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DOI:
10.1097/BRS.0b013e318257fdd3

Document Version
Peer reviewed version

Citation for published version (Harvard):
Moghadas, P, Shepherd, D, Hukins, D & Mahomed, A 2012, 'Polymer-on-Metal or Metal-on-Polymer Total Disc Arthroplasty: Does it Make a Difference?', *Spine*. https://doi.org/10.1097/BRS.0b013e318257fdd3

Polymer-on-metal or metal-on-polymer total disc arthroplasty: does it make a difference?

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Author generated final version. Published as:

Moghadas P, Shepherd DET, Hukins DWL & Mahomed A (2012). Polymer-on-metal or metal-on-polymer total disc arthroplasty: does it make a difference? *Spine* 37: 1834-1838.

1. Introduction

Severe disc degeneration can be treated by spinal surgery, which involves implanting a Total Disc Arthroplasty (TDA), although these devices are not accepted by all surgeons or in all countries.[1-6] There are different designs of TDA, but most have a ball-on-socket configuration where the bearing surfaces articulate against each other. This articulation leads to friction. Friction needs to be minimised for two reasons; firstly, if friction is high there is the possibility of the implant becoming loose as a result of the fixation failure between the implant and bone. Secondly, friction should be minimised to prevent the generation of wear debris. Although there is no simple relationship between wear and friction, it is expected that implants which offer less friction perform better[7] and may create less wear debris. The generation of wear debris can cause osteolytic loosening of implants; this is well known for hip arthroplasty[8-10] and several studies have noted this for total disc arthroplasty.[11,12] In hip implants the idea of "low friction arthroplasty" was initiated by Charnley; he designed a hip replacement with a metal femoral head articulating against polymer acetabular cup.[13,14] TDAs have been designed with the material combination the other way round, with a polymer ball articulating against a metal socket. Typical examples include the Charité® Artificial Disc (Depuy Spine, Raynham, MA, USA) and the ProDisc-L® Total Disc Replacement (Synthes, West Chester, PA, USA). The material combination of hip implants has never been applied for ball and socket disc arthroplasty; hence, one may ask whether a similar approach to the Charnley hip implant (with a polymer socket and a metal ball) can benefit disc prostheses by means of generating less friction between the bearing surfaces. The aim of this work was to compare the friction between disc arthroplasty with a polymer ball/metal socket and metal ball/polymer socket.

2. Materials and Methods

2.1 Disc design and manufacture

Two ball-and-socket models of TDA were designed. One design had a metal socket/polymer ball and the other a polymer socket/metal ball. The metal in each design was Cobalt Chrome Molybdenum (Co-27Cr-5.5Mo-0.06C)[15], while the polymer was Ultra High Molecular Weight Polyethylene (UHMWPE)[16]. In both groups two ball radii of 10 and 14 mm were used, with each radii having a radial clearance of 0.35 mm between the ball and socket, similar to the ProDisc-L® Total Disc Replacement device.[17] The selection of the ball radii are based on existing designs of disc arthroplasty (Charité ®, Maverick™, ProDisc-L®) and the endplates were designed to fix to a spine simulator.

The metal and polymer samples were manufactured by Westley Engineering Ltd. (Birmingham, UK). The samples were machined from bar, using a 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. The manufactured discs are shown in Figure 1. 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 average surface roughness for the balls and sockets are shown in table 1 and were comparable to suggested values for metal and polymer hip implants[10,18] as well as the in-house measurements of the Maverick™ and the Charite® disc replacement devices, where the average surface roughness for metal and polymer bearing surfaces were 0.05 ± 0.001 and

0.80 ± 0.052 µm, respectively. The polymer samples were soaked in distilled water and kept at 37° C for two weeks before the start of each test to allow for any fluid uptake to stabilise.

2.2 Frictional torque

Frictional torque tests were performed using a single station 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[19] and ASTM F2423-05[20], 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.[19] 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. 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°. Flexion was also investigated from 0° to 2° so that a comparison could be

made with axial rotation and lateral bending. Each sample was tested four times in total; tests were not necessarily performed consecutively, to ensure reproducibility of 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). An average frictional torque was calculated based on the values from the last 10 cycles.

In order to compare the effect of different material combinations and ball radii in similar frequencies, graphs of mean frictional torque against frequency were plotted.

2.3 Statistical analysis

To investigate significant differences between the material combinations, error bars to represent the 95% confidence intervals were added to the graphs of frictional torque against frequency. These confidence intervals represent the regions in which there is a 95% probability of finding the true mean value.[21] 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. [22] No overlap would indicate a significant difference. This method has been used previously to determine whether materials used for implantation have different mechanical properties.[23]

3. Results

The frictional torque was found to be significantly higher for a TDA with a metal socket/polymer ball compared with a disc with a polymer socket/metal ball for both the 10 and 14 mm sample in axial rotation (Figure 3). At a frequency of 1 Hz (which is the

frequency used for wear testing disc arthroplasty, ISO 18192-1:2008) the frictional torque for the 10 mm radii was 1.49 N.m for the metal socket/polymer ball disc and 0.66 N.m for the polymer socket/metal ball disc. The 14 mm radii had frictional torque values of 2.31 N.m (metal socket/polymer ball) and 1.28 N.m (polymer socket/metal ball). Similar results were also found for lateral bend and extension. The frictional torque in flexion (0° to 6°) was not found to be significantly different between the two different material combinations (Figure 4). However, when the flexion motion was reduced to 0° to 2°, the metal socket/polymer ball was found to be significantly higher than the polymer socket/metal ball (Figure 5). At 1 Hz, the metal socket/polymer ball frictional torque was 2.34 N.m, while the polymer socket/metal ball was 1.39 N.m, for the 10 mm radii; values for the 14 mm radii were 3.21 N.m and 1.78 N.m for the metal socket/polymer ball and polymer socket/metal ball, respectively.

4. Discussion

Current designs of disc arthroplasty with a ball and socket design, have a metal socket articulating against a polymer ball. This is the opposite way round to hip arthroplasty that have a polymer socket articulating against a metal ball. This study compared the friction between disc arthroplasty with metal socket/polymer ball and polymer socket/metal ball articulations. The frictional torques for metal socket/polymer ball devices were found to be significantly higher than frictional torques for polymer socket/metal ball devices in axial rotation, lateral bending and extension. A significant difference was also found in flexion, when the range of motion was limited from 0 to 2°. These findings have implications in the design of TDA, where friction should be minimised to prevent loosening and the generation of wear debris.[11] Future designs of TDA may benefit from having a metal ball articulating against a polymer socket. This study has only investigated one aspect of mechanical testing, namely measuring friction. Further development and testing mechanical testing would be

required to fully investigate the concept, such as undertaking wear testing, to investigate if there were differences in the generation of wear debris between the polymer-on-metal or metal-on-polymer TDA.

The reasons for the difference seen between TDA with a metal socket/polymer ball and a polymer socket/metal ball articulation are likely to be due to deformation of the polymer under load. For the design with a metal socket and a polymer ball, as the load is applied the polymer ball will deform to take up the shape of the metal socket (which has a radius of 10.35 mm or 14.35 mm in this study). For the design with a polymer socket and a metal ball, as the load is applied the polymer socket will deform and take up the shape of the metal ball (which has a radius of 10 mm or 14 mm in this study). The radius for the metal socket/polymer ball combination will be larger than the polymer socket/metal ball and therefore the frictional torques will be higher. The increase in radius from 10 mm to 10.35 mm is 3.5 %, whereas there is an increase of 2.5% going from 14 mm to 14.35 mm. Therefore, a higher relative difference in frictional torque would be expected for the 10 mm radius polymer-on-metal/metal-on-polymer devices, compared with the 14 mm radius devices. The results of this study are consistent with this expectation. Although conventionally friction is assumed to be independent of area, it has been shown for total hip replacement (with a polymer socket and a metal head) that friction coefficient decreases with increasing contact stress.[24] Therefore, for the metal socket/polymer ball device in this study, the contact stress will be low (as the radius is larger) and the friction will be higher.

Regardless of the material combination, the implants with 10 mm ball radius showed lower frictional torque than the implant with 14 mm ball radius. This is in agreement with studies on polymer-on-metal hip implants.[25] For example, Charnley designed a “low friction” hip

implant by reducing femoral head diameter;[13] (similar results were observed by the authors on a study on metal-on-metal TDAs).[26]

5. Conclusions

TDA with a combination of a polymer socket/metal ball has lower friction than conventional total disc arthroplasty that have a metal socket/polymer ball. This finding has implications in the design of TDA since future designs may benefit from this material combination.

Acknowledgments

This work was supported by the Engineering and Physical Sciences Research Council [grant number EP/F014562/1]. The AR-G2 rheometer (TA Instruments, West Sussex, UK) used in this research was obtained, through Birmingham Science City: Innovative Uses for Advanced Materials in the Modern World (West Midlands Centre for Advanced Materials Project 2), with support from Advantage West Midlands (AWM) and part funded by the European Regional Development Fund (ERDF).

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Table 1. Average surface roughness of the samples from 6 measurements

Testing group	Ball radius (mm)	material	specimen	Average roughness Sa (µm) ± standard deviation
A	10	UHMWPE	ball	1.04 ± 0.010
A	10	CoCr	socket	0.05 ± 0.003
A	14	UHMWPE	ball	1.05 ± 0.010
A	14	CoCr	socket	0.05 ± 0.001
B	10	CoCr	ball	0.05 ± 0.001
B	10	UHMWPE	socket	0.94 ± 0.075
B	14	CoCr	ball	0.05 ± 0.002
B	14	UHMWPE	socket	0.96 ± 0.006

Figures

Figure 1. The generic model with polymer socket (top right) on metal ball (top left), and metal socket (bottom left) on polymer ball (bottom right) with 10 mm ball radius

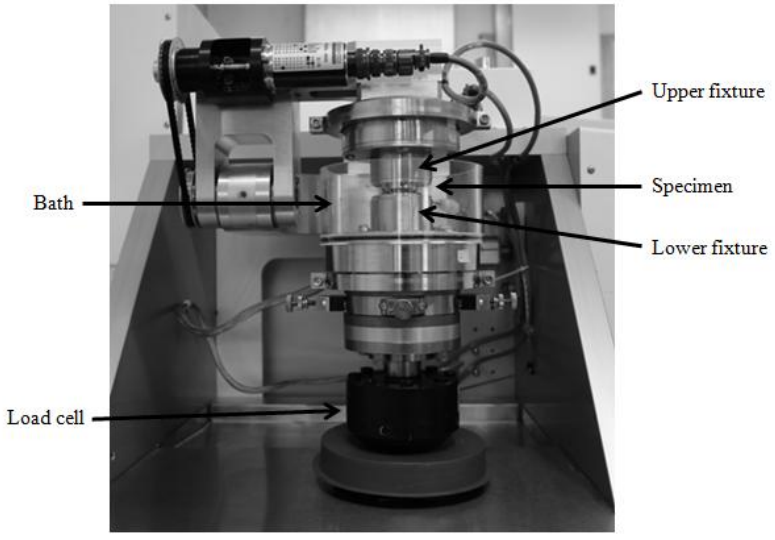

Figure 2. Bose Spine Simulator

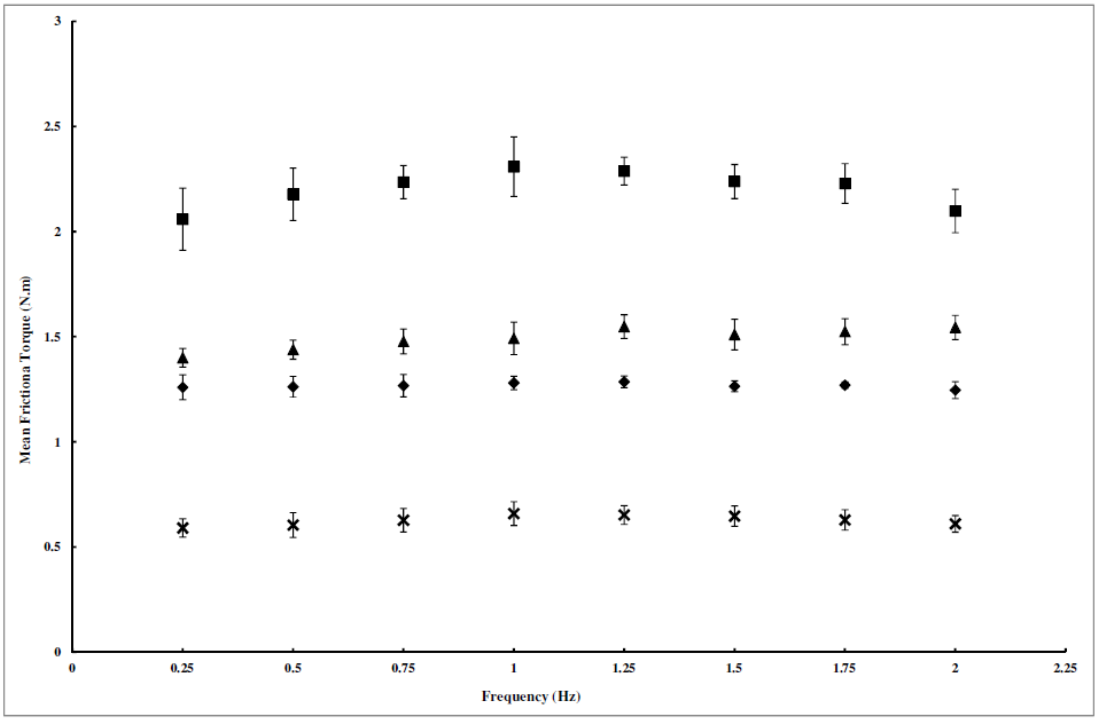

Figure 3. Mean frictional torque plotted against frequency, in axial rotation, for the samples with 10 mm ball radius in polymer socket/metal ball (✕) and metal socket/polymer ball (▲) combination, and samples with 14 mm ball radius in polymer socket/metal ball (◆) and metal socket/polymer ball (■) combination. Error bars represent 95% confidence intervals

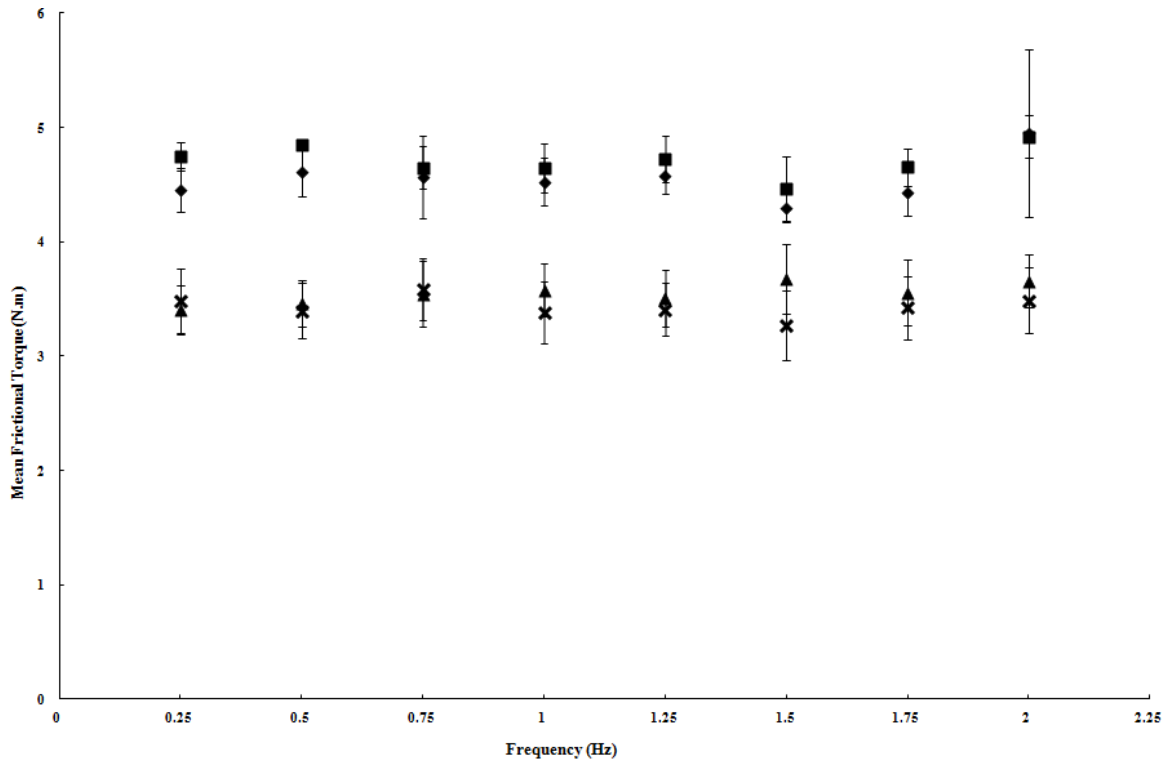

Figure 4. Mean frictional torque plotted against frequency, in flexion between 0° to 6°, for the samples with 10 mm ball radius in polymer socket/metal ball (✕) and metal socket/polymer ball (▲) combination, and samples with 14 mm ball radius in polymer socket/metal ball (◆) and metal socket/polymer ball (■) combination. Error bars represent 95% confidence intervals

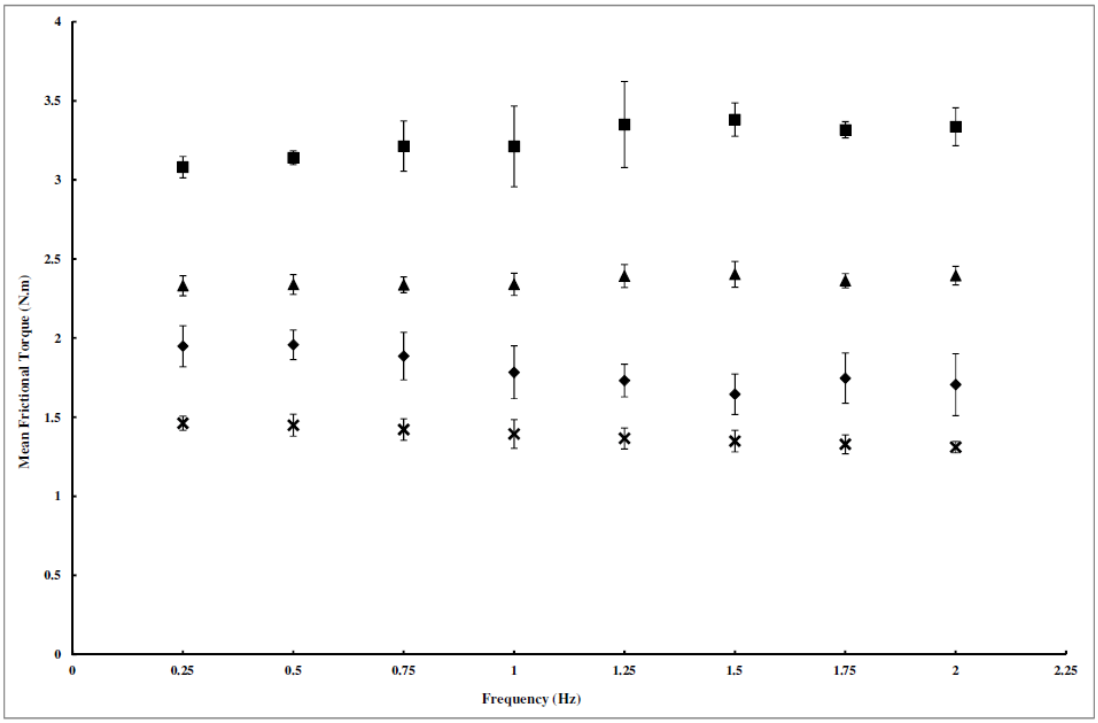

Figure 5. Mean frictional torque plotted against frequency, in flexion between 0° to 2°, for the samples with 10 mm ball radius in polymer socket/metal ball (✕) and metal socket/polymer ball (▲) combination, and samples with 14 mm ball radius in polymer socket/metal ball (◆) and metal socket/polymer ball (■) combination. Error bars represent 95% confidence intervals