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Abstract:

Total Disc Arthroplasty (TDA) can be used to replace a degenerated intervertebral disc in the spine. There are different designs of prosthetic discs, but one of the most common is a ball-and-socket combination. Contact between the bearing surfaces can result in high frictional torque, which can then result in wear and implant loosening. This study was designed to determine the effects of ball radius on friction. Generic models of metal-on-metal TDA were manufactured with ball radii of 10, 12, 14 and 16 mm, with a radial clearance of 0.015 mm. A simulator was used to test each sample in flexion-extension, lateral bending and axial rotation at frequencies of 0.25, 0.5, 0.75, 1, 1.25, 1.5, 1.75 and 2 Hz under loads of 50, 600, 1200 and 2000 N, in new born calf serum. Frictional torque was measured and Stribeck curves were plotted to illustrate the lubrication regime in each case. It was observed that implants with a smaller ball radius showed lower friction and showed boundary and mixed lubrication regimes, whereas implants with larger ball radius showed boundary lubrication only. This study suggests designing metal-on-metal TDAs with ball radius of 10 or 12 mm, in order to reduce wear and implant loosening.

Keywords: Ball-and-Socket, Friction, Lubrication, Radius, Total Disc Arthroplasty

1. Introduction

Severe disc degeneration associated with chronic low back pain may be treated by spinal surgery (Gamradt and Wang, 2005). The traditional surgical treatment is spinal fusion (Marcolongo et al., 2006). However, in recent years Total Disc Arthroplasty (TDA) has been introduced as it offers motion preservation at the treated levels (Frelinghuysen et al., 2005; Gamradt and Wang, 2005; Hall et al., 2006; Lee et al., 2008). There are different designs of prosthetic discs, but most involve a ball-and-socket combination, with a metal-on-polymer or metal-on-metal bearing surface, similar to Total Hip Replacement implants. Examples of metal-on-polymer devices include the Charité® Artificial Disc (Depuy Spine, Raynham, MA, USA) and the ProDisc-L® Total Disc Replacement (Synthes, West Chester, PA, USA). Examples of metal-on-metal devices include the Maverick™ and the Prestige® (Medtronic, Minneapolis, MN, USA) (Kurtz, 2006).

Studies on hip replacement implants indicate that the wear rate of metal-on-metal bearing surfaces is less than metal-on-polymer combinations (Lee et al., 2008). Therefore, such a bearing material combination may be favourable for disc arthroplasty. One of the main concerns of metal-on-metal disc implants is creation of wear debris. Studies show that wear particles can result in tissue reaction and metal toxicity, which can lead to implant loosening and failure (Affatato et al., 2008; Jin et al., 1997). However, creation of wear particles can be minimised if the articulating surfaces are in less contact and less friction is created between the surfaces. In addition, it is beneficial to reduce friction because, by analogy with Total Hip Arthropasty, a high frictional torque may lead to loosening of the implant (Simon et al., 1975).

When a prosthetic disc is implanted, it is lubricated by the natural interstitial fluid; however, the nature of the lubrication regime could vary for different designs of disc prosthesis. Depending on the lubrication regime, the articulating surfaces may still be in direct contact (boundary lubrication), partly separated by the fluid (mixed lubrication) or fully separated by the fluid (fluid film lubrication) (Dowson and Jin, 2006; Hall et al., 1994). In comparison, friction in the boundary lubrication regime is the highest (Hutchings, 1992); hence, it is possible that more wear debris is created. Therefore, an understanding of the friction created by the implant is important from a design point of view and also in understanding the likely lubrication regimes between the bearing surfaces. The aim of this work was to investigate the effect of change in radius on friction in a metal-on-metal disc arthroplasty.

2. Materials and Methods

2.1 Disc design and manufacture

A generic ball-and-socket model of TDA was designed (Figure 1a) based on the dimensions and geometry of the metal-on-metal Maverick™ device (Medtronic, Minneapolis, USA). The Maverick™ consists of bearing surfaces manufactured from Cobalt Chrome Molybdenum alloy (Co-Cr-Mo) (ASTM F 1537 – 08), with a ball radius of 10 mm and radial clearance of 0.015 mm between ball and socket. The generic ball-and-socket model was designed with ball radii of 10, 12, 14 and 16 mm, each with a radial clearance of 0.015 mm (Figure 1b). These ball radii were based on existing designs of disc arthroplasty (Charité ®, Maverick™, ProDisc-L®) and enabled a range of ball radii to be considered and compared in the friction tests. The endplates were designed to fix to a spine simulator.

The samples were manufactured from Co-27Cr-5.5Mo-0.06C by Westley Engineering Ltd. (Birmingham, UK). The samples were machined from bar, using MIKRON VCP600 and WS71D Machining Centres (Rottweil, Germany) and highly polished by a Black & Decker Bench Grinder (Berkshire, UK); for the final surface finish the grinding wheel was changed to a polishing mop. Prior to testing, the specimens were washed with Virkon disinfectant (Antec International, Sudbury, UK), then ultrasonically cleaned in a propan-2-ol bath (Scientific Laboratory Supplies, Hessle C, 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 average surface roughness for the balls and sockets were 48.5 ± 11.9 and 47.9 ± 23.0 nm, respectively. These values are comparable to measurements made on a Maverick™ prosthesis, where the average surface roughness was measured to be 50 ± 0.55 nm.

2.2 Frictional torque

Frictional torque tests were performed using a Bose SDWS-1 Spine Simulator (Bose Corporation, Minnesota, USA) fitted with a multi-axial load cell (Figure 2). The simulator has 6 degrees of freedom and enables ± 15° flexion/extension, ± 12° lateral bend, ± 9° axial rotation and 3 kN axial load. Frictional torque was measured (with a precision of 0.01 N.m) using an AMTI MC3-6-1000 load cell (Berkshire, England), supplied with the simulator, that was calibrated every 12 months. The simulator is fitted with a temperature controlled fluid bath.

The specimens were mounted on custom-designed fixtures to allow the correct alignment within the simulator. The fixtures were then placed inside the bath and mounted to the machine with the ball endplate connected to the base of the simulator and the socket to the top. The testing was guided by the standards ISO 18192-1:2008 and ASTM F2423-05, which were developed for the wear testing of disc arthroplasty. The specimens were tested in a solution of new born calf serum (SeraLab, West Sussex, UK) diluted with de-ionised water to a concentration of 30 ± 2 g protein per litre, at a controlled temperature of 37°C (BS ISO 18192-1:2008). Each specimen was tested under a constant axial compressive load of 50, 600, 1200 and 2000 N. At each load, the sample was 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. Each test was carried out for 100 cycles and the frictional torque was measured. The procedure was then repeated under flexion to +6°, extension to -3° and lateral bending to +2°.

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). An average peak frictional torque was calculated based on the values from the last 10 cycles. In order to observe the effects of frequency and load on frictional torque, graphs of mean frictional torque against both frequency and load were plotted. For these graphs a linear regression analysis was performed, using Minitab software (Minitab Inc., Pennsylvania, USA).

2.3 Stribeck analysis

To indicate the lubrication regime under which the samples were acting, Stribeck analysis was used where the friction factor, f, was plotted against the Sommerfeld number, Z (Scholes and Unsworth, 2006). Frictional torque measurements, from the experiments, were converted to a friction factor from:

$$f = \frac{T}{rL} \quad (1)$$

where T is the frictional torque between the bearing surfaces, r is the ball radius and L is the applied load. The Sommerfeld number, Z, was calculated from:

$$Z = \frac{\eta u r}{L} \quad (2)$$

where η is the lubricant viscosity, u is the entraining velocity of the bearing surface, which is conventionally defined by

$$u = \frac{\omega r}{2} = \pi \phi r \quad (3)$$

where ω is the angular frequency and ϕ is the frequency at which the test was performed (Mattei et al., 2011; Shaheen and Shepherd, 2007; Wang et al., 2008).

When the friction factor decreases, with increasing Sommerfeld number, a mixed lubrication regime is indicated, whereas an increasing friction factor, with increasing Sommerfeld number, indicates a fluid film regime; a constant friction factor indicates a boundary lubrication regime (Jones et al., 2009). The viscosity of the lubricant was measured using an AR-G2 cone-on-plate rheometer (TA Instruments, West Sussex, UK) under 0.5% constant strain, at 37º C. The viscosity of diluted new born calf serum was found to be 1.44 ± 0.4 mPa.s.

3. Results

3.1. Frictional torque

The results show that there was variation in frictional torque with frequency (Figure 3). The maximum mean frictional torque was about 9.5 N.m, which occurred for the specimen with a ball radius of 16 mm, in flexion at a frequency of 0.25 Hz, under a load of 2000 N. The results also show that, for all four motions and for all four sample radii, frictional torque increased with load, as expected.

There was a positive linear correlation between mean frictional torque and load for all motions and all ball radii, in the range investigated. An example is shown in Figure 4, where there is a significant linear correlation between the mean frictional torque and load, in flexion, for all ball radii.

Figure 5 shows a significant linear correlation between frictional torque and radius, in flexion, at a frequency of 1 Hz, for the range of loads investigated. Similar results were observed for the other motions.

3.2 Lubrication regime analysis

To investigate the lubrication regimes, Stribeck curves were plotted for each motion. The Stribeck curves for the sample with a ball radius of 10 mm, in flexion, (Figure 6a) showed an initial decrease in friction factor and a gradual increase as Sommerfeld number increased. It was observed that the graphs go through a clear minimum. The results for 50 N load has been omitted from the graphs, as the values of friction factor were much higher than those for other loads and so could not be shown clearly on the same axes. For the 16 mm ball (Figure 6b), the friction factor initially decreased and then flattened out of a fairly constant value, with increasing Sommerfeld number. The graph has clear minimum for 600 N but not for higher loads. The results for 12 mm samples followed the same pattern as 10 mm sample, whilst the graphs for 14 mm sample showed clear minimum for all loads except 2000 N.

4. Discussion

A linear correlation between frictional torque and load was found, as expected. This indicates that by increasing the axial load on the spinal implant, a higher frictional torque between the articulating surfaces is created. Ma *et al.* (1983) and Unsworth (1978) found a similar correlation between frictional torque and load in metal-on-metal and metal-on-polymer hip implants. The frictional torque significantly decreased with ball radius; this result is also to be expected since the average frictional torque is given by $T = \mu L r$, where μ is the coefficient of friction. Streicher et al. (1996) reported similar results for metal-on-metal hip implants; they observed that by reducing the diameter, the friction is reduced due to the reduction in contact area. Bishop et al. (2008) in another study on metal-on-metal hip joint bearings concluded that bearings with smaller diameter have lower frictional torques. The maximum frictional torque found in this study was 9.5 N.m and this is well below the torques generated in the natural spine (Adams and Dolan, 1991) and so metal on metal disc arthroplasty is unlikely to affect spinal kinematics.

The friction factors in this study were found to be of the same order as those found in other studies on hip implants, under similar loads (Scholes et al., 2000a; Scholes et al., 2000b; Scholes and Unsworth, 2000). Frictional torque plotted against frequency showed varying trends and this was analysed further by producing Stribeck curves which can give an indication of the lubrication regime (Scholes and Unsworth, 2000). A decrease in friction factor with increasing Sommerfeld number is an indication of boundary or mixed lubrication, whilst a gradual increase from a low friction factor with increasing Sommerfeld number suggests the possibility of a fluid film regime. Such results were observed in the sample with ball radius of 10 mm; the sample showed mixed lubrication at low frequencies and the possibility of fluid film at higher frequency. However, within a motion cycle, different lubrication regimes are likely to be acting at different times and hence the amount of contact between the bearing surfaces (leading to wear) will vary. The sample with ball radius of 16 mm appeared to demonstrate boundary lubrication as the friction factor was fairly constant with increasing Sommerfeld number. Although a theoretical study (Shaheen and Shepherd, 2007) of ball-and-socket disc prostheses with radii of 14, 21 and 28 mm, suggested that metal-on-metal disc implants are more likely to show boundary lubrication, the current experimental study showed that it is also possible to achieve mixed or fluid film lubrication. Such lubrication regimes were also found in a study (Smith et al., 2001) of metal-on-metal hip joint replacements, where hip implants with 14 and 18 mm femoral head radii showed mixed and fluid film lubrication, respectively.

Although not within the scope of this study, the size of radial clearance will also affect the friction and lubrication in disc arthroplasty, as seen in hip arthroplasty (Jacobs et al., 1998; Scholes et al., 2000a; Scott and Schroeder, 1997).

The ultimate test of a TDA is after implantation into the human body, but pre-clinical wear testing can be used to determine the potential performance of devices. Based on experience of Total Hip Arthroplasty, understanding the factors that influence friction in the prosthesis is likely to aid the development of improved designs, as creating less friction can result in the creation of less wear debris, and reduced implant loosening (Simon et al., 1975). However, the friction and lubrication results shown here cannot be used to determine the wear mechanism; this can only be determined from wear tests.

5. Conclusions

This study has investigated the friction in metal-on-metal TDA. Frictional torque has been found to increase with load and also with the radius of the bearing surface. The analysis of the Stribeck curves indicated that most metal-on-metal TDAs operate in the boundary/mixed lubrication regime. However, discs with ball radius of 10 mm offer the possibility of fluid film lubrication under high loads and frequencies.

Conflict of interest statement

The authors have no conflict of interests.

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Figure Captions

Figure 1. a) The generic ball (right) and socket (left) model with 10 mm ball radius , b) the side view of four TDAs with radii of 10, 12, 14 and 16 mm and identical core diameter of 18 mm

Figure 2. Specimen mounted in the Bose Spine Simulator

Figure 3. Mean frictional torque plotted against frequency for the sample with a ball radius of 10 mm, in flexion, under the loads of 50 (■), 600 (▲), 1200 (✕) and 2000 N (◆). Error bars represent standard deviations; when error bars are not shown they are smaller than the symbols used to represent the data points

Figure 4. Mean frictional torque plotted against load for flexion at a frequency of 1 Hz, for implants with ball radii of 10 (■) (R^2 = 0.99, p = 0.004), 12 (▲) (R^2 = 0.98, p = 0.012), 14 (✕) (R^2 = 0.98, p = 0.009) and 16 mm (◆) (R^2 = 0.99, p= 0.006). Error bars represent standard deviations; when error bars are not shown they are smaller than the symbols used to represent the data points. Linear regression lines are fitted through the data points

Figure 5. Mean frictional torque against radius for a frequency of 1 Hz in flexion motion, under the loads of 50 (■) (R^2 = 0.95, p = 0.028), 600 (▲) (R^2 = 0.98, p = 0.011), 1200 (✕) (R^2 = 0.95, p = 0.025) and 2000 N (◆) (R^2 = 0.99, p = 0.006). Error bars represent standard deviations; when error bars are not shown they are smaller than the symbols used to represent the data points. Linear regression lines are fitted through the data points

Figure 6. Stribeck curves for sample with a ball radius of a) 10 mm and b) 16 mm, under loads of 600 (▲), 1200 (✕) and 2000 N (◆), operated in flexion. A third order polynomial has been fitted to the points

a)

b)

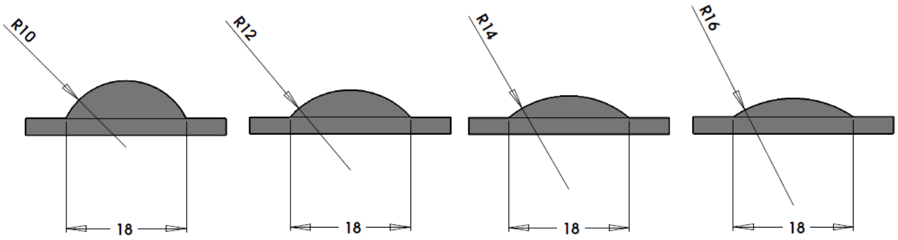


Figure 1

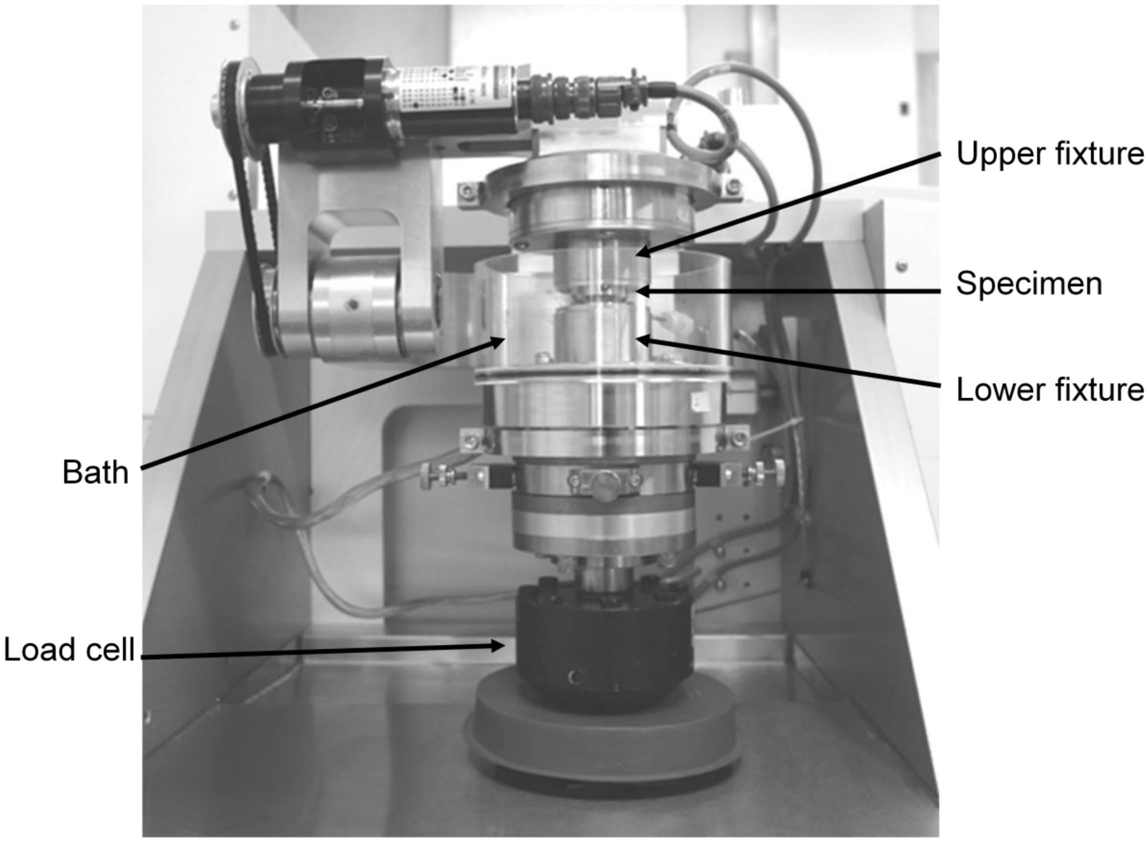


Figure 2.

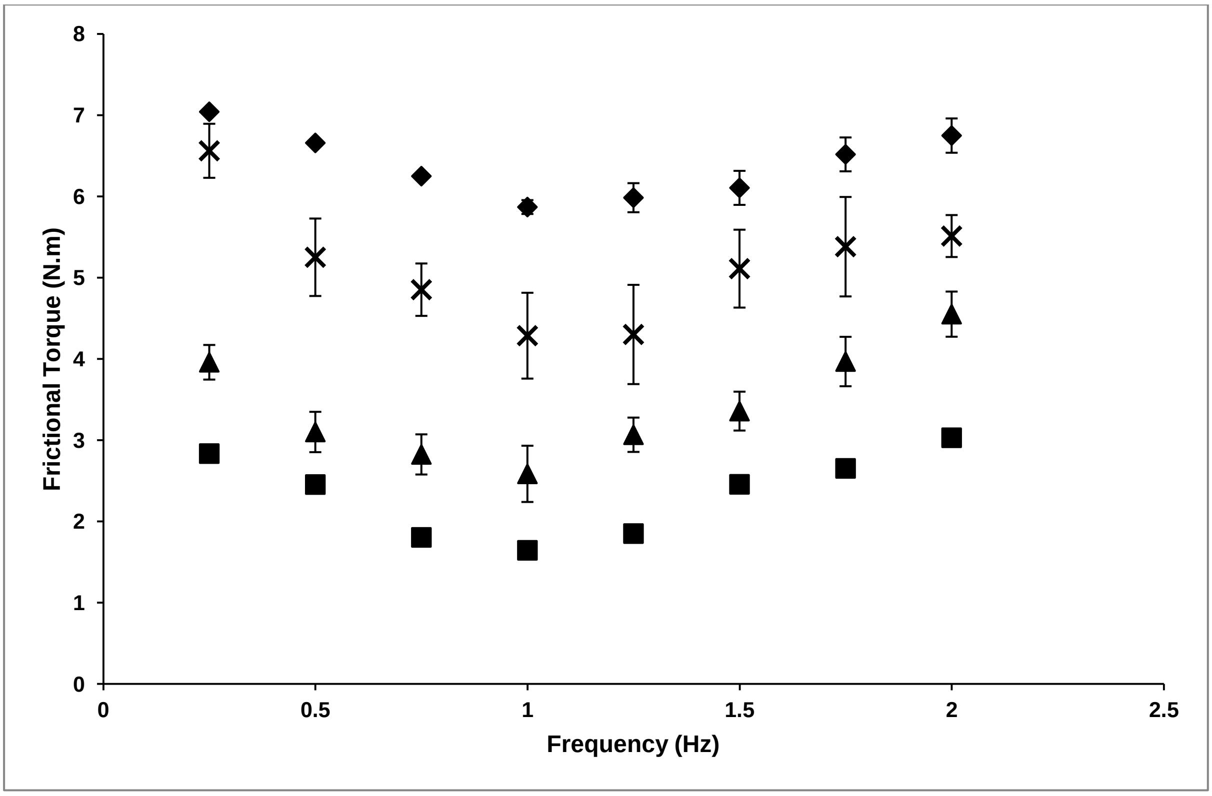
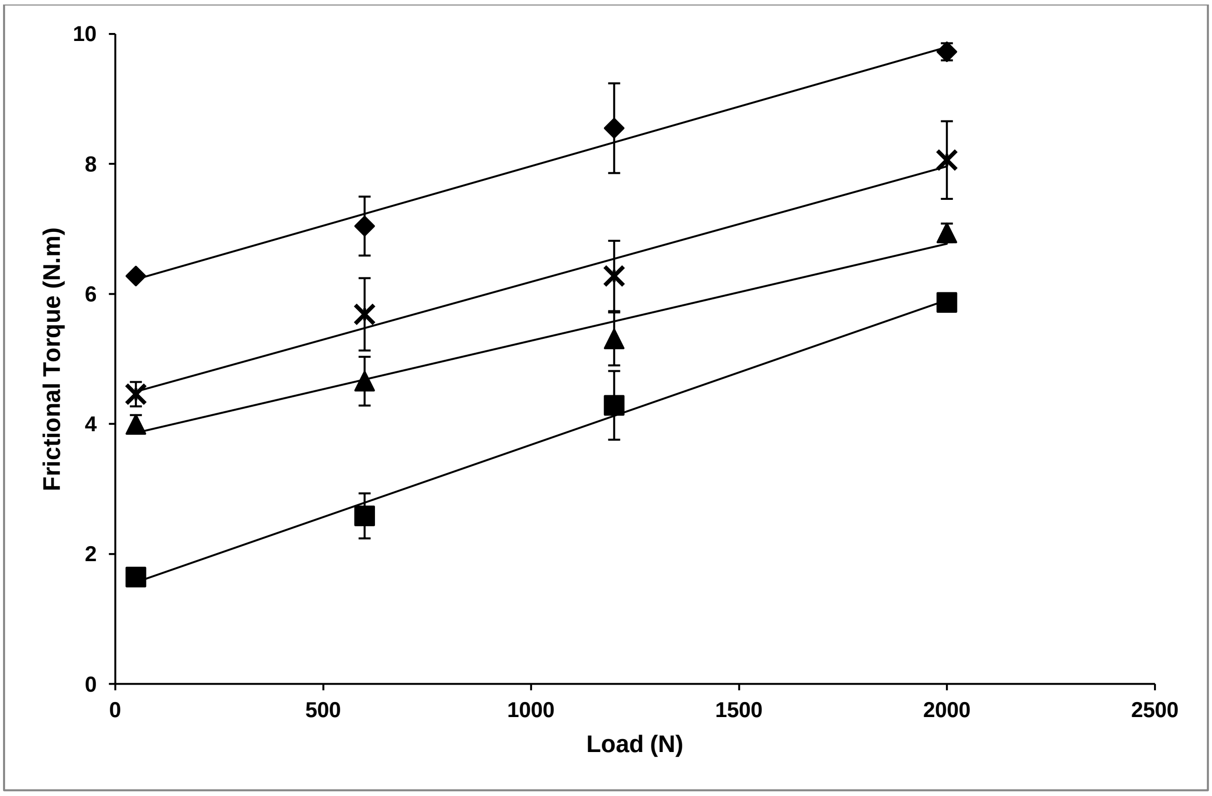


Figure 3.



Frictional Torque (N.m)
10
8
6
4
2
0
0
500
1000
1500
2000
2500
Load (N)

Figure 4.

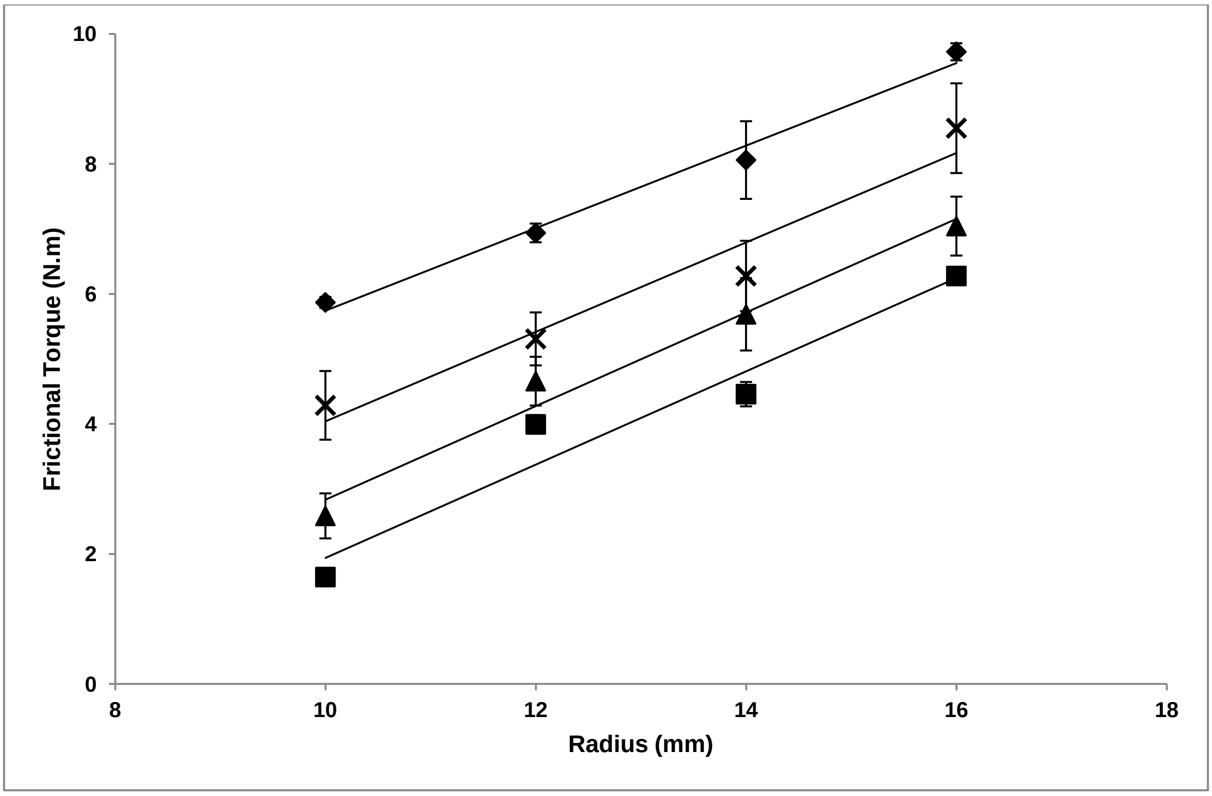
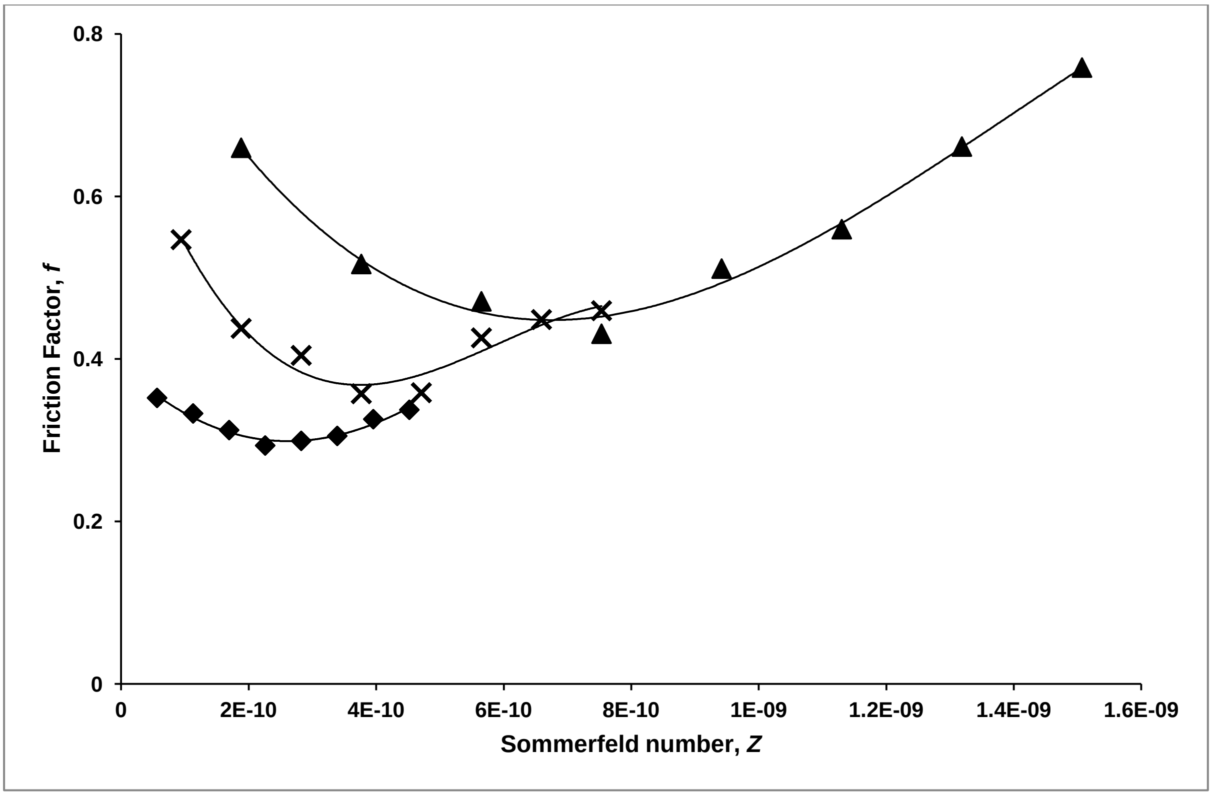


Figure 5.

a)


0.8
0.6
0.4
0.2
0
Friction Factor, f
0
2E-10
4E-10
6E-10
8E-10
1E-09
1.2E-09
1.4E-09
1.6E-09
Sommerfeld number, Z

b)

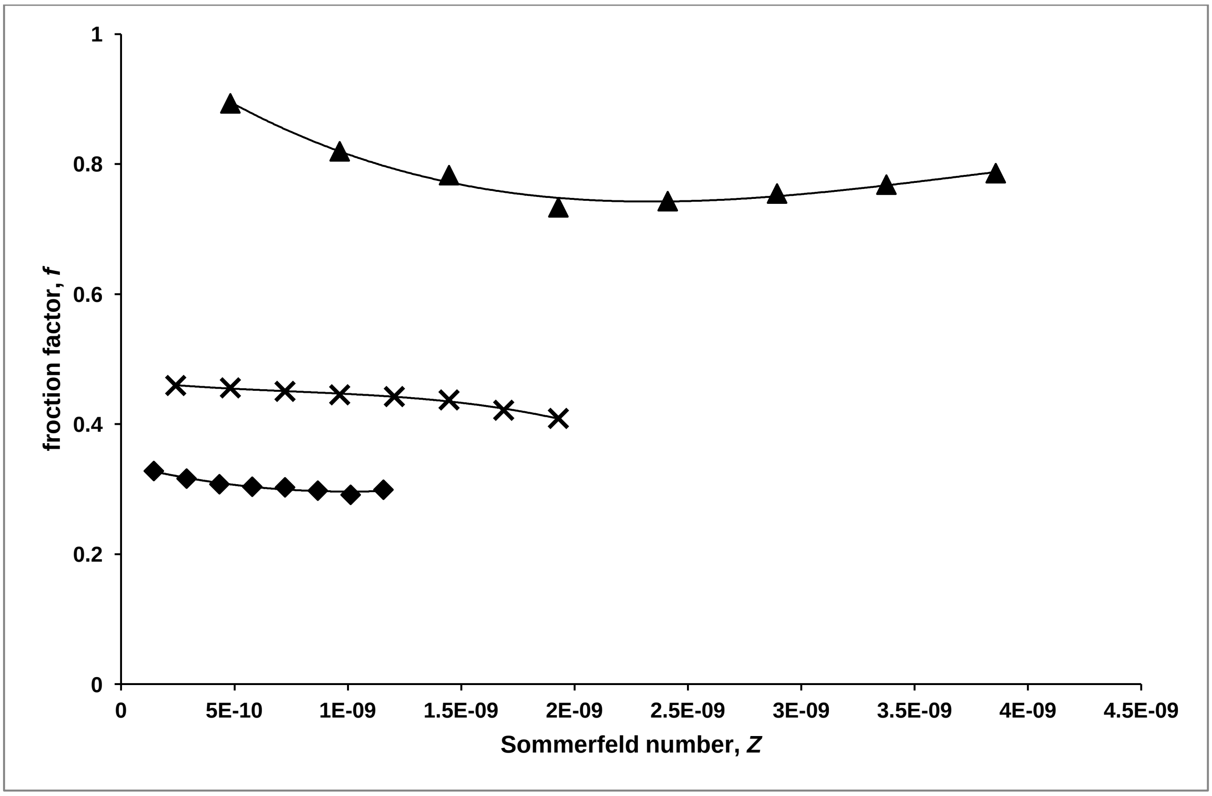

1
0.8
0.6
0.4
0.2
0
froction factor, f
0
5E-10
1E-09
1.5E-09
2E-09
2.5E-09
3E-09
3.5E-09
4E-09
4.5E-09
Sommerfeld number, Z

Figure 6.