An in vitro biomechanical comparison of CadiscTM-L with natural lumbar discs in axial compression and sagittal flexion

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Abstract

Introduction The elastomeric, monobloc disc prosthesis (CadiscTM-L, Ranier Technology, Cambridge, UK) aims to preserve biomechanics of an implanted spinal motion segment.

Study design This study presents the findings of an in vitro investigation on the effect of implantation of CadiscTM-L. Compressive stiffness, flexion stiffness at 10, 20, 30 and 40 Nm and the instant-axis-of-rotation (IAR) loci are compared before and after implantation of a MC-10 mm-6° CadiscTM-L.

Methods Fresh frozen human monosegmental lumbar spines ($n = 8$) were prepared, potted and tested in an environmentally controlled chamber to simulate in vivo conditions. Specimens were preconditioned by loading to 500 N for 30 min. Compressive stiffness of the specimen was determined by applying pure compression of 1 kN at 250 N/s via a loading roller positioned at the central loading axis (CLA). The roller was then offset 12.5 mm anterior of the CLA and the loading regime repeated to test specimens in flexion. Bending moments were calculated from the applied load and corresponding flexion angle. The IAR locus was tracked by a motion-tracking camera.

Results Compressive stiffness was reduced by 50 % ($p = 0.0005$), flexion stiffness was not statistically significantly reduced (40 % reduction, $p > 0.05$). IAR locus maintained a ‘horizontal figure of eight’ characteristic. Change in the locus width in the AP plane of 6.4 mm ($p = 0.06$) and height in the SI plane of 1.3 mm ($p = 0.44$) were not significant. The centroid was displaced 4.44 mm ($p = 0.0019$) and 5.44 mm ($p = 0.025$) at 3° and 6° flexion, respectively.

Conclusions Implantation of CadiscTM-L caused a reduction in axial stiffness, but maintained disc height and flexion stiffness. IAR loci remained mobile without large displacement of the centroid from the intact spine position.

Keywords Lumbar spine · Disc replacement · Biomechanics · In vitro · CadiscTM-L

Introduction

As with most parts of the human body, inter-vertebral-discs (IVDs) are subject to degenerative changes caused by ageing. This process is widely described as degenerative disc disease (DDD), which is a natural and highly prevalent condition [1]. It is widely accepted that DDD alters mechanical properties of IVDs, and therefore biomechanics of the motion segment [2–4]. Degenerated discs that cause back pain and do not respond to conservative treatment are traditionally treated by spinal fusion. Total disc replacement (TDR) is an alternative to fusion in which diseased discs are replaced with motion preserving implants. TDR has gained popularity as a treatment for DDD, and a number of artificial discs are available. Most TDR implant designs derive their biomechanical properties from low-friction articulations (metal-on-metal or metal-on-polymer)

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that have several criticisms; whilst allowing motion they do not resist bending, they are relatively non-compliant under compressive load and the fixed articulations constrain the motion of the joint differently to natural discs. Wear of the articulating surfaces has also been found to generate debris [5, 6] which may result in adverse biological responses.

Elastomeric TDR devices provide the opportunity to restore axial compressive stiffness and flexural stiffness characteristics to more closely replicate the biomechanics of an IVD. The monobloc elastomeric disc prosthesis (CadiscTM-L, Ranier Technology, Cambridge, UK) (Fig. 1) is a polycarbonate-polyurethane, graduated modulus, compliant TDR device. CadiscTM-L has no articulating surfaces, minimising the potential for wear debris [7]. The internal structure of CadiscTM-L has a lower modulus ‘nucleus’ region surrounded by a higher modulus ‘annulus’ region, the modulus of the two regions is graduated seamlessly [8].

The objective of the study is to characterise in situ biomechanical performance of the CadiscTM-L implant. To satisfy this objective the response of a single cadaveric lumbar motion segment to mechanical loads was assessed before and after replacement of the IVD with the CadiscTM-L. Compressive stiffness, disc height, flexion stiffness and locus of instant axis of rotation (IAR) of the motion segment were compared.

Materials and methods

Specimen inclusion and preparation

A statistical power analysis was conducted using spinal flexibility data [9] that determined the minimum detectable

difference in stiffness was 2.3 Nm° , when sample SD was 2 Nm° with significance level $p = 0.05$ and power $\alpha = 0.8$, $n = 8$. Intact single level motion segments (L3–L4 and L4–L5) were selected from previously harvested, fresh frozen cadaver material, mean age 76.7 ± 13 (years $\pm$ SD).

Prior to testing, specimens were radiographed to determine suitability for experimentation. A scale was included in the radiographs to allow measurements, including posterior disc height, to be taken. Any specimens presenting gross abnormalities, DDD beyond grade II [10] or substantial osteophytes, were excluded. Posterior disc height was $10.2 \pm 1.2 \text{ mm}$ (mean $\pm$ SD). All specimens were DEXA scanned at Queen’s Medical Centre, Nottingham, UK, and osteoporotic specimens excluded.

Specimens were tested with osteoligamentous tissue intact. Musculature and soft tissue were removed by dissection before potting into test fixtures with Wood’s metal. Specimen position within the potting fixtures was controlled so the mid-plane of the disc was horizontal. Specimens were potted with superior and inferior faces of the fixtures parallel to one another. Retro-reflective markers were added for motion tracking.

In order to simulate in vivo conditions, testing was conducted in a test chamber at $37 \pm 2^\circ \text{C}$. Humidity within the chamber was maintained at 95–100 % to prevent specimen dehydration [11, 12].

Loads were applied to the specimen using a roller apparatus (Fig. 2) and an Instron 3367 test machine (Instron, High Wycombe, UK) with a 30 kN load cell. The central loading axis (CLA) of each specimen was identified in the horizontal plane by applying a 40 N test load and moving the loading roller in an anterior–posterior (AP) direction until the segment returned to within 1° of the

Fig. 1 The CadiscTM-L prosthesis

Fig. 2 Loading apparatus; A: inclinometer, B: retro-reflective markers for motion tracking $\times 7$

neutral position, identified by the top plate being parallel with the machine bed, as measured by an electronic inclinometer (Level Developments, SCA121T-D07). Prior to testing, specimens were loaded to 500 N in compression for 30 min as pre-conditioning to reduce the effect of over hydration of disc tissue [12].

Axial compression testing

With the roller positioned directly above the CLA in the AP plane a compressive load was applied that did not induce bending moments in the specimen. Compressive load was applied at a rate of 250 N/s to a maximum load of 1,000 N. Five loading cycles were applied and data was analysed from the fifth cycle. Load was plotted against displacement and a linear trend line fitted to the data using the least squares method. The gradient of the trend line was taken as the compressive stiffness of the specimen. An estimation of effect of implantation on disc heights was calculated by comparing digitised lateral fluoroscope images. From marker position data an estimate of the change in lordotic angle was made.

Flexion testing

After compressive testing the loading roller was offset anteriorly from the CLA by 12.5 mm and the loading cycle repeated, inducing a bending moment in the specimen. The inclinometer recorded the angle of bending. Five loading cycles were applied and data was analysed from the fifth cycle. Out of plane movements were minimised as specimens were tested in flexion which produces small couple motions ($<0.5^\circ$) [13]. The design of the rollers also constrained coupled motion so that no out of plane rotation could occur.

Bending moment was calculated using Eq. 1 from load, bending angle and dimensions of the apparatus. Angle was plotted against bending moment to produce response curves, which were fitted with logarithmic functions using the least squares method ($R^2 > 0.95$). Stiffness values were obtained by calculating first order differential of the fitted functions and evaluating at the different bending moment increments.

$$BM = F(x \cos \theta + y \sin \theta) \quad (1)$$

BM Bending moment

x Distance between roller contact point and CLA in horizontal plane

y Distance between roller contact point mid -plane of the disc

θ Angle of flexion

F Applied force

IAR calculation and plotting

A Qualysis MCU120 camera and QTrack software was used to record the motion of the superior vertebra during the flexion test by recording the position of retro-reflective markers attached to the specimen. Three markers were located on the upper vertebra to allow calculation of the IAR. Four additional markers were located on the base of the machine and inferior vertebra to allow IAR position loci to be scaled and orientated for comparison. Tracking was performed at 50 Hz.

IAR was calculated using the 2D Reuleaux method [14]. The accuracy of this technique is highly sensitive to the angle through which the body is rotated. When angle of rotation is 0° then there is no intersection of the bisecting lines, therefore at small angles the method becomes unstable. By tracking three markers on the apparatus further analysis of the IAR is possible as multiple IAR points are constructed (Fig. 3). If co-ordinate data were perfect then all three IAR points would coincide. Therefore, unstable outliers generated when angles of rotation are small can be identified by considering the differences between the three IAR points. Validation testing on a fixed hinge indicated that triplets that fell within a 1.5 mm (± 0.75 mm in X and Y co-ordinate) region were stable; these were then averaged to create a single point. Data was smoothed by median filtering. An algorithm was developed in MatLab to calculate the IAR triplets, apply filters and produce a plot of the loci.

CadiscTM-L implantation

A size MC-10 mm- 6° (medium footprint, posterior height 10 mm, lordotic angle 6°) CadiscTM-L was implanted into the specimen by an anterior surgical approach, without removal of the specimen from the potting fixtures. Mounting of the specimen to the test apparatus was achieved by

Fig. 3 Construction of IAR using Reuleaux method with 3 markers

sockets that accepted the inferior potting fixture and maintain alignment of the specimen between tests. Clearance between sockets and the fixture was 0.5 mm and clamped with bolts. Implantation was performed by a trained individual using the instrument set developed for Cadisc™-L. A window was cut in the anterior annulus of the IVD, a discectomy was performed and endplates were prepared for implantation.

The CLA of the specimen was then identified as before and the testing regime was repeated to evaluate the effect of implantation on the spine. A two-tailed paired Student's *t* test was used to compare the intact and implanted response data. Where data was non-parametric, a paired Wilcoxon signed-rank test was used.

Results

Compressive stiffness

The stiffness of the implanted specimens was normalised against the intact stiffness to determine the effect of implantation. The mean effect was a 50 ± 11 % (mean $\pm$ SD) reduction in compressive stiffness which was statistically significant $p = 0.0005$. The standard deviation of intact stiffness was large (SD 476 N/mm), indicating that mechanical properties of IVDs are highly variable. Specimens implanted with Cadisc™-L had a more consistent stiffness (SD 142 N/mm). An overall comparison of compressive properties is shown in Fig. 4.

The mean posterior disc height prior to implantation was 10.2 ± 1.2 mm (mean $\pm$ SD). Posterior disc height was increased by 27 ± 13 % (mean $\pm$ SD). Disc height change was measured from lateral fluoroscopy images taken before and after implantation. Change in lordotic angle of the specimens was calculated from marker position data, after

Fig. 4 Mean compressive stiffness data (* $p = 0.0005$)

Table 1 Flexion stiffness values at discrete bending moment increments for intact and implanted specimens

Bending moment (Nm)	Intact specimens		Implanted specimens	
	Mean flexion stiffness (Nm/°)	SD	Mean flexion stiffness (Nm/°)	SD
10	4.5	2.2	3.5	2.3
20	8.9	4.3	7.1	4.6
30	13.4	6.5	10.6	6.9
40	17.8	8.6	14.2	9.2

implantation specimens assumed a more extended position, $-2.7 \pm 3.4^\circ$ (mean $\pm$ SD).

Flexion stiffness

The effect of implantation of the Cadisc™-L on flexion stiffness was found by normalising the stiffness of each implanted specimen against its intact performance. The median of the effects on stiffness was a 40 % reduction; a paired Wilcoxon signed-rank test indicated that this difference was not statistically significant ($p > 0.05$). Mean stiffness and standard deviations at each bending moment increment are presented in Table 1.

IAR position

After IAR data was calculated and filtered, loci were overlaid onto corresponding radiographs for comparison (Fig. 5). The IAR of intact and implanted specimens was

Fig. 5 Example IAR locus plot

Table 2 IAR locus range and centroid displacement over full range of motion

	Range of IAR locus				Position of centroid		
	Intact AP range (mm)	Change in AP range on implantation (mm)	Intact SI range (mm)	Change in SI range on implantation (mm)	AP movement of centroid on implantation (mm)	SI movement of centroid on implantation (mm)	Magnitude of centroid displacement (mm)
Mean	8.6	6.4	9.4	−1.3	−8.15	0.5	8.17*
SD	2.1	8.2	3.5	4.5	6.52	3.4	n/a

* statistically significant

shown to migrate in both the AP and superior–inferior (SI) directions. The locus of the implanted specimen was altered compared to the intact. To quantify the displacement of the IAR locus, the range and centroid were calculated (Table 2). The range of the loci of implanted were not significantly altered in either plane. The position of the centroid moved superiorly 0.50 mm and posteriorly 8.15 mm.

Discussion

A 50 % reduction in axial stiffness was seen after implantation of CadiscTM-L, this was coupled with a 27 % increase in disc height. Although the reduction in stiffness is significant, the total disc height of the specimen will be maintained or increased at loads up to 4.4 kN, a load approximately equal to the mean failure load of L4 vertebrae [15]. Compressive stiffness for the whole motion segment was found to be less than that of an isolated CadiscTM-L indicating that the vertebral body had a compressive stiffness that contributed significantly to the mechanical properties of the segment.

The intact specimen flexion response curve exhibited a toe-in region of varying width followed by a more linear region; this characteristic is the result of the neutral zone of the disc and is widely reported [16]. Flexion stiffness values for the intact specimens showed substantial specimen to specimen variability, as was suggested by previous studies [17, 18]. Implantation of the CadiscTM-L did not significantly alter the flexion stiffness of the specimens; however, the toe-in region was reduced. The orientated collagen fibres of the lamellar layers which make up the annulus fibrosus of the natural IVD result in a structure that, when subjected to bending moment shows a markedly different neutral and elastic zone. Although the CadiscTM-L implant exhibits a graduation in material properties within its core, the device does not exhibit a large neutral zone. Increased disc height will also increase tension in the surrounding ligaments, which may also be contributory.

Testing showed that the position and shape of the IAR locus of the intact and implanted specimen is consistent

with published data [19–24]. The motion-tracking camera recorded the position of the markers used to generate the IAR locus in 2D space only, and therefore movement of the markers perpendicularly to the plane of measurement were not captured. Preliminary studies qualified that IAR tracking determined the centre of rotation of a simple hinge within ± 1.5 mm of its location throughout a 15° range of motion, validating the technique and method.

Implantation of CadiscTM-L maintained a mobile IAR. Although implantation resulted in movement of the IAR locus posteriorly by 8.15 ± 6.4 mm (mean $\pm$ SD), the flexion testing suggests that the total range of motion of the specimens varied considerably; therefore, the IAR loci are not directly comparable. For meaningful comparison the range of motion must be consistent. By segmenting the IAR plot into comparable ranges (0–3° and 3–6°) comparison can be made (see Table 3). Data for CadiscTM-L is also compared to data presented by Rousseau [19] for two other TDR implants. The magnitude of the centroid displacement, calculated by combining AP and SI shift is presented to negate variations in specimen alignment between the studies. CadiscTM-L is shown to produce a small displacement in IAR that is consistent across the range of motion. Rousseau reports that the change in IAR location after ProDisc implantation was not significant; however, a significant increase in the height of the IAR relative to the endplate was noted after Charité III implantation. Neither device resulted in increased facet loading during flexion–extension. The IAR centroid movement resulting

Table 3 Comparison of the displacement of CadiscTM-L centroid compared to other TDR implants [19]

Implant	Range of motion (°)	Total centroid displacement (mm)
Cadisc TM -L	0–3	4.44
	3–6	5.44
Charite [19]	0–3	11.21
	3–6	3.20
ProDisc [19]	0–3	8.25
	3–6	9.15

Fig. 6 Comparison of CadiscTM-L IAR centroid displacement to ProDisc and Charité III [14]

from CadiscTM-L implantation (Fig. 6) is smaller in all except one case compared to the ProDisc and Charité III devices, and suggests that the IAR location is unlikely to result in an increase of facet loads. However, it is important to compare this with caution, as these experiments were carried out on different apparatus that applied a different combination of moment and shear force.

Implantation of CadiscTM-L resulted in a reduction in axial stiffness of a motion segment, but maintained disc height at loads within the physiological range. Further study is required to determine the importance of this change to the biomechanics of the segment; however, implantation of the CadiscTM-L implant maintains the flexion stiffness properties and the IAR loci remains mobile without substantial displacement of the centroid from the intact spine position.

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Conflict of interest Donal McNally is a member of the Scientific Advisory Board of Ranier Technology Ltd. Scott Johnson is an employee of Ranier Technology Ltd.

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