

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

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86 ABSTRACT

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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
90 in challenging operative procedures like pedicle screw insertions. The TSYM Symgery simulator
91 platform is a virtual reality spine simulator capable of deconstructing and simulating complex
92 spine procedures, including pedicle screw insertions. This case series study aims to investigate
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
97 into skilled groups (post-graduate year (PGY) 5-6, fellows, and consultant neurosurgeons or
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
104 group rated all face and content validity statements with a median ≥ 4 . Significant differences
105 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.

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

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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
137 comme les insertions de vis pédiculaires. Le simulateur TSYM Symgery propose une plateforme
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
146 moins compétents (résidents en PGY 1-4). La validité de face et contenu ont été évaluée en utilisant
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.
152 Le groupe compétent a évalué toutes les déclarations de validité de face et de contenu avec une
153 médiane ≥ 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 vertébrale.

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216

217 PREFACE AND CONTRIBUTION OF AUTHORS

218

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.

241

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

243 review & editing.

244

245 Ali Fazlohllahi: Contributed to conceptualization and methodology.

246

247 Rolando Del Maestro: Contributed to project creation, conceptualization, methodology,

248 resources, and investigation, project funding, guidance, and supervision of this research,

249 interpreting results, writing - original drafts and writing – review & editing.

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251 ABBREVIATIONS

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253 OSATS: Objective Structured Assessment of Technical Skills

254 PGY: Post-Graduate Year

255 3D: Three Dimensional

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263 THESIS INTRODUCTION

264
265 Mastering technical skills is an essential learning objective in surgical training, as technical
266 errors can contribute to poor patient outcomes^{3,4}. Historically, acquiring technical skills follows
267 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
272 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}.

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

283 The TSYM simulator is a non-immersive, virtual reality platform capable of deconstructing an
284 L4-L5 bilateral pedicle screw insertion. It comprises a single robotic arm that provides haptic
285 feedback during the simulated operation. This new platform has the potential to be a valuable,
286 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

311

312 **Surgical Education**

313 Surgical education involves the simultaneous mastery of complex skills, experienced and taught
314 knowledge, and composure in an unpredictable and, at times, highly stressful environment²³. It is
315 defined as a life-long learning process that begins in residency and continues during the
316 surgeon's career²³. Since its inception over 100 years ago, its founding principles remain, but its
317 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
325 independence through repetitive, supervised opportunities to take care of surgical patients^{5,6}.
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
330 to this day^{5,6}.

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
335 surgeons and progressively gain more patient care responsibilities and independence in the
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
341 as well as the incorporation of feedback, a critical component for trainee improvement³. While
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**

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

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

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

358 Additionally, varying exposure poses an issue among surgical trainees^{28,29}. Exposure relies on the
359 surgical cases available, which can be unpredictable in terms of duration and frequency^{28,29}. In
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
362 for some surgical residents to acquire the appropriate technical skills^{28,29}. This limitation has led
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
365 concerns about career development and burnout²⁶. At the same time, the introduction of reduced
366 hours to address burnout issues has further decreased learning opportunities for surgical
367 trainees³⁰. Moreover, varying exposure presents a complex issue in surgical education.

368 Finally, gaining feedback is another challenge in surgical education²⁷. Positive and negative
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
371 training³¹. While it is a requirement for surgical educators to provide feedback to their trainees,
372 meaningful, postoperative feedback tends to be given irregularly²⁷. However, this is largely due
373 to surgical instructors' demanding schedules and responsibilities^{21,27}. Solutions are needed to
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
377 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**

381 To address key challenges in surgical education and the evolving field of medicine, medical and
382 surgical education have shifted towards implementing a competency-based model into training^{7,8}.

383 This model's learning objectives are centered on competence, or how well learners can
384 accomplish a task, rather than time⁷. As a result, this framework ensures the safety of patients
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
388 of Entrusted Professional Activities (EPAs) into surgical training³². EPAs are tasks or
389 responsibilities that can be entrusted to an unsupervised trainee after showing sufficient
390 competence over several occasions^{32,33}. Such tasks and responsibilities range from technical to
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
395 safety and quality outcomes³². However, while EPAs construct a buildable framework for
396 competency-based education, challenges related to its effective execution remain, including
397 uniform implementation across residency programs and the lack of science that guides the
398 direction and implementation of EPAs³⁴. In Canada, post-graduate training is based on a
399 physician competency framework called CanMEDS³⁵. In this framework, a physician is
400 considered a medical expert with 6 intrinsic roles, communicator, collaborator, leader, advocate,

401 scholar, and professional³⁵. Further, in Canadian post-graduate training, EPAs are composed of 5
402 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
404 assessment among surgical educators and researchers³⁶. A common and widely accepted
405 performance assessment tool in surgical education research, evaluation, and training is the
406 objective structured assessment of technical skills (OSATS)³⁷. This subjective Likert scale
407 assessment comprises several items reflecting technical surgical skills that surgical educators use
408 to evaluate their trainees, including hemostasis, respect for tissue, instrument handling, economy
409 of movement, flow, knowledge of procedure, and an overall rating³⁷. The hemostasis item refers
410 to the ability to control bleeding while respect for tissue relates to the ability to avoid and
411 minimize potential harm to surrounding anatomical structures³⁸. Instrument handling relates to
412 the surgeons' or trainees' ability to effectively use instruments, and the economy of movement
413 refers to the extent to which repetitive, non-purposeful movements are made³⁸. Flow refers to the
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
416 entire procedure including the steps, instruments, and relevant anatomy³⁸. OSATS is considered
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
419 have recently criticized its inability to oversee all aspects of surgical training^{39,40}.

420 Lastly, the current surgical curriculum requires surgical residents to enter their cases into the
421 Accreditation Council for Graduate Medical Education (ACGME) resident case log system.
422 Graduating surgical residents must enter 750 major operative cases with at least 150 entered
423 during their final year^{5,41}. However, as requested by the ACGME, residents may only log an

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

430 The movement toward competency-based training facilitates standardized competence across
431 surgical programs and their respective trainees⁷. Not only does this contribute to increased
432 patient safety, but it can also contribute to reduced burnout among surgical residents^{7,43,44}. The
433 latter can be explained by competency-based training's ability to offer equal training
434 opportunities, translating to an increased level of readiness⁴⁴. Through standardizing assessment
435 and creating milestones, surgical residents can feel more confident in their operative abilities, a
436 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
439 surgical cases varies per residency program^{39,40,46}. For example, spine operations are specialized
440 neurosurgical and orthopedic residency procedures^{39,40,46}. Moreover, depending on the hospital
441 and program, exposure and experience to spine surgery greatly varies among surgical
442 residents^{29,39,40,46}. While curricular measures can be put in place to ensure all residents gain
443 exposure to a specific operation, case availability is the limiting factor to this, which can make
444 such a curricular objective difficult to achieve⁴⁵. Surgical simulation may be a valuable tool in
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
449 learning by practicing clinical skills in a simulated environment⁹. Simulation can come in various
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
454 integral components of competency-based training⁹.

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
459 without putting patient safety and quality of care at risk¹⁴. Further, surgical trainees can master
460 skills and make errors without the stress and potential harm associated with learning in the
461 operating room⁹. This translates to a better understanding of when errors can take place and
462 instigates the development of mitigation and prevention strategies for such errors; gaining this
463 skill in a simulated environment enhances the surgical trainees' readiness as independent
464 surgeons while ensuring patient safety¹⁴. Simulation training also allows trainees to be exposed
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.

468 Scientific data supporting simulation training in surgical education continues to emerge,
469 highlighting its ability to develop diverse aspects of clinical skills for trainees⁴⁷. While
470 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**

475 As simulation gains traction in surgical education, validation emerges as a pivotal foundational
 476 phase in assessing the effectiveness of simulators for surgical training¹⁰. Validation studies aim to
 477 understand the appropriateness of a tool for a particular goal¹¹. For example, in the context of
 478 surgical simulation, a validation study for a surgical simulator would aim to understand its utility
 479 as a learning tool in surgical training. Currently, surgical simulation literature primarily follows a
 480 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 procedure
		Content: the extent to which the simulator measures the skills they were designed to simulate
		Construct: the ability of the simulator to distinguish different operative skill levels and includes convergent validity
		Predictive: 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 measure
		Response Process: the integrity of the data collection
		Internal Structure: the measures taken to determine the degree to which items of an instrument align with the underlying construct and are reported as statistical measures
		Relationship to Other Variables: the degree of relatedness between assessment measures and external independent measures
		Consequences: the potential and observed consequences of the tool of interest

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

506 face, content, and construct validity of a simulator. This framework of validity is used
507 extensively in surgical simulation literature, although a contemporary framework is accepted in
508 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
511 population³⁷. It postulates that all evidence of validity relates to construct and comes from five
512 sources, content, response process, internal structure, relation to other variables³⁷, and
513 consequences. The "test content" dimension refers to the relationship between a tool's content
514 and the construct it aims to measure^{11,52}. This source of evidence must be based on the input
515 from participants who are experts in the procedure of interest^{11,52}. "Response process" pertains to
516 the integrity of the data collection, including standardized instructions and blinded raters^{11,52}.

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
519 internal consistency and reliability^{11,52}. The "relationship to other variables" dimension refers to
520 the degree of relatedness between assessment measures and external independent measures such
521 as proficiency level and experience^{11,52}. Finally, the "consequences" concept refers to evidence
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
524 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
528 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
542 in evaluating the utility of simulation in surgical training, a compromise between the frameworks
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

552 Reality simulation is an emerging tool in surgical education, although its application to spine
553 surgery is minimal⁵⁵. In past years, studies have evaluated the utility of virtual reality spine
554 simulators with many focusing on the pedicle screw insertion technique ^{15,55}. Nonetheless, only a
555 limited number of spine surgery pedicle screw insertion simulation platforms exist; however, they
556 lack comprehensive validity and high fidelity, highlighting the need for the development of more
557 pertinent simulation training tools^{15,16,17,18,19}.

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

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
575 in procedures like scoliosis, spine tumors, trauma, infection, and degenerative disease⁵⁶. The
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
578 advances through the vertebral cancellous bone⁵⁷. At this point, the surgeon largely depends on
579 tactile feedback and experience-based judgment to determine the location of the channel.⁵⁶ To
580 identify any errors in channel preparation, a ball tip probe is inserted into the channel, where the
581 surgeon feels for any breaches that may have been made in the process⁵⁷. The channel is pre-
582 threaded using a tap before further breach verification with a ball tip probe and insertion of the
583 screw. Final X-Rays can be performed to ensure the proper positioning of the screw.⁵⁶
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
586 safety of the procedure⁵⁷. This aspect becomes crucial given this technique's limited margin of
587 error, as the pedicle is close to many vital neural and vascular structures^{56,57}. Today, image-
588 guided techniques are employed in place to prevent the malplacement of screws, including
589 fluoroscopy, intraoperative navigation, and robotic assistance⁵⁶. Despite the advancements in
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

596 pseudoarthrosis formation.⁵⁷ Moreover, the potential harm associated with the malplacement of
597 pedicle screws is well documented with an incidence ranging between 4.2-7.8%.^{58,59}
598 The pedicle screw insertion proves to be complex and demanding, necessitating a steep learning
599 curve.⁵⁶ Recent publications showed that trainees need to place 60 to 80 pedicle screws under
600 direct supervision before being able to independently perform accurate and safe pedicle screw
601 insertions^{12,13}. With varying exposure, limited cases, and restricted hours,^{22,29,60} such a degree of
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
618 limited to the screen, unlike immersive virtual reality platforms that provide a 360-degree virtual

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
621 virtual reality training for hip arthroscopy found similar outcomes related to skill and procedural
622 acquisition and skill transfer⁶². Further, such features of the TSYM simulator make it a more
623 promising tool for surgical training.

624 The TSYM simulator offers an L4-L5 bilateral pedicle screw insertion scenario, an essential
625 technique in spine surgery with a steep learning curve^{12,13}. The following manuscript aims to
626 establish the foundational principles of the L4-L5 bilateral pedicle screw insertion scenario,
627 investigating face, content, construct, and convergent validity. To our knowledge, this is the first
628 study to assess convergent validity for an L4-L5 bilateral pedicle screw insertion on a virtual
629 reality platform.

630

631 STUDY RATIONALE, HYPOTHESIS, AND OBJECTIVES

632 **Rationale**

633 Surgical training involves acquiring complex, bimanual skills while ensuring patient safety under
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
636 comprehensive training is essential^{29,60,8}. Virtual reality simulators may be a valuable tool to
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
643 insertion scenario, a critical skill in spine surgery with a steep learning curve. In this study, a
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**

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

652 **Objectives**

653 The objectives of this case series study are:

- 654 1. To evaluate face and content validity for an L4-L5 bilateral pedicle screw insertion
655 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
659 relationship between the simulation-derived metrics and simulated pedicle screw insertion
660 operative performance OSATS.
- 661 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.

663

664

MANUSCRIPT

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666
667 Face, Content, Construct, and Convergent Validity of a Surgical Spine Simulator for Pedicle
668 Screw Insertions

669
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686
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.

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695 INTRODUCTION

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

707
708 The role of virtual reality simulation in enhancing surgical education and providing a risk-free
709 environment for procedural learning and skill refinement continues to develop^{57,65,66}. There are a
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
712 relevant simulation training tools^{15,16,17,18,19}. The need to shift towards quantitative competency-
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
717 patient outcomes^{58,59}.

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
721 metrics useful to assess surgical techniques, offering an innovative approach to surgical training⁶⁸⁻
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,
724 specifically face, content, construct, and convergent validity^{10,50,71}. Face validity refers to the
725 extent to which the simulator replicates the real procedure while content validity refers to the extent
726 to which the simulator measures the skills they were designed to simulate^{10,48}. Face and content
727 validity can be determined through questionnaires⁴⁸. Construct validity is a type of objective
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"
730 groups^{71,48,72}. Simulation-derived performance metrics on tool handling and the Objective
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
733 validity^{73,74}. Convergent validity, a subgroup of construct validity, explores the degree of
734 agreement between different measures of the same construct and is typically evaluated by
735 correlating the measure of interest to a well-known measure^{50,51}. We examine convergent validity
736 by investigating how well the simulation-derived performance metrics relate to OSATS^{50,51}.

737
738 Gallagher and co-workers have reviewed and outlined fundamental principles of the traditional
739 framework of validation by applying scientific methods for the assessment of surgical education
740 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
745 learners in complex procedures like the pedicle screw insertion simulation^{10,48}. Therefore, the
746 objectives of this case series study were (1) to evaluate face and content validity for an L4-L5
747 bilateral pedicle screw insertion simulation on the TSYM simulator platform, (2) to use simulation-
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 Quebec, 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
771 TSYM simulator. No time limit was imposed but each step was dependent, and once completed,
772 required participant confirmation before proceeding. This article follows the Strengthening the
773 Reporting of Observational Studies in Epidemiology (STROBE) reporting guidelines⁷⁵.

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

786 pedicle screws in a predetermined order left L5, left L4, right L5, right L4, (see supplemental
787 information). Participants had access to live X-rays to verify the entry point and angles for pedicle
788 cannulation and confirm inserted screw accuracy. Video 1 shows a skilled participant performing
789 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
794 on an acceptable median value for sufficient face and content validity has not been established^{72,76}.
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
798 with our previous studies^{72,76}.

799 **Construct Validity**

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

803 *Simulation-Derived Tool Metrics:* The TSYM simulator continuously assessed several features of
804 performance during pedicle screw insertion. Data on each tool's 3D velocity, 3D force, maximum
805 force, 3D acceleration, and tool tissue contact were collected for each screw. The 3D force and
806 maximum force refer to the forces applied on the haptic arm while using the tool. The 3D velocity
807 and 3D acceleration of each tool are derived from the position of the tool's tip in space. The tools

808 that were assessed can be found in Table 2. The rationale to treat each pedicle screw insertion by
809 each participant independently was that each screw insertion involved a different simulated
810 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
813 surgical educators in human operative settings, OSATS ratings, to determine construct validity^{29,30}.
814 Each participant's simulated L4-L5 bilateral pedicle screw insertion was recorded on-screen,
815 which was later subdivided into four videos, one for each pedicle screw insertion. Video recordings
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 (α
821 = .97 [95% CI, .96, .98]) and excellent inter-rater reliability (α = .97 [95% CI, .97, .98]).

822 **Convergent Validity**

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

827 **Statistical Analysis**

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

830 SPSS (version 29.0; IBM, Armonk, New York). The data was not normally distributed as assessed
831 by Shapiro-Wilk's test ($P < .05$). Mann-Whitney tests assessed statistical differences between
832 groups for each performance measure. A two-tailed Spearman Rank Order Correlation Coefficient
833 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 Quebec universities were included in
838 this investigation. The skilled group reported a mean of 452 pedicle screws ($SD = 883.6$) inserted
839 independently while the less skilled group reported a mean of 0.5 pedicle screws ($SD = 1.4$)
840 inserted independently. The difference between the two groups was statistically significant, (P
841 $< .001$). Since each participant inserted 4 screws, a total of 108 simulated screws were inserted.
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
844 OSATS.

845 Face and Content Validity

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

851 was rated a median of 3.5 (range 1.0-5.0). The skilled group rated the simulated procedure's overall
852 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
855 groups (Table 5). Significant differences were found between the two groups in 4 of 25
856 performance metrics. According to how convergent validity is assessed in studies in the literature,
857 there is a documented anticipated result^{50,51}. We therefore anticipated observing group differences
858 between 3D velocity and 3D acceleration of the tap screw at step 3A and tool contact and maximum
859 force of the screwdriver in step 4⁷⁷⁻⁷⁹. While pre-threading the channel with the tap, the skilled
860 group showed a significant increase in 3D velocity when compared to the less skilled group (.0014,
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 [-
863 7.26e-9, 16e-9] vs 5.43e-10, 95% CI [-5.19e-9, 6.28e-9]; P = .01). Although the 3D acceleration
864 values were small across both groups, statistical analysis confirmed a significant difference (P
865 = .01). During the insertion of the screw with the screwdriver, the less skilled group applied
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
868 than the skilled group (.22, 95% CI [.18, .25] vs .11, 95% CI [.09, .13]; P <.001). These group
869 differences are depicted in Figure 2.

870 *Randomized, Blinded OSATS Ratings:* An average rating for each OSATS item was calculated for
871 each screw video by blinded ratings provided by two experts. The skilled group achieved a
872 significantly higher mean overall OSATS rating compared to the less skilled group (5.02, 95% CI
873 [4.63, 5.41] vs 3.30, 95% CI [2.92, 3.69]; P <.001). In each OSATS item (instrument handling,

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

877 **Convergent Validity**

878 A two-tailed Spearman Rank Order Correlation Coefficient was calculated between each item of
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
881 maximum force using the screwdriver had significant negative correlations with all OSATS items:
882 respect for tissue, instrument handling, economy of movement, flow, knowledge of procedure, and
883 overall (Spearman's Coefficient = $-.32$, $P < .01$; Spearman's Coefficient = $-.39$, $P < .01$; Spearman's
884 Coefficient = $-.37$, $P < .01$; Spearman's Coefficient = $-.38$, $P < .01$; Spearman's Coefficient = $-.29$,
885 $P < .01$; Spearman's Coefficient = $-.33$, $P < .01$, respectively). As predicted tool contact using the
886 screwdriver significantly correlated with respect for tissue, instrument handling, economy of
887 movement, flow, knowledge of procedure, and overall. (Spearman's Coefficient = $-.25$, $P < .01$;
888 Spearman's Coefficient = $-.34$, $P < .01$; Spearman's Coefficient = $-.42$, $P < .01$; Spearman's
889 Coefficient = $-.43$, $P < .01$; Spearman's Coefficient = $-.31$, $P < 0.01$; Spearman's Coefficient = $-.31$,
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.

893

894 DISCUSSION

895 The results of this case series study may be useful for surgical educators and researchers
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
901 knowledge, this is the first study to correlate simulator-derived metrics with OSATS ratings to
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**

908 The traditional validation framework investigates types of validity like face, content, and construct;
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
911 for a particular purpose and population³⁷. This study combines both frameworks, using traditional
912 types of validity to help construct a validity argument for the TSYM simulator's educational utility
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
918 validity^{72,76}. While these results are consistent with our definition of “adequate” face and content
919 validity, this evidence can be considered “mixed” for two reasons. First, we did not anticipate
920 participants providing a rating of “totally realistic” (7) and our group has, accordingly, previously
921 considered a median of “4” as sufficient for providing evidence of face and content validity^{72,76}.
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
933 simulated tap, and the maximum force and the tool contact of the simulated screwdriver (Figure
934 2). The skilled group had higher 3D velocity than the less skilled associated with tap screw use.
935 The skilled group’s familiarity with the procedural components⁷⁷ and operative technical skills
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
940 experience in pedicle screw fixation is an important factor distinguishing participant expertise^{12,13}.
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
943 application⁷⁷⁻⁷⁹. Studies using artificial neural networks (ANN) were able to assess junior and
944 senior residents, neurosurgeons, and orthopedic surgeons' performance and identify different
945 patterns of force application, which is considered a safety metric⁷⁹⁻⁸¹. From a clinical standpoint,
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
951 high forces during screwdriver use may impact patient safety and therefore moderate this metric
952 during their training and career⁷⁹. A different pattern may be the reason why the less skilled group
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
976 significant simulation-driven performance metrics, 3D velocity, and 3D acceleration using the tap,
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
981 channel^{79,82}. Although OSATS is a validated method to assess surgical performance, several studies
982 have questioned the ability of OSATS to fully measure the complexities of surgical operating room
983 performance^{39,40}. This study suggests that the consideration of utilizing OSATS and other surgeon
984 educator assessments of surgical performance in combination with those provided by simulator-

985 derived metrics may enhance our understanding, assessment, and training of surgical skills and be
986 useful for formative assessment. Integration of these two methodologies may result in a more
987 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
997 pedicle screw placement training and have improved the accuracy of screw placement^{8,60,70,83}. A
998 study investigating simulation training has shown its utility in accelerating skill acquisition in
999 pedicle screw placement³⁷. Less skilled trainees may benefit from incorporating virtual reality
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.

1004 With the vast data generated from virtual reality simulators like the TSYM platform, artificial
1005 intelligence methodologies may be useful for enhancing the understanding of the precision and
1006 granularity of surgical skills⁸⁴. Artificial neural networks can utilize this data to identify new
1007 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
1009 simulated pedicle screw operative performance data from novices and experts and the utilization
1010 of deep learning algorithms can be used to create intelligent tutoring systems like the Intelligent
1011 Continuous Expertise Monitoring System (ICEMS) developed by our group^{42,84}. However,
1012 artificial intelligence-enhanced curriculum can be associated with unintended outcomes, and care
1013 is required in developing programs necessitating human educator input⁸⁵. Deep learning
1014 applications utilizing simulator-derived metric results and the equivalent OSATS video ratings for
1015 each procedure may allow future artificial intelligence systems to predict OSATS scoring utilizing
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
1024 not capture the dynamic intraoperative environment consisting of the learner and surgical educator
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
1030 procedures^{40,69,82}. This study included neurosurgeons and orthopedic surgeons focused on spine

1031 surgery, as well as fellows, and neurosurgical and orthopedic residents. While significant attempts
1032 were made to increase the participant pool, the scheduling of participants due to respective clinical
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 I 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
1040 points, screw angulation, and anatomy. Larger studies will be necessary to evaluate the impact of
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
1043 screw was utilized, however, the TSYM platform offers a wide variety of screw sizes and lengths
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
1048 performance differences in the other metrics assessed. Future studies should determine skill
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
1051 clarity of instructions for some participants, which could have limited the participant's
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.

1085

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
1090 argument, supporting the educational utility of the TSYM virtual reality simulator in surgical
1091 training.

1092 This validation study can be viewed through the lens of Messick's contemporary validity
1093 framework. As previously mentioned, Messick'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
1096 orthopedic spine surgeons and spine fellows rated statements related to the content of the pedicle
1097 screw insertion simulation using assessed with a 7-point Likert scale^{72,76}. All but one statement
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

1110 between two simulation-derived metrics and all OSATS ratings also contributes to this avenue of
1111 evidence. However, the study was not designed to gather evidence of validity relating to
1112 Messick's "consequences" concept, which entails the potential and actual consequences related
1113 to the assessment tool. Moreover, this study was able to gather evidence from four out of five
1114 sources of validity, supporting the TSYM simulator's educational potential in surgical training.

1115 **Future Directions**

1116 **Surgical Simulation Timeline**

1117 The implementation of simulators into surgical residency training follows a methodological
1118 timeline. Surgical simulators must undergo several steps of validation, involving thoroughly
1119 planned research studies¹⁰. The initial phases of validation include establishing features
1120 involving visual and methodological realism of the simulated procedure and the capability of
1121 discriminating skill proficiency⁴⁸. Following this phase, investigations directly related to surgical
1122 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
1126 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
1128 to the manufacturer to help the engineers involved improve the educational utility of the
1129 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
1132 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
1135 longitudinal and track the progress of surgical trainees to reflect and investigate the simulator's
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.

1142 As mentioned previously, the study has other implications, related to the simulator's ability to
1143 produce large amounts of data. The TSYM simulator generated 3D reconstructions of inserted
1144 pedicle screws within the vertebra. This data can be used to evaluate more clinically relevant
1145 aspects of surgical performance such as entry points, screw angles, and breaches. Because this
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
1148 as identifying critical features of performance^{80,84}. Such findings can contribute to enhancing
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
1153 feedback on how to avoid errors and improve performance⁸³. However, future studies should
1154 assess the impact of teaching skill features identified by artificial intelligence to understand the
1155 varying effects such methodology can have⁸⁵. These research avenues can contribute toward the

- 1156 shift to competency-based training to the development of quantitative assessment and training
- 1157 curriculum development.
- 1158

1159 THESIS SUMMARY

1160

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
1169 evidence of construct and convergent validity. This evidence may help contribute to the validity
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
1172 of face and content validity, the fact that only 4 of 25 performance metrics significantly
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.

1183 Pedicle screw insertions are a common yet technically challenging skill for stabilizing the spine
1184 in neurosurgery and orthopedic surgery^{8,57}. However, mastery of this technique involves a steep
1185 learning curve with trainees needing to practice between 60 to 80 screws with direct supervision
1186 to be able to independently perform pedicle screw insertions accurately and safely^{12,13}. Technical
1187 errors in this procedure may cause significant patient harm, posing high risks when acquiring the
1188 skillsets for this technique⁵⁸. Virtual reality surgical simulators may be a valuable, risk-free tool
1189 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
1195 utilizing OSATS to assess construct validity, 3) establish convergent validity of the simulation's
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,
1205 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,
1207 as the skilled group significantly outperformed the less skilled group in each OSATS item and
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
1215 educational utility of the TSYM simulator's L4-6 bilateral pedicle screw insertion and the
1216 aspects needing improvement. The findings of this study may help to begin to construct a
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
1225 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

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

1486 scenario

1487 The TSYM Symgery platform is a virtual reality simulator platform with one haptic arm
1488 and a number of interchangeable handles, including a Kerrison and a straight handle. Participants
1489 performed two tasks before proceeding with the pedicle screw insertion 1) a Dry Lab which was
1490 followed by 2) a L2 laminectomy simulation scenario to become acquainted with the TSYM
1491 simulator the simulated instruments and their function.

1492 The Dry Lab involved an interactive display of instrument handling utilizing the haptic
1493 handle. Participants used the straight handle to perform the following tasks: 1) creating a hole
1494 utilizing the awl, 2) removing a spherical object with the burr, and 3) creating a trajectory using
1495 the pedicle finder. Participants then were asked to utilize the simulated Kerrison handle to bit off
1496 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

1507 which involves utilizing a Woodson to verify the complete bilateral removal of the ligamentum
1508 flavum.

1509 After completing the Dry Lab and L2 laminectomy participants are then provided with
1510 verbal and written instructions on how to perform the L4 & L5 pedicle screw insertion placement
1511 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
1514 was maintained for all participants and a specific order for screw placement was outlined. This
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
1519 procedure to verify the entry point, insertion angulation and screw placement. The next step was
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
1524 possible breach. The last step involved inserting a standardized to 6.5 mm x 45 mm simulated
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
1527 participant involved a 3D reconstruction of each of the 4 pedicle screws along with written
1528 feedback on the participant's overall performance.

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1541 Figures



Figure 1. TSYM Virtual Reality Simulator Platform Developed by Cedarome Canada Inc. dba 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.

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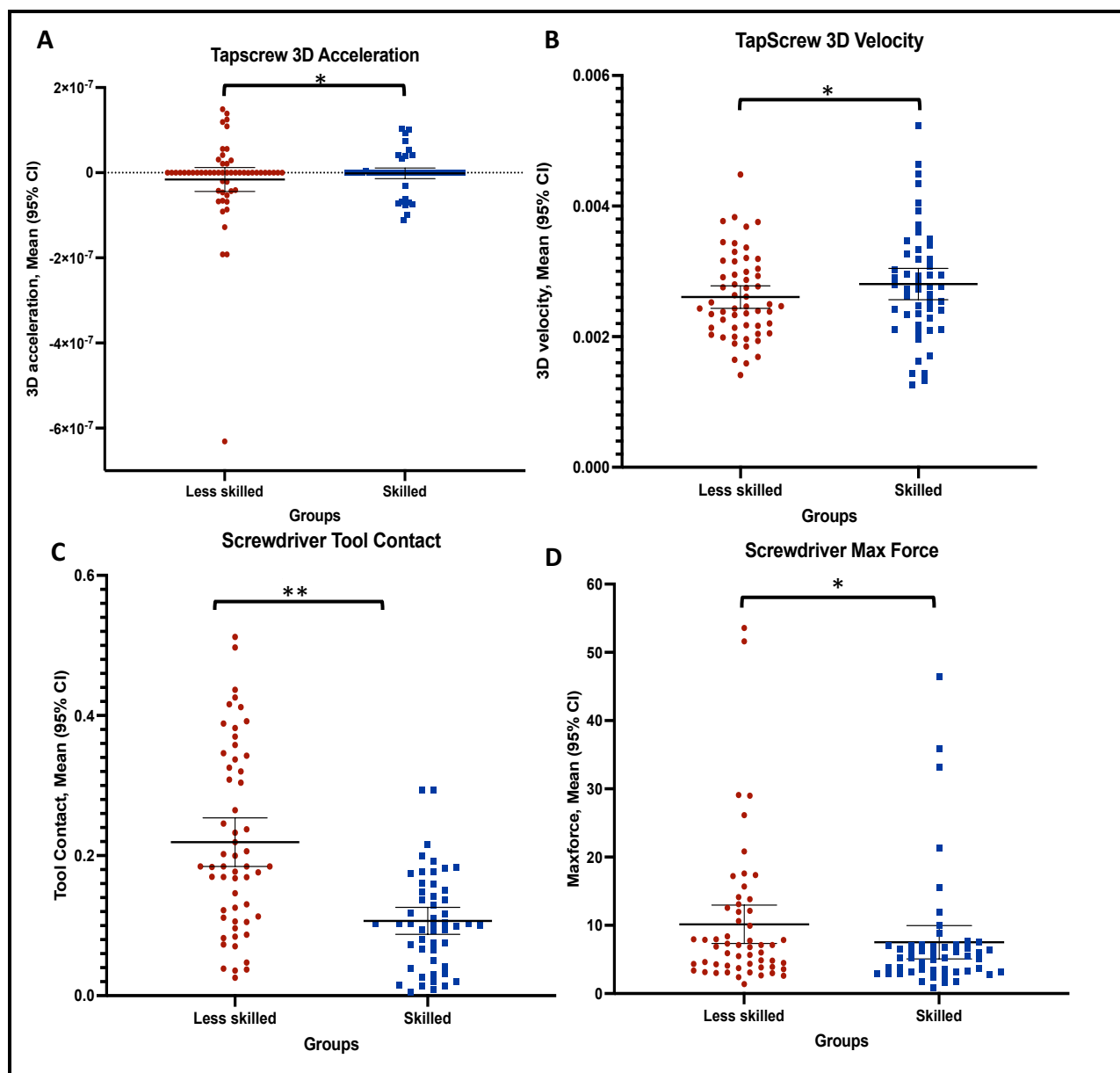


Figure 2. Significant Performance Assessments of the Task Using Simulation-Generated Performance Metrics. **A**, Tap screw's 3D Velocity. **B**, Tap screw's 3D Acceleration. **C**, Screwdriver Max Force on the pedicle. **D**, Screwdriver Contact with pedicle. The central line indicates the mean value 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, nonparametric test ($p < .01$).

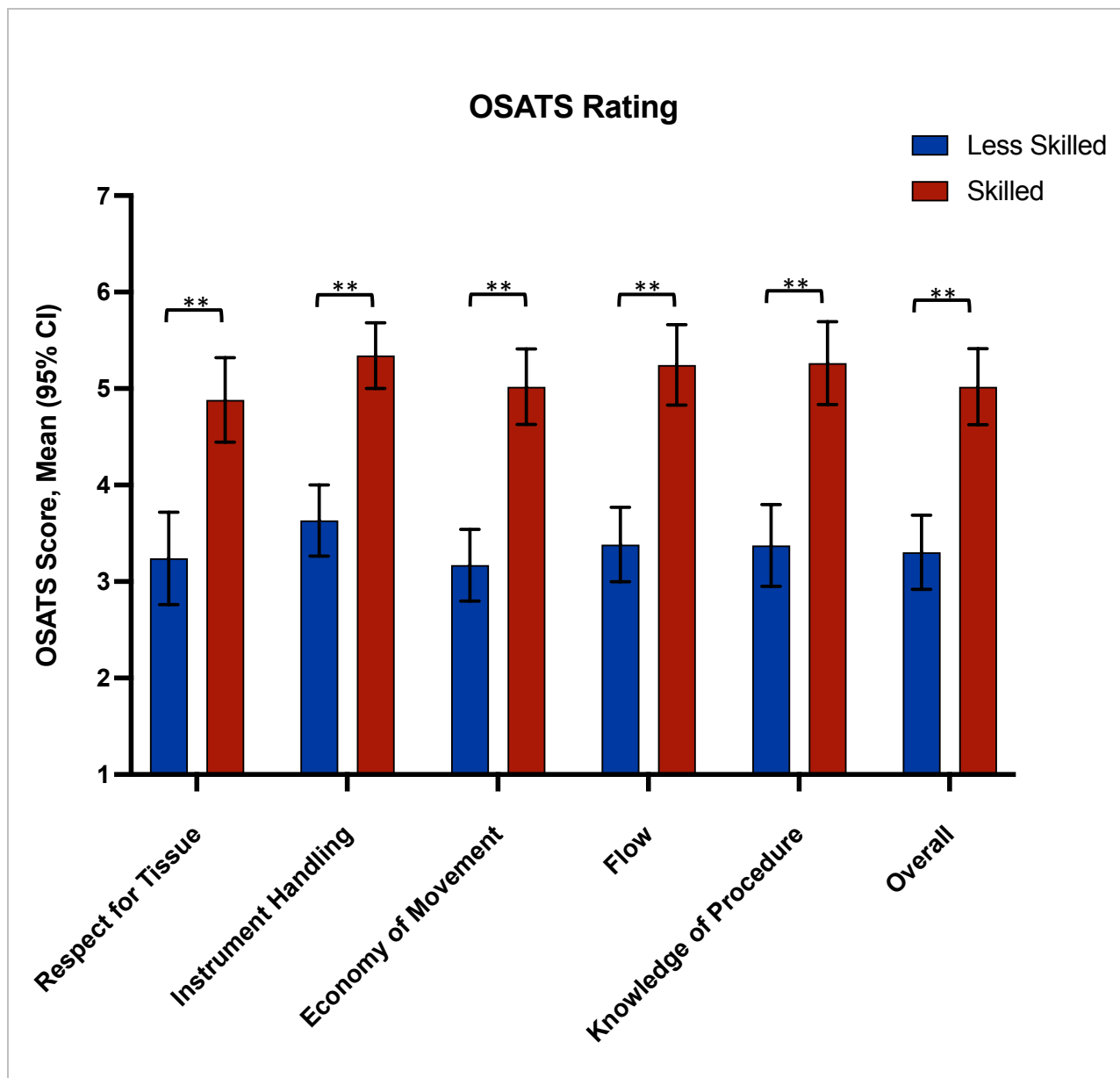


Figure 3. Performance Assessment of the Pedicle Screw Insertion Task Using OSATS.

*Represents a significant difference between groups after Mann-Whitney U, nonparametric test ($p < .05$). **Represents a significant difference between groups after Mann-Whitney U, nonparametric test ($p < .01$).

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1558 **Tables**

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

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Table 3: Demographic Data for the Two groups Performing the Simulated Pedicle Screw Insertion on the TSYM Simulator Platform		
	Less Skilled	Skilled
Number of participants	14 (52%)	13 (48%)
<i>Age (years)</i>		
Mean (SD)	29 (1.7)	38 (8.1)
<i>Gender</i>		
Male	12 (86%)	13 (100%)
Female	2 (14%)	0 (0%)
<i>Specialty</i>		
Neurosurgery	10 (71%)	8 (62%)
<i>PGY 1-4</i>	10	-
<i>PGY 5-6</i>	-	5
<i>Non-spine Fellow</i>	-	2
<i>Spine Surgeon</i>	-	1
Orthopedics	4 (28%)	5 (38%)
<i>PGY 1-4</i>	4	-
<i>PGY 5-6</i>	-	-
<i>Spine Fellow</i>	-	1
<i>Spine Surgeon</i>	-	4
<i>Affiliation</i>		
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%)

No	11 (79%)	8 (62%)
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1572 PGY = Post Graduate Year

1573 SD = Standard Deviation

1574 **No significant difference was found between the two groups except for the mean number of
1575 reported pedicle screws inserted. (P< .001)

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Table 4: Face and Content Validity			
Validity Type	Validity Statements	Median Response of Spine Fellows and Spine Surgeons Group	Observed Range
Content Validity	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)
	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)
Face Validity	Please rate the overall anatomical realism of the simulated spine.	4.00	(3.0-5.0)
	Please rate the overall realism of the colour for the simulated anatomical structures.	4.00	(4.0-6.0)
	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)

1613
 1614 The median score on a 7-point Likert scale for face and content validity for the spine fellows and
 1615 surgeons after completing the pedicle screw simulation.
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Table 5: Simulation-Derived Metrics Obtained from the L4-L5 bilateral Pedicle Screw 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 Mann-Whitney U, nonparametric test ($P < .05$).

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Table 6: Concurrent Validity Determination Between Simulation-Derived Performance Metrics and OSATS Scoring

Simulation-Derived Performance Metrics ^a	OSATS Scoring											
	Respect for Tissue		Instrument Handling		Economy of Movement		Flow		Knowledge of Procedure		Overall	
	Spearman's Coefficient	ρ Value	Spearman's Coefficient	ρ Value	Spearman's Coefficient	ρ Value	Spearman's Coefficient	ρ Value	Spearman's Coefficient	ρ Value	Spearman's Coefficient	ρ Value
Screwdriver 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**
Screwdriver 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 Acceleration	-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.

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