ORIGINAL ARTICLE

Robot-assisted spinal augmentation procedures: is it worth the increased effort?

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Abstract

Purpose Spinal augmentation procedures (SAP) are standard procedures for vertebral compression fractures. Often, SAPs are carried out in a minimally invasive, percutaneous way. Certain anatomic conditions such as small pedicles or kyphotic deformities resulting from a significant collapse of the vertebral body might render the operation more difficult and increase the risk of complications. Thus, robot assistance might be useful to optimize the trajectory and to reduce procedure-associated complications. In this study robot-assisted percutaneous SAPs are compared with conventional fluoroscopy-guided percutaneous SAP.

Methods A retrospective observational analysis was carried out. Standard demographic parameters were analyzed. Procedural data including radiation dosage records were screened. Biomechanical data were recorded. Cement volumes were analyzed. The precision of the pedicular trajectory was reviewed, and misplaced trajectories were categorized. Procedure-associated complications were analyzed and evaluated for their clinical significance.

Results A total of 130 procedures were reviewed, and 94 patients were finally included. Osteoporotic fractures (OF) were the main indication (60.7%; OF 2–44%, OF 4–33%). Demographic parameters and clinically relevant complications were equally distributed between the two groups. Duration of surgery was significantly longer in robot-assisted procedures ($p < 0.001$). Intraoperative radiation exposure was equally distributed. Injected cement volume was similar in both groups. There was no significant difference in pedicle trajectory deviation.

Conclusion The use of robot assistance in SAP seems not to be superior with regard to accuracy, radiation exposure and the rate of complications when compared to fluoroscopy-guided SAP.

Keywords Robot-assisted spine surgery · Spinal augmentation procedure · Osteoporosis · Complications

Introduction

About 1.4 million vertebral compression fractures (VCF), mainly caused by osteoporosis but also by malignancies, annually occur worldwide [1, 2]. As a consequence, spinal augmentation procedures (SAP) as a minimally invasive procedure are increasingly performed, above all aiming to reduce pain [3–6]. SAPs are typically performed using fluoroscopy [4]. High accuracy allows to prevent complications in SAP; therefore, image guidance

(spinal navigation) is increasingly used in the last years. One recent further development of image guidance is a spinous process-mounted miniature robot (SpineAssist™, Mazor Robotics, Caesarea, Israel), which has been proven to achieve high accuracy in pedicle-screw placement [7, 8]. Certain anatomic conditions like small/thin pedicles, scoliotic deformities, or kyphosis as a VCF sequela make SAP challenging [9, 10]. In addition, osteoporosis contributes to the challenges in spinal navigation, since the resolution of the intraoperative fluoroscopy image, which has to be matched with the preoperative CT images, is reduced and renders interpretation more difficult. Misplaced trajectories for the Jamishidi needle could either lead to injury of neural or thecal structures and, if not identified and corrected during surgery, to misplacement of cement with its specific complications. Our hypothesis was, that, in comparison with intraoperative fluoroscopy,

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robot-assisted placement of the transpedicular working trajectories for the Jamshidi needles might be useful to improve the SAP results by increased accuracy, leading to higher volumes of cement application with a better restoration of the vertebral body height and, in cases of kyphosis, better deformity correction. Additional hypotheses were, that robot assistance reduces radiation exposure and procedure-associated complications. The objective of this study was to compare robot-assisted SAP with conventional fluoroscopy-guided percutaneous SAP.

Methods

We performed a single-center retrospective observational analysis. The surgical database was screened for the procedures (OPS code 5-839.ax). Our study was carried out in accordance with the 1964 Helsinki Declaration and its later amendments. All patients gave informed consent prior to surgery.

Surgical protocol

SAPs were performed either using conventional two-dimensional fluoroscopic guidance (BV Endura, Philips, Hamburg, Germany) or robot-assistance (Mazor Renaissance™ Mazor Robotics, Caesarea, Israel), both via a percutaneous bilateral approach. All patients were operated in prone position. In case of conventional fluoroscopic guidance, a skin incision was made, followed by fluoroscopy-guided (posterior–anterior and lateral plane) transpedicular placement of Jamshidi needles, followed by K-wire placement. In case of robot-guidance, a preoperative CT was performed, and three-dimensional reconstructions of this CT were used to plan the transpedicular trajectory using the Mazor Renaissance™ planning software. Registration of the Mazor Renaissance™ robot was performed by matching the preoperative CT scans with two intraoperative fluoroscopies [7] (AP view and 60° oblique view, for further details, see [4]). The robotic platform was attached to the iliac crest and a random spinous process using the Hover-T frame (Mazor Robotics, Caesarea, Israel). Pedicle drilling was performed through the guiding tube in direction of the robot-guided transpedicular trajectory followed by the K-wire placement into the vertebral body.

The SAP was performed by placing the kit's introducer over the inserted K-wire, and the procedure was performed according to the manufacturer's protocol [11]. Polymethyl-methacrylate (PMMA) cement was injected with 5 ml syringes under intermittent fluoroscopic monitoring (Fig. 1).

Statistical analysis

Standard descriptive statistics were analyzed as mean values with standard deviation (SD). Procedural data including radiation dosage records were screened. Biomechanical data were recorded. Osteoporotic fractures were categorized based on the OF classification [12]. Cement volumes were analyzed. The precision of the transpedicular trajectory was reviewed, and misplaced trajectories were categorized using the Gertzbein and Robbins classification [13]. Procedural associated complications were noted, analyzed and categorized according to the Clavien-Dindo classification [14]. The two patient cohorts (the fluoroscopy-guided "conventional cohort" and the robot-assistance cohort) were compared using Mann–Whitney test for nonparametric data and Fishers exact test for categorical data, respectively. The entire analysis was performed using SPSS version 23.0. p values < 0.05 were considered significant.

Results

Demographic data

One hundred seven consecutive patients underwent SAP between 2008 and 2018 at our department. Thirteen patients were excluded because additional spinal instrumentation was performed so that 94 patients ($n = 66/70.2\%$ female) were finally included. In those 94 patients, 113 SAPs (88/77.8% robot assisted) were performed. The mean age in the conventional cohort was 72.58 ± 12.22 and 72.81 ± 9.49 in the robot-assisted cohort, respectively. Most VCFs were caused by osteoporosis (59/62.7%), followed by trauma (22/23.4%) and neoplasm (13/13.8%). The demographic baseline parameters are displayed in Table 1.

Treatment data

If multilevel SAP was required, and robot assistance was applied ($p = 0.04$). The pedicle diameter was similar in both groups ($p = 0.08$). In terms of injected cement volume, no significant difference was seen between the two groups ($p = 0.19$). Our analysis for one level revealed that the duration of surgery was significantly longer in robotic-assisted SAP than in the conventional cohort (82.0 ± 36.4 min vs. 101.3 ± 32.8 min, $p < 0.001$). However, when subtracting the time for registration of the spine robot, the mean duration of the SAP procedure per level was 23.2 ± 12.8 min and consequently significantly shorter than in the conventional group ($p < 0.001$). Intraoperative radiation exposure per level (kVp and time, $p = 0.18$ and 0.92, respectively) was equally
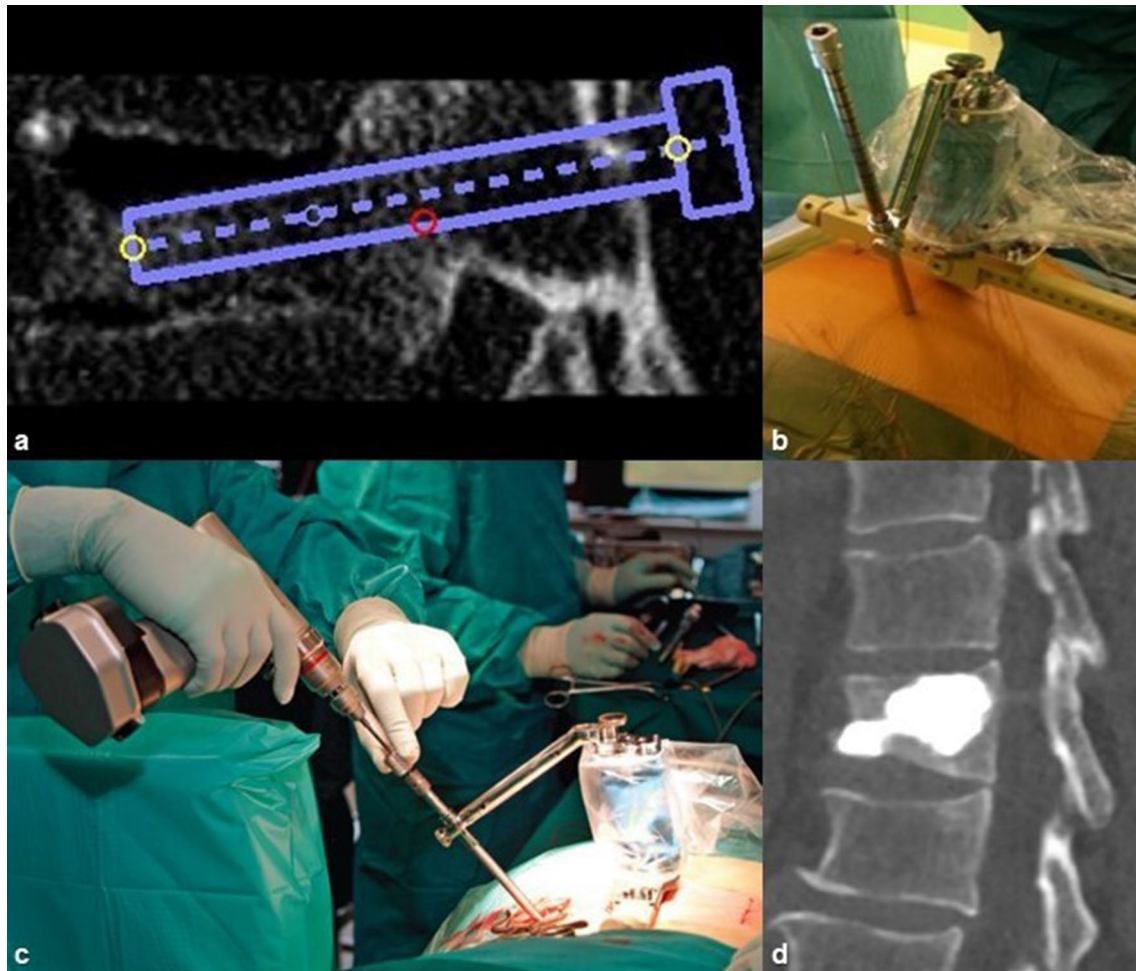
Fig. 1 **a** Preoperative planning of the transpedicular approach using the Mazor Renaissance™ planning software **b** the robot has steered to the suggested trajectory, and the cannula is inserted to the surface of the bone via a stab incision **c** transpedicular drilling is performed, a K-wire is inserted, the cannula is removed, and the kit's introducer is placed over the inserted K-wire **d** every patient received a postoperative CT scan

Table 1 Demographic parameters

	Manual Kyphoplasty $n=24$	Robot-assisted Kyphoplasty $n=70$	p value
Age (SD)	72.58 ($\pm$12.22) y	72.81 ($\pm$9.49) y	0.78
BMI (SD)	25.60 ($\pm$3.61)	26.30 ($\pm$4.98)	0.74
Sex			
Female	16 (66.7%)	50 (71.4%)	0.66
Male	8 (33.3%)	20 (28.6%)	
Osteoporosis	13 (54.2%)	46 (65.7%)	0.54
Trauma	7 (29.2%)	15 (21.4%)	
Neoplasm	4 (16.7%)	9 (12.9%)	

n, number; SD, standard deviation; y, years

distributed. The absorbed radiation dose was slightly higher in the robot-assisted cohort but statistically not significant (0.20 ± 0.15 mGy/m^2 vs. 0.38 ± 0.31 mGy/m^2, $p=0.09$). We did not find a significant difference in the length of stay ($p=0.98$, Table 2).

Complications

The overall complication rate was 6/24 (25%) patients in the conventional cohort and 12/70 (17.1%) patients in the robot-assisted cohort, respectively ($p=0.39$). Symptomatic cement leakage ($p=0.27$), classification of complications according to Clavien-Dindo ($p=0.5$), occurrence of a misplaced transpedicular trajectory based on the Gertzbein and Robbins classification ($p=0.75$), and complications resulting from a misplaced trajectory ($p=0.09$) were equally distributed (Table 3). There was no difference in the occurrence

Table 2 Procedural data

	Manual Kyphoplasty	Robot-assisted Kyphoplasty	*p* value
Operated levels (*n*)	25	88	
Localization			
Thoracic spine	5 (20.0%)	21 (23.9%)	0.33
TLT	12 (48.0%)	51 (58.0%)	
Lumbar spine	8 (32.0%)	16 (18.2%)	
Multilevel SAP	0 (0%)	15 (21.4%)	0.04
Duration (SD) one level	82.05 (± 36.43) min	101.31 (± 32.76) min	< 0.001
Duration (SD) one level sub-tracting registration	82.05 (± 36.43) min	23 (± 12.80) min	< 0.001
LOS	10.92 (± 8.29) days	10.07 (± 6.82) days	0.98
LOS postoperative	6,87 (± 6.56) days	5,67 (± 3.81) days	0.97
Radiation exposure			
Time	141.30 (± 113.94) s	135,44 (± 93,76) s	0.92
kVp	82.55 (± 19.89)	86.77 (± 15.66)	0.15
mAs	3.43 (± 1.92)	3.07 (± 1.22)	0.80
mGy	12.38 (± 9.29)	21.88 (± 17.57)	0.13
mGy/m^2	0.20 (± 0.15)	0.38 (± 0.31)	0.09
Pedicle diameter			
Total	8.47 (± 2.78) cm	7.47 (± 2.84) cm	0.08
Thoracic Spine	5.84 (± 0.82) cm	5.42 (± 1.16) cm	
Thoracolumbar transition	7.93 (± 1.45) cm	7.03 (± 1.69) cm	
Lumbar spine	10.86 (± 3.17) cm	11.48 (± 3.33) cm	
Injected cement volume			
Total	3.62 (± 1.21) ml	3.32 (± 1.66) ml	0.19
Thoracic Spine	3.22 (± 0.51) ml	2.28 (± 0.97) ml	
TLT	2.99 (± 0.86) ml	3.59 (± 1.66)	
Lumbar spine	4.67 (± 1.21) ml	3.85 (± 1.85) ml	

n, number; TLT, Thoracolumbar transition; SAP, Spinal augmentation procedure; SD, Standard deviation; LOS, Length of stay; kVp, peak kilovoltage; s, seconds; mAs, milliampere-seconds; mGy, miligray; mGy/m^2, miligray per squaremeter; cm, centimeter; ml, mililiter

of complications between both groups when adjusting for the thoracic spine (*p* = 0.64).

Discussion

The main result of the study is that robotic assistance does not lead to better results. When compared to "standard" fluoroscopic SAP, accuracy, radiation exposure and length of stay were equally distributed in both groups. The rate of complications was not different, nonetheless, the rate of complications resulting from misplaced transpedicular trajectories was lower in the robot-assisted cohort by trend. But, the use of robotic assistance in SAP is more time-consuming than performing conventional fluoroscopy-guided SAP.

Robotic assistance is useful in pedicle-screw fixation of the spine as higher accuracy, reduced intraoperative radiation exposure, reduced blood loss and shorter postoperative length of stay have been reported in several studies [7, 8, 15–17]. However, there is lack of data concerning the usefulness of robot assistance in SAP. A case series

compared SAP with fluoroscopy guided and navigated procedures. The data showed that the use of navigation significantly decreased the radiation exposure of the surgeon and the operating room staff [18]. This finding is in contrast to our results, as the assistance of the robot fails to significantly reduce radiation exposure. One possible explanation might be that the registration process for the use of robotic technology might be challenging in osteoporosis and obese patients. Osteoporosis per se results in reduced image quality, which might lead to false matches between the preoperative CT scan and the intraoperative X-rays, requiring repeated X-rays for successful registration. The consequence is a higher radiation exposure, as shown in our results. Another explanation might be that the radiation exposure in our conventional cohort was about 20% lower than those being reported in the literature (141.30 ± 113.94 s vs. 175 ± 23 s [18]), thereby eliminating the statistically significant difference between the groups. The substantial influence of the registration process on our results was seen when considering the duration of surgery. Surgery was significantly longer in the robot-assistance group, exclusively due to the registration

Table 3 Complications

	Manual Kyphoplasty	Robot-assisted Kyphoplasty	p value
Complications (n)	6 (25%)	12 (17.1%)	0.39
Cement leakage	13 (54.2%)	26 (37.1%)	0.14
Complications caused by cement leakage	2 (8.3%)	2 (2.9%)	0.27
Localization cement leakage			
Paravertebral	6	8	0.18
Intradiscal	5	7	0.68
Epidural	1	7	0.09
Vascular	1	3	0.26
Intradural	0	1	0.45
Clavien-Dindo classification			
0	18	58	0.5
1	1	6	
2	2	3	
3a	1	1	
3b	1	3	
4a	1	0	
4b	0	0	
5	1	0	
Gertzbein and Robins classification			
A	23 (92.0%)	78 (88.6%)	0.75
B	0 (0.0%)	2 (2.3%)	
C	0 (0.0%)	4 (4.5%)	
D	2 (8.0%)	4 (4.5%)	
Complications due to misplaced puncture	2 (100%)	2 (20%)	0.09
Complication thoracic spine	3 (50%)	5 (41.6%)	0.64

n, number

process. Once the registration was successful, the SAP procedure itself was significantly shorter than in the conventional group, rendering robot-assistance more useful in multilevel than in single-level SAP. In terms of accuracy, cement leakage and complication rate, the robot assistance showed no clear advantages, which questions the suitability and necessity of robot assistance in SAP, despite its undoubted usefulness in pedicle-screw fixation. We did not analyze the costs of the two methods but assume that the costs in the robot-assisted group are higher because of additional single-use material for the registration process.

Strengths and limitations

We acknowledge several limitations in the present study. Data were collected in a retrospective fashion. We did not consider the clinical effect of both methods. In a retrospective post hoc power analysis, we found that our retrospective dataset is well suited to assess radiation exposure and absorbed radiation per level, has limited power to compare duration of surgery and is insufficient to compare complication rates. On the other hand, this is the largest study cohort comparing robot assisted with conventionally performed SAP.

Conclusion

Robot assistance in single-level SAP is time-consuming and seems not to be superior with regard to radiation exposure when compared to fluoroscopy-guided SAP. The rate of complications did not differ in our study, taking the limitations of this study into account. However, for multilevel SAP robot assistance might have a positive effect on the duration of surgery.

Declarations

Conflict of interest On behalf of all authors, the corresponding author states that there is no conflict financial or non-financial interests that are directly or indirectly related to the work submitted for publication.

Ethical approval Our study was carried out in accordance with the 1964 Helsinki Declaration and its later amendments.

Informed consent Due to its retrospective design, informed consent was not obtained.

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