with those provided by simulatorderived metrics may enhance our understanding, assessment, and training of surgical skills and be
useful for formative assessment. Integration of these two methodologies may result in a more
comprehensive assessment of learner surgical expertise.

988 These studies allow further investigations related to the predictive validity of the TSYM simulator.
989 This would necessitate that participants' results, obtained from their simulated performance on the
990 TSYM simulator with pedicle screw insertion, would predict their future pedicle screw insertion
991 performance on human patients.

992 TSYM as an Educational Tool

993 The result of this investigation suggests that certain aspects of TSYM simulator pedicle screw 994 insertion scenario may be useful for training less skilled learners. Specifically, trainees having 995 access to performance ratings on the 4 metrics, which provided evidence of construct validity, may 996 improve their pedicle screw insertion results. Virtual reality simulators have been assessed in pedicle screw placement training and have improved the accuracy of screw placement^{8,60,70,83}. A 997 998 study investigating simulation training has shown its utility in accelerating skill acquisition in pedicle screw placement³⁷. Less skilled trainees may benefit from incorporating virtual reality 999 1000 simulation for performing complex spine procedures into the spine surgery learning curriculum 1001 and as a potential formative educational tool^{69,70}. While specific features of the TSYM simulator 1002 pedicle screw insertion scenario may be useful, this simulation platform may need modification to 1003 meet its full potential as a surgical educational system.

With the vast data generated from virtual reality simulators like the TSYM platform, artificial intelligence methodologies may be useful for enhancing the understanding of the precision and granularity of surgical skills⁸⁴. Artificial neural networks can utilize this data to identify new metrics and rank their importance in simulated operative performance helping surgical educators

1008 focus on critical metrics for gaining specific operative technical skills^{79,80,83}. The availability of simulated pedicle screw operative performance data from novices and experts and the utilization 1009 1010 of deep learning algorithms can be used to create intelligent tutoring systems like the Intelligent Continuous Expertise Monitoring System (ICEMS) developed by our group^{42,84}. However, 1011 1012 artificial intelligence-enhanced curriculum can be associated with unintended outcomes, and care is required in developing programs necessitating human educator input⁸⁵. Deep learning 1013 1014 applications utilizing simulator-derived metric results and the equivalent OSATS video ratings for each procedure may allow future artificial intelligence systems to predict OSATS scoring utilizing 1015 1016 only the evaluation of the simulator-derived metrics.

1017 One objective of virtual reality studies is to combine artificial intelligence approaches, which can 1018 assess human instrument tracking data critical to optimal operative performance³³. This data along 1019 with OSATS ratings and intelligent tutoring systems can be incorporated into a human "Intelligent 1020 Operating Room" that could possess the ability to continually assess and train learners while 1021 minimizing surgical errors ^{76,82,83,86}.

1022 Limitations

1023 The TSYM simulation platform has limitations. First, the pedicle screw insertion simulation does not capture the dynamic intraoperative environment consisting of the learner and surgical educator 1024 1025 providing continuous personalized feedback. Second, the simulated procedure was developed with 1026 one animated and 4 deconstructed steps in a linear, unidirectional sequence of pedicle screw 1027 insertions, which does not represent the flexible approach available during human pedicle screw 1028 insertion procedures. Third, the TSYM simulator consists of a single-handed robotic arm setup, 1029 which does not reproduce the bimanual psychomotor skills utilized during patient spinal procedures^{40,69,82}. This study included neurosurgeons and orthopedic surgeons focused on spine 1030

1031 surgery, as well as fellows, and neurosurgical and orthopedic residents. While significant attempts were made to increase the participant pool, the scheduling of participants due to respective clinical 1032 1033 commitments limited the number of study participants, thereby limiting the generalization of 1034 results. The small sample size also meant that statistical analyses for construct and convergent 1035 validity were underpowered, meaning that some significant differences may be the result of a type 1036 1 error. While a common limitation in surgical education studies, especially with medical residents, 1037 fellows, and surgeons, future studies must include larger numbers of skilled and less skilled 1038 participants from multiple institutions to improve the robustness of results and generalizability⁸⁴. 1039 In this study, each pedicle screw insertion was evaluated individually due to differences in entry points, screw angulation, and anatomy. Larger studies will be necessary to evaluate the impact of 1040 1041 repeated pedicle screw insertion on the learning curves of skilled and less skilled groups associated 1042 with this simulated procedure. To standardize the pedicle screw insertion procedure a fixed-size screw was utilized, however, the TSYM platform offers a wide variety of screw sizes and lengths 1043 1044 to assess learners' ability to perform these procedures. While PGY5-6 residents and non-spine 1045 fellows possess significantly greater anatomical and practical knowledge in pedicle screw 1046 insertions, these study participants outlined high variability in prior experience with this technique. 1047 This variability could contribute to the limitations in the findings, particularly in distinguishing performance differences in the other metrics assessed. Future studies should determine skill 1048 1049 groupings based on experience, such as including a pre-requisite number of screws for each group. 1050 Finally, because the study was administered in English, language barriers could have affected the clarity of instructions for some participants, which could have limited the participant's 1051 1052 performance on the simulated task. Future Canadian studies should provide an option for all 1053 instructions to be administered in both French and English.

1054 CONCLUSION

1055	While several limitations and challenges exist with the TSYM simulator platform pedicle screw
1056	insertion scenario, some aspects of this simulator's scenario, such as performance metrics of
1057	screwdriver maximum force and screwdriver tool contact, show potential to assist in surgical
1058	teaching. Information garnered from this study may allow improvements in the TSYM simulator
1059	so that it can be even more useful in this regard in the future.
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1076 THESIS DISCUSSION

1077 Contributions to Original Knowledge

1078 This study contributes to the surgical education literature, specifically concerning gaining

- 1079 evidence of validity for surgical virtual reality spine simulators, in the following ways:
- 1080 1. To our knowledge, this study is the first time in which OSATS have been employed for
- 1081 determining construct validity of a virtual reality spine simulator platform for simulated
- 1082 pedicle screw insertion, and
- 1083 2. To our knowledge, this investigation is the first to utilize the evaluation of convergent
- 1084 validity to provide evidence for the validity of a virtual reality spine simulator.

1086 Validity Evidence

1087 The validation study combines Messick's contemporary framework and the traditional
1088 framework of validity. While the traditional validity types are evaluated in this study, the
1089 implications of the findings are viewed as an attempt to find evidence for constructing a validity

argument, supporting the educational utility of the TSYM virtual reality simulator in surgicaltraining.

1092 This validation study can be viewed through the lens of Messick's contemporary validity 1093 framework. As previously mentioned, Mesick's contemporary validity framework involves 1094 accumulating evidence of validity from five sources: test content, response process, internal 1095 structure, relations to other variables, and consequences. In this study, neurosurgical and orthopedic spine surgeons and spine fellows rated statements related to the content of the pedicle 1096 screw insertion simulation using assessed with a 7-point Likert scale^{72,76}. All but one statement 1097 1098 was deemed adequate; however, the results should be viewed with caution given the variability 1099 of responses. This measure meets the "content" criteria of Messick's contemporary validity 1100 framework, whereby the content of the simulated task aligns with the components and skills of 1101 the real procedure. Additionally, the study included measures to reduce bias in the assessment 1102 process including standardized verbal and written instructions, uniform steps and tools, and 1103 randomized-blinded rating. These efforts to maintain the integrity of the data constitute gaining 1104 "response process" evidence. The validation study also gathered "internal structure" evidence, 1105 which relates to the measures taken to explore the reliability of scores to measure the same 1106 construct, often through statistical means. Specifically, this study evaluated the OSATS ratings' 1107 inter-rater reliability and internal consistency, which resulted in excellent values. Finally, the 1108 validation study demonstrated a "relationship to other variables" by observing significant group 1109 differences in OSATS ratings and simulation-derived metrics. The significant correlation

between two simulation-derived metrics and all OSATS ratings also contributes to this avenue of
evidence. However, the study was not designed to gather evidence of validity relating to
Messick's "consequences" concept, which entails the potential and actual consequences related
to the assessment tool. Moreover, this study was able to gather evidence from four out of five
sources of validity, supporting the TSYM simulator's educational potential in surgical training.

1115 Future Directions

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1116 Surgical Simulation Timeline

timeline. Surgical simulators must undergo several steps of validation, involving thoroughly
planned research studies¹⁰. The initial phases of validation include establishing features

The implementation of simulators into surgical residency training follows a methodological

1120 involving visual and methodological realism of the simulated procedure and the capability of

discriminating skill proficiency⁴⁸. Following this phase, investigations directly related to surgical

trainees' learning can be performed⁴⁸. Such studies increase the understanding of a simulator's

1123 potential role in surgical training⁴⁸.

1124 This study demonstrates mixed and variable evidence for face, content, construct, and

1125 convergent validity of the TSYM simulator's L4-L5 bilateral pedicle screw insertion. These

results provide some evidence of the educational potential of TSYM simulator's L4-L5 bilateral

1127 pedicle screw insertion for surgical training. All the data outlined in this study will be provided

to the manufacturer to help the engineers involved improve the educational utility of the

simulator. The study serves as an important assessment of the utility of the L4-L5 pedicle screw

1130 insertion scenario on the TSYM simulator, paving the way for future modifications and

1131 improvements of the simulator. More investigations will be essential to further evaluate its

educational utility, including skill development, training methods, and clinical implications.

1133 Future studies related to the TSYM simulator's L4-L5 bilateral pedicle screw insertion should be 1134 carried out to greater understand its implications in surgical training. These studies should be longitudinal and track the progress of surgical trainees to reflect and investigate the simulator's 1135 1136 role as a formative training tool. Future studies should provide targeted feedback, as this is a 1137 crucial component in learning and skill development. The incorporation of such features enables 1138 the generation of learning curves that can increase the understanding of its impact as a training 1139 tool. Finally, determining skill transfer from the simulator to real operations is instrumental in 1140 elucidating the simulator's role in surgical training. Such a study would more clearly identify the 1141 simulator's utility and its clinical implications.

As mentioned previously, the study has other implications, related to the simulator's ability to 1142 1143 produce large amounts of data. The TSYM simulator generated 3D reconstructions of inserted pedicle screws within the vertebra. This data can be used to evaluate more clinically relevant 1144 aspects of surgical performance such as entry points, screw angles, and breaches. Because this 1145 1146 study was able to establish a degree of construct validity, surgical performance data can be 1147 assessed with artificial intelligence algorithms to uncover the granularity of surgical skills, such as identifying critical features of performance^{80,84}. Such findings can contribute to enhancing 1148 1149 surgical education, as surgical educators can focus on teaching these skill features to trainees. 1150 Artificial intelligent tutors can also be developed, which provide continuous personalized 1151 feedback during the simulated procedure and tailored feedback after the simulated procedure 1152 completion. These systems may identify weaknesses in learner technical skills and provide feedback on how to avoid errors and improve performance⁸³. However, future studies should 1153 1154 assess the impact of teaching skill features identified by artificial intelligence to understand the varying effects such methodology can have⁸⁵. These research avenues can contribute toward the 1155

- shift to competency-based training to the development of quantitative assessment and training
- 1157 curriculum development.

1159 THESIS SUMMARY

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1161 Surgical education is shifting from an apprenticeship framework to competency-based 1162 quantifiable frameworks. While this transition addresses several challenges in surgical training, it 1163 requires tools that can accurately and continuously quantify the expertise composites of surgical 1164 performance. Virtual reality simulators provide a safe and risk-free environment for developing 1165 critical and technically challenging realistic scenarios which can assess and train learners to 1166 acquire the psychomotor technical skills required for mastery of operative performance. 1167 This case series investigation demonstrates that the pedicle screw insertion simulation employed 1168 demonstrated varying degrees of validity: mixed levels of face and content, as well as mixed evidence of construct and convergent validity. This evidence may help contribute to the validity 1169 1170 argument for this platform's potential as a formative educational tool in spine surgery training. 1171 However, the variability in the median response of the spine fellows and spine surgeons in terms of face and content validity, the fact that only 4 of 25 performance metrics significantly 1172 1173 discriminated skilled from less skilled surgeons, and the mixed evidence of construct and 1174 convergent validity, suggest that the true value of the TSYM simulator's L4-L5 pedicle screw 1175 insertion at its current form must be interpreted with caution. Improvements in the simulator 1176 and/or scenario will be needed to allow it to meet its full potential as a surgical teaching tool. To 1177 our knowledge, this is the first investigation to assess the convergent validity of a simulated 1178 operative procedure on a virtual reality spine surgery platform by correlating simulator-derived 1179 metrics and OSATS ratings. The utilization of OSATS ratings in simulator performance 1180 assessment together with simulator-derived metrics may be useful to researchers interested in 1181 designing and validating simulators and curricula focused on improving technical skills during 1182 surgical training.

Pedicle screw insertions are a common yet technically challenging skill for stabilizing the spine in neurosurgery and orthopedic surgery^{8,57}. However, mastery of this technique involves a steep learning curve with trainees needing to practice between 60 to 80 screws with direct supervision to be able to independently perform pedicle screw insertions accurately and safely^{12,13}. Technical errors in this procedure may cause significant patient harm, posing high risks when acquiring the skillsets for this technique⁵⁸. Virtual reality surgical simulators may be a valuable, risk-free tool in developing technical operative skills, like pedicle screw insertion^{57,65,66}.

1190 This case series study investigated the potential educational utility of a simulated L4-L5 bilateral 1191 pedicle screw insertion on the TSYM virtual reality spine simulator study to gather validity 1192 evidence. The objectives of the study were to 1) evaluate face and content validity for an L4-L5 1193 bilateral pedicle screw insertion simulation on the TSYM simulator platform, 2) use simulation-1194 derived metrics and the assessment of simulated pedicle screw insertion operative performance utilizing OSATS to assess construct validity, 3) establish convergent validity of the simulation's 1195 1196 performance metrics by assessing the relationship between the simulation-derived metrics and 1197 simulated pedicle screw insertion operative performance OSATS, and 4) to attempt to use the 1198 results to construct an argument supporting the TSYM simulator's use for training residents and 1199 fellows in the L4-L5 bilateral pedicle screw insertion.

1200 The TSYM simulator's L4-L5 bilateral pedicle screw insertion demonstrated emerging face,

1201 content, construct, and convergent validity. The simulated procedure's visual and content-related

1202 realism was considered adequate based on the inputs of participating spine fellows and surgeons.

1203 However, due to the variability in median responses (ranging from 1.0 to 7.0), the true adequacy

1204 of face and content validity must be interpreted with caution. Related to construct validity,

significant group differences were only found in 4 out of 25 simulation-derived performance

1206 metrics assessed. However, significant group differences were consistent among OSATS ratings, as the skilled group significantly outperformed the less skilled group in each OSATS item and 1207 1208 the overall OSATS rating. Finally, 2 out of 4 simulation-derived performance metrics 1209 significantly negatively correlated with each OSATS item and the overall rating. The two 1210 significant negative correlations were consistent with convergent validity, as the finding matched 1211 the predicted relationship. The varying degree of consistency related to construct validity and the 1212 limited number of participants cautions against the generalizations of the study's findings, hence, 1213 the results are considered mixed.

1214 The validity evidence gathered in this study lays the groundwork for understanding the

1216 aspects needing improvement. The findings of this study may help to begin to construct a

educational utility of the TSYM simulator's L4-6 bilateral pedicle screw insertion and the

1217 validity argument supporting the TYSM's potential as a formative training tool for surgical

1218 training. However, the strength of this argument should be interpreted with caution given the

1219 various limitations highlighted throughout the thesis. Future studies are required to elucidate its

1220 learning potential, impact on surgical proficiency, and clinical implications.

1221 In summary, this case series study suggests that the TYSM simulator's L4-L5 bilateral pedicle

1222 screw insertion scenario has some degree of educational potential for skill development among

1223 surgical trainees, but improvements are needed to optimize this potential. Virtual reality

1224 simulators capable of replicating pedicle screw insertions, like the TSYM simulator (but

improved based upon research studies like the one presented here), may be useful in surgical

1226 education, as they provide a safe, risk-free environment for surgical trainees to focus and develop

1227 essential and technically challenging operative skills.

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1483 APPENDIX

1484

1485 Supplemental Digital Content 1. Methods. Simulated L4 & L5 pedicle screw placement
1486 scenario

The TSYM Symgery platform is a virtual reality simulator platform with one haptic arm and a number of interchangeable handles, including a Kerrison and a straight handle. Participants performed two tasks before proceeding with the pedicle screw insertion 1) a Dry Lab which was followed by 2) a L2 laminectomy simulation scenario to become acquainted with the TSYM simulator the simulated instruments and their function.

The Dry Lab involved an interactive display of instrument handling utilizing the haptic handle. Participants used the straight handle to perform the following tasks: 1) creating a hole utilizing the awl, 2) removing a spherical object with the burr, and 3) creating a trajectory using the pedicle finder. Participants then were asked to utilize the simulated Kerrison handle to bit off three simulated bony areas.

1497 When the Dry Lab is completed successfully participants are given verbal instructions on 1498 the performance of the L2 laminectomy procedure that they will be asked to complete and 1499 provided with written information concerning each step of the procedure. The L2 simulation 1500 includes 1 animated and 4 interactive steps. The animated step begins with a pre-exposed 1501 surgical cavity with the spinous process and the interspinous ligaments removed from the 1502 simulated patient's spine. The first interactive step involved the use of the 4mm burr to thin the 1503 L2 lamina by removing the cancellous bone component. In the second interactive step the 1504 ligamentum flavum was detached using an angled curette, in the third interactive step a 4mm 1505 Kerrison was used to remove the remaining lamina and resect the detached ligament flavum. 1506 Once the participant is satisfied with the decompression, the fourth interactive step follows

which involves utilizing a Woodson to verify the complete bilateral removal of the ligamentumflavum.

After completing the Dry Lab and L2 laminectomy participants are then provided with verbal and written instructions on how to perform the L4 & L5 pedicle screw insertion placement simulation.

1512 This simulation also starts with an animated component outlining the L4 & L5 vertebrae 1513 being completely dissected from a posterior approach. The standardized screen magnification was maintained for all participants and a specific order for screw placement was outlined. This 1514 1515 involved beginning with the left L5 screw, followed by the left L4, then the right L5 and 1516 concluding with the right L4. Each step was associated with a restricted list of simulated 1517 instruments which participants had to pick before moving to the next step. Participants started at 1518 left L5, creating an entry point with the awl. Live fluoroscopy was available during the procedure to verify the entry point, insertion angulation and screw placement. The next step was 1519 1520 to create a channel in the pedicle utilizing the pedicle finder. Then, a 2 mm ball tip probe was 1521 used to check for any evidence of a pedicle breach. The participant must declare the presence of 1522 a breach from an automatic prompt before moving to the next step. The screw channel was then 1523 tapped using a 5.5 mm tap, and the 2 mm ball tip probe was used once again to check for any possible breach. The last step involved inserting a standardized to 6.5 mm x 45 mm simulated 1524 1525 pedicle screw. On completion of each screw insertion, the simulator created a 3D model, 1526 illustrating the individuals' placed screw placement. The final information available to the participant involved a 3D reconstruction of each of the 4 pedicle screws along with written 1527 1528 feedback on the participant's overall performance.



Symgery (Montreal, Canada) A, The TSYM simulator set up, showing the (1) robotic arm that

uses and provide advanced haptic feedback technology, (2) the different tool handles that can be used in the simulated scenario, (3) 3D monitor, (4) pedals for activating fluoroscopy and (5) secondary monitor. **B**, A neurosurgical resident performing a task on the simulator, demonstrating its practical use in a training scenario. **C**, The tool handles available to mimic an array of tools in the virtual environment.



Figure 2. Significant Performance Assessments of the Task Using Simulation-Generated Performance Metrics. **A**, Tap screw's 3D Velocity. **B**, Tap screw's 3D Acceleration. **C**, Screwdriver Max Force on the pedicle. **D**, Screwdriver Contact with pedicle. The central line indicates the mean value for each group. *Represents a significant difference between groups after Mann-Whitney U, nonparametric test (p < .05). **Represents a significant difference between groups after Mann-Whitney U, whitney U, nonparametric test (p < .01).



1558 Tables

Table 2: Steps and Tools Utilized for Each Pedicle Screw Insertion Simulation Employing the TSYM Simulator Platform Objective **Tool required** Steps Step 1: Entry point Choose entry point for the pedicle Awl screw, and verification using creation fluoroscopy Step 2: Channel Create channel in the pedicle and Pedicle finder Creation verification using fluoroscopy Step 3: Channel Breach Check for presence or absence of a 2mm ball tip probe Verification pedicle breach Step 4: Tap Insertion Pre-thread the previously created 5.5mm tap channel in the pedicle and verification using fluoroscopy Step 5: Pedicle Breach Check for presence or absence of a 2mm ball tip probe Verification pedicle breach Step 6: Screw insertion Insertion of the selected screw by Screwdriver and Screw (6.5 rotation the screwdriver and verify mm diameter and 4.5mm using fluoroscopy length)

Table 3: Demographic Data for the TwoInsertion on the TSYM Simulator Platf		the Simulated Pedicle Screw			
	Less Skilled	Skilled			
Number of participants	14 (52%)	13 (48%)			
Age (years)					
Mean (SD)	29 (1.7)	38 (8.1)			
Gender					
Male	12 (86%)	13 (100%)			
Female	2 (14%)	0 (0%)			
Specialty					
Neurosurgery	10 (71%)	8 (62%)			
PGY 1-4	10	-			
PGY 5-6	-	5			
Non-spine Fellow	-	2			
Spine Surgeon	-	1			
Orthopedics	4 (28%)	5 (38%)			
PGY 1-4	4	-			
PGY 5-6	-	-			
Spine Fellow	-	1			
Spine Surgeon	-	4			
Affiliation					
McGill	11 (41%)	9 (33%)			
Université de Montréal	3 (11%)	4 (15%)			
Number of Reported Pedicle Screws					
Inserted**					
Mean (SD)	0.5 (1.4)	452 (883.6)			
Median (Range)	0 (0-5)	100 (10-3000)			
Prior Experience with any Virtual					
Reality Surgical Simulator					
Yes	3 (21%)	5 (38%)			

Table 4: F	ace and Content Validity			
Validity Type	Validity Statements	Median Response of Spine Fellows and Spine Surgeons Group	Observed Range	
	Using the awl to create the entry point for the pedicle screw.	5.00	(2.0-6.0)	
	Using the curved pedicle finder to develop the screw channel in the pedicle.	4.00	(1.0-5.0)	
Content Validity	Using the ball tip probe to assess for pedicle breach in the created channel in the pedicle.	4.00	(2.0-6.0)	
	Using the tap to create threads to the inner canal.	3.50	(1.0-5.0)	
	Inserting the screw into the created channel in the pedicle.	4.50	(1.0-6.0)	
	Please rate the overall anatomical realism of the simulated spine.	4.00	(3.0-5.0)	
Face	Please rate the overall realism of the colour for the simulated anatomical structures.	4.00	(4.0-6.0)	
Validity	Please rate the overall realism of the procedure.	5.00	(3.0-5.0)	
	If this simulator was available in your program, you would use this simulation scenario for training of the technical skills simulated.	4.50	(1.0-7.0)	

The median score on a 7-point Likert scale for face and content validity for the spine fellows and surgeons after completing the pedicle screw simulation.

Insertion Simulation on the TSYM Simulator and Corresponding Mann-Whitney U P-									
Value									
Tool and Metrics	P value								
Awl									
3D Velocity	0.75								
3D Force	0.23								
Max Force	0.37								
3D Acceleration	0.16								
Tool Contact	0.51								
Pedicle finder									
3D Velocity	0.71								
3D Force	0.12								
Max Force	0.54								
3D Acceleration	0.52								
Tool Contact	0.28								
Ball Tip Probe									
3D Velocity	0.10								
3D Force	0.12								
Max Force	0.92								
3D Acceleration	0.23								
Tool Contact	0.31								
Tap Screw									
3D Velocity	0.04*								
3D Force	0.40								
Max Force	0.37								
3D Acceleration	0.01*								
Tool Contact	0.45								

	Screwdriver	
	3D Velocity	0.52
	3D Force	0.12
	Max Force	0.04*
	3D Acceleration	0.94
	Tool Contact	<0.001*
1622	* Significant p-value for Man	n-Whitney U, nonparametric test ($P < .05$).
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Table 6: Concurrent Validity Determination Between Simulation-DerivedPerformance Metrics and OSATS Scoring

	OSATS Scoring											
Simulati on- Derived	Respect for Tissue		Instrument Handling		Economy of Movement		Flow		Knowledge of Procedure		Overall	
Perform ance Metrics ^a	Spearm an's Coeffici ent	ρ Valu e										
Screwdriv er Maximum Force	-0.32	<0.01 **	-0.39	<0.01 **	-0.37	<0.01 **	-0.38	<0.01 **	-0.293	<0.01 **	-0.33	<0.01 **
Screwdriv er Tool Contact	-0.25	0.01*	-0.34	<0.01 **	-0.42	<0.01 **	-0.43	<0.01 **	-0.31	<0.01 **	-0.31	<0.01 **
Tap 3D Velocity	-0.01	0.90	0.06	0.54	0.11	0.28	0.09	0.34	0.01	0.88	0.01	0.89
Tap 3D Accelerati on	-0.17	0.09	-0.12	0.21	-0.18	0.07	-0.15	0.12	-0.13	0.19	-0.14	0.16

1649 *Significant ρ -value for Spearman's Rank Coefficient of Correlation ($\rho < 0.05$).

1650 ** Significant ρ -value for Spearman's Rank Coefficient of Correlation ($\rho < 0.01$).

1651 ^aSimulation-derived performance metrics that showed construct validity.