Introduction

Total disc replacement (TDR) surgery has been proposed as a viable treatment for severely degenerated discs. Short-term results following TDR are comparable with fusion\(^1\)\(^-\)\(^2\) while long-term results are limited in number, and are generally characterised by poor outcomes\(^3\)\(^-\)\(^4\). The reasons for this remain unclear and are likely to be multifactorial. One of the contributing factors may be due to an alteration in the natural mechanics of the spine following TDR.

Spine mechanics has been investigated by a number of authors\(^5\)\(^-\)\(^8\) using a variety of techniques, the most complete consisting in the determination of the stiffness matrix of functional spinal units (FSUs) and isolated disc specimens (ISD), which comprise a FSU with the facets and processes removed.

The aim of this study was to develop a pre-clinical testing protocol, which would provide a means to compare the dynamic stiffness matrix of spinal specimens with an intact disc and with a TDR implanted into it.

Materials and Methods

To determine the stiffness matrix, linearly independent displacements along each of the axes must be applied individually to the specimen, with the other axes held in a stationary position. Five triangle wave cycles were completed at 0.1 Hz for each axis, with the last 3 cycles used for analysis. The order of testing each axis was randomised within the matrix. Applied amplitudes matched those by Stokes et al.\(^9\) of t±4° in rotational axes (RX, RY, RZ), ±3 mm in anterior/posterior shear (TX), ±1.5 mm in lateral shear (TY), and ±0.4 mm in axial compression/extension (TZ).

A custom-developed six-axis spine simulator (Figure 1) was used to perform such tests on lumbar porcine FSU (n=6) and ISD (n=6) specimens with an intact disc, and after a total disc replacement. The implant used for the procedure was a DePuy In Motion device (Figure 2).

Tests were completed without an axial preload, and with a preload of 500 N. The preload was equilibrated for 30 minutes prior to testing, and testing repeated 60 minutes after initial preload application.

Stiffness terms were calculated from the load data (FX, FY, FZ, MX, MY, MZ) acquired from the six-axis load cell positioned beneath the caudal vertebra and the displacement applied to the superior vertebra using the linear least squares method. This resulted in 36 stiffness terms organised in a 6x6 matrix, with the diagonal corresponding to the principal stiffnesses.

Statistical comparisons were made between the stiffness of the intact disc and the disc replacement device using independent t-tests. The effect of preload and equilibration time on stiffness was assessed using ANOVA.

Results

The characteristics of different stiffness terms varied considerably, some appearing highly linear, and others demonstrating S-curves (Figure 3).

More terms were significantly different in ISD specimens, due to the shielding effect of the facets and ligaments of the FSU specimens. Three of the 36 terms were significantly lower with the disc replacement in all comparisons with the intact disc. These were the axial rotation stiffness (RZ/MZ), the anterior/posterior shear stiffness (TX/FX), and the stiffness of lateral shear force due to axial rotation (RZ/FY). Nine terms were significantly lower with the In Motion device in all comparisons of the ISD specimens, and without an axial preload, all six principal stiffnesses were significantly lower (Figure 4).

An increased equilibration time had little affect on the stiffness, irrespective of specimen type or disc type. No significant differences were found in any comparison of equilibration time.

Discussion

The stiffness of the intact FSU and ISD porcine specimens compared reasonably with previously published stiffness matrix data of porcine and cadaveric specimen\(^5\)\(^-\)\(^8\).

The In Motion disc replacement compared favourably with the intact porcine disc in shear and axial stiffness, with the In Motion disc within 25% of the intact disc stiffness in tests with an axial preload. However, the low-friction design of the In Motion device lacks stiffness in the three rotational axes. Rotations are the primary movements in the spine, and it is crucial if the natural biomechanics are to be restored, that a disc replacement device should replicate the stiffness of these axes.

Conclusions

A dynamic pre-clinical testing protocol has been developed to quantitatively assess the efficacy of disc replacement devices. The protocol would also provide valuable data during the design stages of devices, aiding the development of the next generation of artificial discs.

Stiffness matrix testing has shown that whilst disc replacements demonstrate the potential to provide motion-preserving restoration to severely degenerated joints, further research using the above testing protocol may provide a means to improve device design, and thus clinical outcomes.

An equilibration time of 30 minutes appears to be suitable for porcine specimen testing. A longer equilibration time of 60 minutes does not greatly alter the construct stiffness with either the natural disc, or a disc replacement device.