Time-dependent Biomechanical Behaviour of a Hydrogel-based Disc Arthroplasty

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Introduction: Degenerative disc disease (DDD) is one of the most common diseases resulting from inflammation and instability around the affected spinal disc. Total disc replacement (TDR) is one non-fusion technique emerging as potential solutions to this condition, which can be used to restore normal motion in the spine. However, several concerns in the current technologies are the inability to provide adequate shock absorption capability and time-dependent biomechanical behaviors. Therefore, the objective of this study is to develop a novel biomimetic TDR device that comprises two circular metal endplates and a ring-shaped hydrogel, which surrounded by a silicone shell sheath. Its concept was based on the hypothesis that the better the material and structure of the intervertebral disc (IVD) was mimicked, and the better its functionality was mimicked. The goals of this study were to evaluate the dynamic response of the hydrogel-based TDR device, and to demonstrate whether its axial deformation behavior is similar to that of a natural disc.

Methods:
Specimen Preparation
Six hydrogel-based TDR devices were prepared and used for creep (n=3), and dynamic response test (n=3). A custom-made clamping fixture was developed to ensure that the sheath was surrounded and firmly attached to the baseplates.

Creep-recovery Test
The creep-recovery test was performed with an MTS 858 universal testing system, fitted with a 1 kN load cell, and equipped with specially designed fixtures (Fig. 1). The time-response during loading period and unloaded recovery was quantified in this experiment. Three hydrogel-based TDR specimens were subjected to three creep-recovery cycles, consisting of 20 min compression at 85.5 N (about 0.1 MPa), and 40 minutes recovery at 5 N. The compression pressure was chosen to be 0.1 MPa, which is the physiologic swelling pressure of the IVD [1]. The last two creep curves were recorded and compared to the range of natural disc responses. The initial dimensions of the hydrogel-based TDR devices were 35.1±0.2 mm in diameter, and 10.2±0.25 mm in height. Force-displacement curves were recorded during the loading and recovery periods.

Dynamic Response Test
The hydrogel-based TDR devices were tested on the same system for the creep test. The TDR device was firmly gripped by the fixtures. An initial compressive force of 5N was applied and used to define a reference configuration. Tests were then subjected to a sinusoidal loading profile at three frequencies (0.1Hz, 1Hz, and 10Hz) in the range of 0.1-10 Hz. The compression level was 1.5 mm (37.5 % of the total average height of the ring-shaped hydrogel) and the amplitude was 0.5 mm. Preconditioning cycles were required in order to ensure reproducible measurements [2]: 10 cycles were sufficient for tests.
performed at 1 and 10 Hz, and 3 cycles were enough for tests performed at 0.1 Hz. The zero-displacement was defined for an un-deformed TDR device (10 mm in height). This sequence was repeated three times with 30 min recovery in between. The dynamic stiffness was calculated for each frequency from the averaged force-displacement curves.

**Results:**

**Creep-recovery Test**

Fig. 2 shows the average creep-recovery curve for the hydrogel-based TDR devices. Specimens were loaded with 85.5 N for 20 min. This load resulted in an immediate implant height reduction of a median 1.34 mm (range from 1.31 to 1.40 mm) as compared to the unloaded specimens. The following implant height measurements showed a typical time-dependent creep behavior. After the 20 min compression, the implant height decreased by 1.52 mm (min: 1.49 mm and max: 1.58 mm). This means the hydrogel-based devices lost 0.18 mm in height due to creeping during the 20 min compression. At the end of recovery (60 min), 78% of the creep displacement was recovered.

**Dynamic Response Test**

The dependency of $\Psi$ on the loading frequency is given in Fig. 3. There was a moderate effect of frequency on the specific damping capacity of the hydrogel-based TDR device. The specific damping capacity was no significantly different for frequencies between 0.1 and 1 Hz by $10.1 \pm 7.4$ at 0.1 Hz, and $14.8 \pm 6.0$ at 1 Hz. In addition, the specific damping capacity at 0.1 Hz was statistically lower compared to the value at 10 Hz ($p= 0.037$).

**Discussion:** Our results support the hypothesis that the hydrogel-based TDR device exhibited an axial creep and dynamic responses. The creep response of the TDR device was slower than a natural disc [3]. In our experiment, however, only one tenth of the physiological load (standing position) was applied during creep testing for 20 minutes on the TDR samples. The lower load may produce minor deformation and slower rates of creep. The specific damping capacity of the hydrogel-based TDR device was determined for a physiological large deformation of 15% and for frequencies ranging between 0.1 and 10 Hz. This TDR device consisting of a silicone membrane and two metal endplates allowed us to obtain a semi-confined condition for the swollen hydrogel samples. This mechanical condition is closer to the physiological environment of the nucleus pulposus. Vogel and Pioletti [4] measured the specific damping capacity to be ranging between 18% and 36% when the nucleus pulposus of the bovine coccygeal was tested in cyclic compression; the specific damping capacity increases as the loading frequency increases. The present study results were consistent with the work of Vogel and Pioletti in that the damping capacity tends to be lower at lower frequencies (0.1 and 1 Hz). Moreover, the specific damping capacity of the hydrogel-based TDR device fell within one standard deviation of the mean stiffness of the bovine coccygeal nucleus pulposus but was only about one quarter of that of the human disc.

**Significance:** The current study has developed a first-stage prototype of the hydrogel-based TDR device and incorporated mechanical tests to prove that the TDR device possessed visco-elastic behavior and shock absorption capacity close to the natural disc.
Figure 1 Experimental setting for the creep test.

Figure 2 Experimental creep-recovery curves for the hydrogel-based TDR devices. Note: SD: standard deviation.
Figure 3 The specific damping capacity $\Psi$ of the hydrogel-based TDR device is moderately dependent on the loading frequency.