

Performance in a Simulated Virtual Reality Anterior Cervical Discectomy and Fusion Task: Disc Residual, Rate of Removal, and Efficiency Analyses

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BACKGROUND AND OBJECTIVES: Anterior cervical discectomy and fusion (ACDF) is among the most common spine procedures. The Sim-Ortho virtual reality simulator platform contains a validated ACDF simulated task for performance assessment. This study aims to develop a methodology to extract three-dimensional data and reconstruct and quantitate specific simulated disc tissues to generate novel metrics to analyze performance metrics of skilled and less skilled participants.

METHODS: We used open-source platforms to develop a methodology to extract three-dimensional information from ACDF simulation data. Metrics generated included, efficiency index, disc volumes removed from defined regions, and rate of tissue removal from superficial, central, and deep disc regions. A pilot study was performed to assess the utility of this methodology to assess expertise during the ACDF simulated procedure.

RESULTS: The system outlined, extracts data allowing the development of a methodology which accurately reconstructs and quantitates 3-dimensional disc volumes. In the pilot study, data sets from 27 participants, divided into postresident, resident, and medical student groups, allowed assessment of multiple novel metrics, including efficiency index (surgical time spent in actively removing disc), where the postresident group spent 61.8% of their time compared with 53% and 30.2% for the resident and medical student groups, respectively ($P = .01$). During the annulotomy component, the postresident group removed 47.4% more disc than the resident groups and 102% more than the medical student groups ($P = .03$).

CONCLUSION: The methodology developed in this study generates novel surgical procedural metrics from 3-dimensional data generated by virtual reality simulators and can be used to assess surgical performance.

KEY WORDS: Anterior cervical discectomy and fusion, Simulation, Surgical education, Surgical performance, Surgical simulation, Virtual reality

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Studies have demonstrated the effectiveness of surgical simulators in surgical skill evaluation and training along with the transferability of acquired surgical skills to patient operative environment.^{1–9} The use of validated performance

metrics in addition to simulated models can provide surgical educators with tools to assess trainee performance and improve their skills.^{10–12} Virtual reality (VR) surgical simulation is an evolving technology useful in the training and assessment of surgical trainees.^{12,13} One of the main advantages of VR simulators is their ability to record vast amounts of data during simulated tasks.¹⁴ These data sets are essential to develop validated performance metrics, which provide quantitative performance

ABBREVIATIONS: ACDF, anterior cervical discectomy and fusion; EI, efficiency index; PLL, posterior longitudinal ligament; VR, virtual reality.

goals for learners to aspire to.¹¹ The Sim-Ortho VR simulator is one of the few simulators that can deconstruct and simulate complex, multifaceted spine procedures, such as anterior cervical discectomy and fusion (ACDF).^{2,15,16} Data obtained from this simulator were used to obtain face, content, and construct validity of the ACDF task.¹⁵ Because this simulator records large data sets including constructed 3-dimensional (3D) representations of all simulated structures, it provides a useful platform for further exploration of 3D surgical performance.¹⁵

The objectives of this study were to (1) develop a system to extract 3D data recorded by the Sim-Ortho VR simulator; (2) use this methodology to accurately reconstruct and quantitate disc dimensions and volumes; (3) develop a series of novel metrics to assess simulated disc removal including efficiency, volume removal, and rate of disc removal; and (4) perform a pilot study to assess the performance of skilled and less skilled participants using these metrics in specific disc areas.

METHODOLOGY

Participants

Previous data collected from 33 neurosurgeons and orthopedic surgeons, fellows, residents, and medical students who performed an ACDF on the Sim-Ortho simulator were used.^{2,15} This study focuses on the annulotomy and discectomy components of the procedure. Experience using the Sim-Ortho platform to perform the ACDF simulation was an exclusion criterion. One fellow and 2 neurosurgeons were excluded because their training and/or practice was not spine-focused. Because the Sim-Ortho VR platform is optimized for right-handed users, 3 left-handed participants were excluded. The remaining 27 participants were categorized a priori into 3 groups: postresident (neurosurgical and orthopedic spine surgeons and spine fellows, $n = 9$), resident (senior and junior neurosurgical and orthopedic residents, $n = 12$), and medical student ($n = 6$) groups.

The Virtual Reality Simulator

Sim-Ortho is a VR simulator platform that uses 3D stereoscopic glasses, advanced haptic technology, audio feedback, and realistic simulated structures to help achieve an immersive simulated experience

(Figure 1).^{2,15} The simulator collects information during the task, including instrument tip position, instrument angulation, number of contacts of each simulated structure, force applied to, and amount of tissue removed from each structure. This information is collected every 20 ms, allowing the generation of new information, including the rate of tissue removal.

The Simulated ACDF Task

The simulated C4-C5 ACDF task consists of 3 animated and 4 interactive steps including annulotomy, discectomy, osteophyte removal, and posterior longitudinal ligament (PLL) removal as previously described.¹⁵ During the annulotomy step, participants use a simulated number 15 scalpel to make a box-like incision to expose the disc. The participants then have the option to use a bone curette, a disc Kerrison rongeur, and/or a 2-mm pituitary rongeur to complete the discectomy to the PLL.^{2,15,16} After completion of the discectomy, a simulated 3 mm burr is used for osteophyte removal, and a simulated Kerrison rongeur is used to remove the PLL. In this study, we focused on data from the first and second stages of the procedure, annulotomy and discectomy components, respectively. Participants were provided with standardized verbal and written instructions along with a demonstration of simulated instruments. Each step is distinctive, and once completed, the participant proceeds to the next step and is not allowed to revisit previous steps. The segmentation of the simulated task allows each step to be evaluated and taught separately. No time limit was set for the procedure, and no questions were allowed once the simulated procedure commenced.

Three-Dimensional Disc Structure

We processed the three-dimensional data generated by the simulator using 3D slicer software (version 4.10.2; <https://www.slicer.org/>), an open-source platform for the analysis of medical imaging information and similar data sets.^{2,15} We used the segmentation tool to extract the 3D structures from their background. An automated thresholding method (Otsu thresholding) was used in our segmentation process.¹⁷ The information generated was further edited through Meshmixer (3.5 version, <http://www.meshmixer.com>, Autodesk Meshmixer [RRID:SCR_015736]), an open-source 3D modeling software that has a variety of tools to manipulate 3D meshes. The baseline

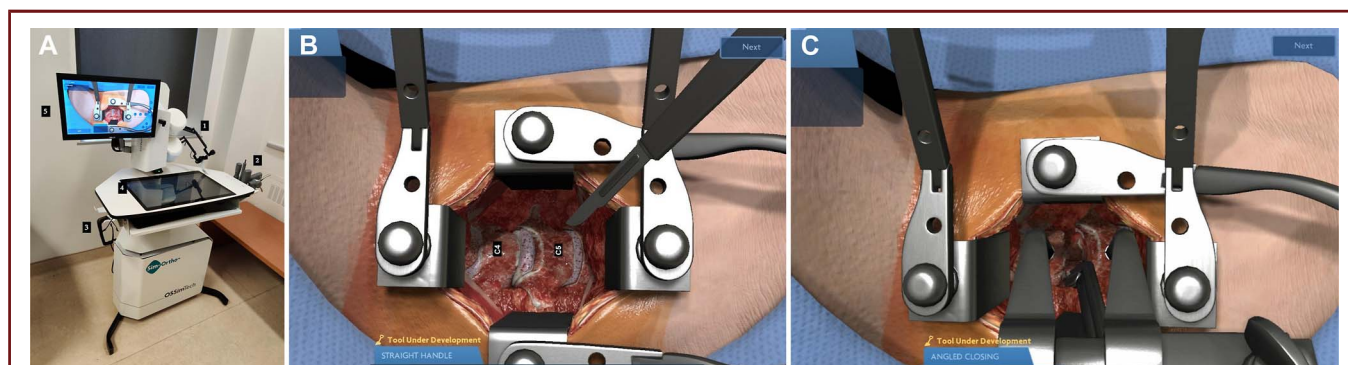


FIGURE 1. A, Sim-Ortho virtual reality simulator showing the (1) robotic arm that uses advanced haptic feedback technology to provide tactile feedback to the user. (2) Different tool handles that can be used in the simulated scenario, (3) 3D glasses, (4) 3D monitor, and (5) secondary monitor. B, The surgical view before starting the simulated C4-5 anterior cervical discectomy and fusion procedure showing the surgical field and a number 15 blade. C, The simulated task at the end of the discectomy, showing a pituitary rongeur removing the last piece of the simulated disc. 3D, 3-dimensional.

TABLE 1. Summary of Some Abbreviations and Equations Used in This Study

Disc removal: includes the annulotomy (first stage), discectomy (second stage), and total task	
$V, V_A,$ and V_N	Basic volumes for disc (V), disc annulus (V_A), and disc nucleus (V_N)
$V_1, V_{A1},$ and V_{N1}	Volumes of the disc and its components at the end of the first stage
$V_2, V_{A2},$ and V_{N2}	Volumes of the disc and its components at the end of the second stage
$\Delta V_1 = V - V_1$ $\Delta V_2 = V_1 - V_2$ $\Delta V = V - V_2$	$\Delta V_1, \Delta V_2,$ and ΔV represent the volume of the disc (in cm^3) that was removed during the first stage, the second stage of the discectomy, and the total discectomy task, respectively. Similar equations were used to calculate the volumes of the disc components (annulus and nucleus) at the end of each stage
Duration and EI	
$D, D_1,$ and D_2	D represents the total duration of the discectomy task. D_1 and D_2 represent the duration of the first stage and second stage, respectively.
EI	This is a ratio that is calculated by dividing the amount of time spent actively removing tissues by the total amount of time spent to complete the task. We reported it in this article as a percentage of time.
Rate of removal	
Rate, $\text{Rate}_A,$ and Rate_N	Rate: The rate of removal of the disc during the discectomy procedure. It is calculated as $\Delta V/D$ and reported as cm^3/s . Rate_A and Rate_N are calculated similarly (volume removed/time) and represent the rate of removal of the annulus and nucleus during the discectomy procedure, respectively.

EI, efficiency index.

volumes of the anterior annulus and remaining posterior disc components were determined.

Quantification of Disc Volumes and Rate of Disc Removal

We recorded the baseline volumes in cm^3 of the disc (V), including the anterior disc annulus (V_A) and posterior disc nucleus (V_N). In addition, we calculated the volume removed of the disc structures after each step. The total duration of the procedure (D) and duration of each step were recorded. We calculated the rate of removal by dividing the volume removed by the duration in seconds and is reported in cubic millimeters per second (mm^3/s). We also determined an efficiency metric called the efficiency index (EI). EI is a measurement of time spent in active contact with simulated structures over the total time expended and can be outlined as an index or percentage value.^{18,19} The EI of each area of the disc was calculated using the time spent with

the instrument tip present in the areas studied. Table 1 summarizes the abbreviations and equations used to calculate the volumes and rate of disc removals.

Statistical Analysis

The data were analyzed using R software version 4.0.2 (the R Foundation for Statistical Computing <http://www.r-project.org/>). Owing to the small size of the groups, we used the Kruskal-Wallis test to compare the mean of the groups. The Dunn multiple comparison test was used to perform post hoc analysis of the groups. Statistical significance was set as $P < .05$.

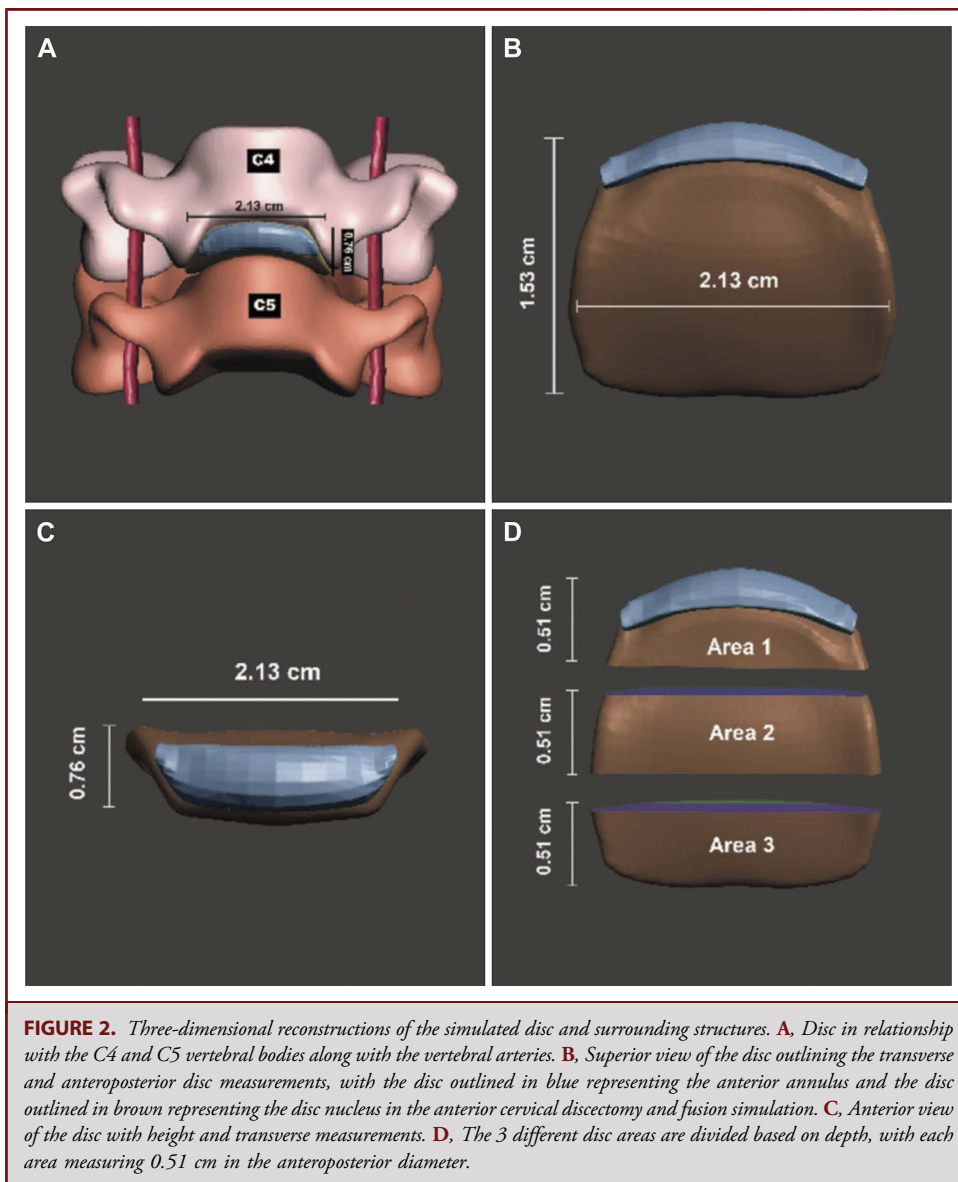
Ethical approval was obtained through the Research Ethics Board. Each participant signed an informed consent form before participation and provided demographic data regarding age, sex, level of training, and VR simulator experience.

TABLE 2. Participants Demographics

Groups	Medical students Medical students	Residents		Postresidents	
		Junior residents	Senior residents	Fellows	Spine surgeons
Number of participants	6	7 (3 neurosurgery and 4 orthopedics)	5 (3 neurosurgery and 2 orthopedics)	5 (3 neurosurgery and 2 orthopedics)	4 (2 neurosurgery and 2 orthopedics)
Mean age (SD)	23.67 (1.03)	27.4 (1.4)	30.6 (2.3)	36.2 (3.19)	54.3 (14.48)
Previous VR simulation experience	5 (83.3%)	5 (71.4%)	4 (80%)	3 (60%)	4 (100%)

VR, virtual reality.

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RESULTS

Participants

Demographic data and VR experience of the 27 trial participant data included in this pilot study are presented in Table 2.

System to Extract Data and Disc Reconstruction and Quantitation Methodology

The system we outline extracts data from the Sim-Ortho VR spine simulator platform allowing the development of a methodology which accurately reconstructs and quantitates 3D disc volumes. Our results demonstrate that the simulated disc in this platform contains an anterior annulus and a posterior disc

component representing the nucleus pulposus (Figure 2A-2C). The simulated C4-C5 disc had a maximum transverse diameter of 2.13 cm, an anteroposterior diameter (depth) of 1.53 cm, and a height of 0.76 cm (Figure 2B and 2C). The total simulated disc volume was 1.03 cm³, with the disc annulus measuring 0.07 cm³ and the disc nucleus measuring 0.96 cm³. Previous studies demonstrated variation in surgical performance when users interacted with critical components of simulated tissues.^{15,20} The disc was further subdivided into 3 areas based on the anteroposterior disc diameter (disc depth), with each area having an anterior-posterior length of 0.51 cm (Figure 2D). This division allows assessment of each region separately and detection of performance differences, especially in areas closer to the dura. The

TABLE 3. Summary of the Duration and EI of the Groups

	Medical students (n = 6)	Residents (n = 12)	Postresidents (n = 9)	P value (Kruskal-Wallis test)
Duration				
Duration of first stage in seconds (SD)	109.1 (28.0)	91.3 (20.1)	95.4 (18.0)	0.25
Duration of second stage in seconds (SD)	454.1 (217.0)	382.9 (145.9)	379.2 (172.2)	0.71
Mean total duration in seconds (SD)	563.3 (234.7)	474.2 (148.0)	474.6 (180.4)	0.67
EI (first stage—annulotomy)				
EI of first stage (SD)	25.0 % (12.7)	35.0 % (16.8)	47.5 % (14.6)	0.02*
EI of area 1 (SD)	9.8 % (4.0)	14.9 % (6.4)	11.0 % (6.8)	0.13
EI of area 2 (SD)	10.2 % (6.8)	10.0 % (4.9)	21.5 % (8.0)	0.003*
EI of area 3 (SD)	5.0% (9.9)	10.2% (13.1)	15.0 % (15.2)	0.23
EI (second stage—discectomy)				
EI of second stage (SD)	31.2% (12.0)	57.9 % (23.2)	66.3% (18.5)	0.013*
EI of area 1 (SD)	15.6% (6.0)	21.7 % (8.0)	20.7% (6.3)	0.13
EI of area 2 (SD)	10.6 % (5.4)	21.3 % (10.9)	25.6 % (6.4)	0.01*
EI of area 3 (SD)	4.9 % (4.5)	14.9 % (10.2)	20.1 % (8.6)	0.025*
EI (total task—both stages)				
EI of total task (SD)	30.2 % (8.6)	53.0 % (19.2)	61.8 % (16.1)	0.01*
EI of area 1 (SD)	14.1 % (4.4)	20.2 % (7.4)	18.5 % (5.6)	0.15
EI of area 2 (SD)	11.0 % (4.3)	19.0 % (8.9)	24.3 % (5.3)	0.009*
EI of area 3 (SD)	5.1 % (3.7)	13.7 % (8.0)	19.1 % (8.0)	0.017*

EI, efficiency index.

*Statistically significant result.

calculated volumes of areas 1, 2, and 3 were 0.29, 0.45, and 0.29 cm³, respectively (Figure 2D). These results allowed the creation of several novel metrics to assess VR disc removal.

Procedure Duration and Efficiency

Table 3 presents group performance in duration and EI in the pilot study. Postresident and resident groups took less time to execute the discectomy than the medical student group, but differences between groups were not statistically significant. For the total discectomy task, the average EI was 61.8% for postresident, 53.0% for resident, and 30.2% for the medical student groups. The difference between the groups was statistically significant ($P = .01$), but post hoc analysis demonstrated statistically significant difference only between postresident and medical student groups ($P = .01$). The largest difference in the EI between groups was seen in area 2 of the disc during the annulotomy stage ($P = .003$), with post hoc analysis demonstrating statistically significant differences between postresident, resident ($P = .004$), and medical student ($P = .04$) groups.

Volume and Rate of Disc Removal

During the annulotomy component of the discectomy, a trend was observed for more disc removal at a higher rate with increased level of expertise (Table 4). The postresident group removed 22.3% of disc, resident group 15.3%, and medical student group 11.0%. The difference between the groups was statistically significant ($P = .03$), and post hoc analysis showed a statistically significant difference only between the postresident and medical student groups ($P = .03$). The postresident group removed the disc at a higher rate compared with the resident and medical student groups. A statistically significant difference was found when comparing the mean of the groups ($P = .02$). On post hoc analysis, only postresident and medical student groups showed a statistically significant difference ($P = .02$).

During the second stage of discectomy, the postresident and resident groups removed the disc at a higher rate with less residual disc compared with the medical student group, but no statistically significant difference was found between the groups. For the total discectomy procedure, the difference between the groups for

TABLE 4. Summary of the Amount and Rate of Removal of the Disc During the Simulated Discectomy Procedure

	Medical students (n = 6)	Residents (n = 12)	Postresidents (n = 9)	P value (Kruskal-Wallis test)
Volume removed during the first (annulotomy) stage				
ΔV_1 mean in cm^3 [SD] (% of total disc)	0.11 [0.08] (11.0%)	0.16 [0.08] (15.3%)	0.23 [0.08] (22.3%)	0.027*
ΔV_{A1} mean in cm^3 [SD] (% of total annulus)	0.022 [0.02] (33.5%)	0.0365 [0.02] (55.6%)	0.039 [0.02] (59.5%)	0.25
ΔV_{N1} mean in cm^3 [SD] (% of total nucleus)	0.09 [0.06] (9.5%)	0.12 [0.07] (12.5%)	0.19 [0.07] (19.7%)	0.02*
Rate of removal during the first stage				
Rate ₁ mean (in mm^3/s) (SD)	1.03 (0.56)	1.71 (0.86)	2.52 (1.15)	0.018*
Rate _{A1} mean (in mm^3/s) (SD)	0.20 (0.12)	0.40 (0.23)	0.43 (0.26)	0.07
Rate _{N1} mean (in mm^3/s) (SD)	0.83 (0.45)	1.31 (0.68)	2.09 (0.94)	0.015*
Volume removed during the second stage				
ΔV_2 mean in cm^3 (% of V_1) [SD]	0.77 (84.1%) [0.30]	0.84 (95.8%) [0.11]	0.74 (92.5%) [0.11]	0.42
ΔV_{A2} mean in cm^3 (% of V_{A1}) [SD]	0.04 (95.8%) [0.02]	0.03 (91.8%) [0.02]	0.02 (92.0%) [0.02]	0.2
ΔV_{N2} mean in cm^3 (% of V_{N1}) [SD]	0.73 (83.5%) [0.29]	0.81 (95.9%) [0.10]	0.72 (92.5%) [0.10]	0.37
Rate of removal during the second stage				
Rate ₂ mean (in mm^3/s) (SD)	1.79 (0.74)	2.42 (0.77)	2.17 (0.60)	0.17
Rate _{A2} mean (in mm^3/s) (SD)	0.111 (0.07)	0.0697 (0.05)	0.065 (0.05)	0.23
Rate _{N2} mean (in mm^3/s) (SD)	1.68 (0.71)	2.35 (0.59)	2.10 (0.76)	0.12
Volume removed during the total discectomy task				
ΔV mean in cm^3 (% of total disc) [SD]	0.88 (85.5%) [0.28]	0.99 (96.2%) [0.05]	0.97 (94.3%) [0.07]	0.78
ΔV_A mean in cm^3 (% of total annulus) [SD]	0.064 (97.3%) [0.003]	0.0632 (96.3%) [0.005]	0.0635 (96.8%) [0.002]	0.51
ΔV_N mean in cm^3 (% of total nucleus) [SD]	0.82 (85.1%) [0.28]	0.93 (96.4%) [0.06]	0.91(94.0%) [0.07]	0.84
Rate of removal during the whole discectomy task				
Rate mean (in mm^3/s) (SD)	1.66 (0.60)	2.27 (0.67)	2.24 (0.61)	0.15
Rate _A mean (in mm^3/s) (SD)	0.13 (0.06)	0.15 (0.05)	0.15 (0.04)	0.80
Rate _N mean (in mm^3/s) (SD)	1.53 (0.58)	2.13 (0.63)	2.09 (0.56)	0.13

*Statistically significant result.

volume removed and rate of removal was not statistically significant (Table 4).

Residual Disc Location

During the first stage of discectomy, a decrease in the amount of the residual disc in all 3 areas of the disc was associated with an increased level of expertise. A statistically significant difference between the groups was found in area 2 ($P = .04$). Looking at the areas of the residual disc at the end of the procedure, we found a trend of increasing residual as one moves toward the deeper areas of the disc. Residual disc in area 3 is almost double the residual in area 2 for both the resident and postresident groups. No statistically significant difference exists

between the groups when comparing the average residual per area (Table 5). Figure 3 shows some of the main findings of this study using boxplot graphs.

DISCUSSION

In this study, we used open-source platforms to develop a methodology to extract 3D data from a VR spine simulator and obtain disc measurements and volumes. The data obtained from this system permitted a more granular assessment of several novel performance metrics and helped begin outlining specific components associated with skilled performance.

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TABLE 5. Summary of the Disc Residual by Area

	Medical students (n = 6)	Residents (n = 12)	Postresidents (n = 9)	P value (Kruskal-Wallis test)
Volume removed during the first stage				
Area 1 mean removed volume in cm ³ [SD] (% of total area)	0.06 [0.04] (21.5%)	0.10 [0.04] (34.0%)	0.12 [0.03] (39.8%)	0.072
Area 2 mean removed volume in cm ³ [SD] (% of total area)	0.04 [0.04] (8.8%)	0.05 [0.04] (10.5%)	0.09 [0.04] (19.4%)	0.035*
Area 3 mean removed volume in cm ³ [SD] (% of total area)	0.01 [0.014] (3.5%)	0.012 [0.011] (4.1%)	0.027 [0.036] (9.2%)	0.63
Residual at the end of the task (per area)				
Area 1 mean residual volume in cm ³ [SD] (% of total area)	0.021 [0.045] (7.3%)	0.003 [0.004] (1.0%)	0.004 [0.007] (1.4%)	0.37
Area 2 mean residual volume in cm ³ [SD] (% of total area)	0.07 [0.003] (15.4%)	0.01 [0.005] (3.1%)	0.03 [0.002] (5.6%)	0.5
Area 3 mean residual volume in cm ³ [SD] (% of total area)	0.06 [0.11] (19.0%)	0.02 [0.03] (6.4%)	0.03 [0.04] (10.3%)	0.57

*Statistically significant result.

The pilot study using previous data from participant ACDF performance on the Sim-Ortho platform demonstrated the ability of this methodology to generate 3D tissue data, which may provide new insights into surgical performance. For example, during annulotomy, most medical students' and many residents' initial incisions were line-like compared with larger and deeper incisions extending to the endplates seen with more skilled performance (Figure 4). Disc area analysis demonstrated a statistically significant difference between all the groups for EI in area 2 of the disc. The postresident group spent more percentage of their time using the scalpel to remove the disc in area 2 and therefore had a statistically significantly higher EI compared with resident and medical student groups in this central disc area. EI is used to assess efficiency, in the form of cognitive-motor skills that focus on decision-making abilities related to next-step planning while performing the task.²¹ This difference between groups may indicate a feature of skilled performance associated with annulotomy stage scalpel use. Postresident group procedural knowledge may result in larger and deeper initial scalpel incisions and removal of more overall disc volume, particularly involving disc area 2. Because it is safe to do so, the metric of making a larger incision and removing more disc underneath the annulus at a faster rate is consistent with more skilled performance.

Although several trends were identified, the small sample size and variation among the resident and medical student groups made it difficult to determine significant differences between groups. The validation study of this ACDF procedure has demonstrated a statistically significant difference between the groups related to force application, with senior residents applying increased force.¹⁵ Future studies are needed to assess the new metrics outlined in this study and evaluate instrument force application in different parts of the disc to further explore the role of force in defining surgical expertise.

The application of our methodology to extract 3D data and accurately reconstruct and quantitate tissue dimensions and

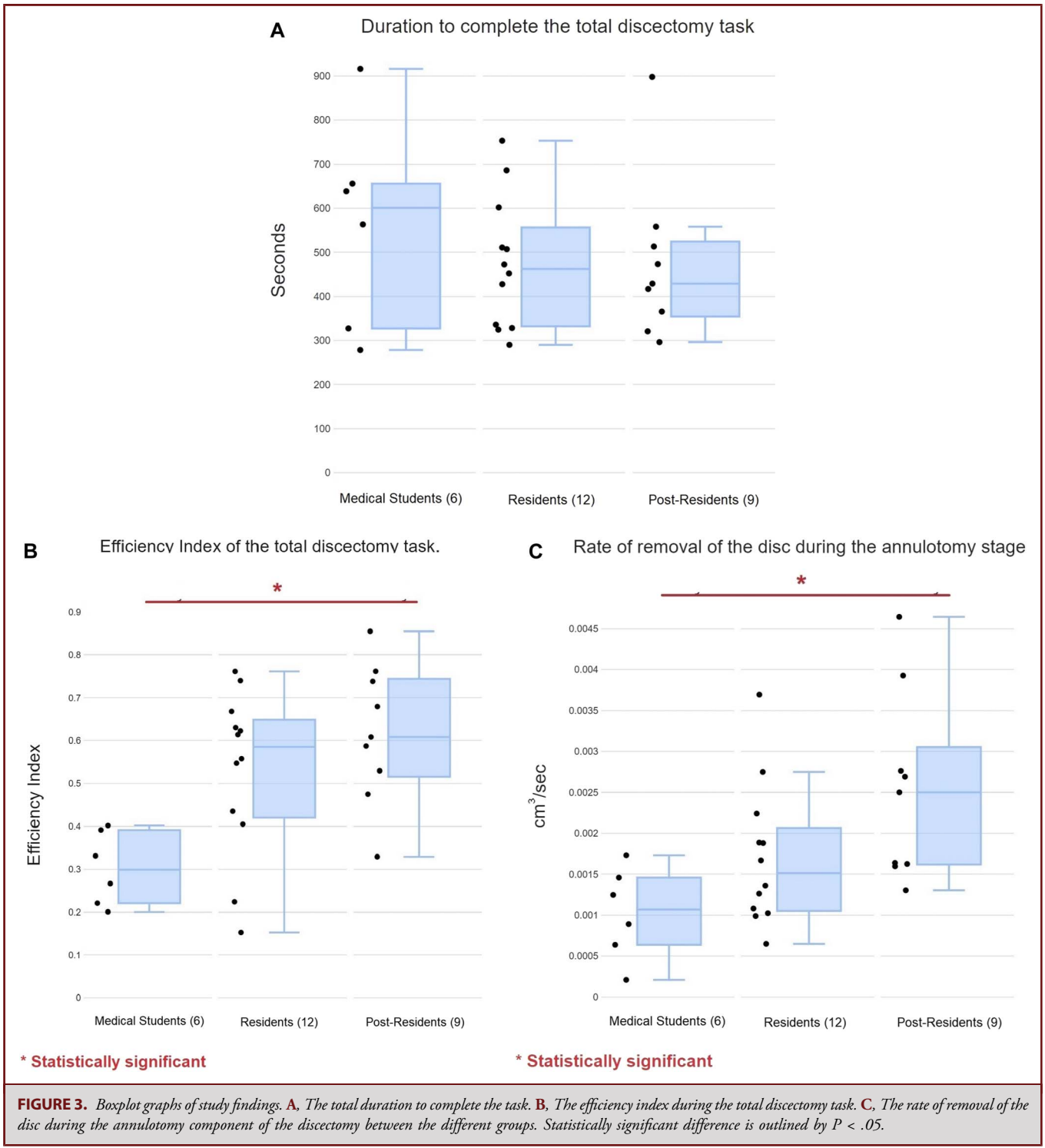
volumes can be applied to any simulated scenario using the Sim-Ortho platform and other VR simulators that have the capacity to generate 3D data.^{13,14} Combining 3D data with other information such as force and accurate instrument tracking may allow the determination of individual forces that instruments apply at any tissue location at any specific time during the operative procedure. This information will continue to improve the ability of educators to not only understand surgical expertise but how to enhance learner acquisition of surgical skills.

Artificial intelligence systems were able to classify surgical expertise with greater granularity than previously available systems using VR simulators.^{2,16,22-25} AI-powered tutoring systems can analyze performance and provide continuous and postprocedural feedback during skill acquisition training.^{14,26,27} The integration of 3D simulator data involving instrument utilization may facilitate the development of AI-powered personalized spatial feedback systems creating novel educational tools that surgical educators can use to teach surgical expertise and improve surgical performance.^{9,28}

Limitations

The 3D methodology and metrics developed in this study can only be used in simulators that provide continuous 3D data for analysis. Many simulators, including the NeuroVR, have this capability.¹³ The Sim-Ortho VR surgical simulator has limitations in simulating realistic ACDF procedure complexity. This platform's annulus simulation does not extend further than the anterior disc and needs improvement. This finding was shared with the developers of the simulator, and a newer version of simulated scenarios are currently in progress, incorporating the feedback from our study. In addition, this simulator relies on a single-handed haptic feedback arm optimized for right-handed participants preventing the evaluation of left-handed individual performance and limiting the ability to assess bimanual performance.^{20,29} In the pilot study using data from a small

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number of participants from 1 institution limited our ability to find significant differences and comment on the generalizability of these results. Future studies should attempt to include

participants from multiple institutions to assess the utility and generalizability of this methodology for formative and summative trainee assessment.^{26,28}

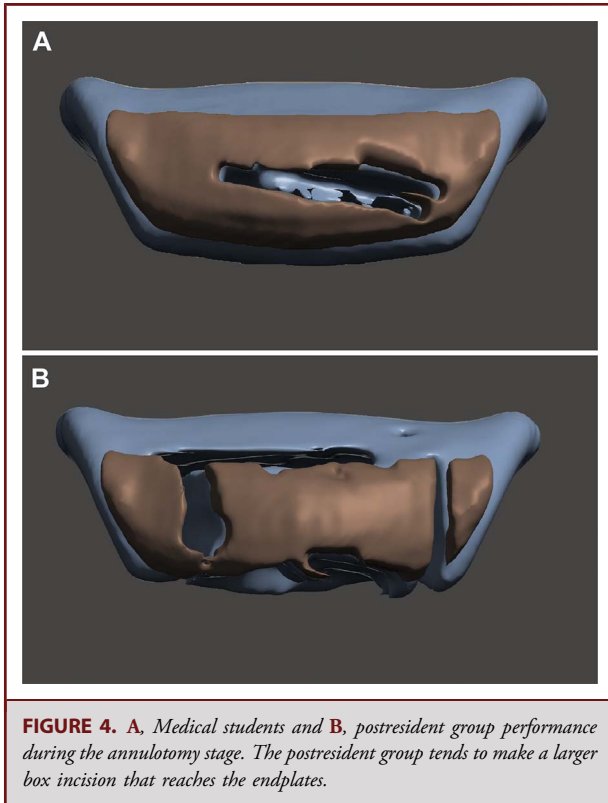


FIGURE 4. A, Medical students and B, postresident group performance during the annulotomy stage. The postresident group tends to make a larger box incision that reaches the endplates.

CONCLUSION

This study demonstrates a system to reconstruct and quantitate VR structures from 3D data sets and provides novel insights into surgical performance. The application of this methodology can be used to any simulated scenario using a simulation platform capable of providing continuous 3D data. These 3D data sets can be used to develop novel metrics, which, combined with instrument force application and instrument tracking along with AI-powered tutor systems, may provide surgical educators with new tools to improve trainee surgical performance.

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The authors have no personal, financial, or institutional interest in any of the drugs, materials, or devices described in this article.

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