Peer review file

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Reviewer A

Some questions and comments:

Comment 1: Have the authors been trained for other robotic procedures?

Reply 1: Prior to this study, the attending surgeons have undergone robotic cadaveric training, but other than that have had no previous experience. Additionally, the research assistants and resident in this study have experienced similar training as the attending surgeons.

Comment 2: Line 122:" Post-operative 3D fluoroscopic imaging was evaluated using both the axial and sagittal planes". Who did the evaluation? The reviewer purpose the accuracy should be judged by different spine surgeons.

Reply 2: We added this information to our text as advised (see page 10, line 220-221).

Changes in the text: Screw accuracy was evaluated by a research assistant and resident with oversight from the attending spine surgeon.

Comment 3: Line 128 Method "Pedicle Screw Evaluation": does the surgeon himself check the screws accuracy during the decompression procedure? After the operation, these patients underwent CT to confirm the screws accuracy? The evaluation criteria should be shown in the figures.

Reply 3: We have modified our text as advised (see page 4, line 91-94).

Changes in the text: Following pedicle screw placement, all patients underwent an intraoperative scan with a three-dimensional mobile C-arm (Ziehm imaging GmBH, Nuremberg, Germany). Screw position was checked intraoperatively by the attending surgeon.

We have modified our text and added our evaluation criteria as a table (see page 42, Table 1).

Changes in the text: Table 1: Evaluation Criteria - Gertzbein and Robbins System (GRS)

Comment 4: Line 198 “”Screw Position Analysis“” Who did the analysis?

Reply 4: We added this information to our text as advised (see page 10, line 220-221).

Changes in the text: Screw accuracy was evaluated by a research assistant and resident with oversight from the attending spine surgeon.

Comment 5: Line 226 “A total of 17(5.5%) critical breaches (≥2-4mm) were recorded in eleven different patients.” How about those pts? Symptomatic? revised?

Reply 5: We modified our text as advised (see page 12, line 243).

Changes in the text: A total of 17(5.5%) critical breaches (≥2-4mm) were recorded in 11 out of 65 patients (16.9%).

We added this information to our text as advised (see pages 12-13, line 244-252)

Changes in the text: Nine (2.9%) of the critical breaches due to soft tissue pressure onto drill guide from midline incisions, causing displacement from the planned trajectory and resulted in skive. All patients were asymptomatic after surgery and zero patients were taken back for revision surgery in this cohort. The critical breaches that were found and were reported as lateral breaches. As intraoperative breaching was found, the attending surgeon would use intraoperative C-arm and intraoperative 3d fluoroscopy. When breaching was confirmed through intraoperative imaging, the surgeon corrected breaching intraoperatively. The surgeon would remove the RNA placed screw by FH, and place the screw in the proper position to avoid any type of breaching. After the screw was placed, another 3d fluoroscopy image was taken to confirm place and avoid critical breaching.

Comment 6: Also some figures of the robot procedure should be given.

Reply 6: We added figures of the robot procedure to our text as advised (see page 23, Figure Legend, and see page 29, Figure 1).

Changes in the text: Added Figure 1. A: Drill guide during surgical procedure combined with real-time visual feedback from the surgical navigation monitors B: Navigation instrumentation used during procedure C: Navigation monitor showing real-time visual feedback based on positioning of navigated instrument.

Reviewer B

Comment 1: This paper would be strengthened significantly by including a historical cohort for operative times, screw revision rates, and complications. Additionally, there is no patient outcome data.

Reply 1: We added this information to our text as advised (page 15, lines 315- 328).

Changes in the text: When comparing RNA to FH pedicle screw placement in spine surgery, studies have reported FH screw misplacements that have involved implants impinging or deforming the walls of major vascular structures, such as the aorta, common iliac vein, and internal iliac vein. The aorta is the highest risk of surgery in FH pedicle screw placement in the thoracic and thoracolumbar spine (15). Additionally, FH misplacement rates range from 3%-55% in the thoracic spine and 5%-41% in the lumbar spine (15). Studies reported a 12.1% breach rate, 1.1% revision rate, and a 2.3% rate of neurological complications (13). When comparing these results, our data show a lower breach rate of 5.5% all of which were without adverse clinical sequelae. No patients in the study group were taken back to the OR for robotic screw malposition and no neurological complications were observed.

We added this information to our text as advised (see page 18-19, line 407-419).

Changes in the text: Reoperation rates secondary to pedicle screw misplacement were estimated from nationally available data (23). Schröder et al. reported a study with 94 patients, none of the pedicle screws required intraoperative repositioning, and conversion to an open procedure was never required (23). There were no implant-related revisions or complications, which were assessed clinically rather than on postoperative radiological studies, to avoid excessive radiation exposure (23). Kantelhardt et al reported the rate of revision surgery for screw malposition was significantly higher in the freehand pool than in the robotic guided pool. However, the navigated technique tended toward more revisions in which many of the malpositioned screws were detected intraoperatively and immediately revised (5). Therefore, no significant difference was observed in postoperative revision rates between the navigated group and the robotic guided group (5). Similarly, to Schröder and Kantelhardt's intraoperative pedicle screw positioning, our study detected malpositioned screws intraoperatively and immediately revised with 3D fluoroscopy.

We added this information to our text as advised (see page 19-20, lines 421-434).

Changes in the text: In addition to that, Schröder et al. reported average skin-to-skin time of surgery to be 161 ± 50 minutes (2.6 ± 0.8 hours) (23). Bai et al. compared a learning curve between two surgeons for computer-assisted navigation (CAN) group and conventional intraoperative image intensifier (CIII) group and only considered the cases after 6 months of computer-assisted navigation (CAN) was implemented. There was a significant (p=0.026) decrease in operative time for the CAN group of surgeon A, 106.9 versus 121.3 minutes for the conventional intraoperative image intensifier (CIII group), averaging 14.4 minutes less per case in the CAN group (25). A more significant (p=0.003) decrease in operative time for the CAN group was seen with surgeon B's cohort; 158.0 for CAN patients versus 189.8 minutes (25). In our study, we recorded the total of 65 surgical cases skin to skin surgery time to be 306 ± 42 min (5.1 ± 0.7 hours). Surgical cases compromised of 16 (24.6%) done via the anterior-posterior approach, 27 (41.5%) with the lateral-posterior approach, and 22 (33.8%) with only a posterior approach. RNA skin start time and skin closing were recorded in all cases, with an average time of 200 ± 6 min (2.1± 0.1 hours), which is a 65.4% decrease in total time (p=0.04).

We added this information to our text as advised (see page 8, lines 160-164).

Changes in the text: During each scheduled post-operative visits, including their preoperative visit, patients fill out their patient reported outcome measures (PROMs), which are questionnaires that will assess patient's health and quality of life. PROMs include: Modified Oswestry Low Back Disability Questionaire (ODI), Scoliosis Research Society (SRS-22r), and the Numeric Rating Scale (NRS) for back and leg pain.

We added this information to our text as advised (see page 12-13, lines 261-270).

Changes in the text: Clinical outcomes were recorded during each preoperative and postoperative visit, where patients filled out their patient reported outcome measures (PROMs): Modified Oswestry Low Back Disability Questionaire (ODI), Scoliosis Research Society (SRS-22r), and the Numeric Rating Scale (NRS) for back pain and leg pain.

All postoperative visit scores were compared to final preoperative visit scores, and on average scores decreased throughout each visit. ODI scores decreased by 27.8% form 41.3 ±16.9 (p=0.005), NRS leg pain decreased by 39.1% from 6.4 ± 2.7 to 2.6 ± 2.5 (p=0.044) and NRS back pain scores decreased by 70.4% from 7.1 ± 2.4 to 5.0 ± 2.7 (p=0.049). SRS-22r on average did show a decrease of scores over time and did not show statistical significance.

Comment 2: The technical notes are valid, but their accuracy data carries little significance without outcome data to support it.

Reply 2: We added this information to our text as advised (see page 8, lines 160-164).

Changes in the text: During each scheduled post-operative visit, including their preoperative visit, patients fill out their patient-reported outcome measures (PROMs), which are questionnaires that will assess patient's health and quality of life. PROMs include Modified Oswestry Low Back Disability Questionaire (ODI), Scoliosis Research Society (SRS-22r), and the Numeric Rating Scale (NRS) for back and leg pain.

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All postoperative visit scores were compared to final preoperative visit scores, and on average scores decreased throughout each visit. ODI scores decreased by 27.8% form 41.3 ±16.9 ($p=0.005$), NRS leg pain decreased by 39.1% from 6.4 ± 2.7 to 2.6 ± 2.5 ($p=0.044$) and NRS back pain scores decreased by 70.4% from 7.1 ± 2.4 to 5.0 ± 2.7 ($p=0.049$). SRS-22r on average did show a decrease of scores over time and did not show statistical significance.

Comment 3: The title is not descriptive enough. K-wireless robot assisted surgery is not novel in itself. Perhaps they could refocus the reader by including phrases like "technical notes from the learning curve" in the title.

Reply 3: We have modified our text as advised (see page 1, lines 1-2)

Changes in the text: Title: Evaluation of K-wireless Robotic and Navigation Assisted Pedicle Screw Placement in Adult Degenerative Spinal Surgery: Learning Curve and Technical Notes.

Comment 4: This manuscript is missing a limitations section. Limitations must include lack of clinical outcome data, and lack of a control group. The authors must also acknowledge that accuracy in itself is not a clinically important outcome, and that further study must be done to determine if this new technology improves patient outcomes or has cost savings compared to existing techniques. Also, the authors should acknowledge that cost-effectiveness of implementing robotic technology remains to be studied.

Reply 4: We added this information to our text as advised (see page 21, lines 464-466)

Changes in the text: Furthermore, this study has a lack of a control group and further studies must be done to determine if new technology has cost savings compared to existing techniques.

Specific comments:

Comment 1: Including "navigation" when referring to robot-assisted spine surgery is not necessary, as I am unaware of a robotic system that does not utilize stereotactic navigation. In my opinion, "robot-assisted spinal surgery" is likely the most apt term.

Reply 1: Older generations of Mazor software systems did not include navigation. You are correct, current and modern robots utilize stereotactic navigation. Older generations of Mazor robotics, specifically the SpineAssist robot was the first K-wire based robot and the first generation of its kind. Since then, Mazor introduced additional robots the Renaissance and Mazor X both of which were K-wire based systems and did not feature navigation. In 2017 Globus Medical introduced their version of a robotic arm that is based on navigation. Medtronic in 2018 purchased Mazor and integrated its navigation system with the Mazor robot introducing the Mazor X Stealth Edition.

Comment 2: If screws were "planned robotically," 15 screws cannot have a reason to not be placed robotically as "planned freehand."

Reply 2: In our study, we tried to implement robotics in all aspects of our surgical cases. Before each case, the attending surgeon reviews a pre-operative plan of screw and rod placement for each patient. We established three categories for a method of screw placement which consisted of screws either being planned and placed robotically navigated (RNA), screws planned robotically but were either converted to K-wire (KW), or freehand (FH) techniques and screws that were not planned robotically but were decided to be placed freehand during preoperative planning. Fifteen screws, in particular, were decided not to be planned robotically, under the attending surgeon's discretion.

Comment 3: "Morphology and spinal instability from isthmic spondylolisthesis skive with a breach (0.3%) occurred in one patient." This sentence from the abstract needs to be rewritten to make sense. I think in the manuscript they included the words "Due to."

Reply 3: We have modified our text as advised (see page 2, lines 25-26).

Change in the text: One patient (0.3%) experienced skive due to morphology and spinal instability from isthmic spondylolisthesis.

Comment 4: "A total of 17(5.5%) critical breaches (≥2-4mm) were recorded in eleven different patients." This is misleading. The rate of critical breaches is 11 out of 65 patients (17%). This number must be reported and acknowledged as more important than 5.5% of screws.

Reply 4: We have modified our text as advised (see page 11, line 243).

Changes in the text: A total of 17(5.5%) critical breaches (≥2-4mm) were recorded in 11 out of 65 patients (16.9%).

Comment 5: "While fluoroscopy has been reported to offer significant improvements, there are risks that remain, such as . . . intraoperative radiation exposure." I think the authors meant to say "radiation exposure for surgical staff." It should be noted in the manuscript that two intra-operative 3D fluoro scans is likely more radiation for the patient.

Reply 5: We have modified our text as advised (see pages 3, lines 64-66).

Changes in the text: While fluoroscopy has been reported to offer significant improvements, there are risks that remain, such as nerve injury, vascular injury, and radiation exposure to surgical staff.

Comment 6: "Robotic navigation offers solutions to address these risks while improving surgical efficiency . . . to improve patient outcomes." There is no published evidence that robot-assisted spinal surgery improves outcomes.

Reply 6: We have modified our text as advised (line was removed).

Comment 7: While "time per screw" data is interesting, total case time needs to be reported/ Preferably it would be compared to a matched, historical cohort.

Reply 7: We have added our text as advised (see page 19-30, lines 421- 434).

Changes in the text: In addition to that, Schröder et al. reported average skin-to-skin time of surgery to be 161 ± 50 minutes (2.6 ± 0.8 hours) (23). Bai et al. compared a learning curve between two surgeons for computer-assisted navigation (CAN) group and conventional intraoperative image intensifier (CIII) group and only considered the cases after 6 months of computer-assisted navigation (CAN) was implemented. There was a significant (p=0.026) decrease in operative time for the CAN group of surgeon A, 106.9 versus 121.3 minutes for the conventional intraoperative image intensifier (CIII group), averaging 14.4 minutes less per case in the CAN group (25). A more significant (p=0.003) decrease in operative time for the CAN group was seen with surgeon B's cohort; 158.0 for CAN patients versus 189.8 minutes (25). In our study, we recorded the total of 65 surgical cases skin to skin surgery time to be 306 ± 42 min (5.1 ± 0.7 hours). Surgical cases compromised of 16 (24.6%) done via the anterior posterior approach, 27 (41.5%) with the lateral posterior approach, and 22 (33.8%) with only a posterior approach. RNA skin start time and skin closing was recorded in all cases, with average time of 200 ± 6 min (2.1± 0.1 hours), which is a 65.4% decrease in total time (p=0.04).

Comment 8: "Within the axial plane, the first ten cases had an average displacement of 2.9 ± 0.6 mm from preoperative plan, which was not significantly greater when compared to the last ten cases that reported an average of 1.3 ± 0.5mm." May need to recheck the stats on this finding.

Reply 8: We have modified our text as advised (see page 11, lines 224-227).

Changes in the text: Within the axial plane, the first ten cases had an average displacement of 0.8 ± 0.7mm from preoperative plan, which was not significantly less than when compared to the last ten cases that reported an average of 1.0 ± 0.8mm.

Comment 9: "There was statistical significance found in pedicle screws that had the same screw trajectory and position as the preoperative plan. In addition to that, registration time between the first to last ten cases and speed of workflow was found to be significant as the study proceeded." These sentences need to be rewritten. I think they intend to say "statistically significant improvements" and/or "reductions."

Reply 9: We have modified our text as advised (see pages 14, lines 298-299).

Changes in the text: Throughout this study, statistically significant improvements were found in pedicle screws that had the same screw trajectory and position as the preoperative plan.

Comment 10: "...with a fellowship-trained attending adult spine surgeon performing all left all the right-sided surgeries, under direct supervision and guidance of the attending surgeon." Please rewrite this sentence.

Reply 10: We have modified our text as advised (see pages 21, lines 453- 458).

Changes in the text: This study has several limitations, one limitation is that surgeries were performed by a single fellowship-trained attending spine surgeon, who has 10+ years in practice and recorded a learning curve experience. The attending spine surgeon performed all the left side of surgeries, and the majority of the right side of surgeries were performed by surgical assistants, such as residents, fellows, physician assistants, under direct supervision and guidance of the attending surgeon.

Comment 11: "Additionally, RNA screw placement was as fast as, if not quicker than FH or KW technique relatively early in the surgeon experience of 65 cases." There is no data presented in the paper to support this statement.

Reply 11: We have modified our text as advised (line was removed).