ELSEVIER

The Spine Journal ■■ (2016) ■■–■■

THE SPINE JOURNAL

Clinical Study

Risk-benefit analysis of navigation techniques for vertebral transpedicular instrumentation: a prospective study

David C. Noriega, PhD[a,*], Rubén Hernández-Ramajo, PhD[a], Fiona Rodríguez-Monsalve Milano, MD[a], Israel Sanchez-Lite, MD[b], Borja Toribio, MD[b], Francisco Ardura, PhD[a], Ricardo Torres, PhD[c], Raul Corredera, PhD[a], Antonio Kruger, PhD[d]

[a]*Unidad de Columna, Servicio Cirugía Ortopédica, Hospital Clínico Universitario de Valladolid, Calle Ramón y Cajal, 47008 Valladolid, Spain*
[b]*Servicio de Radiología, Hospital Clínico Universitario de Valladolid, Calle Ramón y Cajal, 47008 Valladolid, Spain*
[c]*Servicio de Radiofísica y Protección Radiológica, Hospital Clínico Universitario de Valladolid, Calle Ramón y Cajal, 47008 Valladolid, Spain*
[d]*Center for Orthopaedics and Trauma Surgery University Hospital Giessen and Marburg GmbH, Marburg, Germany*

Received 9 February 2016; revised 30 June 2016; accepted 2 August 2016

Abstract

BACKGROUND CONTEXT: Pedicle screws in spinal surgery have allowed greater biomechanical stability and higher fusion rates. However, malposition is very common and may cause neurologic, vascular, and visceral injuries and compromise mechanical stability.

PURPOSE: The purpose of this study was to compare the malposition rate between intraoperative computed tomography (CT) scan assisted-navigation and free-hand fluoroscopy-guided techniques for placement of pedicle screw instrumentation.

STUDY DESIGN/SETTING: This is a prospective, randomized, observational study.

PATIENT SAMPLE: A total of 114 patients were included: 58 in the assisted surgery group and 56 in the free-hand fluoroscopy-guided surgery group.

OUTCOME MEASURES: Analysis of screw position was assessed using the Heary classification. Breach severity was defined according to the Gertzbein classification. Radiation doses were evaluated using thermoluminescent dosimeters, and estimates of effective and organ doses were made based on scan technical parameters.

METHODS: Consecutive patients with degenerative disease, who underwent surgical procedures using the free-hand, or intraoperative navigation technique for placement of transpedicular instrumentation, were included in the study.

RESULTS: Forty-four out of 625 implanted screws were malpositioned: 11 (3.6%) in the navigated surgery group and 33 (10.3%) in the free-hand group (p<.001). Screw position according to the Heary scale was Grade II (4 navigated surgery, 6 fluoroscopy guided), Grade III (3 navigated surgery, 11 fluoroscopy guided), Grade IV (4 navigated surgery, 16 fluoroscopy guided), and Grade V (1 fluoroscopy guided). There was only one symptomatic case in the conventional surgery group. Breach severity was seven Grade A and four Grade B in the navigated surgery group, and eight Grade A, 24 Grade B, and one Grade C in free-hand fluoroscopy-guided surgery group. Radiation received per patient was 5.8 mSv (4.8–7.3). The median dose received in the free-hand fluoroscopy group was 1 mGy (0.8–1.1). There was no detectable radiation level in the navigation-assisted surgery group, whereas the effective dose was 10 µGy in the free-hand fluoroscopy-guided surgery group.

FDA device/drug status: Not applicable.

Author disclosures: ***DCN:*** Speaking and/or Teaching Arrangements: Vexim (C, Paid directly to the author), Medtronic (B, Paid directly to the author), outside the submitted work. ***RH-R:*** Nothing to disclose. ***FR-MM:*** Nothing to disclose. ***IS-L:*** Nothing to disclose. ***BT:*** Nothing to disclose. ***FA:*** Speaking and/or Teaching Arrangements: Vexim (C, Paid directly to the author), outside the submitted work. ***RT:*** Nothing to disclose. ***RC:*** Nothing to disclose. ***AK:*** Consulting: Vexim, Spineart (B, Paid directly to the author); Speaking and/or Teaching Arrangements: Vexim, Spineart, Medtronic, Soteira, DFine, Biomet (C, Paid directly to the author); Research Support (Investigator Salary, Staff/Materials): Vexim (D, Paid directly to the author), outside the submitted work.

The disclosure key can be found on the Table of Contents and at www.TheSpineJournalOnline.com.

* Corresponding author. Unidad de Columna, Servicio Cirugía Ortopédica, Hospital Clínico Universitario de Valladolid, Calle Ramón y Cajal, 47008 Valladolid, Spain. Tel.: +34 630 381 468.

E-mail addresses: noriega1970@icloud.com, dcnoriega1970@gmail.com (D.C. Noriega).

http://dx.doi.org/10.1016/j.spinee.2016.08.004

CONCLUSIONS: Malposition rate, both symptomatic and asymptomatic, in spinal surgery is reduced when using CT-guided placement of transpedicular instrumentation compared with placement under fluoroscopic guidance, with radiation values within the safety limits for health. Larger studies are needed to determine risk-benefit in these patients.

Keywords: Cone-beam computed tomography; Fluoroscopy; Guided surgery; Navigation; Pedicle screw; Spine surgery

Introduction

The primary objective of this study was to compare the malposition rate between intraoperative computed tomography (CT) navigation and free-hand fluoroscopy-guided techniques.

The use of pedicle screws in spinal surgery has represented a great advancement over the last decades, permitting greater biomechanical stability and achieving higher fusion rates. However, pedicle screw malpositioning is very common, with rates reported in the literature ranging from 3% to 55% [1–3]. As a result, image-guided surgical techniques have been developed, aimed at improving the accuracy of pedicle screw placement, reducing the risk of serious complications, and improving the mechanical stability of pedicle screws [4–7].

The use of navigated surgery in pedicle screw placement allows real-time obtainment of a three-dimensional image of the vertebra, improving the accuracy of screw placement and decreasing the malposition rate up to 3.6% (range 0%–11%) [7], thus reducing the complications derived from screw malpositioning. Additionally, a decrease has been observed in the reoperation rate owing to screw malposition from 8.8% in conventional surgery to 2.9% in navigated surgery [6].

The comparative studies in the literature regarding navigation versus fluoroscopy are favorable to navigation with a difference in errors that was statistically significant in all of the studies, a difference that increases with small pedicles and altered anatomies, as in the case of deformities [4,6–8].

Regarding the radiation received in navigated surgery by the use of intraoperative CT, it has been observed that radiation rates received by both the surgical team and the patient are lower than radiation rates received in conventional surgery [9,10].

Studies that combine effectiveness of navigation systems with radiation levels for both the surgical team and the patients have not been published yet.

Secondarily, analyses were performed on surgical team radiation, patient radiation, symptomatic screws, malposition according to operated vertebral level operated on, right-left malposition, and reoperation rate.

Methods

Patients and design

This was a single-center, prospective and randomized study, conducted between May 2011 and May 2013 after institutional review board approval.

Adult (≥18 years) patients with degenerative disease, with instrumentations between T10 and S1, who underwent surgical procedures using the free-hand or intraoperative navigation technique for placement of transpedicular instrumentation, were included in the study. Treatments were allocated at random in a ratio of 1:1 in blocks of sizes 2 or 4. A randomization list was established by an independent statistician, and programmed using SAS 9.4 (SAS Institute Inc., Cary, NC, USA). All patients signed informed consent to participate in the study.

Radiological analysis of the position of the transpedicular screws was performed using a 1-mm spinal CT scan. Evaluation of axial slices as well as sagittal and coronal reconstructions was carried out. Analysis of screw position was performed using the Heary classification [11]. Breach severity was defined according to the Gertzbein classification [12].

Radiation dose assessment

The assessment of the radiation doses received by patients was performed by two different methods. On one hand, measurements were made in real patients by means of the use of thermoluminescent dosimeters (TLDs) to obtain direct reading of the cumulative skin dose during the procedure, and on the other, estimates of the effective dose and organ dose were made based on the technical parameters of the scans.

Skin dose with thermoluminescent dosimeters

In each procedure, a total of 21 TLD-100 dosimeters (Harshaw Bicron, Solon, OH, USA) were placed around the patient to measure the cumulative skin dose during the complete study. To cover the anatomical area irradiated during the surgical procedure, the dosimeters were distributed in three rings of seven TLDs surrounding the patient's torso and separated from each other by a variable distance (10–15 cm). This ensures that at least one ring is covered by one of the tomographic scans. Dosimeters were placed in each ring so that they surrounded the patient at approximately equidistant positions: three TLDs aligned in the anteroposterior projection, another in each of the lateral projections, and the other two in the posteroanterior projection, flanking the zone of the surgical procedure. Each of the dosimeters was numbered so that its position on the patient could be identified.

After completing each procedure, these TLDs were collected and read with a TLD reader (Harshaw TLD Model 4500, Thermo Fisher Scientific, Waltham, MA, USA) using WinREMS software (Thermo Fisher Scientific, Waltham, MA, USA).