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A STUDY OF THE WEAR OF EXPLANTED METAL-ON-METAL RESURFACING HIP PROSTHESES

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Abstract

Due to their recent introduction there are few studies of retrieved resurfacing hip prostheses. Nine such components associated with groin pain in patients, and five associated with early fracture of the femur, were obtained and analyzed using a roundness measuring machine. While the ‘fracture’ components showed no more than 3 μ m out of roundness, components associated with groin pain showed between 15 and 92 μ m out of roundness values. These latter results indicate wear and correlated with high metal ion levels in these patients, therefore the groin pain was likely associated with an adverse reaction to excessive metal wear debris.

Introduction

A recent article in the Lancet was entitled ‘the operation of the century: total hip replacement’ [1]. Tribological expertise has contributed greatly to the success of this surgical procedure which helps many patients suffering from common musculo-skeletal diseases. Hip replacement is now commonplace in many countries and the most recent data indicates that in England and Wales in the year 2008 more than 64,000 primary hip replacement procedures were undertaken [2]. The average age of these patients was 67 years [2]. The majority of these people will enjoy the benefits of pain relief, increased independence and enhanced mobility. Moreover, the success of the procedure has led to increased demand for surgical intervention and, coupled with an ageing population, it has been recognised that the prevalence of hip replacement will grow rapidly [3].

Unfortunately, not all of the hip prostheses which are implanted will show long term success. The majority of total hip prostheses employ a hard metal or ceramic femoral component which articulates inside a polyethylene acetabular socket. It is now recognised that excessive wear from the polyethylene component can result in a negative cascade of events within the body which can eventually result in osteolysis, loosening of the implant, pain, and the need for revision surgery [4]. It is also acknowledged that younger patients tend to place greater demands on their hip prostheses, which in turn leads to greater wear and consequently reduced longevity and survivorship [5]. Much effort has therefore been directed at reducing wear volumes from hip prostheses so patients of all ages can benefit from hip replacement. For example, the wear properties of polyethylene can be improved by irradiation cross-linking. From one clinical trial a 40% lower wear rate of cross-linked polyethylene acetabular cups has recently been reported [6].

One method of eliminating the problem of polyethylene wear debris is to employ a wear couple of cobalt chrome molybdenum (CoCr) articulating against itself. This material combination has led to a renaissance of metal-on-metal hip prostheses [7]. An exciting subsequent development has been to offer metal-on-metal resurfacing prostheses [8]. These have a relatively large articulating diameter and are therefore less likely to dislocate [9]. They also offer the potential benefits inherent in removing less femoral bone stock compared with conventional total hip replacement. For such reasons these resurfacing hip prostheses tend to be implanted in younger patients. Recent data from the UK has shown that for patients under the age of 55 who receive a hip replacement, 46% will receive a resurfacing implant [10].

What then are the tribological benefits of metal-on-metal resurfacing hip prostheses? By minimising surface roughness as far as possible, controlling sphericity and reducing the clearance between the head and cup, and given the material properties of CoCr plus the relatively large size of the articulation, this theoretically allows fluid film lubrication to be achieved during part of the gait cycle [11]. In turn this should mean that wear of the articulating surfaces is minimised.

Various designs of metal-on-metal hip resurfacing prostheses are offered by several orthopaedic joint manufacturers [8]. The market leader is the earliest contemporary design, the Birmingham Hip Replacement (BHR). This device has shown some very good mid-term clinical results [9, 10]. More recent designs include the Durom™ from Zimmer and the

Articular Surface Replacement (ASR™) from De Puy. Both of these designs differ from the BHR in that they employ a sub-hemispheric acetabular cup to reduce acetabular bone removal prior to implantation and smaller diametral clearances to promote fluid film lubrication.

Like many other hip resurfacing systems, the ASR™ is designed so that the femoral component is cemented in place whereas the acetabular component is a cementless press-fit. Heads are as cast while cups are also subject to hot isostatic pressing [8]. Both components are manufactured from high carbon ($\geq 0.15\%$) CoCr. An image of an ASR™ prosthesis is shown in figure 1. To the left is the sub-hemispheric acetabular cup component. The porous coating designed to encourage bone ingrowth can be seen on the outside of the cup. Note that the inner, articulating surface does not extend all the way to the rim of the cup. Instead there is a step which matches with an ‘introducer’ – a device used during surgery to aid fitting of the cup within the pelvis. To the right is the femoral component. In comparison with a traditional total hip replacement, note the short stem which can be seen protruding to the right.

As may be appreciated, the truest test of any replacement joint occurs when it is implanted into the body. Although it may be of small consolation to the individual involved, an examination of a failed replacement joint can provide crucial evidence as to how these devices can be improved for the benefit of future patients suffering from crippling musculo-skeletal diseases. Such explant analysis has usefully been undertaken for knee [12], finger [13] and toe [14] prostheses as well as for total hip replacements [15]. Given their relatively recent introduction there are comparatively few papers which have investigated explanted resurfacing hip prostheses [16-19].

An important issue with metal-on-metal hip joints, total replacement as well as resurfacing, is the exposure of the body to metal ions. There are concerns that high levels of systemic chromium (Cr) and cobalt (Co) ions may cause organ toxicity, carcinogenicity [20, 21] and teratogenicity [22]. There is currently no conclusive evidence of these adverse effects but, as yet, there is an absence of large epidemiological studies in the literature [21]. Clearly it is desirable to reduce the metal ion loads to which patients are exposed.

One accepted concern related to metal-on-metal hip resurfacing prostheses is early fracture of the femur [23, 24]. This is thought to be due to a number of reasons including the surgeon’s

learning curve, gender differences in patients, as well as their body mass [25]. Such fractures generally occur soon after implantation, usually within one year. It has therefore been stated that femoral neck fractures are the main reason for early hip resurfacing failure [17].

Very recently there has emerged a body of evidence which suggests that, despite the theoretical advantages of metal-on-metal hip resurfacing prostheses in terms of promoting fluid film lubrication and minimising surface-to-surface contact, wear may be a serious problem in some of these devices [18, 26-28]. By examining a number of explanted metal-on-metal hip resurfacing devices, it was intended to offer some evidence to inform this nascent concern.

Material and methods

The largest independent, single surgeon cohort of resurfacing hip prostheses in the UK [26] has formed part of an ongoing clinical investigation which includes approximately 500 ASR™ prostheses. Patients in this clinical study were monitored in a number of ways. Standing antero-posterior pelvic radiographs were taken and Einzel-Bild-Roentgen-Analyse (EBRA) software was used to measure acetabular cup inclination and anteversion angles [29, 30]. Many of the patients underwent whole blood metal ion analysis (Co and Cr concentrations) at a minimum one year following their resurfacing hip replacement [26]. After one year, it has been argued that the ‘bedding-in’ period will have ceased and steady state wear has been achieved [31, 32]. Whole blood samples were measured by inductively coupled plasma mass spectrometry (ICPMS), which is regarded as the most sensitive method for measuring systemic exposure to Cr and Co ions [22].

From ten patients within this ASR™ cohort, fourteen explanted components were obtained for analysis. Five of these patients had reported pain and a characteristic effusion was seen at revision operation. From four of these patients, ASR™ femoral head and acetabular cup were available for explant analysis. From the fifth patient, only the femoral component was available. All five patients were female. Duration of implantation varied between 8 and 28 months. The remaining five ASR™ explants were obtained from patients whose femurs had fractured. In these cases only the femoral component was available for analysis. Here, devices were obtained from males and females and within eight months of implantation.

Each explanted component was examined using a Zeiss TSK Rondcom60A roundness measuring machine. Essentially, out of roundness refers to the deviation in shape from a perfect circle. Modern manufacturing of resurfacing hip prostheses allows acetabular and femoral components to be produced with an out of roundness of less than 5 microns. Explanted components with greater out of roundness values imply that either material has been removed locally (wear) or that the component has been deformed. Devices such as the Zeiss TSK Rondcom60A roundness measuring machine have a resolution of approximately 0.1µm. Out of roundness measurements were taken on three planes for each acetabular and femoral component. For the acetabular cups these planes were at 3mm, 7mm and 11mm below the rim. For the femoral heads these were at 3mm, 7mm and 11mm from the 'pole' of the head. Three traces were used at set distances between 3mm and 11mm as this gave a consistent procedure. As each prosthesis was subject to a unique range of loading and motion in the individual patient, so the exact area of wear or deformation would be unique too. The aim of measurements between 3mm and 11mm was to take in a substantial region where any changes might have occurred.

Results

The maximum out of roundness values for the fourteen ASR™ components taken from the ten patients are given in table 1. As can be seen, those components associated with early fracture of the femur all showed the lowest out of roundness values, with a maximum of 3.1µm. Given such low out of roundness values, all within manufacturing tolerances, these components showed minimal wear or deformation. A typical set of roundness traces can be seen in figure 2 and the consistency and circularity of the traces is obvious. In fact it is difficult to discern the three individual traces, so consistent are they. As can be seen from figure 2, values of out of roundness on the three measuring planes were 1.4µm, 0.7µm and 2.0µm respectively. Out of roundness traces for the other 'fracture' components looked almost identical to figure 2, with the three traces overlapping. Note that in figure 2 and in all subsequent figures the same magnification (x500) has been offered therefore roundness traces can be compared directly.

Table 1 shows that, where pain and effusion were associated with the reason for revision, the out of roundness values were much greater, up to a maximum of 91.8 μm in the case of the femoral head from patient 3. The roundness traces from this component are shown in figure 3, and it can be seen that the maximum out of roundness is on the plane 3mm from the pole of the femoral head. The contrast with the circular shape of figure 2 is notable.

The roundness traces from the retrieved femoral head of patient 5, another 'effusion' failure, are shown in figure 4. On the three planes, maximum out of roundness values of 18.3 μm , 24.9 μm and 32.9 μm have been measured. This implies that wear or deformation was taking place over a substantial area of the femoral head. Such a result was seen with all of the ASR™ femoral heads associated with 'effusion' failures.

For the acetabular cups associated with pain and effusion, out of roundness traces for patients 3 and 4 are shown in figures 5 and 6 respectively. All of these signify that the greatest wear or deformation took place towards the edge of the cup, as this is indicated by the third measurement, that on a plane 3mm below the rim. Figure 5 shows that out of roundness values of 38.5 μm , 48.1 μm , and 64.0 μm were measured on the three planes, and therefore that wear or deformation took place deep inside the acetabular cup. With out of roundness values on the three planes of 15.1 μm , 20.8 μm and 28.8 μm figure 6 similarly shows that with this component wear or deformation again occurred over a substantial area of the articulating surface of the cup.

The clinical data in table 1 shows that patients who suffered from groin pain and an effusion also had high ion levels. In turn they had high angles of acetabular cup anteversion and/or inclination. It has been shown in the larger ASR™ cohort that high anteversion and inclination are directly related to high ion levels [26].

Discussion

For a new ASR™ component, a typical out of roundness value would be of the order of 4 μm [33]. Therefore, from table 1, it can be seen that all the five components taken from patients whose femurs had fractured (maximum out of roundness 3.1 μm) showed minimal deformation or wear after removal. As such they serve as controls against which the effusion

failure components can be judged. Additionally, the out of roundness values of the ‘fracture’ components help to verify the accuracy of the measuring technique and match such measurements to independent data [33]. From a clinical failure analysis point of view, it could be concluded from the out of roundness results related to the early ‘fracture’ failures that these are not correlated to the wear of material from the articulating surfaces of the femoral components. However, the contrast with the ‘effusion’ failure components and their high out of roundness values is stark.

Could the ‘effusion’ components have shown deformation rather than wear? There are two key reasons why deformation is unlikely to have caused the high out of roundness values seen with the effusion failures. Firstly, all retrieved components were likely to have been subject to a similar range of loading within the various patients. Why then should only the components associated with effusion failures have deformed when all those associated with fracture of the femur have shown minimal deformation? Secondly, and perhaps most importantly, deformation cannot explain the high ion levels seen in the blood of patients with effusion failures but wear from the articulating surfaces of the metal-on-metal resurfacing hip prostheses can explain these high ion levels. Therefore the out of roundness measurements provided valuable information about the wear of the metal-on-metal resurfacing prostheses.

From the out of roundness measurements, the maximum out of roundness (defined as the deviation from a perfect circle) was taken as indicative of the maximum linear wear depth. On the ‘effusion’ failures these linear wear depths were significant and contrasted with the early fracture failures where it was not possible to separate out any wear from the manufacturer’s tolerances for out of roundness.

To the authors’ best knowledge, the dichotomy between low wear components associated with early femoral fracture and high wear explants associated with groin pain and effusion has not previously been reported. Moreover we are not aware of other researchers having offered out of roundness measurements from failed resurfacing hip prostheses. A roundness measuring machine has recently been used to measure the wear of explanted metal-on-metal total hip prostheses [34]. The authors described these explanted prostheses as ‘bearing couples that had been in successful use for more than seven years (range, seven to thirty-four years)’ [34]. Therefore they differ from the cohort described in this paper, which concerns itself with resurfacing devices which are considered failures.

However, other researchers have offered wear assessments of retrieved metal-on-metal resurfacing hip prostheses, but using co-ordinate measuring machines (CMM). While CMM do have certain advantages, they lack the sensitivity found with a dedicated roundness measuring machine. For example in an early study it was noted that when a CMM with a claimed accuracy of $\pm 2 \mu\text{m}$ was used, only a limited number of the explanted resurfacing hip components could be measured which were outside of manufacturing tolerance [35]. Where wear could be measured, for paired head and cup components, wear depths per year of 4.4, 16 and $58 \mu\text{m}$ were offered. If the roundness values reported in the current paper are taken as the maximum wear depth then the values of Beaule et al would compare with values of 21.7, 233.7, 29.7 and $39.5 \mu\text{m}$ wear depth per year for patients 2, 3, 4 and 5 respectively.

Using another CMM to examine various designs of explanted resurfacing hip prostheses, values of maximum wear depth in the range of $< 2 \mu\text{m}$ to $164 \mu\text{m}$ have been reported [16]. Two microns was therefore offered as the resolution of the CMM. As with other studies, there is a considerable range of wear values, but the data of Campbell et al offers agreement with the values of up to $98.1 \mu\text{m}$ found in this study.

Another recent study used a CMM to look at a large number of explanted resurfacing components of various designs [36]. An accuracy of $3 \mu\text{m}$ was claimed for the CMM. Wear was given in the form of mm^3 per day. Again, a wide variation in wear rates was reported, between 22 and 27 times higher wear being measured in 'edge-loaded' implants rather than non edge-loaded. The authors also noted that two-thirds of their components were revised due to fracture of the femur.

Most recently, the wear of eight femoral and two acetabular explanted BHR components was reported [19]. Time in vivo of the components was between 7 and 24 months, similar to the 1 to 28 months reported in this paper. A CMM was used and a spatial resolution of $1 \mu\text{m}$ was claimed. Linear wear of the eight BHR heads was measured to be between 1.7 and $44.7 \mu\text{m}$, which compares with a range of 1.7 to $98.1 \mu\text{m}$ reported in this paper for ten ASR™ femoral heads. For the two BHR acetabular components Witzleb et al reported linear wear of 9.2 and $31.5 \mu\text{m}$, which compares with 14.8 to $64.0 \mu\text{m}$ for the four ASR™ acetabular components measured in this paper. These results, based on a limited sample size of explanted components, suggest that the wear of ASR™ prostheses is greater than that of the BHR.

A conventional method of offering wear is to give the weight change. Unfortunately however, for explanted components this is generally not possible, as the precise weight prior to implantation is not recorded by manufacturers. Therefore, given that gravimetric methods of wear measurement are inappropriate, so wear measurements based on dimensional changes are employed, such as out of roundness and those obtained from a CMM. It should also be noted that the exact engineering specification relating to the prostheses prior to implantation cannot be known precisely. Manufacturers tend not to release figures related to their products such as out of roundness. Moreover, as would be expected from modern engineering components like hip prostheses, such values fall within a range of tolerances and again manufacturers do not disclose such figures which could be valuable to competitors. However some independent comparative measurements have been done. For example, and most applicable to this study, out of roundness values of the order of 4 μ m have been offered for ASR™ components [33].

Can the high angles of acetabular cup inclination and anteversion have been a contributing factor to the failure of these ASR™ resurfacing hip prostheses? This is certainly possible as, at high angles of inclination, not only have higher metal ion levels been reported in patients [37], but so too has edge loading [16]. Such edge loading was also seen in the form of rim damage on the explanted cups studied. In addition to noting the correlation between acetabular cup inclination and ion levels in patients fitted with resurfacing hip prostheses, the importance of edge loading has also been reported recently [38]. These authors postulated that at such high angles the ‘arc of cover’ between femoral head and acetabular cup was reduced and they found that smaller arcs of cover were associated with higher wear [38]. Such an explanation could also apply to the ASR™ prostheses discussed in the current paper. One study has reported a twenty-one to twenty-seven fold greater wear rate in rim loaded hip resurfacing explants compared with non-rim loaded samples [17]. It should also be recognised that in ‘conventional’ metal-on-polymer total hip prostheses failure rates have increased with inclination of the acetabular cup [39] while the importance of acetabular position to low wear has also been identified in ceramic-on-ceramic total hip prostheses [40].

In a recent paper a number of explanted ASR™ components, all associated with pain and effusion in patients, were measured to determine their surface roughness and thus the lubrication regime during gait [18]. It was found that all surfaces had roughened compared

with an unused pair of head and cup ASR™ components, so much so that instead of operating under fluid film lubrication during gait, they would instead operate in the boundary lubrication regime [18]. In the boundary lubrication regime, with its preponderance of surface-to-surface interaction, increased wear would be expected. In turn this would result in higher volumes of metallic wear debris. In addition the relatively large size of the resurfacing hip prostheses means that, under boundary lubrication conditions, wear is taking place over a large sliding distance so that volumes of wear debris are maximised. Recently, large amounts of particulate wear debris have been linked with a toxic reaction in localised cells and the attendant failure of resurfacing hip prostheses [27]. Clearly the high wear could also be directly linked with the higher ion levels which were measured in the patients from whom these explanted resurfacing hip prostheses were obtained [26].

Conclusion

From a series of explanted metal-on-metal resurfacing hip prostheses with a known clinical history it was found that failures associated with effusion and pain in patients were associated with values of out of roundness far higher than at manufacture. These changes were associated with wear of the devices and this assertion was supported by the high ion levels seen in the blood of patients. In addition, all of these failures were associated with cups which had been positioned at high angles of inclination and anteversion. The effusion failures contrasted markedly with those associated with early fracture of the femur. Here, all components had an out of roundness no greater than three microns, which strongly implied that little or no wear of these components had taken place prior to retrieval.

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Figure 1: An unused ASR™ resurfacing hip prosthesis, acetabular cup to the left and femoral head to the right

Roundness

Data No. : 1, 2, 3

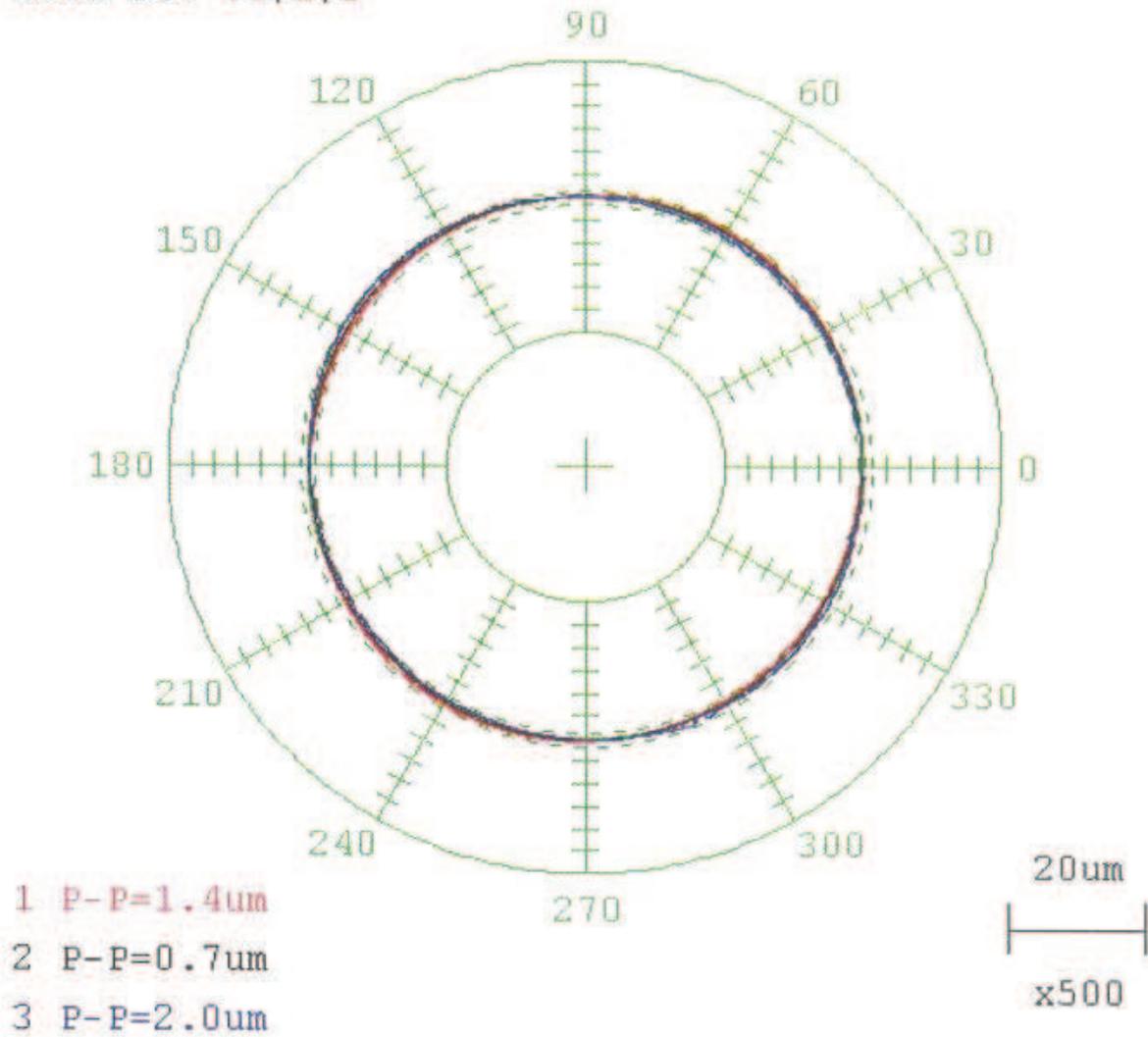


Figure 2: roundness traces taken of an ASR™ femoral head associated with fracture of the femur (patient 10)

Roundness

Data No. :1,2,3

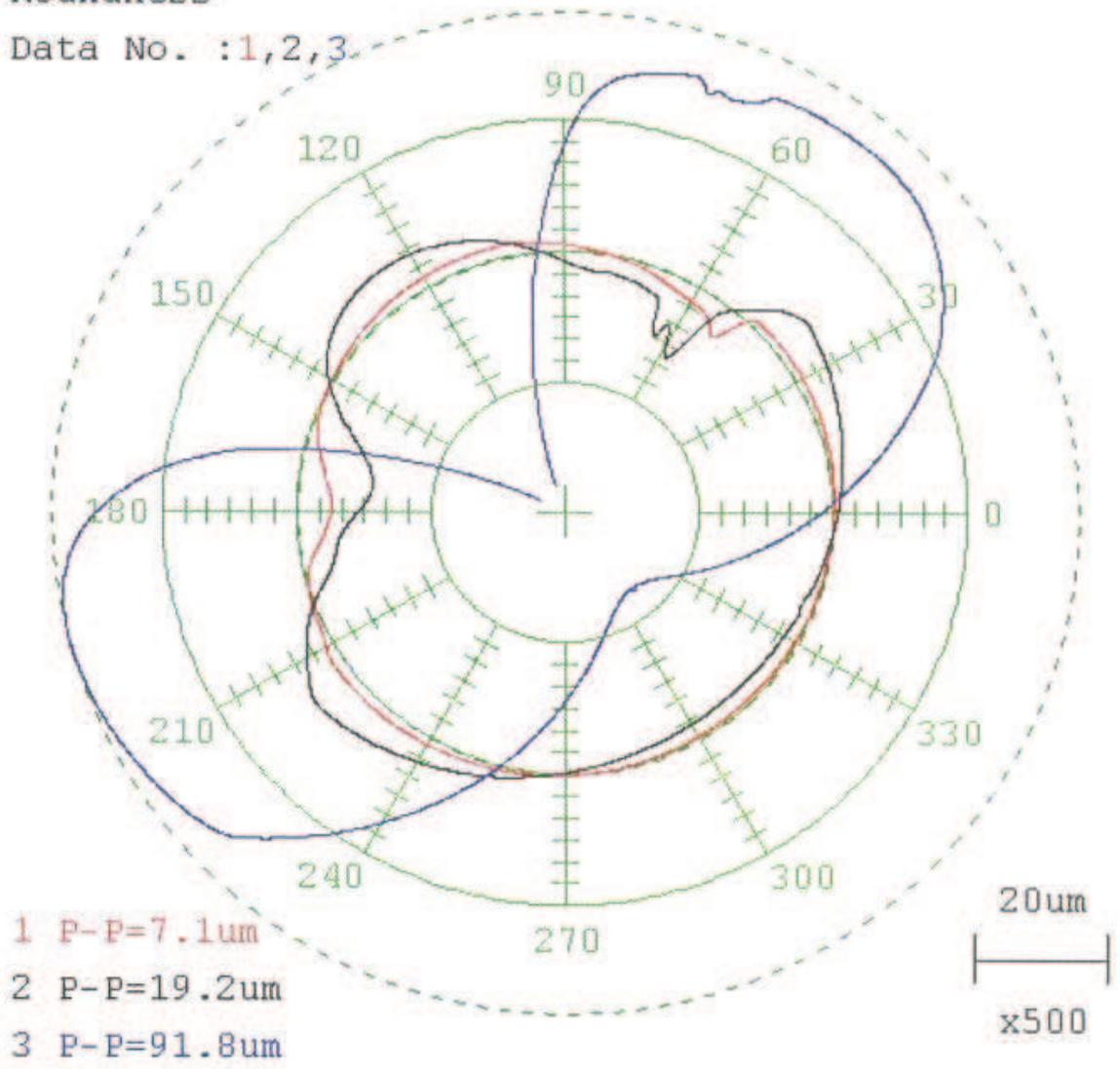


Figure 3: roundness traces taken of an ASR™ femoral head associated with an ‘effusion’ and groin pain failure (patient 3)

Roundness

Data No. :1,2,3

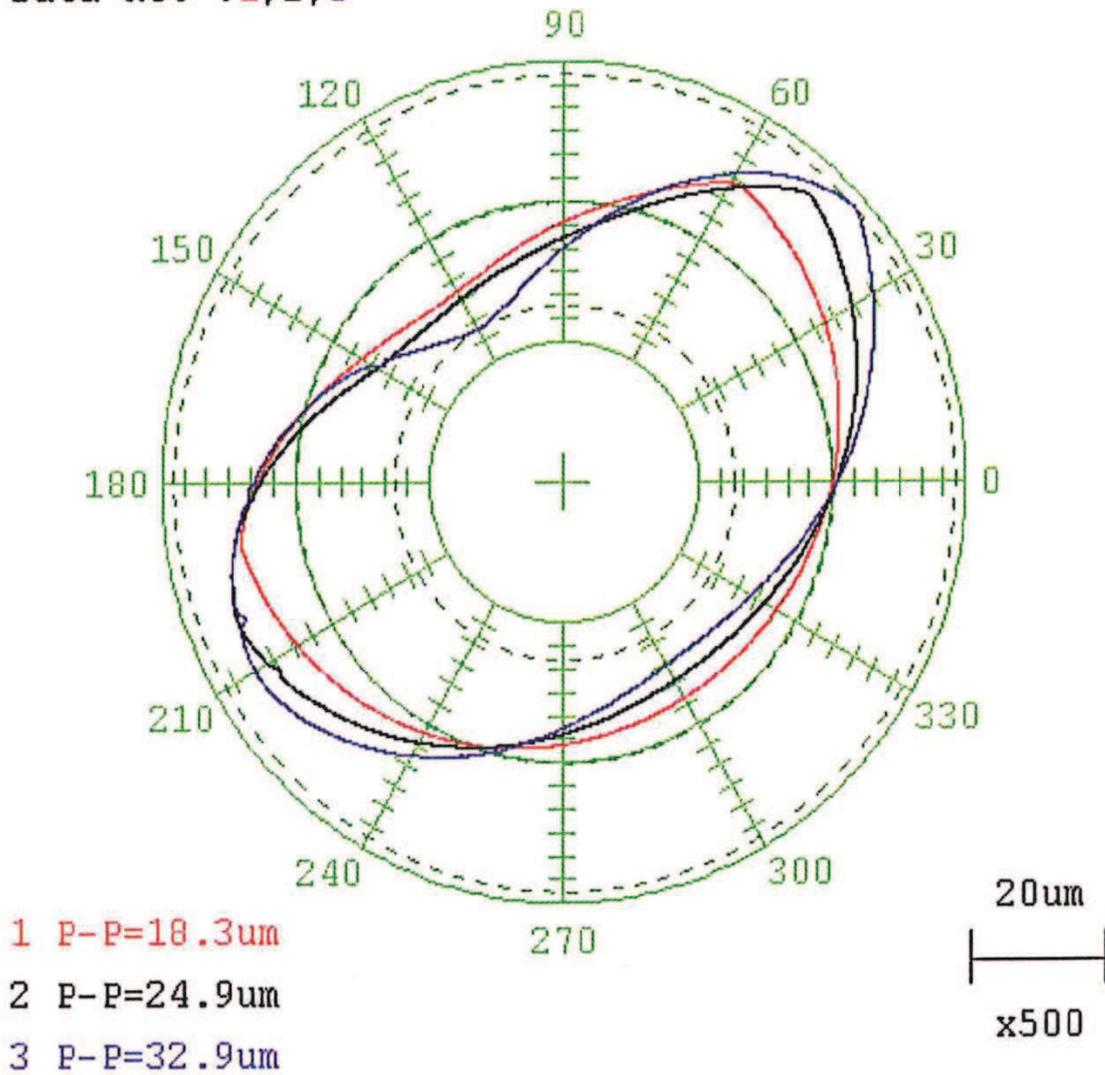


Figure 4: roundness traces taken of an ASR™ femoral head associated with an ‘effusion’ and groin pain failure (patient 5)

Roundness

Data No. :1,2,3

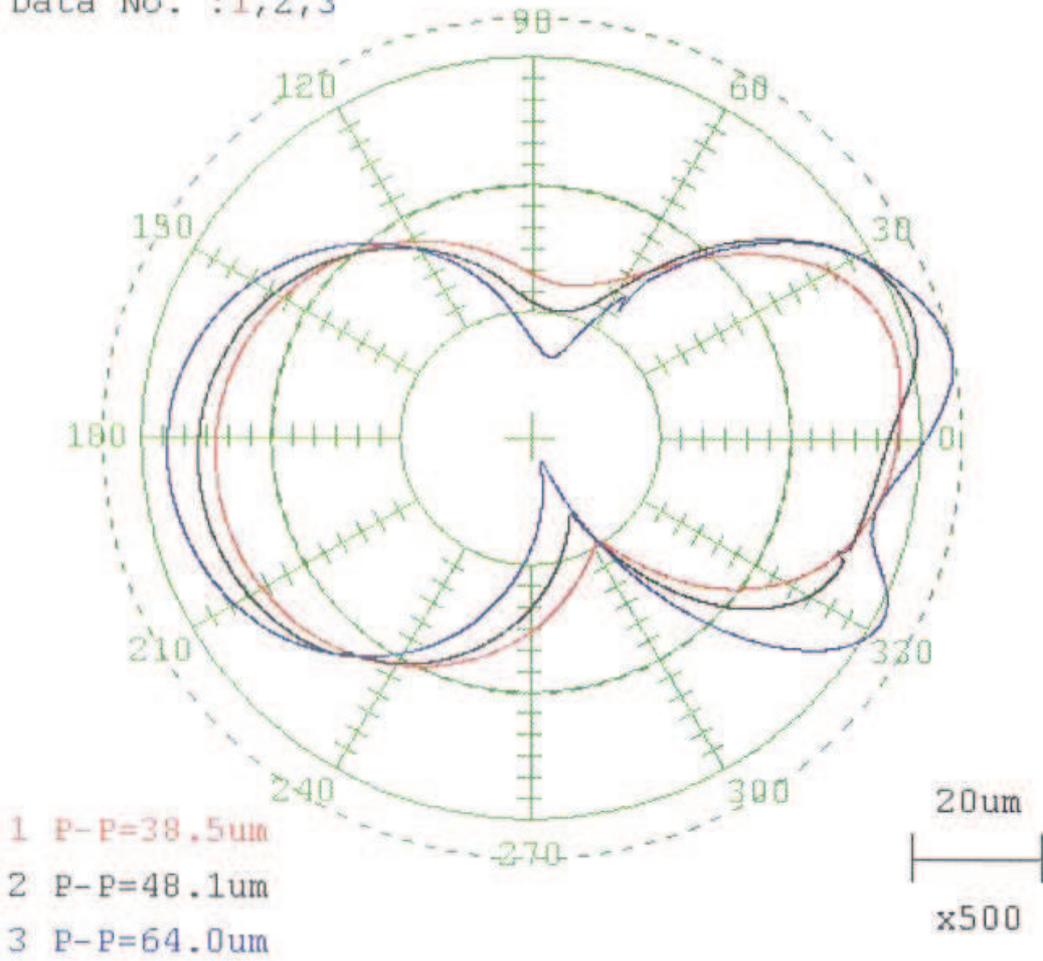


Figure 5: roundness traces taken of an ASR™ acetabular cup associated with an ‘effusion’ and groin pain failure (patient 3)

Roundness

Data No. :1,2,3

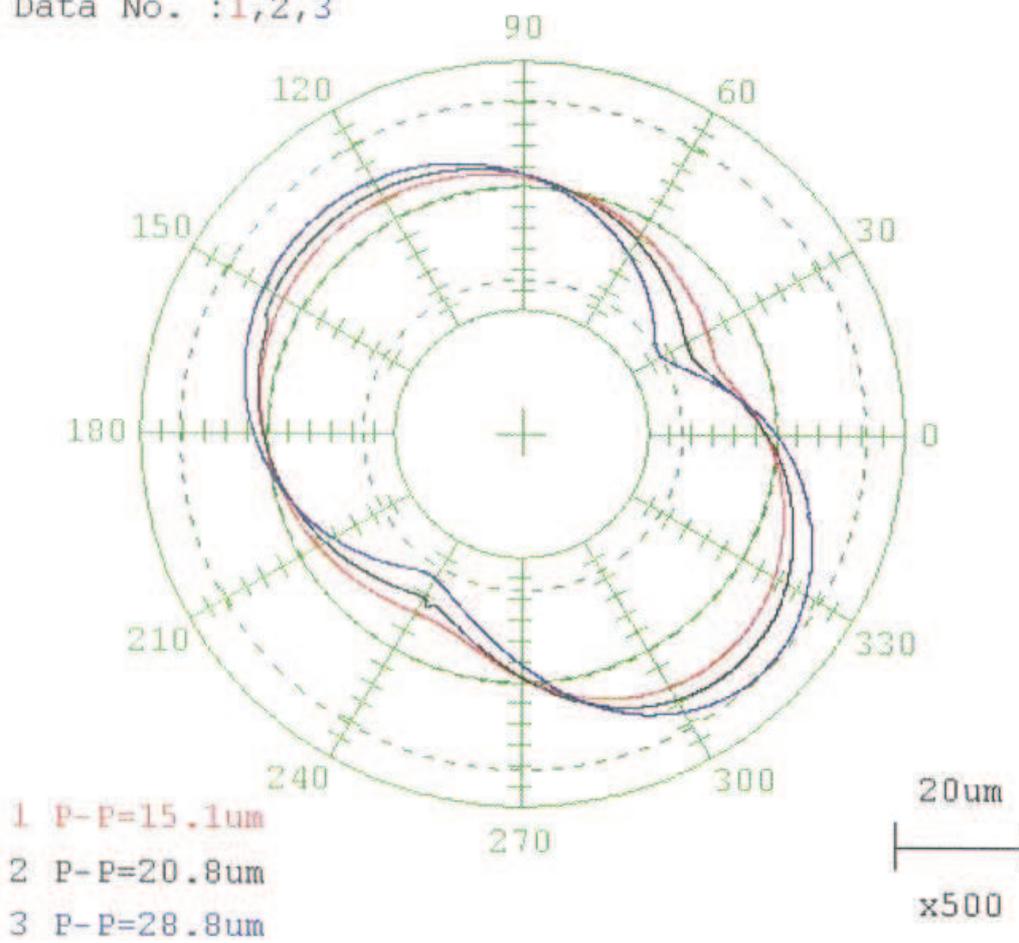


Figure 6: roundness traces taken of an ASR™ acetabular cup associated with an ‘effusion’ and groin pain failure (patient 4)

Table 1: Maximum out of roundness (OOR) values of the explanted components and associated clinical data.

Patient	Head OOR (μm)	Cup OOR (μm)	Reason for revision	Duration (months)	Cr ($\mu\text{g/l}$)	Co ($\mu\text{g/l}$)	Cup inclination ($^{\circ}$)	Cup anteversion ($^{\circ}$)
1 ♀	31.3	---	Pain, effusion	28	---	---	62	26
2 ♀	17.7	14.8	Pain, effusion	18	---	---	58	29
3 ♀	91.8	64.0	Pain, effusion	8	36	88	65	39
4 ♀	38.0	28.8	Pain, effusion	27	5	8	50	32
5 ♀	32.9	23.1	Pain, effusion	17	15	19	51	18
6 ♀	1.8	---	Fracture	2	---	---	---	---
7 ♂	3.1	---	Fracture	5	---	---	46	31
8	2.5	---	Fracture					
9 ♂	1.7	---	Fracture	8	---	---	---	---
10 ♂	2.0	---	Fracture	1	---	---	47	7