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Effect of lubricants on friction in laboratory tests of a total disc replacement device

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Abstract

Some designs of total disc replacement devices have articulating bearing surfaces and these devices are tested *in vitro* with a lubricant of diluted calf serum. It is believed that the lubricant found in total disc replacement devices *in vivo* is interstitial fluid that may have properties between that in Ringer's solution and diluted calf serum. To investigate the effect of lubricants, a set of friction tests were performed on a generic model of a metal against metal ball-and-socket total disc replacement device. Two devices were tested: one with a ball radius of 10 mm and one with a radius of 16 mm; each device had a radial clearance of 0.015 mm. A spine simulator was used to measure frictional torque for each device in axial rotation, flexion-extension and lateral bending at frequencies of 0.25 to 2 Hz, under 1200 N axial load. Each device was tested with two different lubricants: a solution of new born calf serum diluted with de-ionised water and Ringer's solution. The results showed that the frictional torque generated between the bearing surfaces was significantly higher in Ringer's solution than in diluted calf serum. The use of Ringer's solution as a lubricant provides a stringent test condition to detect possible problems. Diluted calf serum is more likely to provide an environment closer to that *in vivo*. However, the precise properties of the fluid lubricating a total disc replacement device is not known; hence, tests using diluted calf serum may not necessarily give the same results as those obtained *in vivo*.

Keywords: Calf serum; Friction; Lubricant; Ringer's Solution; Total Disc Replacement

1. Introduction

Joint replacements have been used to overcome problems associated with natural joints. For example, total hip and total knee replacement devices are used to treat joints affected by diseases such as osteoarthritis and rheumatoid arthritis.^{1,2} In the spine, total disc replacement devices are used to replace the degenerated intervertebral disc.^{3,4} Designs of total hip and total knee replacement devices involve articulating bearing surfaces; some designs of total disc replacement devices can also involve articulating bearing surfaces, although single-piece elastomer devices also exist.⁵ It is important to understand the tribological behaviour and performance of devices with articulating bearing surfaces and, therefore, *in vitro* tests need to be carried out.⁶ Hip and knee joints are lubricated by synovial fluid.^{7,8} The intervertebral joint is not a synovial joint, so an artificial disc with bearing surfaces is assumed to be lubricated by interstitial fluid.^{9,10}

Various tribological tests have been performed on total hip and total knee replacement devices, in which different lubricants have been used. Harsha and Joyce⁵ divide these lubricants into two groups. The first group is non-physiological fluids, which contain no proteins, for example, de-ionised water and Ringer's solution. The second group are physiological fluids, which contain protein, such as calf serum. The composition of the fluid is important as it could have an appreciable effect on the results of any tribological tests. For example, the protein concentration may have a significant effect on the friction factor between the articulating surfaces.^{6,11-13}

Calf serum is the most common lubricant used for *in vitro* experiments on artificial joints such as total hip and knee replacement devices¹⁴, as it is believed to have properties that are close to those of synovial fluid. Calf serum is also the recommended lubricant by the American Society for Testing and Materials (ASTM) and the International Organization for Standardization (ISO) for the wear testing of total disc replacement devices^{15,16}, despite intervertebral joints not being synovial and so not lubricated by synovial fluid. Diluted calf

serum has been used in several studies of wear in total disc replacement devices.^{4,17,18} The composition of the interstitial fluid that lubricates the bearing surfaces in total disc replacement devices is not fully understood, but is likely to be somewhere between Ringer's solution and diluted calf serum.¹⁹⁻²¹ Therefore, in this study the performance of a generic design of a total disc replacement device has been investigated *in vitro*, using both fluids as lubricants. The aim of this study was to investigate the effect of diluted calf serum and Ringer's solution on friction in this total disc replacement device.

2. Materials and Methods

2.1. Disc design and manufacture

A generic total disc replacement device was designed with a ball and socket articulation (Figure 1). Both bearing surfaces were manufactured from a cobalt-chrome-molybdenum alloy (Co-27Cr-5.5Mo-0.06C) which met the standard ASTM F1537²². Two generic total disc replacement devices were manufactured: one with a ball radius of 10 mm and the other with a ball radius of 16 mm. Each disc had a radial clearance of 0.015 mm between the ball and socket, similar to the Maverick™ (Medtronic, Minneapolis, USA) metal-on-metal total disc replacement device. The endplates were designed for easy fixation to a spine simulator. Further details have been published previously.²³

The metal samples were manufactured by Westley Engineering Ltd. (Birmingham, UK). The samples were machined from bar, using a MIKRON VCP600 and WS71D Machining Centre (Rottweil, Germany) and highly polished by a Black & Decker Bench Grinder (Berkshire, UK). For the final surface finish, the grinding wheel was replaced with a polishing mop.

Before testing, the specimens were washed with Virkon disinfectant (Antec International, Sudbury, UK), washed again with distilled water, then ultrasonically cleaned in a propan-2-ol bath (Scientific Laboratory Supplies, East Yorkshire, UK) and washed again with acetone (Sigma-Aldrich, MO, USA). After being left at room temperature for 48 hours, the surface

roughness of each sample was measured using a Taylor Hobson Form Talysurf-120L (Leicester, UK). The measurements were made at the centre of the balls and sockets. An area of 3 mm x 3 mm was selected at the centre of the ball or socket and then six measurements (1.25 mm x 1.25 mm each) were performed within that area. The data were analysed using the TalyMap Universal 3.1.8 software (Taylor Hobson Limited, Leicester, UK). The data were filtered to remove any high frequency data that resulted from noise and vibration, with a cut-off wavelength of 0.25 mm.^{24,25}

The average surface roughness for the 10 mm radius ball was 53 ± 3 nm, with the corresponding socket 40 ± 4 nm. The values for the 16 mm radius ball and corresponding socket were 40 ± 4 nm and 43 ± 3 nm, respectively. In-house measurements of the Maverick™ total disc replacement device found the average surface roughness for the bearing surfaces to be 50 ± 1 nm. The values of surface roughness for the bearing surfaces of the two generic total disc replacement devices were not significantly different to the Maverick™ total disc replacement device, as assessed using a Kruskal-Wallis one way analysis of variance on ranks using the Tukey method for multiple comparisons to investigate significant differences between the groups (SigmaPlot, version 12, Systat Software Inc, Hounslow, London, UK).

2.2. Frictional torque

Frictional torques were measured using a single station Bose SDWS-1 Spine Simulator (Bose Corporation, Minnesota, USA), shown in Figure 2, which has been previously used for testing a range of spinal implants.^{5,23} The simulator has 6 degrees of freedom: 4 active (flexion/extension, lateral bend, axial rotation and axial load) and 2 passive (anterior-posterior translation ± 4 mm and side-to-side translation ± 4 mm). The simulator enables $\pm 15^\circ$ flexion/extension, $\pm 12^\circ$ lateral bend, $\pm 9^\circ$ axial rotation. These angular displacements were measured with angular displacement transducers (series 605, Trans-Tek Inc., Ellington, CT, USA) with a precision of 0.08° . The simulator can apply a maximum axial force of 3 kN

and a maximum torque for each rotation of 15 N.m. A multi-axial load cell (AMTI MC3A-6-1000, Watertown, MA, USA) fitted below the lower plate (Figure 2) was used to make measurements of the axial force (precision of 3.6 N) and torques (precision of 0.02 N.m). The simulator is fitted with a temperature controlled fluid bath.

The two generic total disc replacement devices (one with a ball radius of 10 mm and the other with a ball radius of 16 mm) were tested with two different lubricants:

- a solution of new born calf serum (SeraLab, West Sussex, UK) diluted with de-ionised water to a protein concentration of 30 ± 2 g/L, at a controlled temperature of 37°C.¹⁶
- Ringer's solution, also at a controlled temperature of 37°C. The solution was produced by dissolving a 1.2 g Ringer's solution tablet (Oxoid Ltd., Hampshire, UK) in 500 mL of distilled water.

The viscosity of the lubricants was measured using an AR-G2 cone-on-plate rheometer (TA Instruments, West Sussex, UK) under 0.5% constant strain, at 37° C. The viscosity of the diluted new born calf serum and Ringer's solution were found to be 1.4 ± 0.4 mPa.s and 0.72 ± 0.05 mPa.s, respectively.

The specimens were mounted on custom-designed fixtures to allow alignment of the disc with the axes of the spine simulator. The fixtures were then placed inside the bath and mounted on the machine with the ball endplate connected to the base of the simulator and the socket on the top. The testing was guided by standards ASTM F2423¹⁵ and ISO 18192-1¹⁶, which were developed for the wear testing of total disc replacement devices. Each specimen was tested under a constant axial compressive load of 1200 N and subjected to a sinusoidally varying axial rotation from 0° to 2° at frequencies of 0.25, 0.5, 0.75, 1, 1.25, 1.50, 1.75 and 2 Hz. The anterior-posterior and side-to-side translations were unlocked and free to move during the tests, but all other axes were locked. Each test was carried out for 100 cycles and the frictional torque was measured; 2048 data points were collected per test. The

procedure was then repeated under flexion to $+6^\circ$, extension to -3° and lateral bending to $+2^\circ$. Each disc was tested four times for each lubricant; lubricants were used in random order, to avoid the order of testing affecting the results.

To determine the maximum torque generated in each test condition, a graph of frictional torque against angle was plotted for each test, using Excel software (Microsoft Office, Washington, USA). The mean maximum frictional torque was calculated based on the maximum frictional torque from the last 10 cycles.²³ In order to compare the effect of different lubricants, graphs of mean maximum frictional torque against frequency were plotted.

2.3. Statistical analysis

To investigate possible differences between the results from the two lubricants, error bars representing the 95% confidence intervals were added to the graphs of mean maximum frictional torque against frequency. These confidence intervals represent the regions in which there is a 95% probability of finding the true mean value.²⁶ Therefore, if there is an overlap between the two regions defined by the 95% confidence intervals, difference between them at the 5% level is not significant.²⁷ No overlap would indicate a significant difference. This method has been used previously to determine whether materials used for implantation have different mechanical properties.²⁸

3. Results

The mean maximum frictional torque was found to be significantly higher for a total disc replacement device with Ringer's solution as the lubricant, compared with discs lubricated by diluted calf serum for both the 10 and 16 mm radii samples in axial rotation; Figure 3a presents the results for 16 mm samples under axial rotation. At a frequency of 1 Hz (which is the frequency used for wear testing disc replacement devices, ISO 18192-1, 2008) the mean maximum frictional torque was 3.5 N.m for diluted calf serum and 4.5 N.m for Ringer's solution. Similar behaviour was observed for flexion, extension and lateral bending, for both disc radii. Figures 2b, 2c and 2d show the results for 16 mm samples during lateral bending, flexion and extension, respectively. It can be seen that the mean maximum frictional torque in a total disc replacement device lubricated by Ringer's solution was always significantly higher than that in diluted calf serum, since the confidence interval error bars overlapped in none of the graphs.

Results for the 10 mm radius total disc replacement device in flexion could not be obtained as the maximum measured frictional torque, with Ringer's solution as the lubricant, was higher (> 15 N.m) than the limits for the spine simulator. It can be seen that for the 16 mm radius sample (Figure 3c), the mean maximum friction in flexion with Ringer's solution as the lubricant, was around 14 N.m.

4. Discussion

Some design of total disc replacement devices have articulating bearing surfaces and they are currently tested, in the laboratory, using a lubricant of diluted calf serum. The exact nature of the lubricant found in total disc replacement devices in the human spine is unknown, but is likely to be interstitial fluid.^{8,9} The composition of interstitial fluid is likely to be somewhere between that of Ringer's solution and diluted calf serum (Table 1). The protein content is expected to increase the viscosity²⁹ and, therefore, the lubricity of the

liquid.³⁰ The results of this study are consistent with this expectation by showing that frictional torques generated in diluted calf serum are significantly lower than those in Ringer's solution.

The results presented here are consistent with those from studies of THA. In a study by Scholes and Unsworth²⁷ on metal-on-metal hip implants, it was observed that presence of proteins in the lubricant decreases the friction between the articulating surfaces. When the implant is lubricated by bovine serum, the proteins form a layer on the surface which reduces the contact and results in a mixture of metal-on-metal and protein-on-protein contact.^{12,31} Such behaviour cannot be expected in Ringer's solution.

The viscosity of interstitial fluid lies between that of water and that of body plasma, and varies according to the total protein content and the relative fractions of large and small proteins.²⁹ The viscosity of water at body temperature is 0.70 mPa.s and the viscosity of body plasma ranges from 1.2 to 2 mPa.s at 37°. ^{32,33} The measured viscosity of Ringer's solution at 37°, (see Methods section) was 0.72 mPa.s which is comparable to that of water. The measured viscosity for diluted calf serum at 37°, at 1.4 mPa.s, was similar to that reported for plasma.^{32,33} Moreover, the viscosity of the plasma is very close to the average viscosity of interstitial fluid, which is 1.24 mPa.s.^{9,34}

The question that then arises is what lubricant should be used for laboratory testing of friction on total disc replacement devices with articulating bearing surfaces. The results of this study show that Ringer's solution leads to significantly higher friction than a fluid containing protein. However, it could be used for stringent tests to ensure that friction problems were unlikely to occur *in vivo*. Diluted calf serum, as usually used for laboratory testing of total disc replacement devices with articulating bearing surfaces, appears to have higher protein content than interstitial fluid and, therefore, might be expected to have a higher viscosity and lubricity, as discussed above.

However, the measured viscosity of diluted calf serum is comparable to that of plasma and the average interstitial fluid viscosity. Therefore, it appears to be reasonable to use diluted calf serum to mimic the fluids surrounding a total disc replacement device. Also, the protein concentration of calf serum can be controlled by diluting with more distilled water; although standards suggest 25 to 30 g/L protein concentration.^{15,16}

Currently, the exact nature of the fluid surrounding a total disc replacement device, and precise values for its physical properties are unknown. As a result, tribological studies of total disc replacement devices, in the laboratory, provide useful indications of the behaviour that may be obtained *in vivo*, but do not necessarily replicate the true *in vivo* behaviour.

This study has only investigated a metal-on-metal total disc replacement device, but the issue of lubricant choice will also apply to metal-on-polymer total disc replacement devices. The issue of lubricant choice for laboratory testing is not exclusive to total disc arthroplasty as there is debate about the correct lubricant to use for other devices such as total knee replacement devices.^{35,36}

Conclusions

The frictional torque generated between the bearing surfaces in generic design of total disc replacement device with a ball and socket articulation was significantly higher in Ringer's solution than in diluted calf serum. The use of Ringer's solution as a lubricant provides a stringent test condition to detect possible problems.

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Table 1. Comparison of some of the components of lubricants^{6,19-21}

Constituent	Human Synovial fluid (g/L)	Human Interstitial fluid (g/L)	Diluted calf serum (g/L)	Ringer's solution (g/L)
Protein	17	20.6	30	-
Sodium	3.3	3.1 – 3.56	1.75-3.55	3.6
Potassium	0.16	0.12	0.07-0.11	0.21
Calcium	0.06	0.06	0.025-0.035	0.05
Chloride	3.8	4.44	1.5-2.5	5.7

Figures

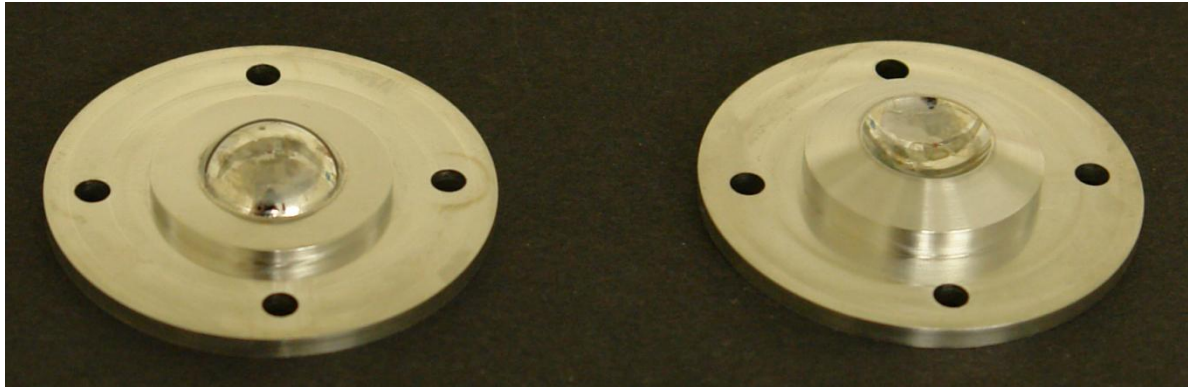


Figure 1. The generic ball (left) and socket (right) model with 10 mm ball radius

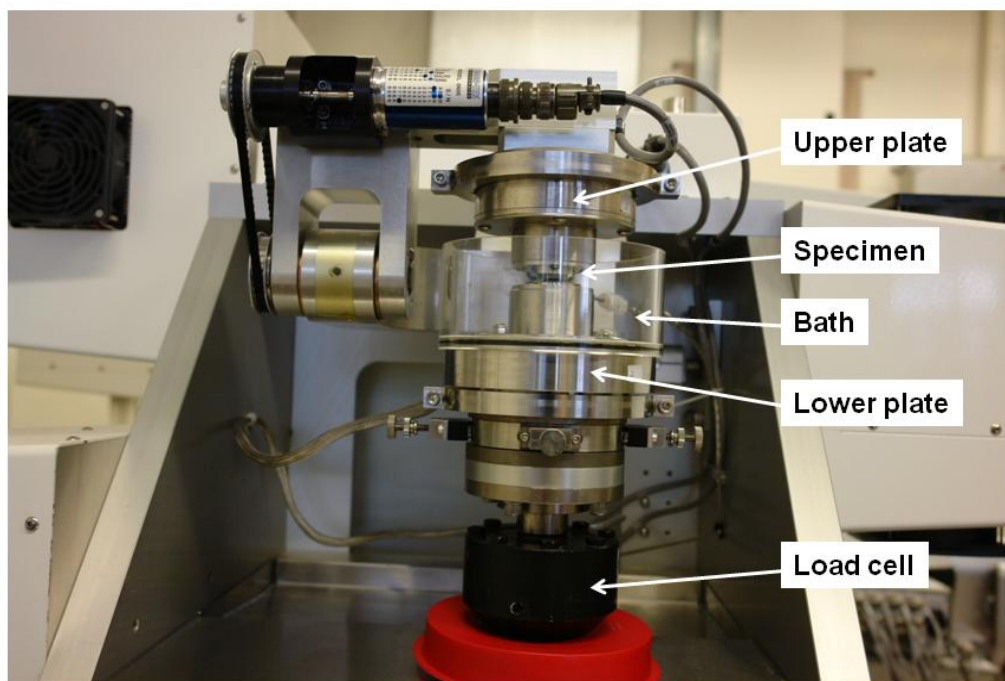
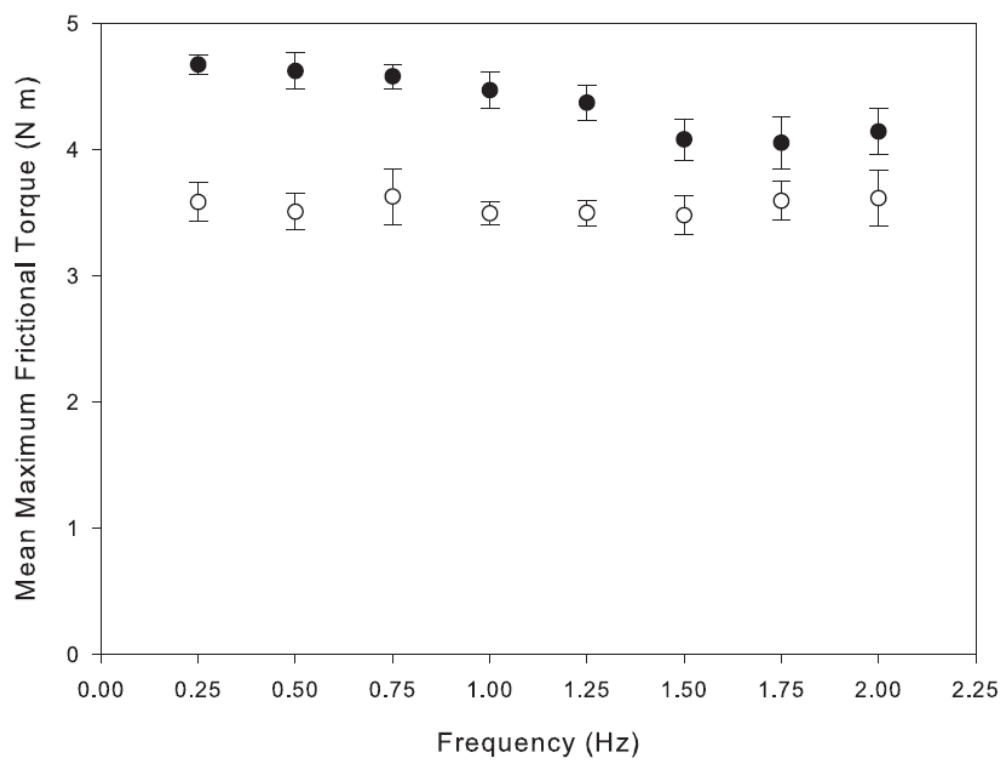
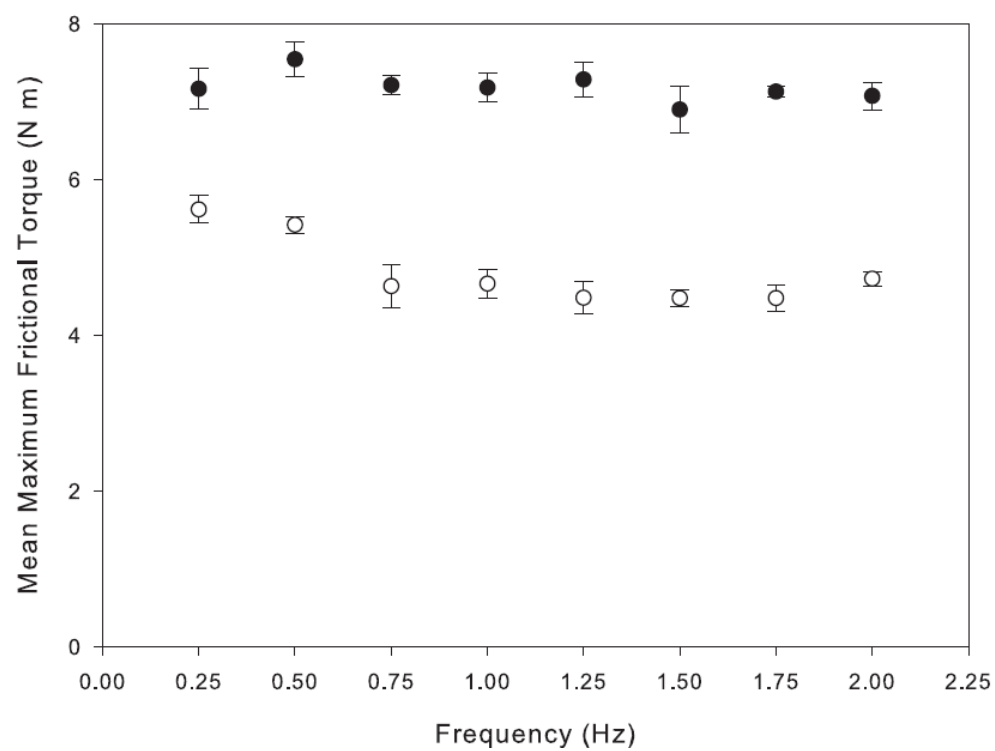


Figure 2. Bose Spine Simulator.



a



b

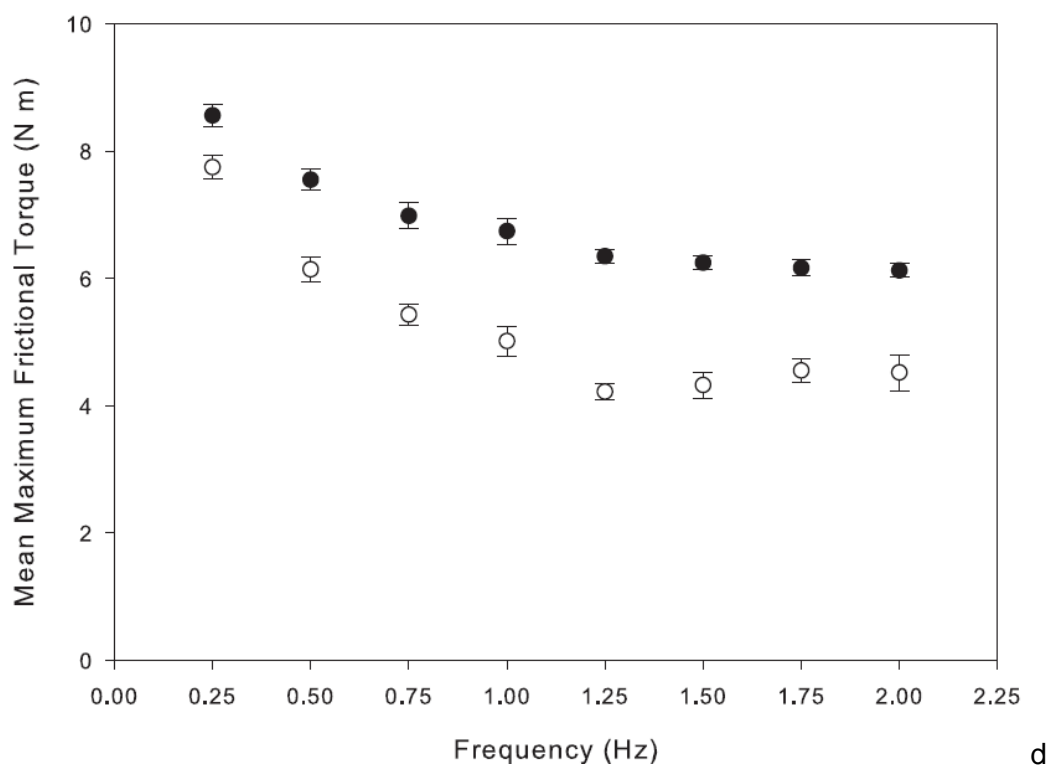
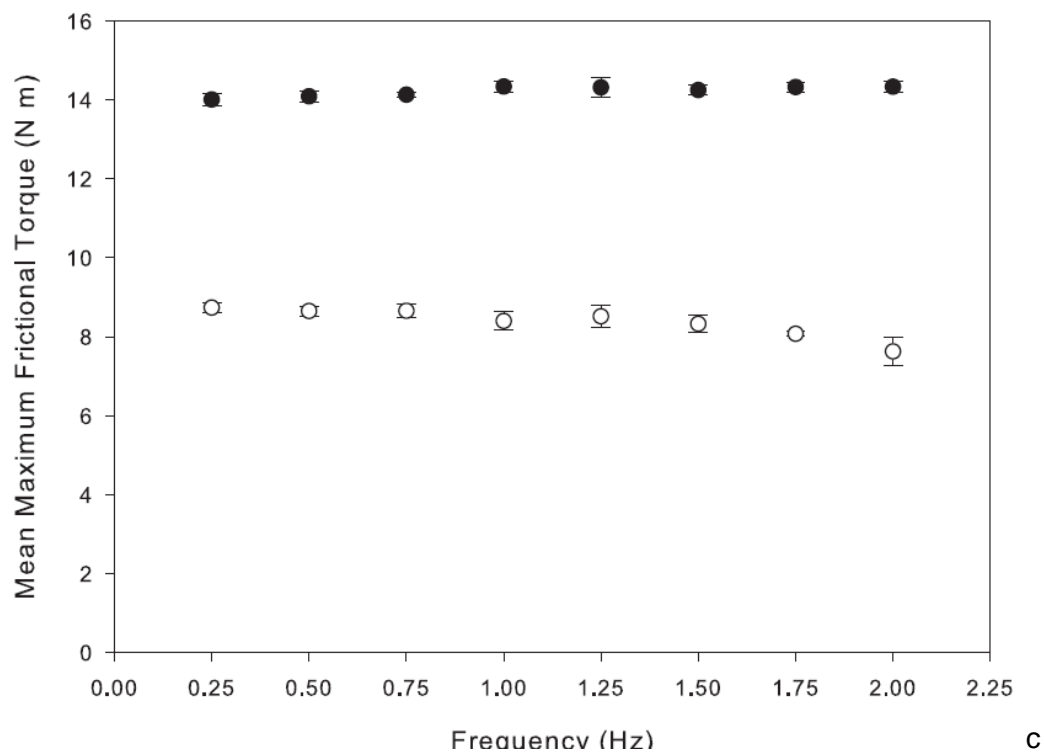


Figure 3. Mean maximum frictional torque plotted against frequency, for the samples with 16 mm ball radius in bovine serum (O) and Ringer's solution (●) for a) axial rotation; b) lateral bending; c) flexion; d) extension. Error bars represent 95% confidence intervals.