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Cirq® robotic assistance for thoracolumbar pedicle screw placement – feasibility, accuracy, and safety

Nikolay Gabrovsky *, Petar Ilkov, Maria Laleva

Department of Neurosurgery, University Hospital "Pirogov", Sofia, Bulgaria

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ABSTRACT

Introduction: New technologies providing higher degree of precision, less risk for damage and less harmful exposure to radiation are necessary for correct transpedicular screw trajectory, but their efficacy should be evaluated.
Research Question: Evaluate the feasibility, accuracy and safety of Brainlab Cirq® navigated robotic arm assistance for pedicle screw placement in comparison to fluoroscopic guidance.
Material and Methods: Group I "Cirq® robotic-assisted group" – 97 screws in 21 prospectively analyzed patients. Group II "Fluoroscopy-guided group" – 98 screws in 16 consecutive patients analyzed retrospectively. Comparative evaluations included screw accuracy on Gertzbein-Robbins's scale and fluoroscopy time. Time per screw and subjective mental workload (MWL) measured with the raw NASA task load index tool were assessed for Group I.
Results: 195 screws were evaluated. Group I: 93 screws grade A (95.88%); 4 grade B (4.12%). In Group II, 87 screws grade A (88.78%); 9 grade B (9.18%); 1 grade C (1.02%); 1 grade D (1.02%). While the screws placed using the Cirq® system were more accurate overall, there was no statistical significance between the two groups, $p=0.3714$. There was no significant difference in operation length or radiation exposure between the two groups, however with the Cirq® system the radiation exposure for the surgeon was limited. Reduction in time per screw ($p<0.0001$) and in the MWL ($p=0.0024$) correlated with the surgeon's experience with Cirq®.
Discussion and Conclusion: The initial experience suggests that navigated, passive robotic arm assistance is feasible, at least as accurate as fluoroscopic guidance, and safe for pedicle screw placement.

1. Introduction

Transpedicular screw fixation has become a paramount step for the treatment of a wide variety of spinal pathologies. The correct screw trajectory is of critical importance and misplacement may lead to injury of neural, vascular structures or reduced stability of the instrumentation. Consequently, there is a need for new technologies providing higher degree of precision, less risk for damage to neurovascular structures and less harmful exposure of patients and the operative team to ionizing radiation. Introduction of computer assisted navigation and surgical robotic technology has a promising potential for achieving these goals. However, it is imperative to objectively look at the efficacy of these systems and the benefit they bring to the operating room.

The aim of this study is to evaluate the feasibility, accuracy and safety of pedicle screw placement using navigated Brainlab Cirq® passive robotic arm.

2. Materials and methods

This is a prospective study which includes 97 screws in 21 patients who underwent robot-assisted pedicle fixation utilizing Brainlab Cirq® arm coupled with Brainlab Curve® navigation system (Group I). The study included all consecutively admitted patients planned to undergo stabilization procedure that involves pedicle screw placement between February 2021 and April 2021. The control group includes 98 screws placed with conventional freehand technique and fluoroscopic guidance in 16 consecutive patients with retrospectively collected data (Group II).

2.1. Robotic-assisted technique

The equipment used consisted of intraoperative Siemens Arcadis Orbic 3D C-arm in conjunction with Curve® Navigation and Cirq® Alignment spine (Brainlab AG, Munich, Germany), and cannulated transpedicular screw system (Armada, Nuvaisive). Under general

* Corresponding author. Department of Neurosurgery, University Hospital "Pirogov", 1606, Sofia, Bulgaria.
E-mail address: gabrovsky@gmail.com (N. Gabrovsky).

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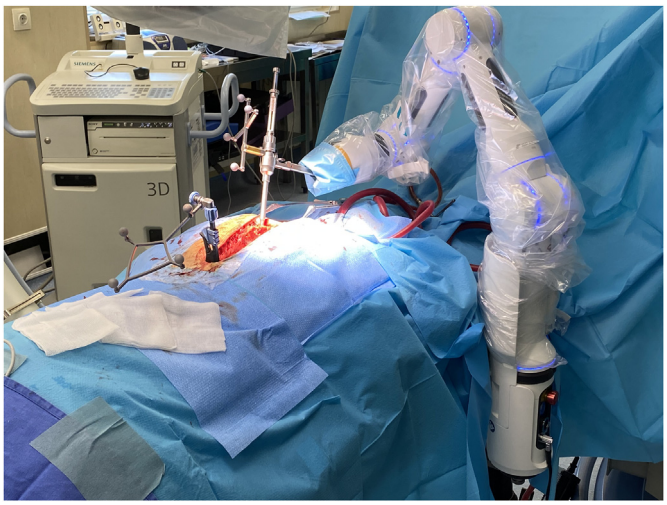

Fig. 1. A reference array is attached to a spinous process, usually caudal to the operative field. Cirq® is aligned and locked within the desired screw trajectory.

anesthesia, the patient is placed prone on a radiolucent table. Cirq® is directly mounted to the O.R. table rail. The surgical field and the Cirq® arm are prepared and draped. After the completion of the surgical approach (conventional or minimally invasive), a reference array is attached to a spinous process, usually caudal to the operative field (Fig. 1). Attaching the reference array caudally regarding the operative field was found to be more comfortable because in this way the robotic arm doesn't interfere with the infrared camera line of sight. A 3D X-ray scan is completed, images are automatically transferred to the Curve® Navigation system. Navigation tools are then registered. In cases of a minimally invasive spinal surgery (MISS) procedure a navigated probe is used to plan the skin incisions. Cirq® is then engaged, aligned, and locked within the desired screw trajectory. A 3.2-mm drill is used through the cannula on the robotic arm to create a pilot hole, after which a K-wire is inserted. The procedure is repeated for each pedicle. Position of the K-wires is confirmed with anterior-posterior (AP) and lateral fluoroscopy. Once good positioning is confirmed, cannulated screw insertion is performed along the K-wire using standard MISS technique. The position of the screws is reconfirmed either with AP/lateral fluoroscopy or a new 3D scan.

2.2. Fluoroscopy-guided technique

In the fluoroscopy-guided group (Group II), the pedicles were tapped, and the screws were inserted using anatomical landmarks and AP/lateral fluoroscopic guidance. Either standard open approach or MISS was used.

The primary endpoint was pedicle screw placement accuracy assessed by the Gertzbein-Robbins's method of measuring screw placement deviation with grades from A to E. Grade A was no breach/deviation, grade B was breach <2 mm, grade C was breach< 4 mm, grade D was breach <6 mm, and grade E was breach >6 mm (Gertzbein and Robbins, 1990). Breach direction (cranial, lateral, caudal, or medial) was also recorded. Rating of grade A or B was considered clinically acceptable.

All patients underwent postoperative CT scan. Axial, coronal, and sagittal reconstructions were used to assess the accuracy of screw placement according to the Gertzbein-Robbins scale. The slice with the largest deviation from the pedicle was chosen for grading. A radiologist and a neurosurgeon evaluated all CT scans in both groups using Siemens Syngo.plaza software.

Secondary endpoints included the time to place one screw, radiation exposure time and subjective mental workload (MWL) assessed using the raw NASA task load index (NASA TLX) tool (Hart, 2006). Time to place one screw was measured intraoperatively by additional personnel using a chronometer from the moment Cirq® was engaged until the screw was securely seated. Radiation exposure time for each patient was measured and recorded automatically by the C-Arm. The learning curve was assessed by how long it took a single surgeon to place one screw with increasing number of cases and analysis of the correlation between MWL and experience.

2.3. Statistical analyses

The patient sample size to be enrolled in this study was calculated using the following parameters: 1. Procedure: Non-inferiority; 2. Design: Parallel; 3. Endpoint: Binary; 4. Power: 0.9; 5. Significance level: 0.05; 6. non-inferiority limit: 0.1; The number of screws was calculated to be 59. At least 4 screws must be placed per patient, therefore, the total number of patients to be enrolled is 15.

Statistical analyses were performed using IBM SPSS Statistics version 22.0 and Prism 8 GraphPad statistical software. Mann-Whitney test was used to compare the differences in operation length, radiation exposure and accuracy of screw insertion between Group I and Group II. The correlation between experience in using the Cirq® robotic arm and shorter screw insertion times as well as a lighter subjective mental workload were analyzed using correlation matrix, linear and non-linear regression models. A p value of <0.05 was considered statistically significant.

3. Results

A total of 195 screws were placed at 109 levels in 37 patients. Treated levels ranged from T3 to S1. The average patient age at the time of surgery was 51.4 years (range 13–76 years), 17 were male and 20 females. The pathology was traumatic in 15 cases, degenerative in 12, oncologic in 8 and infection in 2 cases (Tables 1 and 2). In the robotic-assisted group (Group I; n = 21; 97 screws), 93 screw placements were grade A (95.88%); 4 were grade B (4.12%) - two lateral, one medial and one cranial; grade C and D – 0. Average screw diameter to pedicle width ratio for this group was 0.77. No revision surgeries were needed, the postoperative period for all patients was uneventful, all patients were verticalized, mobilized and discharged according to the standard protocol of the department. In the conventional group (Group II, n = 16; 98 screws), 87 screw placements were grade A (88.78%); 9 were grade B (9.18%) - 6 lateral and 3 medial; 1 was grade C (1.02%) - lateral and one was grade D (1.02%) - lateral. Average screw diameter to pedicle width ratio for this group was 0.79. When comparing the two groups using a non-parametric Mann-Whitney test we found better accuracy with the use of Cirq®

Table 1
Type of pathology, age, and sex distribution for Group I.

	Gender	Age	Pathology
patient 1	male	37	traumatic
patient 2	male	64	degenerative
patient 3	female	66	oncologic
patient 4	female	16	degenerative
patient 5	female	76	degenerative
patient 6	male	13	oncologic
patient 7	female	60	traumatic
patient 8	female	44	traumatic
patient 9	male	57	oncologic
patient 10	male	67	degenerative
patient 11	female	72	infection
patient 12	female	58	traumatic
patient 13	male	60	degenerative
patient 14	female	56	oncologic
patient 15	male	48	degenerative
patient 16	male	70	traumatic
patient 17	male	67	degenerative
patient 18	female	46	degenerative
patient 19	male	41	traumatic
patient 20	female	72	traumatic
patient 21	male	51	infection

Table 2
Type of pathology, age, and sex distribution for Group II.

	Gender	Age	Pathology
patient 1	female	68	traumatic
patient 2	male	51	oncologic
patient 3	female	42	traumatic
patient 4	female	21	traumatic
patient 5	male	34	degenerative
patient 6	female	19	traumatic
patient 7	female	70	degenerative
patient 8	male	64	oncologic
patient 9	female	29	oncologic
patient 10	female	48	traumatic
patient 11	male	31	traumatic
patient 12	female	62	degenerative
patient 13	female	55	degenerative
patient 14	female	60	traumatic
patient 15	male	51	oncologic
patient 16	male	54	traumatic

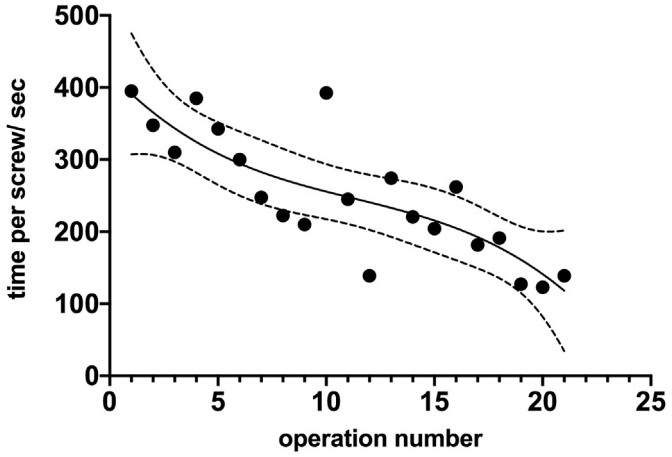

Fig. 2. There was a significant reduction in the time spent per screw with the increase in the surgeon's experience in using the robotic arm ($p < 0.001$, ***) as determined by a correlation matrix analyses where r = −0.814, R^2 0.6626. Curve estimation regression demonstrated best fit with a cubic regression model where $R^2 = 0.6791$, B0 = 420.6, B1 = −31.56, B2 = 2.132 and B3 = −0.06264, represented by the central curve above. The two curves parallel to it represent the 95% confidence interval with B0: 300.6 to 540.5, B1: -77.7 to 14.58, B2: 2.682 to 6.946, B3: -0.2067 to 0.081.

robotic arm, however no statistical significance was yielded with our current sample, $p = 0.3714$.

There was no significant difference in the operation time length (Group I, 210.0 min [130.00–260.00]; Group II, 180.0 min [100.00–280.00], $p = 0.2734$) or radiation exposure (Group I, 98.00 s [78.00–159.00]; Group II, 110.0 s [53.00–121.00], $p = 0.5492$) to the patient between the two groups. However, the radiation exposure for the surgical team in Group I was limited compared to Group II as they were outside of the operation room during the 3D image acquisition and fluoroscopy control.

There was a significant correlation between the increasing experience of the surgeon with Cirq® robotic arm and the reduction of time to place one screw (Group I, $p < 0.0001$, r −0.8140, R^2 0.6626) (Fig. 2). The mean time per screw was 250.45 s [123.00–395.00] or 4.2 min. There was also a significant reduction in the NASA TLX index over time with using the robotic arm. ($p = 0.0024$, r −0.627, R^2 0.3925) (Fig. 3). Curve estimation analyses demonstrated best fit with a cubic regression model in both cases.

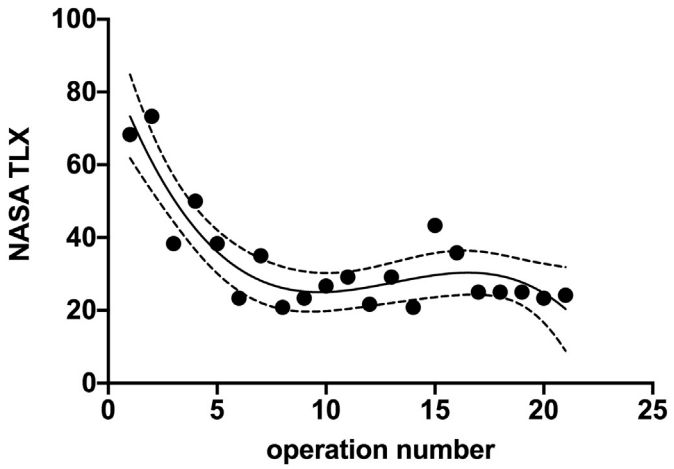

Fig. 3. There was a significant reduction in the subjective mental workload score of the surgeon, represented by NASA task load index (TLX), with increasing experience in using the Cirq® robotic arm system. Correlation analyses between the two showed statistical significance with $p = 0.0024$ **, r = −0.627, $R^2 = 0.3925$. The curve shown above demonstrates the relationship between the two variables and represents a cubic regression model that best fits the data. $R^2 = 0.7878$, B0 = 88.27, B1 = −16.23, B2 = 1.328, B3 = −0.033. The space between the two parallel curves on either side delineates the 95% confidence interval with ranges of B0: 71.81 to 104.70, B1: -22.56 to −9.89, B2: 0.67 to 1.99, B3: -0.05 to −0.01.

4. Discussion

Transpedicular screw fixation has been performed for decades and presents a crucial step in the treatment of a wide variety of spinal pathologies such as trauma, deformity, oncology, degenerative disease, and infection. Accurate placement of pedicle screws is essential for achieving stability of the spinal construct as well as avoiding damage to neural and vascular structures. Consequently, there has always been a search for new technologies providing higher degrees of precision, less risk for damage to neurovascular structures and less harmful radiation exposure. As a result of this search over the past several decades, spine surgery has seen many innovations in operative techniques, implants, and equipment such as software for pre-planning screw size and trajectory, intraoperative CT, computer-assisted navigation and, what could probably become a game changer for spine surgery, the emerging robotic platforms. Multiple manufacturers have introduced robotic systems for use in spine surgery, however, in general they all share a similar workflow. First 3D imaging modality obtained either with preoperative CT or intraoperative fluoroscopy, CT or 3D C-arm is registered into the coordinate system of the computer navigation. Then the software of the navigation is used for preoperative planning of screw size and trajectory and finally a navigated robotic arm usually with an instrument guide is used for creating a pilot hole in the pedicle and the screw is placed. In this respect, the current generation of surgical robots do not operate autonomously, instead they are additional tools for achieving good and consistent results in spine surgery (Khalsa et al., 2021). Depending on their function, autonomy and the level of assistance provided, the existing robotic platforms could be classified as passive, semi-active or active systems. The first-generation surgical robots, represent a mechanical guidance unit, that is pre-attached to the spine. The second group are systems with active robotic arms, which means that the arm moves autonomously and is automatically positioned according to the preplanned trajectory. In this study, we utilized the recently released Cirq®robotic arm for pedicle screw placement. Cirq® is table-mounted robotic arm that uses the same described above workflow principle as the active robotic platforms, but the positioning of the arm is not automatic and relies on “passive” robotics,

where the position of this robotic arm is directly controlled by the surgeon, who manually aligns the trajectory according to the navigation data (Krieg and Meyer, 2018). Once the Cirq® arm is aligned in the appropriate trajectory, the position is locked in place to provide a rigid guide. In our series we did not preplan the screws to the desired trajectory which is also possible with the system but instead we aligned Cirq® according to a trajectory obtained in real time during the surgery. In our opinion this allowed us to achieve surgery duration time results for the robotic group similar to the conventional group. Literature reports slightly longer operative times for the robotic-assisted group which is not surprising given the features specific to the robotic-assisted technique (such as a robot mounted to the patient and the use of navigation software) represent additional challenges for surgeons. If the surgeon is able to safely avoid additional steps for planning the screw trajectory, positioning the robotic arm etc., this might help to achieve better results regarding time to place one screw and total operative time (Lonjon et al., 2016; Roser et al., 2013).

Probably, the most important advantage of robotic surgery is lower radiation exposure, especially for the surgeon. It has been demonstrated that ionizing radiation exposure is considerably higher in spinal surgery than in other subspecialties for all operating room staff (Theocharopoulos et al., 2003). This has become even more valid in recent years with the wide adoption of minimally invasive spinal surgery techniques. Computer assisted navigation and robotic spinal surgery have the potential to lower the X-ray exposure to both patient and surgeon in comparison to traditional fluoroscopic guidance without a significant increase in operative time (Kim et al., 2008). Fomekong et al. proved that the cumulative radiation exposure remained below measurable levels with the use of robotic systems (Fomekong et al., 2017). Fan et al. reported that the average fluoroscopy time for screw placement with robotic assistance was 4.02 $\pm$ 1.6 min vs 8.89 $\pm$ 3.1 using the free hand technique (Fan et al., 2017). In our study there was also no significant difference in radiation exposure time between the robotic assisted group and the fluoroscopy guided group (Group I, 125.1 $\pm$ 52.64 s; Group II, 102.5 $\pm$ 21.46 s; $p = 0.794$) for the patient. The radiation exposure time for the patients in the robotic group (Group I) was mostly due to the 3D fluoroscopic preregistration and was higher in the cases that needed a second intraoperative 3D scan. However, the radiation exposure for the surgical team in this group was very limited in comparison to the fluoroscopy guided group, as they were outside of the operation room during the image acquisition and fluoroscopy control.

Probably the most discussed topic in the literature on spinal robotic spine surgery is screw accuracy. As previously mentioned, the correct screw trajectory is of critical importance and misplacement may lead to injury of neural or vascular structures, or reduced stability of the instrumentation (Hicks et al., 2010). The accuracy of pedicle screw placement for conventional fluoroscopic guided and freehand techniques depends mainly on the anatomical landmarks and the experience of the surgeon. Malposition rates in conventional screw placement series can be significant as in studies analyzing postoperative CT scans, these rates could reach up to 15.7% although the frequency of symptomatic cases is still relatively low (Gautschi et al., 2011). In minimally invasive spine surgery, the rate of this complication could be even higher because of the lack of visible anatomical landmarks. The computer assisted navigation systems and emerging robotic platforms have the potential to reduce screw misplacement rates, including in minimally invasive procedures. Several studies have been published in recent years examining the safety and accuracy of robotic-assisted pedicle screw placement versus fluoroscopic guided and free-hand placement. Huyn et al. demonstrate 100% clinically acceptable screw accuracy with the use of the Mazor Renaissance robotic platform (Hyun et al., 2017). Lonjon et al. achieved 97.3% accuracy in the robotic group versus 92% for the conventional group (Lonjon et al., 2016). Several other studies also demonstrate over 95% accuracy with robotic assisted pedicle screw placement utilizing different platforms (Fan et al., 2018; Li et al., 2020). As far as we know our study is the first to evaluate the feasibility, accuracy, and safety of pedicle screw placement using Cirq® robotic arm assistance. We have found all the screws placed with the technique to be clinically acceptable (Gertzbein-Robbins's grades A and B). Despite the limitation of the small series, we can conclude that pedicle screw placement with the Cirq® is safe and at least as accurate as fluoroscopic guidance and good results could be achieved early on.

In this study we assessed the learning curve by analyzing the decrease of the time to place one screw with increasing number of cases and the correlation between MWL and experience. Our results suggest that proficiency with the technique is achieved relatively rapidly. However, a larger and less heterogenic patient sample is needed to better define the learning curve of Cirq® robotic assisted pedicle screw placement. Other authors suggest that the learning curve for robotic-assisted spine surgery lies in the range between 20 and 50 cases (Jiang et al., 2020; Kam et al., 2019).

When troubleshooting the reasons for reduced accuracy with the Cirq® system we analyzed the cases with B-graded screws by comparing the intraoperative screenshot from the navigation with the postoperative CT. We found a difference between the navigated trajectory and the achieved result. In our opinion this is a result of a possible slippage of the tubular instrument guide of the Cirq® on the facet. Such slippage was observed mainly in cases with advanced degenerative changes of the articular facets. We found that this could be avoided if the surgeon firstly localizes the desired entry point with the navigated pointer and opens the cortical bone with a high-speed drill or a rongeur before engaging Cirq®. Another way to avoid slippage of the guide, especially in minimally invasive cases, is to first advance the drill a few millimeters in the bone and then use its tip as a pivot point to adjust the desired trajectory.

5. Conclusion

The aim of robotic assistance is to further improve modern spinal surgery by increasing accuracy, dexterity, consistency of the results and safety. Our initial results suggest that transpedicular screw fixation can be performed effectively and safely using navigated, passive robotic arm assistance, but accuracy and operative time is similar to conventional technique. Further evaluation of a larger cohort is required to confirm our conclusions and elaborate on future applications, limitations, and areas of improvement.

Ethical approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. The study was approved by the local Institutional ethics committee of University Hospital “Pirogov”.

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Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Nikolay Gabrovsky reports financial support as a research grant was provided by Brainlab AG (Munich, Germany) as part of a research agreement with University Hospital “Pirogov”.

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