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Investigation of the *in-vitro* loading on an artificial spinal disk prosthesis

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Abstract. Spinal diseases imposes considerable burden to both patients and society. In recent years, much surgical efforts have been made in advancing the treatment of neck and back pain. Of particular prominence is the increasing clinical acceptance and use of intervertebral artificial disk prosthesis for the treatment of discogenic back pain. Despite this increased use of such disks, their *in-vivo* monitoring remains rudimentary. In an effort to develop an intelligent artificial spinal disk where the *in-vivo* loading of the spine can by studied for the first time an experimental set up has been created in order to initially study the *in-vitro* loading on an artificial disc prosthesis. Eight strain gauges and two piezoresistive sensors were used and placed suitably in the artificial disk prosthesis. The results from the *in-vitro* loading showed linear relationship between loading and the outputs from the sensors with good repeatability and less hysteresis.

1. Introduction

Low back pain is one of the most common diseases that can cause chronic disability and incapacity to work. Low back pain is highly correlated with mechanical loading of the spine (Stokes and Iatridis, 2004; Liuke et al., 2005). The anatomical part that has a main role in low back pain is the spinal disk as one of its main functions is to handle all the mechanical body stresses. The spinal disk's loss of ability to handle mechanical stresses is known as Disk Degenerative Disease (DDD). In order to correct for such a disease surgeons perform an operation where they replace the damaged spinal disc and replace it with an artificial disc prosthesis. Despite this increased use of such artificial disks, their *in vivo* monitoring remains rudimentary. Also, detailed knowledge of the *in vivo* loading and the viscoeleasticity of the human spine will enable artificial spinal disc manufacturers to design and develop artificial discs which behave very close to the human natural discs. In the past, many researchers have adopted different techniques to measure the *in vivo* loading of the spine. They have used techniques such as mathematical modelling, experiments on animals or by measuring the pressure inside the spinal disk (Nachemson and Elfstrom, 1970; Ledet et al., 2000; Ledet et al., 2005; McGill, 1992; Morlock and Schneider, 1998; Han et al.,1995; Kromodihardjo and Mital,1987; Schultz and Ashton-Miller, 1991; Dolan et al., 1998; Farfan, 1995; Rohlmann et al., 1997; Patwardhan et al., 1999). As of today there is no comprehensive *in vivo* loading data available. The *in vitro* loading data records show that the load on the lumbar spine vary from 29% to 5306% of the body weight (Cholewicki et al., 1991; Granhed et al., 1987; Leskinen et al., 1983; Nachemson et al., 1966). The measurement of *in vivo* loading and the detail investigation of the spine's behaviour under different conditions will open up many avenues for the solution of the low back pain. As mentioned above the acquisition of *in vivo* spinal loading data will assist in the design and development of more representative spinal implants especially spinal disk prosthesis. The artificial disk prosthesis is the only most suitable device to measure true *in vivo* spinal loading in humans. The aims and objectives of this work is to design and develop an intelligent artificial spinal disk prosthesis with an ultimate aim in acquiring a comprehensive understanding of the *in vivo* spinal loading in humans. As a preliminary of developing such an intelligent system, this paper describes the incorporation of sensors within a commercial artificial spinal disk prosthesis and the *in vitro* loading evaluation of such sensors.

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2. Material and methods

2.1 Design and development of the load cell

The design of the loading cell was based on a commercial Activ-L™ artificial spinal disk prosthesis (Aesculap, B-Braun, Germany). The artificial disc used was a L4/L5 (between lumbar 4 and 5 vertebrae), which is one of the most common used discs that receives replacement in humans. The artificial disk comprises of mainly three parts (see figure 1), the upper end-plate, the lower plate (both made-up of Cobalt-Chromium alloy) and the inlay material (made-up of visco-elastic ultra-high molecular weight Polyethylene).

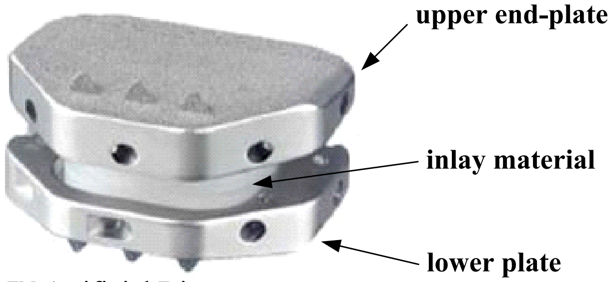

Figure 1: Aesculap Activ-L™ Artificial Disc

Two types of sensors were selected to be placed inside the disc. The sensors were strain gauges and piezoresistive (FlexiForce®, Tekscan Inc., MA, USA) sensors. Four strain gauges were placed according to manufacturer's instructions on the four corners of the upper plate (Figure 2a) and another four strain gauges were placed at the four corners of the lower plate (Figure 2b). The strain gauges in this experimental setup are intended to measure strain on the disc's end-plates and accordingly give an output in terms of changes in resistance proportional to the applied load/force. The FlexiForce® was placed on the top and at the bottom (interchangeably) of the inlay material (Figures 2c, 2d). The piezoresistive sensor is a load bearing sensor for measuring force and in this experimental setup will be measuring the compressive forces subjected to the disc in the normal direction. The positioning of the piezoresistive sensor above and below the inlay material will enable the investigation of the visco-elastic behaviour of the inlay material and hence of the disc. Therefore, all sensors together will allow the complete mapping of forces on the disc in different directions.

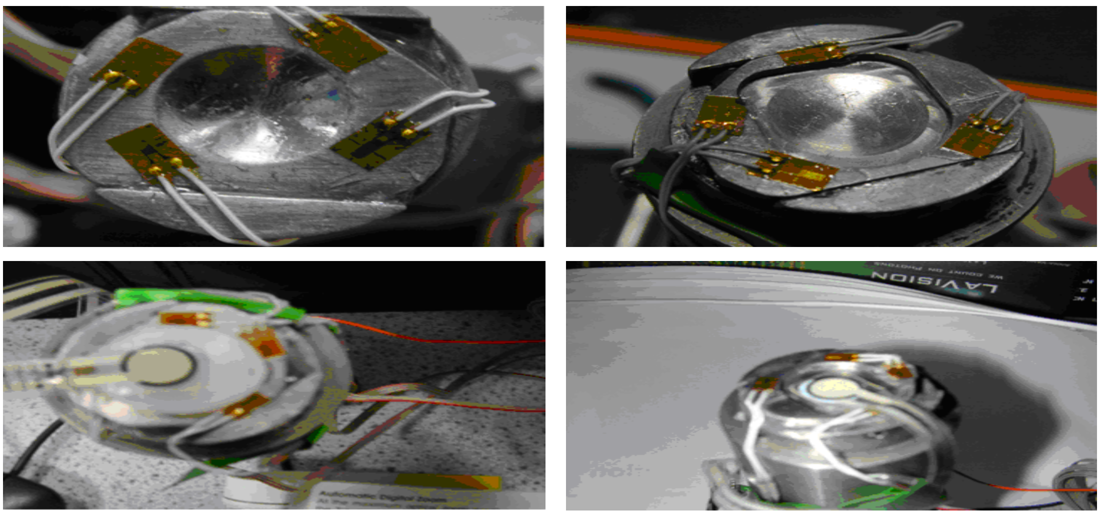

Figure 2a (top left): Superior plate with four strain gauges; Figure 2b (top right): Inferior plate with four strain gauges; Figure 2c (bottom left): FlexiForce® sensor on top of the inlay material; Figure 2d (bottom right): FlexiForce® sensor under the inlay material

2.2 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 (Figure 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.

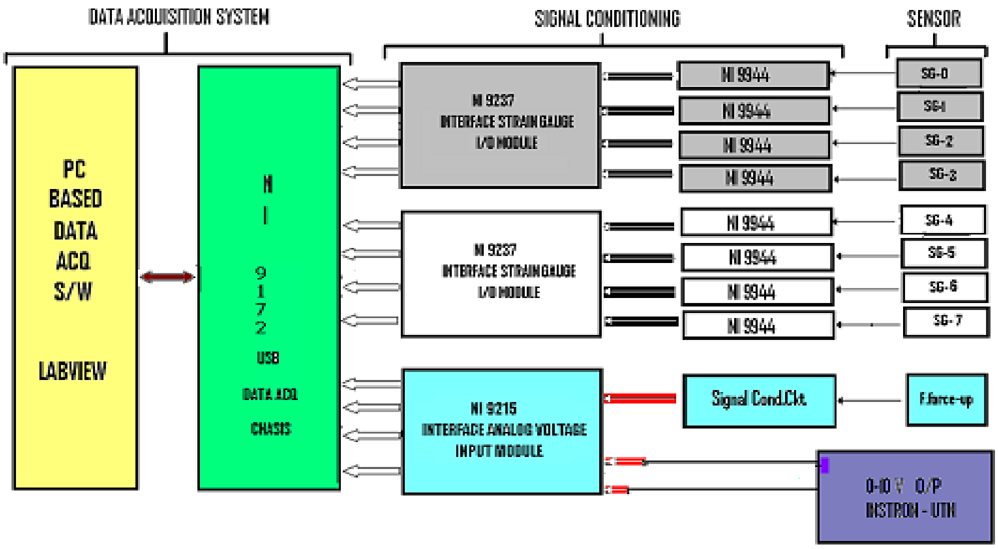

Figure 3: Block Diagram of Signal Conditioning and Data Acquisition system

Loading was applied to the artificial disc (with all sensors embedded) using a Universal Testing Machine (Instron, Bucks, UK). For this study only normal application of compressive load to the artificial disk prosthesis was performed. In this preliminary study the main objective was to evaluate all experimental set-up and confirm that all sensors produce meaningful outputs when loaded. The load that was applied to the disc was from 0 to 4 kN, which is the natural range of loads that the human spinal disc can be exposed (White and Panjabi, 1990).

3. Results and Analysis
Figure 4 shows a typical output of the S_7 – strain gauge installed on the inside of the periphery of the inferior disc plate. Figure 5 shows the mean value of the outputs of all eight strain gauges with respect to the applied load. Figures 6 and 7 show the FlexiForce® sensor's output in volt against applied load. In Figure 6 the FlexiForce® sensor is placed under the inlay material and in Figure 7 the FlexiForce® sensor is placed on top of the inlay material. In all experiments the loading speed when loading from 0 to 4 kN is 10 mm/min and the return speed from 4 to 0 kN is much higher than 10 mm/min. The same experiment has been repeated 20 times in order to find out the repeatability and consistency of the output. In completion of all repetitive measurements it was found that the repeatability is less than ±4.5% of full-scale. The actual peak loading shown in all Figures (4 to 7) is not exactly 4 kN and this was due to the inaccuracy of the machine to deliver the exact load as dialed in the system.

One interesting result is when the FlexiForce® sensor's location is changed (as seen in Figures 6 and 7) the hysteresis is reduced and the sensor's response time is also reduced significantly.

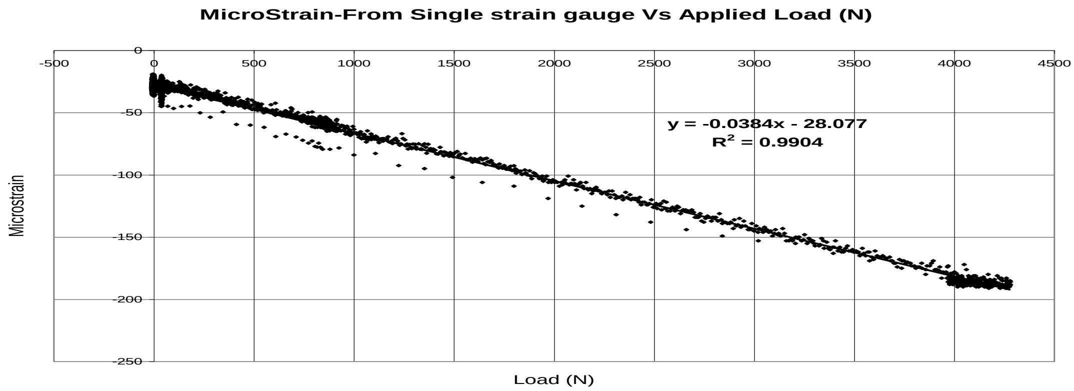

Figure 4: Strain Gauge-S_7 o/p when Loading from 0-4-0 kN with 10 mm/min Loading Speed

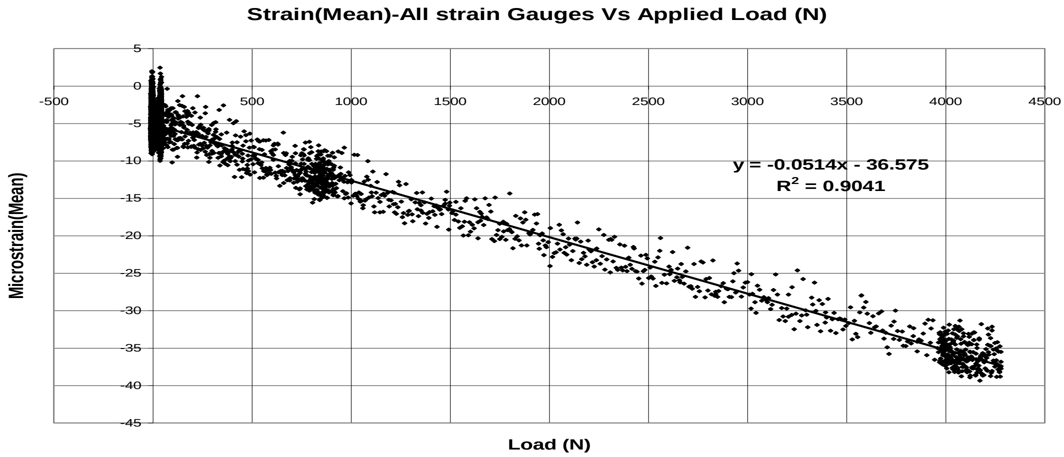

Figure 5: All Eight Strain Gauges (Mean Value) Output when Loading from 0-4-0 kN with 10 mm/min Loading Speed

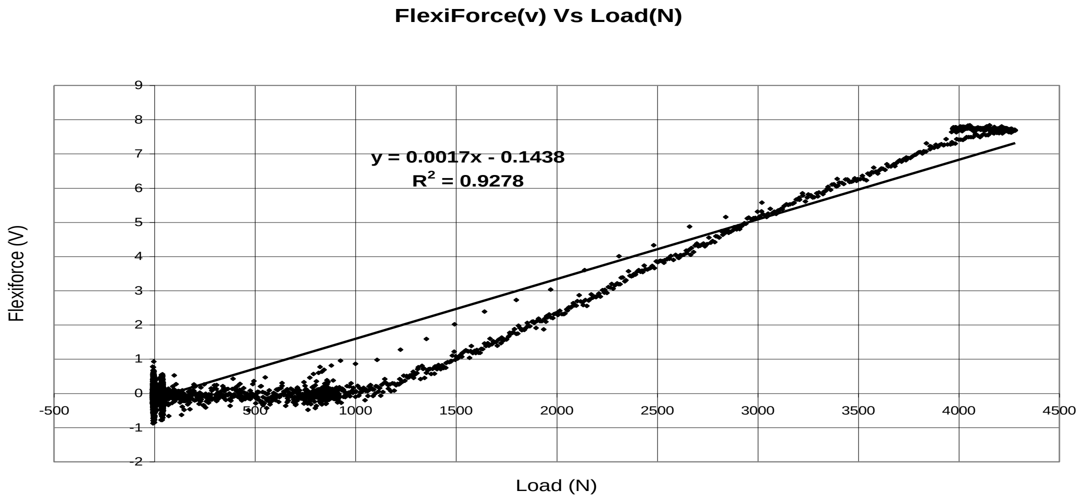

Figure 6: Piezoresistive Thin Layer-Flexi Force Sensor's output when Loading from 0-4-0 kN (FlexiForce® sensor is placed under the inlay material).

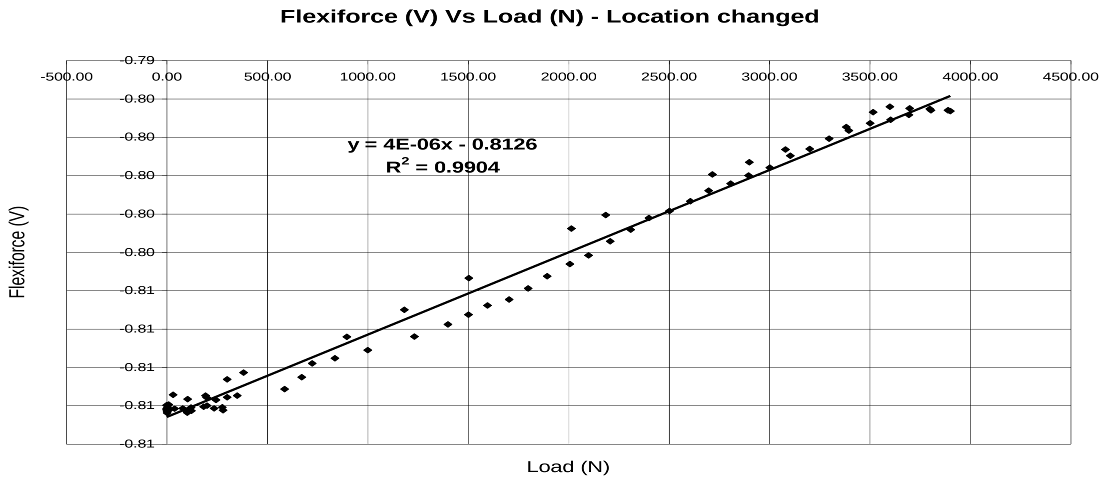

Figure 7: Flexi Force Sensor's output when loading from 0-4-0 kN (FlexiForce® sensor is placed on top of the inlay material).

4. 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 4 kN generated adequate surface strain/stress on both disc plates. The results show good repeatability of less than ±4.5% of the full scale, high precision and better accuracy with fewer tolerances. 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. However, the use of the piezoresistive sensor is essential as due to its very thin size (paper thin) can be comfortably placed on the top or at the bottom of the inlay material without altering any of the properties or functions of the material. One of the disadvantages of the piezoresistive sensor is its poor performance against the shear forces which are very common due to the movement of the disc plates with each other. Also, the piezoresistive sensor needs to be calibrated for every different loading speed of the disc. In summary, the strain gauges proved more reliable and suitable for this application. The results of this experiment have paved the way for more detailed *in vitro* and *in vivo* loading studies.

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