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In vivo evaluation of edge-loading in metal-on-metal hip resurfacing patients with pseudotumours

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Objectives

Pseudotumours (abnormal peri-prosthetic soft-tissue reactions) following metal-on-metal hip resurfacing arthroplasty (MoMHRA) have been associated with elevated metal ion levels, suggesting that excessive wear may occur due to edge-loading of these MoM implants. This study aimed to quantify *in vivo* edge-loading in MoMHRA patients with and without pseudotumours during functional activities.

Methods

The duration and magnitude of edge-loading *in vivo* was quantified during functional activities by combining the dynamic hip joint segment contact force calculated from the three-dimensional (3D) motion analysis system with the 3D reconstruction of orientation of the acetabular component and each patient's specific hip joint centre, based on CT scans.

Results

Edge-loading in the hips with pseudotumours occurred with a four-fold increase in duration and magnitude of force compared with the hips without pseudotumours ($p = 0.02$).

Conclusions

The study provides the first *in vivo* evidence to support that edge-loading is an important mechanism that leads to localised excessive wear (edge-wear), with subsequent elevation of metal ion levels in MoMHRA patients with pseudotumours.

Keywords: Pseudotumours, Edge-loading, *In vivo* evaluation, Metal-on-metal, Hip resurfacing, Metal ions

Article focus

- Quantification of *in vivo* edge-loading in MoMHRA patients with and without pseudotumours during functional activities

component sizes may be limited as the femoral component sizes in the current study are ≤ 50 mm

Key messages

- Edge-loading is an important *in vivo* mechanism that leads to localised excessive wear with subsequent elevation of metal ion levels in MoMHRA patients with pseudotumours
- Although orientation of the acetabular component appears to be an important factor in edge-loading, the aetiology of edge-loading is likely to be multifactorial

Strengths and limitations

- This is the first study to provide *in vivo* evidence of edge-loading in MoMHRA patients
- Generalisation of the current study findings to MoMHRA with larger femoral

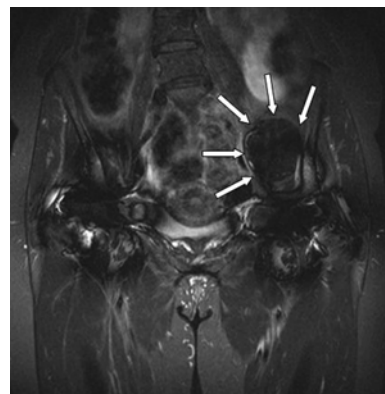
Introduction

Despite the encouraging short-term clinical follow-up studies of metal-on-metal hip resurfacing arthroplasty (MoMHRA),¹⁻³ recent reports of abnormal peri-prosthetic soft-tissue reactions are causing concerns.⁴⁻¹⁰ These so-called soft-tissue pseudotumours,⁹ defined as non-infected solid and/or cystic soft-tissue mass in patients with MoMHRA,¹¹ have been associated with elevated serum and hip aspirate levels of cobalt (Co) and chromium (Cr), the principal elements in the CoCr alloy used in MoMHRA implants.^{9,12,13} As metal-on-metal (MoM) implant wear has been reported to be positively correlated with the elevation of metal ion concentrations *in vivo*,¹⁴ this suggests that pseudotumours in patients with contemporary

Table I. Summary of study patient groups

Characteristic	Pseudotumour	Non-pseudotumour
Patients	6	15
Hips	9	24
Male	1 (1 bilateral)	3 (3 bilateral)
Female	5 (2 bilateral)	12 (6 bilateral)
Mean age (yrs) (range)	55 (44 to 58)	56 (46 to 60)
Implant type*		
BHR	7	18
Conserve Plus	2	6
Median femoral component size (mm) (range)	45 (44 to 50)	46 (46 to 50)
Mean time since surgery (mths) (range)	60 (36 to 79)	64 (32 to 88)
Surgical approach	Posterior	Posterior

* BHR, Birmingham Hip Resurfacing (Smith & Nephew); Conserve Plus (Wright Medical Technology)

**Fig. 1**

Coronal Short TI Inversion Recovery (STIR) MRI image of a typical example of predominantly solid pseudotumour with low signal intensity (arrows).

MoMHRA implants are associated with increased wear at the MoM articulation.

Recently, the maximum wear of the MoMHRA acetabular components revised due to pseudotumour has been observed to occur near the edge of the implant, indicating edge-loading.¹⁵ Although retrieval studies provide valuable information, these studies are limited by the fact that the implants were retrieved as a result of failure, with inevitable selection bias. This selection bias excludes examination of well-functioning implants or implants prior to failure. The extrapolation of *in vitro* retrieval study results to *in vivo* conclusions may therefore not always be appropriate.

In order to determine if there is edge-loading *in vivo*, it is necessary to determine where the hip joint reaction force passes through the acetabular component. If the resultant hip joint force were directed near the edge of the acetabular component, edge-loading would be indicated. Measuring *in vivo* hip joint forces in patients with implants *in situ* during functional activities, however, presents numerous difficulties. Researchers have utilised both instrumented total hip prostheses with in-built force transducers¹⁶⁻¹⁹ and mathematical modelling²⁰⁻²³ in order to measure or predict *in vivo* resultant forces across the hip joint. Video fluoroscopy has been used to determine the *in vivo* kinematics of the hip joint.^{24,25} More recently, a combination of the computed tomography (CT) and three-dimensional (3D) lower limb motion capture data has been used to determine the *in vivo* hip contact force vector with the acetabular component in MoMHRA patients during functional activities such as walking and stair descent.²⁶ However, the incidence, duration and magnitude of edge-loading during functional activities have not been previously quantified.

The aim of this study was to assess whether edge-loading occurs in MoMHRA patients with and without pseudotumours by quantifying the *in vivo* resultant hip joint segment force relative to the acetabular component (force path) during functional activities.

Patients and Methods

The duration and magnitude of edge-loading *in vivo* was quantified during functional activities by integrating the dynamic hip joint segment contact force calculated from the 3D motion analysis system with the 3D reconstruction of orientation of the acetabular component based on the CT scan, as recently described by Mellon et al.²⁶

Patient selection. A total of 21 patients (33 hips) were investigated in this study, which received local research ethics committee approval. The patients were divided into two groups (Table I): Group 1 – MoMHRA patients with pseudotumours (abnormal soft-tissue reactions with or without cystic elements) confirmed with MRI (six patients (nine hips)); the three patients with bilateral implants in this group were found to have pseudotumours in both hips (Fig. 1); and Group 2 (control) – patients with well-functioning MoMHRA implants without pseudotumours (15 patients (24 hips)). These patients were recruited from a population of patients who had participated in a MoMHRA surveillance study at the authors' institution,¹³ as screening hip ultrasound/MRI scans had been performed in these patients to detect the presence of pseudotumours. Those patients with pseudotumours were invited first, and the invitation to other patients among the total population was subsequently based on matching approximately two individuals from the control group to one from the pseudotumour group with respect to gender, age, size of the femoral component and time since surgery. Exclusion criteria included the presence of significant pain or impairment which would restrict walking, stair climbing, or sitting onto or rising from a chair. This was to ensure that patients in the study were able to perform these functional activities for the motion analysis study.

3D lower limb motion analysis. Markers were attached on specific anatomical landmarks in accordance with the

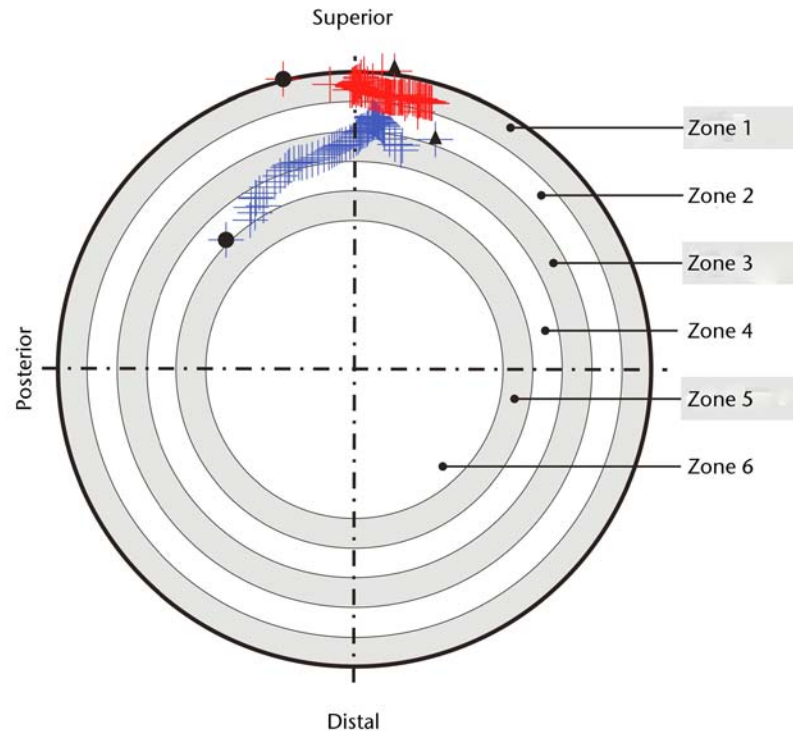


Fig. 2

Diagram showing force paths projected on the acetabular component viewed in the direction through the centre of the component. The inner bearing surface was divided into concentric zones defined in 10% increments of the component face radius, with the zone at the edge designated as zone 1. In hip A (in blue), the force path does not enter the outer most radial zone (zone 1), thus no edge-loading is observed. In hip B (in red), during walking, the force path enters the outer most radial zone (zone 1), indicating edge-loading. The black circles (●) indicate force path at heelstrike and the black triangles (▲) indicate force path locus at toe-off.

Plug-In-Gait lower body marker set.²⁷ Data was captured using a 12-camera Vicon Nexus Motion Analysis System (Oxford Metrics Ltd, Oxford, United Kingdom) operating at a video capture rate of 100 Hz and two floor-embedded force platforms (Advanced Medical Technology Inc., Watertown, Massachusetts) with an analogue data capture rate of 1000 Hz, while patients performed functional activities (level walking, rising from and sitting down onto a chair, and stair climbing). Data processing was performed with commercially available software (BodyBuilder) (Vicon Motion Systems; Oxford Metrics., Oxford, United Kingdom) using the Plug-In-Gait model (Version 1.9) with customisation of the model on a patient-specific basis to account for individual hip joint centre location determined using CT data. Inter-segmental hip joint force and moments were calculated in a sequential process using a well-established inverse dynamics method.²⁷

CT scans. CT scans of the patients' pelvis and lower limbs were obtained using a high-resolution 64-slice CT scanner (Siemens Somatom; Siemens Medical Solutions USA Inc., New York, New York) with metal artifact reduction sequence. In order to ensure that the pelvic coordinate system in the motion analysis system (defined by three

pelvic markers) could also be defined within CT data, the pelvic motion analysis markers were replaced with radio-opaque markers at the end of the motion analysis, prior to CT scanning. The medical imaging software package SliceOmatic v.4.2 (Virtual Magic Inc., Montreal, Canada) was used to locate the coordinates of multi-modality markers, anatomical pelvic landmarks and to determine orientation of MoMHRA acetabular components (relative to the anterior pelvic plane defined by anterior superior iliac spines and pubic tubercle) within the CT images. The location of the patient-specific hip joint centre in each resurfaced hip was determined by extracting the 3D coordinates of a minimum of 30 points distributed over the head of the femoral and the acetabular components. **Definition of edge-loading.** Edge-loading was defined to occur when the 'force path' (the locus of the force vector intersection with the acetabular component throughout the load bearing) was within a distance $\leq 10\%$ of the radius from the edge of the component (i.e. the zone at the edge of the acetabular component designated as zone 1) (Fig. 2). The figure of 10% was based on observations of edge-wear scars from a previously reported MoMHRA retrieval study.¹⁵

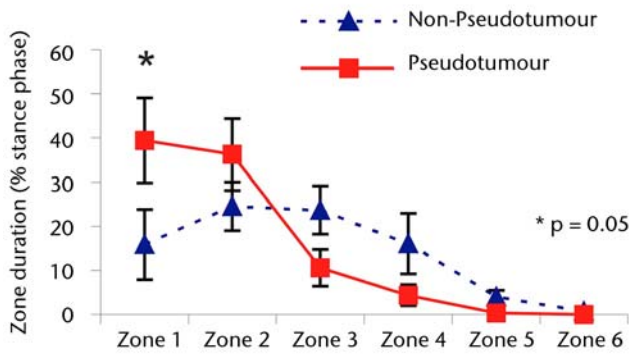


Fig. 3a

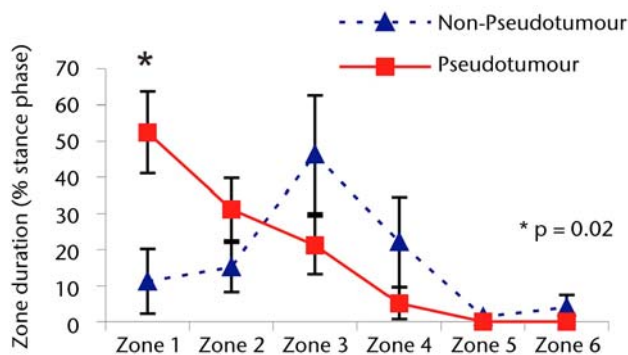


Fig. 3b

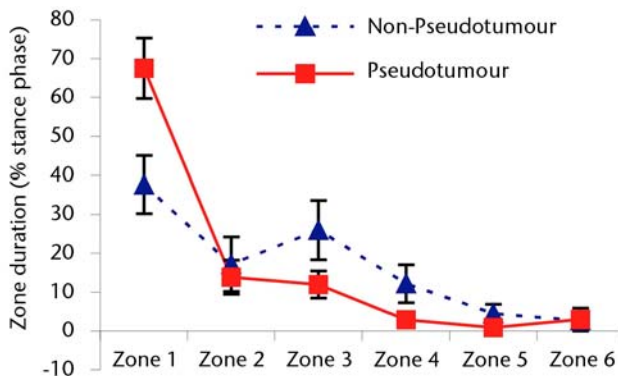


Fig. 3c

Graphs showing the distribution of 'zone duration' (the percentage of total stance time spent by the force path in each zone) during a) walking, b) stair climbing and c) rising from a chair. Zone 1 is defined as the edge-loading zone. The error bars represent standard errors of mean. An asterisk (*) indicates significant difference between the two MoMHRA patient groups.

Serum metal ion analysis. The venous blood samples were collected from all patients in the study in accordance with the consensus protocol.²⁸ Serum Co and Cr levels were analysed in a blinded fashion using Inductively-Coupled Plasma Mass Spectroscopy (ICP-MS). The detection limit of Co and Cr in serum was 0.25 µg/l.

Statistical analysis. The data set was assessed for normality. Inter-group comparisons of the zone duration and the force impulse variables between the hips in groups 1 and 2 were performed using the Student's *t*-test. Inter-group comparisons of the angles of the acetabular components and serum metal ion levels were performed using the Mann-Whitney non-parametric tests. Differences at $p < 0.05$ were considered to be significant. SPSS statistical software release 13.0 (SPSS Inc., Chicago, Illinois) was used to perform the statistical analyses.

Results

Of the 21 MoMHRA patients analysed, data from two patients (three hips) in the control group were excluded due to loss of the sacrum marker during motion analysis in one patient and movement artefact in the CT images in the other. Thus, complete data from 30 hips (nine hips with pseudotumours in six patients in group 1; and 21 hips without pseudotumours in 13 patients in group 2) were available for analysis.

Edge-loading. During walking, edge-loading (predominantly superiorly at the 12 o'clock position) was observed in all nine hips (100%) in the pseudotumour group compared with five of 21 hips (24%) in the group without pseudotumours. However, during more strenuous activities of daily living, such as rising from a chair and stair climbing, edge-loading (predominantly posteriorly at the 10 o'clock position) was observed in all hips in both groups. Representative force path plots for non-edge-loading and edge-loading hips during walking are shown in Figure 2.

Zone duration of force paths. Although edge-loading occurred in all hips in both groups, the distribution of the time spent by the force path in each zone differed significantly. During the stance phase of walking, the mean duration of force path in zone 1 (edge-loading zone) was greater in the hips with pseudotumours (39% of the stance phase) compared with those without pseudotumours (39% *versus* 15% of the stance phase; $p = 0.05$).

The differences in zone duration between the groups were activity-dependent (Fig. 3). During stair climbing, the differences were accentuated. There was a statistically significant four-fold increase in the mean edge-loading zone duration in the hips in the pseudotumour group compared with those in the non-pseudotumour group (51% *versus* 11% of the stance phase; $p = 0.02$). This indicated that the edge-loading lasted for five times as long in the hips with pseudotumours compared with those without during stair climbing activity. The overall trend in zone duration between stair ascent and descent was similar in both groups.

The differences between the two groups were less pronounced during rising from and sitting down to a chair (Fig. 3). In fact, the highest zone duration occurred in the edge-loading zone for both groups, suggesting that, in terms of edge-loading, rising from and sitting down to a

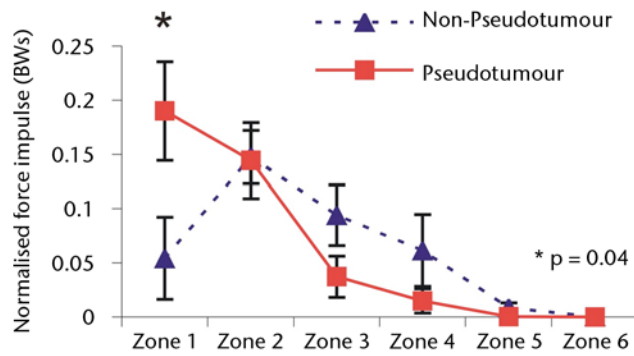


Fig. 4a

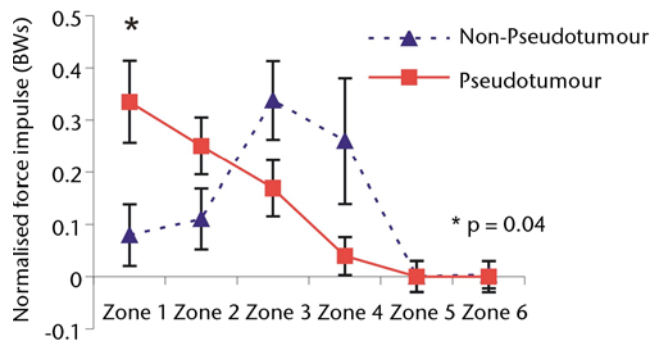


Fig. 4b

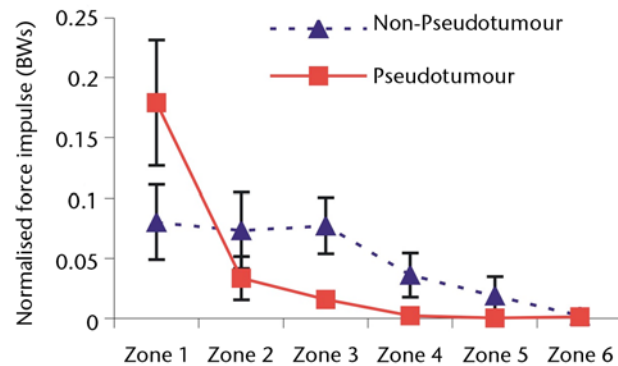


Fig. 4c

Graphs showing the distribution of normalised hip joint 'force impulse' (the cumulative magnitude of the segment force throughout activity over time estimated by calculating the area under the force/time curve normalised to patient body weight) in each zone during a) walking, b) stair climbing and c) rising from a chair. Zone 1 is defined as the edge-loading zone. The error bars represent standard errors of mean. An asterisk (*) indicates significant difference between the two MoMHRA patient groups.

chair was the most provocative activity in the hips without pseudotumours. There was no significant difference in time duration spent in the edge-loading zone between the hips with and without pseudotumours during this activity ($p = 0.15$).

Force impulse distribution of force paths. Overall, a similar trend was observed with force impulse distribution of

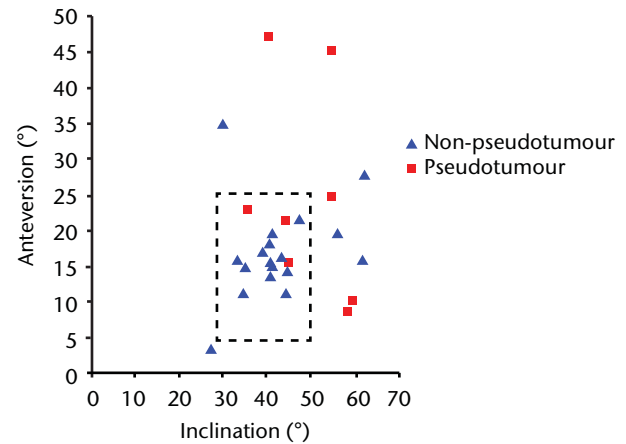


Fig. 5

Scatter graph showing the angles of inclination and anteversion of the acetabular component for the pseudotumour group (9 hips in 6 patients) and the non-pseudotumour group (21 hips in 13 patients). Lewinnek's safe zone²⁹ is outlined by the dotted rectangle.

force paths as seen with zone duration (Fig. 4). During stair climbing, there was a significant four-fold increase in the value of normalised force impulse located in the edge-loading zone in the hips with pseudotumours compared with the hips without ($p = 0.04$). This indicated that edge-loading occurred with four times greater force impulse in the hips with pseudotumours than the hips without for each stair climbing cycle.

Orientation of the acetabular component. The hips with pseudotumours were associated with a higher median inclination angle of the acetabular component compared with those without (52.0° (35.5° to 60.7°) versus 45.1° (27.5° to 62.0°), $p = 0.10$), higher anteversion angle (21.2° (8.8° to 47.0°) versus 16.0° (3.4° to 35.0°), $p = 0.18$) and significantly higher median combined inclination and anteversion angle (75.6° (58.4° to 100.0°) versus 58.75° (30.1° to 90.0°), $p = 0.04$).

Of the 21 hips without pseudotumours, 16 (76%) had inclination and anteversion angles within the safe zone of Lewinnek²⁹ (Fig. 5). In comparison, only three of the nine hips with pseudotumours (33%) had their orientation angles within the safe zone.

Serum metal ion levels. The patients with a pseudotumour had significantly higher median serum Co levels compared with the patients without ($14.3 \mu\text{g/l}$ (10.6 to 64.1) versus $1.9 \mu\text{g/l}$ (1.2 to 5.0), $p < 0.001$) and Cr levels ($21.2 \mu\text{g/l}$ (13.8 to 45.2) versus $1.8 \mu\text{g/l}$ (0.7 to 7.6), $p < 0.001$) (Fig. 6).

Discussion

Although previous retrieval studies have reported edge-loading as a mechanism that leads to increased wear in MoMHRA implants,^{14,15,30-32} this study integrating dynamic motion analysis with CT data is the first to quan-

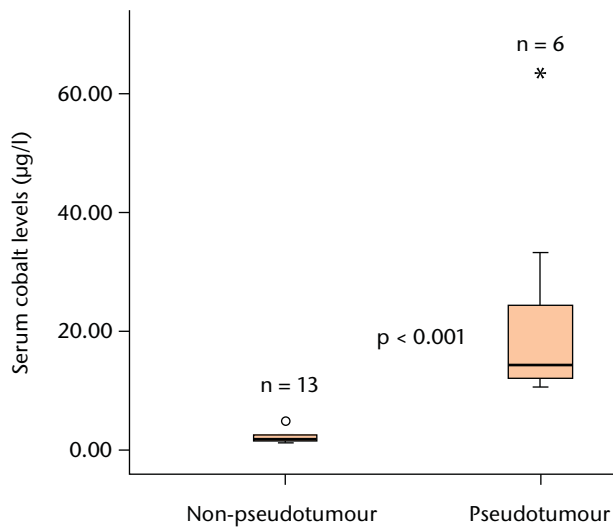


Fig. 6a

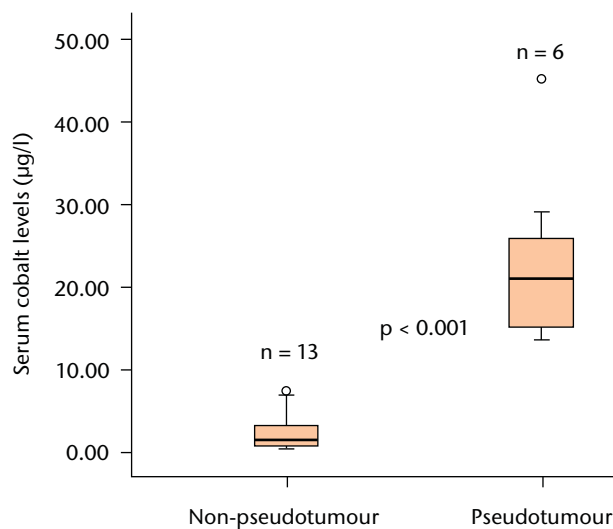


Fig. 6b

Boxplots showing the median serum cobalt (Co) (a) and chromium (Cr) (b) level measurements in the six patients with pseudotumour and the 13 patients without. The boxes represent the median and interquartile range, and the whiskers denote the range of data excluding outliers (*, between 1.5 and 3×IQR) and extremes (*, > 3×IQR).

tify duration and magnitude of edge-loading *in vivo* during functional activities in MoMHRA patients. The observation of edge-loading in patients with well-functioning MoMHRA in the current study has not been previously reported; however, similar findings have been reported with the multi-directional *in vivo* wear paths measured in patients with metal-on-polyethylene total hip replacement.³³ In this study by Bennett et al,³³ the 3D loci of points on the acetabular component over which the femoral component moved, clearly demonstrated that the wear path extended over the edge of the acetabular component during level walking. Furthermore,

in vivo studies using video fluoroscopy have reported that edge-loading with heelstrike can occur during normal walking due to microseparation in metal-on-metal hip bearings.^{24,25}

While edge-loading occurred in MoMHRA hips both with and without pseudotumours during functional activities, the distribution of 'time duration' and 'force magnitude' differed significantly. Edge-loading in the hips with pseudotumours occurred when significantly greater magnitudes of force impulse were experienced near the edge of the acetabular component for a significantly longer period of time. The significant differences in time and force impulse distribution of force paths in the edge-loading zone were activity-dependent, with proportionally greater difference observed during stair climbing. During a 12-hour period, it has been reported that patients with total hip arthroplasty perform 42 cycles of stair climbing, with estimates of 15 000 cycles per year.^{34,35} These significant increases in time and force impulse distribution of force paths in the edge-loading zone during more strenuous activities of daily living may be important factors responsible for increased wear in MoMHRA patients with pseudotumours. It may be hypothesised that there is a cumulative threshold of contact stress that must be exceeded by repeated episodes of edge-loading before resulting in significant localised excessive wear (edge-wear). Therefore, edge-loading can be a 'benign' process that occurs during activities of daily living in patients with well-functioning MoMHRA. However, once the contact stress generated by edge-loading exceeds the tolerance of the MoM bearing due to increase in frequency, duration and/or magnitude of contact force, a vicious cycle of wear may ensue that leads to edge-wear scars reported in retrieval study of MoMHRA implants revised due to pseudotumours.¹⁵ Thus, the *in vivo* observation of edge-loading with significantly increased duration and magnitude of force impulse may, in part, explain significantly elevated serum metal levels in the pseudotumour patient group. In fact, no patient in the pseudotumour group had 'normal' median serum and aspirate levels of Co and Cr ions reported in well-functioning MoMHRA.³⁶⁻³⁹

Retrieval studies of MoM prostheses have reported that acetabular components with high inclination angles demonstrate increased wear secondary to edge loading.^{31,40} In addition, increased risk of pseudotumour formation has been correlated with steep positioning of the acetabular component in MoMHRA patients.^{30,41} In the current study, there was a trend towards patients in the pseudotumour group having a steeper acetabular component, although the difference was not statistically significant ($p = 0.10$). Increased anteversion combined with increased inclination has also been reported to be associated with elevated concentration of metal ions.⁴² Increases in anteversion and inclination have been suggested to decrease cover of the femoral component by

the acetabular component, thus decreasing the area for generation of fluid-film lubrication. This is consistent with the current study's finding that the patients with pseudotumours, who had significantly elevated metal ion levels compared with the patients without pseudotumours, were found to have a significantly greater median combined inclination and anteversion angle (75.6° versus 58.75° , $p = 0.04$), with 67% (six of nine) of acetabular components found outside the safe zone of Lewinnek.²⁹

Although explained in part by the orientation of the acetabular component, the aetiology of edge-loading is likely to be multifactorial. Edge-loading was observed in all hips, including those with acetabular components within the safe zone of Lewinnek.²⁹ This indicates that there may be other important causative factors. These may include implant, patient and surgical factors. Different implant designs may influence safe inclination and anteversion angles of the component. Implants with a greater angle subtended by the acetabular component would shift the loci of hip joint force vector away from the edge for any given orientation by providing more cover. Although the implants in the pseudotumour group were predominantly Birmingham Hip Resurfacing systems (BHR; Smith & Nephew, Memphis, Tennessee) (seven of nine, 78%), which have a lower included angle than the Conserve Plus (Wright Medical Technology, Memphis, Tennessee) implants, the number of implants in this study was too small to detect any difference. Moreover, the optimal implant orientation may also be different for each individual patient due to variables such as bony anatomy.

The results of this study need to be considered in light of the potential limitations. First, a resultant hip joint segment force measured in this study is a computational quantity derived from combined measurement of body position and simultaneous measurement of ground reaction force, representing the sum of hip joint reaction forces and muscle forces. As such, hip joint segment force does not provide any specific information in terms of muscle activation nor account for the stress on the MoMHRA implants at the articulation. However, the focus of the study was on the comparative differences between the two patient groups. Secondly, the sizes of the femoral component in the well-functioning MoMHRA group in the current study were ≤ 50 mm, which were deliberately matched to the small sizes in the pseudotumour group. Thus, any generalisation of the current study findings to MoMHRA with larger femoral component sizes should be done with caution. Lastly, the power of the study may be low due to small sample sizes. The sample size of the pseudotumour group was limited clinically by the number of patients with MRI confirmed diagnosis from the on-going clinical study. However, the selection of the control group was carefully matched for gender, age, femoral component size and time since index surgery, in order to minimise the potential confounding factors. Despite the small number of patients, the trends observed were consistent and significant differences were found.

In conclusion, edge-loading in MoMHRA hips with pseudotumours occurred *in vivo* with significantly longer duration and greater magnitude of force compared to the MoMHRA hips without pseudotumours during activities of daily living. The results of this study, therefore, provide the first *in vivo* evidence to support that edge-loading is an important mechanism that leads to localised excessive wear, with subsequent elevation of metal ion levels in MoMHRA patients with pseudotumours. Although orientation of the acetabular component appears to be an important factor in edge-loading, the aetiology of edge-loading is likely to be multi-factorial. Further research is required to elucidate the relative importance of implant, patient, and surgical factors that lead to edge-loading in order to minimise the occurrence of such an adverse clinical outcome and to ensure long-term implant survivorship.

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- Y-M. Kwon: Study design, Data collection, Data analysis, Manuscript writing
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- P. Monk: Data collection
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ICMJE Conflict of Interest:

- None declared

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