POLYCAPROLACTONE-BASED SCAFFOLD PLUS RECOMBINANT HUMAN BONE MORPHOGENIC PROTEIN (rhBMP-2) IN AN SHEEP THORACIC SPINE FUSION MODEL

Yong M[1,2], Adam CJ[1,2], Askin GN[1], Labrom RD[1], Domingos M[3], Bartolo P[3], Melchels F[2], Hutmacher D[2]

1. QUT/Mater Paediatric Spine Research Group, Brisbane, Queensland, Australia
2. Institute of Health and Biomechanical Innovation, Queensland University of Technology, Brisbane.
3. Centre for Rapid and Sustainable Product Development, Polytechnic Institute of Leiria, Portugal.

INTRODUCTION

Adolescent idiopathic scoliosis is a complex three dimensional deformity affecting 2-3% of the general population. The resulting spinal deformity consists of coronal curvature, hypokyphosis of the thoracic spine and vertebral rotation in the axial plane with posterior elements turned into the curve concavity. The potential for curve progression is heightened during the adolescent growth spurt. Success of scoliosis deformity correction depends on solid bony fusion between adjacent vertebrae after the intervertebral (IV) discs have been surgically cleared and the disc spaces filled with graft material. Recently a bioactive and resorbable scaffold fabricated from medical grade polycaprolactone has been developed for bone regeneration at load bearing sites [1]. Combined with rhBMP-2, this has been shown to be successful in acting as a bone graft substitute in a porcine lumbar interbody fusion model when compared to autologous bone graft alone. The study aimed to establish a large animal thoracic spine interbody fusion model, develop spine biodegradable scaffolds (PCL) in combination with biologics (rhBMP-2) and to establish a platform for research into spine tissue engineering constructs.

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 semicircular scaffold contour to confer additional strength for surgical handling and implantation of the prepared disc space. The scaffolds were fabricated using PCL and a BioExtruder, a computer-controlled extrusion- based additive manufacturing device developed at the Polytechnic University of Leiria, Portugal [2]. The treated IV disc spaces were stabilized with a 5.5mm titanium rod secured with vertebral screws. The study had approval by the University Animal Ethics Committee. Explanted thoracic spinal segments (T4-L1) were CT scanned using a high-speed tomography scanner (Phillips Brilliance 64) with the following parameters, current (200mA), voltage (120kV), with 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 [3].

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 higher grades of radiologically evident bony fusion across all levels when comparing fusion scores between the 3 and 6 month groups 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 constructs.

REFERENCES

1. Abbah SA, et al, 2009. Biological performance of a polycaprolactone-based scaffold used as fusion cage device in a large animal model of spinal reconstructive surgery. Biomaterials 30(28); 5086-93.
2. Domingos M, et al, 2010. Advanced research in virtual and rapid prototyping (Boca Raton ed.) CRC Press, Taylor & Francis Group: 67 – 73.
3. Sucato DJ, et al, 2004. Recombinant human bone morphogenetic protein-2 enhances anterior spinal fusion. *J Bone J Surgery* 86(4):752–62.