The Universal Clamp – A New Method of Thoracic Fixation in the Treatment of Adolescent Idiopathic Scoliosis

a report by

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Numerous implants have been devised in spinal surgery for osteosynthesis of the thoracic vertebrae. Among these devices, pedicle and laminar hooks are the most widely used, but some surgeons consider them to have insufficient initial stability. Very good corrections have been reported with the use of sublaminar wiring – such as that described by Luque – in thoracic curves, but all of the forces that maintain the reduction and fixation of the vertebrae are concentrated in the extremely small area of contact between the sublaminar wires and the laminae, sometimes leading to rupture of the cortical bone.

Recently, Suk et al. reported excellent results with thoracic pedicle screws, but the paucity of anatomical studies of thoracic pedicles and the learning curve for thoracic pedicle screw use hamper its widespread use. Furthermore, recent biomechanical and clinical studies have failed to confirm the previously reported superiority of pedicle screws, which are more dangerous than other conventional implants.2,3

We have developed a novel thoracic implant that combines the initial stability of pedicle screws with the straightforwardness and correcting potential of Luque wiring, but with an increased bony contact area.

Description of the Universal Clamp

The Universal Clamp consists of a polyester band passed under the lamina or around a lamina and transverse process, and connected to the rod by a titanium clamp (see Figure 1). With little bulk, the Universal Clamp evenly distributes forces over extensive areas of cortical bone, permitting application of increased reduction forces. In addition, mechanical tests performed before the initial clinical trials showed quite low levels of debris produced during fatigue tests (see Figures 2 and 3).

The types of correction possible with this innovative implant include translation, in situ bending, compression/distraction and de-rotation. The sublaminar construct acts essentially by posteromedial translation of the vertebrae, which are applied against pre-bent rods with physiological sagittal curves. ‘Figure-of-eight’ lamina-transverse process constructs are used to tilt the proximal extremity of the construct in order to restore the balance of the shoulders and rectify T1. For several years, we have been using hybrid constructs combining: pedicle screws at the lumbar level to mediate de-rotation and restore lordosis; sublaminar Universal Clamps in the concavity and apex of the thoracic deformity to untwist the thoracic spine by posteromedial translation; and figure-of-eight lamina-transverse process clamps at the proximal end to balance the construct by compression and distraction. In situ bending can also be used at any time during the procedure.

Clinical Series

We conducted a prospective study on 45 patients who had undergone operations for adolescent idiopathic scoliosis by the same surgeon between 2003 and 2005, with a minimum follow-up of two years. All of the arthrodeses were performed through a posterior approach using a hybrid construct with pedicle screws at the lumbar level and Universal Clamps at the thoracic level. At the proximal extremity of the construct, we used either pedicle and laminar hooks (between January 2003 and January 2004) or figure-of-eight lamina-transverse process Universal Clamps (between February 2004 and July 2005). Thoracoscopic anterior release was systematically performed in cases of reducibility lower than 50% on traction radiographs.

During the intervention, evoked potentials were recorded to detect possible signal modifications during the sublaminar passage of the polyester bands. The average age of the patients was 16.2 years (range: 11–23). The average operation duration was 210±47 minutes. Average blood loss was 953±210ml. A comparison of the pre- and post-operative Cobb angles showed an average correction of 65±6%, with a 4% loss of correction between the immediate post-operative films and final follow-up. The average correction of thoracic kyphosis was 16° (range: 10–34), with an average thoracic kyphosis (measured between T4 and T12) of 37° (range: 19–50). No neurological complications occurred and no significant modification of evoked potentials was detected during passage of the bands under the laminae. One patient had an early infection, which was successfully treated by surgical debridement and extended antibiotic therapy.

Discussion

Although numerous authors have recently touted the advantages of thoracic pedicle screws, that tendency may be changing. Vora et al. demonstrated that pedicle screws are less effective in restoring the
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Figure 1: The Universal Clamp, Consisting of a Polyester Band and a Titanium Connector

Figure 2: Microscopic View of an Intact Clamp, Before Biomechanical Testing

Figure 3: Microscopic View of a Clamp After Fatigue Tests

Figure 4: Pre-operative Anteroposterior and Lateral Films of a Girl with Thoracic Idiopathic Scoliosis
sagittal balance of the spine compared with hooks or sublaminar wiring. Furthermore, the risk of pedicle fractures and neurological complications remains non-negligible, particularly in patients with osteoporosis.

Pedicle screws are likely the most effective implant for the de-rotation technique. However, in a study of 60 patients treated for adolescent idiopathic scoliosis, Sales de Gauzy et al. demonstrated that there was no significant difference among the methods of reduction, and that de-rotation, translation and in situ bending provide similar frontal and sagittal corrections. The Universal Clamp acts essentially by posteromedial translation, but in situ bending, distraction and compression remain possible during the course of the surgical intervention. The efficacy of the technique was demonstrated in our prospective series, with an average reduction of 65% – very close to the best figures reported in the literature (see Figures 4 and 5). The primary advantages of the clamp are its excellent initial stability, which facilitates surgery, and the simplification of the construct: the same implant can be used at all thoracic levels, in both the concavity and the convexity of the deformity. In contrast to Luque sublaminar wiring, a tightened clamp can be loosened at any time, then repositioned to modify the obtained correction.

Post-operatively, imaging studies – particularly magnetic resonance imaging (MRI) of the canal – are possible because the Universal Clamp is made of titanium, which greatly limits artefacts (see Figure 6). One of the initial concerns during the development of the Universal Clamp was whether the polyester band would interact with the dura mater. However, three-month animal studies showed no fibrous scarring reaction. Consequently, removal of the bands in cases of surgical revision is not prone to duro complications. Furthermore, as the pedicles, laminae and transverse processes are preserved, the secondary use of other types of implant is not compromised in cases of subsequent interventions. Even though the band markedly increases interactions with the environment, we have had only one case of infection in the current series. To diminish this risk, we insist on the observation of strict precautions during implementation of the clamps and the use of suitable techniques.

Conclusion
The Universal Clamp combines simplicity of use, primary stability, safety and efficacy in deformity reduction. This innovative implant extends our therapeutic armamentarium against adolescent idiopathic scoliosis. The device is currently being evaluated for neurological and congenital scoliosis, spondylolisthesis and spinal fractures, but longer-term results are needed before it can be recommended in these indications.