INTRODUCTION

Pedicle screw fixation plays an important role in many spinal surgeries, providing superior post-operative spinal stability. Stabilization methods for better consolidation of arthrodesis evolved through the decades.\(^1\)\(^-\)\(^3\)

Pedicle screw instrumentation was used by Roy-Camille in the 1960s and 1970s however, it was with the work by Cotrel-Dubousset, in the 1980s, that the pedicle screw fixation gained popularity as the third generation of spine instrumentation.\(^2\) In 1998, pedicle screw instrumentation was downclassified from an FDA Class III to Class II, and has been since then gaining popularity. This technology is now the standard care in arthrodesis of the thoracolumbar spine, due to the improved fusion rates and rigidity provided by these constructs.\(^1\)\(^-\)\(^2\)

Studies have found that pedicle screws are biomechanically advantageous when compared to the previously used rod and hook systems.\(^3\)

As the morphology of the pedicle is complex and due to its proximity to a number of significant tissues (e.g., the spinal cord and nerve roots), screw misplacement might lead not only to a decreased stability but also to neurological, vascular, and visceral injuries.\(^4\) Many surgeons...
consider the majority of cortical violations to be clinically silent depending on the location and the length of penetration — that can be categorized according to the length of perforation (up to 2 mm, 2-4 mm or greater than 4 mm). However, even those initially silent perforations may be responsible for instability of the biomechanical construct, reduced fusion rates, or accelerated adjacent-level degeneration.

The normal anatomy is naturally complex, and pedicles can be difficult to instrument due to pathological abnormalities. Scoliosis, rotation and asymmetric compression of vertebrae can significantly alter pedicle anatomy and complicate pedicle screw placement. The freehand technique for the placement of the pedicle screw is essentially a blind technique that depends on the correct identification of anatomical landmarks and experience of the surgeon to ensure proper insertion. Misplacement rates have been reported to range from 5% to 41% in the lumbar spine and from 3% to 55% in the thoracic spine when using conventional techniques. A recent review on the subject brings us the result of nine studies based on the freehand technique insertion of pedicle screws in the thoracolumbar spine, revealing an accuracy rate of 71.9% to 98.3%. Due to the difficulties and risks inherent to the implant insertion, new techniques have been developed to decrease the rate of misplaced screws and to increase the accuracy of positioning. The technology more widely used is the intraoperative fluoroscopic C-arm. Studies have generally shown that accuracy rates of screws placed with this technique have ranged from as low as 27.6% to above 90%. Fluoroscopy-assisted instrumentation has a much smaller learning curve when compared with the freehand technique. In theory, the error rate should be lower, since fluoroscopy can give surgeons a chance to correct the mistakes before inserting the screw. However, this additional safety mechanism is associated with potential safety disadvantages, as the increased exposure of the surgeon and his staff to radiation. Alternatively, a monitoring method that came up with the aim of increasing the accuracy of screws insertion and reducing exposure to radiation was computer-assisted navigation. Following the introduction of CT–guided spinal navigation (O-arm), numerous reports in the literature have been published demonstrating its utility in increasing the accuracy of pedicle screw placement and, at the same time, decreasing the incidence of neurological injury from misplaced pedicle screws. There have been many studies about pedicle screw placement accuracy with this technique, but due to differing definitions of breach and the lack of control groups, many of these studies are difficult to compare. Therefore, there is a shortage of direct comparison studies with standardized methodology.

OBJECTIVE

The objective of this experimental study was to compare the accuracy of insertion of pedicle screws in the thoracic spine using fluoroscopy or computer-assisted navigation techniques.

MATERIALS AND METHODS

Ethical Committee

This study was submitted to the Ethical Committee through the Plataforma Brasil by the CAAE 37515014.3.0000.5054 and approved with the protocol 1.000.463 on 03/24/2015.

Study design and setting

This is an experimental study with unclaimed fresh cadavers, obtained from the local Forensic Institute. Only the thoracic vertebrae of the cadavers were used. Cadavers presenting spinal trauma or important spinal deformities were excluded. The project was approved by the Research Ethics Committee of the Walter Cantidio University Hospital, where the experiments took place, and all institutional and governmental regulations concerning the ethical use of human cadavers were followed.

METHODS

All vertebrae samples in the Navigation group were submitted to computed tomography (CT) scans before the surgical experiment. All the pieces were then positioned on the surgical table and fixed by positioners used for hip replacement surgery for operations. The same surgeon performed all procedures. In the Fluoroscopy group, the screws were inserted with the guidance of a combination of anterior-posterior and lateral view images. In the Navigation group, the screws were inserted using a computer-assisted navigation system. CT scans from the Navigation group were inserted into the navigation software and selected points were marked for navigator calibration.

The violation cases were recorded as frequencies. The rates of pedicle breach were compared in both groups using the exact Fisher test (as the number of expected events was below 5). A significant value of $p < 0.05$ was adopted.

RESULTS

No cadaver presented morphological abnormalities that would justify exclusion from the experiment. A total of 80 pedicle screws were inserted, 40 in each group. A total of 350 fluoroscopic images were necessary in the Fluoroscopy group, 8.75 per screw or pedicle in average. No fluoroscopy image was produced in the navigation group. In the Fluoroscopy group, 1 out of 40 screws was misplaced (2.5%). This was a medial cortical breach, between 2-4 mm. In the Navigation group, there was also 1 case of pedicle violation (2.5%), of equal position and size of perforation.

No statistically significant differences between the two methods were found ($p > 0.05$).

Figure 1. Spine section (1) prepared to be dissected and instrumented, fixed by retractors (2).
DISCUSSION

Fluoroscopy is currently the most widely used method of pedicle screws insertion. However, as mentioned above, it has some intrinsic disadvantages, such as the amount of radiation to which the surgical team is exposed. Numerous studies show good accuracy rates in the insertion of pedicle screws with computer-assisted navigation when compared to the conventional method of fluoroscopy, but the superiority of navigation in terms of insertion accuracy is still doubtful, with variable breach rates between studies. Laine et al. demonstrated a greater misplacement rate in fluoroscopy group (13.4%) when compared to the navigation (4.6%). However, in that study, rates were not significantly different when only the breaches greater than 4 mm were considered (1.4% in fluoroscopy group versus 0% in the navigation group). Another study also found superior accuracy in the screws insertion with computer-assisted navigation (2% of breach rate versus 23% with use of fluoroscopy). Tabaraee et al. conducted an experimental study in cadaver, similar to the present study, performing a direct comparison of the two methods, and also found no statistically significant differences between the groups. In a meta-analysis of 130 studies involving clinical and cadaveric, prospective and retrospective studies, there were no statistically significant differences between the insertion of screws by two methods in the thoracic spine. Another systematic review of 30 studies, more recently published, found greater accuracy in the insertion of pedicle screws with navigation (84.3%) compared to fluoroscopy (68.1%). However, only 1 of the 30 studies was a randomized controlled trial. All others were only level 3 (observational studies with control groups) and 4 (observational studies). The comparison between studies, is difficult, due to lack of standardization of the imaging methods and the lack of uniform criteria for classifying the violations as events. Different screw misplacement grading systems are used to assess the screw placement accuracy, but usually including the following categories: Grade 0, no pedicle perforation; Grade 1, perforation of 0-2 mm; Grade 2, 2-4 mm; Grade 3, perforation greater than 4 mm. Another cause of the difficulty in comparing and interpreting studies is that the accuracy depends on the assessed levels. A preponderance of lumbar levels tends to increase the overall rate of success since the pedicles of these vertebrae are larger and easier to be instrumented when compared to the thoracic levels. For this reason, even the published systematic reviews can not be taken in consideration as the real accuracy for all levels. We chose to use thoracic vertebrae due to the smaller diameter of the pedicles and a smaller available space for spinal cord at this level.
CONCLUSION

The accuracy in the insertion of pedicle screws in the thoracic spine is equal comparing the computer-assisted navigation and fluoroscopy-assisted methods. As the safety of the procedure is greater for the surgical team with the navigation method, due to the absence of exposure to radiation, there is a need for randomized controlled trials in the clinical setting that evaluate other outcomes, such as the safety for the patient too, considering the surgical time, bleeding and other potentially serious complications related to surgical time in the instrumentation of the thoracic spine using fluoroscopy or navigator-assisted methods.

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