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ABSTRACT

Background: Surgeons' reliance on intraoperative fluoroscopy during vertebroplasty procedures has raised concerns regarding the level of patient and surgeon radiation. Navigation systems have shown a potential to reduce the overall patient and medical staff exposure during dose exposure studies. The main objective of this study was to determine whether the Surgivisio platform (eCential Robotics, France), a unified imaging and navigation platform, lowers the patient dose during routine clinical usage as compared with published fluoroscopy and other navigation options that are published in the literature.

Methods: To accomplish this, we evaluated the radiation exposure dose during routine vertebroplasty procedures in which the surgeon was not trying to limit radiation and then compared the results to best-case dose assessment studies. Since a decreased radiation dose can lead to decreased image quality, we also quantified the surgeon's perception of image quality and ease of use. Two hundred and seventy-four Surgivisio-assisted vertebral augmentations were pooled from a broader 1694-patient protocol (not focusing on radiation outcomes) and analyzed.

Results: We measured a median dose-area product and effective dose equal to 3.47 Gy.cm² and 0.81 mSv. The 3-dimensional image acquisitions contributed to 56.3% of the total dose-area product. When screening the literature, fluoroscopy dose levels (8.37–15.1 Gy.cm²) and navigation dose levels (9.12–9.83 Gy.cm²) were generally higher than those delivered with the Surgivisio protocol. Surgeon satisfaction for image quality and overall system experience was 95.8% and 85% for ease of use.

Conclusions: The Surgivisio platform provided surgeons with high-quality images and ease of use. Since the surgeon is out of the room during the 3-dimensional image acquisition, this also substantially decreased their radiation exposure. This study demonstrates the efficiency of the Surgivisio platform to assist surgeons during vertebral augmentations, as the reported radiation levels are reduced in routine cases compared with published scenarios reported for other guidance methods.

Other and Special Categories

Keywords: spine surgery, vertebral augmentation, navigation, radiation levels, usability

INTRODUCTION

Across the globe, spinal fractures are observed in 24 to 90 cases per 100,000 people and are often associated with a high level of pain, thus greatly impairing the patient's quality of life and representing a significant social and economic burden.[1] Vertebroplasty is a commonly performed percutaneous procedure to reduce the level of pain,[2] with previous research demonstrating its efficiency.[3,4] To optimize the procedure workflow, surgeons or interventional radiologists generally rely on intraoperative fluoroscopy guidance to percutaneously access the zone of interest. This raises concerns regarding patient but also surgeon radiation levels,[5,6] which are among the highest in orthopedics.[7,8] Indeed, the extended radioscopy durations (up to 60 minutes),[9,10] the intense primary and scattered beams,[11] and the close proximity of the x-ray source increase the risks of radiation-induced injuries and cancers.[12] Wearing protective lead equipment or moving away from the source helps reduce the total dose, yet often at the cost of more fatigue and workflow complexity. Therefore, the interest in navigation systems for vertebroplasty

Figure 1. Depiction of the Surgivisio surgical platform. Left: Unified platform composed of a C-arm, a navigation station, and an infrared camera. Right: Surgivisio disposable instruments (from top to bottom): imaging phantom, patient tracker, and navigated trocar.

has been growing, as several studies have emphasized their role in reducing the overall patient and medical staff radiation dose while achieving accurate needle placement.[8,13] The 2 main factors are high-resolution guidance based on a few 1-time 3-dimensional (3D) image acquisitions (no fluoroscopic controls needed) along with the surgical team leaving the operating room (OR) during the image acquisition process. This supports the "as low as reasonably achievable" radioprotection principle and the implementation of diagnostic reference levels in different countries[14,15] to increase awareness.

The Surgivisio platform (eCential Robotics, France) brings together 2-dimensional (2D) and 3D imaging and navigation in a unified design (Figure 1). While dividing patient radiation exposure by 10 compared with another commonly used navigation platform,[16] its singular design may contribute to solve recurrent usability issues encountered with spinal systems, such as cumbersome registration processes[17–19] and difficult steering in the OR.[20] The main objective of the present study is to demonstrate that lower radiation doses are delivered to patients during vertebral augmentations when using the Surgivisio system in relation to fluoroscopy guidance and alternative navigation options. For our secondary objective, we measured the platform's image quality and ease of use via a questionnaire to assess whether these parameters were affected by our low-dose approach.

MATERIALS AND METHODS

This study is part of a larger protocol that included all spine procedures carried out with the Surgivisio platform in 5 French hospitals between January 2018 and December 2021. Because this protocol's primary endpoint did not focus on dose levels, the bias related to the use of radiation is limited. Two hundred and seventy-four patients were either included retrospectively if the surgery was performed before the clinical study launch or prospectively otherwise. This study was registered in the database of the Health Data Hub with the number I24100506202020. It complies with the Declaration of Helsinki.

The present analysis focuses on screwless procedures (vertebral augmentation)—vertebroplasties and SpineJack (Stryker, USA) interventions (Figure 2)—carried out by 9 neurosurgeons or orthopedic surgeons.

Outcomes of Interest

Basic patient characteristics (eg, age, sex, body mass index), and procedure information (eg, vertebrae treated, total surgical time) were collected retrospectively. Dose data were extracted from the Surgivisio dosimetry reports such as the dose-area product (DAP) and total radiation time. The total effective dose (ED) was calculated using the following equation:

$$E\left(mSv\right) = DAP\left(Gy.cm^2\right) \times k$$

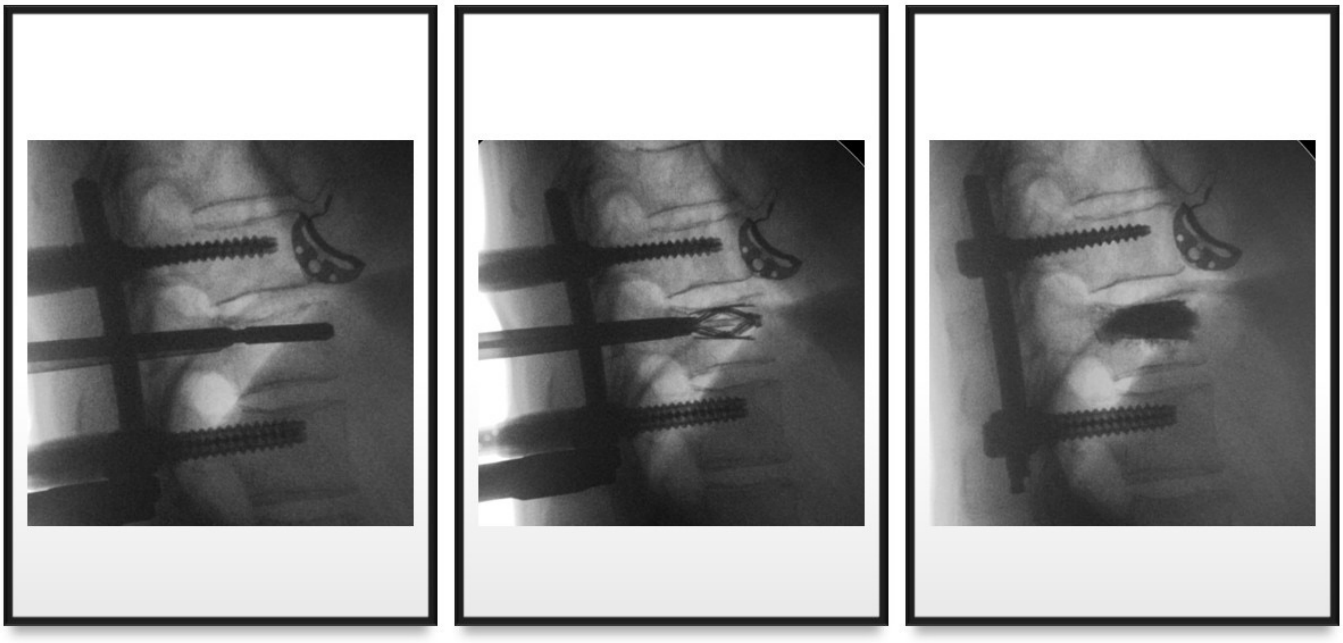

Figure 2. SpineJack is a titanium implant designed to restore the anatomical height of the vertebral body. It is inserted into the vertebral body and positioned in a craniocaudal orientation (from left to right): SpineJack before expansion, SpineJack after expansion, and SpineJack with cement injected into the vertebra.

The conversion factor k was set to 0.19 (mSv/Gy.cm²) for the thoracic spine and 0.26 (mSv/Gy.cm²) for the lumbar spine in accordance with the *Radiation Protection N° 154* report from the European Commission.

Dosimetry reports also captured the delivered radiation during each 2D and 3D sequence, which enabled us to calculate the resulting 2D and 3D radiation levels.

The system's usability was assessed through a multiple-choice questionnaire submitted to the surgeon after the procedure; the topics included 2D and 3D image quality, ease of use, and overall surgeon satisfaction.

Surgical Technique

The Surgivisio technique applied to vertebral augmentation procedures has already been described for vertebroplasties[16] and SpineJack.[21] In the following paragraphs, we synthesize the main steps followed for each procedure.

A patient reference was fixed on 3 spinous processes in the vicinity of the fractured vertebra by inserting metal pins (Figure 3A). An imaging phantom was magnetically fixed on the reference (Figure 3B), and 2 fluoroscopy shots (anteroposterior and lateral) were acquired using a dedicated pedal (Figure 3C). The phantom's radiopaque beads were detected in the images, which automatically registers the patient with the C-arm. A 3D acquisition and reconstruction process were then launched without interrupting patient breathing. The medical team left the OR before starting the x-ray beams, which set their received dose to 0. After replacing the phantom by a navigation tracker (Figure 3D), a precalibrated Jamshidi-style trocar was unboxed, directly registered with the platform, and displayed on the navigation screen. Once the trocar was advanced toward the medial wall of the pedicle, it was placed inside the vertebral body. A lateral fluoroscopic image was usually acquired to verify that the needle tip passed the posterior vertebral body margin. The trocar stylet was removed, and cement was injected under continuous fluoroscopy.

If a SpineJack was used prior to the cement injection step, a guidewire was inserted through the trocar at the adequate depth. The trocar cannula was then extracted, and a preassembled reamer cannula was inserted in the vertebral body along the wire. The SpineJack device was implanted by sliding an expansion kit through the reamer and expanded by rotating the butterfly handle clockwise. The deployment of the implant was monitored with lateral fluoroscopic images to verify the resulting fracture reduction. Once the desired vertebral augmentation was achieved, the kit was removed, and cement was injected to consolidate the structure.

Survey

Since a decreased radiation dose can lead to decreased image quality, we also wanted to quantify the surgeon's

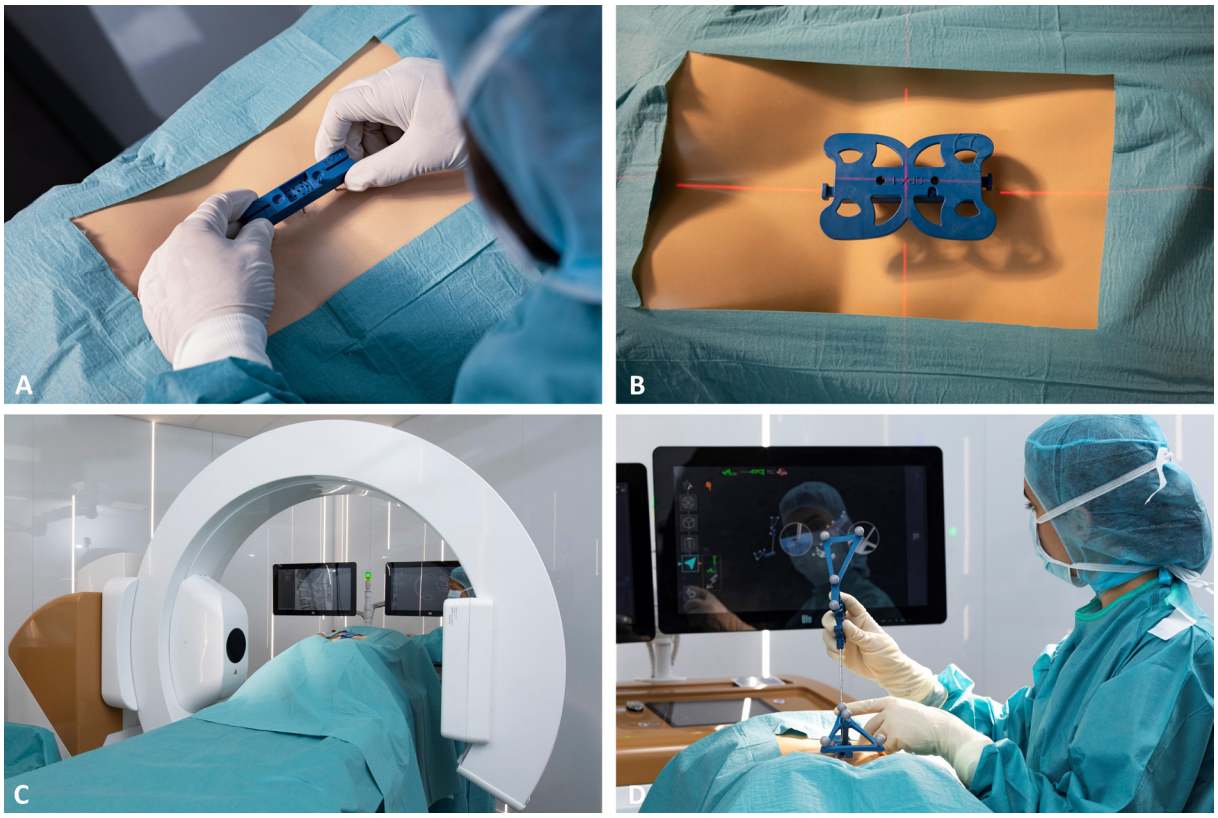

Figure 3. Presentation of the surgical platform setup and instrumentation. (A) Placement of the patient reference using 3 metal pins. (B) Imaging phantom magnetically fixed to the patient reference; the lasers are used to correctly center the C-arm. (C) Surgivisio C-arm during the image acquisition process. (D) Navigation of the trocar after placing the patient tracker on the reference.

perception of image quality and ease of use. The following survey questions were asked:

1. Was the 2D image quality satisfactory?
2. Was the quality of the 3D reconstruction sufficient to provide guidance throughout the procedure?
3. Are you satisfied with the ease of use of the Surgivisio?
4. How would you rate your experience with the Surgivisio during the surgery?

The respondents could answer the first 3 questions with a grade between 0 and 5 (0 = not satisfied at all; 5 = very satisfied). Only 3 possibilities were offered for question 4: not satisfied, neutral, and satisfied. The minimal rating to consider a user as satisfied was 4/5.

Statistical Analysis

The statistical analysis was done using both RStudio software (version 4.1.0) and Excel (Microsoft). The Shapiro-Wilk test was selected to characterize the normality of the distributions. Parameters were described using median, first quartile, and third quartile. Two-tailed Mann-Whitney *U* tests were used to compare numerical variables and Fisher's exact test for categorical variables. The level of significance was set to 0.05.

RESULTS

We included 274 patients divided into 2 groups: vertebroplasty ($n = 252$) and SpineJack implant ($n = 22$) for a difference in cases equivalent to a ratio of 11 between the 2 groups. The thoracic and lumbar regions were evenly treated; the surgeons performed a few sacroiliac procedures in the vertebroplasty group (Table 1). Most cases were single-level interventions—64% in the vertebroplasty group and 100% in the SpineJack group—with a median time of around 30 minutes. The median ED and DAP were similar between the 2 groups. We measured a median DAP and ED equal to 3.47 Gy.cm² and 0.81 mSv for vertebroplasty procedures (resp. 3.80 Gy.cm² and 0.80 mSv for SpineJack procedures). The contribution to DAP of 3D image acquisitions was slightly superior to 50% in both groups. We found significantly lower values in the vertebroplasty group when calculating the median DAP and ED per treated vertebra (2.90 vs 3.80 Gy.cm² and 0.65 vs 0.80 mSv; Table 2).

Table 1. Patient and surgical characteristics.

Characteristic	Vertebroplasty (*n* = 252)	SpineJack (*n* = 22)	*P*
Age, y, median (IQR)	75 (62.5–82)	53 (48–61.5)	**<0.001**
Sex, *n* (%)			
Men	90 (35.8%)	14 (61.9%)	**0.012**
Women	162 (64.2%)	8 (38.1%)	
BMI, median (IQR)	24.1 (22–27.5)	21.7 (20.7–23.4)	**0.03**
Regions treated, *n*			
Thoracic	127	9	0.59
Lumbar	120	13	
Sacroiliac	5	0	
No. of levels treated, *n*			
1	161	22	**0.005**
2	54	0	
3	20	0	
≥4	17	0	
Mean No. of treated vertebrae, median (IQR)	1 (1–2)	1 (1–1)	**0.001**

Abbreviations: BMI, body mass index; IQR, interquartile range.
Note: Boldface indicates statistically significant findings at $P < 0.05$.

We also segmented our interventions based on the number of 3D acquisitions (≤1 or >1) after merging both groups (vertebroplasty and SpineJack) to avoid analyses on very small sample sizes (Table 3). DAP and dose values doubled in the subgroup with several 3D images, which created significant differences.

Finally, we assessed the Surgivisio image quality and surgeon experience (Table 4). The surgeon satisfaction rate regarding 2D and 3D image quality reached 95.8%, just like the full experience with the unified navigation platform. Eighty-five percent of surgeons found the system easy to use.

DISCUSSION

Patient Dose: Comparison With the Scientific Literature

We examined the effect of the Surgivisio platform on patient radiation levels for procedures not requiring pedicle screw placement. Contrary to other studies in the literature, these procedures were carried out for postmarket surveillance purposes and not in the context of a radiation-oriented analysis. This suppresses the bias of surgeons subconsciously focusing on the emitted radiation to achieve optimal scores. Thus, the data collected here genuinely represent the levels achieved by surgeons in their day-to-day practice. Finally, accuracy was not a point of focus, as related data are already available.[21] However, no complication related to the use of the Surgivisio platform occurred.

Radiation levels remain a key concern in vertebral augmentation interventions.[6,9,22] The median DAP per vertebra (respectively ED per vertebra) in the vertebroplasty and SpineJack groups total 2.90 and 3.80 Gy.cm² (respectively 0.65 and 0.80 mSv). The higher dose levels are linked to the additional implant expansion step monitored using fluoroscopy. This aligns with recently published vertebroplasty data, which report a mean ED per level equal to 0.88 mSv when using the Surgivisio system compared with a 10-fold increase with the commonly used O-arm system (9.83 mSv).[16] Wojdyn et al also studied the contribution of navigation for vertebroplasty procedures.[8] While highlighting its benefits to cut down patient dose, the mean DAP per vertebra delivered by the O-arm reached 6.0 Gy.cm,² which is double the value of our results.[8] This corroborates the

Table 2. Radiation exposure and operative time comparisons between vertebroplasty and SpineJack.

Outcome Measure	Vertebroplasty	SpineJack	*P*
DAP, Gy.cm²			
Total	3.47 (2.70–5.73)	3.80 (2.83–4.62)	0.83
3D	1.90 (1.5–3)	2.05 (1.60–3.10)	0.90
2D	1.30 (0.9–2.2)	1.44 (1.13–1.90)	0.68
3D contribution to DAP, %	56.30	53.70	
DAP per treated vertebra, Gy.cm²	2.90 (1.90–4.37)	3.80 (2.83–4.62)	**0.03**
Dose, mSv	0.81 (0.57–1.30)	0.80 (0.69–1.12)	0.81
Dose per treated vertebra, mSv	0.65 (0.41–1.04)	0.80 (0.69–1.12)	**0.049**
Operative time, min	30 (23–41.25)	33 (28–38.5)	0.67

Abbreviations: 2D, 2-dimensional; 3D, 3-dimensional; DAP, dose-area product.
Note: Data presented as median (interquartile range) unless otherwise specified. Boldface indicates statistically significant findings at $P < 0.05$.

Table 3. Subgroup analysis results based on the number of 3D acquisitions.

Image and Dose measurements	Procedures With ≤1 3D Acquisition	Procedures With >1 3D Acquisition	*P*
No. of procedures	239	35	
No. of vertebrae per 3D image	1.45 (343–237)	0.99 (73–74)	
Median No. of 3D image	1 (1–1)	2 (2–2)	**<0.001**
DAP per vertebra, Gy.cm²	2.8 (1.9–3.9)	6.05 (2.71–9.8)	**<0.001**
Dose per vertebra, mSv	0.65 (0.42–0.96)	1.57 (0.54–1.92)	**<0.001**

Abbreviations: 3D, 3-dimensional; DAP, dose-area product.
Note: Data are presented as median (interquartile range) unless otherwise specified. Boldface indicates statistically significant findings at $P < 0.05$.

side-by-side comparison performed on phantoms by Rousseau et al, who found a 5 to 6 times lower ED when using Surgivisio.[23] Moreover, when using C-arm–based fluoroscopic guidance, radiation levels per vertebra were either comparable (0.50 mSv)[5] or higher (ranging from 8.37–15.1 Gy.cm² for vertebroplasties and kyphoplasties)[8,24] than the ones reported here. Even when using a double C-arm setup to avoid unnecessary radiation caused by C-arm repositioning, the ED was close to 1 mSv.[25] Very few articles have focused on dose considerations when inserting a SpineJack implant. A Surgivisio-related study reported an average overall DAP of 4.43 Gy.cm² for navigated cases, which is a little higher than the present data. Yet, the surgeons carried out the procedures just a few months after acquiring the platform and were thus assimilating the device-specific steps. In this same study, the mean fluoroscopic DAP was significantly lower than that for navigation (0.5 Gy.cm²). This may be due to significant surgeon experience, intensive practice of the fluoroscopy-guided approach, and low-dose C-arm modes. Furthermore, as mentioned above, surgeons monitored with standard fluoroscopy the SpineJack expansion of navigated procedures, which reduces its low-dose potential for this indication.[21]

We also focused on the 2D and 3D dose contributions. In both groups, they each accounted for just above 50% of the total DAP, regardless of the number of 3D acquisitions. When analyzing our platform's workflow, the user may expect the 3D process to be more irradiant, as it relies on multiple 2D acquisitions (90 or 180) and is more time-consuming than the 2D step. Several explanations can be raised, such as the frequent use of 2D image controls to monitor the instrument insertion and cement injection steps or the effectiveness of the 3D reconstruction process which relies on relatively few images—even 180 shots is low based on the current market standards. The focus on optimizing the 3D image generation process is linked to its increased potential for computer-assisted spine surgery compared with conventional 2D fluoroscopy,[26,27] as it enables the surgeon to follow in real-time the instrument trajectory in all spatial planes. After screening the literature, the only comparable data found was the Surgivisio-related study published by Prod'homme et al, which yielded similar 3D dose results (58% of the total ED).[16]

Additionally, we split the included surgeries based on the total number of 3D acquisitions (at most or more than 1). Unsurprisingly, the DAP and ED per vertebra were significantly higher in the subgroup with more than 1 3D image. The main causes reside in either the large number of levels treated—17/35 procedures included 2 to 9 vertebrae—or the need for a 3D control often resulting from unexpected complexity.

Survey

We attempted to quantify the image quality and usability of our platform through an in-house survey. Indeed, achieving low patient radiation levels becomes pointless if the levels are obtained at the cost of degraded image guidance or increased workflow complexity. The aim of bringing a surgical platform to the market is for OR teams to use it. The 95.8% ratings established a high user satisfaction regarding image quality and overall experience with the system. This means that the system was able to provide surgeons with both suitable guidance in the 2D and 3D modes and efficient assistance

Table 4. Survey question results.

Survey Item	Total No. of Answers	No. of Respondent Surgeons	No. of Positive Ratings (4/5 and 5/5)	Satisfaction Rate, %
2D image quality	24	7	22	95.8
3D image quality	24	7	23	95.8
Ease of use	40	8	34	85.0
Full experience with Surgivisio	24	7	23	95.8

Abbreviations: 2D, 2-dimensional; 3D, 3-dimensional.

during their procedures. A slightly lower score came out for ease of use (85%), given that more than 50% of the procedures were performed shortly after the start of the system's commercialization (less than 2 years). Surgeons were thus going through the learning curve and adjusting to the new workflow. Additionally, most surgeries were performed percutaneously, which adds complexity to the workflow and may hamper the OR staff's training. However, an 85% rate constitutes an encouraging result, and the company has implemented several technical developments to fulfill the users' requests. As usability and OR workflow integration are becoming new benchmarks to evaluate spine robots, these criteria are of prime importance.[28] The adoption of a navigation platform no longer exclusively relies on technical and safety criteria. It must be user friendly and easy to comprehend in order to gain the support of the medical team. Surgeons will then have the optimal tools to effectively treat patients while operating in a safe environment.

Limitations

This clinical protocol only included navigated procedures, which means we could not directly compare our results to conventional image guidance methods. We tried to limit the bias of bibliographic comparisons by only comparing normalized radiation levels per vertebra, but differences relating to the imaging systems and dose sensors used may not have been captured. Regarding our survey, the number of respondents is low compared with the total number of procedures. Having the surgeons fill out the same form after each surgery could be repetitive, and surgeons did not always have the time to complete the survey. In addition, some surgeons answered the survey for procedures not included in the present analysis. Incidentally, the 2 surgeons not represented in the survey results performed 4 of the procedures.

CONCLUSION

This study demonstrates the efficiency of the Surgivisio platform to assist surgeons during vertebral augmentations. The procedures were performed without a specific focus on patient dose. Radiation levels were generally lower compared with those reported in the literature for fluoroscopy guidance or other navigation options, limiting radiation-related hazards for the patient. Moreover, users from different hospitals expressed satisfaction with the image quality and usability, showing that the latter were not impeded by the low-dose protocol. As usability is becoming a major criterion when selecting a surgical platform, it was necessary to highlight the device's potential to provide adequate guidance and workflow integration to surgeons. The next step should be to conduct a study that directly compares our platform to conventional methods.

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