Evaluation of the modern luque trolley construct for treatment of early onset scoliosis using a gliding implant in an immature animal model

Ouellet, Jean A; Ferland, Catherine E; Racloz, Guillaume; Klein, Karina; Richter, Henning; Steffen, Thomas; von Rechenberg, Brigitte

Abstract: STUDY DESIGN: Experimental animal study. OBJECTIVE: To determine biological compatibility, stability, and growth potential of the Trolley Gliding Vehicle (TGV) used in a novel surgical technique for guided spinal growth. SUMMARY OF BACKGROUND DATA: Current treatments for Early Onset Scoliosis (EOS) maintaining spinal growth consist of posteriorly based spinal constructs requiring repetitive lengthening. Such interventions have a high rate of complications. Using a muscle sparing technique, a modified dual growing rods construct and new sliding spinal anchors, we set out to test a Modern Luque Trolley construct in an immature animal model. METHODS: Six matched pairs of 3 month old lambs were randomized to an observation or surgical group and were followed for 9 months. The surgical group underwent implantation of a Modern Luque Trolley construct with the new TGV inserted in a minimally invasive transmuscular technique capturing the spine and the 2 overlapping rods on either side. Physical exams and imaging were conducted at routine intervals, with a subsequent necropsy. RESULTS: The spines of the study group grew 96% between the instrumented segments compared to the control group without evidence of implant failure. Forty-two % of the fixed anchors (pedicle screws) and 13.9% of the TGV were loose. All 6 animals had some heterotrophic bone formation tracking along the rods (<20%) mainly originating from the distal anchor point. We identified 19 unplanned spontaneous facet arthrodesis out of the 132 mobile facets found between the fixed proximal and distal anchors. An additional 10 facets spontaneously fused proximal to the most proximal instrumented implants. CONCLUSIONS: Implantation of a Modern Luque construct with Trolley gliding vehicle allows for spinal growth in a non-scoliotic animal model. Implant loosening was likely mechanical as no sign of reactive inflammatory reaction were found. Reducing heterotrophic ossification and spontaneous facet arthrodesis remains a challenge in managing immature spine.

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Evaluation of the Modern Luque Trolley Construct for the Treatment of Early-onset Scoliosis Using a Gliding Implant in an Immature Animal Model

Jean A. Ouellet, MD, FRCSC,* Catherine E. Ferland, PhD,* Karina Klein, VMD,† Guillaume Racloz, MD,‡ Karina Klein, VMD,‡ Henning Richter, VMD,‡ Thomas Steffen, PhD,§ and Brigitte von Rechenberg, VMD¶

Study Design: This was an experimental animal study.

Objective: To determine biological compatibility, stability, and growth potential of the Trolley Gliding Vehicle (TGV) used in a novel surgical technique for guided spinal growth.

Summary of Background Data: Current treatments for early-onset scoliosis maintaining spinal growth consist of posteriorly based spinal constructs requiring repetitive lengthening. Such interventions have a high rate of complications. Using a muscle-sparing technique, a modified dual-growing rods construct, and new sliding spinal anchors, we aimed to test a modern Luque Trolley construct in an immature animal model.

Materials and Methods: Six matched pairs of 3-month-old lambs were randomized to an observation or a surgical group and were followed for 9 months. The surgical group was subjected to implantation of a modern Luque Trolley construct with the new TGV inserted using a minimally invasive transmuscular technique capturing the spine and the 2 overlapping rods on either side. Physical examinations and imaging were performed at routine intervals, with a subsequent necropsy.

Results: The spines of the study group grew 96% between the instrumented segments compared with the control group without evidence of implant failure. In total, 42% of the fixed anchors (pedicle screws) and 13.90% of the TGV were loose. All 6 animals had some heterotrophic bone formation tracking along the rods (<20%) mainly originating from the distal anchor point. We identified 19 unplanned spontaneous facet arthrodesis out of the 132 mobile facets found between the fixed proximal and distal anchors. An additional 10 facets spontaneously fused proximal to the most proximal instrumented implants.

Conclusions: Implantation of a modern Luque construct with TGV allows for spinal growth in a nonscoliotic animal model. Implant loosening was likely mechanical as no signs of reactive inflammatory reaction were found. Reduction of heterotropic ossification and spontaneous facet arthrodesis remains a challenge in the management of immature spine.

Key Words: early-onset scoliosis, growth guidance, growing rod, modern Luque Trolley, posterior spinal instrumentation, gliding vehicle, growth modulation, animal model

and distal spine glides apart from its apical anchor, whereas the Modern Trolley construct fixes one pair of rods proximally and 1 pair of rods distally, with apical gliding anchors capturing all 4 overlapping rods. As the spine grows, the proximal and distal fixed anchors grow apart while still capturing the apical gliding anchors.

The classic Luque Trolley technique as described by Eduardo Luque has led to a high rate of implant failures, spontaneous fusion, and poor deformity control, resulting in alternative procedures for the management of EOS. As implant technology has evolved and the shortcomings of the Luque Trolley have been better understood, a new surgical technique has been developed and takes advantage of a muscle-sparing surgical approach. A new gliding spinal anchor, Trolley Gliding Vehicle (TGV) (Depuy Synthes Spine, Switzerland), has been developed to minimize the rate of implant failure. The implant consists of a dual core threaded pedicle screw coupled to a peak cable tie lined with a dual saddle polyethylene spacer. As the cable tie is tightened, the paired highly polished 5 mm titanium bullet-nosed rods are captured and seated side by side, still allowing the rods to glide (Fig. 2).

The purpose of this research was to investigate the biological impact of implanting a growth guidance system using a muscle-sparing approach with the newly developed gliding spinal anchors in a growing animal model.

**MATERIALS AND METHODS**

All experiments were conducted according to Animal Welfare and permission was granted by the local federal authorities (application #181/2009). Twelve skeletally immature (3 mo old) male Swiss alpine sheep were used for this study. To remove bias in variations in sheep size and age, we paired the sheep by matching them for size, weight, and age. Then, we randomly assigned one of the paired sheep to either the control group or the study group and followed them for 9 months. The control group was not subjected to any surgical intervention. The study group was subjected to 3-midline incisions spanning the 3 segments of the spine to be instrumented: T3–T4; T8, T10, T12; and L3–L4. A standardized construct was created spanning the proximal thoracic spine down to the high lumbar segments. The proximal and distal fixed anchor consisted of 2 sets of standard pedicle screws (USS II, Depuy Synthes Spine) inserted into 2 adjacent vertebrae (T3–T4 and L3–L4). Three middle levels were skipped, followed by three pairs of TGV inserted at alternative levels (T8, T10, T12). The resulting construct had a total of 11 pairs of mobile facet joints between the proximal and the distal anchors. At the fixed proximal and distal anchorage points, a classic subperiosteal dissection was performed as these segments were fused using local bone graft augmented with chronOS Strip (Depuy Synthes Spine). With the middle incision using a paralateral approach, TGV were inserted with a freehand technique into the pedicle. A transmuscular dissection, lateral to the midline erector spinae, was performed directly onto the transverse process, avoiding the lamina and the facets, leaving muscles and ligaments intact across the midline spine. The dissection for these gliding anchors was kept to a minimum to avoid exposure of the bone or periosteum (Fig. 3). With the proximal incision (T3–T4), 2 identical 5 mm rods were inserted, one on either side of the spinous processes, and tunneled in a submuscular manner down past the T8, T10, and T12 gliding pedicle screws until L2. The rods were fixed tightly with the usual collar and nuts at the pedicle screws T3, T4. With the distal incision at L3–L4, 2 identical rods were inserted, one on either side of the spinous processes, and tunneled upwards in a...
submuscular manner passing the T8, T10, and T12 gliding vehicle until T5. At the T8, T10, and T12 levels, the TGV captured the rods using the cable ties. The ties were tightened, ensuring that the rods were parallel (Fig. 4). Once the construct was completed, the soft tissues closure was performed in a standard manner.

All 12 animals were examined 3, 6, and 9 months to assess for the presence of deformity, tenderness, masses, or evidence of neurological deficit. Imaging modalities consisting of plane radiographs and computed tomographic (CT) scans were performed at 3, 6, and 9 months and after euthanasia. The 6 surgical animals and 2 control animals were euthanized after the 9-month observation.

Spinal growth was measured by acquiring true sagittal images from the CT scans (Fig. 5). Different segments of the spine were then measured, allowing monitoring of differential growth across different instrumented and noninstrumented segments of the spine (Fig. 6). Lengths of the segments were measured twice by 2 independent reviewers, and means were reported in centimeters using 2 decimal points. Percentage of growth was calculated by measuring the defined segment at time X—defined segment at time 0, divided by defined segment at time 0 multiplied by 100.

The spine was harvested, including the entire instrumented segment plus 1 vertebra above and below. The presence of facet arthrodesis was assessed and documented (Fig. 7) by CT scan, and manual testing of facets mobility was performed once the spine was explanted. No abnormalities of the spine were found for the 2 control animals. The entire spine was examined macroscopically to document any abnormal soft tissue reactions around the spinal implants. Particular attention was paid to the soft tissue around the TGV looking for granulomas and reactive tissue. Juxta-positional soft tissues directly above the screws were histologically analyzed. The extracted spines were radiographed after removal of the rods. Macroscopic findings such as evidence of spontaneous heterotrophic bone formation, hardware failure, and/or screw loosening were documented.

A detailed histologic evaluation of the facets, disks, growth plates, and the surrounding soft tissues was performed on selected ground section samples (Fig. 8). On a cellular level, a pragmatic approach was used to confirm our CT imaging findings. Any segment, with abnormalities found on imaging, was subjected to a detailed histologic analysis. The corresponding normal control segments were also analyzed for direct comparison. Randomly chosen normal-looking segments (eg, with no apparent pathology) in the surgical group were also evaluated to identify any additional adverse event. In total, 80% of the segments were histologically assessed. Hence, current histologic results provide a good general tendency, but no statistical analysis could be generated. In addition, microradiographs of the segments histologically analyzed were obtained and compared with the results of CT imaging.

The occurrence of spinal fusion in the sections was scored in a semiquantitative analysis described in Table 1. The soft tissues harvested around the TGV were analyzed for the cellular reaction and tissue scarring, including wear debris particles of the polyethylene, with light microscopy. A semiquantitative histologic evaluation using a scoring system was performed for microscopic cell
counts of macrophages, mononuclear cells (lymphocytes, plasmocytes, and monocytes), and fibroblasts (in the granulation tissue) as described in Table 1.

RESULTS

The modern Luque Trolley self-growing rod constructs were successfully implanted in all 6 immature animals without any perioperative complications. Throughout the 9-month observation period, all 6 surgical sheep behaved and roamed identically to the 6 control animals.

The matching CT evaluation was found to be effective as our groups had similar spinal lengths at time zero. The surgical group had an average spinal length across the instrumented spine of 32.5 cm, whereas the observation group had a spinal length of 32.2 cm. At the 9-month follow-up, the surgical group had grown, on average, 17% across the instrumented segments T3–L3, representing 5.6 cm, whereas the control group had grown across the similar segments 6.6 cm, representing 20% of their initial average length at time zero. This 3% difference in growth can be explained by the planned fusion across the 2 proximal and distal fused segments for the proximal and distal fixed anchors. If one excludes the planned fused segments, that is, the growth between the proximal and distal fixed anchors (T5–L1), the spines grew on average 4.6 cm in the surgical group, representing 21% of its original length, whereas the control group grew 4.9 cm for the same segments, representing 22% of their original lengths. On the basis of the CT data, the modern Luque Trolley system allows the instrumented segment of the spine to grow approximately 96% of the total length of a noninstrumented spine.

On examining heterotrophic bone formation, all 6 instrumented animals showed heterotrophic bone along short segments of their rods, representing <20% of the entire length of the rods. In 2 of these animals (5107, 5108), the heterotrophic bone was part of a spontaneous fusion (bilateral facet arthrodesis) cranial to the caudal anchors (L2–L3). Only 1 animal (5110) had heterotrophic bone formation at the level of a Trolley screw (T6, right side) traveling cranially and caudally. This sheep developed broad ossification on either side of the spine.

On examining spontaneous facet arthrodesis specifically, all 26 planned fused facet joints of the cranial and caudal fix anchors fused as expected (Fig. 8, segment 4), whereas an additional 29 facet joints fused spontaneously. Ten of these additional fused facets were cranial and bilateral to the proximal anchor, which resulted in an additional fused segment in five animals (5105, 5107, 5108, 5109, 5110) cranial to the instrumented spine. The other 19 spontaneously fused facets were between the...
fixed cranial and the caudal anchors, resulting in a 14% spontaneous fusion rate (19/132 mobile facets across the instrumented spine). Five animals (5105, 5106, 5107, 5108, 5109) showed a spontaneously fused segment (bilateral facet arthrodesis) just cranial to the fixed caudal anchor, representing 10 of the 19 fused facets in between the instrumented area. The remaining 9 facet arthrodeses were detected cranially to a TGV (Fig. 8, segment 2): 4 animals (8 facets) had bilateral facet arthrodesis cranial to a TGV (5106 T11–T12, 5108 T10–T11, 5109 T11–T12, 5110 T10–T11) and 1 animal had a unilateral facet arthrodesis cranial to a TGV (5107 T10–T11). Overall, these spontaneous facet arthrodeses resulted in an additional unplanned 2-level fusion in 5 of 6 animals across the instrumented spine.

All spinal segments with abnormalities found on plain x-ray and/or CT scan were histologically analyzed. For comparison, their corresponding normal control segments were also evaluated histologically. The randomly chosen normal-looking segments that were analyzed showed no abnormal findings. All macroscopic and CT imaging findings were confirmed by microradiographs and histology. At necropsy, there was no evidence of implant failure. However, it was apparent that half of the animals had various loose screws. With manual testing and using plain radiographs, it was found that 42% (20/46) of the pedicle screws were loose, all of which were at the caudal fixed anchor point, whereas only 13.90% (5/36) of the TGV were loose. This bone-screw interface loosening was confirmed by microradiographs and histology (Fig. 8, segment 1). No granulomas were found locally surrounding the implants and there was no systemic evidence of particle polyethylene or peak debris around the TGV. Titanium debris was found in 2 animals, where there was evidence of rod-on-rod friction. Evaluation of paraffin sections above the TGV found in 2 animals, where there was evidence of rod-on-rod friction. Evaluation of paraffin sections above the TGV found in 2 animals, where there was evidence of rod-on-rod friction. Evaluation of paraffin sections above the TGV found in 2 animals, where there was evidence of rod-on-rod friction. Evaluation of paraffin sections above the TGV found in 2 animals, where there was evidence of rod-on-rod friction.

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**DISCUSSION**

In this study, the biological impact of implanting a growth guidance system using a muscle-sparing approach with the newly developed gliding spinal anchors was assessed in a growing animal model. Lamb spines have similar morphometric dimensions as a typical spine of a child with EOS. Moreover, sheep have a high predilection to spontaneous fusion similar to young children, thus making it the best-suited animal model to investigate growth guidance systems. The gliding spinal anchors evaluated in this study showed high potential for self-lengthening as a treatment option for EOS. The results confirm that without additional lengthening procedures, a modern Luque Trolley construct allows for a 96% spinal growth to that of noninstrumented nonscoliotic sheep spines. The slightly retarded growth can be attributed primarily to the fusion of the proximal and distal anchored segments, but not to the dynamic segments containing the TGV. This growth occurred despite evidence of spontaneous facet arthrodesis adjacent to the proximal and distal fixed pedicle and partial heterotrophic bone formation along the rods. A possible explanation for the maintenance of growth could be that these spontaneous fusion and heterotrophic bone are not solid enough to inhibit vertebral growth. Interestingly, the vertebrae maintained their height comparable with those of the control group, in contrast to the disks at the levels of the planned or spontaneous facet fusion, which lost some of their height, thus explaining the difference between the study and the control groups. It is believed that the subperiosteal dissection, the muscle stripping, and the repetitive muscle contusion by the rods triggered this spontaneous heterotrophic bone formation originating from the fixed anchors. In contrast, at the level of the transmuscular, lateral para-spinal minimal invasive approach, only 1 animal showed heterotrophic bone formation along its rod and had few spontaneous facet arthrodesis. A 9-month follow-up is a relatively
short follow-up period for growth-sparing surgery and further spontaneous fusions or additional heterotrophic bone formation may occur over an extended period of time. Such findings match clinical findings when growth-sparing surgeries are converted to final fusion with evidence of partial fusion across the growing constructs. Spontaneous fusion and/or heterotrophic complications remain one “drawback” of posteriorly based growing rod constructs. Considering that the current goal of spine deformity management is a solid spinal fusion, it is hoped that we can develop a growing rod construct that will not result in spontaneous fusion.

Comparative research on posterior growth guidance system in animals is limited to the McCarthy et al. 


Early onset idiopathic scoliosis, a deformed spine needs further investigation.

The assessment of the Trolley to provide similar results in a deformed spine needs further investigation.

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REFERENCES