POLYCAPROLACTONE-BASED SCAFFOLD PLUS RECOMBINANT HUMAN BONE MORPHOGENIC PROTEIN (rhBMP-2) IN AN OVINE MODEL OF ANTERIOR SPINAL FUSION

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INTRODUCTION

Synthetic scaffolds combined with growth factors have the potential to replace allograft or autograft as a graft material for spinal interbody fusion. Such tissue engineering approaches may be useful in Adolescent Idiopathic Scoliosis (AIS) surgery, however there are no studies to date examining the use of such biodegradable implants in combination with biologics in a thoracic spine model. This *in vivo* study examines the use of biodegradable polycaprolactone (PCL) based scaffolds with rhBMP-2 as a bone graft substitute in a sheep thoracic fusion model, where an anterior approach is used to simulate minimally invasive surgical deformity correction in the setting of AIS.

METHODS

14 male Merino sheep aged 4 to 6 years and weighing 45 – 50 kg were divided into two groups and evaluation time points; three months (n=7) and six months (n=7) respectively. Three thoracic intervertebral spaces (T6/7, T8/9 & T10/11) in each animal were randomly allocated to receive either (i) PCL Calcium phosphate (CaP) coated scaffold with rhBMP-2, (ii) CaP coated scaffold alone or (iii) rib head autograft. The scaffold design was based on a 0-90° lay-down pattern plus scaffold contour to confer additional strength for surgical handling and implantation of the prepared disc space. The scaffolds (Figure 1) were fabricated using PCL and a BioExtruder, a computer-controlled extrusion-based additive manufacturing device developed at the Polytechnic University of Leiria, Portugal [1]. The treated intervertebral disc spaces were stabilized with a 5.5 mm titanium rod secured with two vertebral screws. All animal related procedures were approved by the animal ethical review committee. Explanted thoracic spinal segments (T4-L1) of all the animals were CT scanned using a high-speed tomography scanner (Phillips Brilliance 64) with the following parameters. X-Ray source current and voltage of 200mA and 120kV respectively, and a 14cm field of view at 0.7 mm slice thickness. Reformatted sagittal, coronal and axial images were generated from the CT data using *ImageJ* software and fusion scores were assessed (Glassman [2]). To date, CT fusion grading has been conducted on two sheep sacrificed at the 6-month time point. Additionally non-destructive biomechanical testing and histology will also be performed.

RESULTS

A mean fusion grade of 4.3 was observed at the PCL CaP coated scaffold with rhBMP-2 level with attainment of solid unilateral fusion. At the autograft level, grade 4 mean fusion was observed and grade 1 mean fusion at the scaffold only level.

CONCLUSION

Preliminary results demonstrate radiologically evident bony fusion at the PCL CaP coated scaffold level which is observed to be a similar grade to autograft, while no fusion is seen at the scaffold only level. Results to date suggest that the combination of rhBMP-2 and scaffold engineering actively promotes bone formation, laying the basis of a viable tissue engineered constructed.

Figure 1. μCT scan of a fabricated scaffold

REFERENCES

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2. 2005 Glassman S, et al. Initial fusion rates with rhBMP-2/compression resistant matrix and a hydroxyapatite and tricalcium phosphate/collagen carrier in posterolateral spinal fusion. *Spine* 30(15):1694–98.