Novel Radiopaque UHMWPE Sublaminar Wires In A Growth-guidance System For The Treatment Of Early Onset Scoliosis: Feasibility In A Large Animal Model

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Introduction: Growth-guidance or self-lengthening rod systems are an alternative to subcutaneous growing rods and the vertical expandable prosthetic titanium rib (VEPTR) for the surgical treatment of early onset scoliosis (EOS). The main perceived advantage in comparison to growing rods is the marked decrease in subsequent operative procedures. Therefore growth-guidance systems are especially suitable for neuromuscular EOS patients, who often suffer from significant comorbidities. The Shilla growth-guidance system and a modern Luque trolley are examples of such systems; both depend on gliding pedicle screws and/or sliding titanium sublaminar wires. However, the unknown consequences of metal-on-metal wear debris are reason for concern in young patients. Another disadvantage of gliding pedicle screws is that thoracic pedicle screw placement can be difficult due to the distorted vertebral anatomy often seen in scoliosis. Easy placement of sublaminar wires offers surgeons a valuable alternative to pedicle screws in those technically challenging cases. Ultra high molecular weight polyethylene (UHMWPE) or other polymeric sublaminar cables have already been introduced for spinal deformity surgery; the soft and flexible structure of woven UHMWPE wires decreases the risk of neurological injury, while the broad shape distributes contact forces over a greater area, thus allowing for higher correction forces. Despite the increased contact surface, internal data has shown that UHMWPE cables exhibit lower friction during longitudinal sliding along spinal rods as compared to titanium sublaminar wires in an in vitro test setup, indicating the potential for allowing continuation of longitudinal spinal growth. Until now, radiolucency of UHMWPE wires has limited the possibility for postoperative radiological assessment and subsequent clinical use. The development of novel radiopaque UHMWPE wires, with bismuth-oxide particles blended into each fiber, allows for clinical application. The goal of this study consists of two parts: (1) to test the stability and biocompatibility of novel radiopaque UHMWPE wires as sublaminar wire, and (2) to assess the potential of using UHMWPE sublaminar wires in a growth guidance system for EOS.

Methods: An intervention group of twelve immature sheep (18 weeks old) received posterior segmental spinal instrumentation; pedicle screws were inserted at L5 and UHWMPE wires were passed sublaminarily at each level between L3 and T11. Dual cobalt-chromium rods were placed along the spine between levels L5 and T11 and fixed by set-screws at the pedicle screw attachment sites. The UHMWPE sublaminar wires were secured used a double-loop sliding knot, tightened to 100N, and secured with multiple granny knots. The control group consisted of four age-matched, unoperated animals in order to determine ‘normal’ spinal growth. Lateral radiographs were taken at 4-week intervals to evaluate growth of the instrumented segment. After 24 weeks, the animals were sacrificed and the spines were harvested for histological and high-resolution peripheral quantitative computed tomography (HR-pQCT) analysis. Prior to HR-pQCT scanning, the spinal rods were removed. The occurrence of spontaneous spinal fusion was assessed by manual palpation.

Results: No neurological deficits occurred during the postoperative period. One animal died during follow-up (7 weeks postoperatively) due to unknown cause. At sacrifice, none of the cables had loosened and all instrumentation remained stable. Substantial growth occurred in the instrumented segments (L5-T11) in the intervention group (2.67 ± 0.16 cm). Spinal growth was slightly higher in the control group, (2.96 ± 0.35 cm), but this difference was not statistically significant (p=0.42). Manual palpation revealed a solid, spontaneous fusion across all instrumented levels. HR-pQCT analysis (figure 1) showed interlaminar ossification, possibly a result of periosteal stripping. Typical bone formation encircling the posterior rods coupled with degenerative facet joint changes were also seen. Histological analysis revealed fibrous encapsulation of the novel radiopaque UHMWPE sublaminar wires in the epidural space (typical physiological response to foreign materials), with no evidence of chronic inflammation or wear debris.

Discussion: Despite the occurrence of spontaneous fusion in all cases, UHMWPE sublaminar cables allowed for almost normal continued growth of the instrumented spinal segments during follow-up. Extrapolation of these results to the pediatric patient population is difficult due to a much higher growth velocity in animals, but also due to the exaggerated bone formation response typical for quadrupedal animal models in which higher spinal loads lead to stronger mechanical stimuli to form new bone (Smit). Fibrous encapsulation of the cable and preservation of instrumentation stability during the course of this study show that the application of these novel radiopaque UHMWPE sublaminar cables in spinal deformity correction surgery is safe. Further research into the fate of bismuth-oxide particles however is ongoing.
**Significance:** Novel radiopaque UHMWPE sublaminar cables allow for almost normal growth of the spine in an immature sheep model, while first in vivo application gives a positive indication for biocompatibility of these cables. Therefore, the application of UHMWPE sublaminar cable in a growth guidance system for EOS seems feasible.

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