In-vitro spinal loading experiments on an animal spine utilizing an intelligent spinal artificial disk prosthesis

M. P. Pancholi, P. A. Kyriacou, and J. Yeh

Abstract—The knowledge of the *in-vivo* loading on the spinal disk is of paramount importance in the understanding of low back pain. In this study an artificial spinal disk is used as a base for making an in-body intelligent implantable load-cell which can measure the *in-vivo* loading on the spinal disk. A commercially available spinal disc was utilized and was loaded with eight strain gauges and two piezoresistive sensors placed at different locations on the disc in order to enable the complete load mapping on the disk. With the aid of a cadaveric animal spine the artificial disc with all sensors was loaded in a laboratory environment. The *in-vitro* loading produced reliable and repeatable results and therefore suggesting that such approach might aid in the development of an artificial intelligent disc which will aid in the better understanding of the *in vivo* loading of the human spine.

Keywords: *in-vivo* spinal loading, spinal disk, Artificial spinal disk prosthesis, Disk Degenerative Diseases, Lumbar spinal disk, Low back pain, Intelligent artificial disk prosthesis, Biomechanics, myeloma.

I. INTRODUCTION

Low back pain is an economic and social burden to society. Its total solution requires a systematic, long term, multi-angle and multi-disciplinary approach. The causes of low back pain are mainly caused by the back tissue-muscles, the degenerative/harinated spinal disk and the damaged bones/vertebrae. Low back pain which is due to tissues or muscles is not considered as chronic and can be treated easily. However, low back pain due to degenerative disk and damaged vertebrae is considered to be a chronic problem and in many cases requires a surgical intervention. The main causes for degenerative disk are extremely complex and still not well understood, although in their majority are

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strongly related to the acute and frequent mechanical loading on the spine [1] [2] [3] [15]. Knowledge that might shed more light in such pathologies is the availability of *in-vivo* data of loading of the human spinal disk, which at the moment does not exist. Many efforts had been made by researchers to investigate and understand the *in-vivo* loading of the human spinal disks. All such techniques were not true *in-vivo* techniques and hence, their findings are questionable [1] [4] [5] [6] [7] [8] [9] [10] [11] [12] [15] [13]. Not only a full understanding of the *in-vivo* loading of the human spine, but also the distribution of the loading on the spinal disk are of prime importance in order to comprehensively understand the biomechanics of the human spine and its parts, and therefore enable the creation of solutions (surgical, technological) for the low back pain pathologies. Such new knowledge will also be helpful for treatment of the vertebrae compression fractures due to trauma or low bone mineral density or multiple myeloma. The aim of this work is to engage in such investigation by developing a prototype intelligent artificial spinal disc with the capability to provide a "map" of all loads applied to the disc when is loaded in an *in-vitro* environment. The initial technological developments and preliminary loading investigations using a cadaveric animal spine will be presented and discussed.

II. MATERIAL AND METHODS

An artificial commercial spinal disk embedded with stress/strain sensors is used as a base for monitoring in-vivo loading using an animal spine. All instrumental developments, both hardware and software, and experimental set-up will be described in this section.

Design and development of the load cell

A commercial, L4/L5 (between lumbar 4 and 5 vertebrae) Activ-L™ artificial spinal disk prosthesis (Aesculap, B-Braun, Germany), was selected as a base for the development of the load cell (Fig. 1). The entire load on the real spinal disk is the same as the entire load on the artificial spinal disk prosthesis
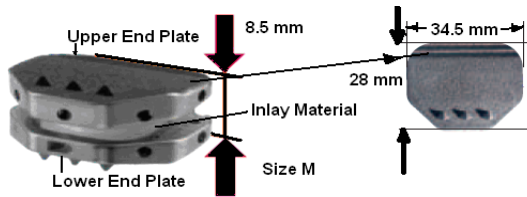
Fig. 1 Aesculap Activ-L™ Artificial Disc (size M)

Another advantage of using the artificial disc is that it enables the use of sensors to be incorporated within its structure in order to measure the *in vivo* loading on the spinal disk. This type of artificial disc is one of the most common used discs.

The artificial disk comprises of mainly three parts (see Fig. 1), the upper end-plate, the lower plate (both made-up of Cobalt-Chromium alloy) and the inlay material (UHMW Polyethylene). A total of eight strain gauges (Linear Foil Strain Gauges, OMEGA, KFG-02-120-C1-11L3M3R) were installed (placed) on both plates of the disc. Four strain gauges were installed on the upper end-plate (strain gauges 4-7) and the other four on the lower end-plate (strain gauges 0-3). Two piezoresistive (FlexiForce®, Tekscan Inc., MA, USA) sensors were also utilized and placed at the top and at the bottom of the inlay material. Further details on this set-up are described by Kyriacou et al. [1].

Signal conditioning and data acquisition system

A signal processing and data acquisition system has been developed to process all the signals acquired from all sensors, digitise, display and store them on a computer (Fig. 3). All sensor output signals were digitized (sampling rate at 100 Hz) using an *NI CompactDAQ USB Data Acquisition System* (National Instruments Corporation, Austin, Texas). The digitized signals were analyzed by a *Virtual Instrument (VI)* implemented in *LabVIEW®* (National Instruments Corporation, Austin, Texas). This *VI* read the voltage outputs from all sensors, converted them into a spreadsheet format and saved them into a file specified by the user and displayed the signals in real time on the screen of the computer.

Harvested animal spine vertebrae

An animal cadaveric spine is used in this study. A calf's spine was used as it was the only spine available with vertebrae of similar size as those found in the human spine. A freshly harvested calf spine was prepared in the laboratory at the Royal Veterinary College, University College London, UK. The spine was cleared of all tissue and then a section (two consecutive vertebrae with in-between spinal disk) of the spine was removed to be used in the loading exercise. The middle animal spinal disk was removed from the selected spinal section and replaced by the artificial disc incorporating all the sensors. This procedure was performed in order to mimic the replacement of a human real biological damaged disc with an artificial disc. The animal spinal section containing the loading cell was held in a vertical position with a custom made cylindrical hollow aluminium fixing. Polyester filler was also placed around the spinal vertebrae in the hollow cylindrical tool in order to hold the vertebrae firmly in place.

Experimental set-up

The compressive loading was applied in the normal direction to the artificial disc (with all sensors embedded) using a DARTEK®, Universal Testing Machine (computer controlled by Instron®, Bucks, UK). In this study the main objective was to evaluate the experimental set-up and confirm that all sensors produce meaningful outputs when the artificial disc (loading cell) between the two animal vertebrae was loaded. The load that was applied to the disc was from 0 to 1 kN, which was the maximum load we could apply without causing damage to the animal vertebrae or causing slippage of the artificial disc, from the two animal vertebrae holding the disc.

In this experiment the loading speed was 10 NPS (Newton per Second)

III. RESULTS

Fig. 2 shows the results of all sensors (strain gauges and piezoresistive) output versus time (seconds) when loaded from 0-1 kN with 10 NPS loading speed. Fig. 3 shows the results of all sensors output versus applied load when loaded from 0-1 kN with 10 NPS loading speed. In Fig. 2 the traces shown in red represent the row data where the black lines represent the best curve fitted to the raw data after they have been filtered. In Fig.3 the results from strain gauges 1 and 3 (st1, st3) produced some undesirable results (non-linear behaviour) and this was due to dislocation of the artificial disc during loading.
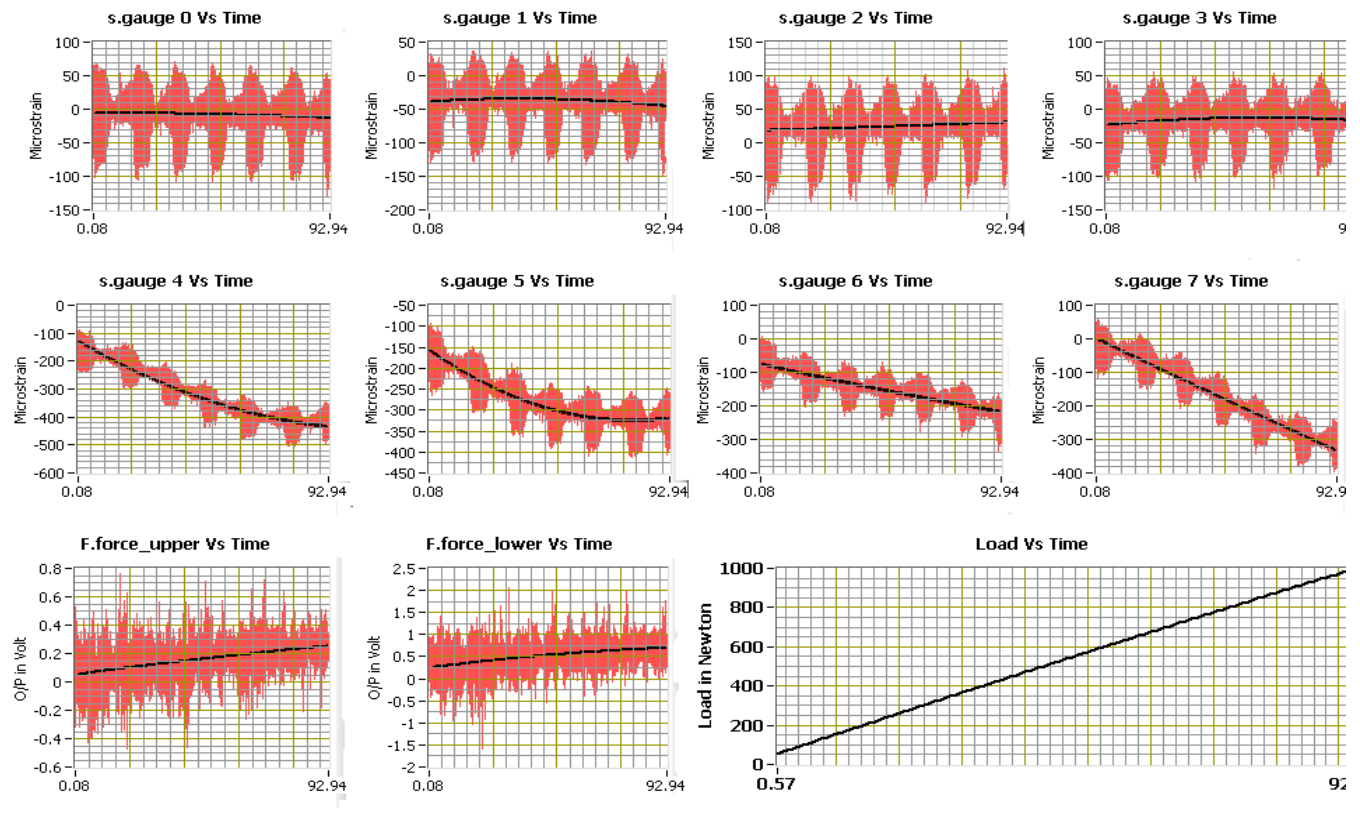
Fig 2: First two rows: Strain gauge (0-7) output (microstrain) vs Time (seconds); Third row: Output from Piezoresistive sensors (volts) vs Time (seconds). The first graph is from the Flexiforce sensor placed on the top of inlay material and the second graph is from the Flexiforce sensor placed on the bottom of the inlay material. The last graph on the third row represents the applied load vs time recorded from the loading machine directly.
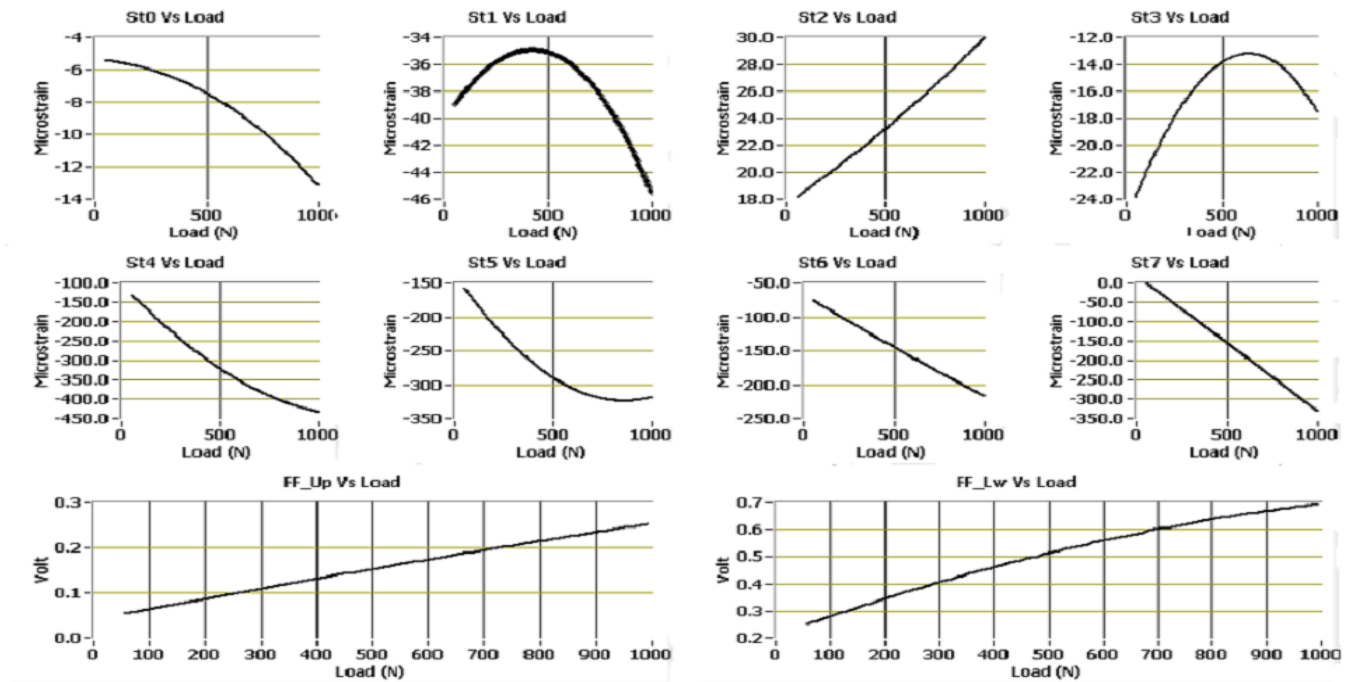

Fig 3: First two rows: Strain gauge (0-7) output (microstrain) vs Load (Newtons); Third row: Output from Piezoresistive sensors (volts) vs Load (Newtons).

I. CONCLUSION

An artificial spinal disc loading cell has been successfully developed and tested *in vitro* in this pilot study. The loading to the disc up to 1 kN generated adequate surface strain/stress on both disc plates. The outputs from all sensors used were very much linear which is very important for this application. The strain gauge proved to have better accuracy, hysteresis, repeatability and sensitivity when compared with the piezoresistive sensor. Fig.2 and Fig.3 show that all strain gauge output characteristics are similar in nature and that the upper plate exhibits more strain than the lower plate. It was also interesting to notice in these experiments that the outputs of the sensors demonstrate a degree of visco-elastic behaviour which was expected. Such behaviour was due to the properties of the viscoelastic material and also the animal vertebrae. One interesting fact observed here is for proper and stable working of spinal disk, it's proper and strong anchoring in the spine is very much crucial otherwise it cannot withstand the loading and start dislocating from it's original place. These preliminary results have paved the way for more detailed *in vitro* and *in vivo* spinal loading studies.

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