Whitepaper

Saving intraoperative imaging time with the robotic 3D C-arm CIARTIC Move

Results of a pre-clinical human-specimen study

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Executive Summary

In the complex realm of operating room (OR) workflows, healthcare professionals will face a significant difficulty in remaining operational as well as efficient. The World Health Organization (WHO) estimates a global deficit of about 10 million healthcare workers by 2030. This intensifies the chance of delays, miscommunication, and inefficiency during surgeries, and amplifies apprehensions regarding communication mistakes between radiation technologists and surgeons.

To overcome these challenges, it may be crucial to implement workflow automations in the OR. CIARTIC Move* is is a new class of robotic C-arm designed to help OR teams addressing these challenges by enabling automated intraoperative imaging workflows.

Subject of the study presented here is a) to compare intraoperative imaging time (IIT**) for certain procedures performed with CIARTIC Move against the same procedures performed with a conventional mobile 3D C-arm and b) to evaluate whether CIARTIC Move enables surgeons to fully control intraoperative imaging on their own from within the sterile field.

The study demonstrates, that using CIARTIC Move led to a significant reduction in IIT by about 50% ($p < 0.001$) across all procedures evaluated, indicating clinically meaningful outcomes. The studys participating surgeons confirmed that they could perform all intra-operative imaging tasks from within the sterile field.

* *CIARTIC Move is not available in all countries. Its future availability cannot be guaranteed.*
** *IIT= time used for all procedure related imaging tasks.*

Contents

Introduction

Operating room (OR) workflows are complex and dynamic, characterized by time and resource constraints. Surgical procedures require well-trained staff to possess specific skills and adaptability, while facing challenges such as the pressure to be efficient. OR teams require a complex balance between control and flexibility for patient safety.[1,2] However, **in times of skilled staff shortages, the OR workforce must perform multiple tasks**. Globally, the World Health Organization (WHO) estimates a projected shortfall of 10 million healthcare workers by 2030, mostly in low- and lower-middle income countries (Figure 1).[3]

Staff shortage and its impact on surgery

In order to prevent large surgical incisions, many procedures are now being performed minimally invasive where applicable, with a rising trend.[4] **Here, intraoperative fluoroscopic imaging is essential. Mobile C-arms are the most frequently employed imaging systems to enable these types of surgeries.** The C-arm requires multiple precise re-positionings, providing the anatomical relevant views.[5] In pelvic surgery, for instance, re-positioning of various standard projections throughout the procedure can be difficult[6] and due to staff shortage, **situations may arise in which a radiation technologist is not readily available to help with operational imaging or is not able to find exact desired imaging position within a reasonable time-scale.**

Maintaining trained personnel is essential in surgery. **Inexperienced or even missing staff as well as miscommunication can cause avoidable delays during operations.** Delays, responsible for a major impact on patient flow and overall OR utilization, were ranked highest (33.6%) among common errors in the OR in a Canadian single-center analysis (Figure 2).[7] Even with a radiation technologist present, challenges can arise when surgeons communicate instructions for positioning the C-arm correctly.

Figure 1: Projected shortage of healthcare personnel globally, adapted from[3]

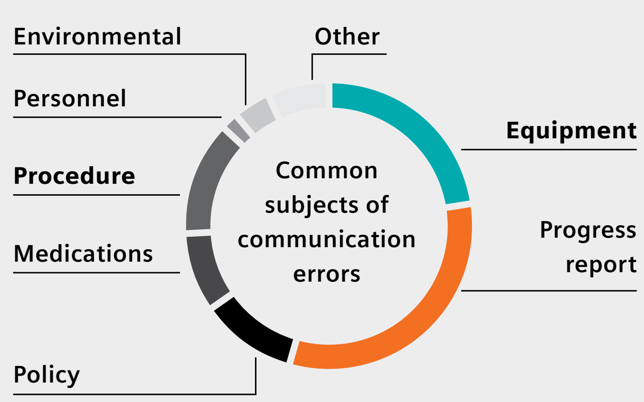


Figure 2: Results and common subjects of miscommunication in the OR, adapted from[7,8]

Material & Methods

Types of communication errors may include content, occasion, purpose, audience, and omission, causing substantial inefficiency.[8] Additionally, lacking standard terminology is a well-known problem during intraoperative communication between radiation technologists and surgeons, which is heavily influenced by experience and knowledge.[9] At times, achieving accurate projections may require additional radiation release, a concern for both the patient and the OR staff.[10]

Study objective and scope

One solution to alleviate these issues is to automate intraoperative imaging workflows. Thus, this study evaluates the operational **capabilities of CIARTIC Move, a fully motorized robotic 3D C-arm, enriched with a selfdriving chassis.**

These automation features shall make the execution of imaging tasks in course of surgical processes less dependent on the availability and experience of technologists moving and operating the imaging system.

The goal of this study was to assess:

1) whether with a remote control a single surgeon can **operate the system remotely,** from inside the sterile field**.**

2) whether returning to previously saved positions at the touch of a button with CIARTIC Move **reduces intraoperative imaging time** compared to the same procedure performed with a conventional mobile 3D C-arm.

The test objects

This study compared CIARTIC Move to Cios Spin, the latter representing the class of conventional mobile 3D C-arms. Unlike Cios Spin, the fully motorized CIARTIC Move can be automatically and effortlessly moved using a wireless remote control **(Smart Control[a])** and can store up to 12 procedure-specific C-arm positions and 2 dedicated park and return to table positions **(Position Assist[a])** – along with imaging parameters such as operating mode, organ program, and collimation. Thus, CIARTIC Move is ready to to automate and accelerate intraoperative imaging workflows.

Procedures in scope

Three types of simulated surgeries with human specimens were performed to compare the test objects. Both the spinal fusion and distal radius osteosynthesis were conducted with similar protocols, instrumentation, and implants. In the spinal operations, six screws were inserted (Th11–L1 and L2–L4). In distal radius osteosynthesis, a distal radius plate and five screws were inserted under fluorscopic image guidance as required by the surgical routine.

Imaging for the pelvic procedure involved identifying the typical pelvis projections without insertion of any implants. When using CIARTIC Move, the system transitioned from the parked position to the table position and captured the anterior-posterior (AP), lateral, inlet, outlet, as well as obturator projections as controlled by the surgeon. This sequence was performed three times to simulate the necessity of multiple projections in a realistic OR scenario. The same X-ray projections were performed with the Cios Spin. However, here the surgeon communicated the projections to the surgical assistant who was responsible for finding the exact position by manual adaptation.

After completing the initial surgical procedure on one station, each surgeon performed the same surgery again with the alternate C-arm on the opposite station. In general, all teams started with the pelvic procedure. Depending on the specialty, the spine surgeon proceeded with the lumbar spinal fusion while the orthopedic trauma surgeon performed contralateral distal radius surgery with a second specimen.

[a] *Position Assist and Smart Control are both specific features of CIARTIC Move.*

Consequently, each surgeon conducted four surgeries per day using both C-arms twice.

Simulated OR workspace setup

The experimental OR workspace setup is illustrated in **Figure 3.** Next to each other, there were two identical stations featuring a C-arm (either CIARTIC Move or Cios Spin), an OR table, an OR team, and surgical instrumentation, as well as implants tailored to the specific procedure. Each team consisted of one surgeon (either specifically qualified as orthopedic trauma or spine surgeon) and one surgical assistant. Additionally, one staff member (monitor) was responsible for ensuring completion of the protocols, measuring times with a chronometer.

At the OR simulation space with Cios Spin, an additional OR technologist was continuously present and followed the surgeon's commands to operate the C-arm.

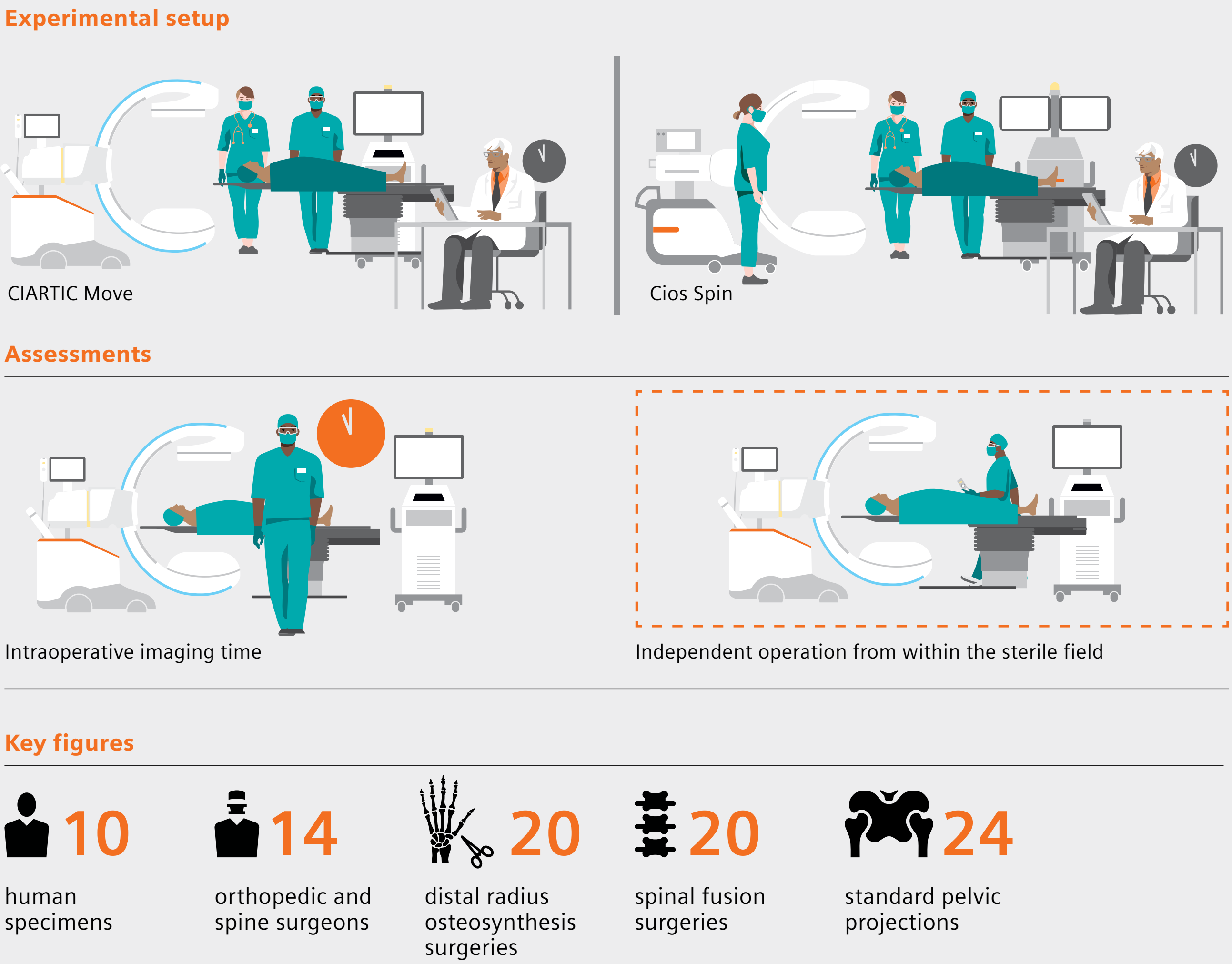


Figure 3: Preclinical study design

On every study day, two freshly frozen whole-body human specimens were prepared on the OR tables.

Assessments

In total, 3 assessments were performed to compare the OR performance of CIARTIC Move with the Cios Spin:

1) Assessment of the **required intraoperative imaging time** (IIT) with CIARTIC Move vs. conventional mobile 3D C-arm in all three surgical procedures.

2) Assessment of hypothesis that CIARTIC Move can be fully operated remotely by a single trained person from inside the sterile field.

3) Assessment of the surgeons' opinion and qualitative feedback on the applicability of CIARTIC Move's automation features on the broad spectrum of clinical interventions, on handling (ease of use) and on time-saving potentials in clinical routine.

Statistical analysis

Continuous data were assessed for normal distribution using the Shapiro-Wilk test and Q-Q plots. Two-sample t-tests were used to analyze normal distributed continuous data for group differences, while the Mann-Whitney U test was used for non-normal distributed data. Additionally, multivariate regression analysis was conducted to adjust dose for body mass index (BMI).

Results

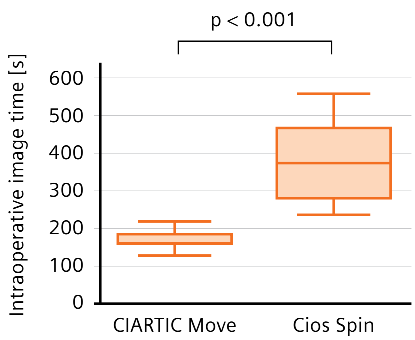
Substantial reduction of intraoperative imaging time (IIT)

The main goal of this study was to assess whether employing position assistance **(Position Assist[a])** and a wireless remote control **(Smart Control[a])**, which the surgeon can use independently in the sterile field, generate intraoperative time savings in regards to imaging related tasks. The study design comprised three prevalent surgical procedures, namely typical pelvic projections, spine surgeries, and distal radius surgeries.

For pelvic projections, the mean IIT was 173.6 ± 22.7 seconds (139s to 220s) for CIARTIC Move, and 387.8 ± 106.2 seconds (239s to 579s) for the reference C-arm (Cios Spin; **Figure 4**), resulting in a **IIT difference of approximately 55% or 3.5 min.** The median IIT for the CIARTIC Move was 172.5 seconds, whereas for the reference C-arm, it was 384 seconds.

For spinal surgeries, the average IIT was 234.8 ± 50.9 seconds (146s to 285s) in the CIARTIC Move group, and 463.9 ± 101.1 seconds (337s to 646s) in the control group **(Figure 5). The mean difference between the IIT with CIARTIC Move and Cios Spin was about 50% or approximately 4 min.**

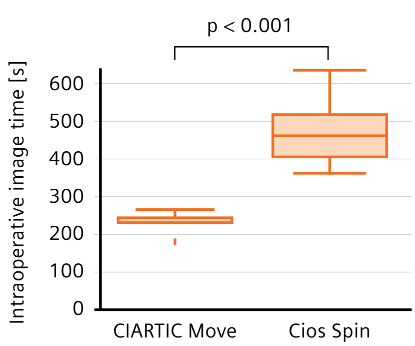
Meanwhile, for distal radius procedures, the mean IIT was 187.68 ± 18.5 seconds (163s to 217s) for those performed with CIARTIC Move, and 383.9 ± 120.4 seconds (211s to 514s) when conducted with Cios Spin **(Figure 6)**, resulting in an **IIT difference of about 50% or approximately 3 min.** The median IIT of the CIARTIC Move group was 182 seconds, while it was 412 seconds in the reference group.



55%

Less intraoperative imaging time when finding the pelvic projections

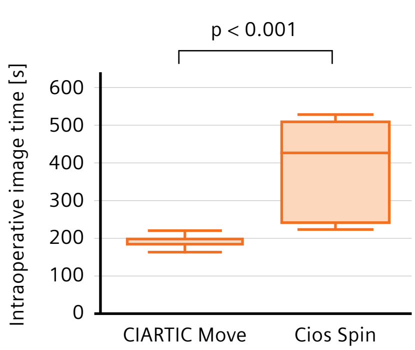
Figure 4: IIT measurements when finding pelvic projections



50%

Almost 50% less intraoperative imaging time in spine surgery

Figure 5: IIT measurements in spine surgery



50%

Over 50% less intraoperative imaging time in distal radius surgery

Figure 6: IIT measurements in distal radius surgery

Independent operation of CIARTIC Move

In all procedures performed with CIARTIC Move, the surgeons were able to operate the C-arm without any assistance. This included moving the C-arm from the parking position to the table position and then finding and saving the required projections using the wireless handheld Smart Control and the user interface mounted on the mini cart, ultimately **resulting in 100% autonomous movements by the surgeon (Figure 7).**

Results of the questionnaire

The surgeons rated the Position Assist[a] feature of CIARTIC Move at up to 12 procedure-specific C-arm positions and 2 dedicated park positions highly applicable to their clinical procedures, which include orthopedic trauma and/or spine (n = 13; mean 87% ± 5). They also rated it as easy to use (n = 13; mean 86% ± 6) and potentially useful in dose reduction (n = 13; mean 81% ± 9), receiving high overall satisfaction rates of 87% and 81%, respectively. Finally, **the potential for saving time in clinical procedures was rated as high as 84% by the surgeons** (n = 13; mean 84% ± 9; **Figure 8**).

According to all 13 surgeons surveyed, CIARTIC Move has the potential to enhance workflows with the wireless Smart Control[a] and its ability to recall pre-saved positions. The increased automation provided by CIARTIC Move could improve communication in the operating room, as reported by 8 out of 13 surgeons. Additionally, 12 out of 13 surgeons see **potential for autonomous operation of CIARTIC Move during routine procedures.**

100%

of all imaging related tasks were performed by the surgeons from within the sterile field

Figure 7: Fully independent operation of CIARTIC Move

Discussion

This study aimed to evaluate whether the technological advancements of CIARTIC Move lead to significant reductions in intraoperative imaging times in a trial consisting of repeated pelvic standard projections, spinal fusion surgeries, and distal radius osteosynthesis surgeries.

IIT and OR delays

Across all parameters, using CIARTIC Move led to substantial reductions of IIT at about 50% ($p < 0.001$), suggesting clinically meaningful differences. This was also confirmed by the surveyed surgeons via the subsequent questionnaire.

According to Wong et al., intraoperative radiography accounts for 22% of delays during spine surgery.[7] Delays during the first case of the day are likely to have negative impacts on the daily operating room schedule.[5]

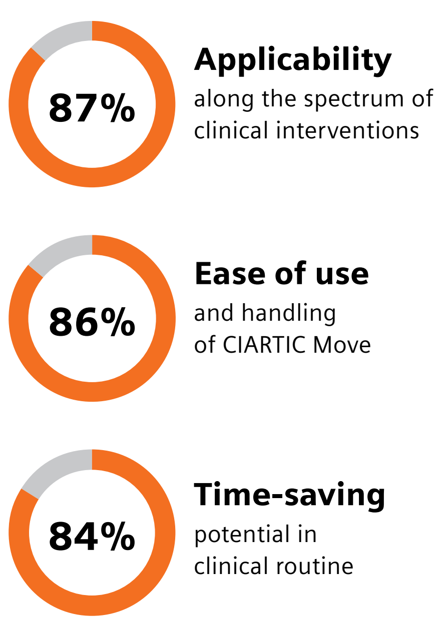


Figure 8: Overview of the questionnaire results (n = 13 surgeons)

The operating room staff must be flexible in coping with these delays, which can result in additional costs. The use of CIARTIC Move has proven time-saving capabilities and can help mitigate these delays.

Staff shortages are an additional cause of delays. A report by **the World Health Organization (WHO) describes a current deficit of approximately 7.2 million skilled health professionals and a projection model based on population growth estimates a global deficit of about 10 million healthcare workers by 2030.**[3] This will also affect OR workflows and potentially result in delays impacting preparation, surgery, and follow-up procedures. To cope with accompanied increases of patient numbers,[11] saving intraoperative time where possible is a critical factor to further enable efficient hospital turnover. This study shows that CIARTIC Move can add value in several common surgeries, already today.

Automated C-arm repositioning and remote control to prevent communication failures

Recent studies have identified discrepancies in the quality of communication perceived by members of the surgical team in the OR. Communication breakdowns mostly involved equipment (23%) and keeping team members informed on the progress of an operation (32%). These communication issues led to inefficiencies, delays, and heightened tensions among team members.[7,12]

During a surgical procedure, surgeons must instruct unsterile staff operating the C-arm to position it multiple times in the correct projection. This communication poses a significant challenge. During spinal implant placement, C-arm positioning typically requires multiple X-rays ($n = 7 \pm 5$) and positioning time ($t = 82 \pm 63$ s), which can vary according to surgeon experience.[13]

However, in this study, **surgeons operated the C-arm without the assistance of technical personnel from start to finish during all 32 procedures.**

They saved the required positions just before the surgery and were able to move or restore the respective position using CIARTIC Move by pressing the appropriate button during the procedure (Position Assist). If adjustments were needed, the surgeons could make them themselves using the wireless Smart Control, which was draped and accessible on the instrumentation table. On the one hand, this simplification may enable the development of new workflows and gives technologists the possibility to focus more on patient care or implant preparation while in the operating room. On the other hand, this may ultimately lead to time savings related to waiting for the radiation technologist to become available if they are performing other tasks or assisting in other ORs at the same time. Further studies are needed to verify this hypothesis in real-life OR routine.

Potential of CIARTIC Move in the OR, as rated by surgeons

Time is one of the critical factors to assess OR efficiency,[14] which has important implications for cost savings, patient satisfaction, and medical team morale.[15] The 13 surgeons surveyed acknowledge that **CIARTIC Move has the potential to improve the OR workflow** thanks to its wireless Smart Control and ability to recall pre-saved positions.

Conclusion

CIARTIC Move is a new class of robotic C-arm that has the potential to address operational challenges related to intraoperative imaging caused by staff shortages and overloaded surgical teams in the OR. The system is specifically designed to help OR teams overcoming these limitations by enabling automated intraoperative imaging workflows. It effectively reduces the time, effort, and workforce capacity needed to move and position the system. In this human-specimen study, the surgeon controlled CIARTIC Move entirely remotely while working within the sterile field for pelvic, spine, and distal radius surgical procedures. The device includes the capability to save and recall preconfigured C-arm positions, with relevant projections for each procedure, consistently reducing IIT across all cases tested.

However, further studies are required to validate the benefits of CIARTIC Move in more advanced surgical procedures, as the study described herein is a human specimen study in a controlled environment. In addition, it is necessary to gain insight into the magnitude of OR workflow optimization based on the observed time savings of 3–4 minutes during each surgical procedure observed in the experimental setting. In real clinical situations, surgeries typically take longer, raising the question of how the observed time savings will translate to a real clinical setting.

Since the participating surgeons in the study acknowledged the significant potential of CIARTIC Move in terms of saving time and simplifying communication, CIARTIC Move already shows promising enhancements towards surgical workflows and efficient capacity utilization in the OR.

References

1) Göras C, Nilsson U, Ekstedt M, et al. Managing complexity in the operating room: a group interview study. BMC Health Serv Res. 2020; 20(1): 440.

2) Undre S, Sevdalis N, Healey AN, et al. Teamwork in the operating theatre: cohesion or confusion? J Eval Clin Pract. 2006; 12(2): 182–189.

3) WHO. Health workforce. https://www.who.int/health-topics/health-workforce#tab=tab_1. Accessed: December 2023.

4) Camacho JE, Usmani MF, Strickland AR, et al. The use of minimally invasive surgery in spine trauma: a review of concepts. J Spine Surg. 2019; 5(Suppl 1): 91–100.

5) Keil H, Beisemann N, Swartman B, et al. Intra-operative imaging in trauma surgery. EFORT Open Rev. 2018; 3(10): 541–549.

6) Stöckle U, Schaser K, König B. Image guidance in pelvic and acetabular surgery--expectations, success and limitations. Injury. 2007; 38(4): 450–462.

7) Wong j, Khu KJ, Kaderali Z, et al. Delays in the operating room: signs of an imperfect system. Can J Surg. 2010; 53 (3): 189–195.

8) Halverson AL, Casey JT, Andersson J, et al. Communication failure in the operating room. Surgery. 2011; 149(3): 305–310.

9) Pally E, Kreder HJ. Survey of terminology used for the intraoperative direction of C-arm fluoroscopy. Can J Surg. 2013; 56(2): 109–112.

10) Lee K, Lee KM, Park MS, et al. Measurements of surgeons' exposure to ionizing radiation dose during intraoperative use of C-arm fluoroscopy. Spine. 2012; 37(14): 1240–1244.

11) WHO. A universal truth – No health without a workforce. Page 38. https://cdn.who.int/media/docs/default-source/health-workforce/ghwn/ghwa/ghwa_auniversaltruthreport.pdf?sfvrsn=966aa7ab_7&download=true. Accessed: December 2023

12) Pally E, Kreder HJ. Survey of terminology used for the intraoperative direction of C-arm fluoroscopy. Can J Surg 2013; 56 (2): 109–112.

13) Kausch L, Thomas S, Kunze H, et al. C-arm positioning for standard projections during spinal implant placement. Med Image Anal. 2022 Oct: 81: 102557.

14) Statton J, DeCook CA. OR Efficiency: Radical Time Transparency and Operational Excellence. Anterior Hip Replacement 2022. Springer, Cham. pp 155–169.

15) Rothstein DH, Raval MV. Operating room efficiency. Semin Pediatr Surg. 2018; 27(2): 79–85.

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