



Comparison of 3D-navigation and fluoroscopic guidance in percutaneous pedicle screw placement for traumatic fractures of the thoracolumbar junction

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ABSTRACT

Introduction: Fractures of the thoracolumbar junction are the most common vertebral fractures and can require surgical treatment. Several studies have shown that the accuracy of pedicle screw placement can be improved by the use of 3D-navigation. Still only few studies have focused on the use of navigation in traumatic spine injuries.

Research question: The aim of this study was to compare the screw placement accuracy and radiation exposure for 3D-navigated and fluoroscopy-guided percutaneous pedicle screw placement in traumatic fractures of the thoracolumbar junction.

Materials and methods: In this single-center study 25 patients undergoing 3D-navigated percutaneous pedicle screw placement for traumatic fractures of the thoracolumbar junction (T12-L2) were compared to a control group of 25 patients using fluoroscopy. Screw accuracy was determined in postoperative CT-scans using the Gertzbein-Robbins classification system. Additionally, duration of surgery, dose area product, fluoroscopy time and intraoperative complications were compared between the groups.

Results: The accuracy of 3D-navigated percutaneous pedicle screw placement was 92.66 % while an accuracy of 88.08 % was achieved using standard fluoroscopy ($p = 0.19$). The fluoroscopy time was significantly less in the navigation group compared to the control group ($p = 0.0002$). There were no significant differences in radiation exposure, duration of surgery or intraoperative complications between the groups.

Discussion and conclusion: The results suggest that 3D-navigation facilitates higher accuracy in percutaneous pedicle screw placement of traumatic fractures of the thoracolumbar junction, although limitations should be considered. In this study 3D-navigation did not increase fluoroscopy time, while radiation exposure and surgery time were comparable.

1. Introduction

The thoracolumbar junction is the most commonly affected region in traumatic spinal fractures due to the transition from the relatively fixed thoracic spine to the more flexible lumbar spine (Li et al., 2019; Liu et al., 2018; Reinhold et al., 2010). Surgical stabilization is generally recommended for injuries causing neurologic deficits, fractures that are considered unstable or for significant posttraumatic deformities (Verheyden et al., 2018). The most common procedure for stabilization and

internal fixation is dorsal instrumentation, which can be combined with anterior reconstruction depending on fracture morphology (Reinhold et al., 2010). The placement of pedicle screws for dorsal instrumentation can be performed percutaneously or open. Advantages of percutaneous pedicle screw placement include reduced trauma to paraspinal tissue, reduced blood loss and shorter recovery time (Jiang et al., 2012; Vanek et al., 2014). Although dorsal instrumentation is a standard procedure there is still a risk of screw misplacement with incidences reported in literature ranging from 4 to 23 % using standard fluoroscopy

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(Kosmopoulos and Schizas, 2007; Rajasekaran et al., 2007; Winder and Gilhooly, 2017). Most minor perforations of the pedicle, especially laterally, are asymptomatic and don't require revision. Still it has been shown that the pull-out strength of laterally misplaced screws is decreased (Maeda et al., 2018; Korkmaz et al., 2018). Medial or caudal malpositioning on the other hand can lead to injuries of nerve roots and the spinal cord causing neurologic deficits (Lonstein et al., 1999). A rare complication is the anterior perforation of screws and possible subsequent vascular injury affecting the aorta, vena cava or iliac vessels (Lonstein et al., 1999; Foxx et al., 2010).

Modern 3D-navigation or robotic-guided systems aim to improve the accuracy of pedicle screw positioning. There is evidence that the use of intraoperative navigation improves the accuracy of thoracolumbar pedicle screw placement (Kosmopoulos and Schizas, 2007; Rajasekaran et al., 2007; Meng et al., 2016). However, the majority of patients included in previous studies underwent spinal fusion for degenerative disease and there is only limited data on the use of navigation in traumatic spinal injuries. Therefore, this study compares the accuracy of 3D-navigation and conventional fluoroscopy for percutaneous pedicle screw placement in traumatic injuries of the thoracolumbar junction.

2. Materials and Methods

In this single-center retrospective study 25 patients undergoing 3D-navigated percutaneous pedicle screw placement for traumatic fractures of the thoracolumbar junction (defined as T12-L2) were included consecutively between June 2021 and August 2023. The results were compared to a control group of 25 patients who received surgical treatment using conventional fluoroscopic guidance during the period from May 2020 to October 2021. The patients in the control group were selected by the levels instrumented. Exact matches were found for 19 patients while a deviation of one level was accepted in 6 patients. Patients undergoing revision surgery and osteoporotic/pathologic fractures were excluded. The study was approved by the ethics committee responsible (application number 2021–16061).

All patients were placed on a radiolucent carbon fiber surgical table in prone position. For the 3D-navigated procedures the software of the Pulse platform (NuVasive, San Diego, USA) was used. The correct spinal levels were identified using fluoroscopy. Following a small skin incision and soft-tissue preparation the patient array was mounted on a spinous process inside the surgical field, one vertebra cranial of the fracture. This reduces unwanted contact with the patient reference array which is angled 45° caudally. The registration scan was acquired using a mobile 3D C-arm cone beam computed tomography (CBCT, Cios Spin, Siemens Healthineers, Erlangen, Germany). Ventilation was paused during the scan to allow for better image quality. The 3D datasets were automatically transferred to the navigation platform and visualized on the monitor. The navigated drill guide was used to identify and continuously visualize the correct trajectory on the navigation monitor and the screw size was selected intraoperatively. After drilling, a guidewire was inserted into the pedicle through the drill guide. After placing all guidewires, the respective pedicle screws were placed over the guidewires. During navigated screw placement the planned trajectory was continuously visualized on the monitor as well as the progress of the screw insertion. All navigated procedures were performed accordingly. An additional intraoperative 3D scan to control the position of guidewires or screws was performed at the surgeon's discretion (Mandelka et al., 2022, 2023).

In the control group Jamshidi needles were placed in the pedicles under fluoroscopic guidance in anterior-posterior and lateral views using a C-arm CBCT (Cios Spin, Siemens Healthineers, Erlangen, Germany). Guidewires were inserted through the Jamshidi needles and pedicle screws were placed over the guidewires. The screw sizes were determined based on preoperative CT scan measurements using a DICOM viewer (IMPAX 6, Agfa Healthcare, Mortsel, Belgium).

The implant system used was Reline MAS with exception of one case

in the fluoroscopic guidance group in which the system Precept was used (both NuVasive, San Diego, USA).

The electronic patient chart and the dose report were used to collect baseline data, such as operative time (min), intraoperative fluoroscopy time (s) and intraoperative dose area product ($\text{mGy}\cdot\text{cm}^2$). Surgery reports were checked for intraoperative complications.

The screw placement accuracy was determined in postoperative thin-slice (2 mm) CT-scans by an independent investigator using the Gertzbein-Robbins classification system (GRS). The grades are defined as: A: completely intrapedicular screw position, B: pedicle breach < 2 mm, C: pedicle breach 2 to <4 mm, D: pedicle breach 4 to <6 mm, E: pedicle breach >6 mm. Grade A and B are considered accurate (Gertzbein and Robbins, 1990). The screw position was measured medially and laterally in axial slices.

Data were analyzed using Prism 10 (GraphPad, San Diego, USA) and R 4.3.2 (R Core Team, Vienna, Austria). Shapiro-Wilk test was used to test for normal distribution of data. For normally distributed data an unpaired *t*-test was used while Mann-Whitney test was used for non-parametric analysis. For nominal data a two-sided Fisher's exact test was used. Descriptive statistics are shown as means \pm standard deviation for continuous variables and absolute numbers and percentages for categorical variables. P-values <0.05 were considered statistically significant.

3. Results

In total 25 patients undergoing percutaneous 3D-navigated pedicle screw placement were compared to a control group of 25 patients who were treated using fluoroscopic guidance. There were no significant differences regarding demographic data and procedure characteristics between the two groups. The detailed data are shown in Table 1. In both groups males outnumbered females with a ratio of approximately 1.5:1. A total of 177 screws were placed in the navigation group and 151 screws were placed in the fluoroscopy-guided group.

Accuracy was 92.66 % in the navigation group and 88.08 % in the fluoroscopy group. No Grade E perforations were observed in either group. The differences in accuracy were not statistically significant ($p = 0.19$). The detailed screw placement accuracy is shown in Fig. 1 (see Fig. 2).

In both groups screw placement accuracy was significantly lower in the thoracic spine compared to the lumbar spine ($p = 0.04$ (navigation), $p = 0.0006$ (fluoroscopy)). In direct comparison the thoracic spine accuracy was higher in the navigation group, while similar accuracy rates were found for the lumbar spine. Except for one medial breach only lateral perforations were observed. None of the pedicle perforations lead to neurologic deficits and there were no revision surgeries due to screw misplacement.

The intraoperative dose area product was slightly higher in the navigation group compared to the standard fluoroscopy group. A second intraoperative 3D-scan was performed in 7 cases (28 %) in the navigation group leading to a revision of one guidewire in 2 cases. Yet, fluoroscopy time was significantly lower in the navigation group (74.04 ± 30.59 s) than in the fluoroscopy guided group (125.4 ± 52.26 s) ($p < 0.001$). There was a minimal prolongation of surgery time for navigated procedures compared to the control group. The detailed data are shown in Fig. 3.

One of the navigated screws dislocated intraoperatively leading to an extension of the instrumentation by an additional segment. In the fluoroscopy group one screw had to be removed due to backflow of bone cement.

The mean screw diameter/pedicle width ratio was 86.82 % in the navigation group and 84.48 % in the fluoroscopy group ($p = 0.52$). In the thoracic region the screw diameter/pedicle width ratio was 86.03 % for navigated procedures and 82.58 % for fluoroscopic guidance ($p = 0.31$). In the lumbar region the screw diameter/pedicle width ratio was 87.33 % in the navigation group and 85.95 % in the fluoroscopy group

Table 1
Comparison of demographic data and procedure characteristics for both groups.

	Navigation (n = 25)	Fluoroscopy (n = 25)	Total (n = 50)		
Mean age (years)	59.24 ± 17.51	61.72 ± 15.41	60.48 ± 16.37	p = 0.60 ^a	
BMI (kg/m ²)	27.58 ± 7.09	28.60 ± 3.89	28.09 ± 5.68	p = 0.06 ^b	
	n	%	n	%	
Gender					
Male	15	(60.0)	16	(64.0)	p > 0.99 ^c
Female	10	(40.0)	9	(36.0)	
Fractured vertebra					
T12	6	(24.0)	6	(24.0)	p = 0.36 ^c
L1	11	(44.0)	15	(60.0)	
L2	5	(20.0)	4	(16.0)	
multiple	3	(12.0)	0	(0.0)	
3	(12.0)	0	(0.0)	3	
AO Classification					
A1	0	(0.0)	0	(0.0)	p = 0.32 ^c
A2	0	(0.0)	0	(0.0)	
A3	7	(28.0)	12	(48.0)	
A4	9	(36.0)	8	(32.0)	
B1	1	(4.0)	3	(12.0)	
B2	3	(12.0)	1	(4.0)	
B3	4	(16.0)	1	(4.0)	
C	0	(0.0)	0	(0.0)	
multiple	1	(4.0)	0	(0.0)	
1	(4.0)	0	(0.0)	1	
Number of segments fused					
2	12	(48.0)	16	(64.0)	p = 0.21 ^c
3	6	(24.0)	1	(4.0)	
4	6	(24.0)	6	(24.0)	
5	1	(4.0)	2	(8.0)	
3	(12.0)	2	(8.0)	3	
Levels instrumented					
T10	8	(4.52)	8	(5.30)	p = 0.69 ^c
T11	24	(13.56)	24	(15.89)	
T12	38	(21.47)	34	(22.52)	
L1	44	(24.86)	26	(17.22)	
L2	43	(24.29)	39	(25.83)	
L3	20	(11.30)	20	(13.25)	
40	(12.20)				
Additional surgical interventions					
Cement augmentation of screws	5	(20.0)	7	(28.0)	p = 0.40 ^c
Laminectomy	0	(0.0)	2	(8.0)	
Vertebroplasty/Kyphoplasty	3	(12.0)	5	(20.0)	
Stabilization of additional vertebral fractures	2	(8.0)	0	(8.0)	
2	(4.0)				

a: unpaired t-test.
b: Mann-Whitney test.
c: Fisher's exact test.

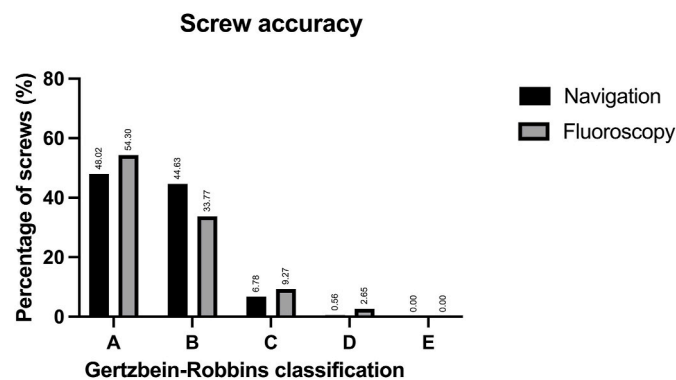


Fig. 1. Screw placement accuracy according to GRS for the navigation and fluoroscopic guidance group. In the navigation group 12 screws were rated Grade C and 1 screw Grade D. In the fluoroscopy group 14 Grade C perforations and 4 Grade D perforations were observed.

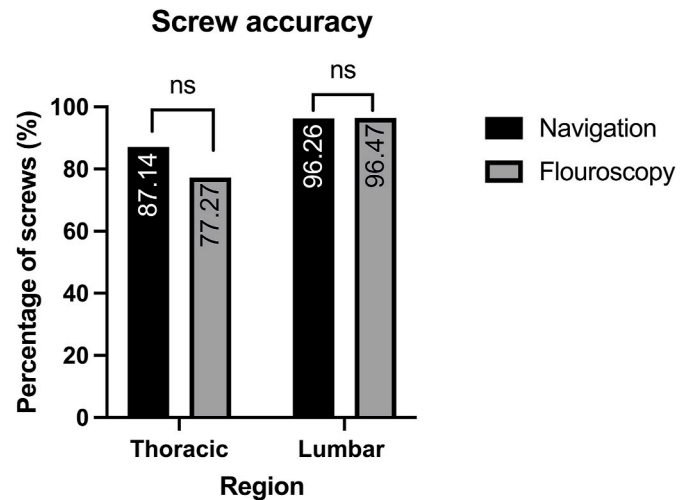


Fig. 2. Comparison of accuracy in the thoracic and lumbar spine between 3D-navigated and fluoroscopy guided pedicle screw placement. The accuracy in the navigation group was 87.14 % in the thoracic spine and 96.26 % in the lumbar spine. In the fluoroscopy group the accuracy was 77.27 % in the thoracic spine and 96.47 % in the lumbar spine. There was no significant difference between the navigation and fluoroscopy group in the thoracic (p = 0.18) or lumbar spine (p > 0.99).

(p = 0.96).

4. Discussion

In this study the accuracy of percutaneous pedicle screw placement in traumatic fractures of the thoracolumbar junction using 3D-navigation and fluoroscopic guidance was investigated. In line with previous studies a higher accuracy was found for navigated compared to fluoroscopy-guided procedures (Meng et al., 2016; Noriega et al., 2017; Tian and Xu, 2009; Tkatschenko et al., 2020; Waschke et al., 2013; Yao et al., 2022; Ling et al., 2014). In the present study only patients with traumatic fractures of the thoracolumbar junction were analyzed. Dorsal instrumentation of traumatic fractures can be challenging due to higher instability which might lead to differences between the displayed anatomy and the actual intraoperative situation. Hence, extensive pressure should be avoided during guidewire or screw placement to prevent changes in anatomy after image acquisition since this can lead to inaccuracy. Therefore, it is recommended to regularly use the navigation pointer to verify navigation accuracy on different anatomic landmarks.

This circumstance should find consideration when comparing the present study with previous studies which did not exclusively focus on dorsal instrumentation of traumatic injuries.

Despite the challenges due to the unstable fracture situation accuracy levels of 92.66 % for navigated screw placement and 88.08 % for fluoroscopic guidance in this study are comparable with results from previous studies including different indications for dorsal instrumentation (Meng et al., 2016; Noriega et al., 2017; Tian and Xu, 2009). The difference regarding accuracy rates between the groups is notable, yet slightly less pronounced compared to other studies. This is possibly due to higher instability caused by fractures. While screw placement was more accurate using navigation, the effect was not statistically significant which might be due to the limited sample size.

In a meta-analysis by Tian et al. an overall pedicle screw placement accuracy of 90.76 % for CT-based navigation and 85.48 % for standard fluoroscopy was found, concurring with the results presented (Tian and Xu, 2009). A meta-analysis of Kosmopoulos et al. showed a median pedicle screw placement accuracy of 95.2 % in navigated procedures compared to 90.3 % without navigation, though they did not

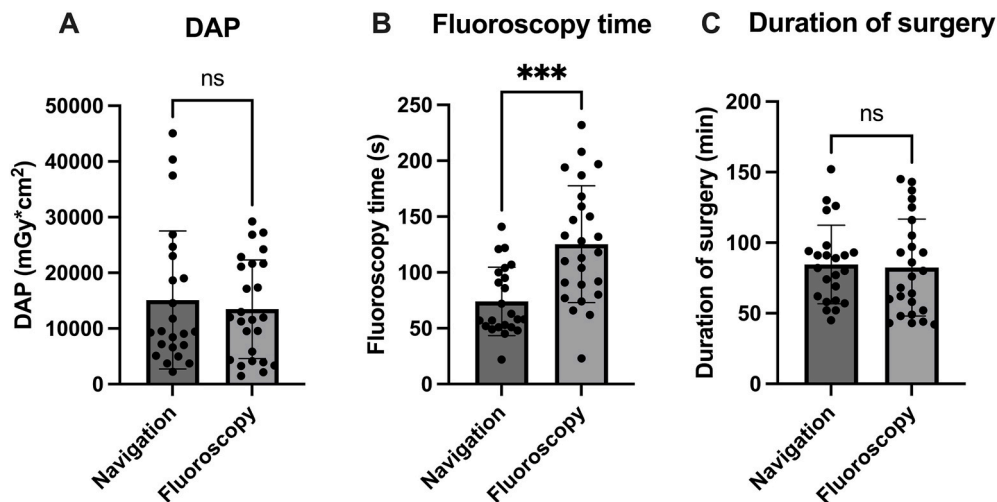


Fig. 3. A: The dose area product (DAP) was slightly elevated in navigated procedures. The mean DAP was 15124 ± 12384 mGy*cm² in the navigation group compared to 13469 ± 8855 mGy*cm² in the fluoroscopy group ($p = 0.97$). B: The fluoroscopy time was significantly lower for navigated pedicle screw placement (74.04 ± 30.59 s) compared to standard fluoroscopy (125.4 ± 52.26 s) ($p = 0.0002$). C: The duration of surgery was slightly longer in the navigation group (84.57 ± 27.83 min) compared to the standard fluoroscopy group (82.40 ± 34.39 min) ($p = 0.63$). Data are displayed as means \pm standard deviation. Normally distributed data (fluoroscopy time) were analyzed using an unpaired *t*-test, for non-normally distributed data the Mann-Whitney test was used. *** $p < 0.001$.

differentiate between different techniques (Kosmopoulos and Schizas, 2007). Recently even higher accuracy rates for navigated procedures have been reported. Tkatschenko et al. found an accuracy of 95.2 % for percutaneous pedicle screws in the thoracolumbar region and 97.8 % in the lumbar region using iCT and CBCT navigation (Tkatschenko et al., 2020). Although recent studies have found a higher accuracy for navigated pedicle screw placement compared to fluoroscopic guidance, clinical implications of these findings have yet to be studied. Fluoroscopy-guided pedicle screw placement is a well-established and widely used method to place pedicle screws in a safe and reliable manner.

Higher misplacement rates are usually seen in the thoracic spine compared to the lumbar spine (Winder and Gilhooly, 2017; Waschke et al., 2013; Charles et al., 2021). Charles et al. found perforation rates of 16.7 % in the caudal thoracic spine (T7–T12) and 6.9 % in the lumbosacral spine (L1–S1) in an in vitro model for percutaneous placement of pedicle screws using fluoroscopic guidance (Charles et al., 2021). In the current study the accuracy of pedicle screw placement was also significantly higher in the lumbar spine compared to the thoracic spine in both groups. At the thoracic spine a noticeably higher accuracy was found for navigated procedures, although this effect was not statistically significant it suggests that the use of 3D-navigation may be especially beneficial in the thoracic region.

Percutaneous pedicle screw placement is considered a safe and accurate alternative to traditional open techniques, although it relies mainly on precise intraoperative imaging due to reduced visual control (Kreinst et al., 2021; Chapman et al., 2016; Lu et al., 2020). Tkatschenko et al. found an improved accuracy in percutaneous navigated pedicle screw placement compared to open procedures, except for the thoraco-lumbar region where the accuracy was higher in open than in percutaneous procedures (Tkatschenko et al., 2020). In the current study exclusively percutaneous procedures were included, therefore a comparison with open procedures was not possible. However, a previous study using the same navigation software and technique for thoracolumbar pedicle screw placement showed a significantly higher accuracy in percutaneous procedures using 3D-navigation compared to fluoroscopy while there was no significant difference in open procedures, which might be due to the additional visual control (Mandelka et al., 2023). Yang et al. found a higher accuracy especially in the thoracic region for O-arm navigated percutaneous short segment pedicle instrumentation for thoracolumbar fractures compared to open

fluoroscopy-guided procedures (Yang et al., 2020).

Fichtner et al. showed that the rate of revision surgeries for misplaced pedicle screws was significantly lower in 3D-navigated compared to fluoroscopy-guided pedicle screw placement in the thoracolumbar spine (Fichtner et al., 2018). In the present study there were no revision surgeries due to misplaced screws in either group. One medial perforation was observed in the navigation group. Even though the perforation was considered relevant according to the GRS the respective patient did not show any neurological deficits. According to previous studies neurologic impairments are only expected in medial perforations >4 mm (Gertzbein and Robbins, 1990; Laine et al., 1997).

Previous studies have also investigated implications of accuracy rates and screw diameter/pedicle width ratio. It has been shown that navigation allows an increase of screw diameter/pedicle width ratio for thoracolumbar pedicle screw placement (Mandelka et al., 2023). Du et al. found an improved accuracy, increased screw diameters and a lower loosening rate in robotic-assisted navigated pedicle screw placement (Du et al., 2022). The results regarding screw diameter/pedicle width ratio in the current study are in accordance with these findings. A higher screw diameter/pedicle width ratio was found in the navigation group, while perforation rates were lower. This effect was more pronounced in the thoracic spine than in the lumbar spine.

Interestingly in this study 9 perforations in the navigation group were observed within the first year after the implementation of the navigation system compared to 4 perforations in the second year which might suggest a learning curve regarding screw placement accuracy. Similar developments have been observed by other authors as well (Rivkin and Yocom, 2014; Hadgaonkar et al., 2023).

Regarding the slightly higher dose area product in 3D-navigated procedures it should be considered that the surgeon and operating room staff leave the control area during acquisition of scans which means that the patients might be exposed to a higher radiation dose but the exposure of operating room staff can be reduced. Villard et al. found that the surgeons radiation exposure was nearly 10 times higher in non-navigated compared to navigated dorsal instrumentation (Villard et al., 2014).

Since this study is a retrospective single-center study there are some limitations regarding the generalizability of the results. While a higher accuracy was observed for navigated procedures the limited number of patients and pedicle screws included in this study prevents this effect from reaching statistical significance. Although the differences in

demographic data and procedure characteristics between the two groups were not statistically different there were minor differences regarding the AO Spine Classification, numbers of segments fused and number of screws. In total there were more segments fused and screws placed in the navigation group which might lead to an underestimation of the advantages of intraoperative navigation especially regarding the duration of surgery. The focus of this study on traumatic fractures of the thoracolumbar junction as the most common site of spinal injuries limits its transferability to other spinal regions or other indications for dorsal instrumentation.

5. Conclusion

This retrospective study suggests that a higher pedicle screw placement accuracy may be reached using intraoperative 3D-navigation, when placing percutaneous pedicle screws in fractures of the thoracolumbar junction compared to standard fluoroscopy. Additionally in this specific study group, the use of navigation did not negatively affect surgery time or radiation exposure.

Contributions

Conception and design of the study: PAG, JG, SYV. Data Acquisition: FB, EM, JG. Analysis and Interpretation of Data: JG, BB, SYV. Writing of the manuscript: FB, JG, BB. Revision of the manuscript: PAG, JG, SYV. All authors have read and approved the final version of the manuscript.

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IRB approval

The study was reviewed and approved by the responsible Ethics Committee (application number 2021–16061). All patients provided verbal and written consent. All procedures were performed in accordance with the ethical standards of the institutional and/or national research committee and the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Data availability

All data and statistics are available on request from the corresponding author.

Declaration of competing interest

PAG reports a relationship with Siemens Healthineers that includes: consulting or advisory and travel reimbursement.

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