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Clinical Studies

Accuracy and safety of percutaneous pedicle screw placement using the K-wireless minimally invasive spine percutaneous pedicle screw system in Japan: A randomized active controlled study

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ABSTRACT

Background: Minimally invasive lumbar fusion has recently become a widely used technique worldwide. This randomized active controlled study was conducted to demonstrate the non-inferiority of the K-wireless Minimally Invasive Spine (MIS) Percutaneous Pedicle Screw (PPS) system compared with use of the six pedicle screw systems currently used in our practices with respect to the accuracy of pedicle screw placement.Also to compare the screw-insertion time and number of fluoroscopic observations during screw insertion between the groups.

Methods: A total of 80 patients with degenerative spinal diseases or vertebral fractures were assigned, including 41 patients in the K-wireless MIS PPS system group (K-wireless group) and 39 in the control group (K-wire group).

The accuracy of the screw insertion, screw-insertion time, number of fluoroscopic observations during screw insertion, and the incidence of adverse events were compared between the K-wireless group and the K-wire group. The accuracy rate was calculated as the number of screws with no breach divided by the total number of screws.

Results: The accuracy rates of screw insertion were 85.7% and 75.0% in the K-wireless and K-wire groups, respectively, with an intergroup difference of 10.7% (95% confidence interval: 2.3–19.1%). The K-wireless group demonstrated non-inferiority compared with the K-wire group. The mean screw-insertion time was significantly shorter in the K-wireless group (2.62 and 2.97 min in the K-wireless and K-wire groups, respectively; P=0.005). There were also significantly fewer fluoroscopies in the K-wireless group (10.7 and 17.4 in the K-wireless and K-wire groups, respectively; P<0.001). There were no device-related or study treatment-related adverse events in either group.

Conclusions: The accuracy of pedicle screw insertion using the K-wireless MIS PPS system was not inferior to that of existing products. In terms of safety, no product-related or treatment-related adverse events were identified in this study and no new safety concerns were noted.

Introduction

The percutaneous pedicle screw (PPS) technique was introduced in Japan in 2005, giving spine surgeons the opportunity to conduct minimally invasive spine (MIS) fusion surgery [1,2]. MIS fusion surgery is becoming widely used in Japan because of its lower levels of complications, bleeding, and muscle injuries compared with conventional open surgeries that require opening up the major paraspinal muscles [3–8]. Although several spinal-fixation instruments have been developed for MIS fusion surgery, MIS fusion surgery has a smaller surgical field with limited visualization compared to conventional procedures, and there are learning curves for the operator's experience and technical skills [9,10]. Furthermore, the procedure involves multiple steps, and a guide wire must be controlled with a limited view field.

DePuy Synthes Spine obtained marketing approval for a K-wireless MIS PPS system (VIPER PRIME^{TM} System, DePuy Synthes Spine, Raynham, MA, USA; Fig. 1), from the US Food and Drug Administration in December 2016. The K-wireless MIS PPS system was subsequently approved in Japan in December 2017. This system represents a rationalized approach to the procedures previously used for minimally invasive pedicle screw placement and is designed to reduce the number of steps required for the insertion of pedicle screws (no needles, guide wires, or taps required), and the number of devices delivered to the operation room.

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Fig. 1. Illustration of VIPER PRIME™ System. The system features a new screw-tip design and a stylet that is fully controlled by the screwdriver. Using the stylet control handle and the modular handle, surgeons can target pedicles and insert screws in a single instrument pass.

The K-wireless MIS PPS system is expected to fulfill needs in clinical practice, including decreasing the time spent on each PPS surgery and decreasing guide wire-related adverse events by the design features of the K-wireless MIS PPS system, although guide wire related complications are generally known in PPS surgery [11]. The decreasing the time spent on each PPS surgery is also expected to decrease the number and time of fluoroscopic observations for surgery (C-arm). The existing products have been confirmed to have sufficient screw-insertion accuracy based on clinical trials [12,13].

We conducted a randomized active controlled study in Japan to demonstrate the non-inferiority of the K-wireless MIS PPS system compared with existing standard-of-care PPS systems (K-wire PPS systems) which has similar design and surgical steps as a technology alternative group, with respect to the safety and accuracy of pedicle screw placement in patients with degenerative spinal diseases or vertebral fractures.

Methods

Trial design

This was a confirmatory, parallel-group, open-label, controlled, randomized study, with use of an approved spinal-fixation instrument as the control. The study was approved by the Institutional Review Board of Nippon Medical School Foundation (trial ID: jRCTs032190039; approved May 13, 2019). The full study protocol is available on the jRCT website.

Participants

This study included patients in two study sites who were diagnosed with a spinal degenerative disease (e.g., degenerative disc disease, lumbar spinal stenosis, spondylolisthesis, or scoliosis) or vertebral fractures, and who required pedicle screw placement and were considered suitable for PPS. The overall target sample size was 80 patients which was established to provide sufficient power for a successful non-inferiority study. Based upon the results of previous clinical trials in Japan and the United States accuracy rate of approximately 93% was anticipated, and the clinical non-inferiority (NI) margin for comparison with the existing products was assumed to be 10%. Under this anticipated success rate and NI margin, One hundred forty-four screws per group was estimated to provide a power of >90% at a one-sided significance level of 2.5%. Assuming that a mean of 4 screws would be used for one patient, 36 patients per group was estimated. Considering that approximately 10% of patients could be excluded or drop out, a target sample size of 40 patients per group was adopted. The inclusion and exclusion criteria are shown in Table 1.

Site registration and subject enrollment and randomization

The registration center registered and randomized subjects using the electronic data capture (EDC) system. The investigators at each study site asked the registration center to register the site after approval by the certified review board. The registration center registered the site and sent notification of the completion of site registration to the investigator. Subject enrollment and randomization were conducted as follows.

After providing written informed consent, each potential subject was screened by the investigator or sub-investigator to judge their eligibility. Subjects were included in this study if the investigator or sub-investigator confirmed that they met all the inclusion criteria and none of the exclusion criteria.

The investigator or sub-investigator entered the required subject information into the EDC system. At this time, an arbitrary subject-identification code was provided, which did not contain any information that could identify the individual.

If the EDC system determined that the patient was eligible, it automatically randomly allocated the subject to the trial treatment or control group in a ratio of 1:1. Study site was used as a stratification factor for randomization to avoid significant bias among the sites. The investigator and sub-investigator at each site were not notified of the detailed randomization procedures.

Study patients

Eighty patients were randomized by the EDC system, 41 patients to the K-wireless MIS PPS system group (K-wireless group) or 39 to the control device group (K-wire group). Subjects in both groups had to undergo lumbosacral surgery within 60 days after enrollment, and patients who did not undergo surgery within this period were asked to re-sign the informed consent form if they wished to participate in the study.

Table 1
Inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
• Individual aged ≥20 years at the time of surgery. • Diagnosis of a spinal degenerative disease (e.g., degenerative disc disease, lumbar spinal stenosis, spondylolisthesis, or scoliosis), spinal tumor, or vertebral fracture • First instrumentation lumbosacral surgery with percutaneous pedicle screw and undergoing an instrumentation lumbosacral surgery involving at least one intervertebral segment • Voluntarily participated in this study and signed the informed consent form stating that patient information • Understanding the purpose of the clinical trial in the opinion of the investigator or sub-investigator, and is willing and able to follow the surgical and study procedures • Able to read and understand the Japanese informed consent form	• Pregnant or breastfeeding woman • Revision surgery of the lumbar spine • Prior pedicle screw placement in the lumbar spine • Severe osteoporosis • Severe spinal deformity due to scoliosis • Extremely narrow or severe osteosclerotic change in the target pedicle • Drug or alcohol abuse (in the past 5 years) or psychiatric disorder and considered in the opinion of the investigator or sub-investigator to be unable to comply with the study requirements defined in the protocol

Table 2
Percutaneous pedicle screw systems used in this study.

K-wireless group	Number of patients	Number of screws
VIPER PRIME™ System	39	187
K-wire group		
PathFinder NXT® Minimally Invasive Pedicle Screw System	4	25
RELINE® System	9	44
M.U.S.T. Pedicle Screw System	6	34
CD HORIZON® SOLERA® VOYAGER™ 5.5/6.0 mm Spinal System	3	12
CREO® MIS Stabilization System	11	56
Associa spinal system	1	6

Table 3
Surgical procedures for the K-wireless and K-wire groups.

K-wireless group	K-wire group
• Make a skin incision • Insert the screw-loaded inserter through the incision and dock the stylet tip on an entry point at an appropriate position • Extend the stylet into the pedicle • Advance the screw into the pedicle • Remove the inserter and stylet	• Make a skin incision • Insert the needle or probe through the incision and advance it to the pedicle • If the needle or probe enters into the centrum, remove the inner needle, and then insert the guidewire into the centrum • Remove the needle or probe • Insert the tap along the guidewire • Remove the tap • Insert the screw • Remove the guidewire • Remove the driver from the screw

Seventy three patients (39 in the K-wireless group and 34 in the K-wire group), a total of 364 screws (187 in the K-wireless group and 177 in the K-wire group) were included in the final analysis. Excluding 25 screws that were used to intentionally perforate the anterior wall to undergo bi-cortical fixation at S1 (12 screws in K-wireless group, 13 screws in K-wire group), 339 screws were evaluated for screw insertion accuracy (175 screws in K-wireless group, 164 screws in K-wire group). Details of the screws used in this study are shown in Table 2.

Treatment plan

The surgeon chose the appropriate screw size preoperatively based on computed tomography (CT) images of each subject. Intraoperative fluoroscopy (antero-posterior and lateral) without navigation was used to guide insertion of all screws. PPS insertion was performed in the prone position, and the C-arm positioning was adjusted for the target vertebra before skin incision for screw insertion. The pre-specified steps for each group were followed sequentially for each screw insertion. Notably, this study did not impose any restrictions on the surgical procedure, fixation level, or target vertebrae, which were determined by the surgeon. The time spent on each screw insertion and the number of fluoroscopic observations required per screw insertion were measured and recorded intraoperatively by a site member.

The surgical procedure in the K-wireless group was performed according to the VIPER PRIME™ System operation manual. Surgeries in the K-wire group were performed according to the operation manual for the respective spinal-fixation system. The procedures in both groups are shown in Table 3.

Assessment of outcome

The following variables were assessed: (1) accuracy of PPS, (2) time spent on each screw insertion, and (3) number of fluoroscopic observations required per screw insertion. All patients underwent fine-cut (1.5 mm) CT within 2 weeks postoperatively, and the accuracy of screw placement, specifically axial, coronal, and sagittal CT images of each pedicle screw, was evaluated by an independent spine surgeon or radiologist other than a co-investigator, based on CT data. The position of each screw relative to the pedicle was assessed and graded according to a previous report [14] as follows: grade A: no breach; grade B; breach <2 mm; grade C: breach 2–4 mm; grade D: breach >4 mm.

The time required for each screw insertion and the number of fluoroscopic observations for all patients were summarized and compared between the K-wireless and K-wire groups. Adverse events associated with screw insertion were also investigated.

Statistical analysis

Effectiveness analyses were performed using the full analysis population who underwent surgery with the randomized device without major protocol deviations. Safety analyses were performed using the safety analysis population who underwent surgery with the randomized device.

The accuracy rate was calculated according to the formula below. Differences in accuracy rates between the K-wireless and K-wire groups, and 95% confidence intervals (CIs) were calculated and compared. Non-inferiority of the K-wireless group compared with the K-wire group was concluded if the lower limit of the CI of the intergroup difference was not below −10%. The non-inferiority one-sided test was performed using the Wald test with a 10% non-inferiority margin.

$$\text{accuracy rate}(\%) = \frac{\text{number of screws, grade A}}{\text{number of screws, grades A + B + C + D}}$$

The screw-insertion time and number of fluoroscopic observations per screw during screw insertion were summarized using descriptive statistics for each treatment group. Group comparisons were made using Student's *t*-test.

Results

The enrollment period was from June 2019 to May 2020, and the follow up period for each subject was from the informed consent to the discharge date or day 14 post-surgery, whichever came first. Eighty patients, which was the overall target sample size were enrolled.

Fig. 2 shows a flow chart of the study. Eighty patients were randomized by the EDC system into the K-wireless group (n=41) and the K-wire

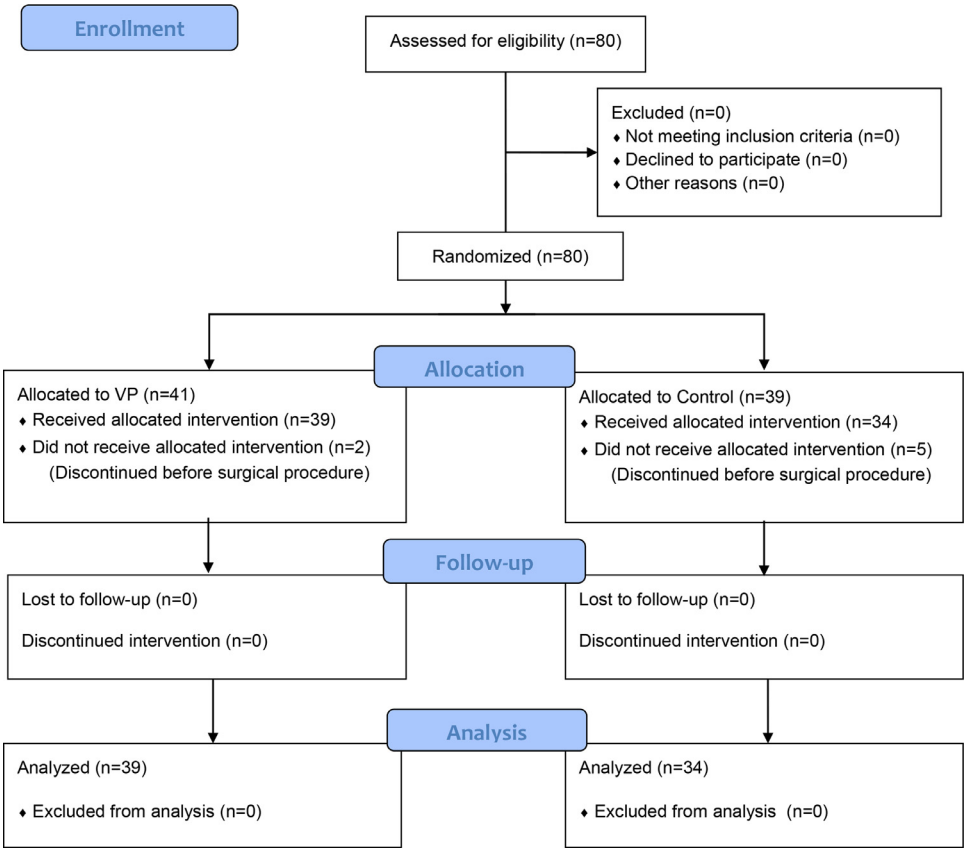

Fig. 2. CONSORT flow diagram.

Table 4
Basic data for randomized groups.

Group		Randomized group	
		K-wireless	K-wire
Number of patients		39	34
Sex	Male	18 (46.2%)	19 (55.9%)
	Female	21 (53.8%)	15 (44.1%)
Mean age (range), years		67.2 (50–84)	67.6 (40–88)
Primary disease	Lumbar spinal canal stenosis	19	19
	Spondylolisthesis	15	9
	Vertebral fracture	4	4
	Degenerative scoliosis	0	1
	Lumbar disc herniation	1	1

Table 5
Basic surgical data.

Group		Randomized group	
		K-wireless	K-wire
Number of patients		39	34
Mean operating time (range), min		125.8 (30–253)	128.1 (27–269)
Mean amount of bleeding (range), ml		67.9 (5–250)	86.2(6–450)
Surgical method	TLIF	22	16
	LLIF or XLIF(R)	7	7
	OLIF/ATP	3	2
	HA insertion	4	4
	XLIF+TLIF	3	4
	OLIF+TLIF	0	1

TLIF: Transforaminal Lumbar Interbody Fusion; LLIF: Lateral Lumbar Interbody Fusion; XLIF: Extreme Lateral Interbody Fusion; OLIF: Oblique Lateral Interbody Fusion; ATP: Anterior to Psoas; HA: hydroxyapatite

group (n=39). Seven patients who did not undergo surgery were excluded, and a total of 73 patients (39 in the K-wireless group, 34 in the K-wire group) were therefore included in the final analysis. The reasons for discontinuation were withdrawal of patient consent (n=1), failure to meet selection/exclusion criteria (n=3), and other reasons (n=3). The characteristics of each group, including sex, age, and primary disease, are shown in Table 4 and the surgical data are shown in Table 5.

The accuracy of the screw-insertion position is shown in Table 6. The accuracy rates were 85.7% and 75.0% in the K-wireless and K-wire groups, respectively, with an intergroup difference of 10.7% (95% CI: 2.3–19.1%). The lower limit of the 95% CI of the intergroup difference exceeded the pre-specified −10%, which verified the non-inferiority of K-wireless group compared with the K-wire group (P<0.001).

The accuracy of screw placement by vertebral level is indicated in Table 7. The accuracy rates were 79.7% in the K-wireless group and 68.5% in the K-wire group for L4, and 87.9% in the K-wireless group and 80.4% in the K-wire group for L5. The accuracy was approximately 10% higher in the K-wireless group in all categories. There was no screw misplacement in the S1 vertebra in either group.

Table 8 shows the number of screws in the direction of the pedicle crossing according to the adjudicated grading. The proportion of lateral breaches was >50% at Grade B and C in both groups. One screw in the K-wire group was judged as grade D, however, none in the K-wireless group. None of the patients with grade B, C and D required any further treatment and caused any symptoms in both groups in this study during the study follow up period.

The insertion time and number of fluoroscopic observations required for insertion of each screw are shown in Table 9. The mean insertion time was significantly shorter in the K-wireless group (2.62 min in the K-wireless group and 2.97 min in the K-wire group; P=0.005). Similarly, the mean number of fluoroscopic observations was significantly lower

Table 6
Accuracy of screw placement.

		Randomized group	
		K-wireless	K-wire
Number of screws		175	164
Accuracy of screw placement	Grade A	150 (85.7%)	123 (75.0%)
	Grade B	22 (12.6%)	33 (20.1%)
	Grade C	3 (1.7%)	7 (4.3%)
	Grade D	0 (0.0%)	1 (0.6%)
Accuracy rate (%)		85.7	75.0
P-value*		P<0.001	

Grade A: no breach; Grade B: breach <2 mm; Grade C: breach 2–4 mm; Grade D: breach >4 mm

Table 7
Accuracy of screw placement by vertebral level.

Vertebral level of allocated screw insertion			Randomized group	
			K-wireless	K-wire
L1	Number of allocated screws		6	6
	Accuracy of screw placement	Grade A	6 (100.0%)	4 (66.7%)
		Grade B	0 (0.0%)	2 (33.3%)
		Grade C	0 (0.0%)	0 (0.0%)
		Grade D	0 (0.0%)	0 (0.0%)
	Accuracy rate (%)		100	66.7
L2	Number of allocated screws		4	14
	Accuracy of screw placement	Grade A	4 (100.0%)	8 (57.1%)
		Grade B	0 (0.0%)	5 (35.7%)
		Grade C	0 (0.0%)	1 (7.1%)
		Grade D	0 (0.0%)	0 (0.0%)
	Accuracy rate (%)		100	57.1
L3	Number of allocated screws		24	30
	Accuracy of screw placement	Grade A	19 (79.2%)	25 (83.3%)
		Grade B	3 (12.5%)	5 (16.7%)
		Grade C	2 (8.3%)	0 (0.0%)
		Grade D	0 (0.0%)	0 (0.0%)
	Accuracy rate (%)		79.2	83.3
L4	Number of allocated screws		59	54
	Accuracy of screw placement	Grade A	47 (79.7%)	37 (68.5%)
		Grade B	12 (20.3%)	12 (22.2%)
		Grade C	0 (0.0%)	4 (7.4%)
		Grade D	0 (0.0%)	1 (1.9%)
	Accuracy rate (%)		79.7	68.5
L5	Number of allocated screws		66	56
	Accuracy of screw placement	Grade A	58 (87.9%)	45 (80.4%)
		Grade B	7 (10.6%)	9 (16.1%)
		Grade C	1 (1.5%)	2 (3.6%)
		Grade D	0 (0.0%)	0 (0.0%)
	Accuracy rate (%)		87.9	80.4
S1	Number of allocated screws		16	4
	Accuracy of screw placement	Grade A	16 (100.0%)	4 (100.0%)
		Grade B	0 (0.0%)	0 (0.0%)
		Grade C	0 (0.0%)	0 (0.0%)
		Grade D	0 (0.0%)	0 (0.0%)
	Accuracy rate (%)		100	100

Grade A: no breach; Grade B: breach <2 mm; Grade C: breach 2–4 mm; Grade D: breach >4 mm

in the K-wireless group (10.7 in the K-wireless group and 17.4 in the K-wire group; $P<0.001$).

Adverse events were observed in 12.8% and 20.6% of subjects in the K-wireless and K-wire groups, respectively (Table 10). There were no device-related or study treatment-related adverse events in either group. Moreover, there were no adverse events attributable to device malfunction, and no new safety concerns were noted.

Discussion

The usefulness of PPS insertion by robot-assisted [15–18] and O-arm navigation [19–21] has recently been reported. Both systems are expensive technologies and thus are frequently impractical. Conventional fluoroscopy is therefore considered the mainstream method of PPS insertion.

Table 8
Direction of pedicle breach.

			Randomized group	
			K-wireless	K-wire
Number of screws			175	164
Direction of pedicle breach	Grade B		22	33
		Medial	7 (31.8%)	14 (42.4%)
		Lateral	12 (54.5%)	15 (45.5%)
		Cranial	3 (13.6%)	3 (9.1%)
		Caudal	0 (0.0%)	1 (3.0%)
	Grade C		3	7
		Medial	1 (33.3%)	1 (14.3%)
		Lateral	2 (66.7%)	6 (85.7%)
		Cranial	0 (0.0%)	0 (0.0%)
		Caudal	0 (0.0%)	0 (0.0%)
	Grade D		0	1
		Medial	0	0 (0.0%)
		Lateral	0	1 (100.0%)
		Cranial	0	0 (0.0%)
		Caudal	0	0 (0.0%)

Grade A: no breach; Grade B: breach <2 mm; Grade C: breach 2–4 mm; Grade D: breach >4 mm

Table 9
Insertion time and number of fluoroscopic observations per screw insertion.

	Randomized group	
	K-wireless	K-wire
Number of screws	175	164
Mean time (range), min	2.62 (1.3–9.3)	2.97 (1.3–6.2)
P-value*	0.005	
Mean number of fluoroscopic observations (range)	10.7 (4–43)	17.4 (5–57)
P*-value	<0.001	

* Student's *t*-test

The current study was conducted to verify the accuracy and safety of pedicle screw insertion using the K-wireless MIS PPS system in Japan, in comparison to the existing standard PPS systems. A recent retrospective study reported that the K-wireless MIS PPS system shortened the screw-insertion time approximately 0.4-fold, with equivalent insertion accuracy [22], however, no prospective, randomized studies have investigated the accuracy of screw insertion, insertion time, and fluoroscopy frequency between the K-wireless MIS PPS system and control systems.

In this study, the accuracy rate of screw placement was 85.7% (150/175 screws: 95% CI: 79.6–90.5%) in the K-wireless group and 75.0% (123/164 screws: 95% CI: 67.7–81.4%) in the K-wire group, with an intergroup difference of 10.7% (95% CI: 2.3–19.1%), which indicates non-inferiority of the K-wireless compared with the K-wire group. In addition, the lower confidence interval limit exceeded 0.0%, which suggests superiority of the K-wireless group over the K-wire devices regarding the accuracy rate of screw placement. We confirmed that the accuracy of screw insertion by the K-wireless MIS PPS system was not inferior to that of the existing products, and that the insertion accuracy was maintained. The screw is inserted along the stylet in the VIPER PRIME™ System procedure and it is easy to be aligned, and would therefore the accuracy rate in the K-wireless group was higher than the K-wire group. The reason why the accuracy rate of this study was slightly lower than the target accuracy rate of 93% is considered that the small number of patients and different fluoroscopic techniques in the clinical studies by citing to this study.

In the assessment of insertion accuracy, the directions of perforated pedicle screws (Grade B, C, or D) were similar in both groups, with the most common breach being lateral (K-wireless group 56.0%, K-wire group 53.7%), followed by medial breach (K-wireless group 32.0%, K-

Table 10
Adverse events.

	Randomized group					
	K-wireless (*N*=39)			K-wire (*N*=34)		
	Number of patients	%	Number of cases	Number of patients	%	Number of cases
Any adverse event	5	12.8%	7	7	20.6%	7
Skin and subcutaneous tissue disorders	4	10.3%	4	5	14.7%	5
Gastrointestinal disorders	2	5.1%	2	1	2.9%	1
Respiratory, thoracic, and mediastinal disorders	1	2.6%	1	0	0.0%	0
Injury, poisoning, and procedural complications	0	0.0%	0	1	2.9%	1

wire group 36.6%). This suggests that the risk of neurological complications caused by screw perforation could be reduced by paying attention to medial perforation.

The highest radiation exposures in patients during spinal surgery have been reported in the surgical field, gonad area, and thoracic region, while the surgeon was exposed to significantly higher radiation than other operating room personnel, with the surgeons' dominant hand, which is mainly used to fix the screw in the surgery field, receiving the highest radiation dose. Furthermore, the surgeon's eye-lens region was exposed to significantly higher radiation doses compared with the assisting surgeon [23]. Spinal surgeons and other operating room personnel who are routinely exposed to occupational radiation should thus take care not to exceed the dose equivalent limit (eye lens: 20 mSv averaged over 5 years with no more than 50 mSv in any single year; skin and extremities: 500 mSv per year) [24][25].

In this study, the mean screw-insertion time was significantly shorter (K-wireless group 2.62 min, K-wire group 2.97 min; P=0.005) and the number of fluoroscopy observations was significantly smaller (K-wireless group 10.7; K-wire group 17.4; P<0.001) in the K-wireless group than in the K-wire group. In this study, the average number of fluoroscopies was reduced by approximately 40% in the K-wireless compared with the K-wire group. The reason of this result is considered that the K-wireless MIS PPS system have fewer operative steps than K-wire group as shown in Table 3. Although there was a statistically significant difference in the screw-insertion time, it may not be of great clinical significance. On the other hands, it is considered that a decrease in the number of fluoroscopy observations is of great clinical significance.

Although no measured data on actual radiation exposure were obtained in this study, we showed that the new procedure could reduce the number of fluoroscopic imaging required per surgery compared with the use of conventional products, which suggests that it would also contribute to reduce the hazards associated with radiation exposure among patients, surgeons, and surgical staff. In addition, this advantage of the K-wireless MIS PPS system could potentially provide additional surgical opportunities for more patients with excellent spine surgeons.

The K-wireless MIS PPS system reduced screw-insertion time, which might in turn contribute to a shorter operation time and reduce the burdens on patients (in terms of duration of anesthesia, amount of bleeding, infection risk, etc.) and on spinal surgeons and medical staff (in terms of physical and mental workloads, distribution of resources or operating room efficiency, etc.).

Complications associated with MIS fusion generally include large vessel and intestinal tract injuries caused by guide wire perforation. A study of 781 patients who underwent percutaneous pedicle screw insertion showed guide wire breakages in three patients (0.4%) and aortic guide wire-related injury in one patient (0.13%) [11]. The K-wireless MIS PPS system does not require guide wires in its procedure, and would therefore reduce the incidence of these complications, although it could not be evaluated in this study because no adverse events related to the guidewires occurred. Accordingly, no guide wire-related complications were observed in the current study.

The limitations of this study include the use of various different systems in control group, relatively small number of sites (total two sites), and the learning curve of PPS. The results of this trial are not generalizable to all surgeon because the accuracy of PPS depends upon the surgeon's experience. In addition, there is a limitation that the radiation dose was not evaluated in this study, although the number of fluoroscopy was evaluated.

Conclusion

Our study results confirmed that the accuracy rate of pedicle screw placement using the K-wireless MIS PPS system is non-inferior to that of existing products and can indirectly reduce radiation exposure to patients and surgical staff.

Declarations of Competing Interests

None.

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Supplementary materials

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