



Mega-granuloma After Using the Universal Clamp for Adolescent Idiopathic Scoliosis: What Is It and Can It Be Prevented?

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Abstract

Study Design: Clinical case series.

Objective: To characterize the postoperative course and histopathology of peri-implant tissue of adolescent idiopathic scoliosis patients who experienced postoperative development of an aseptic soft tissue reaction, with granulomas adjacent to the sublaminar polyethylene terephthalate strap–titanium clamp used in Zimmer’s Universal Clamp (UC) spinal fixation system after spinal surgery.

Background Summary: The UC was designed for use with spinal deformity procedures in place of pedicle screws, hooks, or sublaminar wiring in fusion constructs. Recent studies of the UC lack emphasis on implant-related postoperative complications.

Methods: A total of 26 consecutive patients who underwent spinal deformity correction for scoliosis were reviewed for implant-related postoperative complications. Histology, scanning electron microscopy with energy-dispersive X-ray spectroscopy, fractional culture/biopsy, and Gram stain examination of the peri-implant tissue of patients with complications was performed.

Results: The authors reviewed 26 cases for correction of scoliosis. Two patients with adolescent idiopathic scoliosis who used the UC experienced implant-related complications with development of an aseptic soft tissue reaction with granulomas adjacent to the sublaminar polyethylene terephthalate straps–titanium clamp mechanism of the UC 8 months after AIS correction surgery. There were no signs or symptoms of wound infection. Gram stain revealed no organisms. There were many neutrophils and the surface of the wound revealed rare *Staphylococcus aureus* but the deep portions of the wounds were negative for organisms. Histopathology revealed extensive granulation tissue and histiocytes with engulfed birefringent particles or debris, and scanning electron microscopy with energy-dispersive X-ray spectroscopy analysis revealed macrophages containing many particles identified as titanium.

Conclusions: adolescent idiopathic scoliosis patients who use the novel UC construct may develop postoperative foreign-body reaction.

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Keywords: Universal clamp; Adolescent idiopathic scoliosis; Granuloma; Polyethylene terephthalate; Titanium implant debris

Introduction

The Universal Clamp (UC) was developed in 2003 to be used in place of sublaminar wiring, pedicle screws, or hooks to bind vertebrae to fusion rods [1–3]. It consists of a polyester (polyethylene terephthalate [PET]) band, titanium alloy clamp, and titanium locking screw. Recent studies evaluating the efficacy of the UC lacked emphasis on implant-related postoperative complications [1–4]. In the current study, the authors present 2 patients with adolescent

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idiopathic scoliosis (AIS) with an unusual implant-related complication that occurred 8 months after spinal deformity correction that used the UC fixation system.

Methods

Sixty consecutive patients with AIS who underwent spinal deformity correction that used posterior instrumentation surgery for scoliosis in a single senior spine surgeon's practice between 2008 and 2010 were retrospectively reviewed for implant-related postoperative complications. A total of 26 of these had surgery that used the UC spinal fixation system, which consisted of 5.5-mm clamps. Two patients who underwent scoliosis corrective surgery in January 2010 and December 2010, respectively, experienced the postoperative development of granulomas that were adjacent to sites of the sublaminar PET straps—titanium clamp mechanism used in the UC spinal fixation system. Both patients studied had removal of the implant, resection of the granulomas, and histopathologic analysis that included scanning electron microscopy with energy-dispersive X-ray spectroscopy, fractional culture and biopsy, and Gram stain examination of the peri-implant granuloma tissue.

Results

Detailed case information

Case 1

A 15-year-old girl with AIS was initially diagnosed at age 12 years. Physical examination revealed a right thoracolumbar curve with a 2+ rotation. At that time the patient had good range of motion with no neurological loss in the legs and some pain in the low back. Plain 36-inch standing radiography demonstrated a 47° curve from T6 to T12 and a 30° curve from T12 to L4, classified as Lenke type 1. The patient underwent posterior instrumentation and fusions using a hybrid construct of 5.5-mm UCs and pedicle screws; all clamps were adequately tightened. The patient had a total blood loss of 500 mL. Spinal cord and nerve root monitoring remained intact. A 10-day postoperative plain 36-inch standing radiograph demonstrated that the curve from T6 to T12 was 18° (47° preoperatively) and the curve from T2 to L4 was 12° (30° preoperatively).

Postoperative follow-up

During the next 8 weeks the patient developed a slight dehiscence that was subsequently determined to be a granuloma approximately 1 cm at the upper portion of the incision site with herniation of a small piece of muscle tissue. At that point the herniated piece of muscle was removed and the area was cauterized. Over the following 8-month postoperative period the patient continued to have an area at the incision site that would not heal. Eventually the patient developed 4 areas of wound dehiscence and granuloma formation around the upper right thoracic area, approximately the T6–T12 region

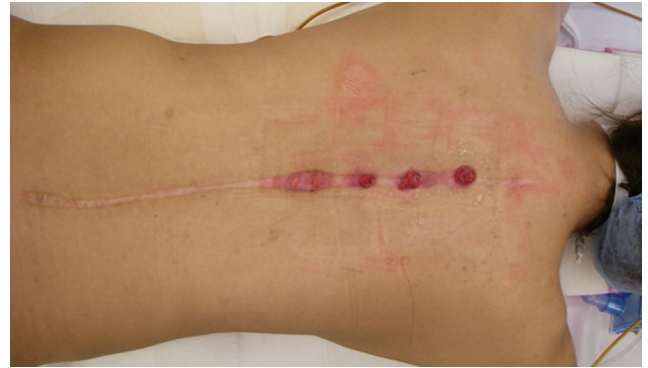


Fig. 1. Patient 1: 8-month postoperative posterior view of 4 external granulomas in upper right thoracic area at the sites of 4 Universal Clamps at T5–T10.

that was at the site of the UC straps (Fig. 1). The areas were 1–2 cm long. Consultation by plastic surgery was done, and the recommendation was that a computed tomography scan be done to rule out connection of this to the fixation of the spine. A fractional 72-hour culture and biopsy was performed. Gram stain revealed no organisms and many neutrophils. The surface of the wound revealed 1+ *Staphylococcus aureus*, with the deep 1 portions of the wounds negative for any organisms, which likely indicates that *S aureus* was only a surface contaminant. Review of the computed tomography was negative. The authors [JWD, ATT] elected to take the patient back to surgery. Subsequently, the patient underwent wound exploration. The friable granulation tissues and 4 open wounds extended to the 4 PET straps bracing the spine to the right fixation rod. The implants on the left were completely incorporated and not exposed. An additional incision was made over the granulomatous area and the granulomas in the area were excised.

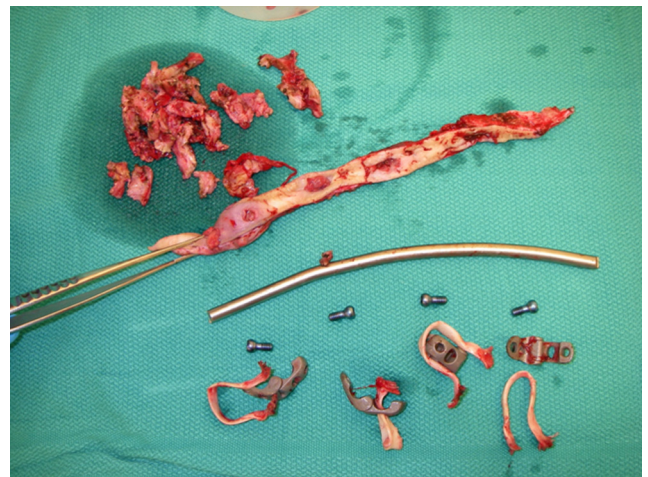


Fig. 2. Patient 1: Explanted UC instrumentation with 4 titanium UCs, 4 titanium locking screws, 4 PET straps, and distal end of right fixation rod. Peri-implant granulation tissue and excised granulomas are at upper portion of image.

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