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Biomechanical assessment of the stabilization capacity of monolithic spinal rods with different flexural stiffness and anchoring arrangement

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ABSTRACT

Background: Spinal disorders can be treated by several means including fusion surgery. Rigid posterior instrumentations are used to obtain the stability needed for fusion. However, the abrupt stiffness variation between the stabilized and intact segments leads to proximal junctional kyphosis. The concept of spinal rods with variable flexural stiffness is proposed to create a more gradual transition at the end of the instrumentation.
Method: Biomechanical tests were conducted on porcine spine segments (L1–L6) to assess the stabilization capacity of spinal rods with different flexural stiffness. Dual-rod fusion constructs containing three kinds of rods (Ti, Ti–Ni superelastic, and Ti–Ni half stiff-half superelastic) were implanted using two anchor arrangements: pedicle screws at all levels or pedicle screws at all levels except for upper instrumented vertebra in which case pedicle screws were replaced with transverse process hooks. Specimens were loaded in forward flexion, extension, and lateral bending before and after implantation of the fusion constructs. The effects of different rods on specimen stiffness, vertebra mobility, intradiscal pressures, and anchor forces were evaluated.
Finding: The differences in rod properties had a moderate impact on the biomechanics of the instrumented spine when only pedicle screws were used. However, this effect was amplified when transverse process hooks were used as proximal anchors.
Interpretation: Combining transverse hooks and softer (Ti–Ni superelastic and Ti–Ni half stiff-half superelastic) rods provided more motion at the upper instrumented level and applied less force on the anchors, potentially improving the load sharing capacity of the instrumentation.

1. Introduction

Spinal fusion is a common treatment to relieve chronic back pain, instability, or neurological injury. Strong and rigid posterior constructs are used to prevent fixation failure and to provide the stability needed for fusion (Kotani et al., 1996; Lorenz et al., 1991). However, because of an abrupt variation in stiffness between the instrumented and the intact spinal segments, the range of motion between the end of the construct and the adjacent segment changes suddenly, which leads to high stress concentration in the transition zone, to the adjacent segment degeneration, proximal junctional kyphosis (PJK), or even fractures (DeWald and Stanley, 2006; Hassanzadeh et al., 2013; Helgeson et al., 2010).

So-called dynamic stabilization systems (DSS) have been proposed to provide more motion at the upper instrumented vertebra (UIV) level and to reduce the risk of adjacent segment degeneration. However, DSS are often mechanically complex, bulky, and frequently associated with inadequate stability or persistent PJK (Bono et al., 2009). For example, Li et al. (2013) reported on 2-year follow-up of 36 patients who underwent surgery using the Isobar TTL Semi-Rigid Rod System. The system did not show superior results compared to traditional fusion constructs, as 14 patients showed signs of PJK despite the use of DSS.

An ideal implant should combine high stabilization capacity where fusion is needed, with a gradual transition between the instrumented and intact spine segments to reduce stress on the adjacent segment, while maintaining a low level of force on the anchors.

Such a transition could be obtained by modifying the rod stiffness or by changing the anchor arrangement. For example Bruner et al. (2010) performed an *in vitro* study to compare titanium and composite rods. They showed that customizing the bending compliance of a dynamic rod according to specific patient needs allows a certain improvement in the load sharing capacity of instrumentation. However, an abrupt change in mobility between the instrumented and the intact spine segments is still problematic even for rods with significantly different flexural stiffness, such as titanium (Young's modulus $E = 110$ GPa) or PEEK ($E = 3.6$ GPa), when they are anchored with pedicle screws (Gornet et al., 2011). On the other hand, Thawrani et al. (2014) showed in an

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in vitro study that transverse process hooks at the upper instrumented vertebrae are effective for creating a gradual transition and relieve the stress on the adjacent segment.

Considering the above, the main objective of this study was to evaluate the effect of the flexural stiffness of the rod, combined with the use of different anchoring techniques at the proximal end of the instrumentation on the load sharing capacity of the dual-rod spinal instrumentation.

A variation of the rod's flexural stiffness was obtained using Ti–Ni shape memory alloys. The mechanical properties of these alloys are strongly processing dependent and can be controlled by local annealing. Previous studies have shown that radically different mechanical properties could be obtained on monolithic Ti–Ni rods using local Joule-effect annealing. For example, a 10-minute annealing of Ti–Ni rods has allowed a variation of mechanical properties from elasto-plastic (Young's modulus E = 50 GPa) to superelastic (E = 36 GPa) or pseudoplastic (E = 83 GPa) (Facchinello et al., 2013). Using this technology, it was possible to produce 5.5-mm-diameter spinal rods with variable flexural stiffness (Facchinello et al., 2014a).

The different anchoring techniques at the proximal end of the instrumentation used in this study were either pedicle screws or transverse process hooks.

To summarize, this paper presents the results obtained by *in vitro* testing of Ti–Ni rods with variable flexural stiffness anchored to a porcine spine specimen with pedicle screws or transverse process hooks, which are compared with conventional Ti rods of the same size.

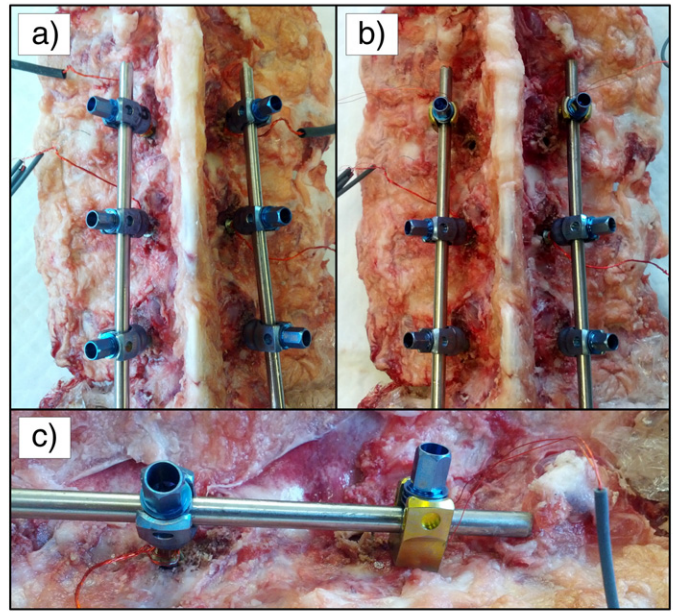

Fig. 1. Pictures of an instrumented specimen with a) all pedicle screws, b) pedicle screws and transverse process hooks at the upper instrumented vertebra, and c) sideview of a pedicle screw and a transverse hook on a specimen.

2. Methods

The biomechanical testing was conducted on six lumbar porcine spine models (L1–L6, 6–8 months, about 220 lb.).

2.1. Specimen preparation and fixation

Upon reception of fresh spines, soft tissues were dissected, while ensuring that the ligaments, intervertebral disks, and bones were preserved intact. On the same day, holes were free-hand drilled in the L5, L4, and L3 vertebrae for subsequent pedicle screw insertion. The specimens were then stored frozen in plastic bags at −20 °C. Prior to testing, the specimens were thawed for 24 hours at 4 °C as recommended (Tremblay et al., 2015b). A saline solution was used to keep the specimen hydrated throughout the experiment.

The dual rods were then implanted using two anchoring strategies: fixed using pedicle screws (PS) (6.5 × 45 mm, Ti, Medtronic, Minneapolis, Minnesota, USA) at all levels (L3, L4, and L5), or instead of pedicle screws, the proximal ends of the rods were anchored using transverse process hooks (TPH) (Extended body, Ti, Medtronic). Polyester resin (Bondo, St. Paul, MN) was used to fix the end vertebrae to the testing apparatus. An aluminum bloc was used to solidly fix the caudal end of the rods. Such configuration was used to simulate an extended segment of dual-rod instrumentation. Fig. 1 shows pictures of the specimens.

2.2. Spinal rods

Three different 5.5-mm-diameter rods were used: Titanium (Ti), Ti–Ni superelastic (SE) and Ti–Ni half pseudoplasic–half superelastic (VAR) (Fig. 2). Titanium rods (Ti-6Al-4V, ELI) provided by Fort Wayne Metals (Fort Wayne, Indiana, USA) exhibit mechanical properties close to commercial titanium implants with a Young's modulus of 86 GPa (Fig. 2a,b).

Ti-55.94wt.%Ni rods (Johnson Mattey Medical, West Chester, PA, USA) were used as completely superelastic (SE) rods (E = 36 GPa) (Fig. 2a,b), or as variable stiffness (VAR) rods (Fig. 2b). To obtain the VAR rods, the SE rods were Joule-effect annealed (585 °C, 10 min) on the half of their length (Facchinello et al., 2013, 2014a). This partial annealing transforms a compliant (E = 36 GPa) SE material into a high-stiffness (E = 83 GPa) pseudoplastic material (Ti–Ni (Mart)) (Fig. 2a). Following this processing, the VAR rods contained superelastic and pseudoplastic parts of equal lengths with a gradual transition between the two (Fig. 2b).

For the installation, the superelastic part of the VAR rods was always oriented toward the intact segment of the construct to reduce stress concentration in the adjacent segments of the spine (Fig. 2c), in conformity with our calculations (Facchinello et al., 2014b).

2.3. Biomechanical testing setup

Non-instrumented and instrumented specimens were tested under displacement-controlled forward flexion (FE), extension (EX), and lateral bending (LB) modes, using an MTS 858 Minibionix II (Eden Prairie, MN, USA: 15 kN, 150 Nm). The order of the tested motions (FE, EX, or LB) was randomized (Table 1). The maximum rotation of the distal end of the construct for all the testing modes corresponded to 18°, which is slightly inferior to the range of motion measured by Wilke et al. (2011) under pure moment loading (7.5 Nm). This precaution was taken to decrease the risk of specimen damage during testing. Loading rate was 1°/s. During all tests, a follower load of 400 N was applied using a cable deadweight system to simulate spine loading conditions when surrounding muscles are kept intact (Panjabi, 2007; Patwardhan et al., 1999, 2003; Wilke et al., 1998). The cables were guided along the spine segment through the eyelets attached to the side of each free vertebra (see Fig. 3a and e). A 400 N value corresponds to the middle of the preload range studied by Patwardhan et al. (2003), and this value is recommended by Goel et al. (2006). Axial rotation tests were not performed in this study since this motion was not considered to be a significant PJK risk factor (Thawrani et al., 2014).

Note that the use of a custom translation table presented in Fig. 3 allows an almost frictionless translation of the caudal end of the specimen, thus resulting in the application of a pure bending moment during testing. It has been shown that these loading conditions acceptably simulate in vivo motions (Wilke et al., 2001). The results of a detailed validation of the testing bench and the testing procedure can be found in (Tremblay et al., 2015a).

To improve repeatability, each specimen was tested with all the configurations without being removed from the test bench. Preliminary experiments (Facchinello et al., 2015) had shown that a 10-cycle stabilization routine was sufficient to obtain reproducible behavior.