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Evaluation of a New Unified Robotic Platform: a Cadaver Study

Nicolas Lonjon[1], Guillaume Cavalié[2], John Sledge[3] and Mehdi Boudissa[2]

[1] Montpellier University Hospital, Montpellier, 34295, France

[2] Grenoble University Hospital, La Tronche, 38700, France

[3]The Lafayette Bone and Joint Clinic, Lafayette, LA 70508, USA.

n-lonjon@chu-montpellier.fr

Abstract

The Spine Cobot System (eCential Robotics, France) is a new platform which unifies 2D/3D imaging, navigation and a robotic arm. The intent is to increase patient and surgeon safety without adding time or complexity to the surgical workflow. The primary endpoint of this cadaveric trial is to assess the precision and safety of pedicular screw positioning. The secondary endpoint is to confirm the system's usability by the operative team. The Spine Cobot System is composed of a C-arm, a station which includes the software, an infrared camera and a collaborative robotic arm (cobot). Screw placement and neural safety were assessed. Precision of screw placement was determined by comparing the final 3D acquisition to the surgeon's planned trajectory. Safety was quantified by 3 blinded surgeons using the Gertzbein-Robbins classification. Additionally, the usability of the integrated system for spine surgery was assessed. A system evaluation was performed in compliance with international standards (IEC, FDA). Three experienced surgeons placed 90 pedicular screws in 3 prone cadavers. 100% (90/90) of the screws were accurately placed according to the Gertzbein-Robbins classification. 97% (87/90) were classified as Grade 0 and 3% (3/90) as Grade 1. The average pilot hole middle point distance deviation is 1.3mm$\pm$0.88 mm. The average pilot hole angular deviation is 0.6°$\pm$0.6°. Only 2 usability errors were observed during the workflow assessment, and none was critical for patient safety. This preliminary study shows the efficiency of the system for pedicular screw placement, with precision and safety results. This confirms the functionality of a unified system for usability and effectiveness.

1 Introduction

As spinal instrumentation is increasingly used in clinical practice, regulations pertaining to spinal surgery have been strengthened to ensure procedural safety [1]. Robotic systems could have the potential to improve surgical outcomes, including pedicle screw insertion [2][3]. They are used alternatively to fluoroscopic approaches to improve precision as well as to reduce patient and surgeon radiation doses [4][5][6].

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2 Materials and methods

2.1 Platform description

The Spine Cobot System is composed of a robotic 3D C-arm, a navigation station which includes the software, an infrared camera and a collaborative robotic arm (cobot) [**Figure 1**]. The imaging and navigation modules have been used clinically since 2018 (CE-marked) [7].

The robotic arm is currently under validation and aims at providing the same precision for the surgeon as during the planning step. It can be handled in 2 modes: manual (arm positioned near the targeted zone) and automatic (arm aligned with the planned trajectory while following patient motions).

Figure 1: Spine Cobot System used for this study

2.2 Methodology

To assess the primary endpoint, the procedure was carried out as follows:

- A patient reference is fixed on the vertebral spinous processes, the calibration phantom is then attached to the patient reference.
- A 3D fluoroscopic acquisition is performed using the Spine Cobot System.
- The surgeon creates a surgical plan by selecting the best implant trajectory on the 3D-image displayed on the navigation monitors.
- An automatic accessibility check is performed to verify that all targets can be reached by the cobot.

- The robotic arm is manually placed near the targeted pedicle. The tool holder axis is then automatically positioned in accordance with the planned trajectory drilling depth set by the surgeon [**Figure 2**].
- A Drill Guide (inner stylet assembled to a sleeve) is inserted in the tool holder. Using a handpiece equipped with the drill bit, the participant drills a pilot hole in the vertebra.
- The drill bit is maintained in its final position while a 3D-image is acquired. The surgeon then removes the drill bit and replaces it with a k-wire. The surgeon then selects the next pedicle to be instrumented and the process begins again.
- A cannulated screw is placed over each k-wire.

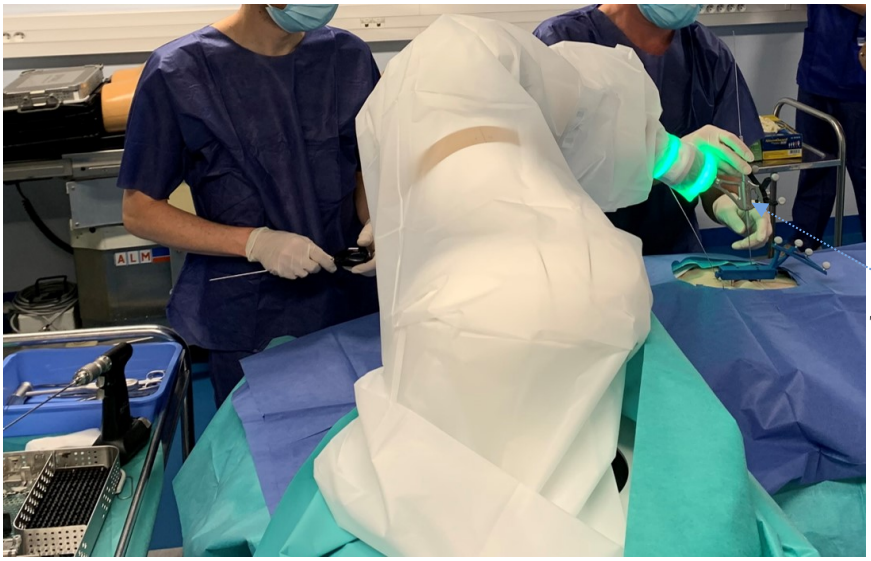

Figure 2: Robotic arm in use. The green light indicates that the arm is aligned with the intraoperatively planned trajectory. The surgeon can then insert the different instruments inside the tool holder.

Three experienced surgeons placed 90 pedicular screws in 3 prone cadavers. Four vertebrae groups between T2 and S1 were targeted.
Screw placement and neural safety was assessed for each placed screw. Precision of screw placement was determined by comparing 3D-images of the final pilot hole to the surgeon's preoperatively planned location with an external software. Distance deviations were calculated using the entry, middle and tip positions of the planned and drilled pilot holes. Angle deviation was determined by using the planned screw position and actual drilled pilot holes. Safety was quantified on the final 3D-images by 3 blinded surgeons using the Gertzbein-Robbins classification to assess screw placement and any medial breaches.

A secondary endpoint, the integrated system's usability, was also assessed. An evaluation was performed in compliance with international standards (IEC, FDA) and designed to answer the requirements of both US and European regulations. The goal was to determine if the Spine Cobot System can be safely and effectively used by potential users in an environment similar to the operation room.
An international panel of 12 healthcare professionals (6 surgeons and 6 nurses) participated in the system evaluation. Three different cadaver specimens were used for this study, six sessions were

organized (2 per specimens). Each of them included a nurse and a surgeon that instrumented 4 vertebrae (located between T4 and S1).
The workflow was divided into 11 steps which correspond to the critical tasks that were determined to impact patient safety. Specific training (theoretical and practical) was provided to the participants before having them carry out the entire workflow. Its analysis was done with the following classification:

- Use error (user action different from that expected by the manufacturer)
- Close call (use error almost committed but the user recovers in time to avoid making it)
- Operational difficulty (participant completed the task normally but struggled to understand the procedure/performed an unexpected action/corrected a committed error)

3 Results

3.1 Accuracy

The average pilot hole middle point distance deviation is 1.3mm±0.88mm. The average pilot hole angular deviation is 0.6°±0.6°.
Using the Gertzbein-Robbins classification, 100% (90/90) of the screws received an acceptable grade of 0 or 1. 97% (87/90) were grade 0 and 3% (3/90) were grade 1 (table below).
There was no robot associated issues or complications.

Parameters		**Mean Values**
Distance Deviation (mm)		1.3±0.88
Angular Deviation (°)		0.6±0.6
Gertzbein-Robbins Classification	Grade 0	87 (97%)
	Grade 1	3 (3%)

Table 1: Accuracy results

3.2 Usability

Only 2 usability errors were observed, and none were critical to patient safety. The first one was independent of the use of the Spine Cobot System (a drill bit was dropped) and the second one occurred during one of the emergency procedure simulations (corrected after 1 minute). 12 “Close Calls” and 9 “Operational Difficulties” were also reported and were immediately handled by corrective actions. 100% of participants correctly answered the final questionnaire and the “clarity of user instructions” received a 4.67/5 rating.

4 Conclusion

This preliminary study shows the efficiency of a unified system for pedicular screw placement. The precision and safety results presented here are slightly superior to published data from both conventional and robotic-assisted methods [8][9][10]. The positioning data according to the Gertzbein-Robbins score was also superior to the ones reported from conventional methods (91.5%) [11]. Moreover, the system is easily mastered by surgeons and nurses in a simulated clinical setup as demonstrated by the usability scores. This study confirms the functionality of an integrated system for usability and effectiveness. Additional evaluations will be conducted to reinforce the statistical power of these preliminary findings.

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