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DOI:

[10.1177/0954411912471768](https://doi.org/10.1177/0954411912471768)

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Document Version

Peer reviewed version

Citation for published version (Harvard):

Moghadas, P, Mahomed, A, Hukins, DWL & Shepherd, DET 2013, 'Wear in metal-on-metal total disc arthroplasty', Institution of Mechanical Engineers. Proceedings. Part H: Journal of Engineering in Medicine, vol. 227, no. 4, pp. 356-61. <https://doi.org/10.1177/0954411912471768>

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Wear in metal-on-metal total disc arthroplasty

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Author generated final version. Published as:

Moghadas P, Mahomed A, Hukins DWL & Shepherd DET (2013). Wear in metal-on-metal total disc arthroplasty. *Journal of Engineering in Medicine*. 227: 356–361.

Abstract

The wear of a model metal-on-metal ball-and-socket total disc arthroplasty was measured in a simulator. The ball had a radius of 10 mm and there was a radial clearance between ball and socket of 0.015 mm. The model was subjected to simultaneous flexion-extension, lateral bending, axial rotation (frequency 1 Hz) and compression (frequency 2 Hz, maximum load 2 kN). Throughout the tests, the models were immersed in calf serum diluted to a concentration of 15 g protein per litre, at a controlled temperature of 37°C. Tests were performed on three models. At regular intervals (0, 0.5, 1, 2, 3, 4 and 5 million cycles), mass and surface roughness were determined; mass measurements were converted into the volume lost as a result of wear. All measurements were repeated six times. Wear occurred in two stages. In the first stage (duration about 1 million cycles) there was a linear wear rate of $2.01 \pm 0.04 \text{ mm}^3$ per million cycles; in the second stage there was a linear wear rate of $0.76 \pm 0.02 \text{ mm}^3$ per million cycles. Surface roughness increased linearly in the first million cycles and then continued to increase linearly but more slowly.

Keywords: Ball-and socket; Meta-on-metal; Total disc arthroplasty; Wear.

Introduction

This paper is concerned with wear in Total Disc Arthroplasty (TDA) in which the prosthesis consists of a metal ball articulating within a metal socket. The conventional surgical treatment for severe intervertebral disc degeneration associated with chronic back pain is spinal fusion in which the flexible disc is replaced by a rigid bone graft.¹ However, TDA has recently been introduced to replace the disc while retaining motion at the treated levels.^{1,2-4} There are many designs of TDA in use or being developed; some of them are flexible elastomeric devices intended to mimic the natural disc but the most common are ball-and-socket joints.⁵ Several of these designs are metal-on-metal devices of the kind investigated here; others involve a polymer ball articulating within a metal socket, although laboratory studies indicate that a metal ball in a polymer socket produces lower frictional torques.⁶ Studies on Total Hip Arthroplasty (THA) indicate that the wear rate of metal-on-metal bearing surfaces is less than metal-on-polymer surfaces.⁷⁻¹² There have been two published studies of wear in metal-on-metal TDA.^{4,13}

Recently a study of friction in a metal-on-metal TDA model was published.¹⁴ In this study the effect on ball radius on frictional torque was investigated for a constant radial clearance between ball and socket of 0.015 mm which is the clearance in the MaverickTM (Medtronic, Minneapolis, MN, USA) TDA.¹⁴ Experience from THA suggests that reducing frictional torque is expected to reduce loosening of the TDA from its attachment to the vertebral bodies.¹⁵ In addition, a reduced frictional torque might be expected to lead to less wear. However, there is no simple relationship between frictional torque and wear. The purpose of this study is to measure wear for the same TDA model that was used for previous frictional torque measurements. In this wear study a ball of radius 10 mm was investigated since it has been shown previously to give a low frictional torque.¹⁴

Materials and methods

TDA models

Experiments were performed on a generic ball-and-socket model of TDA manufactured from Co-27Cr-5.5Mo-0.6C by Westley Engineering Ltd. (Birmingham, UK). The ball had a radius of 10 mm and the clearance between ball and socket was 0.015 mm (Figure 1). The models were machined from bar and polished to give an average surface roughness of 49 ± 12 nm for the balls and 48 ± 23 nm for the sockets; these surface roughness values are comparable to those measured for the Maverick™ TDA of 50.0 ± 0.6 nm (see section 2.4 for details). Further details on the design of the model TDA, its manufacture and the surface roughness measurements have been published previously.¹⁴ Before any wear or surface roughness measurements were made, before and during testing, the models were washed with Virkon disinfectant (Antec International, Sudbury, UK; 10 mg powder per litre of tap water), ultrasonically cleaned in propan-2-ol and washed in acetone. All samples were dried and wiped over with low lint clean-room wipes and kept in plastic boxes in room temperature for 48 hours, prior to any measurement.

Lubrication

Throughout the tests the models were immersed in calf serum (SeraLab, West Sussex, UK), diluted with de-ionised water to a concentration of 15 g protein per litre, at a controlled temperature of 37°C. The protein concentration was less than the value (30 g/litre) recommended in the standard for TDA wear testing (BS ISO 18192-1, 2008). The lower concentration complied with the Standard Operating Protocol for Spine Wear Simulator Studies (SPO01.6, Institute for Medical and Biological Engineering, University of Leeds, UK) to enable the results to be compared with their results for metal-on-polymer TDAs. The effect of reducing the protein concentration is to reduce the viscosity and, hence, the lubricity of the lubricant;¹⁶ thus reducing the protein content provides a harsher wear environment and consequently a harsher wear environment and consequently a more stringent test of the performance of the TDA. There is an argument for attempting to mimic the lubricity of interstitial fluid, since it is generally considered to be the lubricant for ball-and-socket

TDA^s.¹⁷⁻¹⁹ However, the exact nature and composition of the fluid lubricating a TDA is not known.¹⁹ Further details on the choice of lubricant, its relationship to interstitial fluid and its effects on mechanical tests are given elsewhere.¹⁹ Sodium azide (Sigma-Aldrich, Gillingham, Dorset, UK) was added (0.3 g/litre) to the diluted calf serum to minimise bacterial contamination.

The viscosity of the lubricant was measured using an AR-G2 cone-on-plate rheometer (TA Instruments, Crawley, West Sussex, UK) at a 0.5% constant strain at 37°C. The result (1.2 ± 0.3 mPa.s) was slightly less than the value (1.4 ± 0.4 mPa.s; Moghadas et al., 2012b) for the more concentrated serum recommended in the TDA wear testing standard.

Wear testing

Wear tests were performed using a Bose SDWS-1 Spine Simulator (Bose Corporation, Minnesota, USA) fitted with a uniaxial load cell that was calibrated every 12 months by the manufacturer. The models were rigidly fixed to the simulator by the method described previously.¹⁴ Tests were performed on three TDA models, which is a similar number used in some previous wear tests^{20,21}. The fluid bath was topped up with diluted calf serum every day. Every 250 thousand testing cycles (i.e. about every 3 days) the test was stopped and the lubricant replaced. Firstly, the lubricant was drained and the fluid bath was washed with household detergent. Then a solution of Virkon disinfectant was added to the bath and left for 2 hours to remove the bio-film. Finally the bath was washed once with tap water and twice with distilled water before being replenished with lubricant.

The testing conditions followed the standard for TDA wear testing.²² Simultaneous, sinusoidal flexion/extension, lateral bending and axial rotation were performed, under angular displacement control at a frequency of 1 Hz. At the same time a sinusoidal axial compression, between a minimum load of 0.6 kN and maximum load of 2 kN, at a frequency of 2 Hz was applied; limits for the angular displacements are given in Table 1. BS ISO

18192-1²² suggests that the test should be performed for 10 million cycles of angular motion. However, it has been shown that the wear rate during THA tests is constant after the first few million cycles.^{23,24} This result and the results obtained in the TDA tests (see below) enabled the tests to be terminated after 5 million cycles. Models were cleaned (section 2.1) and measured at intervals corresponding to 0.5, 1, 2, 3, 4 and 5 million cycles.

Wear measurement

The ball and socket were weighed separately with a precision of 0.2 mg using a laboratory balance (Model GA200D, Ohaus, Norfolk, UK). The total mass loss of each disc arthroplasty was determined from the mass loss of the ball added to the mass loss of the socket. The total volume loss of each disc arthroplasty was then determined by dividing the mass loss by the density of cobalt-chrome alloy¹³ of 8.29 mg.mm⁻³. Each measurement was repeated six times for each of the three samples.

Surface roughness measurements

Surface roughnesses of the ball and socket were measured by a contact method using a stylus profiler (Talysurf 120L, Taylor Hobson Ltd., Leicester, UK), equipped with a diamond-tip stylus. 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- see section 2.4) were performed within that area.; 164 lines of measurement were used to construct a surface profile.

Results were analysed using TalyMap Universal 3.1.8 software (Taylor Hobson Ltd., Leicester, UK). Since the surface roughness was in the range 0.02-1 µm and the stylus had a radius of 2 µm, a profile filter with a cut-off wavelength of 0.25 mm was used to separate roughness from waviness.²⁵ The average roughness, R_a , of each area was determined by the software. Each determination was repeated six times. Since results were closely similar, average R_a values for balls and sockets were determined.

Determination of wear rates

Graphs of mass loss and R_a plotted against the number of wear cycles appeared to consist of two linear segments. To test this hypothesis it was necessary to reject the null hypothesis that the points could be represented by a single straight line. The hypothesis was tested using the F -test.²⁶ One and two lines were fitted to the data points and

$$F = (Q_1 + Q_2)(N - 4)/(2Q_2)$$

was calculated where Q_1 is the sum of the squared deviations for a single line and Q_2 is that for two lines; N is the number of data points. If the calculated F -value exceeds the $F_{2,N-4}$ value at $p = 0.05$, the null hypothesis can be rejected.²⁷ Here $N = 7$ so the null hypothesis can be neglected at the $p < 0.05$ level when $F > 9.55$, according to the form of the F -distribution.²⁶ Whenever this condition was met, wear was represented by two regression lines and a wear rate calculated from the slope of each. For each line segment, the linear correlation coefficient, R , and the probability, p , that this value of R could have arisen by chance, were calculated.²⁸

Results

Figure 2 shows that volume was lost in two stages in the wear process. The initial stage lasted for about 1 million cycles and corresponded to a mean volume loss of 2.01 ± 0.04 mm³ per million cycles (16.6 ± 0.3 mg per million cycles).. In the next stage, volume was lost more slowly at a rate of 0.76 ± 0.02 mm³ per million cycles (6.3 ± 0.2 mg per million cycles).. In both stages the volume loss increases linearly with the number of wear cycles, i.e. with the duration of the test.

Figure 3 shows a slight but significant ($p < 0.05$) increase in surface roughness during the wear process that occurred in two stages. The first stage lasted for about 1 million cycles and corresponded to the steeper increase in roughness. In both stages, the increase in

surface roughness increased linearly with the number of wear cycles. Figure 4 shows the surface topography for an untested surface and after 1 million cycles.

Discussion

The observation of a two-stage wear process is consistent with previous results on TDA and THA. Paré et al.¹³ observed an initial wear period lasting about 0.5 million cycles in a laboratory test of the metal-on-metal A-Mav™ lumbar TDA (Medtronic, Memphis, TN, USA), followed by a second stage in which the rate of wear was reduced. In a study of metal-on-metal THAs, the initial wear rate reduced after about 1 million cycles.⁹ Vassiliou et al.¹² refer to an initial “running –in” period, in their study of metal-on-metal THA, although they do not analyse their results to distinguish different wear stages; they refer to wear rates becoming “progressively lower” with “run-in” periods of about 2 million cycles. Inspection of their results suggests a qualitatively similar dependence of wear on the number of test cycles but with a longer “run-in” period.

Wear rates are also comparable to those reported previously for TDA and THA. In their study of metal-on-metal TDA, Paré et al.¹³ reported a lower initial wear rate ($0.6 \pm 0.1 \text{ mm}^3$ per million cycles) than that reported here ($2.01 \pm 0.04 \text{ mm}^3$ per million cycles). Studies of metal-on-metal THA report wear rates in the range $0.2\text{-}6.3 \text{ mm}^3$ per million cycles^{7,9-11} and so are consistent with the wear rates reported here. Goldsmith et al.⁹ describe a wear process with an initial rate of 0.5 mm^3 per million cycles followed by a slower wear rate of 0.4 mm^3 per million cycles.

It is likely that changes in wear rate are linked to the same changes in surface topography that give rise to the changes in surface roughness shown in Figure 2. The change in surface roughness is linear for the first 1 million cycles and then continues to be linear but at a slower rate. This is exactly the same pattern of behaviour observed for wear rates. The higher wear rate during the initial “running-in” period for TDA and THA is conventionally

attributed to loss of surface asperities.^{12,13,23,24} This has been referred to as a “self-polishing” mechanism.^{29,30} However, our results show a slow, but significant, increase in surface roughness throughout the wear process. Thus the surfaces were not polished smooth. It appears likely that asperities are lost in the initial wear stage so that later stages must involve cutting grooves into the articulating surfaces. This interpretation is consistent with the appearance of wear scars on the surfaces of explanted metal-on-metal TDAs.¹³

The wear is expected with metal-on-metal disc arthroplasty as it has been suggested analytically that they will operate with a boundary lubrication regime¹⁷ and shown experimentally that they operate with a boundary or mixed lubrication regime¹⁴. Therefore, there will be contact between the bearing surfaces.

The disc arthroplasty market is very immature compared with the hip and knee joint replacement market. The ISO standard for testing disc arthroplasty was only first published in 2008²², with some minor revision in 2011, after the work for this study was started.

Therefore, this study has undertaken wear tests in line with the current thinking. As it is a fairly new technology there is no joint registry for it and there are very few published clinical studies and retrieval studies on metal-on-metal disc arthroplasty. A few studies have raised the possibility of issues with metal wear debris from disc arthroplasty³¹⁻³³, but it is too early to determine if the problems may be of the scale seen with some designs of metal-on-metal hip arthroplasty^{34,35}.

Conclusions

Wear of a metal-on-metal model TDA, with a ball radius 10 mm and radial clearance between ball and socket of 0.015 mm, occurred in two stages. In the first stage there was a linear wear rate of $2.01 \pm 0.04 \text{ mm}^3$ per million cycles; in second stage there was a linear wear rate of $0.76 \pm 0.02 \text{ mm}^3$ per million cycles.

Conflict of interest statement

The authors had no conflicts of interest.

Funding

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. Ranges for angular displacements in TDA wear tests

	Minimum	Maximum
Flexion/extension	-3°	6°
Lateral bending	-2°	2°
Axial rotation	-2°	2°

Figures

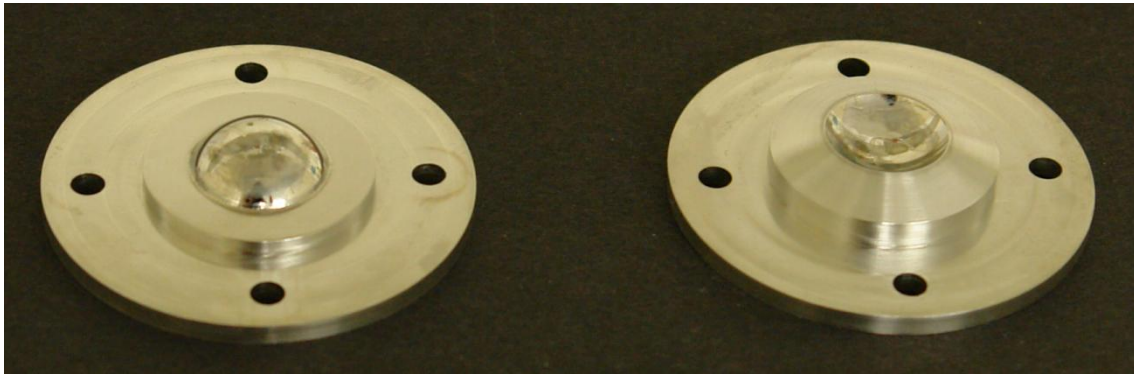


Fig. 1. The generic ball (left) and socket (right) model with 10 mm ball radius

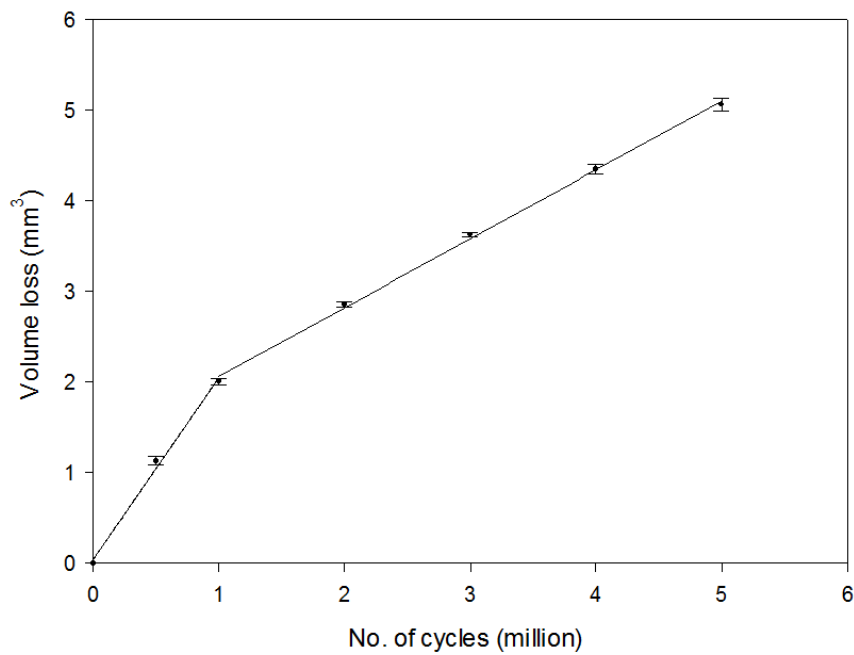


Fig. 2. Mean volume loss for the three disc arthroplasty plotted against the number of wear cycles. Error bars represent standard deviations. A regression line is plotted to represent initial ($R^2 = 0.99$, $p < 0.001$) and second ($R^2 = 0.99$, $p < 0.001$) stages of wear.

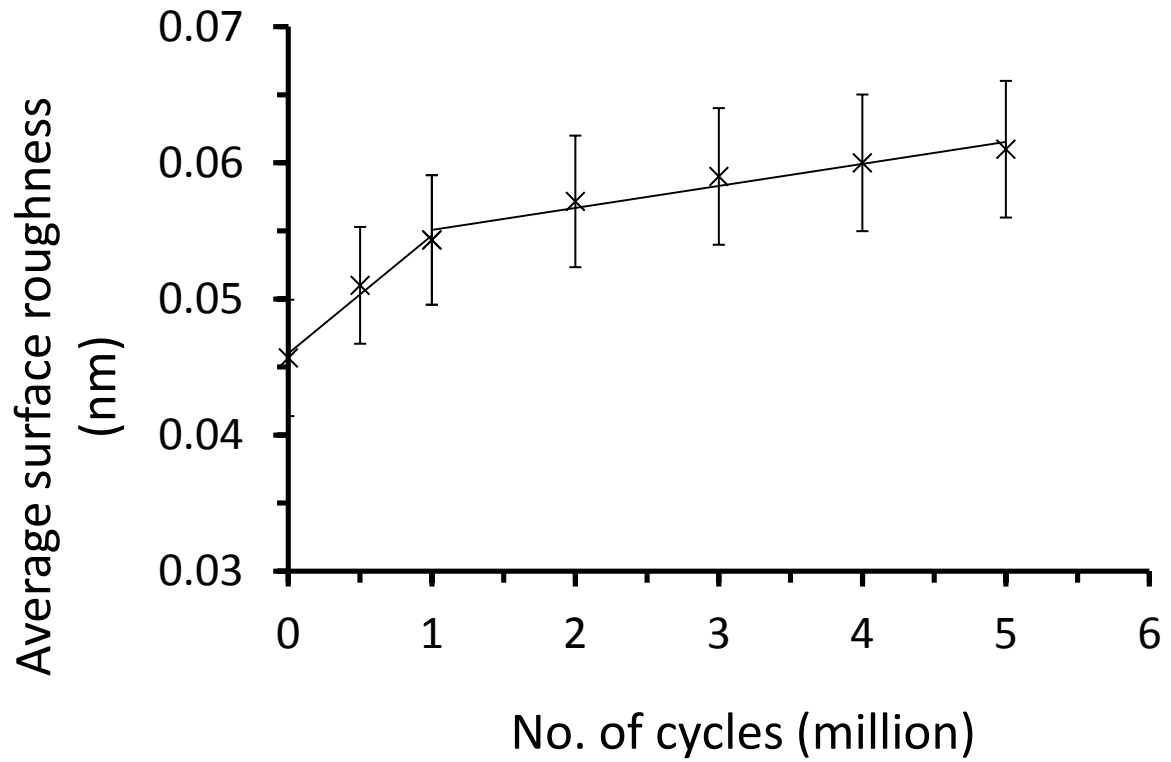


Fig. 3. Mean surface roughness (ball and socket) plotted against number of wear cycles. Error bars represent standard deviations. A regression line is plotted to represent initial ($R^2 = 0.98$, $p < 0.05$) and second ($R^2 = 0.94$, $p < 0.05$) stages of roughening.

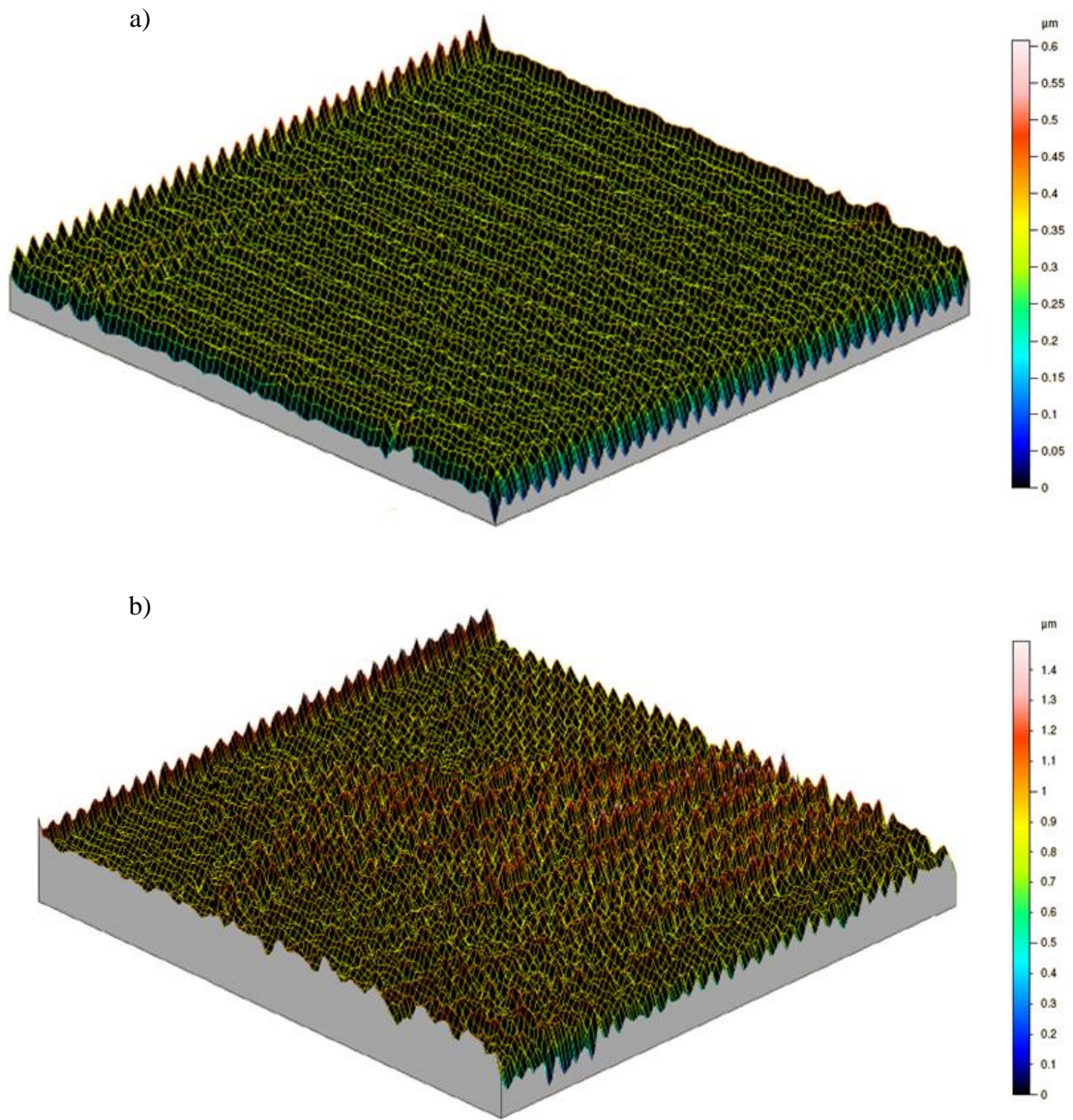


Fig 4. The 3D Taylor Hobson Form Talysurf-120L surface roughness measurement images of a ball sample a) untested; b) after 1 million cycles.