A novel method to measure rim deformation in UHMWPE acetabular liners

Susan Partridge[1*], Paige Buckley[1], Greg de Boer[1], Sophie Williams[1]

1. School of Mechanical Engineering, University of Leeds, LS2 9JT, UK

*corresponding author (s.partridge@leeds.ac.uk)

Abstract

Fluoroscopy studies of total hip replacement (THR) have shown that the femoral head and acetabular cup can separate *in vivo,* causing edge loading on the rim of the cup. Pre-clinical testing of THR involves ISO standard motion and loading parameters that are representative of a standard walking gait. However, a requirement for more robust testing of THR has been identified and protocols for edge loading in hip simulators have been developed. This technical note describes a method to measure rim wear and deformation on ultra-high molecular weight polyethylene acetabular liners using 2D contacting profilometry and Matlab® analysis. The method is demonstrated on liners that have been subjected to edge loading in hip simulator tests and that have been retrieved at revision surgery. A quantitative and qualitative evaluation of the rim deformation was performed with good repeatability using the method.

1. Introduction

Fluoroscopy studies of total hip replacement (THR) have shown that the femoral head and acetabular cup can separate *in vivo,* causing edge loading on the rim of the cup [1–3]. It is thought that this may be caused by sub-optimal component positioning, such as a steeply inclined cup or unmatched centres of rotation of the head and cup, or by joint laxity or lever-out following femoral neck impingement [4–8]. Pre-clinical testing of THR involves ISO standard motion and loading parameters that are representative of a standard walking gait [9]. However, a requirement for more robust testing of THR has been identified [10] and protocols for edge loading in hip simulators have been developed [11].

Rim wear, cracking, fracture and liner dissociation have been reported in retrieved ultra-high molecular weight polyethylene (UHMWPE) acetabular liners and edge loading may be implicated in these failures [12–22]. Edge loading is of particular concern where material degradation or reduced mechanical properties exist, as in the case of oxidised or highly crosslinked UHMWPE [23–26] . Rim damage observed clinically can also be the result of impingement [27,28].

Geometric measurement of acetabular rim deformation may provide important information relating to the prevalence, location, severity and mechanism of *in vivo* rim deformation. This would contribute to our understanding of the effects of edge loading on UHMWPE liners and allows evaluation of the clinical relevance of current simulator edge loading protocols.

Existing geometrical methods to measure wear in acetabular cups often focus on the bearing surface and don't accurately measure geometrical changes high up on the rim or on a chamfered region of the liner [29–32].

This study describes and evaluates a novel method for two dimensional quantitative and qualitative evaluation of rim deformation on UHMWPE acetabular liners.

2. Materials and Methods

2.1. Materials

This study measured UHMWPE acetabular liners of one design (Pinnacle®, DePuy Synthes, UK), which comprised a flat horizontal rim region and a chamfered rim region (Figure 1). The liner was designed to be press fit using a taper lock into a titanium shell with anti-rotation device (ARD) tabs that mated with scallops in the titanium shell at 60˚ intervals.

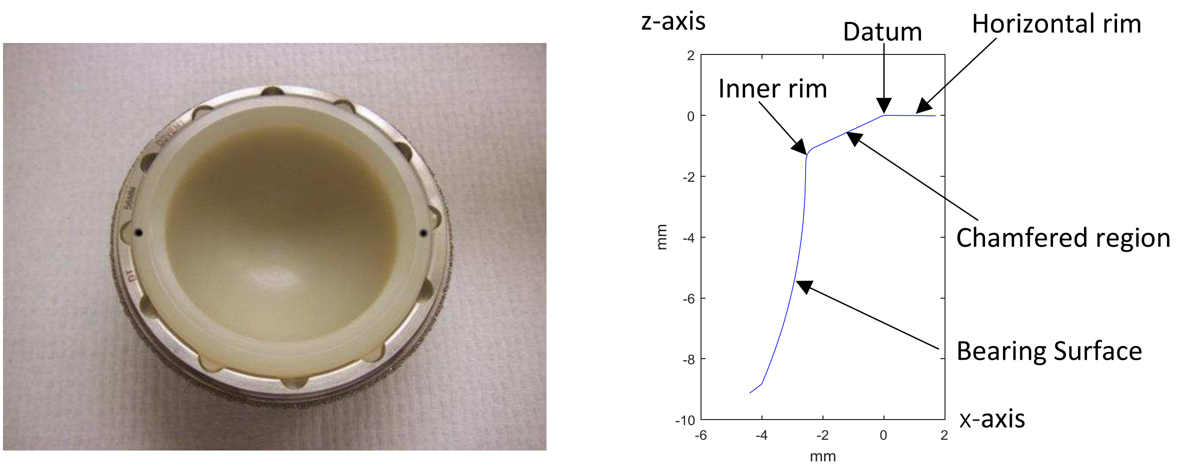

Figure 1 Image of a 36mm Pinnacle UHMWPE liner in a titanium shell (left) and a schematic of a cross-sectional unworn rim profile with the nomenclature used in this study (right)

The liners had either been hip simulator tested under edge loading conditions for 5Mc (simulator samples), as described in a previous study [11] or were retrieved at revision surgery (explants; NHS Ethical approval 09/H1307/60). Four liners were randomly selected from a larger collection of explants to demonstrate the method. Neutral Pinnacle liners with no visible damage on the horizontal rim were selected. The simulator liners were all 36mm inner diameter and 56mm outer diameter and were either cross-linked Marathon® UHMWPE (XLPE) liners or Gamma Vacuum Foil® UHMWPE liners that had been aged at 70°C and 75psi for 14 days in oxygen (aged PE). The explants were various diameters and were either crosslinked or conventional (non-crosslinked) UHMWPE liners. An untested XLPE liner was measured to determine the sensitivity of the method. Summary details of the liners used to evaluate the rim measurement method are provided in Table 1.

Table 1 Details of the UHMWPE liners that were used to evaluate the rim deformation measurement method

Sub group	**Inner Ø (mm)**	**Outer Ø (mm)**	**Material (UHMWPE)**	**Loading Conditions/Time in vivo (months)**	**N**
Control sample XLPE	36	56	XLPE	Untested	1
Simulator sample XLPE	36	56	XLPE	5 million cycles (Mc) of edge loading	4
Simulator sample aged PE	36	56	Aged PE	5Mc edge loading	4
Explanted neutral Pinnacle® Liners	28	Range: 50-56	UHMWPE: crosslinked & non-crosslinked	Time *in vivo* range: 47-101 Revised for various reasons	4

2.2. Measurement procedure

Measurements were performed using a contacting profilometer (Talysurf 120L, Taylor Hobson, Leicester, UK) with a 2µm recessed conical diamond stylus and a contact force of 1mN. A fixture was designed to allow measurement and alignment of a range of liner diameters, rotation of the liners at 10˚ intervals and inclination of the liners to 45˚ (Figure 2: left). Inclination of the liner prevented 'shanking out' of the stylus when taking measurements. The face of the liner was flush with the fixture so that a 45˚ degree angle was maintained when the liner was rotated, preventing tilting of the liner and ensuring a radial trace orientation with respect to the centre of rotation (COR) of the liner. For the simulator samples, five profilometry traces of 9mm length were taken at 10˚ intervals across the worn region of the rim (worn traces) and five across the unworn region of the rim (unworn traces; Figure 2: right). The centre trace on the unworn region of the rim was selected as a reference trace to which all other traces were compared. For the untested liners, the traces were taken in the same way but both regions were unworn. For the explants, where the orientation *in vivo* was unknown, 12 traces at 30˚ intervals were taken around the circumference of the liner. Data points were taken at intervals of 0.25µm for all liners. The raw data (x and z coordinates of each trace) were exported for analysis.

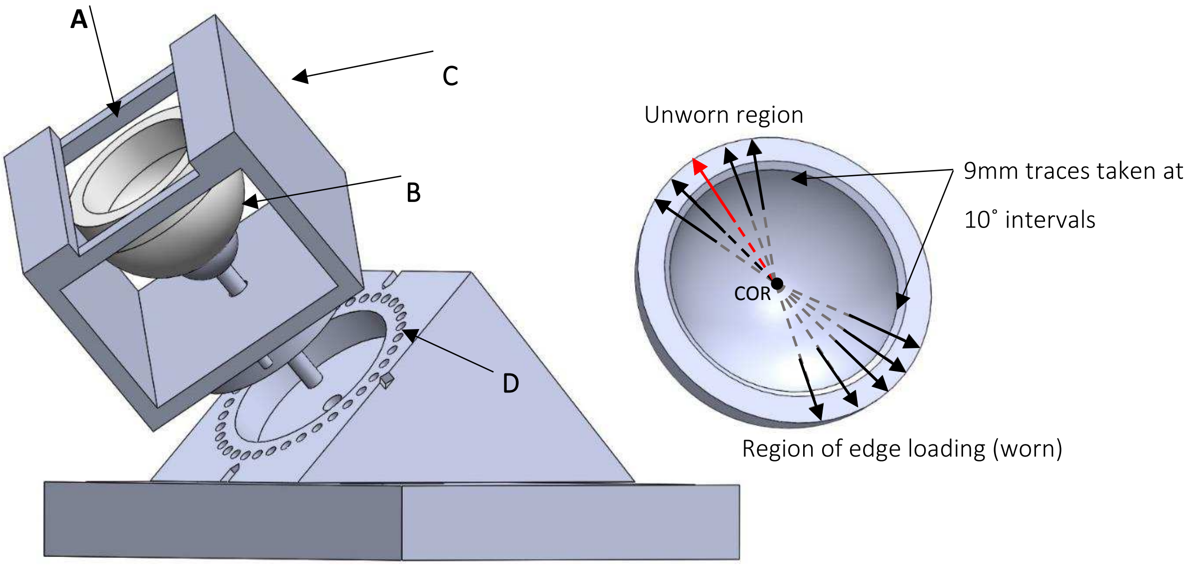

Figure 2 (left): Schematic (Solidworks®, Dassault Systèmes, USA) of the fixture used to take the rim profile traces: (A) the liner was held in place by (B) a stem that pushed the liner against the flat face of the cup holder using a spring (not shown), (C) the cup holder was inclined at 45˚ to prevent 'shanking out' of the stylus and (D) a series of holes at 10˚ intervals that mated with pegs on the cup holder were used to allow rotation of the cup holder without removing the liner between traces and Figure 2 (right) Schematic of a simulator tested acetabular liner showing the locations of the five rim profile traces taken at 10˚ intervals across the worn, edge loaded region of the liner rim and five traces taken across unworn region of the liner. The reference trace is highlighted in red. The trace length was 9mm and was taken perfectly radial with the centre of rotation of the cup.

2.3. Analysis procedure

A Matlab® (version R2016b, The Mathworks Inc., Natick, MA, USA) code was written to plot and align the traces (worn and unworn) from the acetabular rim and to calculate the rim deformation where edge loading had occurred.

To align the traces, a datum was selected where the horizontal rim met the chamfered region of the liner for all traces (Figure 3A). It was assumed that this datum would have undergone relatively little wear and/or deformation compared to other regions on the worn bearing surface and areas of loading. The datum on each trace was translated to the reference trace and the traces were rotated around the datum to align with the reference trace along the horizontal rim (Figure 3B). All of the traces were then rotated around the datum so that the horizontal rims lay along the horizontal plane (Figure 3C). The rim deformation (penetration) was defined as the distance between the reference trace and a worn trace normal to a tangential unit vector obtained between two points along the reference trace. This was calculated where the mean deformation for all traces was at a maximum between z=0 and z=α, where α is to a point defined by the user (Figure 4D).The z cut-off (α) was included to allow the user to exclude areas deemed to be bearing surface rather than rim.

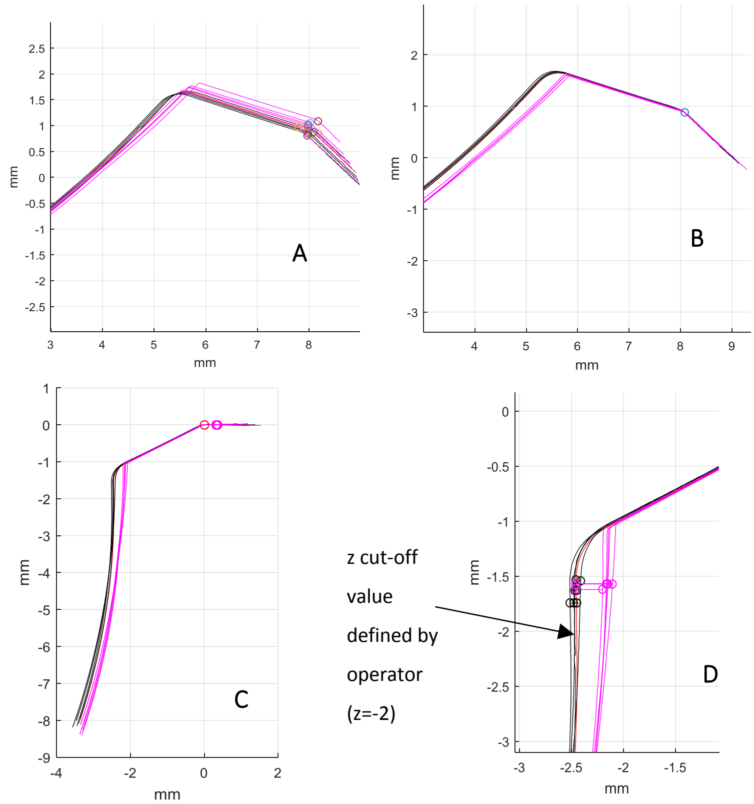

Figure 3 Plots to outline the steps in the analysis procedure for rim deformation on an aged PE liner following 5Mc of edge loading: (A) separate rim profile traces for worn and unworn rim plotted with identification of the datum at the point where the chamfer meets the horizontal rim (raw data), (B) all traces were translated and rotated around the datum to align with the reference trace along the horizontal rim, (C) all traces were rotated around the datum to align with the horizontal plane and (D) a magnified section of the rim area showing the points of maximum deformation where the distance normal to the reference trace was calculated (data analysed between z=0 and user defined z cut-off).Black traces represent the unworn rim and pink traces represent the worn rim.

The mean deformation between the reference trace and the five worn traces and the standard deviations were calculated for each sub group. All unworn traces were plotted to visually confirm that the selected reference trace was representative of the unworn rim.

The sensitivity of the method was established using the untested XLPE liner. To do this, each individual trace (all 10 traces) was assigned as the reference trace in turn and the distances to the remaining traces were calculated to create a matrix of rim deformation values. The mean distance between all traces for each reference trace and the standard deviation was then calculated. This was repeated three times, removing and replacing the liner from the fixture, and the mean of all matrices was used to establish the sensitivity of the method. This was done by a single operator.

The measurements of the aged PE simulator samples were performed by two operators and the mean and standard deviations were obtained. Each operator performed the entire measurement protocol, including set-up of the liner and fixture. Intra-class correlation estimates for the two operators were calculated using SPSS (SPSS Inc, Chicago, IL, USA) based on an absolute-agreement, two-way random-effects model and single measures and was obtained by comparing the distance from the reference trace and each worn trace for each liner for each operator (20 traces). An aged PE liner was measured three times by a single operator and the liner and fixture were removed between each measurement.

For the evaluation of the method in this study, rim deformation on the explants was identified as two or more adjoining traces with reduced radii of curvature at the inner rim, giving a sharpened appearance, and a penetration value exceeding the threshold measurement value obtained by measuring the untested liner. Change in shape or deformation on any other non-adjoining areas of the liner were excluded from the rim deformation calculation. The reference trace for each explant was selected as one of the traces with no change of shape at the rim and a penetration value that did not exceed the threshold value.

3. Results

3.1. Simulator Samples

Deformation at the worn rim was measurable for all of the simulator samples. A mean deformation of 0.11±0.05mm was observed for the XLPE liners (Figure 4A) and 0.21±0.16mm for the aged PE liners (Figure 4B).

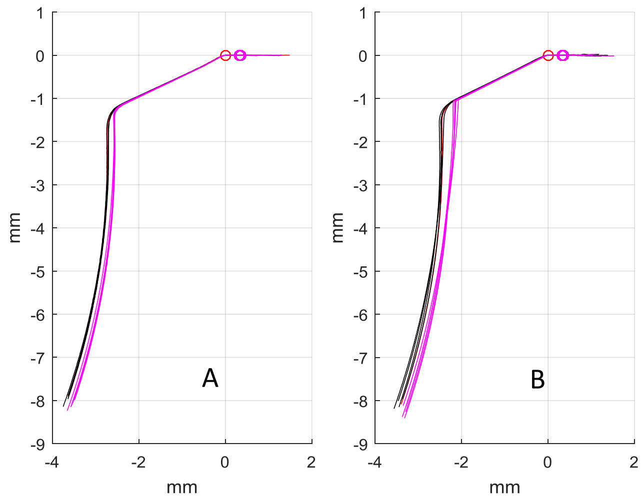

Figure 4 Example rim profiles traces of the worn (pink) and unworn (black) rim regions following 5Mc of edge loading for an (A) XLPE liner (mean deformation 0.11±0.05mm) and (B) an aged PE liner (mean deformation 0.21±0.16mm).

3.2. Explants

Two of the explants exhibited measurable penetration at the rim and the mean values were 0.57 ± 0.11mm and 0.78 ± 0.09mm (Figure 5A and Figure 5B, respectively). The variation in the remaining unworn traces was much greater for the explants than the simulator samples. No measurable deformation at the rim, defined in this study as clear change in shape and a deformation value exceeding the threshold value for two or more adjacent traces, was observed on the remaining explants but changes to the shape of the rim were observed.

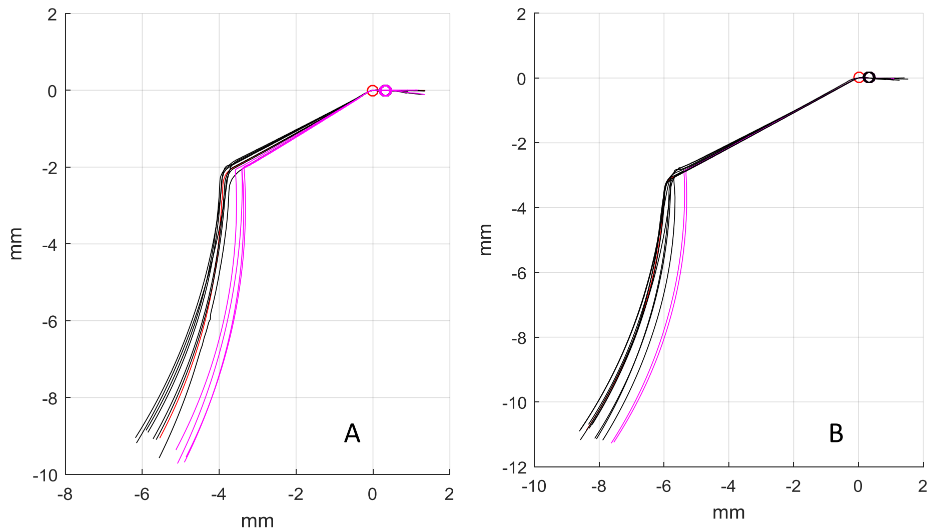

Figure 5 Rim profile traces of the two explanted liners that exhibited measurable rim deformation. The regions of the liner that were identified as exhibiting measurable deformation are shown in pink and the remaining traces are shown in black.

For both simulator samples and explants, the shape of the measured deformation at the rim was observed as a 'sharpening' of the rim. This was more apparent for the aged PE liners and the explants than the XLPE liners.

3.3. Repeatability and Sensitivity Analysis

The mean difference between traces on the untested XLPE liner was 0.02 ± 0.01mm which is smaller than the deformations measured on the simulator samples and explants in this study. A single liner (Aged PE 2) was measured three times by a single operator and a mean deformation value of 0.24 ± 0.08mm was obtained. The rim deformations for the aged PE liners were measured by two operators and an intra-class coefficient of 0.86 was obtained, indicating good agreement between operators. Table 2 provides the mean and standard deviation for each operator. The mean absolute difference between operators for each liner was 0.03mm.

Table 2 Mean deformation measurements and standard deviations for the aged PE liners for two operators

	Operator 1 (deformation mm)		**Operator 2 (deformation mm)**	
	Mean	St.dev	Mean	St.dev
Aged PE 1	-0.016	0.07	-0.06666	0.10
Aged PE 2	0.2363	0.05	0.23206	0.07
Aged PE 3	0.2993	0.03	0.35136	0.02
Aged PE 4	0.3496	0.01	0.353928	0.03
Mean	***0.21 ± 0.16***		***0.22 ± 0.20***	

4. Discussion

A method that can be used to measure rim deformation and to qualitatively evaluate rim deformation in UHMWPE acetabular liners has been demonstrated in this study using Pinnacle® liners that were hip simulator tested and removed from patients. The quantitative measurements can be used to determine the severity of rim deformation and wear and the qualitative observations of the shape of the rim profile have the potential to provide insight into possible damage mechanisms through the identification of distinct rim geometries for different loading conditions.

It has previously been suggested that different rim profiles may have been caused by different loading mechanisms. Hall et al. (1998) suggested that the shape of the rim is different for impingement conditions, observed as a blunted edge on the rim, and articulative wear in the superior region of the bearing surface, observed as a sharpening of the rim [33]. Femoral head edge loading on the rim may again produce a distinct shape to the rim profile. This method therefore has the potential to be used to determine if the cause of deformation can be better understood by analysing the shape of the rim profile. Further to this, the method can be used to evaluate wear and deformation on the chamfer, which is an advantage over many existing methods that measure penetration on the bearing surface only [29–31].

A separation of the femoral head and acetabular cup *in vivo* has been reported [1–3]. This can lead to edge loading of the acetabular rim. Relatively little is known about the prevalence and clinical consequences of edge loading of the femoral head on an UHMWPE acetabular rim but it could potentially lead to excessive wear, rim fracture and/or liner dissociation, which have been associated with other edge loading mechanisms such as impingement, and has been shown to increase stresses in the rim [11,22,34,35]. The method developed and evaluated in the present study could be used to help determine the prevalence, location, severity and mechanism of *in vivo* rim deformation. Validation of the loading mechanisms in edge loading protocols for simulator studies could also be achieved by comparing rim deformation measurements and profiles for varying degrees of edge loading with those measured on explanted liners.

The method may not be suitable for measuring very small rim deformations. Some variation (0.02±0.01mm) between rim profile traces was observed on the untested liner and this may be a result of deformation during manufacture, manufacturing tolerances or due to measurement error. However, the rim deformations measured in this study (0.11±0.05mm, 0.21±0.16mm and 0.57 ± 0.11mm & 0.78±0.09mm for the XLPE liners, aged PE liner and explants, respectively) exceeded this measurement threshold and it may therefore be reasonably assumed that most clinically relevant deformations would exceed this threshold.

The method does not allow distinction between wear resulting in material loss and cold flow or creep. However, this is a common problem when measuring UHMWPE geometrically and a problem that is inherent in many existing measurement methods.

The method described in this study uses contacting profilometry, but the code could be developed to process similar coordinate data from non-contacting profilometers or coordinate measuring machines (CMM). Contacting profilometry provides good resolution and point density compared to CMM methods, allowing visualisation of the shape of the rim. However, a CMM would provide a 3D dataset without the need for rotation of the sample. Contacting methods can potentially mark the material surface, which would be avoided with the use of a non-contact method.

It was also noted that the wear and deformation of the entire liner and therefore the rim is greater in the explanted liners than the simulator liners and identification of worn regions was therefore more challenging. Suitable protocols for identifying areas of edge loading should be developed when using this measurement method. Furthermore, the method relies on the datum not being deformed or worn. In reality, UHMWPE is known to undergo large deformations during implantation and/or testing as well as during manufacturing and it is likely that the datum would experience small deformations and in some cases may be worn. While this may influence the measurements, the datum was identified as the point where least deformation would occur and where wear is less likely to occur. It was thought that any deformation at the datum would be insignificant in comparison to any wear and deformation at the rim. However, in some cases, the datum may be worn and the method would be unsuitable. At present the method has only been evaluated using neutral Pinnacle® acetabular liners. However, it is postulated that the method could be used with minimal or no adaptation to measure any liner with a horizontal rim and a chamfer, which are features of other commonly implanted liners such as the Trilogy® acetabular cup (Zimmer Inc., Warsaw, USA).

Future developments would include modifications to the Matlab analysis and measurement method to include acetabular liners of different designs as well as liners with elevated rims. There is potential to modify the Matlab analysis in future work to create 3D geometric images and calculate wear volumes at the rim. However, a 2D analysis is more effective for visualising rim profiles.

5. Conclusion

A method that can be used to quantitatively and qualitatively evaluate simulated and clinical rim deformation in UHMWPE acetabular liners has been demonstrated. This method has the potential to provide improved understanding of the prevalence and severity of edge loading *in vivo*.

6. Ethical Approval

The explants were collected as part of wider study, which has been given favourable opinion by an NHS Ethics Committee (Reference number: 09/H1307/60).

7. Conflict of Interest Statement

Sophie Williams is a paid consultant to DePuy International, a Johnson & Johnson company.

8. Acknowledgements

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