Comparison of Pre-clinical Testing Protocols for the Evaluation of Spinal Biomechanics

S. Ramos Pascual, P. S. Keogh, A. W. Miles and S. Gheduzzi
S.Ramos.Pascual@bath.ac.uk; Centre for Orthopaedic Biomechanics, Dept. of Mechanical Engineering, University of Bath, Claverton Down Rd, Bath, North East Somerset BA2 7AY

Back pain is the leading cause of disability worldwide, affecting a tenth of the world population and costing £500 million to the UK National Health Service alone. Due to the high cost of chronic back pain to the global economy, it is feasible to invest in surgical solutions to the problem. New implants are constantly being developed to replace the painful intervertebral disc with an artificial device, such as a total disc replacement. These implants must be carefully tested for biocompatibility and to ensure that the artificial device behaves in the same way as the natural spine.

Comparing the behaviour of artificial devices across laboratories can be difficult, because there is a wide range of testing protocols and testing parameters available. In addition, no detailed study in the literature analyses the effect of the testing protocol on the final results. This study aims to fill this gap of knowledge. The unique Spine Simulator at the University of Bath has been used to compare, in six degrees of freedom, the two most widely utilised testing protocols in the literature: stiffness and flexibility. A testing procedure that includes the effect of applying a preload on the specimen was developed. A synthetic model, which replicates a human lumbar isolated disc specimen, was tested.

The results produced from testing include the load-displacement behaviour of the specimen, from which the stiffness matrix was calculated. A quantitative comparison was then made of the six main diagonal terms in the stiffness matrix, and a qualitative comparison was made of the shape of the load-displacement graphs.

The results from the Spine Simulator show that these two main testing protocols produce data that does not match. This important result demonstrates the need to standardise the testing procedure used to evaluate spinal devices, to ensure comparisons can be easily made across laboratories in the future.

(305 words)