Assessing a New Grading System for Virtual Reality Pedicle Screw Placement– A Case Series Study

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Abstract

Introduction

Thoracolumbar pedicle screw placement is an essential surgical skill for spine surgery trainees to master. The TYSM Symgery simulator features a virtual reality platform for pedicle placement, which serves several purposes such as skill training and assessment. The use of virtual reality in spine surgery training and education has shown promising results, with the potential to improve trainees' accuracy in pedicle screw placement. These technological advancements are contributing to the ongoing evolution of surgical training and assessment, offering new opportunities for skill development and patient safety.

Objectives

To

1) assess the accuracy of pedicle screw placement using the Gertzbein and Robbins pedicle breach classification system in TYSM Symgery virtual reality simulator,

2) establish a new and more granular 3D pedicle screw breach classification system in Virtual Reality setting, and performance,

3) Evaluate the ability of the new Virtual Reality 3D classification system to distinguish "skilled" and "less skilled" performance during simulated pedicle screw insertion.

Hypothesis

1) TYSM Symgery simulator will be able to accurately classify pedicle screw placement using the Gertzbein and Robbins pedicle breach classification.

2) The new Virtual Reality 3D pedicle breach classification system will be able to accurately classify pedicle screw placement in a more granular fashion.

Methods

In this case series study, 27 neurosurgical and orthopedic residents, fellows, and spine surgeons were divided into skilled and less skilled groups to perform L4 and L5 pedicle screw placement using the TSYM VR platform. The simulator reconstructed a final 3D model including inserted screws and automatically classified pedicle screw breaches using the Gertzbein and Robbins classification system. The objectives were to determine pedicle breach class utilizing the Gertzbein and Robbins classification and to compare this result to a new 3D proposed virtual reality classification system to assess skilled and less skilled performance.

Results

Using the Gertzbein and Robbins classification, 35 of 52 (67.3%) screws in the skilled group were classified as class A, compared to 31 of 56 (55.4%) screws in the less skilled group, P =

.093. Sixteen of 47 (34%) screws in the skilled group were classified as class 1 based on the new 3D classification, compared to 13 of 51 (25.5%) screws in the less skilled group, P = .045.

Conclusion

A new 3D pedicle breach classification system has been developed to enhance the precision and granularity of categorizing participants performing pedicle screw placement using a virtual reality platform. This system aims to improve the accuracy of assessing pedicle breaches and the overall performance of participants in this surgical procedure. The development of such a classification system reflects the ongoing advancements in technology and its application in surgical training and assessment.

Résumé

Introduction

La mise en place de vis pédiculaires thoraco-lombaires est une compétence chirurgicale essentielle que les stagiaires en chirurgie rachidienne doivent maîtriser. Le simulateur TYSM de Symgery offre une plateforme de réalité virtuelle pour le placement de ces vis pédiculaires, facilitant ainsi la formation et l'évaluation des compétences. L'emploi de la réalité virtuelle dans l'apprentissage et la formation en chirurgie rachidienne s'est révélé prometteur, augmentant potentiellement la précision du placement des vis chez les stagiaires. Ces progrès technologiques contribuent continuellement à la formation et l'évaluation en chirurgie, offrant de nouvelles perspectives pour le développement des compétences et la sécurité des patients.

Objectif

Pour

1) évaluer la précision du placement des vis pédiculaires en utilisant le système de classification des brèches pédiculaires de Gertzbein et Robbins dans le simulateur de réalité virtuelle TYSM Symgery,

2) établir un nouveau système de classification 3D des brèches dans les vis pédiculaires, plus granulaire, dans le cadre de la réalité virtuelle, et évaluer les performances,

3) Évaluer la capacité du nouveau système de classification 3D en réalité virtuelle à distinguer les performances « habiles » et « moins habiles » lors de la simulation de l'insertion d'une vis pédiculaire.

Hypothèse

1. Le simulateur TYSM Symgery pourra classer avec précision les vis pédiculaires insérées en utilisant le système de classification des violations pédiculaires de Gertzbein et Robbins.
2. Le nouveau système de classification des violations pédiculaires en 3D fournira une évaluation plus précise et détaillée des vis pédiculaires en réalité virtuelle.

Méthodes

Dans une étude de cas, 27 résidents en neurochirurgie et orthopédie, ainsi que des fellows et chirurgiens rachidiens, ont été répartis en groupes selon leur compétence (compétents et moins compétents) pour effectuer le placement des vis pédiculaires L4 et L5 à l'aide du simulateur TYSM. Le simulateur a reconstitué un modèle tridimensionnel avec les vis implantées et a automatiquement classé les violations pédiculaires selon Gertzbein et Robbins. Les objectifs étaient de déterminer la classe de brèche pédiculaire en utilisant la classification de Gertzbein et Robbins et de comparer ce résultat à un nouveau système de classification en réalité virtuelle proposé en 3D pour évaluer les performances des personnes qualifiées et moins qualifiées.

Résultats

D'après la classification de Gertzbein et Robbins, 35 des 52 vis (67,3 %) du groupe compétent ont été classées classe A, contre 31 des 56 vis (55,4 %) du groupe moins compétent, avec P = .093. Selon la nouvelle classification en 3D, 16 des 47 vis (34%) du groupe compétent ont été classées classe 1, contre 13 des 51 vis (25,5 %) du groupe moins compétent, avec P = .045.

Conclusion

Un nouveau système de classification des violations pédiculaires en 3D a été développé pour améliorer la précision et le détail de la classification des participants effectuant le placement des vis pédiculaires en réalité virtuelle. Ce système a pour objectif d'affiner l'évaluation des violations pédiculaires et d'optimiser la performance globale des participants à cette intervention chirurgicale. Le développement de ce système illustre les progrès constants de la technologie et son application dans la formation chirurgicale et l'évaluation des compétences.

المستخلص

المقدمة

غرز مسامير عنقيه في الفقرات الصدرية والقطنية مهارة مهمه يجب على المتدربين في جراحه العمود الفقري اتقانها. لقد أظهر استخدام الواقع الافتراضي في تدريب وتعليم جراحات العمود الفقري نتائج واعدة، مع إمكانية تعزيز التدريب في المجال الجراحي وتحسين دقة وضع مسامير الفقرات القطنية. يتميز محاكي (TYSM Symgery) بمحاكاة واقعية افتراضية لوضع المسامير في الفقرات القطنية، مما يوفر فرصًا جديدة لتطوير المهارات الجراحيه وتعزيز سلامة المرضى .

الهدف

لـ

1. تقييم دقة وضع مسامير الفقرات القطنية باستخدام نظام (Gertzbein and Robbins) لتقييم الخرق العنقي للفقرات القطنية في جهاز المحاكاة للواقع الافتراضي (TYSM Symgery)،

2. إنشاء نظام تصنيف جديد وأكثر تفصيلًا مبني على المجسم ثلاثي الأبعاد في الواقع الافتراضي لتقييم الخرق العنقي للفقرات القطنية في جهاز المحاكاة للواقع الافتراضي (TYSM Symgery)،

3. تقييم قدرة نظام تصنيف الواقع الافتراضي ثلاثي الأبعاد الجديد للواقع الافتراضي على التمييز بين الأداء" الماهر" والأداء" الأقل مهارة" أثناء محاكاة إدخال المسمار اللولبي.

الطرق

في الدراسة هذه، تم تقسيم 27 طبيبًا مقيمًا في جراحة الأعصاب وجراحة العظام وزملاء وجراحي العمود الفقري إلى مجموعات ماهرة وأخرى أقل مهارة. قام المشاركون بوضع مسامير الفقرات القطنية في L4 وL5 باستخدام منصة TSYM. يقوم جهاز المحاكاة ببناء نموذج ثلاثي الأبعاد نهائي متضمننا المسامير المدرجة ويصنف تلقائيًا الخروقات العنقية. وتمثلت الأهداف في تحديد فئة خرق العنق باستخدام تصنيف Gertzbein وRobins ومقارنة هذه النتيجة بنظام تصنيف الواقع الافتراضي الجديد ثلاثي الأبعاد المقترح لتقييم أداء المشارك الماهر والأقل مهارة.

النتائج

باستخدام تصنيف Gertzbein وRobins لتقييم الخرق العنقي للفقرات القطنية تم تصنيف 35 من 52 (67.3%) من مسامير الفقرات القطنية في المجموعة الماهرة على أنها الفئة A، مقارنة بـ 31 من 56 (55.4%) من المسامير في المجموعة الأقل مهارة، P = 0.093. وتم تصنيف ستة عشر من أصل 47 (34%) من مسامير الفقرات القطنية في المجموعة الماهرة على أنها فئة 1 بناءً على التصنيف ثلاثي الأبعاد الجديد، مقارنة بـ 13 من أصل 51 (25.5%) من المسامير في المجموعة الأقل مهارة، P = 0.045.

الختام

يعمل نظام التصنيف ثلاثي الأبعاد الجديد لتقييم الخرق العنقي للفقرات القطنية على تحسين دقة تصنيف المتدربين على وضع مسامير الفقرات القطنية باستخدام اجهزه المحاكاة للواقع الافتراضي.

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Preface and Author Contributions

The structure of this thesis follows a manuscript-based format, and the authors of the manuscripts have made substantial contributions to finalize this work. The author's contributions are detailed herein using the CRediT (Contributor Roles Taxonomy) format [1,2]. The following statements outline the specific contributions made by each individual to this research project.

Mohamed Alhantoobi: Contributed to Conceptualization, methodology, data collection, formal analysis, investigation, and writing.

Abdulmajeed Albeloushi: Contributed to conceptualization and methodology, formal analysis, and writing – review & editing.

Trisha Tee: Contributed to participant recruitment, data collection, creating simulated scenarios, writing – review & editing.

Puja Pachchigar: Contributed to participant recruitment, data collection, creating simulated scenarios, writing – review & editing.

Bilal Tarabay: Contributed to participant recruitment, creating simulated scenarios, writing – review & editing.

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

Ali Fazlollahi: Contributed to formal analysis, writing – review & editing.

Daipayan Guha: Contributed to conceptualization, methodology and writing – review & editing.

Desmond Kwok: Contributed to conceptualization, methodology and writing – review & editing.

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

Abbreviations

VR: Virtual Reality

AI: Artificial Intelligence

OR: Operating Room

PGY: Post-Graduate Year

3 D: Three Dimensional

Thesis Introduction

History of Thoracolumbar Spinal Instrumentation

Internal fixation introduction revolutionized modern spine surgery, allowing surgeons to correct spinal deformities and stabilize the spine. Paul Harrington introduced the Harrington rod in 1975 that was initially utilized for deformity correction and later utilized in the treatment of traumatic, degenerative, and metastatic spinal conditions [3–6]. This system offered distraction and compression rods as well as hooks.

In the mid-1970s, Eduardo Luque made a substantial contribution by popularizing the use of sublaminar wires to augment Harrington construct [7]. Subsequently, in the 1980s, more sophisticated multiple hook-rod systems emerged, such as the Cotrel Dubousset (CD) system, providing enhanced strength and flexibility to address deformities in both the sagittal and coronal dimensions [8].

The utilization of the pedicle as a site for segmental fixation, a concept primarily attributed to Roy-Camille, incredibly advanced spinal instrumentation [9]. Pedicle screws present numerous advantages such as superior biomechanical fixation and their ability to be inserted in the sacrum and even after a laminectomy, without affecting the spinal canal[10,11]. This innovation facilitated the widespread implementation of spinal instrumentation in the management of numerous spinal pathologies.

Magerl, in 1977, introduced a breakthrough spine fixation technique called “fixateur externe” which involve the use of pedicle screws that were fixed outside the body and were attached to a unique rod system [12]. Later, Walter Dick modified this idea at Basel, where he created a “fixateur interne” by shortening the screws and inserting the rods inside the body, next to the spine [12]. These advancements in pedicle screw fixation have made a substantial contribution to the field of spinal surgery.

Pedicle screws were popularized in the United States by Arthur Steffee around 1984, employing a contourable plate [13]. Meanwhile, Yves Cotrel developed a screw-rod system that was integrated into the "Universal" CD system in Europe [13]. The controversy between proponents of screw-plate and screw-rod constructs ultimately led to the preference for rods due to their greater flexibility, reduced encroachment on adjacent facet joints, and increased surface area for fusion [14]. The combination of long dual-rod constructs with pedicle screws considerably enhanced surgeons' ability to perform complex spine surgeries, which was further advanced by the use of polyaxial pedicle screws [13].

Risks Associated with Pedicle Screw Breach

Since the widespread adoption of the pedicle screw fixation technique, spinal surgeons have increasingly focused on the accuracy of screw placement [15,16]. Suboptimal screw positions and cortical breaches in various regions of the vertebrae can compromise bone purchase and pose risks to neural, vascular, and visceral structures [16–19]. While minor cortical violations are often considered clinically silent, they can lead to instrumentation failure, instability, reduced fusion rates, and accelerated adjacent-level degeneration [16,18–22].

The extent of pedicle screw malposition in the literature varies between different case series due to different patient demographics, the nature of the surgical intervention as well as the ability to detect on postoperative imaging. However, based on two large literature review articles the incidence of pedicle screw malposition ranges between 4.2 – 7.8% [19,23] . According to Hicks et al., 53% of the malpositioned screws were breaching the lateral cortex, 24% breaching the medial cortex, 14% breaching the inferior cortex, 8% breaching the superior cortex and 1% breaching the anterior cortex of the vertebral body [23].

Although clinically relevant complications from screw misplacement in non-deformity cases are infrequent at the present time and account for less than 0.5%, they can result in devastating consequences such as neurological deficits due to nerve root or spinal cord injury, cerebrospinal fluid leak, spinal instability or pseudarthrosis, revision surgery, and can lead to malpractice claims [19,20,24,25]. Additionally, there are some rare complications associated with pedicle screw placement that have been reported in the literature. These include intraoperative pedicle fractures, screw loosening or pullout, and pulmonary effusion [23]. These rare complications highlight the importance of careful surgical technique and close postoperative monitoring to ensure the best possible outcomes for patients.

Pedicle Breach Classification Systems

Currently, there is no gold standard scale for grading pedicle breaches. There are various scales in the literature including the Heary Classification and Gertzbein–Robbins Classification [25–27].

The most widely accepted method for assessing pedicle screw placement is the Gertzbein–Robbins Classification which was introduced in 1990 [27]. This classification focuses on the position of screws in relation to the pedicle mainly in the medial direction and divides their position outside the pedicle by 2 mm increments [27]. While the ideal position for a screw is entirely within the vertebral body and pedicle, the authors hypothesized that a medial breach of up to 4 mm remains within the anatomical safety zone and can be considered a safely positioned screw[25].

However, a limitation of this scale is the lack of determination of the presence and direction in which the screw breaks through the pedicle beside medial breaches [18–20,25]. Screws breaching the inferior or superior border of the pedicle can cause neurological symptoms due to nerve root injury, dural laceration, or exacerbation of proximal junctional kyphosis [19,20]. Malpositioned screws in other directions hinder objective assessment of less skilled trainee performance since screw breaches in inferior, superior, or lateral borders are scored as no breach.

Heary et al. in 2004 introduced a new classification system for pedicle screw placement that considers the clinical implications of cortical breaches, particularly in the thoracic spine where lateral breaches may be optimal for additional bony rib purchase [26,28] . This classification system distinguishes between screws that require immediate removal due to proximity to critical structures (Grade 5) and those that breach laterally but are still contained within the rib (Grade 2). It also grades anterior breaches (Grade 3) for the first time. However, this classification does not consider the metric extent of breach in any direction [28]. Table 1 provides a summary and comparison of two of the widely accepted pedicle breach classifications.

Evolution of Surgical Education to Competency-Based Training

The landscape of surgical education has undergone a remarkable transformation over the centuries, evolving from informal apprenticeships to structured competency-based training models [29,30]. Initially, in the absence of formal education, individuals pursuing medicine were largely self-taught or acquired knowledge through apprenticeships with experienced physicians. This traditional apprenticeship system required students to shadow a mentor, observe medical practices, and imitate their actions to acquire surgical skills [29,30] . However, the focus during this period was more on practical experience rather than a structured curriculum.

Sir William Osler played a pivotal role in emphasizing the significance of early clinical exposure for medical students [31,32]. His work at McGill University and Johns Hopkins Medical School laid the foundation for more advanced surgical training models [30]. William S. Halsted, influenced by his European surgical experience in Germany, introduced a progressive surgical training model at Johns Hopkins Hospital [30]. This model emphasized supervised training, gradual autonomy development, increased responsibilities, and independence for trainees [30].

In the late 19th century, Abraham Flexner's report highlighted deficiencies in medical and surgical education across various institutions in the United States and Canada [29,32] . This led to the establishment of the American College of Surgeons in 1912 with a primary objective of enhancing training standards for surgical trainees. Concurrently, efforts were made to standardize medical education through initiatives like nationwide examinations for medical school graduates [32–34].

Challenges such as reduced teaching time, growing surgical complexity, patient safety concerns, and the need for operational efficiency have driven a shift towards competency-based approaches in surgical education [35,36]. Competency-Based Medical Education (CBME) has emerged as a solution to ensure that trainees acquire the necessary competencies at each stage of their training [37]. The CanMEDS Competency Framework developed by the Royal College of Physicians and Surgeons of Canada in 1996, with subsequent updates in 2015, marked a significant milestone in this transition [38,39].

In response to the global trend towards CBME, the Royal College of Physicians and Surgeons of Canada launched the Competence by Design (CBD) program. This initiative aims to transform all disciplines into competency-based education models by delineating specific competencies for each stage of postgraduate training [38–41]. Entrustable Professional Activities (EPAs) are utilized to assess competencies and guide progression between training stages [38].

The adoption of competency-based training signifies a paradigm shift in surgical education towards outcome-focused learning and assessment. By emphasizing mastery of specific competencies rather than traditional time-based progression, this approach ensures that trainees are adequately prepared for independent practice. The American Board of Surgery's (ABS) focus on developing EPAs underscores a commitment to enhancing competency-based surgical training across specialties [35,36,39–41].

Surgical Education through Simulation

Surgical education witnessed a profound transformation with the integration of simulation-based training methodologies. The acquisition of surgical skills was defined by Resnick and MacRae into cognitive, integrative, and autonomous phases, which is parallel to pilot training programs that emphasize skill development through pattern recognition and reflection [42]. Simulation offers immersive experiences that replicate real-world scenarios, allowing trainees to practice surgical procedures in a controlled environment [43].

Initially inspired by aviation industry, medical simulators emerged in the 1960s, followed by the introduction of computerized virtual reality platforms by the late 1990s [44]. Surgical simulation labs offer a conducive setting for trainees to practice their surgical skills without the pressure and challenges encountered in the operative room [45].These simulated scenarios not only facilitate practice but also enable objective evaluation of trainee performance using different tools such as Objective Structured Assessment of Technical Skills (OSATS) [46,47]. By allowing repeated practice in a safe environment with performance feedback, simulation facilitates the smooth transition of trainees to the operative theater where they can begin operating on real patients with more confidence and proficiency [48].

Surgical simulators vary in complexity, ranging from basic bench-top models like suture tying boxes to advanced virtual reality (VR) simulators [45,49]. In contrast to bench-top simulators which offer basic surgical skills practice, advanced simulators like VR platforms provide sophisticated anatomical details and realistic visual, auditory, and haptic feedback [49]. To illustrate, the

Da Vinci Surgical Skills Simulator is utilized to train surgeons in robotic surgery, enhancing their hand-eye coordination and fine motor skills [44,45,49,50] .

The rapid evolution of VR technology has enhanced its integration into surgical education. VR simulators are extensively used for teaching endoscopic and laparoscopic procedures, offering high-fidelity simulations with realistic haptic feedback mechanisms [51,52] . For example, the Minimally Invasive Surgery Trainer – Virtual Reality (MIST-VR) has demonstrated significant improvements in operating room performance and error reduction during laparoscopic surgeries [44,53,54].

Despite the cost and availability challenges associated with VR simulators, ongoing technological advancements aim to address these limitations and enhance the operative realism and feedback mechanisms for trainees [44,55] . Simulation-based training stands at the forefront of modern surgical education, offering a dynamic platform for skill development and competency assessment. As technology continues to advance, the integration of surgical simulations promises to reshape surgical training paradigms, ensuring enhanced learning outcomes and competency among future surgeons.

Advancing Spine Surgery Training through Simulation

The introduction and advancement of simulation technology into spine surgical training and education has been slow compared to other specialties like laparoscopic or robotic surgery [56]. Most of the commercially available spine simulators predominantly focus on minimally invasive procedures such as vertebroplasty and pedicle screw placement; there is still limited access to more sophisticated and intricate procedures like anterior cervical discectomy and fusion or scoliosis surgery [56]. This can be attributed to various challenges such as the difficulty in simulating anatomical structures, variations in force application between soft tissues and bone, and cost-related constraints which impede the development of comprehensive and more complex spine simulation platforms [56].

Spine surgery demands a diverse skill set from trainees, necessitating accurate anatomical replication and realistic tactile feedback for bone and soft tissues in any surgical simulator [57,58]. Essential skills like bone drilling require precise tactile and audiovisual feedback to mirror real operative experiences [58]. Technological advancements are key in overcoming these challenges, enabling the creation of highly realistic virtual reality (VR) environments for spine simulation [56]. Furthermore, the introduction of patient-specific VR tools holds promise for enhancing surgical planning and perioperative practices [56].

The development of VR spine simulators faces difficulties in simulating diverse anatomical structures with different tissue densities and force requirements. Simulating bone drilling poses a particular challenge due to force limitations of haptic devices and slow response rates of simulated tools [58]. Despite these obstacles, ongoing advancements aim to enhance haptic feedback modalities and provide users with immersive and high-fidelity educational experiences [56]. Platforms like NeuroVR exemplify this progress by incorporating 3D visual, auditory, and haptic feedback for simulating complex spinal surgeries like hemi-laminectomy [59].

As technology continues to evolve, VR platforms tailored for more complex spine procedures are anticipated to emerge, potentially mitigating risks associated with errors during spine surgeries. The continuous refinement of spine simulators underscores a commitment to enhancing surgical training outcomes and ensuring patient safety. Table 2 summarizes the available interactive VR spine simulators in the literature that offer pedicle screw placement scenarios and a detailed comparison between them.

The TSYM Symgery Virtual Reality Surgical Simulator

The TSYM Symgery Virtual Reality Surgical Simulator (Figure 1 A), developed by Cedarome Canada Inc. dba Symgery in Montreal, Canada, is a state-of-the-art virtual reality (VR) simulator designed to provide a highly realistic and non-immersive training experience for spinal surgical procedures. It employs a voxel-based system to create a realistic three-dimensional (3D) representation of the intraoperative surgical environment, allowing participants to interact with and manipulate surgical instruments with a high degree of fidelity and haptic feedback (Figure 1 C) [60,61] .

TSYM Symgery simulator utilizes haptic feedback technology, which enables participants to experience realistic tissue handling and tactile sensations during the simulated tasks. This non immersive simulator creates a realistic training experience, that enhances the development of essential surgical skills.

The simulator offers a wide variety of tool handles that accurately replicate the look and feel of various surgical instruments used in spinal surgery, in addition to its haptic feedback capabilities (Figure 1 B). Participants can perform a range of simulated procedures, including complex tasks such as laminectomy and pedicle screw placement, using these virtual instruments.

The TSYM Symgery simulator also provides comprehensive auditory and visual feedback to participants as they interact with the virtual environment and perform simulated surgical maneuvers. This includes sounds such as patient cardiac monitoring and instrument sounds, further enhancing the realism and immersion of the training experience.

Furthermore, the simulator is equipped to record a variety of performance metrics at a high frequency. This detailed performance data allows for the analysis of factors such as force, instrument tracking, tissue removal rates, velocity, acceleration, and more, enabling assessment and feedback on participants' performance. In addition, a three-dimensional vertebral body structure is generated by the simulator at the completion of the task outlining the final position of the pedicle screws inserted as a feedback educational tool.

The TSYM Symgery Virtual Reality Surgical Simulator represents a potentially important assessment and training tool for surgical learners, offering a highly realistic environment for the development and refinement of essential psychomotor technical skills. Its advanced features and capabilities make it a potentially valuable resource to increase the understanding of the composites of surgical expertise associated with pedicle screw insertion. The ability of the TSYM Symgery to assess and train surgical trainees may also be useful in the formative and summative assessment of pedicle screw insertion performance. In formative assessments, the simulator can provide real-time feedback to trainees as they perform the procedure, allowing them to identify and correct any errors or deviations from the ideal pedicle screw placement. This can help trainees to develop a deeper understanding of the technical and cognitive aspects of pedicle screw insertion, and to refine their skills in a risk-free environment. For summative assessments, the TSYM Symgery can be used to evaluate a trainee's competency in pedicle screw placement, providing an objective and standardized measure of their performance. This advantage can be integrated in the future into the formative and summative assessment of both Neurosurgery and Orthopedic residency programs.

Lumbar Pedicle Screw Placement Simulation

Pedicle screw placement in the thoracolumbar spine is a crucial technique for spine surgeons in order to stabilize and fuse the spine. The simulated L4-L5 pedicle screw placement task is a complex training scenario that encompasses multiple interactive steps, providing participants with a non- immersive yet realistic learning experience. The simulated L4-L5 pedicle screw placement scenario involves a series of steps designed to replicate the process of pedicle screw insertion in the L4 and L5 vertebrae.

The scenario starts with an animated component outlining the L4 & L5 vertebrae being completely dissected from a posterior approach. The screen magnification is adjusted to a standardized level and a specific order is established for screw placement. Participants start with canulating the pedicle using both an awl and pedicle finder to carefully create and prepare a channel in the pedicle for screw insertion. This step requires precision and an understanding of the anatomical landmarks to ensure accurate screw placement. Following this step, using a ball tip, participants are tasked with verifying the absence of pedicle breaches using a ball tip instrument. This is a crucial aspect of ensuring the safety and efficacy of the screw placement. Participants then use a tap to pre-thread the pedicle, preparing it for the insertion of the pedicle screw. This step requires careful attention to detail and an understanding of the proper technique for preparing the pedicle. Finally, the pedicle screw is inserted into the pre-threaded pedicle, which requires participants to apply their knowledge of screw size, angle, and depth to achieve accurate and stable fixation.

Throughout these interactive steps, participants have access to live X-ray imaging to verify the entry point and the angles of canulating the pedicle, and to confirm the accuracy of the inserted screws. This real-time feedback allows participants to assess their performance and make adjustments as needed to ensure accurate screw placement.

The standardization of screw size (6.5 x 45 mm) in this simulation scenario enables participants to focus on mastering the technical aspects of pedicle screw insertion without variability in screw dimensions. Additionally, participants are guided through a specific sequence of screw placement (left L5, left L4, right L5, and right L4), providing a structured approach to learning and practicing this essential surgical skill.

Overall, the simulated L4-L5 pedicle screw placement scenario offers a comprehensive training experience, allowing participants to develop proficiency in this critical aspect of lumbar spinal surgery while receiving real-time feedback and guidance.

The Rationale of the Thesis

The rationale for the development of a virtual reality (VR) pedicle breach classification system in the TSYM Symgery Virtual Reality Surgical Simulator is multifactorial and aims to enhance the training and assessment of lumbar pedicle screw placement. There are several key points to support the need for this advancement.

The absence of a gold standard pedicle breach classification system and especially one dedicated and validated for VR settings hinders the comprehensive assessment and training of pedicle screw placement using VR simulators. Therefore, the introduction of a new pedicle breach classification system that captures breaches in all directions would significantly enhance the assessment and training of pedicle screw placement, allowing for a more thorough and detailed evaluation of participants' performance.

A new breach classification system that accounts for the percentage of screw diameter breaching the pedicle would enable more discrete measurement of breaches, providing valuable insights into the accuracy and precision of screw placement. Importantly, safety considerations must be contemplated when proposing a new pedicle breach classifications based on the safety threshold zone outlined in the spine literature; namely within 4 mm from the pedicle [62]. The average diameter of pedicle screws used in the lumbar spine typically ranges between 4.5-7.5 mm, emphasizing the need for a classification system that accounts for variations in screw size [63]. The concept that a 50% screw diameter breach is equivalent to less than a 4 mm breach related to the new breach classification emphasises that breaches scored 2 or less (less than 50% of screw diameter) are still within the safety zone.

Incorporating these considerations into the development of a VR pedicle breach classification system within the TSYM Symgery Virtual Reality Surgical simulator may contribute to the comprehensive and effective training of surgeons in lumbar pedicle screw placement, ultimately enhancing patient safety and surgical outcomes.

Furthermore, it is important to emphasize the significance of validating VR simulators, such as the TSYM Symgery platform, to ensure their effectiveness in surgical education. Validation methods, including face and content validity, and construct validity are essential in establishing the capability of simulators to accurately assess and train participants effectively. The ability of TSYM Symgery VR simulators to capture large amounts of objective performance data including 3D reconstruction of surgical outcomes, may provide valuable insights into surgical performance. This can be utilized in the development of a more robust framework for assessing surgical competency and enhancing surgical training and education.

Thesis Goal and Objectives

The primary goal of this thesis is to develop and evaluate a standardized assessment methodology for pedicle screw placement in spinal surgery, utilizing virtual reality simulation. This project will leverage the resources available at the Neurosurgical Simulation and Artificial Intelligence Learning Centre, including the TYSM Symgery virtual reality simulator.

The primary research hypotheses are:

1. The TYSM Symgery virtual reality simulator will accurately classify pedicle screw placement using the Gertzbein and Robbins pedicle breach classification system.
2. The new VR 3D pedicle breach classification will provide a more precise and granular classification of pedicle screw placement.

The research objectives are:

1. To evaluate the effectiveness of the TYSM Symgery virtual reality simulator in accurately classifying pedicle screw placement using the Gertzbein and Robbins pedicle breach classification system.
2. To develop a more precise and granular 3D pedicle screw breach classification system for use in virtual reality spine simulation.
3. To assess the effectiveness of the new 3D classification platform during virtual reality spine simulation.

These objectives align with the broader goals of the thesis, which aim to improve the accuracy and safety of pedicle screw placement in spinal surgery using virtual reality simulation and artificial intelligence.

Manuscript

Assessing a New Grading System for Virtual Reality Pedicle Screw Placement– A Case Series Study

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Abstract

Background

Thoracolumbar pedicle screw placement is a key spinal surgical skill for trainees to master. The TYSM Symgery simulator offers a virtual reality pedicle insertion simulation that can be used to assess technical skills, teach trainees, and improve patient safety.

Objectives:

To 1) evaluate the ability of the TYSM Symgery virtual reality simulator in classifying accuracy of pedicle screw placement using the Gertzbein and Robbins pedicle breach classification system, 2) develop a more granular 3D pedicle screw breach classification system, and 3) evaluate the ability of the new Virtual Reality 3D classification system to distinguish "skilled" and "less skilled" performance during simulated pedicle screw insertion.

Methods

Twenty-seven neurosurgical and orthopedic residents, fellows, and spine surgeons were recruited in this case series study and divided into skilled and less skilled groups. Utilizing the TSYM platform, participants performed L4 and L5 four pedicle screw placement. Final 3D models including the inserted screws were reconstructed by the simulator, which were automatically utilized by the software to classify pedicle breaches. This classification system has

not been validated but developed by the company with neurosurgical educator input. The objectives were to assess pedicle breach class utilizing the Gertzbein and Robbins classification and to compare this result to a new 3D proposed virtual reality classification system.

Results

Thirty-five of 52 (67.3%) screws in the skilled group were classified as class A, compared to 31 of 56 (55.4%) screws in the less skilled group based on Gertzbein and Robbins classification, P = .093. In contrast, utilizing the new 3D VR classification, 16 of 47 (34%) screws in the skilled group were classified as class 1 compared to 13 of 51 (25.5%) screws in the less skilled group, P = .045.

Conclusion

This study proposed a new pedicle breach 3D classification system in the virtual reality setting that improves the precision and granularity of classifying skilled vs non skilled participants performing pedicle screw placement in a virtual reality platform.

Keywords

Artificial Intelligence, Pedicle Breach Classification, Pedicle Screw Placement, Surgical Education, Surgical Spine Simulation, Virtual Reality, 3-Dimensional Vertebral Reconstruction

Short Title

New Grading System for VR Pedicle Screw Placement

Introduction

Mastery of surgical techniques in spine surgery is essential due to the proximity of critical neurological elements. One of the most vital skills is pedicle screw placement which aims to facilitate thoracolumbar spine fixation and fusion [16,19,23,64–66]. Various pathologies causing spinal instability are treated utilizing this technique including spine infections, tumours, and degeneration [19–21,23]. However, substantial risk of complications can be associated with pedicle screw insertion which make the mastering this technical proficiency imperative [19–21]. Misplaced pedicle screws can cause acute neurological injuries and revision surgery to replace the screws [23,67]. Several studies reported a range from 15.7% to 41% misplaced pedicle screws, emphasizing the importance of mastering these skills and ensuring surgical competency both for trainees and surgeons [23,68–70]. Gonzalvo and co-workers outlined in their retrospective study that in order to achieve accuracy rates comparable to established spine surgeons, spine fellows require the insertion of 80 pedicle screws and the performance of 25 procedures independently [69].

Several classifications have been suggested in the spine literature to assess pedicle screw accuracy, however, there is still no gold standard classification to assess pedicle screw breaches [20,25]. One widely accepted classification system was proposed by Gertzbein and Robbins in 1990 [27]. Several limitations are associated with this classification system since it takes into

consideration only medial pedicle breaches [19,20,27]. There are multiple challenges that trainees may encounter in order to master highly demanding technical skills such as pedicle screw placement. Those challenges range from work hour restrictions for residents, patient safety concerns and surgical outcomes [71]. Therefore, leveraging new training methodologies and quantitative assessment tools may complement intra-operative surgical education and exposure for trainees involving these skill sets [71]. Surgical training utilizing virtual reality (VR) platforms has been proposed across various surgical specialties, including spinal surgery to facilitate surgical skill acquisition and competency achievement [72]. The ability of VR simulation to enhance surgical skills has been demonstrated by numerous studies [73–75].
VR simulation in spine surgery can provide quantitative assessment of trainee operative performance and surgical skills in patient risk-free environments [71].

The TSYM Symgery VR platform is a non immersive VR simulator with a robotic arm and different tool handles that utilizes advanced haptic feedback technology to provide a realistic operative experience. One of the advantages of the TSYM Symgery VR simulator platform is analyzing and replicating complex spine surgical tasks, such as lumbar spine pedicle screw placement. It is able to record extensive datasets and provide 3D models of final procedural outcomes, which allow comprehensive analysis of pedicle screw placement performance in real time 3D fashion.

To date, there is no comprehensive 3D pedicle breach classification system developed for VR simulation assessment and training. In this study we intend to 1) evaluate the ability of the TYSM Symergy VR simulator to classify the accuracy of pedicle screw placement using the

Gertzbein and Robbins pedicle breach classification, 2) propose a new pedicle screw breach classification system in the VR setting, and 3) assess the effectiveness of the new 3D pedicle screw breach classification system for VR simulation in accurately classifying participants based on their performance in pedicle screw placement. The coprimary outcomes to accomplish these objectives involve a case series study to determine the utility of pedicle breach class utilizing the Gertzbein and Robbins classification and the comparison of results to a new 3D virtual reality classification system.

Methods

Participants

In this case series study, 27 participants engaged in a virtual reality simulation of L4 and L5 pedicle screw placement with simulated X-ray guidance using the TSYM Symgery platform. Exclusion criteria included prior experience with pedicle screw placement on this platform. The participants were initially categorized into skilled and less skilled groups based on their expertise levels. The skilled group comprised neurosurgery and orthopedic residents (PGY5 and PGY6), spine fellows, and spine surgeons (n=13), while the less skilled group consisted of neurosurgery and orthopedic residents (PGY1 to PGY4) (n=14) (table 3). All authors involved in the study disclosed no conflicts of interest. Participants, along with any identifiable individuals, provided consent for the publication of their images. They signed informed consent forms approved by the Neurosciences-Psychiatry McGill University Health Center Research Ethics Board. All participants signed consent forms approved by the Neurosciences-Psychiatry (NEUPSY) panel of the McGill University Health Centre Research Ethics Board before trial participation. Following consent, participants shared demographic details and estimates of their experience of independently inserted pedicle screws.

Before the task, participants received written and verbal instructions and underwent a Dry Lab session and an initial simulated procedure to familiarize themselves with the functions of simulated instruments (refer to supplementary information). Each step in the simulation required participant confirmation before progression, with no time constraints imposed during the task. This study adheres to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting guidelines to ensure comprehensive reporting of observations and results [76].

Virtual Reality Surgical Simulator

The TSYM Symgery virtual reality simulator employed in this study (Figure 1 A) was developed by Cedarome Canada Inc. dba Symgery. (Montreal, Canada). A variety of tool handles are offered by the simulator (Figure 1 A). each simulates various surgical tools required to perform the surgical procedure (Figure 1 B). This simulator depends on a voxel-based system to simulate a 3D intraoperative spinal surgical procedure (Figure 1 C) [60,61]. Participants experience auditory and visual feedback when utilizing the instruments, whereas haptic feedback permits realistic tissue handling.

Simulated L4 and L5 Pedicle Screw Placement Scenario

The simulated task for L4-L5 pedicle screw insertion involves a total of 5 steps, with 1 step being animated (Figure 1B) and the other 4 steps being interactive. The interactive steps include:

1) Canulating the pedicle using both awl and pedicle finder.
2) Verifying breaches using a ball tip.
3) Pre-threading the pedicle with the tap.
4) Inserting the pedicle screw.

During the task, participants had access to live X-rays to aid in verifying the entry point, determining the angles for canulating the pedicle, and confirming the accuracy of the inserted screw. The screw size used for the procedure was standardized to 6.5 x 45 mm.
Participants followed a specific sequence while performing the task. They started with the left L5 screw, followed by the left L4 screw, then the right L5 screw, and finally the right L4 screw.

Three-Dimensional Vertebrae Structure

Upon the completion of the task, the TSYM simulator generates a three-dimensional vertebral body structure that outlines the final position of the pedicle screws inserted and functions as a feedback educational tool (Figure 2). Pedicle screw breaches were classified automatically by the simulator based on predefined criteria according to Gertzbein and Robbins breach classification system (Table 5). To classify participants' pedicle screw breaches based on the new breach classification system, the final 3D models were utilized. A spine surgeon reviewed each pedicle screw inserted and categorized them accordingly (Figure 3).

New Pedicle Screw Virtual Reality Classification System

Figure 3 outlines the new pedicle breach classification system that was intended to aid trainees in VR pedicle screw insertion tasks. Details regarding the scoring criteria are illustrated in Table 6 A & 6 B**.** Pedicle breaches are categorized based on 1) the direction of the breach, taking into consideration pedicle breaches can occur in 4 directions and 2) the percentage of screw diameter breaching the pedicle. The severity of the pedicle breach in the new classification ranges from grade 1 to grade 4. This system also includes further subclassification groups A, B, C and D based on the direction of the breach. In this study, the pedicle screw size was standardized to 6.5 x 45 mm. Therefore, a breach that is less than 50% of the screw diameter is considered equivalent to a breach of less than 3.25 mm.

Statistical Analysis

We analyzed the data based on SPSS software version 29 (IBM SPSS Statistics). We treated each screw inserted by an individual participant independently due to small sample size (n=27). This decision is based on the rationale that each pedicle screw had a different orientation, entry point, and angle. To examine the relation between the individual expertise group and each pedicle breach classification, the Kruskal-Wallis Test was utilized with $P < .05$ set as threshold for statistical significance. The data set collected during the study is available on a reasonable request from the corresponding author.

Results

Participants

Table 3 provides demographic information about the 27 participants, as well as details regarding their experience with pedicle screw insertion. The skilled group reported a median of 100 pedicle screws independently inserted, with a range of 10 to 3000 screws (mean of 452). In contrast, the less skilled group reported a median of 0 pedicle screws independently inserted, with a range of 0 to 5 screws (mean of 0.5). The difference is statistically significant, ($P < .001$).

Classifying L4 & L5 Pedicle Breaches Based on Gertzbein and Robbins System

Table 4 presents a summary of the data obtained from the Symgery simulator regarding pedicle screw placement. Out of the 108 pedicle screws that were inserted, 35 out of 52 screws (67.3%) in the skilled group were classified as class A according to the Gertzbein and Robbins classification system. In comparison, 31 out of 56 screws (55.4%) in the less skilled group were classified as class A. For class D classification, one out of 52 screws (1.9%) in the skilled group and six out of 56 screws (10.7%) in the less skilled group were categorized as such. None of the skilled or less skilled groups had class E breaches. There was no statistical significance ($P = .093$) between the two groups (Table 4).

Classifying L4 & L5 Pedicle Breaches Based on the New Proposed System

Figure 3 visually represents the new pedicle breach classification system that was utilized in this study. The statistical analysis of pedicle screw placement based on the final generated 3D models is detailed in Table 4. Out of the total 108 pedicle screws, 98 (90.7%) were available in the final 3D reconstruction. However, there were missing data for 10 screws due to a systems error, with 5 missing in both the skilled and less skilled groups. In the skilled group, 16 out of 47 screws (34%) were classified as class 1 using the new classification system, while in the less skilled group, 13 out of 51 screws (25.5%) fell into the same category. In contrast, the skilled group had 6 out of 47 screws (12.8%) classified as class 4, while the less skilled group had 17 out of 51 screws (33.3%) in this category. All the complete pedicle breaches in the skilled group (6 out of 47 screws) were in the medial direction. In the less skilled group, there were 17 out of 51 screws (33.3%) with complete pedicle breaches involving all directions: 13 out of 51 screws (25.5%) breached medially, 1 out of 51 screws (2.0%) breached inferiorly, 1 out of 51 screws (2.0%) breached superiorly, and 2 out of 51 screws (3.9%) breached laterally. In comparison to the skilled group, there was a statistically significant relationship between the level of training and the new pedicle breach classification, with a P-value of .045. The detailed new classification further demonstrated a statistically significant association between the skilled and less skilled groups and the category of pedicle breaches, with a P-value of .042. This finding reinforces the idea that incorporating both the direction and magnitude of pedicle breaches can differentiate participant skill levels effectively, offering a more thorough evaluation of participant proficiency.

Discussion

The goal of this case series study was to assess how well the TYSM Symgery VR simulator classified pedicle screw placement using the Gertzbein and Robbins Pedicle Breach Classification. To enhance and refine the process of categorizing trainees' performance in pedicle screw placement in virtual reality environments, the authors also present a novel pedicle breach classification system. Our data on pedicle screw breaches are in line with other research showing that participants proficiency can be determined in large part by their expertise level with pedicle screw fixation [69,70,77–79]. We evaluated a new pedicle breach classification system using a virtual reality simulation of pedicle screw insertion which revealed improvement in classifying skilled and less skilled individuals with more precision and granularity [80].

Studies employing VR surgical simulation have shown that skilled participants predominantly focus on procedural safety. Therefore, educational curriculum systems, including the virtual operating assistant, have instructed learners to first conduct procedures safely before focusing on efficiency [81–84]. This new 3D pedicle breach classification system was designed to help the student focus first on the procedure's safety. The use of this new 3D pedicle breach classification includes a comprehensive analysis that takes into consideration a variety of safety measures, including the direction of the breach and its severity. By combining these measurements, each aspect of the breach can be precisely quantified and classified, resulting in a more detailed knowledge of the nature of the pedicle breach. The use of real-time feedback methods improves the assessment process by providing quick 3D visual insights regarding the occurrence and types of pedicle breaches during the VR simulated task [85]. This real-time 3D feedback is specifically valuable for less skilled trainees as they can enhance their surgical skills and accelerate their surgical training. The new 3D pedicle breach classification based on personalized screw position data, combined with real-time 3D feedback mechanisms, represents an advanced approach to assessing pedicle breaches in VR simulated tasks.

The Gertzbein and Robbins grading system has limitations, particularly that it only scores medial breaches, disregarding pedicle breaches in other directions. This was especially noticeable when evaluating less skilled pedicle screw placement [19–21]. The ability of the Gertzbein and Robbins pedicle breach classification to objectively evaluate less skilled trainee's pedicle screw placement skills is limited as pedicle screw breaches present in other directions (inferior, superior, or lateral) are rated as no breach. There is a considerable risk associated with malpositioned pedicle screws breaching the inferior or superior pedicle border as this can result in neurological symptoms from dural laceration, nerve root damage, or worsening of proximal junctional kyphosis [19,86–88].

TSYM Simulator as an Education Tool

A key surgical tactic that allows for robust three-column spine fixation is the placement of pedicle screws; nevertheless, mastery of this procedure requires a steep learning curve [69]. This study's findings indicate that the TSYM simulator could be an essential teaching aid, especially when taking into consideration training and evaluating less skilled learners. With instant access to both the performance grading and the 3D vertebral reconstructions of their screw placement positioning, learners will be able to visually compare their surgical outcomes to the ideal screw position and continuously appraise their progress. This enhances the precision and granularity of the feedback provided to the learners. When compared to traditional learning methods, virtual reality simulators with haptic feedback have been evaluated for pedicle screw placement training and have been shown to improve screw placement accuracy compared to traditional learning schemes [16,23,73,89]. Hou and colleagues' work emphasised the advantages of VR simulation training in accelerating pedicle screw placement skill acquisition [90]. The integration of virtual reality simulation in spine surgery curricula could potentially facilitate the attainment of surgical competency among less skilled trainees in complex spine procedures that demand extensive training [73]. Further research is required to validate this newly proposed pedicle breach classification system in various virtual reality contexts and clinical practice.

The distinct features of the 3D reconstruction models generated by the TSYM simulator present a number of avenues for additional research. Final 3D models can yield new metrics for formative and summative evaluation of surgical performance. This comprises the angle of deviation from the ideal screw angle and the distance from the optimal entry point. In addition, various data can also be extracted from the simulated L4 -L 5 pedicle screw placement including number of Xrays taken by the participant which we anticipate would be lower in the skilled compared to the less skilled individuals.

Artificial intelligence (AI) algorithms may improve the accuracy of classifying surgical expertise using VR spine platforms by leveraging the massive data sets produced by VR 3D spine models [80]. 3D spine models can be further clustered and analysed using deep learning techniques [80,90,91]. Additionally, an AI-based software program for preoperative thoracolumbar pedicle screw planning has been proposed in the literature and it automatically determines the pedicle screw size and trajectory by utilizing patient specific computed tomography scans [91,92]. Furthermore, intelligent tutoring systems can be developed by employing various AI techniques that rely on expert and novice participants' data [82–84,93]. These artificial intelligence methods might be able to automatically evaluate the final 3D models that the simulator reconstructs and accurately assess the surgical learners' training year, surgical competency, and aids in formulating an objective assessment [48]. However, curricula utilizing AI technology must be carefully developed with direct supervision and interaction of human educators, as AI-enhanced curricula maybe be associated with unintended outcomes linked to particular metrics [48]. Creating and assessing AI-powered teaching systems in the setting of real operating rooms is a key goal of these virtual reality training methods. The goal of these studies is to create an "Intelligent Operating Room" that can minimize surgical errors by using AI technology to continuously evaluate and train learners while reducing surgical errors [94]. Research utilizing virtual reality surgical simulation has revealed that skilled participants primarily concentrate on procedural safety, therefore, AI teaching curricula systems such as the virtual operative assistant, have taught students to complete surgical procedures safely before concentrating on efficiency [81–84].

Limitations

The TSYM Symgery VR has various limitations such as its limited replication of the dynamic and constantly evolving intraoperative environment. Secondly, in 9% (10 screws) of the pedicle screw placed by participants among all trials, the system failed to store the data and reformat the information in a final 3D vertebral reconstruct. Although a more reliable approach is being developed, the authors believe that using 91% of the data was helpful in achieving the goals of the study. The authors conducted statistical analysis, both including and excluding the 10 screws that were classified following Gertzbein and Robbins system, in order to investigate the impact of the missing screws in the final 3 D models. No statistically significant differences were found between the two approaches. Thirdly, since the TSYM simulator is designed for right-handed users, its utility for evaluating bimanual skills and participant performance of left-handed participants is limited. VR studies show that the ergonomics of the left and right hands differ, necessitating a separate evaluation of each hand's functionality [95–97].

Despite the fact that this study cohort consisted of both orthopedic and neurosurgery residents, spine fellows, and spine surgeons, the sample size of both skilled and less skilled participant was small. This restricts the generalizability of these findings. More participants from various international institutes should be included in future investigations, both in virtual reality and clinical settings, to validate the effectiveness of the newly proposed 3D pedicle breach classification. This would offer a more thorough understanding regarding this methodology's usefulness and its wider applicability in virtual reality environments as well as clinical practice [98–100].

In addition, the author acknowledges that categorizing participants based on their training level may impact the statistical analysis as training years may not always accurately reflect surgical competency. Despite this, the decision to group participants based on years of training aligns with prior research from our group and was consistent with the reported pedicle screw placement experience within each group. To overcome this limitation in future studies, evaluating participant performance in preparatory tasks such as the DryLab and L2 laminectomy in this study, could be beneficial for categorizing individuals in their corresponding expertise cohort. This approach would offer a more nuanced and accurate assessment of surgical proficiency, potentially enhancing the validity and reliability of the study's findings.

The new pedicle breach classification system was also developed to help the learner to initially focus on the safety of the procedure. Nevertheless, instead of utilizing the distance in mm similar to Gertzbein and Robbins classification, this new classification approach has a drawback related to the potential use of different pedicle screw diameters in various VR or clinical scenarios. The new classification system is based on the percentage of the screw diameter that breaches the pedicle; a significant breach is one that exceeds 50%, while a minor breach is one that is less than 50%. To account for possible variances in screw sizes, most lumbar pedicle screw diameters are in the range of 4.5-7.5 mm. A breach of less than 50% of the screw diameter corresponds to a breach of less than 4 mm, which is within the safe zone described by Gertzbein and Robbins [62,63].

Conclusion

This case series study assessed the accuracy of lumbar pedicle screw placement based on two pedicle breach classifications in a VR setting. We developed a new pedicle breach classification which was able to distinguish the skill competency in lumbar pedicle screw placement in a VR simulated task by participants in a more granular and precise fashion.

Thesis Summary

Pedicle screw placement in the thoracolumbar spine is an essential surgical skill required for spine stabilization, however acquiring theses important psychomotor techniques has a steep learning curve [69]. In this case series study, our goal was to establish a new 3D pedicle breach classification system that is more tailored toward the VR setting which would aid in the formative assessment and training of surgical trainees to ensure patient safety. We first evaluated the ability of the TYSM Symgery VR simulator to accurately classify pedicle screw position using the Gertzbein and Robbins pedicle breach classification. We then compared the results of pedicle breach classification scores between the two classification systems in both skilled and less skilled cohorts.

TYSM Symgery VR simulator was able to accurately classify pedicle screw position using the Gertzbein and Robbins pedicle breach classification. The classification system developed by Gertzbein and Robbins did not demonstrate a statistically significant difference between skilled and less skilled groups regarding their proficiency in accurately and safely inserting pedicle screws without the risk of a potential pedicle breach.

The newly introduced 3D pedicle breach classification system revealed a statistically significant difference between skilled and less skilled participants in terms of their ability in placing pedicle screws with respect to the risk of pedicle breaches. Given that the 3D classification assesses breaches in four directions, it indicated that the less skilled group exhibited a higher risk of complete pedicle breaches in all directions, whereas the skilled group primarily encountered medial complete breaches.

The new proposed 3D pedicle breach classification system in virtual reality exhibits enhanced precision and granularity compared to the traditional Gertzbein and Robbins classification. In this context, precision refers to the ability to determine the location of a pedicle screw breach, whether it be medial, lateral superior, or inferior, with greater accuracy and more nuanced details. The new system allows instructors to pinpoint the breach location more precisely, helping to distinguish skilled and less skilled group performance based on the specific nature of the breach. Granularity relates to how complicated or detailed the data or representation is. Since the new classification system provides a more comprehensive 3D representation of the screw position, it enables a higher level of granularity by providing more detailed visual information in three-dimensional space to the learners which may enhance their appreciation of the final surgical outcome.

This study suggests that the TSYM simulator has a potential value for educating and training learners especially less skilled trainees. The advantage of immediate access to 3D vertebral reconstructions and performance grading can help learners compare their results with the optimal screw position and track their improvement over time.

Future Directions

Incorporating VR simulation into a spine surgery learning curriculum may benefit less skilled trainees in achieving surgical competency for complex spine procedures [73]. Future studies should be designed to validate the newly proposed 3D pedicle breach scoring in other VR platforms and its utility in clinical practice. In addition, cooperating with other neurosurgical and orthopedic centers nationally and internationally can aid in obtaining external validity for this simulator and classification scheme.

The unique 3D reconstruction models generated by the TSYM simulator offer several opportunities for further studies. New metrics, such as distance from the ideal entry point and angle deviation from the ideal screw angle, can be extracted from the final 3D models for formative and summative assessment of surgical performance. This may allow a more precise and granular evaluation of trainee performance in pedicle screw placement.

Artificial intelligence and machine learning algorithms can be developed to successfully categorize participants according to their surgical performance [80,101]. The use of artificial intelligence can be employed to advance the development of AI-driven tutor systems which can provide access to real-time performance assessment and offer simultaneous personalized feedback to participants [84]. Machine learning and AI algorithms are valuable for visual pattern recognition and analysis and can integrate 3D data into various AI-based algorithms especially Convolutional Neural Network (CNN) based AI algorithms [102,103]. This integration may also unveil new performance metrics that have not been explored previously.

In summary a new 3D pedicle breaches classification system has been developed to enhance the precision and granularity of categorizing participants performing pedicle screw placement using a virtual reality platform. This new classification system aims to improve the accuracy of assessing pedicle breaches and the overall performance of learners in this surgical procedure.

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Appendix

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

The TSYM Symgery platform, a virtual reality (VR) simulator, features a single haptic arm with interchangeable handles like the straight and Kerrison handles. Prior to performing pedicle screw placment, participants underwent two preparing tasks. Firstly, they completed a Dry Lab session followed by a simulated L2 laminectomy to acquaint themselves with the TSYM VR simulator.

The Dry Lab session entailed an interactive demonstration of instrument handling using the haptic handle. Participants utilized the straight handle to execute tasks such as creating holes with an awl, removing spherical objects with a burr, and creating trajectories using the pedicle finder. Subsequently, participants transitioned to the Kerrison handle to simulate taking three bony bites.

Upon successful completion of the Dry Lab, participants received verbal instructions for the L2 laminectomy procedure they were required to perform, along with written guidelines. This simulation comprised one animated and four interactive steps aimed at enhancing surgical realism. The animated scenario commenced with a pre-exposed surgical cavity where the spinous process and interspinous ligaments were removed from the simulated patient's spine. The interactive steps involved using a 4mm burr to thin the L2 lamina, detaching the ligamentum flavum with an angled curette, utilizing a 4mm Kerrison to remove remaining lamina and resect detached yellow ligament, and verifying complete removal of the ligamentum flavum laterally on both sides using a Woodson.

Following the Dry Lab and L2 laminectomy tasks, participants received verbal and written instructions on performing pedicle screw insertions. Further instructions were provided for the main task: bilateral pedicle screw placement at L4 & L5 vertebrae. The simulation initiated with an animated demonstration of dissected L4 & L5 vertebrae from a posterior approach. Participants adhered to a specific order for screw placement starting from left L5, progressing to left L4, right L5, and concluding at right L4. Each step was accompanied by a designated list of simulated instruments that participants had to verify before proceeding. Live fluoroscopy was available during the procedure to confirm entry points, insertion angulation, and screw placement accuracy. Tasks included creating an entry point at left L5 using an awl, channeling the pedicle with a pedicle finder, checking for breaches with a 2 mm ball tip probe, tapping the screw channel with a 5.5 mm tap, and inserting standardized 6.5 mm x 45 mm pedicle screws. At the conclusion of this scenario, the simulator generated a final 3D model illustrating all placed screws along with written feedback on participant performance.

Table 1: Comparison between Gertzbein & Robbins classification and Heary classification of pedicle breaches [25,28]		
	Gertzbein & Robbins [27] (G & R)	Heary [26]
Grades	A: no cortical breach in medial direction B: Breach ≤2 mm C: Breach 2-4 mm D: Breach >4 mm E: Breach >6 mm	Grade I: Screw fully contained within pedicle. Grade II: Lateral breach contained within the rib. Grade III: Anterior breach into vertebral body. Grade IV: Medial breach into spinal canal. Grade V: Breach requiring immediate screw removal due to proximity to critical structures.
Limitations	• Mainly consider medial pedicle breaches. • Does not capture screws breaching the vertebral body.	• Lacks reliability assessment. • While it takes direction into consideration, it fails to categorize severity of pedicle breaches in each direction.
Similarities	• Both systems provide a standardized way to assess pedicle screw placement accuracy. • Both classification systems are widely used in the literature to evaluate pedicle screw placement.	

Differences	• G & R focuses on the extent of breach in the medial direction measured in mm increments, while Heary considers the location and clinical significance. • G & R classification includes a specific threshold for unsatisfactory results (Grades C-E), while the Heary classification does not have a clear delineation. • G & R "safe zone" of >4 mm may not always apply, as Heary suggests some lateral breaches can be acceptable. • G & R has different reliability in thoracic vs. Lumbar spine, due to the relative differences in pedicle and screw sizes (I.e. a 2mm breach with a 4.5mm screw in a small thoracic pedicle, is potentially more significant (almost 50% breach) than a 2mm breach for a 7.5mm screw in a large lumbar pedicle). • The Heary classification was developed specifically, and validated for, the thoracic spine, and has not been validated in the lumbar spine.

Table 2: Summary of VR simulators used to train pedicle screw placement [104,105]				
No	VR device	Simulator description	Key publications	Advantages & disadvantages of the simulator
1	ImmersiveTouch®	ImmersiveTouch® provide a high-resolution stereoscopic display and haptic feedback. Utilizing head and hand tracking through robotic arms, the system computes the user's perspective and movements within the virtual environment, creating a highly immersive and	Luciano et al (2005,2011,2013) [106–108] Alaraj (2013) [109] Roitberg et al (2013) [110] Gasco et al (2014) [75]	Advantages: 1. **Immersive Experience**: The simulator provides an immersive experience by offering both visual and haptic feedback, allowing users to engage with the virtual environment in a more realistic and intuitive manner. 2. **Performance Data Recording**: The simulator can record performance data, enabling skill level

		realistic training experience. It simulates a wide range of spinal surgery scenarios, such as pedicle screw placement, vertebroplasty, and lumbar puncture.		assessments and validation studies to be conducted. 3. **Patient-Specific Imaging Integration**: The simulator is capable of importing patient-specific imaging studies into the simulation training, enhancing the realism and relevance of the training scenarios. 4. **Versatility in Spinal Procedures**: The simulator can simulate multiple spinal procedures, including pedicle screw placement, vertebroplasty, and lumbar puncture, providing a

				comprehensive training platform. 5. **Widespread Availability and Study**: The ImmersiveTouch® simulator is one of the most widely studied spine simulators, making it a well-established and accessible tool for spinal surgery training. Disadvantages: 1. **Lack of Audio Feedback**: The simulator does not provide audio feedback, which could be a valuable addition to enhance the overall immersive experience.

				2. **Limited Validation Studies**: While the simulator is widely studied, there is a lack of validation studies specifically focused on the accuracy and effectiveness of the simulated spinal procedures.
2	Virtual Surgical Training System (VSTS)	The Virtual Surgical Training System (VSTS) is a virtual reality (VR) simulator designed to provide training for specific spinal surgery procedures, including cervical spine drilling and	Shi (2018) [111] Hou&Shi (2018) [112] Hou&Lin (2018) [113]	Advantages: 1. **Realistic Spine Model**: The spine model used in the simulated VR scenario of the VSTS is obtained from a normal human spine, providing a realistic anatomical representation for training purposes.

		thoracic pedicle screw placement. The key features of the VSTS include the use of a screen to display the virtual environment and a robotic arm to provide haptic feedback, allowing users to experience the tactile sensations associated with the simulated procedures.		2. **Attempted Validation Studies**: While limited, the VSTS has had some validation studies attempted, indicating efforts to ensure the accuracy and effectiveness of the training platform. Disadvantages: 1. **Lack of Comprehensive Validation**: Despite the attempted validation studies, the VSTS has not undergone comprehensive face, content, or construct validity assessments, which are crucial for

				ensuring the reliability and credibility of the training system. 2. **Two-Dimensional Display with 3D Representation**: The VSTS utilizes a two-dimensional screen to display a three-dimensional representation of the tissues, which may not provide the same level of immersion and depth perception as a true stereoscopic display. 3. **Absence of Audio Feedback**: The VSTS does not offer any audio feedback, which could be a

				valuable addition to enhance the overall training experience. 4. **Unclear Performance Data Recording**: There is no available information regarding whether the VSTS records performance data, which could be a valuable feature for assessing trainee progress and providing feedback.
3	The immersive virtual reality surgical simulator for pedicle screws placement. (IVRSS-PSP)	The IVRSS-PSP (Immersive Virtual Reality Surgical Simulator for Pedicle Screw Placement) is a virtual reality	Xin (2019,2020) [114,115]	Advantages: 1. **Immersive Experience**: The IVRSS-PSP simulator integrates a heads-up display (HUD) and haptic feedback to

		(VR) platform designed specifically to simulate pedicle screw placement procedure. The system utilizes a heads-on display (HUD) unit to allow the user to visualize the simulated surgical procedure and the operative environment. To provide a more realistic and immersive experience, the IVRSS-PSP incorporates a robotic arm that delivers haptic		provide an immersive experience by simulating the surgical procedure and the surrounding operative environment. 2. **Realistic Spine Model**: The spine model used in the simulated VR scenario is obtained from a normal human spine, providing a realistic anatomical representation for training purposes. 3. **Realistic Surgical Instrument**: The simulated handle used in the simulator was 3D printed according to the real surgical instrument, enhancing

		feedback, enabling the user to feel the tactile sensations associated with the simulated procedure.		the fidelity of the training experience. 4. **Attempted Validation Studies**: While limited, the IVRSS-PSP has had some validation studies attempted, indicating efforts to ensure the accuracy and effectiveness of the training platform. Disadvantages: 1. **Lack of Comprehensive Validation**: Despite the attempted validation studies, the IVRSS-PSP has not undergone comprehensive face, content, or construct validity assessments, which are crucial for

				ensuring the reliability and credibility of the training system. 2. **Unclear Data Recording Capabilities**: There is no available information about what data could be recorded by the simulator, which could be a valuable feature for assessing trainee performance and providing feedback. 3. **Limited Simulation Scope**: The simulation is limited to pedicle screw placement, with no clear description of the simulated steps or available tools, potentially limiting the

				breadth of training opportunities.
4	Sim-Ortho ®	Sim-Ortho is a comprehensive virtual reality (VR) simulator designed for orthopedic surgical training. Utilizing a voxel-based approach, the simulator provides an immersive and realistic training experience through the use of stereoscopic 3D glasses, haptic feedback, and auditory feedback. It offers a wide	Ledwos et al (2021) [60] Mirchi et al (2020) [101] Alkadri et al (2021)58 Reich et al (in-press) [116] Bakhaidar et al (2023) [61]	Advantages: 1. **Comprehensive Data Recording**: The Sim-Ortho simulator can record a large amount of data, including 3D data of each user's performance, providing valuable insights for assessment and feedback. 2. **Multifaceted Procedure Simulation**: The simulator can simulate complex procedures, such as anterior cervical discectomy and fusion (ACDF), allowing for

		range of simulated scenarios, including anterior cervical discectomy and fusion (ACDF), lumbar discectomy, lumbar laminectomy, lumbar and thoracic pedicle screw insertion, and cervical lateral mass screw insertion.		comprehensive training in advanced spinal surgery techniques. 3. **Versatility in Spinal Procedures**: The Sim-Ortho simulator can simulate a wide range of spinal procedures, including ACDF, lumbar discectomy, lumbar laminectomy, lumbar and thoracic pedicle screw insertion, and cervical lateral mass screw insertion. Disadvantages: 1. **Single Robotic Arm**: The simulator is limited to a single robotic arm, which may not provide the same level of dexterity and

				control as multiple robotic arms or a more advanced haptic interface. 2. **Right-Handed Optimization**: The Sim-Ortho simulator appears to be optimized for right-handed users, which may not be suitable for left-handed medical professionals or those who prefer to use their non-dominant hand for certain surgical tasks. 3. **Lack of Validation for Other Procedures**: While the ACDF scenario has been validated, the other spinal procedures simulated by the Sim-

				Ortho system have not yet undergone similar comprehensive validation studies, which could impact the overall reliability and effectiveness of the training platform.
5	Custom VR simulator	This VR simulator consists of a HUD headset (that provides audio-visual simulation) and two controllers to interact with the simulated structures. The simulator is designed to simulate pedicle screws placement.	Chen (2021) [117]	Advantages: 1. **Realistic Spine Model**: The spine model used in the simulated VR scenario is obtained from patient specific model, providing a realistic anatomical representation for training purposes. Disadvantages: 1. **Lack of Comprehensive**

		The user can use different tools to interact with soft tissue and bone.		**Validation**: This custom VR simulator has not undergone any face, content, or construct validity studies, which are crucial for ensuring the reliability and credibility of the training system. **2. Limited Data Representation**: The simulator does not provide a 3D data representation or any audio feedback, which could enhance the overall immersive and informative experience for the user. **3. Narrow Scope of Simulation**: The custom VR simulator is

				limited to simulating only drilling and pedicle screw placement procedures. 4. **Unclear Data Recording Capabilities**: There is no information available about whether the simulator records any performance data, which could be a valuable feature for assessing trainee progress and providing feedback.
6	TSYM Symgery Virtual Reality Surgical Simulator	The TSYM Symgery VR platform is a non-immersive virtual reality (VR) simulator designed	pending	Unfortunately, no available literature to comment on the advantages or disadvantages of the simulator.

		for spinal surgery training. the system utilizes advanced haptic feedback technology and a robotic arm to deliver a realistic operative experience for users and records extensive datasets, including providing 3D models of the final procedural outcomes. TSYM Symgery VR platform has the capability to analyze and replicate complex spinal procedures		

		such as laminectomies, pedicle screw placement and inter body fusion such as TLIF.		

Table 3. Demographics Information for 2 Groups of Participants Performing the Virtual Reality Surgical Task

	Skilled	Less Skilled
Age (years)		
Mean, SD	*38.4± 8.1*	*29 ± 1.7*
Sex		
Male	*13(100%)*	*12(86%)*
Female	*0(0%)*	*2(14%)*
Number	13	14
Level of training (n)		
Neurosurgery residents		
PGY 1		5
PGY 2		1
PGY 3		3
PGY 4		1
PGY 5	2	
PGY 6	3	
Orthopedic residents		
PGY 1		0
PGY 2		1
PGY 3		2
PGY 4		1
PGY 5	0	
Spine fellows		
Neurosurgical	2	
Orthopedic	1	
Spine surgeons		
Neurosurgeons	1	
Orthopedic surgeons	4	
Number of reported pedicle screws inserted		
Average, SD	*452±883.6*	*0.5± 1.4*
Median,	*100 (10-3000)*	*0 (0-5)*

* PGY: Post Graduate Year

Table 4: Summary of the distribution of pedicle breaches between the different classification systems

Classification	Group	A	B	C	D	E	Total	P value (Kruskal-Wallis test)
Gertzbein and Robbins	Skilled n=13	35 (67.3%)	12 (23.1%)	4 (7.7%)	1 (1.9%)	0 (0.0%)	52	.093
	Less Skilled n=14	31 (55.4%)	11 (19.6%)	8 (14.3%)	6 (10.7%)	0 (0.0%)	56	

Classification	Group	1	2	3	4	Total	P value (Kruskal-Wallis test)
New 3D Classification	Skilled n=13	16 (34%)	15 (31.9%)	10 (21.3%)	6 (12.8%)	47	.045
	Less Skilled n=14	13 (25.5%)	11 (21.6%)	10 (19.6%)	17 (33.3%)	51	

Classification	Group	1	2A	2B	2C	2D	3A	3B	3C	3D	4A	4B	4C	4D	Total	P value (Kruskal-Wallis test)
New 3D Classification Detailed	Skilled n=13	16 (34.0%)	13 (27.7%)	1 (2.1%)	1 (2.1%)	0 (0.0%)	6 (12.8%)	0 (0.0%)	4 (8.5%)	0 (0.0%)	6 (12.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	47	.042
	Less Skilled n=14	13 (25.5%)	7 (13.7%)	4 (7.8%)	0 (0.0%)	0 (0.0%)	5 (9.8%)	2 (3.9%)	0 (0.0%)	2 (3.9%)	13 (25.5%)	1 (2.0%)	1 (2.0%)	2 (3.9%)	51	

Table 5: Gertzbein-Robbins Pedicle Breach Classification System

Breach class	Pedicle Breach in Medial Direction (mm)
Class A	No pedicle Breach
Class B	0 -2 mm Breach
Class C	2.1- 4 mm Breach
Class D	4.1- 6 mm Breach
Class E	>6 mm Breach

Table 6 A: The New Pedicle Breach Classification in VR Setting (Simplified)

Breach class	**% of pedicle screw diameter breaching the pedicle in any direction (medial, inferior, superior, or lateral)**
Class 1	No pedicle Breach
Class 2	< 50 % Breach
Class 3	50 – 99% Breach
Class 4	Complete pedicle breach

Table 6 B: The New Pedicle Breach Classification in VR Setting (Detailed)

Breach class	% of pedicle screw diameter breaching Medial Boarder (subtype A)	% of pedicle screw diameter breaching Inferior Boarder (subtype B)	% of pedicle screw diameter breaching Superior Boarder (subtype C)	% of pedicle screw diameter breaching Lateral Boarder (subtype D)	Final classification
Class 1	No pedicle Breach	No pedicle Breach	No pedicle Breach	No pedicle Breach	1
Class 2	< 50 Breach	< 50 Breach	< 50 Breach	< 50 Breach	2 A, 2 B, 2 C, 2 D
Class 3	50 – 99% Breach	50 – 99% Breach	50 – 99% Breach	50 – 99% Breach	3 A, 3 B, 3 C, 3 D
Class 4	Complete pedicle breach	Complete pedicle breach	Complete pedicle breach	Complete pedicle breach	4 A, 4 B, 4 C, 4 D

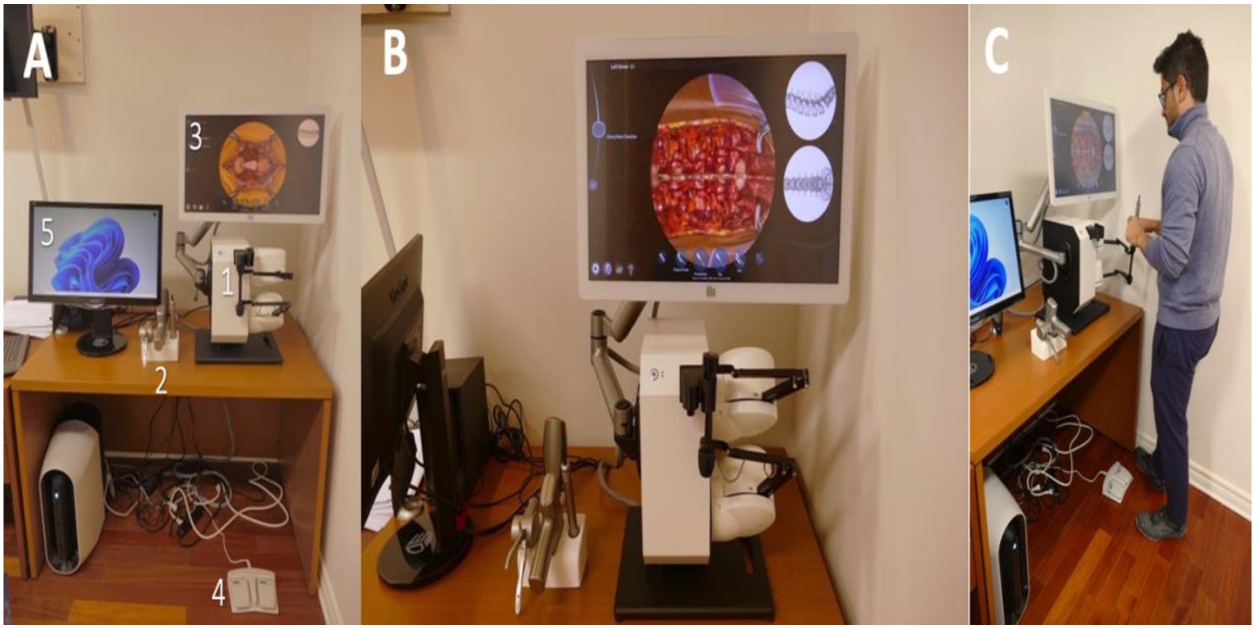

Figure 1: A TYSM Symgery virtual reality simulator showing the (1) robotic arm that utilizes advanced haptic feedback technology to provide tactile feedback to the user, (2) different tool handles utilized in the simulated scenario, (3) 3D monitor, (4) pedals for activating fluoroscopy, and (5) secondary monitor. B, the surgical view before starting the simulated L4-5 pedicle screw insertion procedure showing the virtual reality surgical field along with the fluoroscopy lateral and Anterior-Posterior X-ray images. C, the simulated task with a participant inserting left L5 pedicle screw. 3D, 3-dimensional.

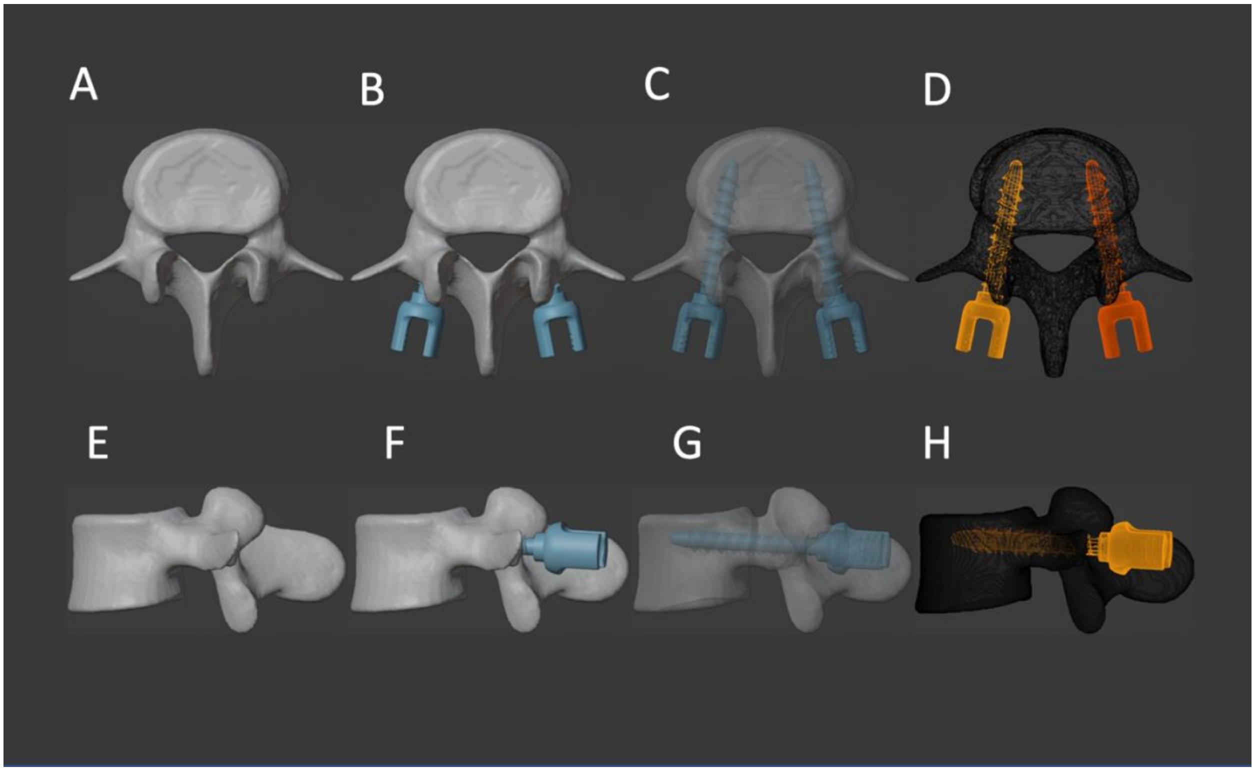

Figure 2: 3-Dimensional Reconstruction of the L4 Vertebral Body Including Inserted Pedicle Screws. (A) Superior View Reconstruction of L4 Vertebral Body. (B) Superior View Reconstruction of L4 Vertebral Body with Inserted Pedicle Screws. (C) Superior View Reconstruction of Translucent L4 Vertebral Body with Inserted Pedicle Screws. (D) Superior View Reconstruction of Wire Mesh L4 Vertebral Body with Inserted Pedicle Screws. (E) Lateral View Reconstruction of L4 Vertebral Body. (F) Lateral View Reconstruction of L4 Vertebral Body with Inserted Pedicle Screws. (G) Lateral View Reconstruction of Translucent L4 Vertebral Body with Inserted Pedicle Screws. (H) Lateral View Reconstruction of Wire Mesh L4 Vertebral Body with Inserted Pedicle Screws.

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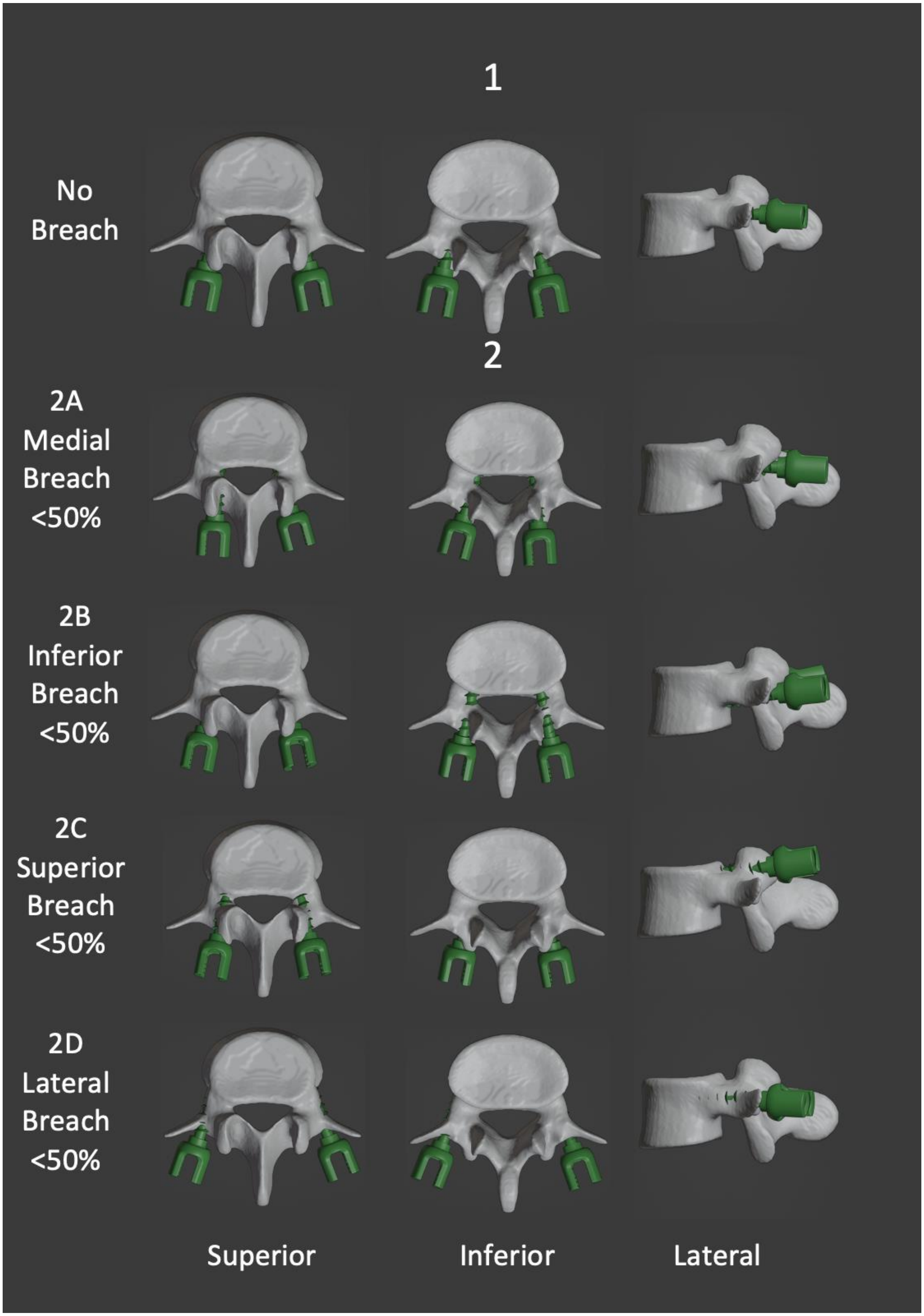
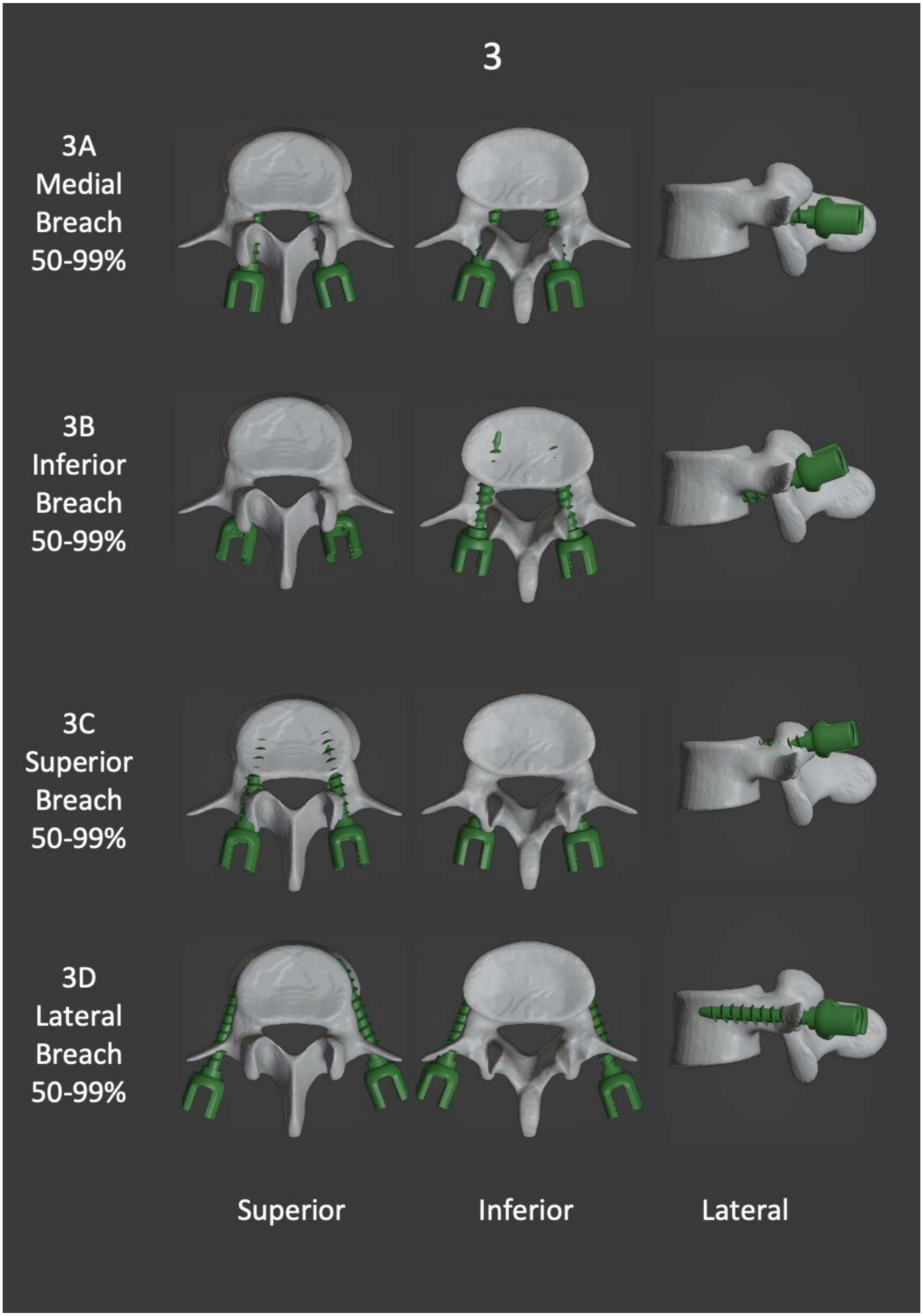

1
No Breach
2
2A Medial Breach <50%
2B Inferior Breach <50%
2C Superior Breach <50%
2D Lateral Breach <50%
Superior
Inferior
Lateral


3
3A
Medial
Breach
50-99%
3B
Inferior
Breach
50-99%
3C
Superior
Breach
50-99%
3D
Lateral
Breach
50-99%
Superior
Inferior
Lateral

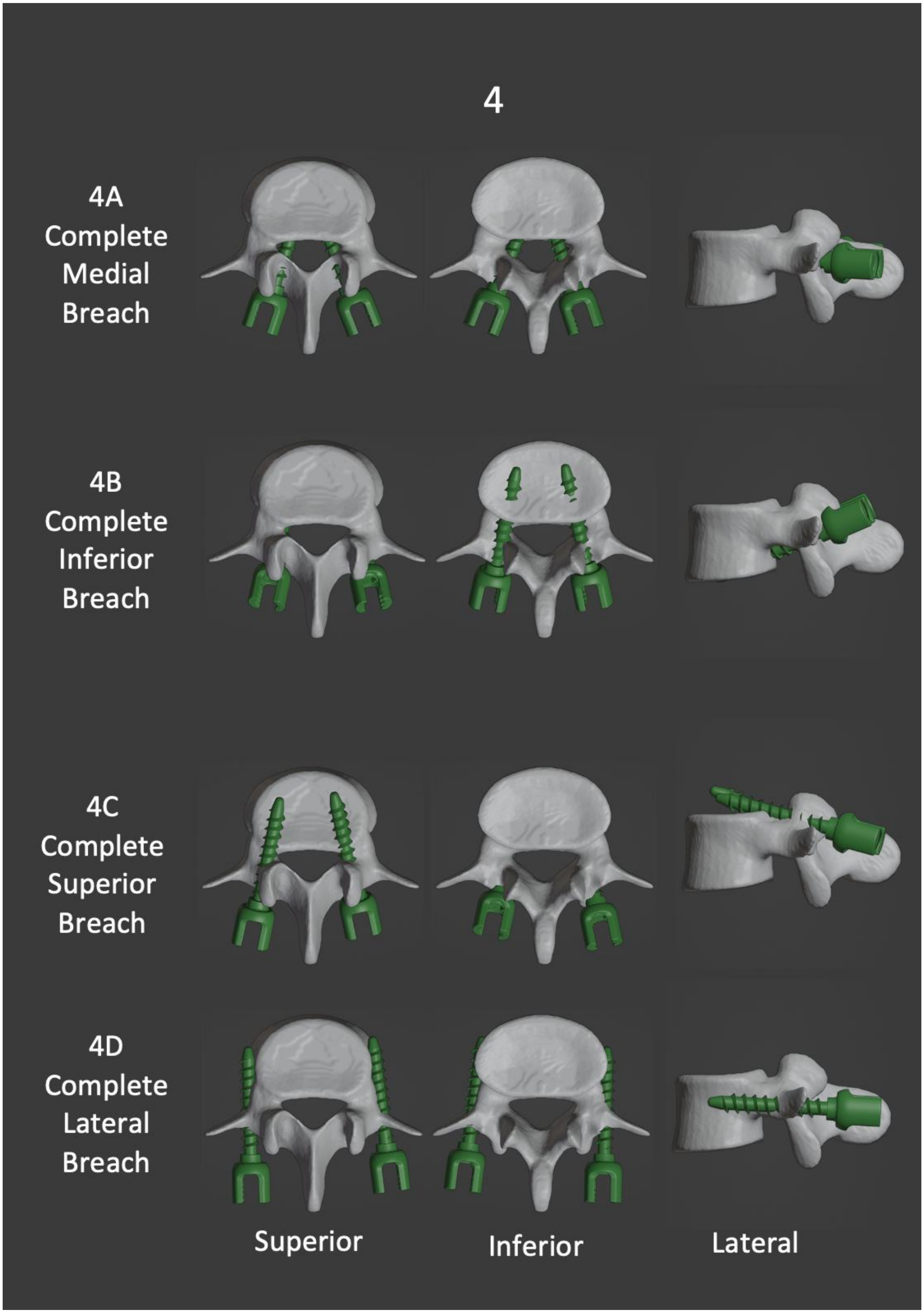

4
4A
Complete
Medial
Breach
4B
Complete
Inferior
Breach
4C
Complete
Superior
Breach
4D
Complete
Lateral
Breach
Superior
Inferior
Lateral

Figure 3: 3D illustrations of the new Proposed Pedicle Breach Classification System for Virtual Reality Simulation. Superior 3D views (left), inferior 3D views (middle) and lateral 3D views (right) of the 3D reconstructed vertebra including the screw positions for each of the 4 classes are shown.