Novel c-arm based planning spine surgery robot proved in a porcine and human cadaver models and quantitative accuracy assessment methodology

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The Master's Thesis submitted to the Department of Medicine, the Graduate School of Yonsei University in partial fulfillment of the requirements for the degree of Master of Medical Science

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December 2020

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December 2020

ACKNOWLEDGEMENTS

This study was supported by Domestic Medical Device Training Support Center (2020-31-1089) funded by Ministry of Health and Welfare (MOHW) and Korea Health Industry Development Institute (KHIDI) and The Development spine surgery robot and animal study funded by Curexo Inc. (2017-31-1035, 2019-31-0831) and funded by the Korea Institute for Robot Industry Advancement and The Technology Innovation Program funded by the Ministry of Trade, Industry & Energy, Korea (10062712)

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ABSTRACT

Novel c-arm based planning spine surgery robot proved in a porcine and human cadaver models and quantitative accuracy assessment methodology

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Background*:* We assessed pedicle screw accuracy utilizing a novel navigation-based spine surgery robotic system by comparing planned pathways with placed pathways in a porcine model and cadaver.

Methods: We placed three mini screws per vertebra for accuracy evaluation and used a reference frame for registration in four pigs (46 screws in 23 vertebrae) and one cadaver (22 screws in 11 vertebrae). We obtained 2-dimensional images from C-arm fluoroscopy and the robotic system allowed the surgeon to make 3-dimensional (3D) surgical planning. We planned screw paths and performed screw insertion under robot guidance. Using C-arm and CT images, we evaluated accuracy by using the Gertzbein–Robbins classification system (GRS) grade and comparing the 3D distance of the placed screw head/tip from the planned screw head/tip and 3D angular offset.

Results: Mean registration deviation between the preoperative 3D space (C-arm) and postoperative CT scans was 0.475±0.119 mm in porcine and 0.408±0.212mm in cadaver. The average offset from preoperative plan to final placement in porcine model was 4.8±2.0 mm from the head (tail), 5.3±2.3 mm from the tip, and 3.9±2.4 degrees of angulation. The average offset those of cadaveric test was 1.8±0.9 mm from the head (tail), 2.3±1.0 mm from the tip, and 2.6±1.1 degrees of angulation.

Conclusions: Our spine surgery robot showed good accuracy in executing an intended planned trajectory and screw path. This faster and more accurate robotic system will be applied in the clinical field in the near future.

Key words : c-arm, minimally invasive, navigation, pedicle screw, robotics, spinal surgery

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I. INTRODUCTION

In recent decades, robotic technology and its various applications in medicine have presented an opportunity for a meaningful change in how physicians treat patients [1]. Especially in spine surgery, robotic technology provides a potential avenue for increased accuracy with minimally invasive surgical (MIS) techniques as well as decreased radiation exposure from imaging [2,3]. In particular, pedicle screw fixation via an MIS approach is becoming increasingly common in spinal surgery. The insertion of pedicle screws can be a technically demanding procedure, with the potential for significant neurologic, vascular, and/or visceral injury [4]. *In vitro* and clinical studies using freehand or fluoroscopy-assisted techniques for lumbosacral (LS) pedicle screw insertion have reported misplacement rates ranging from 3% to 55% in the lumbar and thoracic spine [5,6]. The rate of clinical sequelae related to pedicle screw misplacement is currently reported to range from 0% to 7% for the open technique [7,8]. The advent of computer-assisted surgery in recent decades has decreased the misplacement rate to 4.3% [9,10]; however, most of them utilized a navigation system using preoperative three-dimensional (3D) computed tomography (3D-CT) merging or intraoperative O-arm imaging systems. The adoption of any new technology and its added cost requires justification in the form of either improved outcomes or cost-effectiveness [11]. As one of the ways to overcome these limitations, we are developing a robot-assisted spine surgery system using a C-arm-based navigation system. This new technology is constantly improving and may be particularly useful in patients with challenging anatomy such as a cervical spine pedicle screw, cortical bone trajectory, extremely thin pedicle, or complex deformities of the spine. In addition, we applied the fiducial technique for 3D and quantitative accuracy evaluations of the postoperative results, which is widely utilized for alignment of preoperative data to the physical world. A fiducial technique is used to match each image obtained from two imaging modalities. In this study, by inserting three small screws into each vertebra and matching the intraoperative C-arm image with the postoperative CT image, quantitative measurement of the position error and posture error of the actual inserted pedicle screw was possible. To the best of our knowledge, no previous experimental study has reported applying this fiducial technique to preclinical animal experiments to develop a spinal robot using navigation. Based on the results of ongoing animal experiments regarding the assessment of the accuracy of pedicle screw insertion, the purpose of this study was to determine whether the system currently being developed can be applied to clinical practice in terms of accuracy using a porcine model.

II. MATERIALS AND METHODS

A total of four 85-day-old DanBred Hybrid × DanBred Landrace female pigs (XP Bio Inc., Anseong-si, Republic of Korea) were used in this study (Table 1). The average body mass of the pigs was 40 kg. The Avison BioMedical Research Center (ABMRC) of Yonsei University Committee approved the study protocol. The pigs were positioned on the operating table in the prone position, and we inserted screws into 46 pedicles between the T10 and L5 levels in the four pigs. And pre-clinical study was performed on one fresh male cadaver, which had its entire body form; the soft-embalmed cadavers were fixed by the Thiel method (17% ethylene glycol, 11% ammonium nitrate, 3% chlorate kersol, and 2% formaldehyde). The cadaver was positioned on the operating table in the prone position, and we inserted screws into 22 pedicles between the T7 and L5 levels.

Table 1. Specifications of the CUVIS-spine system (Curexo Inc., Republic of Korea)

Product Name	CUVIS-spine system
Certification	Ministry of Food and Drug Safety (Korean Food and Drug Administration)
Country	Republic of Korea
Operating Mode	Spinal Pedicle Fixation
Specification	Pose repeatability: position error ≤1.00 mm, orientation error ≤1.00° Pose accuracy: position error ≤1.00 mm, orientation error ≤1.00°
Modality	O-arm, C-arm
Tracker	Optical Tracking System (VEGA; NDI)
Guide	Dilator, Tapper, Screwdriver, etc.
Target Tracking	Yes
Size and Weight	Robotic Arm: 1 602 × 648.5 × 1 072 (mm), 280 (kg) Main Console: 2 040–2340 × 650 × 728 (mm), 78 (kg)

1. Surgical robotic system

CUVIS-spine (CUREXO Inc., Republic of Korea) is a surgical robotic system with an image-guided navigation system. The CUVIS-spine system is currently under development and consists of a robotic arm, an optical tracking sensor, optical tracking markers, a surgical planning system, and a real-time visualization system (Fig. 1 & Table 1). The system requires intraoperative images to take the manipulator to the final target pose and allows two- (2D) or three-dimensional (3D) intraoperative radiographic images. In this study, the anterior-posterior (AP) and lateral-lateral (LL) images were used, taken by 2D digital spot fluoroscopy C-arm (OEC 9900 Elite; GE healthcare, USA). Only these two images are necessary for 3D surgical information. Preoperative images, such as 3D computed tomography (CT) images, are not required. The system registers the intraoperative images with the robotic system by the acquired images with the information on the optical markers (Fig. 2). The surgeon plans where to place the pedicle screw on the intraoperative image directly. The manipulator moves to the goal pose according to the surgical plan. The real-time navigated surgical instruments are guided by the manipulator and visualized on the intraoperative images with the planning information (Fig. 3).

Fig 1. Overall view of the CUVIS-spine system (Curexo Inc., Republic of Korea); (left) main console and (right) robotic arm (Courtesy of Curexo, Inc.)

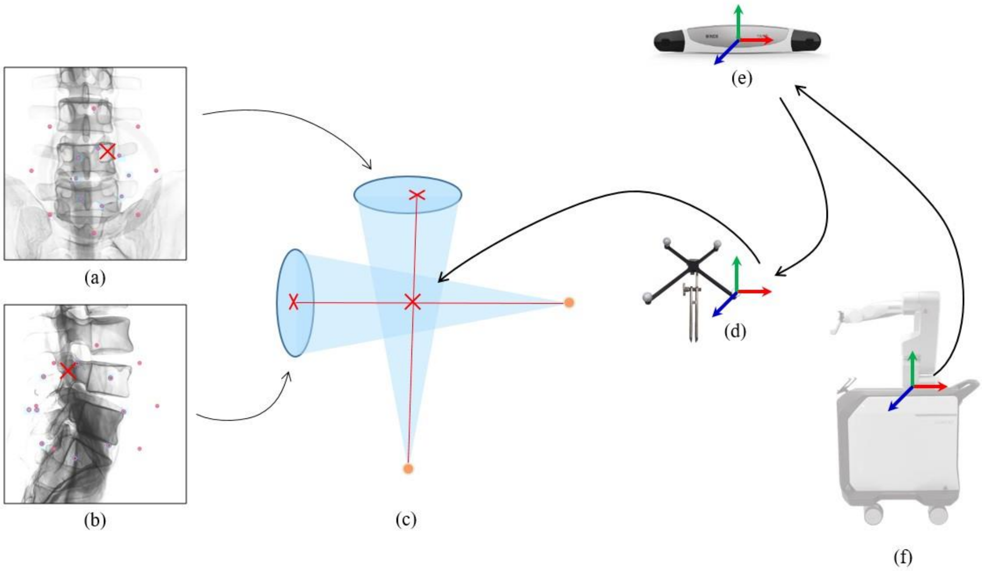


Fig 2. Schematic diagram of the coordinate transform chain (Courtesy of Curexo, Inc.). The two intraoperative images (anterior-posterior (a), lateral-lateral (b)), and the 3D surgical space (c) are correlated by a registration process. The dots in the surgical space indicate x-ray source positions and the circle planes mean image detectors. The cross point in the surgical space is calculated in the reference coordinate system (d). The manipulator coordinate system (f) can be transformed through the optical tracking system coordinates (e) to the reference coordinate system.

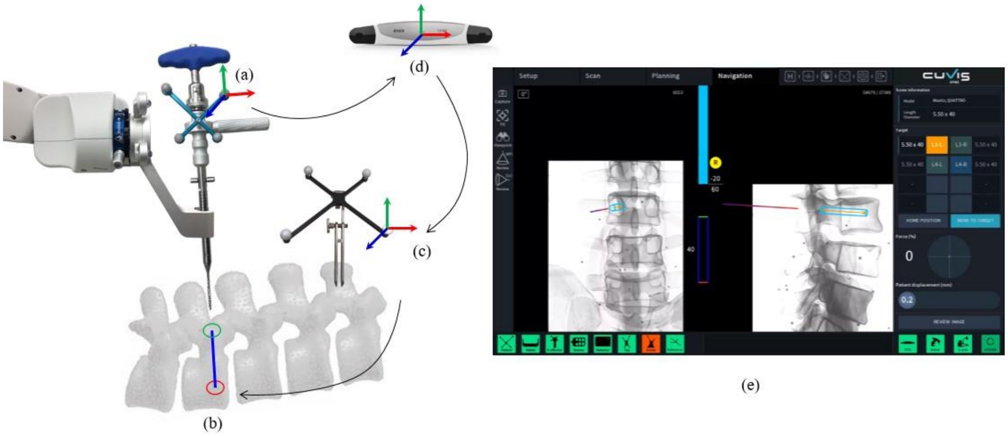


Fig 3. The surgical robotic guidance system with image-guided navigation system (Courtesy of Curexo, Inc.). The surgical instrument (a) is guided by the manipulator. The surgical planning information (b) is represented in the reference coordinate system (c). The optical tracking system (d) supervises the robotic arm, the surgical instruments, and the reference markers in real-time. All real-time information is drawn on the screen (e).

2. Experimental workflow

A C-arm scan of the experimental spinal levels was taken prior to registration, and mini screws for accuracy evaluation and the reference frame were placed in the spinous process of L1 or L2 for registration. To register the 3D image data, we used the detector calibrator with an optical tracking system (OTS) and the source calibrator. With this equipment, the relative position and posture relationship between the reference coordinate system and the OTS reference coordinate system of the C-arm image is obtained using the 2D position information of the markers and the 3D position data traced by the OTS. The data set from the C-arm scan was transferred into the robotic system, and intraoperative planning was performed by a spinal neurosurgeon. After planning, the robotic arm was used to stereotactically position the end effector along the pre-planned screw trajectories to guide incision marking, drilling, taping, and screw insertion (Fig. 4).

Fig 4. Screw placement under robotic arm guidance in cadaveric test

3. Accuracy assessment

After the operation, postoperative CT images were used for accuracy assessment of pedicle screw placement. In previous studies, the Gertzbein–Robbins classification system (GRS) grade was used to evaluate the accuracy of pedicle screw placement [12-15]. However, in this study, it was difficult to evaluate accuracy based on the same criteria in an animal experiment using the porcine model due to the difference in spine structure between humans and pigs. In addition, the GRS is not quantitative; however, it consists of clinical and radiological analyses and has limitations that made it difficult to compare between different experiments using this data. Therefore, we needed a quantitative measurement method that could allow comparison to other data. Thus, the following evaluation criteria were used. The vertebrae are registered respectively from the intraoperative C-arm image to the postoperative CT image by the placement of three mini screws. The mini screws are inserted in advance for the accuracy assessment before taking intraoperative images in porcine model and cadaveric test (Fig. 5). Two different coordinate systems can be registered using more than three well-separated corresponding points from each coordinate system. In this study, the rigid-body landmark transform was used for registration [16]. Based on the images obtained using the C-arm before surgery, the 3D positions of the inserted mini screws were matched, and the 3D position was calculated on the basis of CT images obtained after the operation. The error that occurred in the matching process was defined as mean registration deviation (MRD). This measured MRD is a value that represents the accuracy and consistency between the planned screws before surgery and the actual inserted screws after surgery; in our study, the reliability of the accuracy analysis method is quoted. Additionally, quantitative 3D screw tip, screw tail, and screw angulation accuracies were determined using CT scans, and image overlay analysis was performed to compare preoperative planned trajectories to actual postoperative screw placement. Three-dimensional accuracy was reported for the anterior-most portion of the screw (tip), the posterior-most portion of the screw (tail), and a mean accuracy value. Angular offset was calculated as the difference in the angle between the vector of the planned screw and the placed screw. As shown in Figure 6, we measured the 3D distances and angles between the surgical planning positions and the placed positions, including the 3D distance of the placed screw head (tail) from intended trajectory, the 3D distance of the placed screw tip from intended trajectory, the 3D distance from the planned screw head to the placed screw head, the 3D distance from the planned screw tip to the placed screw tip, and the 3D angular offset. Moreover, we used the GRS grade for analysis of postoperative accuracy (Table 2). Postoperative analysis for accuracy evaluation was not possible for all cases because of technical issues stemming from file compatibility, difficulty with processing trajectory files, and image analysis. All measurements were performed independently by two blinded neurosurgeons.

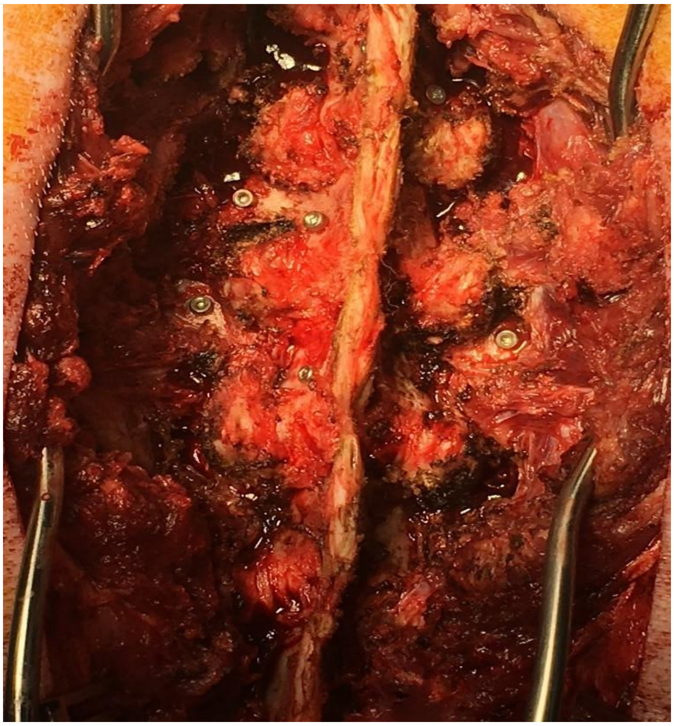


Fig 5. Three mini screws on each lamina for accuracy evaluation are shown at the thoracolumbar junction (T11, T12 and L1)

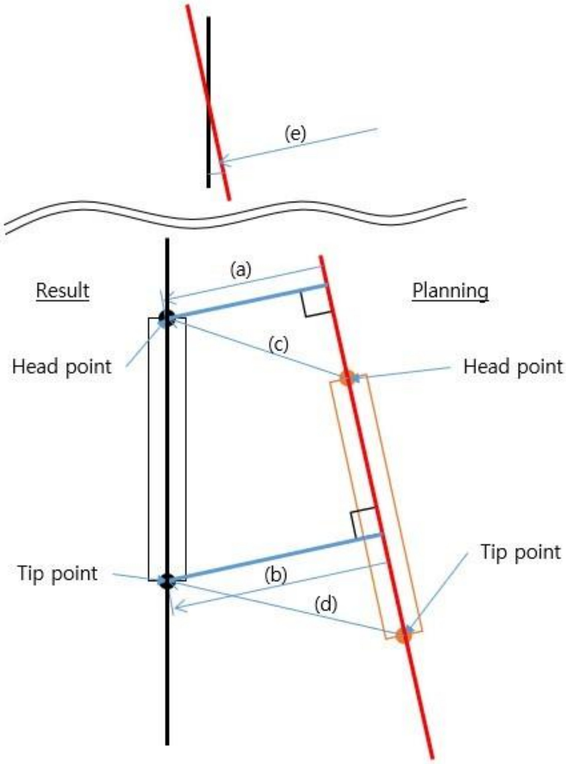


Fig 6. Screw head, tip, and angle offset accuracy assessment (Courtesy of Curexo, Inc.). (a) 3D distance of placed screw head (tail) from intended trajectory. (b) 3D distance of placed screw tip from intended trajectory. (c) 3D distance from the planned screw head to the placed screw head. (d) 3D distance from the planned screw tip to the placed screw tip. (e) 3D angular offset.

Table 2. Gertzbein-Robbins classification system of pedicle screw accuracy

Grade	Brief explanation	Breach distance (mm)
A	an intra-pedicular screw without breach of the cortical layer of the pedicle	0
B	a screw that breaches the cortical layer of the pedicle but does not exceed it laterally by more than 2 mm	< 2
C	penetration of less than 4 mm	< 4
D	penetration of less than 6 mm	< 6
E	screws did not pass through the pedicle or that, at any given point in their intended intra-pedicular course, breach the cortical layer of the pedicle in any direction by more than 6 mm.	> 6

III. RESULTS

1. In porcine model

A total of 46 pedicle screws were placed. We did not insert screws into all pedicles between the T10 and L5 levels in the four pigs because of problems with the screw settings and the instruments used for screw insertion. The distribution of the instrumented levels is shown in Table 3. The overall average MRD between the preoperative 3D space (C-arm) and postoperative CT scans was 0.475±0.119 mm; the values for the first, second, and third experiments were 0.385±0.119, 0.563±0.122, and 0.480±0.102 mm. respectively. The mean 3D distance of the placed screw head (tail) from the intended trajectory (a) was 2.60±1.33 mm, the mean 3D distance of the placed screw tip from the intended trajectory (b) was 3.45±2.22 mm, the mean 3D distance from the planned screw head to the placed screw head (c) was 5.06±2.18 mm, the mean 3D distance from the planned screw tip to the placed screw tip (d) was 5.33±2.37 mm, and the mean 3D angular offset (e) was 3.95±2.40 degrees (Table 4). Figure 7 shows the precise and incorrect cases of pedicle screw insertion using robots and navigation systems in this study. In addition, according to the GRS grades, 28 screws (60.9%) were classified into group A, 9 screws (19.6%) into group B, 5 screws (10.9%) into group C, 2 screws (4.3%) into group D, and 2 screws (4.3%) into group E (Table 5).

Table 3. Distribution of instrumented levels in porcine model

Level	Overall
T10	2 (4.35%)
T11	8 (17.40%)
T12	8 (17.40%)
L1	8 (17.40%)
L2	2 (4.35%)
L3	6 (13.04%)
L4	6 (13.04%)
L5	6 (13.04%)
Total	46 (100%)

Table 4. 3D screw placement accuracies: comparison between actual pedicle screw position and preoperative planned path in porcine model

Pig	(a) mm	(b) mm	(c) mm	(d) mm	(e) degree (°)
#1 (total: 12 screws)	2.60 ± 1.33	3.45 ± 2.22	5.06 ± 2.18	5.58 ± 2.62	2.58 ± 1.27
#2 and #3 (total: 22 screws)	3.41 ± 2.03	4.65 ± 2.14	4.55 ± 1.61	5.40 ±2.14	3.83 ± 2.33
#4 (total: 12 screws)	4.35 ± 2.74	4.47 ± 2.86	4.83 ± 2.57	4.96 ± 2.69	5.53 ± 2.63
Total (46 screws)	3.45 ± 2.15	4.29 ± 2.36	4.76 ± 2.01	5.33 ± 2.37	3.95 ± 2.40

(a) *mean 3D distance of the placed screw head (tail) from the intended trajectory.*

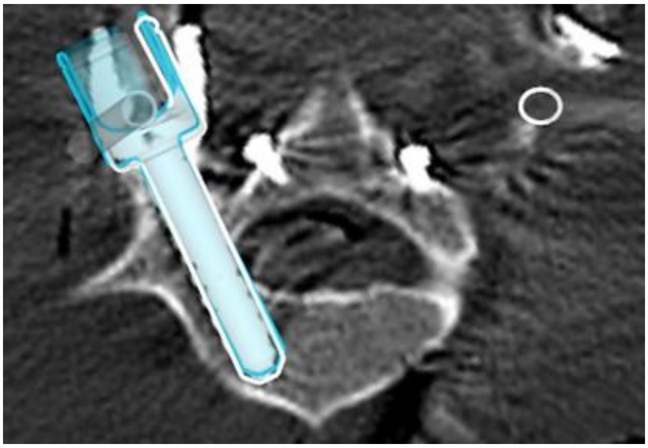
(b) *mean 3D distance of the placed screw tip from the intended trajectory.*

(c) *mean 3D distance from the planned screw head to the placed screw head.*

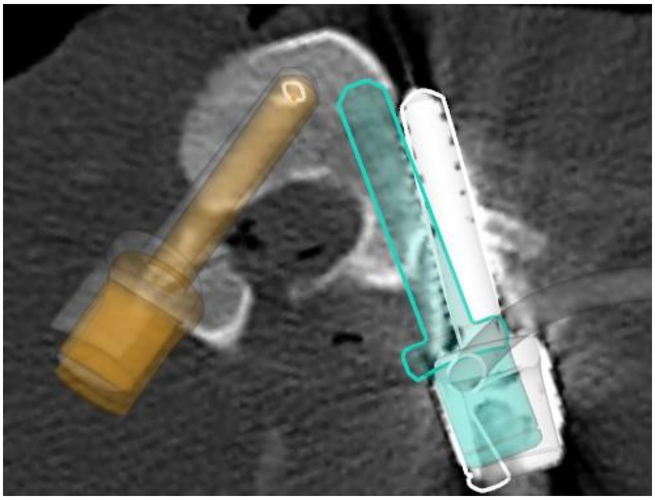
(d) *mean 3D distance from the planned screw tip to the placed screw tip.*

(e) *mean 3D angular offset*

7-A)



7-B)



7-C)

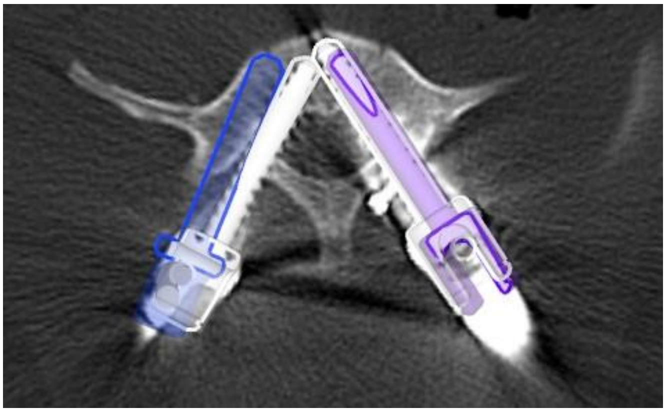


Fig 7. Images comparing postoperative CT scans and the pre-planned path (Courtesy of Curexo, Inc.).

A) The actual pedicle screw (white) was well-inserted into the L4 left pedicle to match the pre-planned path (mint) [(a) 0.7 mm, (b) 0.6 mm, (c) 0.8 mm, (d) 1.0 mm, (e) 2.3 °].

B) The actual pedicle screw (white) was showing lateral breach at the T11 right pedicle, which mismatched the pre-planned path (mint) [(a) 3.3 mm, (b) 6.5 mm, (c) 4.3 mm, (d) 7.3 mm, (e) 8.5 °].

C) The actual pedicle screw (white) was showing medial breach at the L5 left pedicle, which mismatched the pre-planned path (blue) [(a) 4.5 mm, (b) 6.4 mm, (c) 5.1 mm, (d) 6.8 mm, (e) 6.5 °].

Table 5. Pedicle screw placement accuracy grades according to the Gertzbein-Robbins classification system in porcine model

Number of screws (n = 46)					
Grade	A	B	C	D	E
T10	2	0	0	0	0
T11	7	1	0	0	0
T12	5	2	1	0	0
L1	3	3	2	0	0
L2	2	0	0	0	0
L3	3	2	1	0	0
L4	4	1	0	1	0
L5	2	0	1	1	2
Total	28 (60.9%)	9 (19.6%)	5 (10.9%)	2 (4.3 %)	2 (4.3%)

2. Cadaveric study

A total of 22 pedicle screws were placed from T7 to L5. The overall average MRD between the preoperative 3D space (C-arm) and postoperative CT scans was 0.408±0.212 mm. The mean 3D distance of the placed screw head (tail) from the intended trajectory (a) and the mean 3D distance of the placed screw tip from the intended trajectory (b) had little clinical significance, so these values were excluded in cadaveric test. The mean 3D distance from the planned screw head to the placed screw head (c) was 1.78±0.94 mm, the mean 3D distance from the planned screw tip to the placed screw tip (d) was 2.30±1.01 mm, and the mean 3D angular offset (e) was 2.64±1.05 degrees (Table 6). In addition, according to the GRS grades, 16 screws

(72.7%) were classified into group A, 4 screws (18.2%) into group B, 2 screws (9.1%) into group C, and there were no screws classified in group D and E (Table 7).

Table 6. 3D screw placement accuracies: comparison between actual pedicle screw position and preoperative planned path in cadaveric test

	(a) mm	(b) mm	(c) mm	(d) mm	(e) degree (°)
Total (22 screws)	n/a	n/a	1.78 ± 0.94	2.30 ± 1.01	2.64 ± 1.05

(a) mean 3D distance of the placed screw head (tail) from the intended trajectory.

(b) mean 3D distance of the placed screw tip from the intended trajectory.

(c) mean 3D distance from the planned screw head to the placed screw head.

(d) mean 3D distance from the planned screw tip to the placed screw tip.

(e) mean 3D angular offset.

Table 7. Pedicle screw placement accuracy grades according to the Gertzbein-Robbins classification system in cadaveric test

Number of screws (n = 22)					
Grade	A	B	C	D	E
T7	0	2	0	0	0
T8	0	1	1	0	0
T9	0	1	1	0	0
T10	2	0	0	0	0
T11	2	0	0	0	0
T12	2	0	0	0	0
L1	2	0	0	0	0
L2	2	0	0	0	0
L3	2	0	0	0	0
L4	2	0	0	0	0
L5	2	0	0	0	0
Total	16 (72.7%)	4 (18.9%)	2 (9.1%)	0 (0%)	0 (0%)

IV. DISCUSSION

Pedicle screw fixations have achieved widespread use in the surgical treatment of different spinal diseases and conditions, such as degenerative, traumatic, and developmental spinal conditions [17]. Pedicle screw fixation plays an important role in posterior approach spine surgery due to its biomechanical stability and superiority. Accurately placed pedicle screws provide substantial rigidity and firm three-column control to facilitate fusion; however, mispositioning of pedicle screws may cause serious neurovascular complications. Some studies reported that the conventional techniques used in pedicle screw placement can cause screw misplacement, with rates ranging from 3% to 55% [18]. If the pedicle screws were misplaced, this was reported to cause catastrophic neurovascular or visceral complications, which occurred in about 4.2% of patients [19]. Because precise pedicle screw placement is one of most important procedures in spinal surgeries, much research and effort has gone in to improving the accuracy of pedicle screw insertion using robotic and navigation systems recently. As a result of these efforts, pedicle screw insertion using robotics with a CT-based navigation system has been recently conducted in clinical trials. However, some studies have shown that pedicle screw placement using navigation systems with robotics has no advantage in terms of accuracy; therefore, there is still controversy in terms of accuracy and safety [20,21]. On the other hand, the general evaluation is that the accuracy and safety of pedicle screw placement using navigation systems with robotics are superior to that of conventional or freehand techniques [22-27]. Even if the superiority and safety of the navigation and robotic systems using intraoperative O-arm-based images or CT images are secured, in view of the cost aspect, with O-arms being expensive, and the current status of dissemination, if the navigation system using the C-arm already owned by hospitals is available, it is thought that more hospitals will be able to apply efficient and reliable surgical methods at a low cost. This is the reason we are developing a robot-assisted spine surgery system using a C-arm-based navigation system. This new technology is continually improving and may be particularly helpful in patients with challenging anatomies.

Previous studies have evaluated the accuracy of pedicle screw insertion using a robot system with navigation guidance, but there are some limitations to a direct comparison due to slight differences in our experimental design; our results also show acceptable results in terms of accuracy. Chen et al. reported that the mean angular offset was 2.71 ± 1.72 degrees and the mean distance from the planned screw head to the placed screw head was 1.56 ± 0.66 mm when evaluating the accuracy of pedicle screw insertion performed using a navigation robot and preoperative CT on three pigs [12]. Compared with our results (mean angular offset of 3.9 ± 2.4 degrees and mean distance from the planned screw head to the placed screw head of 4.8 ± 2.0 mm), Chen et al. showed more accurate results, but considering that our experiment uses a preoperative image using C-arm, our results are still acceptable in terms of accuracy [13]. Ravi et al. reported that breached pedicles were observed in 37 of the 161 screws, of which 31 were breaching less than 2 mm (clinically acceptable) when performed using a navigation system with a preoperative C-arm image in 41 consecutive patients [4]. Most studies evaluated the accuracy of screw insertion using the GRS grade, but when we evaluated the accuracy of screw insertion using GRS grade in our preclinical animal study, it might seem that our insertions were less accurate than in other studies conducted on human patients. However, 80.4% (37/46 screws) fell into clinically tolerable GRS groups Grade A and B, while groups D and E each had 2 screws in porcine model. Moreover, in cadaveric test, more than 90% of all targets showed clinically acceptable results. This could be attributed to the fact that our robots were in the research and development steps. Additionally, in most of the previous studies, GRS grade was evaluated in human patients, not experimental pigs. As we used experimental pigs, the anatomical structure was different from that of a human; therefore, the results of this study were partially limited in that direct comparison of the accuracy of screw placement could not be carried out between our results and those of other studies. Thus, 3D and quantitative accuracy evaluations of postoperative results were performed using implanted mini screws as fiducials (beads), which were utilized as the point set for registration [28]. This technology using fiducials has been widely utilized for alignment of preoperative data to the physical world and for postoperative evaluation, primarily in implant pose estimation [29]. To the best of our knowledge, no experimental study has reported applying this fiducial technique to preclinical animal experiments to develop a spinal robot using navigation. In our study, MRD between the preoperative 3D space (C-arm) and postoperative CT scans was 0.475±0.119 mm. This was suitable for evaluating the 3D and quantitative accuracy. However, since there was a possibility that some adverse effects, such as pain, may be caused by the insertion of fiducials [30], special care should be taken when fiducials are directly inserted during clinical trials into patients.

Robotic technology and navigation systems in the field of surgery have developed rapidly. As technology evolves, the definition of related terms is also necessary, and the meaning of planning in surgery, which generally uses robots and navigation systems, has mostly referred to preoperative planning [1,12,13,31]. Unlike in other fields of surgery, it is believed that in spine surgery, the definition of planning needs to be subdivided. In our robotic study, we positioned the patient in the operating room, obtained the image using a C-arm and a set of equipment, and then planned the pedicle screw insertion path using a program by the operator in the operating theater. This planning requires a different definition from that of previous preoperative planning; we therefore decided to define this behavior as intraoperative planning. Thus, unlike in traditional preoperative planning, intraoperative planning is undertaken to define the location or path of each apparatus inserted into the patient's body during surgery, by the operator or surgical assistants in the operating room, after the initiation of anesthesia or the initial skin incision. Therefore, intraoperative planning is considered different from intraoperative navigation for determining the direction of the approach, or for checking the area to be operated by real-time feedback in the image.

When analyzing all placed screws per level in our study, especially the results of misplacements (Fig. 4), we considered important factors that cause screw misplacements. In terms of the procedure during surgery, one of the most frequent mechanisms of screw misplacement was skiving at the entry point. In particular, skiving occurred more frequently in the thoracic spine than in the lumbar spine because of the steeper angle formed between the transverse process and superior facet [32]. Other causes were incorrect drilling pressure, excess soft tissue pressure, and thin pedicles [20,33]. Also, on the robot or system side, inaccurate registration or insufficient mounting can cause screws to deviate from the pre-planned path [34-36]. Therefore, to increase the accuracy of pedicle screw insertion using a navigation system-based robot, more research is required on ways to overcome the factors that cause misplacement.

Also, in the next era, robotics is the incorporation of the Internet of Skills and Artificial Intelligence (AI). For example, robots may be trained using AI and machine learning so that they may predict surgical movements and finally enable robotic system to perform totally independent operation. Along these lines, many virtual reality (VR) and augmented reality (AR) systems have already been incorporated into surgical

training programs, and some of these simulation platforms have been correlated with improvements in trainees' operative time and overall performance [37]. The AR headset could display 3D visualizations of screw trajectories and
pre- and intraoperative imaging scans individually. By merging these two, the headset could even project target structures onto the patient [38]. Displays equipped with the ability to overlay images onto the surgical field have previously been found to enhance the surgeons' operating experience [39].

V. CONCLUSION

Our novel spine surgery robot showed good accuracy for the execution of intended planned trajectory and screw path and enabled the use of a navigation system using the existing C-arm. Overall, this study demonstrated the notable accuracy of robot-guided spinal instrumentation procedures and was significant in showing that pedicle screw accuracy can be evaluated using the fiducial technique in preclinical animal experiments. Although, a small number of screw placements showed clinically unacceptable results in porcine model, more than 90% of the screw placements showed clinically acceptable results in cadaveric test. Therefore, further studies are necessary to develop precise execution of planned screw placements, and this faster and more accurate robotic system will be applied in the clinical field in the near future.

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ABSTRACT(IN KOREAN)

돼지 모델 및 인체 카데바의 정량적 정확도 평가 방법론에서 입증된 새로운 씨암 기반 계획 척추 수술 로봇

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김 형 철

배경 : 우리는 새로운 내비게이션 기반 척추 수술 로봇 시스템을 사용하여 실험용 돼지에서 척추경 나사못 삽입의 정확도를 술 전 계획된 경로와 실제 삽입된 경로를 비교하여 평가했습니다.
방법 : 정확도 평가를 위해 실험용 돼지의 척추 한 분절 당 3개의 소형 나사를 삽입하였고, 총 4 마리의 실험용 돼지 (23 개의 척추에 46 개의 척추경 나사못 삽입)와 한 구의 카데바를 (11개의 척추에 22개의 척추경 나사못 삽입) 사용했습니다. 수술 전 씨암으로 2차원적 이미지인 단순 방사선 영상을 촬영하여 이를 이용하여 로봇 시스템이 수술자가 3차원적 수술 전 계획을 할 수 있도록 처리하였습니다. 척추경 나사못의 경로를 계획하고 로봇의 안내에 따라 나사못 삽입을 시행했습니다. 씨암(C-arm) 및 컴퓨터 단층촬영(CT)으로 얻은 영상을 사용하여 수술 전 계획하였던 나사못의 경로와 실제 삽입된 나사못의 경로를 비교하였고, 특히 삽입된 나사못의 두부(head)/첨부(tip)와 계획한 나사못의 두부/첨부의 3차원적 거리 및 삽입 각도의 차이를 비교하였고 Gertzbein Robbins 분류 등급을 이용하여 척추경 나사못의정확도를 평가했습니다.
결과 : 수술 전 3차원 공간 (C-arm 기반)과 수술 후 컴퓨터 단층촬영(CT) 사이의 평균 등록 편차는 실험용 돼지에서는 0.475±0.119 mm, 카데바 실험에서는 0.408±0.212mm였습니다.

수술 전 계획과 수술 후 실제 삽입된 나사못의 배치의 평균 편차는 두부(꼬리)에서 4.8±2.0 mm, 첨부에서 5.3±2.3 mm, 각도가 3.9 ± 2.4°였습니다. Gertzbein Robbins 분류 등급 평가 결과도 실험용 돼지와 카데바 실험 모두에서 임상적으로 적합한 결과를 보였습니다. 결론 : 척추 수술 로봇은 계획된 궤적과 비교하여 실제 나사못 삽입을 실행하는데 있어 우수한 정확도를 보여주었습니다. 이처럼 더 빠르고 정확한 척추 로봇 시스템은 추후에 임상 분야에서 향후 연구에 적용될 수 있을 것입니다.

핵심되는 말 : 씨암, 미세침습, 내비게이션, 척추경 나사못, 로봇학, 척추

PUBLICATION LIST

Kim HC, Jeon H, An SB, Kim H, Hwang S, Cha Y, et al. Novel C-arm based planning spine surgery robot proved in a porcine model and quantitative accuracy assessment methodology. Int J Med Robot 2020;e2182.