Reduction in Radiation Exposure for Spine Fusions with the KICK System: A Case Study

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Abstract:

Objective: Transforaminal Lumbar Interbody Fusion (TLIF) surgery may be performed using minimally invasive techniques that reduce tissue disruption and improve healing times. However, recent systematic reviews highlight the health hazard of radiation exposure using current visualization devices. This study compares fluoroscopy time, overall procedure duration, and individual screw placement time between the KICK System and standard fluoroscopic guidance.

Methods: Between October 2016 and February 2017, 43 TLIF cases were conducted at Holland Hospital in Michigan. Cases comprised 20 (+ 2 pilot) cases with fluoroscopic guidance only, followed by 20 (+1 pilot) KICK System image-guided cases with fluoroscopic guidance. This study was limited to 1-level and 2-level cases. Mean fluoroscopy time (seconds), overall procedure duration (minutes) and individual screw placement time (minutes and seconds) were analyzed using a student's t-test between control and KICK.

Results: The patients were between 30-70+ years of age and comparable between 1-level (control n=13; KICK n=13) and 2-level (control n=7; KICK n=7) cases. In 1-level cases, there was a 65% decrease in mean fluoroscopy time between control (mean [SD] 79.1 [25.0] seconds) and KICK (27.7 [12.5] seconds) (p<0.001). In 2-level cases, there was a 72% decrease between control (133 [59.8] seconds) and KICK (37.2 [18.8] seconds) (p=0.002). There was no difference in overall mean procedure time between control (130.0 [66.4] seconds) and KICK cases (143.6 [40.0] seconds) (p=0.454). The surgeon reported elevated confidence, increased reliability in visualizations, and invigorated emotional energy in post-operative communications with patients.

Conclusion: Compared to fluoroscopic guidance alone, the KICK System is associated with a significant decrease in mean fluoroscopy time without a significant increase in overall procedure duration. The findings suggest that the KICK System has the potential to minimize radiation exposure, which continues to be a source of major concern for MIS TLIF.

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Key Words: Transforaminal Lumbar Interbody Fusion (TLIF); minimally invasive; fluoroscopy; radiation exposure

Introduction:

Transforaminal Lumbar Interbody Fusion (TLIF) is a surgical procedure that stabilizes adjoining vertebrae to facilitate union. TLIF surgeries are indicated for patients suffering from spondylolisthesis (slipped disc), degenerative disc disease, and spinal stenosis (narrowing of the spine)[2]. The goal is to reduce pain and nerve irritation by immobilizing spine segments[3]. It can be performed using minimally invasive surgery (MIS) techniques that reduce tissue disruption and blood loss during surgery, improve healing times, and accelerate return to work compared to open posterior lumbar fusion techniques [1-5]. However, these improved outcomes come with the challenge of decreased direct visualization.

Indirect imaging may be used to improve visualization in MIS TLIF [1,4]. However, the current visualization systems that orient orthopedic- and neuro-surgeons can pose challenges as they may result in excessive radiation exposure [6-8]. These systems are used throughout TLIF surgeries, but surgeons especially rely on them when inserting screws into the pedicle, a bony bridge between the lamina and the vertebral body. The pedicle screws grip the spinal segment and are connected by a rod. The surgeon performs the step by cannulating the pedicle, tapping, and inserting the screw.

There is a slim margin of error for inserting the screws due to the narrowness of the pedicles, and the process takes place without direct visualization of the screw trajectory [9]. Fluoroscopic guidance is often helpful in verifying a screw's position in the patient's anatomy. Unfortunately, given that adjusting a screw's angle of insertion is not uncommon, extensive fluoroscopy may be needed [10,11]. Determining the number of fluoroscopic shots that will be required in advance of surgery is not possible, therefore many patients remain unaware of their exposure to radiation [6]. Previous efforts have attempted to reduce lifetime patient and surgeon radiation exposure with MIS TLIF by altering the surgical technique [7,11]. However, an alternative visualization system that reduces reliance on fluoroscopy could enable surgeons to carry out spinal surgery with greater ease without modifying their surgical technique.

The KICK system is a visualization platform that provides a real-time image of the MIS TLIF procedure without the need for extensive fluoroscopy. The KICK system is comprised of an optical infrared tracking camera, which points toward the surgical field to capture the position of arrays, and a monitor, which displays the position of instruments over fluoroscopic images of the patient. The surgeon can use a pointer that connects to the monitor and shows the tool's anatomical position in the patient. This allows the surgeon to accurately visualize the position of their surgical tools without the need for repeated fluoroscopic images (**Figure 1**).

Figure 1. Kick system intraoperative tracking and planning.

The primary objective of this ethnographic case study was conducted to determine if using the KICK system to supplement fluoroscopic imaging for TLIF was associated with decreased radiation exposure. Secondary objectives were to determine if this procedure was associated with an increased time to position the screw and to collect qualitative observations concerning the surgeon's experience.

Methods:

Study Design

During the period of October 2016 through February 2017, 43 patients with spondylolisthesis, degenerative disc disease, or spinal stenosis underwent TLIF MIS at the Brain and Spine Center, a private practice at Holland Hospital in Holland, Michigan. Holland Hospital is a community-based, non-profit facility with 189 beds and 200 physicians, 2,000-member hospital staff, and 550 registered nurses. The surgeon evaluated in this study specializes is MIS TLIF procedures. Since 2004, he has treated over 3,000 patients with spinal problems, including pinched nerves, disc ruptures, bone spurs, fractures, cysts, and tumors. The same surgical team members present in this study regularly participate in the attending surgeon's procedures.

The cases were consecutive and included:

- 20 (+ 2 pilot) without the KICK System (i.e., control) cases with fluoroscopic guidance only; and
- 20 (+1 pilot) with the KICK System cases and fluoroscopic guidance as an adjunct

This study was limited to 1-level (2 vertebrae) and 2-level (3 vertebrae) cases. Within each type of MIS TLIF, comparisons were made between control and the KICK System cases for the primary outcome measure, fluoroscopy exposure time (in seconds). Secondary outcome measures included the overall duration of the procedure from first surgical step (targeting) to closure, the duration of time required for individual screw placement, and presence of any delays during MIS TLIF. This study was deemed exempt from IRB approval as it was an ethnographic case study and the research entailed evaluating surgeon experience.

Set-up

Kick EM consists of three parts: the field generator, the connection panel, and the Kick monitor cart. The field generator, fixed either on a positioning plate or with a flexible arm for optimized patient setup, creates the electromagnetic field around the patient’s head. The connection panel is the interface between the tracking unit and the navigation system, and is mounted with secure hooks to the operating room table or directly on the monitor cart.

Data Collection and Analysis

Procedural timing data were collected using tablet-based software (DePuy Synthes, USA). Procedures were broken down into discrete steps to target individual pedicle screw placement durations. Delays in procedures were also recorded to isolate procedure time directly related to the standard procedure. Radiology technicians were consulted retrospectively to obtain fluoroscopy time (seconds) for each procedure. Student's t-tests were used to compare mean outcome measures between control and KICK System cases for all procedures as well as the subgroup analysis in 1-level and 2-level cases.

Qualitative data were also collected to assess the user experience with the KICK System, including surgeon satisfaction through interviews conducted pre- and post-operation, and interviews conducted after the conclusion of the study. Case notes described aspects of the case that may have contributed to delays or abnormalities. The surgeon's comments were recorded to provide direct user feedback at the time of cases.

Results

Patient Population

The age ranges of the patients were comparable between 1-level control (50-69 years; n=13) and KICK System cases (30-70+; n=13) and 2-level control (30-70+; n=7) and KICK System (50-69 years; n=7) cases. The percent female ratio was also comparable between 1-level control (57%) and KICK System cases (46%) and 2-level control (46%) and KICK System (14%) cases.

Radiation Exposure

There was a 68% reduction in the total fluoroscopy time (seconds) between control (mean [SD]: 98.1 [46.1]) and KICK (31.1 [14.8]) cases overall ($p < 0.001$; **Figure 2A**). For the subset of 1-level cases, there was a 65% decrease in mean fluoroscopy time between control (79.1 [25.0]) and KICK System cases (27.7 [12.5]) ($p < 0.001$; **Figure 2B**). For 2-level cases, there was a 72% decrease between control (133 [59.8]) and KICK System (37.2 [18.8]) ($p = 0.00157$; **Figure 2C**).

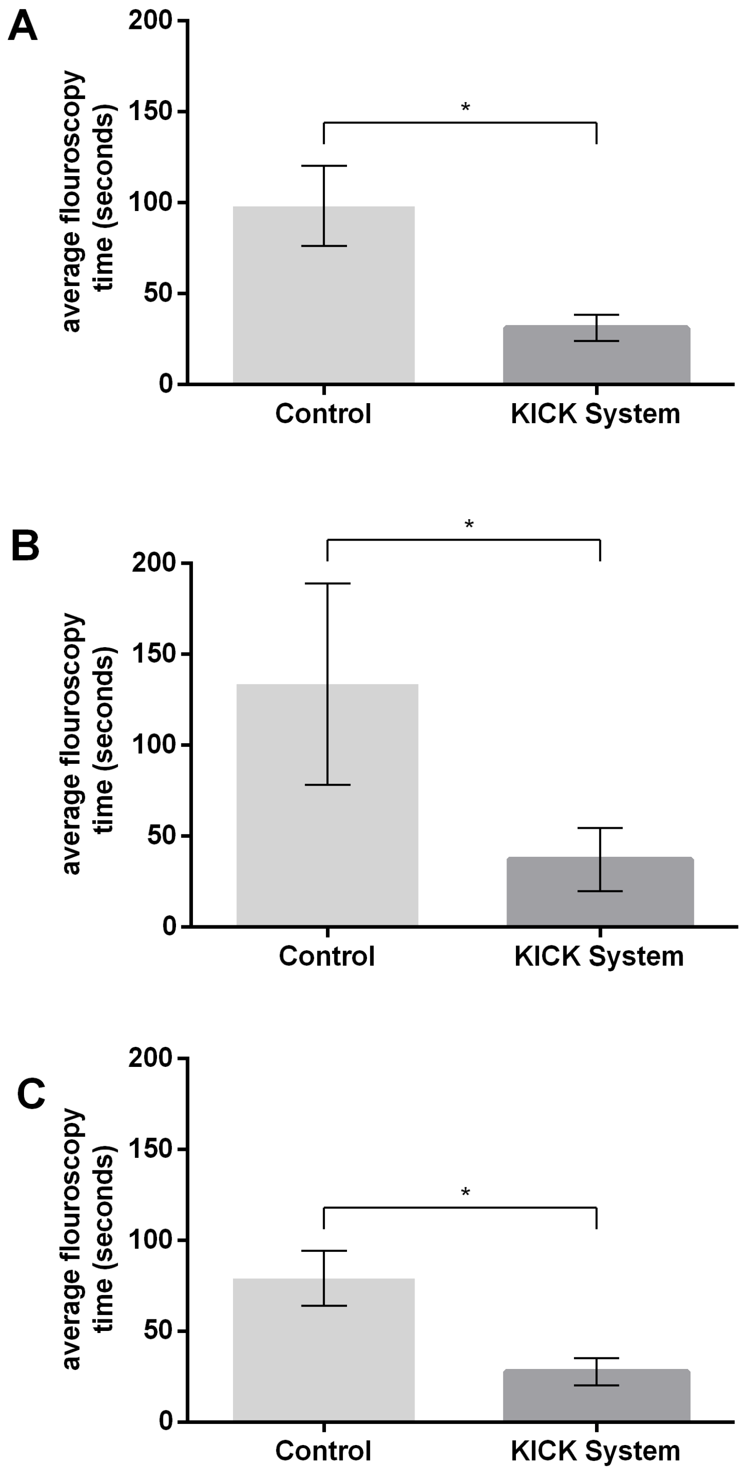
A
B
C
200
150
100
50
0
average flouroscopy time (seconds)
*
Control
KICK System

Figure 2. Average fluoroscopy time (seconds) between control and KICK System cases overall **(A)**, for 1-level **(B)** and 2-level **(C)** procedures. Error bars display 95% Confidence Intervals. * indicates significant differences between cases.

Overall Procedure Duration

There was no significant difference in overall mean procedure duration (minutes) between control (130.0 [66.4]) and KICK System (143.6 [40.0]) cases (p=0.454; **Figure 3A**). For 2-level cases, there was no significant difference between control (199.3 [68.3]) and KICK System (188.1 [26.8]) cases (p=0.693; **Figure 3B**). Conversely, for the subset of 1-level cases, there was an increase in overall mean procedure duration for control (89.5 [15.0]) and KICK System (119.6 [22.8]) cases ($p<0.001$; **Figure 3C**).

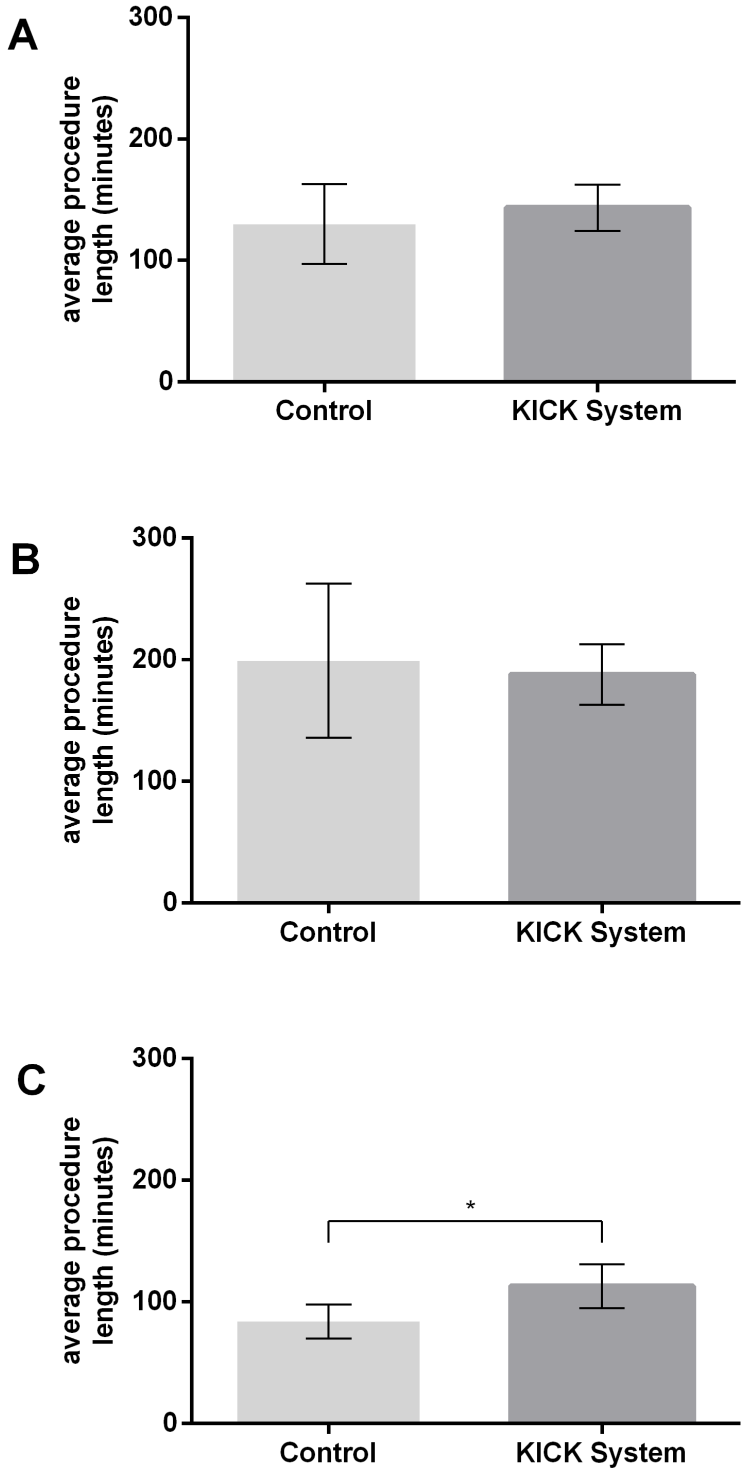
A
300
200
100
0
average procedure length (minutes)
Control
KICK System
B
300
200
100
0
average procedure length (minutes)
Control
KICK System
C
300
200
100
0
average procedure length (minutes)
*
Control
KICK System

Figure 3. Average procedure duration (minutes) between control and KICK System cases overall **(A)**, 2-level **(B)** procedures and for 1-level **(C)**. Error bars display 95% Confidence Intervals. * indicates significant differences between cases.

Individual Screw Placement

There was a difference in average screw placement time (minutes and seconds) between control (3m33s [2m34s]) and KICK System (4m35s [3m22s]) cases (p=0.02; **Figure 4A**). For the 2-level cases, there was no significant difference between control (4m6s; 3m3s) and KICK System procedures (5m5s; 4m14s) (p=0.23; **Figure 4B**). Conversely, for the subset of 1-level cases, there was a significant difference between control (3m4s; 1m57s) and KICK System (4m10s; 2m27s) cases (p=0.02; **Figure 4C**).

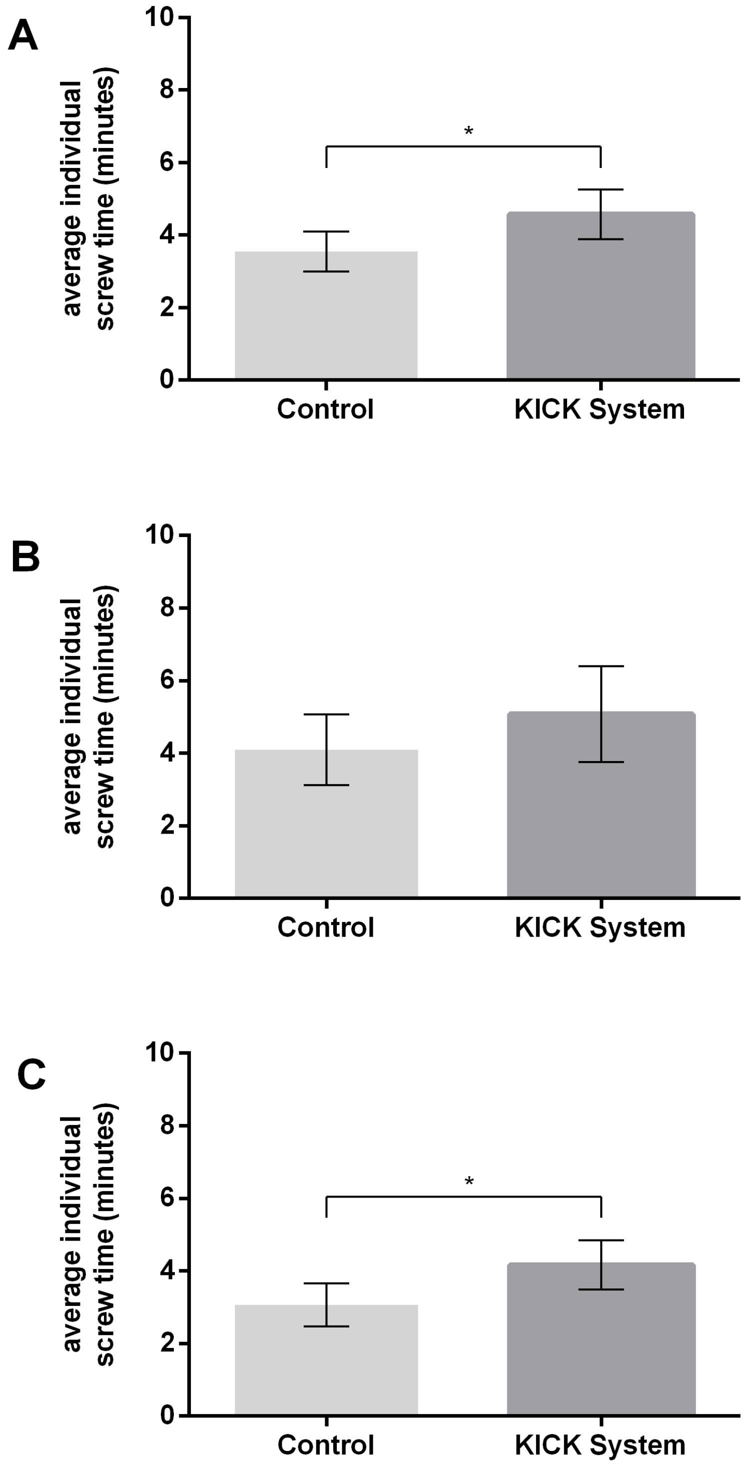
A
B
C
average individual screw time (minutes)
10
8
6
4
2
0
*
Control
KICK System

Figure 4. Average individual screw time (minutes) between control and KICK System cases overall **(A)**, for 2-level **(B)** and 1-level **(C)** procedures. Error bars display 95% Confidence Intervals. * indicates significant differences between cases.

Qualitative Observations

Through interviews, it was reported that the surgeon demonstrated an increase in confidence during procedures as a result of the increased number of data points displayed on the KICK System monitor. Throughout MIS TLIF procedures with the KICK System, the surgeon could reassess instrument positions and ensure accurate screw trajectory prior to insertion, without capturing another fluoroscopic image. Further observations also demonstrated spatial advantages to the KICK System in the OR. During surgeries with the KICK System, fluoroscopic devices were moved to the side of the operating theatre, thereby enabling the surgical team to have greater range of movement around the OR table.

Discussion

One of the main drawbacks of MIS techniques for TLIF surgery is the amount of exposure to ionizing radiation [6]. The present study was designed to evaluate radiation exposure using the KICK System compared to fluoroscopy alone for MIS TLIF procedures. Our results provide evidence that there is a significant reduction in both total fluoroscopy time and radiation exposure using the KICK System overall and within the subgroup analysis for both 1-level and 2-level procedures.

The reductions observed are similar in magnitude to other techniques that decrease radiation exposure during MIS TLIF such as ultra-low radiation imaging [7]. Taken together, this study suggests that using the KICK System for MIS TLIF can reduce fluoroscopy time and potentially harmful radiation exposure. Further, these reductions did not result in a significant increase in procedure duration overall. It is possible that with more complex multilevel deformity type cases, even greater efficiencies would be realized.

Increases in individual pedicle screw placement durations may also suggest that the KICK System afforded the surgeon more time to focus on this critical surgical task and may improve screw placement accuracy. It is important to secure an accurate angle because it establishes the orientation for fusing vertebrae. It is to be noted that for both 1-level and 2-level procedures, KICK guidance added only an additional minute to for each screw. Qualitative observations that the surgeon spent additional time verifying screw trajectory further support potential increases in accuracy.

Additionally, the slight increase in screw placement time may be a consequence of surgeon familiarity with the device. Other studies have noted a distinct learning curve and increasing proficiency over time with MIS techniques [12,13]. It is likely that overall surgical time will further decrease as surgeons become more familiar with the KICK System. MIS TLIF with the KICK System entails new visualization practices. Whereas fluoroscopic guidance generates static imagery, the KICK System monitor displays dynamic imagery. The real-time tracking of instruments moves in concert with the surgeon’s gestures and has the potential to improve workflow as the surgeon does not pause for a static image to be captured.

The KICK System also demonstrated potential to improve operational efficiency. As addressed in the qualitative observations, there was reduced clutter in the OR during procedures with the KICK System. This allowed the surgical team more space to move around the operating table. Follow-up studies should seek to further identify and quantify operational efficiencies.

The limitations of our analysis should be noted. The present case study was conducted using a pre-post design at a single site, involved a single surgeon, and was based on a limited sample size of patients. The design ensured that variability across facilities was limited; it also allowed researchers to track qualitative observations related to the surgeon's experience. However, this may limit the generalizability of the results beyond the case study. Future studies should involve multiple surgeons at various institutions. These larger multi-center studies should also seek to capture patient-reported and clinical safety outcomes.

Conclusion

MIS TLIF procedures using the KICK System significantly reduce the radiation exposure associated with fluoroscopy, without a significant increase in overall procedure duration. These results, in addition to qualitative increase in surgeon confidence, suggest an increased ability to optimize screw trajectory and final placement. Overall, the findings suggest that the KICK System has the potential to minimize radiation exposure, which continues to be a source of major concern for MIS TLIF.

Data Availability:

The data supporting the conclusions of the study can be accessed through the corresponding author.

Conflicts of Interest:

MK receives consulting fees and conducts research with JnJ. MB, MG, and SB are employees of JnJ and own stocks in the company. LM is a contractor with JnJ

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