

## Retention of Spinal Mobility and Growth after Correction of Lordo-Scoliosis; Preliminary Assessment of a Novel Implant Device

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### ABSTRACT

**AIM:** Conventional surgical treatment of adolescent scoliosis results in a rigid spine and cessation of spinal growth. Long-term degeneration can occur at the junction of fused and mobile segments. It would be preferable to have an alternative treatment that retains a mobile and growing spine. To achieve that goal a novel implant was devised to dynamically correct the curve over time. For a proof of concept study, an animal model of lordo-scoliosis was developed.

**MATERIALS AND METHODS:** An implant was fabricated consisting of multi-component modules, each based around a unilateral pedicle screw. Two flat springs from each module applied

forces to its adjacent modules. The cumulative effect was the application of de-rotational forces to the deformed spine. For a “proof of concept” investigation, a right thoracic lordo-scoliosis was formed in lambs using an implanted cable as a tether secured on the left side between pedicle screws. After tether removal, 15 lambs with stable scoliotic curves underwent implantation of the modules at each of the segments along the abnormal curve. Animals were euthanased at skeletal maturity.

**RESULTS:** Serial radiographic measurements over two years, revealed an average of 76% coronal plane correction in 12 of the 15 lambs. Specimens demonstrated independent segmental mobility though three animals had adjacent segmental fusion at two levels. Longitudinal spinal growth over the instrumented region averaged 3.9 cm.

**CONCLUSION:** The novel implant dynamically corrected an induced lordo-scoliosis in 12 lambs whilst permitting continued spinal growth and preserving spinal mobility.

**Key words:** Scoliosis; Surgery; Spine; Correction

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### Device Status Statement

The device described in this work is neither FDA-approved nor approved by corresponding national agencies for this indication. Implant components were fabricated by the second author at Enztec Ltd., Christchurch, New Zealand. A patent has been registered covering the implant device (New Zealand Patent No. 611937). Benefits have not been received from a commercial party related directly or indirectly to the subject of this report.

### INTRODUCTION

There are several principles applied during current conventional

surgical treatment of a progressive structural curve in a child with adolescent idiopathic scoliosis (AIS). They are: halting curve progression; achieving coronal and sagittal balance; correcting the curve maximally without compromising spinal balance; preserving motion of non-involved segments<sup>[1]</sup>. The surgical protocol itself is carried out at an age when the patient still has some remaining osseous growth. The paravertebral soft tissues are extensively exposed and selectively severed to release each vertebral segment in order to mobilise all of the vertebrae involved with the abnormal curve. This permits the manipulation of the spine into a near normal configuration, so correcting the coronal, sagittal and axial plane deformities. The now normalised spinal contour is fixed by longitudinal rods clamped to bilateral pedicle screws. Mechanical fixation is augmented by osseous fusion of the vertebral segments using inter-vertebral bone grafts.

In the 1950's, the use of Harrington's distraction system<sup>[2]</sup> led to improved coronal plane alignment. In the 1980's, Dickson<sup>[3]</sup> emphasised the importance of sagittal plane correction, describing the need to transform the abnormal thoracic apical lordosis into a kyphosis. In essence, correction of the thoracic curve in AIS requires mobilisation of the stiff lordotic apical spinal segments. The lordosis is then carefully translated posteriorly in the sagittal plane to produce a kyphosis. Dickson<sup>[3]</sup> stated that this "unwinds" the rotated vertebrae and leads to a correction in both the sagittal and coronal planes. Therefore the key feature of treatment is one of de-rotation of the abnormally rotated vertebrae.

Unfortunately, as a direct consequence of fixing the corrected configuration, there is a complete loss of inter-segmental mobility and a cessation of normal spinal growth over the instrumented region.

For the patient, the correction of their spinal contours provides a significant improvement in their lifestyle, mostly due to their improved posture. In addition, it decreases their potential long-term morbidity from lung and cardiac complications. Regrettably these gains are offset to a certain extent by both the cessation of any residual spinal growth and the every day limitations caused by having most of the spine rigid. In addition the patient's long term future may hold further complications. Mechanical forces distributed throughout a normal, flexible spine, are now, post surgery, concentrated at the junctions of the rigidly fused and the adjacent mobile segments. Over the succeeding years, such excessive loading in these transitional zones can lead to degeneration and structural instability<sup>[4]</sup>. The associated back pain may become severely incapacitating and in advanced cases lead to a significant change in sagittal, coronal or axial alignment<sup>[5]</sup>. Currently there are no published studies that document the actual incidence of these long-term degenerative complications. However, anecdotal clinical evidence suggests that many years after surgery there are increasing numbers of patients with disabling mechanical back pain secondary to degeneration at the junctional levels<sup>[6]</sup>. Eventually, further fusion surgery may be required to treat these patients.

The everyday limitations imposed by both growth cessation and a lack of spinal mobility are accepted by clinicians and patients alike as unavoidable consequences of major life-improving surgical treatment. Nevertheless, an ideal surgical treatment for AIS would result in permanent curve correction with preservation of full spinal mobility and growth.

With this ideal in mind, a novel modular implant was designed and fabricated with the aim of correcting spinal deformity yet retain its mobility and growth. Consequently there was the requirement for a proof of concept study to investigate whether the principles behind the implant were applicable and effective in practice. This necessitated the use of an *in vivo* animal model. The model needed

to replicate as closely as possible the characteristics of an actively growing spine with a scoliotic-type deformity. The large animal species chosen was the sheep as they have a very similar vertebral anatomy to the human with relatively straightforward surgical accessibility. They are readily anaesthetised and are very compliant to post operative rehabilitation. In addition, as grazing herbivores, they cover large distances so effectively self-remobilise after surgical intervention of their musculo-skeletal tissues. With quadrupeds the intervertebral muscular forces required to maintain the spine horizontally are greater than in the biped where gravitational forces offer some assistance in keeping the spinal column vertical.

## MATERIALS AND METHODS

Concurrent development was undertaken of both a novel implant for correcting a spinal deformity and an animal model of scoliosis that could be used in a proof of concept study.

### Development of a Novel Correction Implant and Surgical Procedure

An implant was designed such that it would enable forces to be applied continuously over time to correct a scoliotic deformity. Unilaterally sited pedicle screws would provide mechanical connections to the spine through which the corrective forces could be applied. If each screw is inserted in an identical anatomical location within its vertebra, then in the scoliotic spine the alignment of all of the screws will not have the same overall configuration of those in a normal spine. Therefore forces can be applied through the screws to bring them, and therefore their associated vertebra, into a more normal configuration. To achieve re-alignment by these means, the assumption is made that the individual vertebra is compliant, that is, that it will, under the influence of time-applied forces, move relative to its adjacent two vertebrae.

Any implanted module attached to each screw needs to be in contact with, but not fixed to the module of the adjacent segment so that dynamic mechanical forces could be applied between them without compromising the independent mobility of each segment. Such independence would also allow continued spinal growth. Each module must apply forces to adjacent (caudal and cephalic) segmental modules in such a way that the abnormal curve tends to be re-aligned towards a kyphosis by de-rotation. To retain post correction control over spinal mobility, the paraspinal muscles and all surrounding soft tissues must remain intact. Imposing this condition means that an expectation of instant correction would be both unrealistic and undesirable as the soft tissues would need time over which to adapt to the altering anatomical orientation of the bones. Applying forces over time would both correct the spatial malignment of the bony elements and permit the slow adaptation of the soft tissues to these anatomical changes. The visco-elastic nature of the intact soft tissues would in itself offer a resistance to realignment of the bones therefore increase the magnitude of the required corrective forces.

Thus the requirements are that the inter-segmental forces generated by the implant must be continuously sustained at an effective intensity to achieve their purpose despite all the multitude of mechanical forces applied to the spine in a patient leading a normal lifestyle. Importantly, the forces must decline as they approach the goal of a near normal spinal configuration, ceasing altogether when that goal has been reached. If they do not, then over-correction would occur. The incorporation of spring components will generate continuous, long-term, yet self-limiting forces.

With all these considerations in mind, a correction system was

designed in a modular form, such that each module at each vertebral level could be tailored to suit the individual bony anatomy and extent of deformity (Figures 1 and 2). Wherever possible, existing pedicle screw designs were adopted, with standard pedicle screw threads. Screw heads, both fixed and mobile, were designed for ease of assembly and to allow optimal correction. Given that each module could move relative to its adjacent two modules, care was taken to minimise wear through the choice of material and treatment of edges and corners.

The springs from each module are not fixed to the wings of the adjacent modules, but are merely held within them and captured there by the overhanging nut. This allows adjacent constructs to move relative to each other, not only for long-term realignment but also for permitting continued normal bodily movements and for any increases in spinal length as a result of vertebral growth. The springs extend well beyond where they engage with the next module so allowing continued force transmission despite spinal growth. The flat springs apply continuous forces downwards on the wings of the adjacent modules. If the long axes of adjacent screws are not parallel in the sagittal plane, then a force from a spring will act one side of the adjacent module such that it will tend to re-align the screws into the same plane. Therefore, over time, there will be an overall tendency to spatially orientate all the screws, and thus their associated vertebrae, into the same sagittal plane. This de-rotation will also re-establish a more normal coronal contour.

Each module can be customised in that: (a) springs of different thicknesses (stiffness) are available; (b) the degree of torque applied to the bolt influences the force applied by the spring. The thickness of the spring and force applied to it needs to be greater in those modules located in regions of greater curvature.

The only moving contacts, and therefore potential sites of wear, would be between the springs of one module and the wings of adjacent modules. Long term cyclical bench testing of various materials showed significantly less wear between stainless steel components than those made of titanium. Consequently the components were fabricated using stainless steel LS316<sup>[8]</sup>.

During the subsequent *in vivo* assessment, refinements to the implant were: (a) increasing the diameter of the locking washers to capture the springs within the arms more securely; (b) increasing the length of the screws so improving their security by penetrating further into the vertebral body; (c) replacement of mono-axial heads by multi-axial screw heads that were better able to accommodate variations in scoliotic vertebra malalignment and anatomical distortion of individual vertebrae.

### Development of an animal model

All protocols involving the use of live sheep received prior approval from our Institutional Animal Ethics Committee, who also monitored progress and outcomes of the study. All surgical procedures were carried out under general anaesthesia using aseptic techniques and with generous applications of systemic and topical analgesics and anti-inflammatories. After immediate post operative recovery, each animal was put into its own pen. After a few days of monitoring and treatment it was released to open fields once it had received veterinarian clearance. Six to 8 week old Romney-Suffolk cross-bred lambs were used.

Previous studies describing the induction of an AIS-type deformity in young goats utilised a unilateral tether (rod or tape) on the left side of the animals' spine (Braun *et al*<sup>[7]</sup> 2003). But securing the tether proved more problematic in the lamb so pedicle screws were used for anchorage.

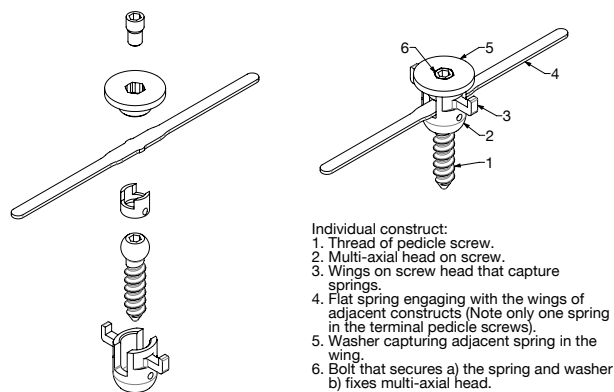


Figure 1 A single segmental module.

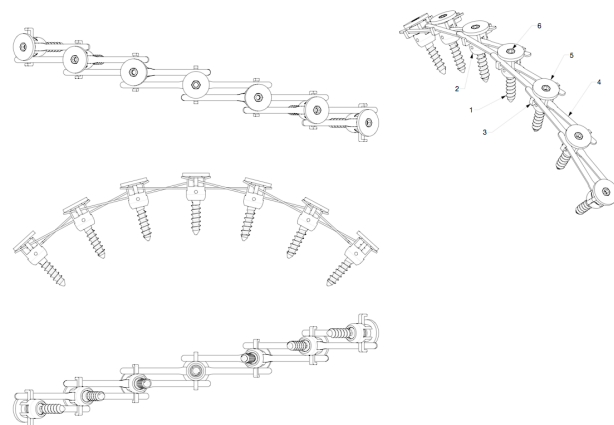


Figure 2 Assembly of the component modules.

### Experimental operative procedure - animal model

To avoid the possibility of single or multi segmental fusion due to spontaneous extraneous, peri-vertebral bone formation after soft tissue surgical injury, a muscle splitting approach was taken to minimally expose the posterior location of the left pedicles of T 7 or 8 and L 2 or 3. Great care was taken to avoid unnecessary exposure of other bony spinal structures or transgression of the overlying periosteum.

Using an awl, a shallow pilot hole was made in the cortical bone above the pedicle. A 3.5mm wide spear-shaped dental hand tool was used to make a hole down through the pedicle into the vertebral body. This was performed slowly with the operator feeling their way down the pedicle whilst ensuring that the wall between the pedicle and spinal canal was not breached. Periodically the tool was retracted and a ball-ended feeler probe inserted into the hole to establish whether the walls of the hole were intact. A screw thread was then tapped down the hole followed by the insertion of a 4.5mm diameter pedicle screw.

During the initial study, a solid rod was passed through the intervening paravertebral muscles then clamped to each screw. However after various periods of implantation, the anchorage points were not always secure within the bone. However, when they were, the rigidity of the system gave rise to a high incidence of inter segmental bony fusions. Therefore, in subsequent animals, pedicle screws were inserted in both T 7 and 8 as well as L 2 and 3, each pair being rigidly linked by a short bar. A braided stainless steel cable was secured as an intramuscular loop between T 7 or 8 and L2 or 3. However, over time, the filaments tended to fatigue fracture around the small diameter of the pedicle screws. This problem was solved by wrapping the cable around 1.5 cm diameter polyethylene capstans on

T7 or 8 and L2 or 3 (Figure 3a).

To further encourage the development of a left sided spinal curvature, approximately 4.0 cm lengths of six ribs on the right side were carefully excised sub-periostally, starting approximately 4.0 cm distally from the midline of the spine. This is a procedure advocated by Braun (2003).

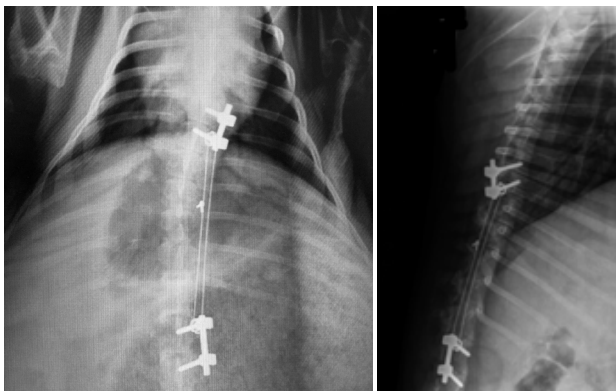
The very long wounds were meticulously closed from the deep layers to the skin with the application of copious amounts of topically applied analgesic.

Before recovery, AP and lateral radiographs were taken and the Cobb angle measured on each and on all subsequent radiographs. After 12 weeks, radiography was repeated under anaesthesia, and at the same time a small incision was made and the tethering cable snapped and extracted.

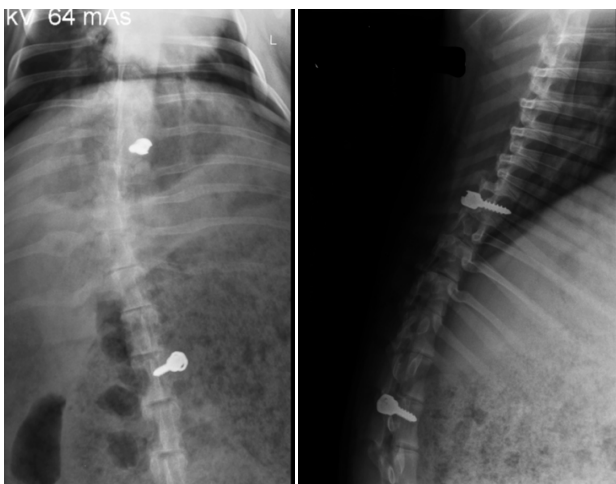
A further 12 weeks were allowed before repeat radiology to establish whether any natural correction occurred after cable removal. Over the first half of the study it was found that all curves only self-corrected very minimally, if at all. Therefore, subsequently, the 12 week interval was reduced to four weeks in order to maximise the period of bone growth during which the correction device could be implanted. Only those animals with a spinal curvature of 15° or more, were used to assess the efficacy of the novel implant.

#### ***In vivo* assessment of the efficacy of the implant**

As there would be movement of metal on metal there was an associated possibility of wear, therefore blood samples were taken at each radiographic exposure and immediately before euthanasia.



**Figure 3a** AP and lateral radiographs before removal of the cable. Note: the rings around the inner two screws are washers holding the capstans.



**Figure 3b** AP and lateral radiographs after cable removal, showing the successful use of single screws which, in this specimen, had unusually remained *in situ*.

Serum metal ion analyses were carried out by inductively coupled plasma mass spectrometry for cobalt, chromium, titanium and aluminum. The pre-implantation results were taken as base values for comparison with those at various periods after implantation.

#### **Experimental operative procedure - device implantation**

A longitudinal incision was made to the left of the midline from approximately T5 to L4. Through a left sided muscle splitting approach, the bone surface above the left pedicles of T7 and T8 as well as L2 and L3 were minimally exposed. The existing pedicle screws used to anchor the tether were extracted and replaced by construct screws with multi axial heads. At each of the other segmental levels between these locations, mono-axial construct screws were inserted into each left side pedicle. In turn, flat springs of appropriate thickness, were positioned in each screw head with their ends resting on the wings of adjacent module. The springs were secured in position by a bolt through a washer. Half springs were used in the terminal proximal and distal screws. Once all the individual modules had been assembled, tension was applied to each spring by torque applied to the locking bolt. The magnitude of torque varied according to the apparent displacement of the engaged vertebrae. After the topical application of copious amounts of analgesic followed by wound closure and radiography, each animal was allowed to recover. No restrictions were made to their mobility once they were released to open fields.

AP and lateral view radiographs were taken at 4 and 12 weeks then 6, 12, and 24 months to monitor any changes in spinal curvature.

Skeletal maturity occurs at 2 years of age (Simmons *et al* 2001), consequently this was taken as the end point of the study with the animals being euthanased and examined post mortem.

## **RESULTS**

#### **Development of an animal model**

All of the animals regained normal behaviours and gait post operatively. Indeed abnormal spinal curvature could only be appreciated by close palpation through the wool and by radiological examination.

Problems with tether anchorage was largely due to the lack of physical strength of the bones of 6-8 week old lambs. A small group of 12 week old animals were used but, though the bones were larger and stronger, these advantages were off-set by the loss of 4-6 weeks of subsequent bone growth during which the correction implant could be effective.

The tension applied to the tethering cable was critical. If it were slack a considerable amount of growth had to occur to render it taut for it then to act as a true tether. Conversely, over-tension would result in an immediate spinal curvature.

#### **Development of a Novel Correction Implant and Surgical Procedure**

Special care needed to be taken during the insertion of the pedicle screws. There were only rare breaches of the spinal canal wall detected by probe inspection during production of the hole using the hand tool. When detected, the hole was re-directed more laterally, so keeping the screw away from the spinal canal. The surgical approach appeared to cause only minimal localised soft tissue injury.

Intra-operatively, the assembly of the modules was straightforward. A particular advantage of the design was that each module could be customised according to the anatomy and extent of deformity of each vertebra as well as the curvature of the spine at that location. The

poly-axial screw heads allowed most of this adaptability. In addition, having the choices of both spring thickness and screw torque, meant that the load applied by the springs could be adjusted according to the need at each location.

### *In vivo* assessment of the efficacy of the implant

Three of the 15 lambs were lost to the study, two due to migration of a pedicle screw into the spinal canal, the other due to respiratory infection. The remaining 12 completed the study to skeletal maturity at two years.

Radiographically the curvature, as measured by Cobb angle, was seen to be corrected to varying degrees over a range of 46% to 100% (mean 75%) over the 2 years (Figure 4). Sagittal plane correction from lordosis to kyphosis averaged 20.3° (range 4° - 36°). In all instances maximum correction had occurred during the first 12 weeks after implantation.

All animals showed some degree of correction over the treatment period. Changes in Cobb angles varied considerably between individual animals, with an overall trend for the greater the abnormal angulation of the spine at the beginning of treatment then the greater the degrees of correction (Figure 5). One animal returned to zero with the others averaging 5° degrees of correction (range 2° - 12°).

Post mortem examinations found no broken or loosened implant components. In six sheep, post mortem macroscopic observations of all modules recorded localized tissue discolouration around the contact area of the springs with their adjacent modules. Randomly selected samples of these soft tissues underwent histological examination. Microscopic metal debris were seen in all samples, but without obvious tissue inflammation.

Manual manipulations of the undissected post mortem spinal segments produced varying degrees of independent inter-vertebral movement of the spinal segments across the instrumented levels. However, there were three of the 12 spines where movement was not detected in all segments and these correlated with radiographic evidence of bony fusion. Two were noted at two years to have developed a partial fusion between two or three segments of the instrumented spines. The third animal had a complete fusion of the spine. In all these three animals, serial radiographs revealed significant correction of the scoliotic spine before fusion was evident. As with all lambs, the three had had the muscle splitting and periosteal protecting surgical approach so the reasons for spontaneous fusion were not determined.

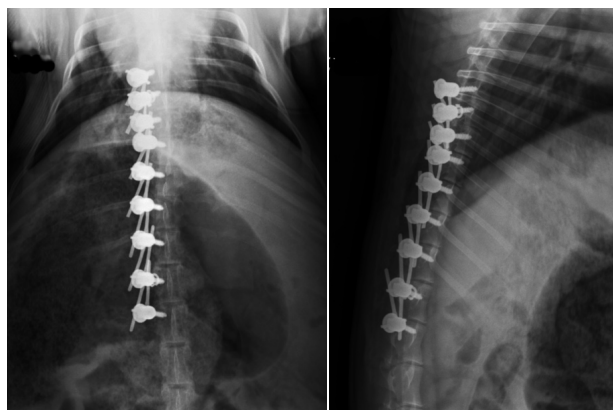
In every animal there was an increase in length of the instrumented spine during the implantation period, with a median value of 3.9 cm (range 1.9 - 5.7 cm). This demonstrates that the modular form of the implant permitted continued longitudinal spinal growth.

Blood serum analyses of all animals revealed no evidence of raised serum cobalt, chromium, titanium or aluminum levels during the period of implantation over those concentrations before implantation.

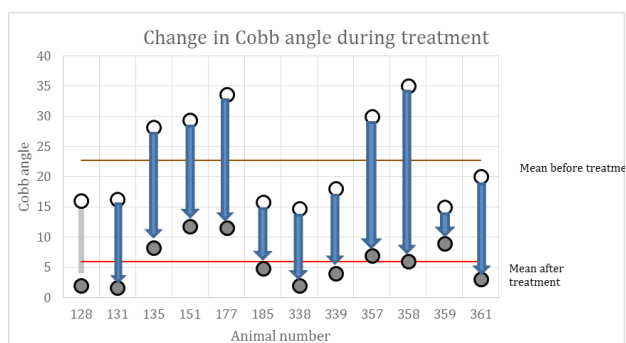
## DISCUSSION

The concepts behind this novel technique for scoliosis correction were proven to be largely correct when applied in practice. The innovative surgical implant applied a unilateral load that could significantly correct the induced structural lordo-scoliosis deformity of an animal model. Additionally the device was shown to permit continued spinal growth as well as mostly preserving independent inter-segmental vertebral movement.

Overall the innovative implant proved *in vivo* to fulfill its intended design outcomes: (1) It is compact so that it can be well enclosed



**Figure 4** AP and lateral radiographs taken immediately after implantation of the construct in an animal with a Cobb angle of 35°, showing that, as in all animals, correction largely occurred at, or soon after, implantation.



**Figure 5** Change in Cobb angle between pre-treatment and completed treatment.

within the tissues of the posterior spine. This is of particular importance because this implant allows the longitudinal paraspinous muscles to continue functioning normally as opposed to the rigid fixation of conventional treatment; (2) Its compactness is due to it consisting of less metal mass than the conventional fixation rods and bilateral pedicle screws; (3) It demonstrates that unilateral forces applied to the scoliotic spine can be used to effect correction; (4) It permits movement between segments so retaining spinal mobility. The two animals with limited inter-segmental bony fusions are undesirable outcomes but in practice would impose little functional limitation on the overall mobility of their spines. However the single sheep with a fused spine is of some concern, especially because no aetiological explanation was forthcoming; (5) It does not inhibit continued longitudinal growth of the spine, as shown by progressive increase in length of the instrumented portion of the spine; (6) It imposes correction by applying continuous, long-term forces, therefore alleviating the necessity to undertake the extensive soft tissue release and subperiosteal “stripping” that is a necessary feature of conventional surgical treatment; (7) It maintains correction through to skeletal maturity. The final average Cobb angle of 5° of correction would be an acceptable result in human clinical practice; (8) Its generated correction forces are self-limiting, thus avoiding over-correction. Once normal anatomical positioning is achieved, the springs reach their resting, non-tensioned state; (9) It readily allows a fall-back procedure to present day treatment as the pedicle screws could be readily removed and replaced by screws for a conventional rigid rod fixation; (10) Its required surgical skill set is little different from current practice. The insertion of pedicle screws is currently totally familiar to scoliosis surgeons. Assembly of the components is straightforward, though achieving the appropriate tensions on each

springs would need some familiarisation; (11) It can significantly correct the abnormal curvature of the spine in the induced model of lordo-scoliosis in lambs. With the evolving versions of the implant assessed in this study, correction was not always complete, but it was demonstrated that in principle the device works significantly towards that goal.

Transposing to the possible application of this device to the human patient, its prime advantages over current practice would be both its ability to allow continued spinal growth and spinal mobility. The current treatment regimen aims to fuse the corrected spine when it still has some growth potential, therefore the height expectancy of the patient is not reached. It also leaves much of the spine rigid, thus seriously limiting the mobility of the patient. Long-term, the inter-vertebral joints at the junctions between the still mobile and rigidly fixed sections of the spine, have the potential for degeneration over time. With the innovative device developed in this study, it would be a reasonable expectation that with AIS children, maintaining mobility of the spine while correcting a curvature in this manner will alleviate the onset of segmental or junctional problems, and long-term incapacitating back pain.

Though not investigated in this study, there is the intention that the device could be explanted some years after correction when the musculo-skeletal tissues have become well adapted to the corrected anatomy as well as skeletal maturity having been reached. In the human patient this could be undertaken 5 - 7 years after implantation.

The development of an induced idiopathic type lordo-scoliosis in the lamb, proved more difficult to achieve than had been indicated by other authors using the goat. Secure anchorage of the ends of the tether being the prime problem in the lambs. Undoubtedly the mechanical loads on the tether attachments must have been very considerable because the lambs were free to behave normally when released to open fields soon after surgery. Eventually the problem was overcome by devising a stronger mechanical attachment to the vertebral column.

Repeating previous authors use of a rigid rod as a tether, was not satisfactory in the lamb as the resulting rigidity increased the possibility of spinal fusion. Wire was a superior tether as it was strong in tension so limiting left side spinal growth, but offered no resistance to compression thus allowing some continued inter segmental movement. Consequently, despite having the induced curvature the resultant scoliotic model retained some inter-vertebral flexibility comparable to the human patient. In general, the more flexible the scoliotic curve is preoperatively in the human patient, the greater the curve correction outcome postoperatively.

The tension of the cable at the time of application proved to be critical, left slack and it would take time for spinal growth to produce any tethering effect, too tight and an instantaneous spinal curvature would result. Therefore the technique finally used was to overtighten to produce a slight curve, then slacken off until the spine was just straight before crimping the cable.

The authors are undecided as to whether the partial removal of six ribs on the right side enhanced, or otherwise, the development of the spinal curvature. It was a major, delicate and time consuming exercise, but was performed in all animals so no evidence was gathered as to any effect due to it not being undertaken.

In the early methodology, 12 weeks after tether removal, there was little change in Cobb angle. What small changes did occur could possibly be accounted for as errors of measurement. So it would appear that there was neither increase (progression) nor decrease (self-correction) in spinal deformity after removal of the tether. The assumption was therefore made that the deformity would remain

permanently if not treated.

Metal wear particles where the springs contacted adjacent screw arms, were to be expected. However they were always embedded in non-reactive tissues and never present excessively as a paste. In addition blood analyses show no increased concentrations of metallic constituents of the implant. The long-term intention in human patients, would be to remove the implant once skeletal maturity was reached. In that scenario any metal wear could be excised when the implant was removed.

There was no evidence of breakage or loosening of implant components. This was testimony to the carefully considered design, fabrication and assembly of the components. But also there was considerable compliance between the modules that helped to dissipate the mechanical loads.

We have developed a combination of a surgical technique and a novel implant that will reliably correct lordotic spinal deformity in the lamb. The original design features have been refined during this proof of concept experimental study, not only improving ease of assembly but also increasing the efficacy of the implant such that the induced lordo-scoliosis in the lamb has been further reduced, and in some instances completely corrected.

Of added importance was that none of the animals demonstrated over-correction of the curve, undoubtedly because the forces applied by the springs were self-limiting.

The production of both an animal model of scoliosis and an implant to correct it were evolutionary processes from which much was learned during this study. As curve correction was largely achieved, the knowledge gained can form the basis for further development.

## CONCLUSION

The development of an induced, stable lordo-scoliosis in the immature sheep has allowed a proof of concept study to be undertaken on a specially designed and fabricated modular implant device designed to correct the deformity. The study revealed that the device can provide correction of the lordo-scoliosis to a kyphotic position while preserving independent segmental mobility and allowing natural growth to occur in the lamb to skeletal maturity. Over-correction did not occur.

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