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Viscoelastic properties of a spinal posterior dynamic stabilisation device

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Abstract

The purpose of this study was to quantify the frequency dependent viscoelastic properties of two types of spinal posterior dynamic stabilisation devices. In air at 37°C, the viscoelastic properties of six BDyn 1 level, six BDyn 2 level posterior dynamic stabilisation devices (S14 Implants, Pessac, France) and its elastomeric components (polycarbonate urethane and silicone) were measured using Dynamic Mechanical Analysis. The viscoelastic properties were measured over the frequency range 0.01 Hz to 30 Hz. The BDyn devices and its components were viscoelastic throughout the frequency range tested. The mean storage stiffness and mean loss stiffness of the BDyn 1 level device, BDyn 2 level device, silicone component and polycarbonate urethane component all presented a logarithmic relationship with respect to frequency. The storage stiffness of the BDyn 1 level device ranged from 95.56 N/mm to 119.29 N/mm, while the BDyn 2 level storage stiffness ranged from 39.41 N/mm to 42.82 N/mm. BDyn 1 level device and BDyn 2 level device loss stiffness ranged from 10.72 N/mm to 23.42 N/mm and 4.26 N/mm to 9.57 N/mm, respectively. No resonant frequencies were recorded for the devices or its components. The elastic property of BDyn 1 level device is influenced by the PCU and silicone components, in the physiological frequency range. The viscoelastic properties calculated in this study may be compared to spinal devices and spinal structures.

Keywords: BDyn Implant, Dynamic Mechanical Analysis, Frequency, Posterior Dynamic Stabilisation, Spine, Viscoelastic Properties

1. Introduction

Between 1998 and 2008, US hospital charges, for spinal fusion, increased from $4.3 billion to $33.9 billion (Rajaee et al., 2012). Spinal fusion is the gold standard surgical treatment of low back pain caused by degenerative disorders (Schwarzenbach et al., 2010; Sengupta, 2004; van den Broek et al., 2012b) even though many problems such as prolonged recuperation time, adjacent segment degeneration and pseudarthrosis are associated with it (Serhan et al., 2011). To alleviate these problems, non-fusion techniques have been suggested as an alternative (Serhan et al., 2011) and Posterior Dynamic Stabilisation (PDS) devices, in particular, are rapidly evolving for spine surgery (Khoueir et al., 2007; Serhan et al., 2011).

The BDyn device (S14 Implants, Pessac, France) is a PDS device that provides an alternative to fusion. This bilateral PDS device is designed to preserve intersegmental range of motion, reduce intradiscal pressure and alleviate loading of the facet joints. It can be used in the bridging of one segment level (vertebra-disc-vertebra) or multiple segment levels. The BDyn device consists of two elastomeric components, a mobile titanium alloy rod, a fixed titanium alloy rod, and it is fixed to the vertebrae by titanium alloy pedicle screws (figure 1). The interaction of the mobile rod and the elastomeric components allow partial three-dimensional spinal movement. An *in vitro* study of the BDyn device showed that the device was successful in limiting the range of motion of the L4-L5 segment following laminectomy (Guerin et al., 2011). The device has also been used in the treatment of degenerative lumbar spondylolisthesis (Gille et al., 2014).

Factors, such as age, whole body vibration, lifting, twisting, psychosocial factors, and low educational status have been associated with low back pain (Hoogendoorn et al., 2000; Hoy et al., 2010). Alongside heavy and frequent lifting, long term vibration exposure was stated as a high risk factor of low back pain (Magnusson et al., 1996). Numerous studies have evaluated the effect of vibration and quantified the viscoelastic properties of the spinal structures *in-vitro* (Gadd and Shepherd, 2011; Holmes and Hukins, 1996; Kasra et al., 1992; Zhou et al., 2014) and *in-vivo* (Panjabi et al., 1986;

Wilder et al., 1982). Others have investigated the dynamic stiffness of spinal implants (Benzel et al., 2011; Dahl et al., 2011; LeHuec et al., 2003), while Gloria et al. (2011) quantified the dynamic viscoelastic properties of a disc prosthesis.

Viscoelastic properties can be quantified by numerous testing methods which include creep, stress relaxation and Dynamic Mechanical Analysis (DMA). Unlike conventional creep and stress relaxation tests, DMA is a dynamic testing method used to determine the viscoelastic properties of a material or multi-component structure. For DMA, the viscoelastic properties are measured following the application of an oscillating force to a specimen and analysis of the out-of-phase displacement response (Menard, 2008). A viscoelastic structure can be characterised in terms of a storage and loss stiffness. The storage stiffness represents the elastic portion of the viscoelastic structure and it describes the ability of a structure to store energy, while the loss stiffness characterises the ability of the structure to dissipate energy through heat and internal motions (Menard, 2008).

In the seated position, the human lumbar spine has been reported to be resonant between 4–5 Hz (Panjabi et al., 1986; Wilder et al., 1982), thus, it is important to understand the frequency dependant behaviour of these viscoelastic spinal implants, its components, and assess how these implants behave at spinal resonant frequencies. The purpose of this study was to measure the viscoelastic properties of the BDyn PDS spinal implants and its elastomeric components using DMA. Comparisons were made between the elastomeric components and the devices to assess if a particular elastomeric component had an influence, or had a dominant effect, on the viscoelastic properties of the device.

2. Materials and Methods

Six BDyn 1 level, six BDyn 2 level PDS devices, six silicone and six polycarbonate urethane (PCU) components (figure 2) were obtained from S14 Implants (Pessac, France). All devices and elastomeric components were sterilised using ethylene oxide (EtO) (Steriservices, Bernay, France).

The viscoelastic properties of the BDyn devices and its components were measured using a Bose ElectroForce 3200 testing machine running Bose WinTest 4.1 DMA software (Bose Corporation, Electroforce Systems Group, Minnesota, USA). The DMA technique, machine and software have been previously used to quantify the storage and loss modulus or stiffness of numerous biological tissues (Barnes et al., 2015; Espino et al., 2014; Omari et al., 2015; Wilcox et al., 2014) and polymers (Mahomed et al., 2008). Custom-designed grips were used to clamp the titanium alloy rods and/or titanium alloy elastomer housing of the BDyn device and the devices were secured by twelve horizontal screws (figure 3).

For testing of the BDyn 1 level and BDyn 2 level devices, the titanium alloy mobile and fixed rods were gripped (figure 3a and 3b). The BDyn device is designed to work in both tension and compression, therefore, a sinusoidally varying load of between +20 N (tension) and -20 N (compression) was applied to the devices.

The silicone and PCU components were tested inside the titanium alloy housing, with the mobile titanium rod and the titanium housing were gripped for testing (figure 3c). The silicone and PCU components are only loaded in compression, therefore, a sinusoidally varying load of between -1 N and -20 N (compression) was applied to the elastomeric components. Testing the elastomeric components to this load range and inside the titanium alloy housing gave a direct comparison between the BDyn devices and the silicone and PCU components.

A custom chamber was constructed to test the devices and components at body temperature. All devices and components were tested in air at 37°C ± 1°C and the temperature was monitored throughout the test. The order of device and component testing was randomised by using the Excel Random Function (Redmond, Washington, USA).

The storage and loss stiffness were calculated for 21 different frequencies from 0.01 Hz to 30 Hz. This frequency range is greater than the ASTM F2346 stated physiological frequency range of 0.1 Hz

to 8 Hz (ASTM, 2011); the maximum tested frequency (30 Hz) is the same as the maximum recommended frequency for cyclical loading of components used in spinal surgical fixation (ASTM, 2014; Kurtz and Edidin, 2006). For each frequency (*f*), a Fourier analysis of the force and displacement waves was performed and the magnitude of the load (*F**), magnitude of the displacement (*d**), the phase lag (*δ*) and the frequency were quantified. The complex stiffness (*k**), storage stiffness (*k'*) and loss stiffness (*k''*) were then calculated using (Barnes et al., 2015; Fulcher et al., 2009):

$$k^* = \frac{F^*}{d^*} \qquad (1)$$

$$k' = k^* \cos \delta \qquad (2)$$

$$k'' = k^* \sin \delta \qquad (3)$$

All statistical analyses were performed using SigmaPlot 12.0 (SYSTAT, San Jose, CA, USA). The 95% confidence intervals were calculated (n = 6). Regression analyses were performed to evaluate the significance of the curve fit. Statistical results with $p < 0.05$ were considered significant. Kruskal-Wallis one way analysis of variance (ANOVA) on ranks was performed to evaluate the differences among the BDyn devices and components. If the Kruskal-Wallis ANOVA showed significant differences ($p < 0.05$), the multiple comparison Tukey test was used to evaluate significant differences ($p < 0.05$).

3. Results

The frequency dependent trends of the storage and loss stiffness of the BDyn 1 level device, BDyn 2 level device, the silicone component and the PCU component are shown in figures 4 and 5, respectively. The BDyn devices and its components were viscoelastic throughout the frequency range tested. Also, the storage stiffness was larger than the loss stiffness for all frequencies tested.

The storage stiffness (equation 4) and loss stiffness (equation 5) of the BDyn 1 level device, BDyn 2 level device, silicone component and PCU component were defined by a logarithmic fit. The mean storage stiffness and loss stiffness logarithmic trends of the devices and components were all found to be significant (p < 0.05).

$$k' = A \ln(f) + B \qquad \text{for} \quad 0.01 \leq f \leq 30 \qquad (4)$$

$$k'' = C \ln(f) + D \qquad \text{for} \quad 0.01 \leq f \leq 30 \qquad (5)$$

The coefficients (*A*, *B*, *C*, *D*), which define the storage and loss stiffness logarithmic trends for individual specimens, are provided in table 1.

The storage stiffness of the individual BDyn 1 level device, silicone component and PCU component specimens also all followed a logarithmic trend which was found to be significant (p < 0.05; table 1). Two, out of the six, BDyn 2 level devices did not follow a significant logarithmic trend. The range of the BDyn 2 level device mean storage stiffness was between 39.41 N/mm to 42.82 N/mm for the 0.01 Hz – 30 Hz frequency range (figure 4); this differed to the BDyn 1 level device storage stiffness range (95.56 N/mm to 119.29 N/mm). Due to this 8% change in the BDyn 2 level storage stiffness range, the mean and standard deviation was analysed individually for all six BDyn 2 level devices (see table 2).

The loss stiffness of the BDyn 1 level device ranged from 10.72 N/mm to 23.42 N/mm while the BDyn 2 level device ranged from 4.26 N/mm to 9.57 N/mm. Unlike the storage stiffness of individual specimens, the loss stiffness of all the individual devices and components followed a significant logarithmic trend (p < 0.05, see table 1).

The Kruskal-Wallis ANOVA on ranks detected significant differences (p ≤ 0.001) for the storage and loss stiffness, for all tested frequencies. The multiple comparison test results are shown in table 3. The frequencies stated in this table indicate that the difference between the components and devices were significantly different (p < 0.05).

4. Discussion

This study has quantified the frequency dependent viscoelastic properties of a posterior dynamic stabilisation (PDS) spinal implant. The BDyn devices and its components were viscoelastic throughout the frequency range tested. As shown in figure 4 and 5, the BDyn 1 level device storage stiffness (95.56 N/mm to 119.29 N/mm) and the loss stiffness (10.72 N/mm to 23.42 N/mm) were less than the storage stiffness (541.7 N/mm to 957 N/mm) and loss stiffness (approximately 62 N/mm to 200 N/mm) of a multi-structural intervertebral disc (IVD) replacement device (Gloria et al., 2011). With less than 10% of the net compressive load transferred through the posterior elements (Kurtz and Edidin, 2006), the differences between the BDyn PDS implant and IVD replacement storage stiffness and loss stiffness ranges were expected. Furthermore, Gloria et al. (2011) applied 40 N ± 10 N sinusoidal load through a frequency range of 0.01 Hz to 30 Hz.

The BDyn 1 level dynamic stiffness ranged from 96.16 N/mm (0.01 Hz) to 120.02 N/mm (30 Hz) while the BDyn 2 level device ranged from 39.66 N/mm (0.01 Hz) to 42.44 N/mm (30 Hz). These values are comparable to the dynamic stiffness of a polyurethane nucleus device (216.24 N/mm–285.47 N/mm; 0.25 Hz–20 Hz), but an order of magnitude less stiff than polyethylene and titanium-alloy, cervical disc replacements (Dahl et al., 2011). The dynamic stiffness for the AxioMed Freedom Lumbar device, tested between 1200 N to 2000 N at 3 Hz by Benzel et al. (2011), varied between 1.55 − 3.48 kN/mm. Rischke et al. (2011) stated that a previous study of the AxioMed Freedom device showed that the response of the polymer core did not change between 1 Hz and 3 Hz, but at 4 Hz, or higher, the core temperature increased and the polymer response decreased. Van der Broek et al. (2012a) demonstrated that the Biomimetic Artificial Intervertebral Disc axial dynamic stiffness, for 0.01 Hz to 10 Hz range, was between 3.0 kN/mm to 4.7 kN/mm; this range was within the standard deviation range of the natural intervertebral disc tested by Smeathers and Joanes (1988). Alongside the variation in material properties, the differences between the dynamic stiffness of the intervertebral

disc replacement studies (Benzel et al., 2011; Dahl et al., 2011; van den Broek et al., 2012a) and the present study are also a result of testing differences.

Another issue with comparison of dynamic stiffness stated from different studies is that various authors calculate the dynamic stiffness by using different techniques. Dahl et al. (2011) determined the dynamic stiffness by calculating the best-fit slope of the force-displacement curve while, Benzel et al. (2011) calculated the force/displacement for the first 1,000 cycles, at 3 Hz. This present study calculated the viscoelastic properties by following ISO 6721 (ISO, 2011). As the dynamic stiffness can be affected by load (Kasra et al., 1992), any comparison between different methods and studies must be compared with caution. To characterise the dynamic viscoelastic properties (storage and loss stiffness) of a structure, one must acquire the dynamic stiffness ($k*$) and the phase angle (δ) between the force and displacement sinusoidal cycle. If δ is not reported with $k*$, then the dynamic viscoelastic behaviour of a structure cannot be ascertained.

Some studies (Dahl et al., 2011; LeHuec et al., 2003) have examined the damping effect of disc replacement spinal implants. Both Dahl et al. (2011) and LeHuec et al. (2003) calculated the transmissibility damping ratio (ζ), but not the loss factor (η), to determine the viscous dissipation of disc replacement implants. As the BDyn devices possess multiple degrees of freedom and are non-linear in behaviour, an approximate comparison to ζ was not performed as the damping ratio is defined on the grounds of the linear single degree of freedom viscous model (Carfagni et al., 1998). Even though an approximate η can be determined from ζ, to fully characterise the viscoelastic properties of a structure or a material, both the storage and loss stiffness (or modulus for a material) should be quantified.

The mean storage stiffness trends of the BDyn devices and its components all followed a logarithmic increasing trend with frequency. This is deemed a positive result for the BDyn devices and its components as the elastic (storage) property, of various spinal structures, has been widely documented to increase as the frequency increases (Gadd and Shepherd, 2011; Holmes and Hukins,

1996; Izambert et al., 2003; Zhou et al., 2014). Discrete Fourier Transforms of load-relaxation curves demonstrated that the storage modulus, of the human lumbar spine, increased as the frequency increased (Holmes and Hukins, 1996). Between 0.01 Hz to 10 Hz, Smeathers and Joanes (1988) reported that the stiffness of the intervertebral disc increased as the loading rate increased; Izambert et al. (2003) also reported that the axial dynamic stiffness, of the intervertebral disc, increased between 10 Hz − 30 Hz. By performing DMA on intact and denucleated intervertebral discs, Gadd and Shepherd (2011) reported an increasing logarithmic trend for the storage stiffness for intact and denucleated IVD, while Zhou et al. (2014) stated a significantly increasing storage moduli of intact, denucleated and hydrogel injected porcine intervertebral disc.

The small standard deviation values (table 2), the minimal logarithmic slope coefficients (coefficient A; table 1) and the varied R^2 values (table 1) questions the storage stiffness logarithmic trends of the BDyn 2 level device. This minimal increase in storage stiffness with frequency, for the BDyn 2 level device, was unexpected as the elastomer components of the device exhibit a logarithmically increasing trend. It is speculated that the minimal storage stiffness increase of the BDyn 2 level device is due to the testing configuration. With the BDyn 2 level device, a mobile rod is located between four elastomeric components. The DMA testing configuration stated here is not similar to the *in vivo* scenario where the mobile rod is secured to the vertebra. By securing the mobile rod to the vertebra, an applied load, to the device, may not displace the two polymer systems equally; hence, the difference in displacement will affect the dynamic stiffness (k^*) and in turn, the storage (k') and loss (k'') stiffness.

The loss stiffness trends, of all of the devices and components, followed a logarithmically increasing trend as the frequency increased; this result is different to the studies of Holmes and Hukins (1996) and Gadd and Shepherd (2011). Holmes and Hukins (1996) reported that the loss modulus decreased as the frequency increased. The authors also showed that the lumbar specimens did not exhibit shock absorbing properties, in pure compression, as there was no sharp peak detected in the

loss modulus for the frequency range (Holmes and Hukins, 1996). This result is similar to Gadd and Shepherd (2011) and Zhou et al. (2014) as they also did not find a peak, in the loss modulus, for a nucleated or de-nucleated ovine and porcine IVD, respectively.

Other studies, which examined *in vitro* human intervertebral disc specimens without the posterior elements, have recorded resonant frequencies between 8 Hz – 10.4 Hz (Izambert et al., 2003), 22.2 Hz – 40.9 Hz (Marini et al., 2015) and 23.5 Hz – 33 Hz (Kasra et al., 1992). The response differences between these studies could be due to the different applied preloads and amplitude of the oscillation (Marini et al., 2015) and the method of testing. In the seated position, Panjabi et al. (1986) recorded the average *in vivo* lumbar vertebrae resonant frequency at 4.4 Hz for the axial direction. This resonant frequency, for the seated position, is similar to the frequencies at which Wilder et al. (1982) recorded the greatest transmissibility in the male and female lumbar spine of 4.9 Hz and 4.75 Hz, respectively. Wilder et al. (1982) also recorded two further resonant frequencies at 9.5 Hz and 12.7 Hz for both genders. Resonant frequencies, of the lumbar spine, may vary with dynamic rocking of the pelvis, posture and bending of the lumbar spine in response to vibration (Sandover, 1988). Also, Sandover and Dupuis (1987) demonstrated coupling of bending between adjacent vertebrae, at a resonant frequency of 4 Hz. There were no resonant frequencies recorded for the frequency range (0.01 Hz – 30 Hz) tested, in this study, as resonant frequencies would have been identified by a sharp increase in the loss stiffness (Holmes and Hukins, 1996). This is a beneficial finding as the device, and its components, do not resonate at *in vivo* spinal resonating frequencies. Any resonance, of the device, at any frequency is a limitation of the device as the resonance may damage the device and in a worst case scenario, the device may fail.

In relation to repetitive cycling of the BDyn device, a paper in a conference proceeding stated no deterioration to the BDyn implant and no visible damage to the polymer elements after 5 million cycles (Monède-Hocquard et al., 2013). However, there was some evidence of changes in the dimensions of the components (Monède-Hocquard et al., 2013). As long term failure of polymers is

associated with environmental stress cracking and ageing mechanisms (Teoh, 2000), further study of the effects of ageing on the BDyn device would be warranted.

The BDyn device is designed to allow partial movement along the anatomical planes. This study quantified the viscoelastic properties of the device and its components uniaxially. Rotation of the moveable rod, around an anatomical plane, may affect the response of the out-of-phase displacement to an applied force and hence, affect the viscoelastic properties. Load has been shown to affect the mechanical properties of an elastomeric total disc replacement (Mahomed et al., 2012) while an increase of preload has been shown to significantly increase the dynamic stiffness of the intervertebral disc (Kasra et al., 1992). A limitation of this study is that physiological loads were not used to quantify the viscoelastic properties. However, these limitations do not alter the conclusions of this study because the sinusoidal applied loads ensured a direct comparison between the device and its components. This gave an understanding of how the individual components influence viscoelastic properties of the device.

5. Conclusion

The viscoelastic properties of the posterior stabilisation BDyn device and its components are frequency dependent. As the frequency increased, the storage stiffness and the loss stiffness increased. The storage stiffness was constantly higher than the loss stiffness and no resonant frequencies were reported. The elastic property of BDyn 1 level device is influenced by the PCU and silicone components, in the physiological frequency range.

6. Acknowledgments

7. Conflict of Interest

8. References

ASTM, 2014. ASTM F2193: Standard Specifications and Test Methods for Metallic Angled Orthopedic Fracture Fixation Devices. doi:10.1520/F0384-12

ASTM, 2011. ASTM F2346-05: Standard Test Methods for Static and Dynamic Characterization of Spinal Artificial Discs. doi:10.1520/F2346-05R11

Barnes, S.C., Shepherd, D.E.T., Espino, D.M., Bryan, R.T., 2015. Frequency dependent viscoelastic properties of porcine bladder. J. Mech. Behav. Biomed. Mater. 42, 168–176. doi:10.1016/j.jmbbm.2014.11.017.

Benzel, E.C., Lieberman, I.H., Ross, E.R., Linovitz, R.J., Kuras, J., Zimmers, K.B., 2011. Mechanical characterisation of a viscoelastic disc for lumbar total disc replacement. J. Med. Device. 5, 011005, 1–7. doi:10.1115/1.4003536

Carfagni, M., Lenzi, E., Pierini, M., 1998. The loss factor as a measure of mechanical damping, in: 1998 IMAC XVI - 16th International Modal Analysis Conference. pp. 580–584.

Dahl, M.C., Jacobsen, S., Metcalf, N., Sasso, R., Ching, R.P., 2011. A comparison of the shock-absorbing properties of cervical disc prosthesis bearing materials. SAS J. 5, 48–54. doi:10.1016/j.esas.2011.01.002

Espino, D.M., Shepherd, D.E.T., Hukins, D.W.L., 2014. Viscoelastic properties of bovine knee joint articular cartilage: dependency on thickness and loading frequency. BMC Musculoskelet. Disord. 15, 205–213. doi:10.1186/1471-2474-15-205

Fulcher, G.R., Hukins, D.W.L., Shepherd, D.E.T., 2009. Viscoelastic properties of bovine articular cartilage attached to subchondral bone at high frequencies. BMC Musculoskelet. Disord. 10, 61–67. doi:10.1186/1471-2474-10-61

Gadd, M.J., Shepherd, D.E.T., 2011. Viscoelastic properties of the intervertebral disc and the effect of

nucleus pulposus removal. Proc. Inst. Mech. Eng. Part H J. Eng. Med. 255, 335–341. doi:10.1177/2041303310393410

Gille, O., Challier, V., Parent, H., Cavagna, R., Poignard, A., Faline, A., Fuentes, S., Ricart, O., Ferrero, E., Ould Slimane, M., 2014. Degenerative lumbar spondylolisthesis. Cohort of 670 patients, and proposal of a new classificatio. Orthop. Traumatol. Surg. Res. 100, 311–315. doi:10.1016/j.otsr.2014.07.006

Gloria, A., De Santis, R., Ambrosio, L., Causa, F., Tanner, K.E., 2011. A Multi-component Fiber-reinforced PHEMA-based Hydrogel/HAPEXTM Device for Customized Intervertebral Disc Prosthesis. J. Biomater. Appl. 25, 795–810. doi:10.1177/0885328209360933

Guerin, P., Gille, O., Persohn, S., Campana, S., Vital, J.M., Skalli, W., 2011. Effect of new dynamic stabilization system on the segmental motion and intradiscal pressure: An in vitro biomechanical study, in: ORS 2011 Annual Meeting.

Holmes, A.D., Hukins, D.W.L., 1996. Analysis of load-relaxation in compressed segments of lumbar spine. J. Med. Eng. Phys. 18, 99–104. doi:10.1016/1350-4533(95)00047-X

Hoogendoorn, W.E., van Poppel, M.N., Bongers, P.M., Koes, B.W., Bouter, L.M., 2000. Systematic review of psychosocial factors at work and private life as risk factors for back pain. Spine (Phila. Pa. 1976). 25, 2114–2125. doi:10.1097/00007632-200008150-00017

Hoy, D., Brooks, P., Blyth, F., Buchbinder, R., 2010. The Epidemiology of low back pain. Best Pract. Res. Clin. Rheumatol. 24, 769–781. doi:10.1016/j.berh.2010.10.002

ISO, 2011. BS EN ISO 6721: Plastics — Determination of dynamic mechanical properties.

Izambert, O., Mitton, D., Thourot, M., Lavaste, F., 2003. Dynamic stiffness and damping of human intervertebral disc using axial oscillatory displacement under a free mass system. Eur. Spine J. 12, 562–566. doi:10.1007/s00586-003-0569-0

Kasra, M., Shirazi-Adl, A., G, D., 1992. Dynamics of Human Lumbar Intervertebral Joints: Experimental and Finite-Element Investigations. Spine (Phila Pa 1976) 17, 93–102.

Khoueir, P., Kim, K.A., Wang, M.Y., 2007. Classification of posterior dynamic stabilization devices. Neurosurg. Focus 22, E3 , 1–8. doi:10.3171/foc.2007.22.1.3

Kurtz, S.M., Edidin, A.A., 2006. Spine Technology Handbook, 1st ed. Elservier Academic Press, USA.

LeHuec, J.-C., Kiaer, T., Freisem, T., Mathews, T., Liu, M., Eisermann, L., 2003. Shock absorption in lumbar disc prosthesis: a preliminary mechanical study. J. Spinal Disord. Tech. 16, 346–351.

Magnusson, M.L., Pope, M.H., Wilder, D.G., Areskoug, B., 1996. Are occupational drivers at an increased risk for developing musculoskeletal disorders? Spine (Phila. Pa. 1976). 21, 710–717. doi:10.1097/00007632-199603150-00010

Mahomed, A., Chidi, N.M., Hukins, D.W.L., Kukureka, S.N., Shepherd, D.E.T., 2008. Frequency dependence of viscoelastic properties of medical grade silicones. J. Biomed. Mater. Res. B. Appl. Biomater. 89, 210–216. doi:10.1002/jbm.b.31208

Mahomed, A., Moghadas, P.M., Shepherd, D.E.T., Hukins, D.W.L., Roome, A., Johnson, S., 2012. Effect of Axial Load on the Flexural Properties of an Elastomeric Total Disc Replacement. Spine J. 37, 908–912. doi:10.1097/BRS.0b013e31824da3ba

Marini, G., Huber, G., Püschel, K., Ferguson, S.J., 2015. Nonlinear dynamics of the human lumbar intervertebral disc. J. Biomech. 48, 479–488. doi:10.1016/j.jbiomech.2014.12.006

Menard, K.P., 2008. Dynamic Mechanical Analysis: A Practical Introduction, 2nd ed. CRC press, Taylor & Francis Group, Boca Raton, Florida.

Monède-Hocquard, L., Mesnard, M., Ramos, A., Gille, O., 2013. Optimization of a dynamic spinal implant: Selection of a polymer material, in: XXIV Congress of the International Society of Biomechanics. Brazil, pp. 3–5.

Omari, E. a, Varghese, T., Kliewer, M. a, Harter, J., Hartenbach, E.M., 2015. Dynamic and quasi-static mechanical testing for characterization of the viscoelastic properties of human uterine tissue. J. Biomech. 48, 1730–1736. doi:10.1016/j.jbiomech.2015.05.013

Panjabi, M.M., Andersson, G.B., Jorneus, L., Hult, E., Mattsson, L., 1986. In vivo measurements of spinal column vibrations. J. Bone Jt. Surg. 68, 695–702.

Rajaee, S.S., Bae, H.W., Kanim, L.E. a., Delamarter, R.B., 2012. Spinal Fusion in the United States. Spine (Phila. Pa. 1976). 37, 67–76. doi:10.1097/BRS.0b013e31820cccfb

Rischke, B., Ross, R.S., Jollenbeck, B.A., Zimmers, K.B., Defibaugh, N.D., 2011. Preclinical and clinical experience with a viscoelastic total disc replacement. SAS J. 5, 97–107. doi:10.1016/j.esas.2011.08.001

Sandover, J., 1988. Behaviour of the spine under shock and vibration: a review. Clin. Biomech. 3, 249–256. doi:10.1016/0268-0033(88)90045-9

Sandover, J., Dupuis, H., 1987. A reanalysis of spinal motion during vibration. Ergonomics 30, 975–985.

Schwarzenbach, O., Rohrbach, N., Berlemann, U., 2010. Segment-by-segment stabilization for degenerative disc disease: A hybrid technique. Eur. Spine J. 19, 1010–1020. doi:10.1007/s00586-010-1282-4

Sengupta, D.K., 2004. Dynamic stabilization devices in the treatment of low back pain. Orthop. Clin. North Am. 35, 43–56. doi:10.1016/S0030-5898(03)00087-7

Serhan, H., Mhatre, D., Defossez, H., Bono, C.M., 2011. Motion-preserving technologies for degenerative lumbar spine: The past, present and future horizons. SAS J. 5, 75–89. doi:10.1016/j.esas.2011.05.001

Smeathers, J.E., Joanes, D.N., 1988. Dynamic compressive properties of human lumbar intervertebral joints: a comparison between fresh and thawed specimens. J. Biomech. 21, 425–433. doi:10.1016/0021-9290(88)90148-0

Teoh, S.H., 2000. Fatigue of biomaterials: a review. Int. J. Fatigue 22, 825–837.

van den Broek, P.R., Huyghe, J.M., Ito, K., 2012a. Biomechanical Behavior of a Biomimetic Artificial Intervertebral Disc. Spine (Phila. Pa. 1976). 37, E367–E373. doi:10.1097/BRS.0b013e3182326305

van den Broek, P.R., Huyghe, J.M., Wilson, W., Ito, K., 2012b. Design of next generation total disk replacements. J. Biomech. 45, 134–40. doi:10.1016/j.jbiomech.2011.09.017

Wilcox, A.G., Buchan, K.G., Espino, D.M., 2014. Frequency and diameter dependent viscoelastic properties of mitral valve chordae tendineae. J. Mech. Behav. Biomed. Mater. 30, 186–195. doi:10.1016/j.jmbbm.2013.11.013

Wilder, D.G., Woodworth, B.B., Frymoyer, J.W., Pope, M.H., 1982. Vibration and the human spine. Spine (Phila. Pa. 1976). 7, 243–254.

Zhou, Z., Gao, M., Wei, F., Liang, J., Deng, W., Dai, X., Zhou, G., Zou, X., 2014. Shock absorbing function study on denucleated intervertebral disc with or without hydrogel injection through static and dynamic biomechanical tests in vitro. Biomed Res. Int. Vol: 2014, 461724, 7 Pages. doi:10.1155/2014/461724
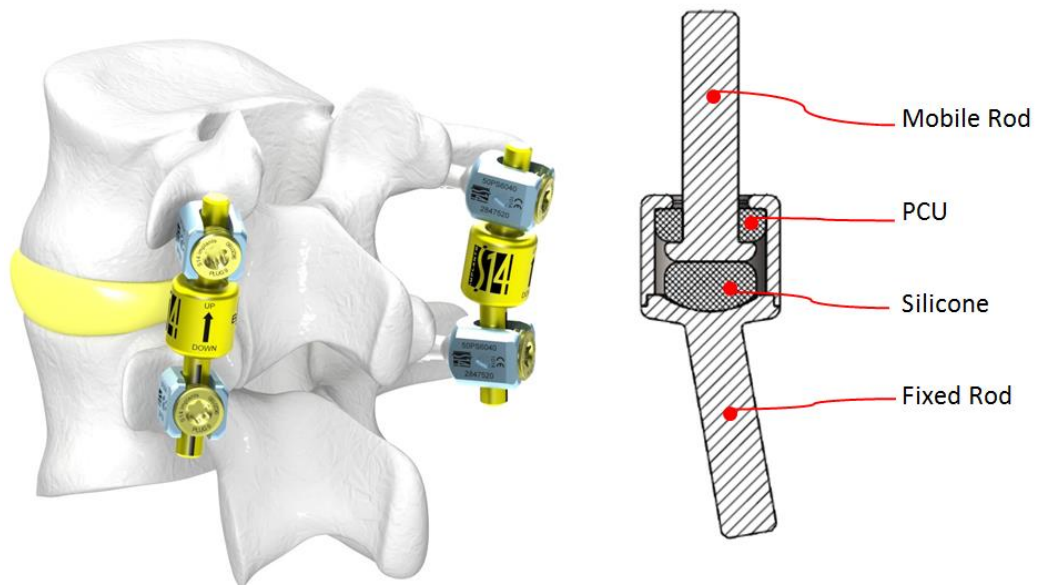
Figures

Figure 1: BDyn 1 level fixed to the vertebrae (Left) [Reproduced with kind permission from S14 Implants, Pessac, France. © S14 Implants] and cross sectional view of the BDyn device (Right). The mobile rod, fixed rod, polycarbonate urethane (PCU) and silicone component are highlighted.
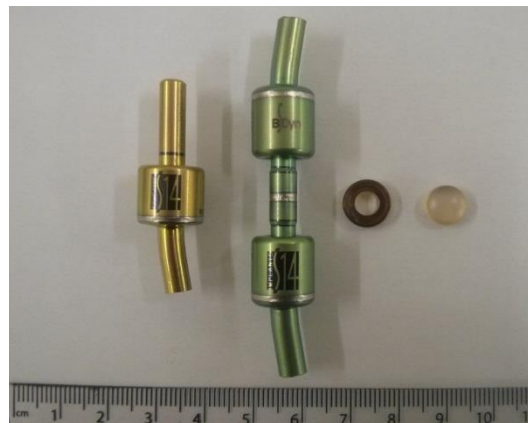
Figure 2: From left to right; BDyn 1 level (BDyn1), BDyn 2 level (BDyn 2), polycarbonate urethane (PCU) component and silicone component

(a)   (b)   (c)
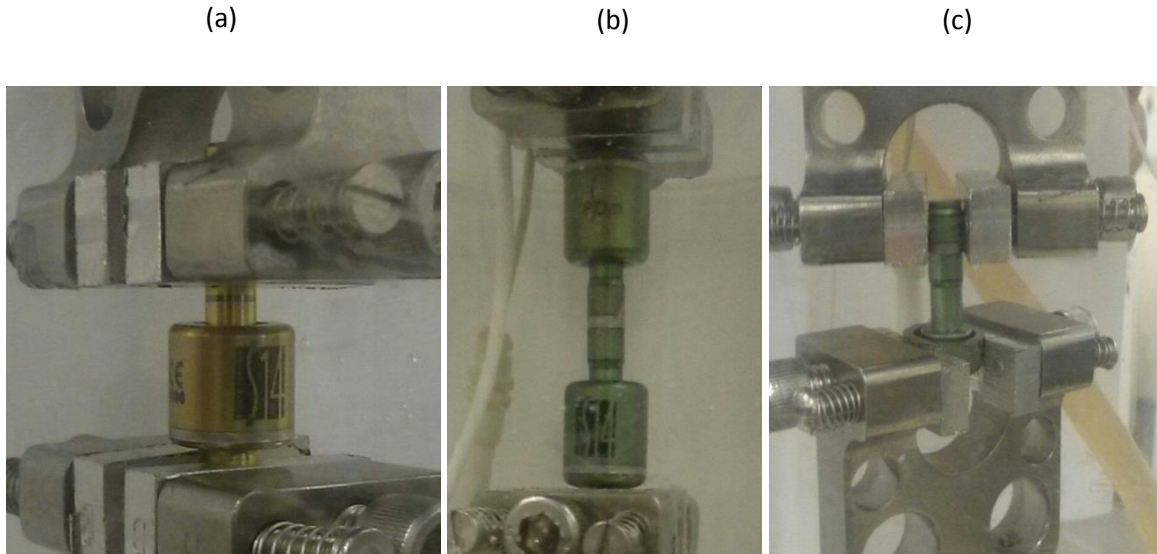
Figure 3: Testing of (a) BDyn 1 level, (b) BDyn 2 level and (c) one of the elastomeric components

Figure 4: Storage stiffness (k') against ln(frequency) for the 1 level BDyn device (BDyn 1), 2 level BDyn device (BDyn 2), silicone component (Silicone) and polycarbonate urethane (PCU) component (mean ± 95% confidence intervals)

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Figure 5: Loss stiffness (k'') against ln(frequency) for the 1 level BDyn device (BDyn 1), 2 level BDyn device (BDyn 2), silicone component (Silicone) and polycarbonate urethane (PCU) component (mean ± 95% confidence intervals)

Tables

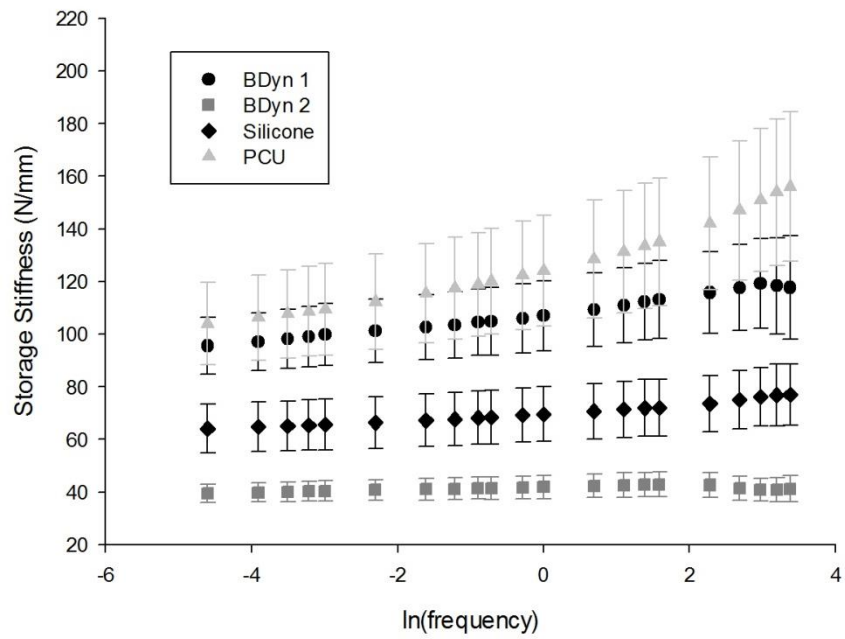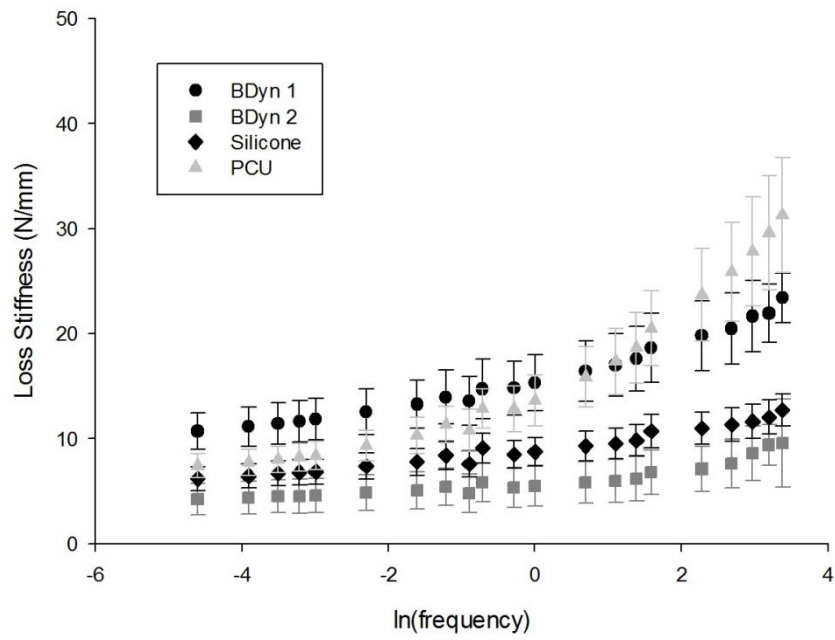**Table 1: Storage stiffness (equation 4) and loss stiffness (equation 5) regression analyses of the BDyn devices and its components. Cofficients for the individual specimens' storage and loss trends are provided.**

Specimen ID	k' = Aln(f)+B				k'' = Cln(f)+D			
	A	B	r²	P Value	C	D	r²	P Value
BDyn 1 - 1	2.86	104.69	0.98	0.0001	1.51	16.69	0.96	0.0001
BDyn 1 - 2	3.03	112.04	0.99	0.0001	1.57	16.60	0.95	0.0001
BDyn 1 - 3	4.11	125.09	0.97	0.0001	1.59	18.16	0.97	0.0001
BDyn 1 - 4	2.56	96.94	0.98	0.0001	1.37	15.65	0.94	0.0001
BDyn 1 - 5	3.85	119.89	0.97	0.0001	1.82	18.69	0.96	0.0001
BDyn 1 - 6	1.68	90.40	0.93	0.0001	1.28	11.68	0.85	0.0001
BDyn 1 - Mean	**3.02**	**108.17**	**0.98**	**0.0001**	**1.52**	**16.25**	**0.95**	**0.0001**
PCU - 1	8.70	158.01	0.96	0.0001	3.76	20.66	0.90	0.0001
PCU - 2	7.70	146.64	0.96	0.0001	3.38	18.86	0.89	0.0001
PCU - 3	5.30	110.92	0.96	0.0001	2.43	13.83	0.88	0.0001
PCU - 4	6.44	129.34	0.95	0.0001	2.93	16.86	0.90	0.0001
PCU - 5	5.53	115.06	0.93	0.0001	2.73	15.89	0.90	0.0001
PCU - 6	4.81	106.65	0.95	0.0001	2.40	13.66	0.90	0.0001
PCU - Mean	**6.41**	**127.77**	**0.95**	**0.0001**	**2.94**	**16.63**	**0.89**	**0.0001**
Silicone - 1	2.02	84.11	0.97	0.0001	0.84	10.76	0.95	0.0001
Silicone - 2	1.76	78.13	0.97	0.0001	0.83	10.51	0.95	0.0001
Silicone - 3	1.37	62.44	0.96	0.0001	0.72	7.90	0.95	0.0001
Silicone - 4	1.53	64.36	0.96	0.0001	0.75	8.87	0.96	0.0001
Silicone - 5	1.28	58.89	0.96	0.0001	0.70	7.56	0.95	0.0001
Silicone - 6	1.72	73.81	0.96	0.0001	0.81	9.65	0.96	0.0001
Silicone - Mean	**1.61**	**70.29**	**0.97**	**0.0001**	**0.78**	**9.21**	**0.95**	**0.0001**
BDyn 2 - 1	0.12	36.40	0.11	0.1405	0.43	4.88	0.82	0.0001
BDyn 2 - 2	0.34	39.79	0.60	0.0001	0.48	4.95	0.83	0.0001
BDyn 2 - 3	0.10	43.32	0.02	0.4991	0.65	6.00	0.71	0.0001
BDyn 2 - 4	0.40	44.92	0.34	0.0055	0.86	9.73	0.77	0.0001
BDyn 2 - 5	0.16	37.61	0.19	0.0454	0.53	4.69	0.70	0.0001
BDyn 2 - 6	0.49	46.11	0.73	0.0001	0.55	6.84	0.90	0.0001
BDyn 2 - Mean	**0.27**	**41.36**	**0.45**	**0.0010**	**0.58**	**6.18**	**0.82**	**0.0001**

Table 2: Mean and standard deviation of the storage stiffness (N/mm) for the BDyn 2 level device.

Specimen ID	Mean	Standard Deviation
BDyn 2 - 1	36.36	0.89
BDyn 2 - 2	39.69	1.10
BDyn 2 - 3	43.30	1.57
BDyn 2 - 4	45.97	1.72
BDyn 2 - 5	37.57	0.91
BDyn 2 - 6	45.97	1.44

Table 3: Multiple comparison test results for the 1 level BDyn device (BDyn 1), 2 level BDyn device (BDyn 2), silicone component (Sil) and polycarbonate urethane (PCU) component. The frequencies stated indicates that the comparison were significantly different ($p < 0.05$).

Multiple Comparison Test	Storage Stiffness	Loss Stiffness
BDyn 2 – BDyn 1	0.01 Hz to 30 Hz	0.01 Hz to 30 Hz
PCU – BDyn 1	-	-
Sil – BDyn 1	-	0.01 Hz to 0.2 Hz, 0.4 Hz, 0.75 Hz, 1 Hz
PCU – BDyn 2	0.01 Hz to 30 Hz	0.1 Hz to 30 Hz
Sil – BDyn 2	-	-
Sil – PCU	1 Hz to 30 Hz	10 Hz to 30 Hz