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The objectives for the mechanical evaluation of spinal instrumentation have changed

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Abstract The objectives for the mechanical evaluation of spinal implants have changed because many modern devices are designed to modify the mechanics of the disc rather than to simply fix the segment. This means that a biomechanical objective must be decided, a priori, for a particular device. It is then relatively straightforward to design a biomechanical evaluation protocol that can either test whether this objective is fulfilled, or optimise the device in the context of the objective. Because 'soft stabilisation' systems are soft, their performance is affected by the magnitude of the loading sustained by the bridged segment. This means that is vital to reproduce a realistic loading regime for the biomechanical evaluation, if its results are to be relevant to a clinical problem. Simi-

larly, the condition of the segment in terms of disc degeneration, facet joint condition, etc. affect the mechanical performance of the segment and must be relevant to the performance objectives set for the device. Loading protocols for testing short and long segments are discussed. Since the aim of many spinal devices is to modify the loading of the intervertebral disc, it is important to quantify their effect in terms of how both the internal loads and deformations are changed. A number of different technologies for quantifying both loads and deformations in intact discs are described and discussed.

Keywords Biomechanics · Motion segment · Intervertebral disc · Instrumentation · Evaluation

Introduction

Historically, the major application of spinal instrumentation has been to provide motional stability in arthrodesis and deformity correction. As such, the principal mechanical objective of the instrumentation has been to control movement of the bridged segment. Consequently, a series of mechanical evaluation protocols have been proposed and developed [1, 33, 35, 49], which are based on the standardised analysis of segment movements resulting from the application of pure rotational moments. This form of biomechanical evaluation is now the gold standard for the characterisation of spinal instrumentation. However, with the increasing introduction of new im-

plants such as soft stabilisation devices, such evaluation protocols need to be revised.

The primary driver for the development of new assessment protocols is the change in mechanical objective of the devices themselves. They are no longer designed simply to control rotational motion of the bridged segment, but also to change particular features of the internal mechanical environment of the disc itself, for example to off-load the whole disc or modify the loading of the posterior annulus. Assessment protocols must be designed to test that such mechanical objectives are being met, and this requires both a range of experimental techniques that characterise the internal mechanics of intact intervertebral discs and a loading protocol that simulates realistic functional loading.

A secondary driver for the development of new protocols arises from the fact that many of the new fixation devices are not in themselves rigid. With rigid fixation devices, compressive loading in addition to the applied bending moments has little effect on the rotation of the segment [43]. This means that parameters such as ligament tension are largely unaffected, and hence the measurements of rotational motion are largely unaffected. However, compressive load has been found to influence the relative loading of the segment and the fixation device [50]. Implants such as the Graf ligament or the Dynesys device will deform under compressive loading of the segment, and hence their mechanical performance will be changed (as has been demonstrated in intact segments [21]). Consequently, it becomes much more important to test the devices under more realistic loading conditions, where muscle forces are simulated. Similarly, the mechanical condition of the bridged segment in terms of disc degeneration, facet joint condition, etc. can have a significant effect both on the behaviour of the segment and on how a fixation device modifies it. Thought must therefore be given to the condition of the specimens used in biomechanical investigations.

The purpose of this paper is to identify a range of novel assessment technologies and to suggest how they might be incorporated into a protocol to evaluate the mechanical performance of spinal instrumentation. Since the mechanical objectives of current spinal instrumentation systems are highly varied, the protocols used to assess their performance must necessarily be diverse. However, the underlying principles of the mechanical evaluation remain consistent and are addressed here.

Defining objectives for biomechanical evaluation

The primary roles of biomechanical evaluation are to confirm that a particular fixation device achieves its functional objectives and to compare the performance of a range of devices in meeting such objectives. It is therefore of vital importance to decide, *a priori*, exactly what functional behaviour is required from the fixation device.

In the case of soft stabilisation systems, determining such an objective is not as easy as it may first appear. For example, a major application of such devices is the relief of discogenic pain through modification of the mechanics of the affected disc. However, at the moment it is not completely clear what features of disc mechanics are responsible for the generation of pain. Clinical measurement of the internal loading of painful discs have shown that there are loading features in the posterior annulus that probably correspond to inward bulging and severe fracturing [24], and disc degeneration has been found to correspond to reduced nucleus loads [44], whilst studies of motion combined with electromyography have indicated that pain is related to increased compression and lateral shear

[20]. However, these features of internal load distribution may be a consequence of the process that causes pain rather than the cause itself. This having been said, such soft fixation devices are designed on the basis of a hypothesis of mechanical modification of a painful process, and therefore it is possible to construct a mechanical objective for the device.

There are two further roles of mechanical evaluation. The first of these is to ensure that the device affects the internal and external mechanical behaviour of the bridged segment in ways that are clinically acceptable; ensuring, for example, that they do not cause undue loading of other structures. The second role is to ensure patient safety by confirming that the device will not fail in use. These two roles are covered fully in other documents and ASTM standards F 1717–96 and F 1798–97, and are common to all spinal instrumentation devices. They will not be addressed further here.

Possible test protocols

Whilst there are a large number of finite element and other models of spinal fixation that might be employed in a modified form to evaluate the performance of soft stabilisation devices theoretically [8, 17, 18, 39, 41], none has been validated in terms of internal loading and deformation of the affected discs. The gold standard for testing soft stabilisation devices remains for the immediate future biomechanical testing using cadaveric specimens.

Specimen loading

As discussed above, it is important to ensure that the spinal device is tested under conditions that simulate the loading conditions that are likely to occur in life. How these loads are applied to the specimen depends upon the nature of the specimen, which in turn depends upon the configuration of the fixation device.

In the case of short segments, all the necessary compressive forces and bending moments can be applied using one or two rollers (see Fig. 1). For longer segments, this form of loading will lead to unstable buckling. To provide stable compressive loading of longer segments, the ‘follower load’ arrangement illustrated in Fig. 1d has become popular [7, 26, 36, 37, 43]. This arrangement is very flexible in the ways that loads can be placed on the specimen, since the compressive load, bending moments and location of the wire guides on the vertebral bodies can be changed independently. A good investigation of the biomechanical effects of the placement of loading wires guides is given by Cripton et al. [7].

A more contentious issue is the application of axial rotations. In the lumbar spine, axial rotation is limited to about 2° by intact facet joints; however, recent measure-

Fig. 1a–d Schematic diagrams of possible loading configurations. All the diagrams will apply compressive loading and bending towards the left. In **a** a small shear component to the right (relative to the disc) will additionally be applied, in **b** the shear component will be towards the left. The arrangement in **c** is good for applying controlled angular rotations (rather than controlled bending moments). Longer segments will not be stable under the arrangements illustrated in **a–c**; the ‘follower load’ arrangement illustrated in **d** will provide stable compressive loading whilst bending couples can be applied to the upper segment

ments of internal disc mechanics suggest that even rotations as small as 0.5° can significantly affect the internal mechanics of the disc [48]. Careful thought should therefore be given as to how the experimenter wishes to test the spinal device.

In terms of general guidelines for the magnitudes of applied loads and moments, the experimenter should base these on the evaluation objectives. For example, Wilke et al. [49] give a sensible set of bending moments to simulate everyday loading, e.g., 7.5 Nm bending moment for the lumbar spine. Corresponding axial compressive loads for the lumbar spine might be of the order of 1–2 kN [29] for moderate activities. If it is required to simulate more extreme activities, such as the sudden application of large, but unknown, loads, higher forces and moments should be used [19].

Measurement of internal loading

A key to understanding the effects of a fixation device on disc mechanics is the measurement of the internal distribution of load within the disc, and how this is affected by the device to be evaluated. This information can be used to give information about the relative load sharing of the disc and fixator [9, 42], but if measured correctly it can give much more information about the behaviour of the disc tissues themselves.

Disc loading has been measured by a wide range of devices, from injection pressure [34], static-fluid coupled catheters [40] and membrane-covered fluid-filled catheters

[30] to needle-mounted solid-state transducers [22]. Such needle-mounted transducers are now commercially available and are recommended for their convenience of use and stability.

Frequently the measurement of disc loads has been restricted to the centre of the nucleus pulposus [27, 28, 29]. Since the centre of the disc is normally under uniform hydrostatic loading [2, 21], such measurements are very good at giving a quantification of overall disc loading, whilst being insensitive to small changes in disc positioning. However, in severely degenerate discs with positive pain reproduction on discography, the centre of the nucleus is often completely depressurised [24]. It is therefore more useful to measure loading in other locations within the disc.

There have been two basic approaches to measurement of loading patterns within the disc: simultaneous measurement from a number of transducers [47] and recording measured stress with position in the disc using a single transducer [21]. The former method is good for measuring the effects of rapidly applied loads to the specimen, but is sensitive to movement of the transducers within the disc tissue. The latter, termed stress profilometry, requires a static load to be applied for 10–20 s, but gives a continuous measurement of stress across the diameter of a disc.

Considerable information can be gained from stress profilometry. For example, in regions where the stress is anisotropic and forms sharp peaks, shear stress will be high and likely to result in fissuring [23]. Other patterns can suggest inward bulging of the inner annulus [24], whilst the loading over the whole profile can be integrated to assess total disc and facet joint loads [38].

Measurement of internal deformation

Of equal importance to the measurement of internal loads is the measurement of internal deformations. Such measurements have been more challenging, since they require the imaging of internal disc structure in intact discs.

Deformation of the outer surface has allowed, for example, disc bulging to be quantified very precisely [3, 4]. Similarly surface strain has been measured using both optical markers and strain gauges [46]. These techniques are very good at measuring surface behaviour and would be excellent for determining whether a fixation device reduced disc bulging. However, they cannot give any information about the deformations within the disc. Similarly measurements have been made of endplate deflections [5, 11].

High-resolution magnetic resonance imaging (MRI) has been used to study the internal structure of the disc under load [6, 51]. In order to perform such an investigation, it is necessary to construct a non-magnetic loading device that can be introduced into the bore of the imaging system without interfering with the radio frequency excitation or MR signals. Image acquisition also takes a finite

Fig.2 High-resolution magnetic resonance (MR) image of a bovine caudal segment, showing clearly the laminate structure of the annulus. (Courtesy of Dr. M. Clemence, Department of Physics, University of Exeter)

Fig.3 In vitro image of a bovine caudal intervertebral disc in the mid-sagittal plane, showing clearly the laminate structure of the annulus. (Courtesy of Miss C. Naish, Department of Anatomy, University of Bristol and Dr. M. Halliwell, Department of Medical Physics and Bioengineering, University of Bristol)

time (normally of the order 10 min), so it is only possible to observe the effects of fairly static loads. Figure 2 gives an indication of the level of detail that can be obtained on the lamellar structure of the disc. This means that it is only possible to study equilibrium mechanics using this technique. More conventional radiographic techniques have been used to quantify internal disc deformations by imaging radiopaque targets (such as wires and balls) implanted into the disc tissue [16, 45].

Fig.4 Diagram showing radial deformation of the mid-sagittal diameter of the bovine caudal disc shown in Fig.3, on application of three 1-min-duration loading cycles. It can be seen that the anterior annulus (pixels 90–210) and outer posterior annulus bulge outwards, whilst the inner posterior annulus bulges inwards. Arrows mark the transition point between outward and inward bulging, where a dark 'fissure' can be seen to open up. (Courtesy of Miss C. Naish, Department of Anatomy, University of Bristol and Dr. M Halliwell, Department of Medical Physics and Bioengineering, University of Bristol)

Ultrasound at clinical imaging frequencies (3–7.5 MHz) gives good detail of the laminate structure of the disc, both in vitro [31] and in vivo [25]. Such imaging in vitro can be used to detect and quantify disc pathologies such as circumferential tears and fissuring [31]. Figure 3 shows an example of the type of image that can be obtained using a 7.5 MHz clinical imaging system.

The considerable advantage of this technology over other forms of imaging is the speed of image acquisition. It is possible to record ultrasound images at 15 frames per second. Hence it is possible to observe internal deformations in response to realistic dynamic loads. Figure 4 shows how the mid-sagittal diameter of the disc shown in Fig.3 (indicated by the blue line) deforms radially. Figure 4 can be thought of as a compilation of vertical strips of pixels taken from sequential images. (Some image analysis has been performed to ensure that the mid-sagittal diameter is always selected irrespective of axial compression of the disc.) It can be seen that the deformation of individual lamellae is clearly visible and that, in the posterior annulus, there is a point (indicated by arrows) where the annulus changes from bulging outwards to bulging inwards. It is therefore possible to use clinical frequency ultrasound imaging as a tool to optimise stabilisation device performance in terms of modification of the internal deformation to achieve a biomechanical goal for the device.

The principle alignment of the collagen fibre bundles has been inferred using diffusion tensor imaging [12].

Fig.5 Acoustic microscope image of a tangential plane within the second lamella of an intact porcine coccygeal disc. The fibre bundle paths are clearly visible. (Courtesy of Mr. S. Johnson, School of Mechanical, Materials, Manufacturing Engineering and Management, University of Nottingham, and Dr. M. Halliwell, Department of Medical Physics and Bioengineering, University of Bristol)

However, this technique requires a large number of separate relaxation time measurements to be made, and hence acquisition times are large (approx. 3.4 h). Alternatively, fibre angle has been quantified using X-ray diffraction [10, 32], and has been used to demonstrate changes in orientation resulting from mechanical loading [14, 15]. Unfortunately, the exposure times required for analysis of intact discs is very large, and there is poor spatial localisation of the tissue interrogated.

A new technique that can be used to image fine structure within intact intervertebral discs is acoustic microscopy [13]. This can be used to image and quantify collagen fibre bundle directions (see Fig.5) in three dimensions. Hence, it is possible to quantify the effect of a stabilisation device on the local mechanics of the fibre bundles themselves. Acoustic microscopy can also be used to give very detailed images of the lamellar structure and pathology of intact discs (see Fig.6). This figure illustrates how it is possible to identify and quantify disc structure and also large- and small-scale pathological features. It is therefore possible to assess how a stabilisation device affects, say, opening a peripheral annular tear or how it prevents fissure propagation.

Conclusions

We need to reconsider the reasons for, and goals of, biomechanical testing non-rigid stabilisation devices that are designed to modify disc mechanics rather than to replace the discs.

Before biomechanical evaluation is considered, it is important to set a mechanical objective for the device to fulfil. This objective must take into account the aspect of internal disc mechanics that needs to be modified by the device and the condition of the segment in terms of existing disc, ligament and facet joint injury and degeneration. It is then possible to design a biomechanical evaluation to confirm that this objective has been met or to optimise the performance of the device against the objective.

To perform such biomechanical evaluation, it is important to simulate the loading conditions that the spinal segment/implant will experience in life.

Fig.6 Comparison of **a** an acoustic image of a region of annulus from an intact porcine intervertebral disc with **b** a corresponding polarised light micrograph of a section taken from the same region. The triangular region marked with an *asterisk* corresponds to a scalpel cut made to localise the region for comparison with histology. The *closed arrowheads* indicate a bifurcation of a lamella that is clearly visible in both images. The *open arrowheads* indicate small regions of delamination that are again visible in both images. (Courtesy of Mr. S. Johnson, School of Mechanical, Materials, Manufacturing Engineering and Management, University of Nottingham, and Dr. M. Halliwell, Department of Medical Physics and Bioengineering, University of Bristol)

The technology required to make measurements of internal loading and deformation within intact discs exists.

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