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Is a gradual reduction of stiffness on top of posterior instrumentation possible with a suitable proximal implant? A biomechanical study

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Abstract

BACKGROUND CONTEXT: Proximal junctional kyphosis (PJK) is a challenging complication after rigid posterior instrumentation (RI) of the spine. Several risk factors have been described in literature so far, including the rigidity of the cranial aspect of the implant.

PURPOSE: The aim of this biomechanical study was to compare different proximal implants designed to gradually reduce the stiffness between the instrumented and non-instrumented spine.

STUDY DESIGN/SETTING: This is a biomechanical study.

METHODS: Eight calf lumbar spines (L2–L6) underwent RI with a titanium pedicle screw rod construct at L4–L6. The proximal transition segment (L3–L4) was instrumented stepwise with different supplementary implants—spinal bands (SB), cerclage wires (CW), hybrid rods (HR), hinged pedicle screws (HPS), or lamina hooks (LH)—and compared with an all-pedicle screw construct (APS). The flexibility of each segment (L2–L6) was tested with pure moments of ±10.0 Nm in the native state and for each implant at L3–L4, and the segmental range of motion (ROM) was evaluated.

RESULTS: On flexion and extension, the native uninstrumented L3–L4 segment showed a mean ROM of 7.3°. The CW reduced the mean ROM to 42.5%, SB to 41.1%, HR to 13.7%, HPS to 12.3%, LH to 6.8%, and APS to 12.3%. On lateral bending, the native segment L3–L4 showed a mean ROM of 15°. The CW reduced the mean ROM to 58.0%, SB to 78.0%, HR to 6.7%, HPS to 6.7%, LH to 10.0%, and APS to 3.3%. On axial rotation, the uninstrumented L3–L4 segment showed a mean ROM of 2.7°. The CW reduced the mean ROM to 55.6%, SB to 77.8%, HR to 55.6%, HPS to 55.6%, LH to 29.6%, and APS to 37.0%.

CONCLUSIONS: Using CW or SB at the proximal transition segment of a long RI reduced rigidity by about 60% in relation to flexion and extension in that segment, whereas the other implants tested had a high degree of rigidity comparable with APS. Clinical randomized controlled trials are needed to elucidate whether this strategy might be effective for preventing PJK.

FDA device/drug status: Approved (Pedicle screw rod system and lamina hooks, uCentum; Stainless steel wire cerclage, Cable System; Spinal bands, Universal Clamp; Hinged pedicle screw, cosmicMIA; Hybrid rods, neon).

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Introduction

Long rigid posterior instrumentation (RI) of the spine is a common procedure in spinal care especially in deformity corrective surgery. Proximal junctional kyphosis (PJK) is one of the most important complications, with an incidence ranging from 6% to 61.7% [1–4]. Proximal junctional kyphosis is defined as a kyphosis characterized by two requirements: (1) segmental kyphosis between the upper instrumented vertebra (UIV) and UIV+2 ≥10°; and (2) the postoperative segmental kyphosis between UIV and UIV+2 is at least 10° greater than the preoperative segmental kyphosis [5]. Several factors have been suggested as contributing to the development of PJK, including insufficient or disrupted posterior ligaments, an imbalanced sagittal profile, or a poor bone quality [6–8]. Furthermore, the high degree of rigidity of the instrumented spine in relation to the flexibility of the adjacent upper segments appears to be of clinical relevance. This sudden change of rigidity over a fairly short distance—that is, in the first adjacent segment—is thought to be a risk factor for PJK. Therefore, it has been hypothesized that a gradual stiffness reduction at the last proximal instrumented segment would help reduce the incidence of PJK [6,9–11]. Few studies in the literature have already addressed this idea by evaluating the potential effect of transverse process hooks (TPH) or spinal bands to gradually reduce the rigidity between the instrumented spine and the non-instrumented flexible spine to reduce the risk for PJK [6,10,12,13]. In accordance to this work, the purpose of this biomechanical in vitro study was to directly compare five "semi-flexible" implants—spinal bands (SB), cerclage wires (CW), hybrid rods (HR), hinged pedicle screws (HPS), and lamina hooks (LH)—at the UIV in a standardized setting to identify which type of implant combination allows the greatest gradual reduction of rigidity at the proximal end of the RI.

Materials and methods

Specimen preparation

Eight calf L2–L6 lumbar spines (age 12–18 months) obtained from a local slaughterhouse were used. The specimens were stored at −20°C and thawed overnight at 4°C before testing [14]. All soft tissues were removed, leaving the supraspinous and interspinous ligaments, the zygapophyseal joint capsules, and other supporting structures intact. The specimens were embedded in polymethylmethacrylate (Technovit 3040, Heraeus Kulzer, Wehrheim, Germany) at the upper half of the L2 and the lower half of the L6 vertebrae. All tests were then carried out at room temperature, and the specimens were kept moist with physiological saline solution during testing.

Rigid posterior instrumentation at L4–L6 was performed by an experienced spine surgeon with fluoroscopic guidance using a bilateral titanium polyaxial pedicle screw rod system (screws: 5.5×45 mm; rod: titanium, rod diameter 6.0 mm; uCentum, ulrich medical, Ulm, Germany).

Instrumentation at L3–L4

Subsequently, the L3–L4 segment of each sample was left without any implant at L3 (native) (Fig. 1A), and then additionally instrumented with all of the following techniques (Fig. 1B–G):

- LHs attached to L3 (Fig. 1B)
- SBs connected to the L3 lamina (Fig. 1C)
- CWs attached to the L3 lamina (Fig. 1D)
- HPS at L3 (Fig. 1E)
- HRs (Fig. 1F)
- all-pedicle screw rod construct (APS) at L3–L6 as RI (Fig. 1G)

Titanium LHs (uCentum, ulrich medical) were placed bilaterally on top of the L3 lamina. The LHs were attached to the lengthened 6-mm rods, and the L3–L4 segment was compressed slightly to ensure proper hook fixation.

Two SBs (Universal Clamp, Zimmer Spine, Minneapolis, MN, USA) were passed bilaterally around the lamina of L3. The 6-mm rods in the L4–L6 instrumentation were replaced with longer 6-mm rods. The SBs were tightened in accordance with the recommended technique.

Two stainless steel CWs (Ø 1.7 mm, Cable System, DePuy Synthes, Raynham, MA, USA) were passed bilaterally around the lamina of L3 and attached to the lengthened 6-mm rods. The CWs were tightened at 16 Nm.

The HPS (5.5×45 mm) (cosmicMIA, ulrich medical) was inserted bilaterally into L3 and attached to the lengthened 6-mm rods.

Conventional titanium pedicle screws (5.5×45 mm, HR: Ø 6–4 mm, neon, ulrich medical) were inserted bilaterally into L3. The 6-mm rods in the L4–L6 construct were replaced with titanium HRs. The L4/L5 and L5/L6 segments were stabilized with the 6-mm diameter, and L3–L4 was stabilized with the 4-mm part of the rods.

Finally, L3–L4 was also instrumented with an APS at L4–L6.

The sequence of the different instrumentations at L3 was alternated for each specimen (Table 1).

Flexibility testing

The specimens were mounted on an established spine tester [15,16] with the middle disc (L3–L4) aligned horizontally.