Efficacy of UHMWPE Dyneema Purity® in fusionless posterior spinal instrumentation in an ovine model

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INTRODUCTION
Currently, there are several options for the surgical correction of spinal deformities in the growing child.1 Spinal instrumentation can be used with or without spinal fusion. The gold standard in scoliosis surgery consists of hybrid constructions with pedicle screw fixation and segmental instrumentation with hooks and sublaminar wires. Sublaminar wiring can be especially helpful in correcting sagittal deformities and provides a solid support as was first described by Luque.2 Neurological complications and wire breakage are the main clinical problems during the introduction and removal of stainless steel and titanium sublaminar wires. Different sublaminar wires have been developed to diminish these complications.3 Although tested in fusion models, no study examined the effects in fusionless scoliosis surgery. The main advantage of fusionless surgery is the ability of growth continuation. In this pilot study a posterior hybrid construction with the use of a medical-grade UHMWPE fiber (Dyneema Purity®) sublaminar wire was assessed in an ovine model.

We hypothesized that such a hybrid construction can safely replace current titanium laminar wires, while providing sufficient stability of the non-fused spinal column with preservation of growth. In addition, the feasibility of this ovine spinal model was tested by using young, skeletally immature, sheep.

MATERIALS AND METHODS
Six skeletally immature sheep (Tesselaar, age 7±2 months, weight 33±6 kg) were used for this study. Each surgery was performed under general anesthesia and strict aseptic conditions. Pain medication was administered and standard cardiological parameters were monitored. Antibiotics were administered preoperatively and continued for 24 hours. Postoperative pain management and wound care were provided until the animals were allowed to return to activities ad libitum.

With the animal in prone position a midline posterior incision was made. Under fluoroscopy two pedicle screws (4.0x25 mm, Legacy, Medtronic) were placed at lumbar level. From the levels above the interpedicular ligaments and the ligamentum flavum were removed and the laminae of two to five levels above were exposed. These four consecutive laminae were attached to two titanium bars (4.5 mm) using 3 mm diameter UHMWPE (Dyneema Purity®) on the left side and 5 mm UHMWPE diameter on the right side. The sublaminar wires were fixed with a modified double loop sliding knot and tightened with a tensioning device. In this manner temporary tension could be applied to each level before permanent knotting. Before closing the wound final fluoroscopy images were obtained to verify proper positioning of the system. As a control, in one animal titanium sublaminar wires (Atlas, Medtronic) were applied on three subsequent levels and fixed on two 4.5 mm titanium bars (Legacy, Medtronic). All animal procedures were approved by the Animal Ethical Committee of Maastricht University.

After sacrifice the spine of the animals was harvested. Radiographs were taken and CT scans were performed. The bone mineral density (BMD) was measured for each vertebral column. The routing of the different wires was evaluated with special focus on the effect of the Dyneema Purity® on the dura and possible loosening of the construction. By comparing preoperative and postoperative radiographs the amount of growth was quantified. The vertebrae were dissected and placed in formaldehyde for macroscopic and histological evaluation.

RESULTS
The animals were sacrificed after a (minimal) postoperative period of 15 weeks. None of the 3 or 5 mm knots loosened during the follow-up period, thus preserving stability of the constructions (Figure 1). No neurological complications occurred. One animal developed a wire fistula with a prominent 5 mm knot. With the infection progressing across the bar the ipsilateral screw loosened. However, the total construction remained stable. One animal died the first postoperative day due to complications of the anesthesia. An average of 8.7 mm growth was seen over the operated segment. Average BMD was 0.65 g/cm² (Table 1).

Figure 1. Left: Laminar wires (arrows) made by Dyneema Purity® with knots across 4.5 mm titanium bars at thoracolumbar level. Right: Coronal CT image showing the non-displaced titanium bars at laminar wire level.

Computed tomography confirmed the preserved stability. Even though no decortication was performed, variable bone bridges with fused levels were seen on CT. Macroscopical and histological analysis showed no inflammation at lamina, dura and transition levels containing Dyneema Purity®, with the exception of the sheep with the fistula where it was observed locally.

<table>
<thead>
<tr>
<th>n</th>
<th>Type of wire</th>
<th>BMD g/cm²</th>
<th>Weight (kg)</th>
<th>FU (days)</th>
<th>Growth (mm)</th>
<th>Laminae knotted</th>
</tr>
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<tbody>
<tr>
<td>1</td>
<td>Ti cable</td>
<td>0.7</td>
<td>35</td>
<td>133</td>
<td>7</td>
<td>6</td>
</tr>
<tr>
<td>2</td>
<td>UHMWPE 3/5 mm</td>
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<td>36</td>
<td>1</td>
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<tr>
<td>3</td>
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<td>0.6</td>
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<td>119</td>
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<tr>
<td>4</td>
<td>UHMWPE 3/5 mm</td>
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<td>112</td>
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<tr>
<td>5</td>
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<td>34</td>
<td>105</td>
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<td>6</td>
<td>UHMWPE 3/5 mm</td>
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<td>112</td>
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<tr>
<td>Mean</td>
<td></td>
<td>0.65</td>
<td>32.8</td>
<td>116.2</td>
<td>8.7</td>
<td>Total 46</td>
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</tbody>
</table>

DISCUSSION
This pilot animal model study shows that the laminar wire made by Dyneema Purity® has good handling and tensioning properties and can provide sufficient stability in fusionless spinal instrumentation while allowing substantial growth of the segment involved. No signs of inflammation of the Dyneema Purity® wires near the dura and laminae were observed, with the exception of the animal with the wire fistula. In this case the 5 mm knot possibly protruded the superficial skin in an animal with lack of subcutaneous fat and low body weight (27 kg). We prefer the 3 mm knots in handling terms above the 5 mm knots, mainly because of the smaller size of the 3 mm knot.

Neurological complications can occur during laminar wiring. Literature shows that especially sheep models often suffer from these complications.3 The examined model, however, showed to be a feasible spinal study model, without occurrence of neurological problems.

The periost reactions with the formation of variable bone bridges might be due to the very young age of the sheep and may have restricted further growth. This problem can be avoided by using more mature, but still growing, sheep in future experiments.

To prove the feasibility of an ovine scoliosis model it will be necessary to induce a scoliotic deformity in future animal experiments. Braun et al. already described several animal scoliosis models including sheep models.5 With the use of fiber constructions made by Dyneema Purity® the model in this study can form the basis for this challenging field from which new surgical methods for scoliosis correction could emerge.

REFERENCES
2. Luque ER et al. (1977), Orthop Trans 1:136–137

ACKNOWLEDGEMENTS
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