The Spine Journal 14 (2014) 2740–2747

Basic Science

A novel anchoring system for use in a nonfusion scoliosis correction device

Martijn Wessels, PhD[a,*], Jasper J. Homminga, PhD[a], Edsko E.G. Hekman, MSc[a], Gijsbertus J. Verkerke, PhD[a,b]

[a]*Department of Mechanical Engineering, Laboratory of Biomechanical Engineering, University of Twente, Faculty of Engineering Technology, Drienerlolaan 5, PO Box 217, 7500 AE Enschede, The Netherlands*
[b]*Department of Rehabilitation Medicine, University Medical Center Groningen, University of Groningen, Hanzeplein 1, Faculty of Medical Sciences, PO Box 30.001, 9700 RB Groningen, The Netherlands*

Received 5 March 2013; revised 19 March 2014; accepted 16 April 2014

Abstract

BACKGROUND CONTEXT: Insertion of a pedicle screw in the mid- and high thoracic regions has a serious risk of facet joint damage. Because flexible implant systems require intact facet joints, we developed an enhanced fixation that is less destructive to spinal structures. The XSFIX is a posterior fixation system that uses cables that are attached to the transverse processes of a vertebra.

PURPOSE: To determine whether a fixation to the transverse process using the XSFIX is strong enough to withstand the loads applied by the XSLATOR (a novel, highly flexible nonfusion implant system) and thus, whether it is a suitable alternative for pedicle screw fixation.

STUDY DESIGN: The strength of a novel fixation system using transverse process cables was determined and compared with the strength of a similar fixation using polyaxial pedicle screws on different vertebral levels.

METHODS: Each of the 58 vertebrae, isolated from four adult human cadavers, was instrumented with either a pedicle screw anchor (PSA) system or a prototype of the XSFIX. The PSA consisted of two polyaxial pedicle screws and a 5 mm diameter rod. The XSFIX prototype consisted of two bodies that were fixed to the transverse processes, interconnected with a similar rod. Each fixation system was subjected to a lateral or an axial torque.

RESULTS: The PSA demonstrated fixation strength in lateral loading and torsion higher than required for use in the XSLATOR. The XSFIX demonstrated high enough fixation strength (in both lateral loading and torsion), only in the high and midthoracic regions (T10–T12).

CONCLUSIONS: This experiment showed that the fixation strength of XSFIX is sufficient for use with the XSLATOR only in mid- and high thoracic regions. For the low thoracic and lumbar region, the PSA is a more rigid fixation. Because the performance of the new fixation system appears to be favorable in the high and midthoracic regions, a clinical study is the next challenge.

Keywords: Scoliosis; Transverse process; Pedicle screw; Anchor; Posterior; Cable

FDA device/drug status: Not applicable.

Author disclosures: ***MW:*** Grant: Technology Foundation STW (F, Paid directly to institution); Research Support (D, Investigator Salary): Technology Foundation STW (F, Paid directly to institution); Research Support (C, Staff/Materials): Technology Foundation STW (F, Paid directly to institution). ***JJH:*** Grant: Technology Foundation STW (F, Paid directly to institution); Research Support (E, Investigator Salary): Technology Foundation STW (F, Paid directly to institution); Research Support (E, Staff/Materials): Technology Foundation STW (F, Paid directly to institution). ***EEGH:*** Grant: Technology Foundation STW (F, Paid directly to institution); Research Support (E, Investigator Salary): Technology Foundation STW (F, Paid directly to institution); Research Support (E, Staff/Materials): Technology Foundation STW (F, Paid directly to institution). ***GJV:*** Grant: Technology Foundation STW (F, Paid directly to institution); Research Support (E, Investigator Salary): Technology Foundation STW (F, Paid directly to institution); Research Support (E, Staff/Materials): Technology Foundation STW (F, Paid directly to institution).

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

* Corresponding author. Department of Mechanical Engineering, Laboratory of Biomechanical Engineering, University of Twente, Faculty of Engineering Technology, De Tuinfluiter 32, 7671WE vriezenveen, The Netherlands. Tel.: 0031 53489 2351.

E-mail address: m.wessels@utwente.nl (M. Wessels)

1529-9430/$ - see front matter
http://dx.doi.org/10.1016/j.spinee.2014.04.028

Introduction

Pedicle screws are commonly used for posterior anchoring of spinal implants [1–3]. Although pedicle screws are now commonly used on the lumbar and thoracic spine [2], the shape of the pedicles in the thoracic region is inconsistent, especially in spinal deformities such as scoliosis [4,5]. As a result of this, pedicle screw placement is very challenging in this region [6–9]. Currently, pedicle screws are inserted by using either the free-hand technique (as in the Roy-Camille procedure), the open lamina technique where a partial laminectomy is performed, or under application of an image-guidance system. In each of these techniques, required accuracy is very high [10,11]. The pedicle entry point for a high or midthoracic pedicle screw is situated at the base of the superior facet [12,13]. Even a well-placed pedicle screw may still violate the facet joint. Particularly in the thoracic region, the size and position of the screw head can result in obstruction of movements of the facet joints. Facet joint violation in pedicle screw anchoring in the thoracic and lumbar regions is a common occurrence in spinal surgery [14,15]. The effect of limited motion of the joints, such as in spondylodesis, is often desirable, but particularly troublesome in the recent trend toward dynamic, nonfusion systems that aim to maintain the flexibility of the spine. Consequently, a demand for an enhanced fixation, which is less destructive to spinal structures, has grown.

For these reasons, a novel fixation system, referred to as XSFIX, was developed; a bridge construction that consists of two anchors, with a bridge in between. Each of these anchors consists of a connector that is attached to a transverse process by means of a cable. This new fixation system can be applied for nonfusion spinal implant systems that will correct spinal deformities, for example, scoliosis. The XSLATOR, a nonfusion scoliosis correction system that is currently being developed (Fig. 1) is able to lengthen (cranially-caudally) to allow for spinal growth and daily motion (including flexion/extension) by making use of sliding bearings. The axial (caused by all spinal motion including growth) and sagittal forces (caused by flexion/extension) remain extremely low, whereas lateral force and axial torque are significant but low [16]. To consider the XSFIX as a solid fixation, the anchor must be able to transfer the forces and moments forces delivered by the XSLATOR, which are (including a design safety factor of 2) a maximal lateral force of 200 N and a maximal axial torque (around the local spinal longitudinal axis) of 7 Nm [16]. These loads are smaller than the loads applied by the fusion systems because the nonfusion implant systems

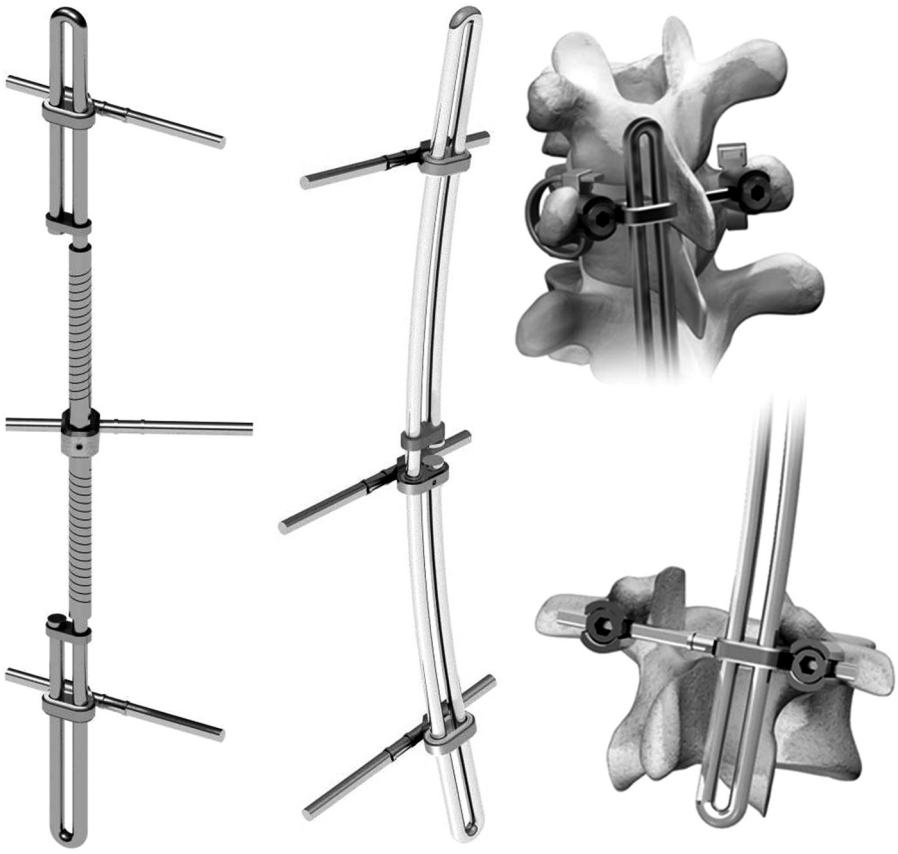

Fig. 1. The XSLATOR consists of two implants (Left and Center) that are posteriorly fixed to the vertebrae. The three bridges (Left and Center) can relatively slide axially, keeping the axial forces extremely low. The bridges are fixed to the spine using transverse process cables (XSFIX; Right Top) or two pedicle screws (Right Bottom).