Development of Metal/Metal Hip Resurfacing

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ABSTRACT: This author's development of metal/metal hip resurfacing began in 1989, with the first patient implantation in February 1991. In the first three years a pilot study identified optimum fixation as hydroxyapatite coated uncemented cups and cemented femoral components. From March 1994 hybrid fixed components have been used. These implants have generally been satisfactory with respect to fixation but high wear of the bearing, metallosis and osteolysis have been seen with some components inserted during 1996, a period during which the metal microstructure was altered by the heat processes, hot isostatic pressing and solution heat treatment. The Birmingham Hip Resurfacing was developed taking account of experience with earlier resurfacing designs. This implant employs hybrid fixation with a porous ingrowth acetabular component and has an as-cast metal microstructure having had no post casting heat treatments. During the past 4 years the author has performed over 1,000 Birmingham Hip Resurfacing's with a total failure rate of less than 1.0%

KEY WORDS: Hip resurfacing, Metal/Metal, As-cast, Hot isostatic pressing, Solution heat treatment, Metallosis, Osteolysis.

INTRODUCTION

Conservative hip arthroplasty with resurfacing of the acetabulum and femoral head is an attractive concept particularly in young and active patients. The natural anatomy, joint biomechanics and stability are all preserved. Non-violation of the proximal femur, retention of upper femoral bone stock and avoidance of stress shielding in the proximal femoral shaft are unique advantages. Unique disadvantages are the potential for failure from femoral neck fracture and collapsed femoral heads from avascular necrosis or osteolysis.

The first resurfacing arthroplasty was performed by Sir John Charnley in 1951 using Teflon/Teflon bearings. Rapid wear of the material occurred and this problem was to plague subsequent resurfacing arthroplasty attempts for the next 40 years. Resurfacing hip arthroplasty using a polyethylene cup and a metal femoral component had gained popularity during the 1970's and by 1978 several systems were in clinical use. By 1982, however, reports of high failure rates resulted in the procedure being abandoned by most surgeons. The inevitable use of a large diameter femoral shell against a polyethylene cup led to excessive polyethylene debris production and osteolysis (1, 2). The importance of precise surgical technique was noted during this early resurfacing era with notching of the femoral neck and varus placement of the femoral component implicated in the causation of early femoral neck fracture (3).

The author had noted the satisfactory bearing performance of large headed metal/metal total hip replacements (Fig.1) and came to the view that a metal/metal articulation might render hip resurfacing arthroplasty a viable proposition. Metal/Metal articulations had in fact been used before with hip resurfacing but in very small numbers (4, 5).

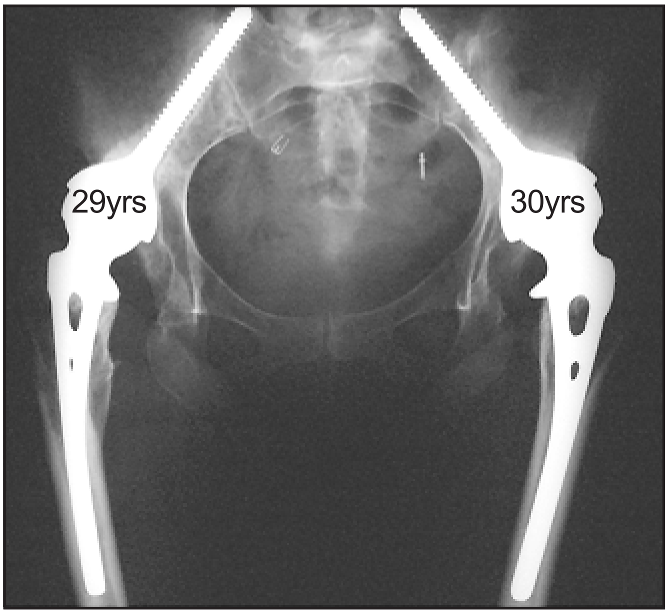

Fig. 1 - 29 & 30 year follow-up of woman aged 26 at original Ring metal/metal THR for old congenital dislocation. No osteolysis.

MATERIALS AND METHODS

From February 1991 a pilot study was performed using three types of fixation, press-fit smooth metal, hydroxyapatite coated and cement fixation on both the acetabular and femoral components (6). The press-fit components had an early 10% aseptic loosening rate and this method of fixation was therefore abandoned. However patients with successful press-fit implants have continued to perform well (Fig. 2). Cement fixation of the acetabular component has given poor results with acetabular component loosening and implant/cement debonding presenting as major problems. Hydroxyapatite coated femoral components have been satisfactory but require good femoral head bone stock. Hydroxyapatite coated (HA) acetabular components and cemented femoral components have both proved very satisfactory and from 1994 hybrid fixation of hip resurfacings have been used exclusively by the author.

From March 1994 until February 2001 the author has performed 1,503 hybrid fixed resurfacing implants, 294 of the McMinn type (HA on smooth metal cup) (Corin Medical Ltd, UK) and 1,209 Birmingham Hip Resurfacings (BHR; HA on porous metal cup) (Midland Medical Technologies Ltd, UK). Mean age was 52.9 yrs and the

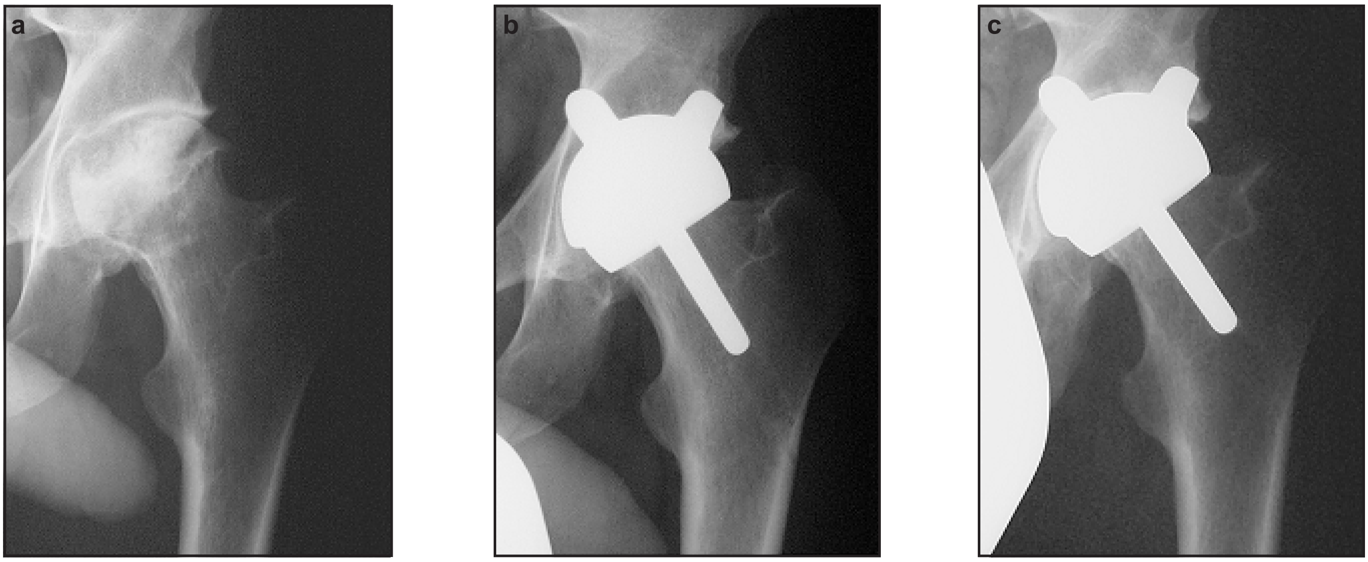

Fig. 2 - Avascular necrosis in 25yr old man **a).** Good result with press-fit resurfacing at 1 year **b)**. Excellent clinical result and patient continues to play football and perform manual work at 10 years **c)**.

PATIENT AGE DISTRIBUTION

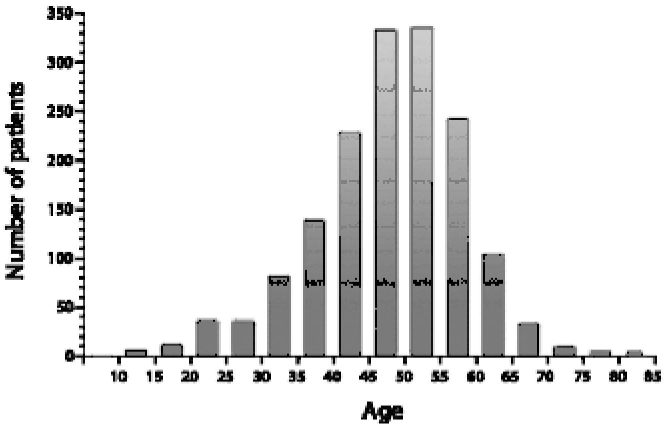

Fig. 3 - Age distribution of author's hybrid fixed resurfacing patients.

largest group was between 45-55yrs (Fig.3). Diagnosis: osteoarthritis 78%; dysplasia 7%; inflammatory 2%; avascular necrosis 5%; other 8%.

In the 294 McMinn Resurfacings 8 have failed and 7 have been revised. The author originally understood that these implants were metallurgically identical to the successful Ring and McKee devices, which had given satisfactory long term bearing performance. It transpired however that while the chemistry of the metal with a high carbon content cobalt chrome was indeed identical to the successful Ring and McKee implants, heat treatments were used on implants during the period 1994-1996 which altered the microstructure of the historically proven material. In 1994 the metal of the McMinn hybrid resurfacing was hot isostatically pressed, in 1995 the metal was solution heat treated and in 1996 the metal was hot isostatically pressed and solution heat-treated (7). These heat treatments were apparently performed to get rid of microporosity and reduce factory scrap rates. It further transpired that cups having had one heat treatment from a castings supplier were randomly paired on occasion with femoral components having had a different heat treatment from another castings supplier. The author was unaware of all these differing heat processes applied to his implant until after the event and when this and other quality control problems (7) were discovered he terminated the licence permitting further manufacture of the McMinn Resurfacing.

During 1994 & 1995 the author performed 107 McMinn hybrid resurfacing implants and these are now at 67mths to 89mths follow-up. These patients have been reviewed clinically and radiographically (8). The Merle D'Aubigne scores in the Charnley A and B category patients were: Pain 5.99, Walking 5.95, Movement 5.96. On radiographic review no osteolysis was seen. No patient had radiographic features of loosening (Fig.4).

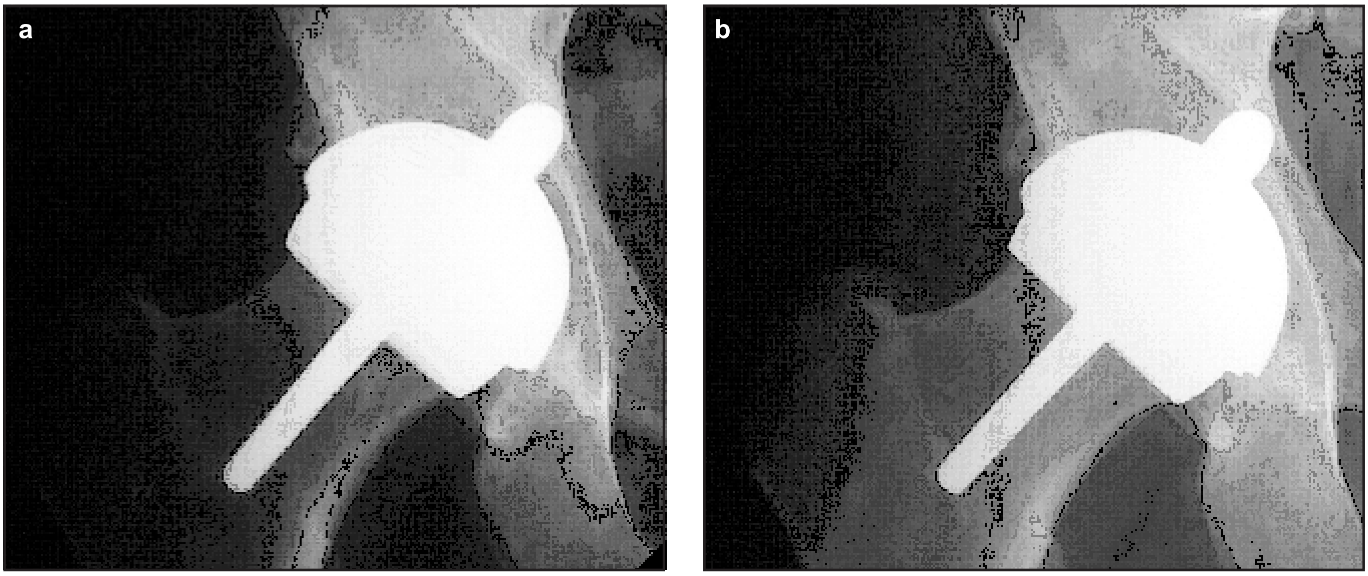

Fig. 4 - 1-year follow-up 1994 McMinn hybrid **a)**. 7-year follow-up. No osteolysis. No loosening **b).**

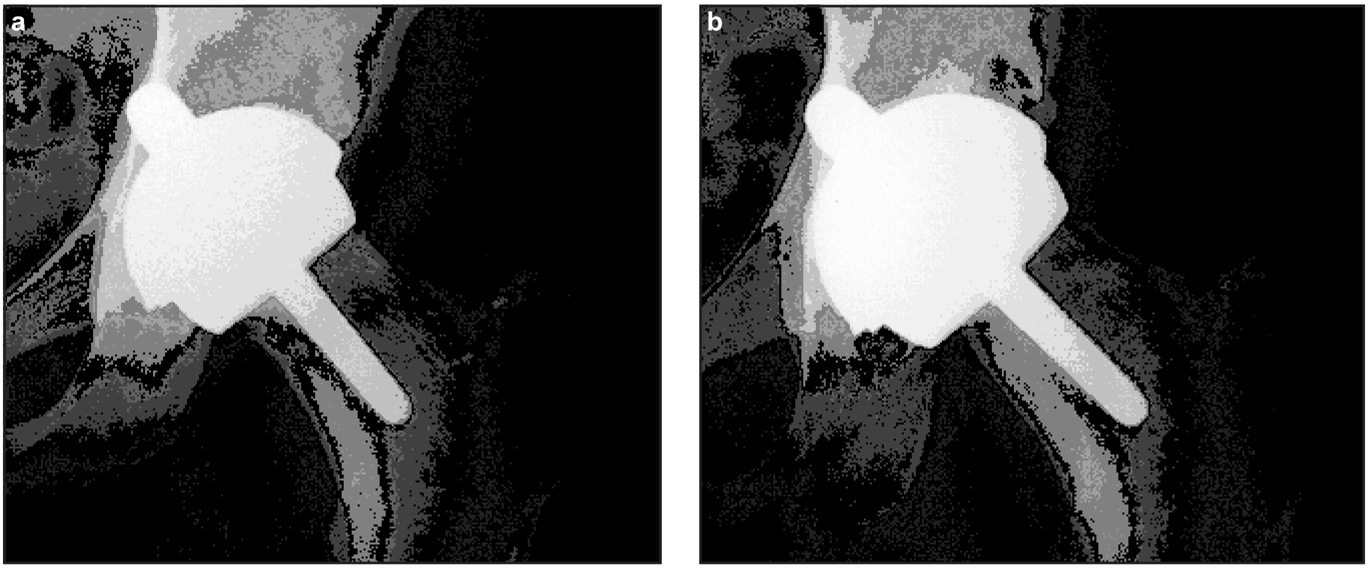

Fig. 5 - 2 year follow-up of McMinn 1996 hybrid resurfacing - early osteolysis at head neck junction **a)**. 4½-year follow-up showing acetabular osteolysis and more marked osteolysis at the head/neck junction. Unrevised **b)**.

Intra-operative seating of the peripherally expanded acetabular component was a problem with incomplete seating in 48% of cases. Three failures requiring revision have occurred. The reasons for failure were: one infection, revised at 42mths, one collapsed femoral head in a patient with pre-existing avascular necrosis revised at 48mths and one early cup loosening in a patient with dysplasia eventually revised at 40mths. In the three revision cases no metallosis from bearing wear was seen. The eventual outcome of patients who had their McMinn resurfacing with double heat-treated metal performed during 1996 is a cause for concern. Of 187 implants five have failed and to date four have been revised. Many of these patients have at the time of writing not had five-year clinical and radiographic review, but even at this stage some patients have worrying radiographic features of osteolysis (Fig.5) (Fig.6). However other patients from 1996 have no osteolysis and the author was initially bewildered as to why some patients from 1996 are fine and others have osteolysis. The answer to this dilemma came from the

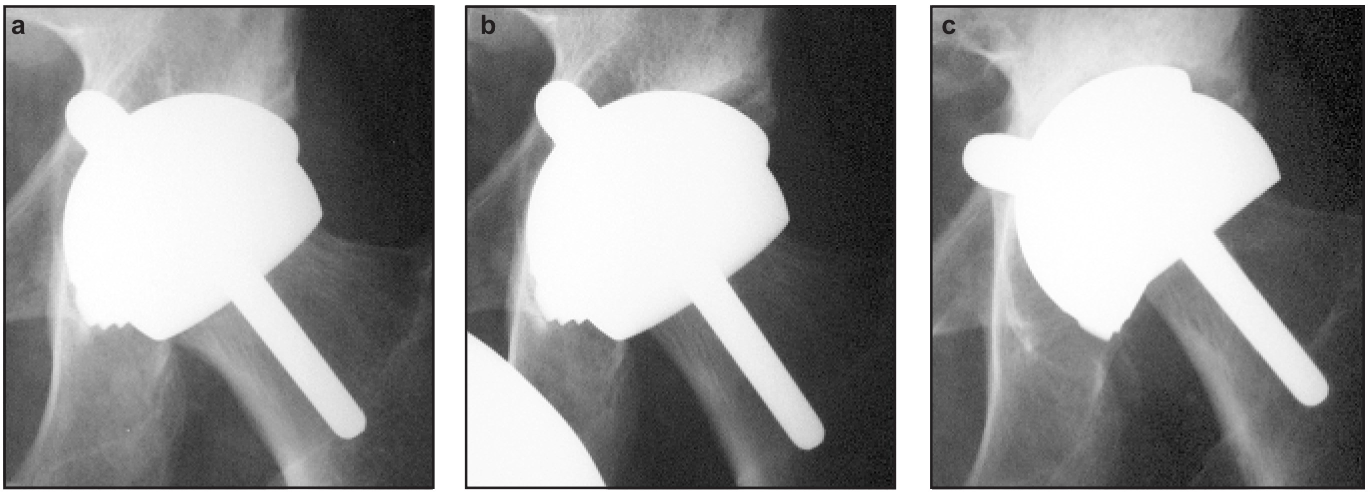

Fig. 6 - Post-op follow-up1996 McMinn Hybrid resurfacing **a)**. Acetabular roof osteolysis at 2 year follow-up **b)**. Gross cup loosening at 5-year follow-up. Awaiting revision **c)**.

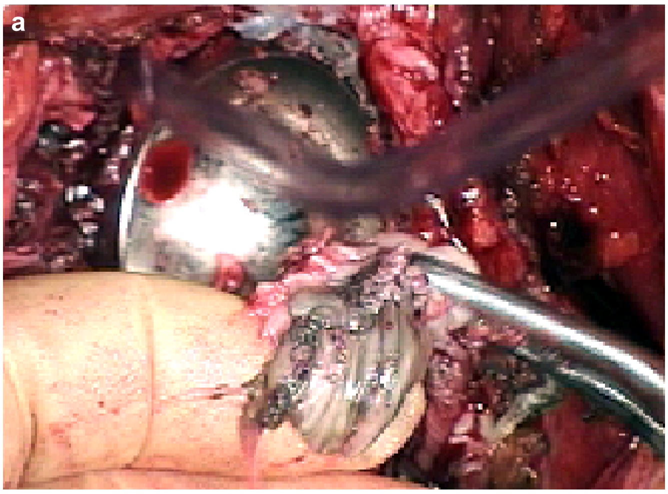
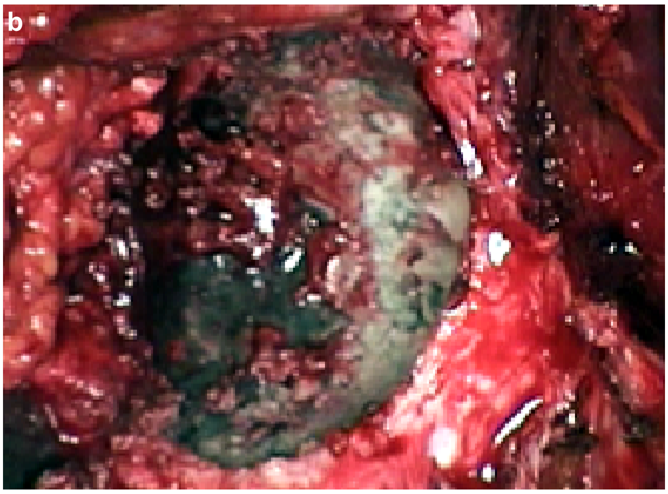

Fig. 7 - 1996 McMinn hybrid resurfacing. Metallosis in capsular tissue at revision surgery 42mths **a)**. Following cup removal, metallosis and osteolysis in the acetabulum **b)**.

revision operations and implant retrieval analysis of these 1996 components. From the four revisions in the author's 1996 series one infection occurred, revised at 14mths; no metallosis was seen. Three revisions were performed for cup loosening with revision occurring at 38mths, 42mths and 61mths. In all three of these revision operations metallosis and osteolysis was observed (Fig.7). One further 1996 resurfacing implant was available from another surgeon's practice where revision was performed at 50mths for pain. At revision operation the components were well fixed but metallosis and osteolysis were observed.

Laboratory Studies

An extensive programme of investigation has been undertaken at the Materials Research Institute at Sheffield Hallam University, UK into the effect of different heat processes on cast cobalt chrome (9). Following investment casting, high carbon cobalt chrome forms a typical microstructure with large blocky carbides precipitating in the metal matrix. These $M_{23}C_6$ carbides are the same hardness as alumina ceramic and confer wear resistance on the material when used as a metal/metal articulation (15). Three heat processes and combinations of these have been investigated, hot isostatic pressing, solution heat treatment and sintering. All these processes involve heating the metal to around 1200°C. The effects of these heat processes on the metal are complex but simply put, during heating the carbides are partially dissolved and during cooling the carbides are reprecipitated. Two main effects can be observed on the metal with these heat processes. First the carbides are rarely precipitated in as great a volume fraction after heat processes as in the original metal (Fig.8).

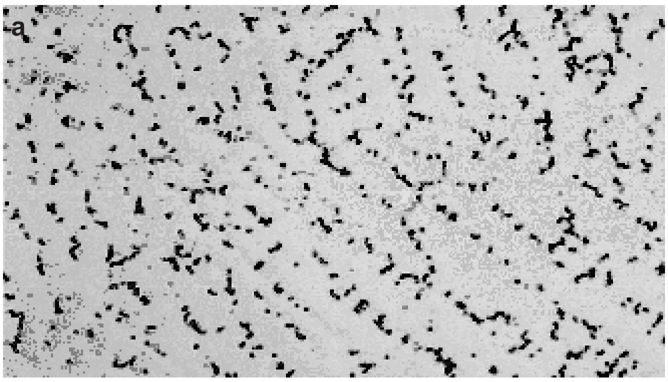
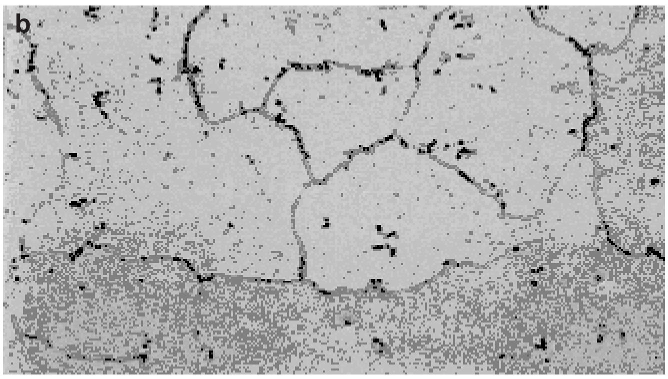

Fig. 8 - Typical blocky carbide in as cast high carbon cobalt chrome. Optical x100 **a)**. Moderate carbide depletion following hot isostatic pressing & solution heat treatment. Optical x100 **b)**.

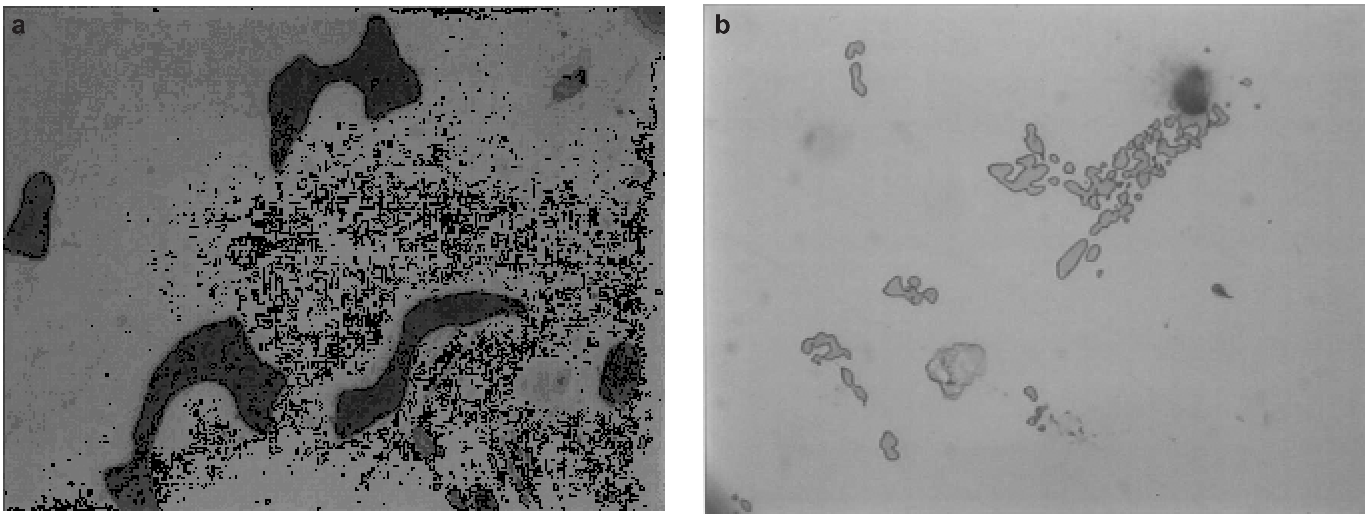

Fig. 9 - Typical blocky carbide in as cast high carbon cobalt chrome. Optical x1000 **a)**. Carbide disintegration following solution heat treatment. Optical x1000 **b)**.

Different heat processes cause more carbide depletion than others, and as will be seen in the wear retrieval analysis, considerable variation in carbide depletion occurs even with the same heat processes. The second effect of the heat processes is that the original large blocky carbides are disintegrated into numerous smaller carbide particles (Fig.9).

Different microstructures have been investigated with adhesive wear testing (Pin on disc) and abrasive wear testing (Calowear). Pin on disc tests revealed a difference in the mechanical stability of the carbides in the metal matrix of the as-cast and heat processed cobalt chrome. In the as-cast metal, examination of the disc wear track showed that the large blocky carbides remained stable in the metal matrix whereas with the disintegrated smaller carbides in the heat processed metal there was evidence of instability with some small carbides torn out of the metal matrix (Fig.10). This phenomenon is partially explained by the reduction in surface area of the smaller carbides reducing the resistance to extraction forces.

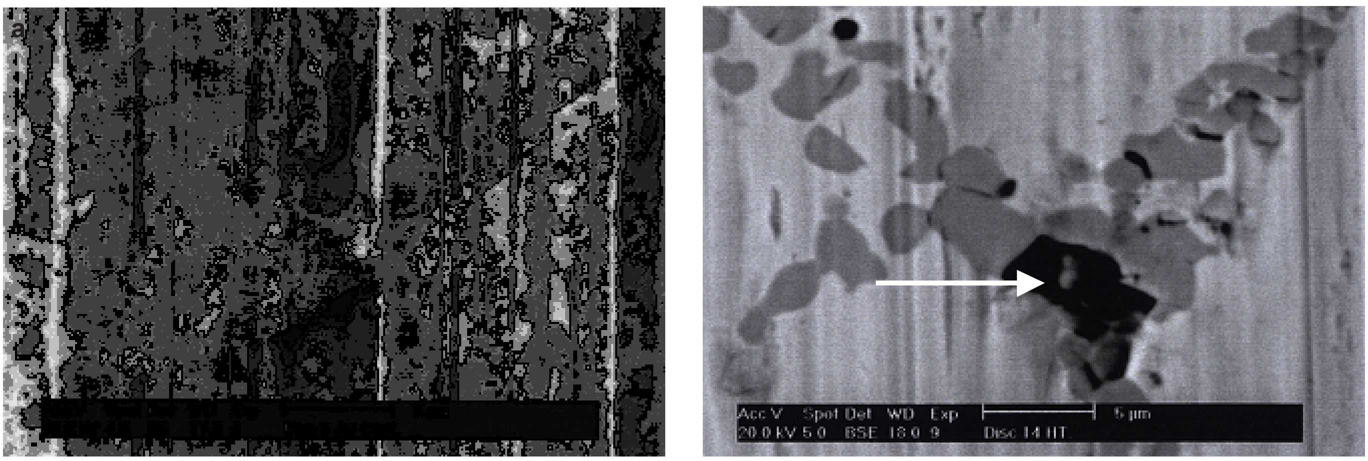

Fig. 10 - Disc wear track following pin on disc test with as cast metal. Irregular blocky carbide seen stable in metal matrix. Viewed by electron scan microscopy **a)**. Disc wear track following pin on disc test with solution heat-treated metal. Small carbide (arrow) has been torn from the metal matrix. Viewed by electron scan microscopy **b)**.

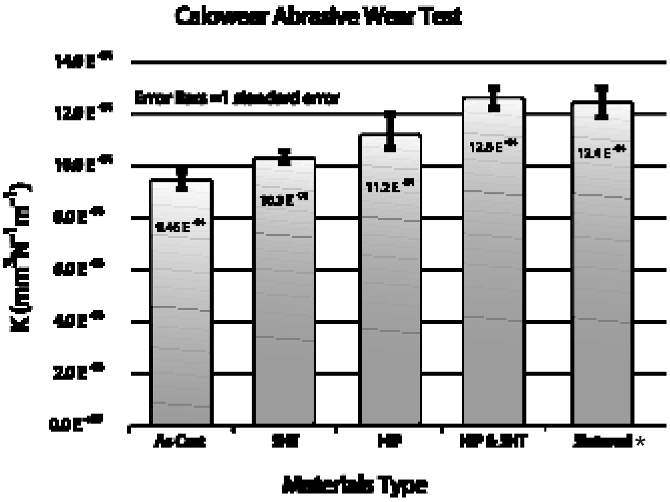

Fig.11 - Wear factor (K) with different materials. All tests repeated five times.
SHT = solution heat-treated.
HIP = hot isostatically pressed.
**Sintering of test pieces performed by Astromet Inc. Cincinnati USA.*

Calowear tests on different metal microstructures showed significant differences in the wear factor of metal from the same master melt subjected to differing heat processes (Fig.11).

Implant retrieval analysis

The four pairs of McMinn 1996 Hybrid resurfacing implants where metallosis and osteolysis were observed at revision operation have been analysed. Wear was measured on a roundness measurement device (Roundtest RA300-Mitutuyo) by multiple traces which first established the original shape, then by tracing across the wear scar, the exact amount of wear on the articulating surfaces of the cup and head was measured as the linear deviation from the original intact circumference. Wear of components is presented as total linear wear and wear rate per year (assuming a constant wear rate). Metal wear of the non-articular surfaces of the cups by abrasion of a loose component against bone was noted after examination under a magnifying glass. The metal microstructure of the articular surfaces was identified using scanning electron microscopy and further examination of the microstructure of the components was identified by sectioning the components and optical microscopy of polished stained surfaces. The presence of carbide in the metal of each component was graded on a scale from zero to forty were zero is no carbide in the metal and forty is the normal carbide presence in high carbon as-cast chrome cobalt. Results of implant analysis from these four patients are summarized in Table i.

Table.i

Sample Name	Linear wear (Micrometres)	Time in situ (Months)	Wear rate (Micrometres per year)	Polishing of non-articular cup surface	Carbide presence in metal (0-40 Scale)
Cup 1(C1)	8	61	1.6	Present	30
Head 1 (H1)	55		10.8		10
Cup 2 (C2)	2	38	0.6	Present	30
Head 2 (H2)	12		3.8		30
Cup 3 (C3)	20	42	5.7	Present	20
Head 3 (H3)	35		10.0		10
Cup 4 (C4)	50	50	10.8	Absent	0
Head 4 (H4)	150		36.0		0

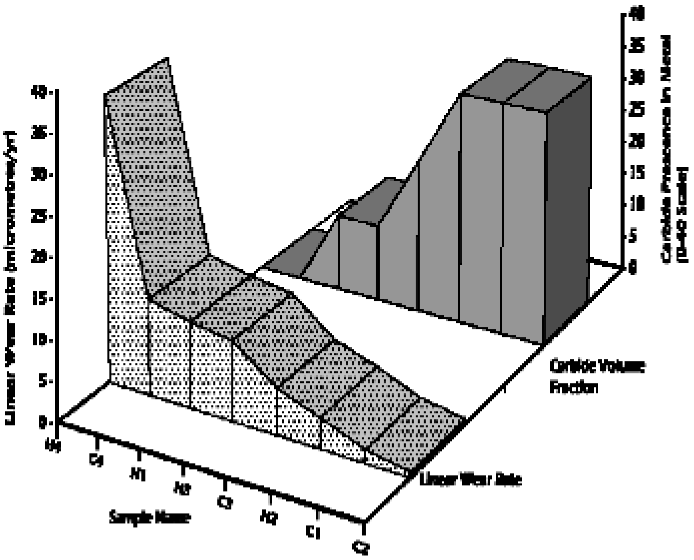

Fig.12 Explant linear wear rate versus carbide volume fraction

When wear rate of implants is plotted against carbide volume fraction in each implant it can be seen that the highest wear rate in these implants occurs when the metal is most carbide depleted and the lowest wear rates occur in less carbide-depleted components (Fig.12).

Today's metal/metal hip resurfacings

The McMinn hybrid resurfacing was withdrawn from clinical use in 1996 and since 1997 three different metal/metal resurfacing devices have been available. The Cormet 2000 (manufacturer: Corin Medical Ltd. UK.) was developed by the manufacturer from the McMinn hybrid and the metal is hot isostatically pressed and solution heat-treated. The Conserve Plus (manufacturer: Wright Medical Technologies Ltd. USA.) has a sintered beaded acetabular component. The Birmingham Hip Resurfacing (manufacturer: Midland Medical Technologies Ltd. UK.) has a cast-in porous acetabular ingrowth surface and has an as-cast metal microstructure having had no post-casting heat treatments.

The author has no experience with the Cormet 2000 or Conserve Plus devices and all resurfacings in the author's practice since 1997 have been with the Birmingham Hip Resurfacing.

Design of the Birmingham Hip Resurfacing (BHR)

It was considered important to remain with hybrid fixation using hydroxyapatite coating of the acetabular component and a cemented femoral component as this seemed the best combination for fixation of metallic resurfacing components. However concern was expressed about the long-term durability of hydroxyapatite on a smooth metal surface if the hydroxyapatite eventually became absorbed. It was decided to have hydroxyapatite on a porous metal surface so that if the hydroxyapatite eventually became absorbed enduring fixation would continue with bone ingrowth in the porous cup network. Deciding on the nature of the porous surface was a major problem. Sintering to apply porous beads was considered unacceptable from a design viewpoint, as the heat required for sintering was known to cause carbide depletion, carbide disintegration and an increased wear in metal subjected to this treatment. Furthermore it is common manufacturing practice to hot isostatically press and solution heat treat metal that has been sintered and again these processes were considered unacceptable. In addition a 10% incidence of bead shedding from sintered uncemented acetabular cups has been reported (10). Plasma sprayed application of a metallic porous surface was considered but again rejected. In revision surgery practice it had been observed that metal particles from the porous surface had dislodged and migrated into the bearing (Fig.13). These metal particles coming off the plasma sprayed surface and getting into the articulation were regarded as potentially detrimental to a metal/metal articulation.

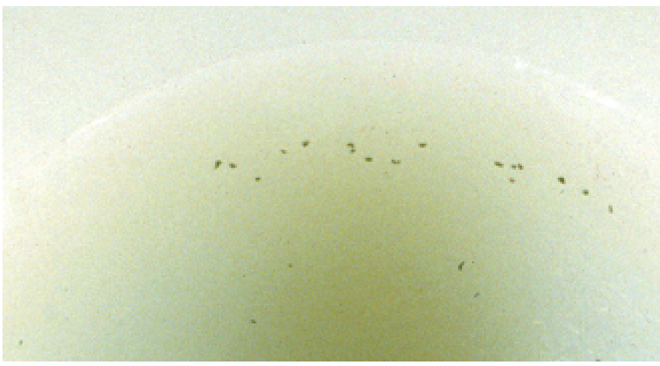

Fig. 13 - 1-year explant for infection. Plasma sprayed metal particles embedded in polyethylene cup articular surface. Plasma sprayed acetabular shell was solid & ingrown. Femoral component was cemented Exeter.

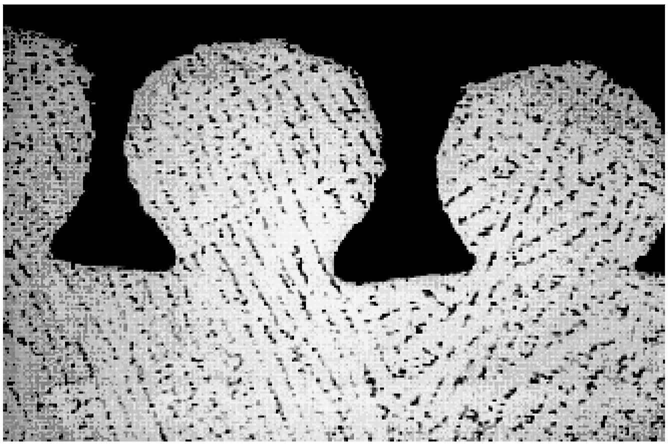

Fig. 14 - Section through BHR cup showing cast in porous beads and rich carbide microstructure. Optical x50

Fig. 15 - Dysplasia cup with screws, plus standard BHR cup & femoral component.

In order to avoid the problems associated with mechanically unstable porous coatings or degradation of the cast cobalt chrome microstructure with heat processes a cast-in porous surface was developed (Porocast ™) for the BHR acetabular component (Fig.14). Acetabular dysplasia is common in the young arthritic hip population and in order to allow conservative hip arthroplasty in this challenging group the BHR dysplasia cup system was developed (Fig.15). Supplementary screws provide secure initial fixation with bone grafting of the deficient acetabulum giving long term component support.

From July 1997 until February 2001 the author has performed 1,209 BHR's, 1,094 with the standard acetabular components and 115 using a dysplasia cup. The complications requiring revision were 4 femoral neck fractures, 2 infections and 1 collapsed head from avascular necrosis.One patient sustained a traumatic dislocation 24mths following operation and was treated with closed manipulation.

The functional outcome has been good in this group of patients as judged by hip scores. Mean Harris hip scores are 95 at one year, 95 at two years and 94 at three years post-op. Harris Hip scores on these patients were obtained from an independent assessment of function by The Oswestry Outcome Centre, Oswestry, UK.

Plain x-rays have shown very satisfactory appearances and there have been no acetabular failures with 1,094 standard cups (Fig.16). The 115 dysplasia cups have done well (Fig.17) with no acetabular failures in the dysplasia group.

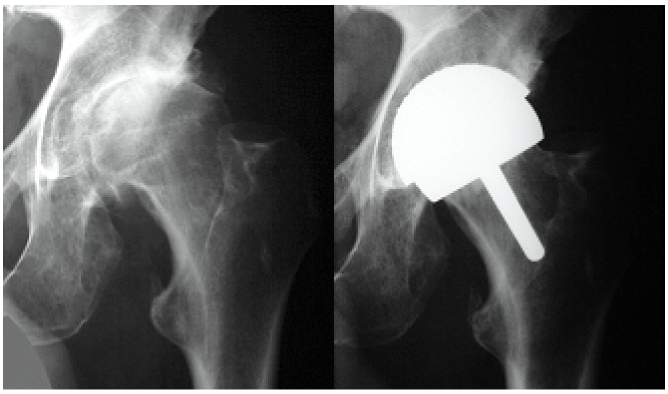

Fig. 16 - BHR in 49-year-old farmer.

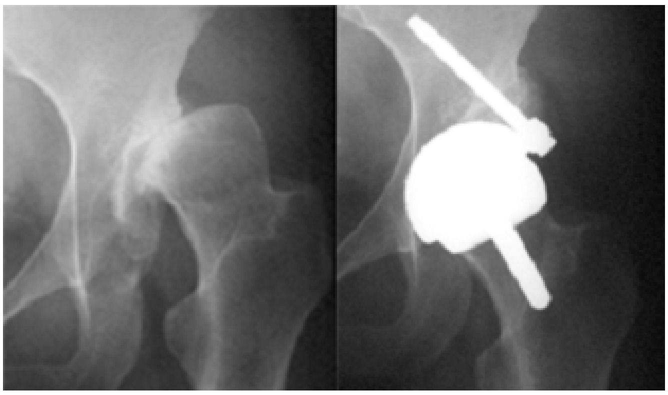

Fig. 17 - Dysplasia BHR with acetabular bone grafting in 34-year-old woman.

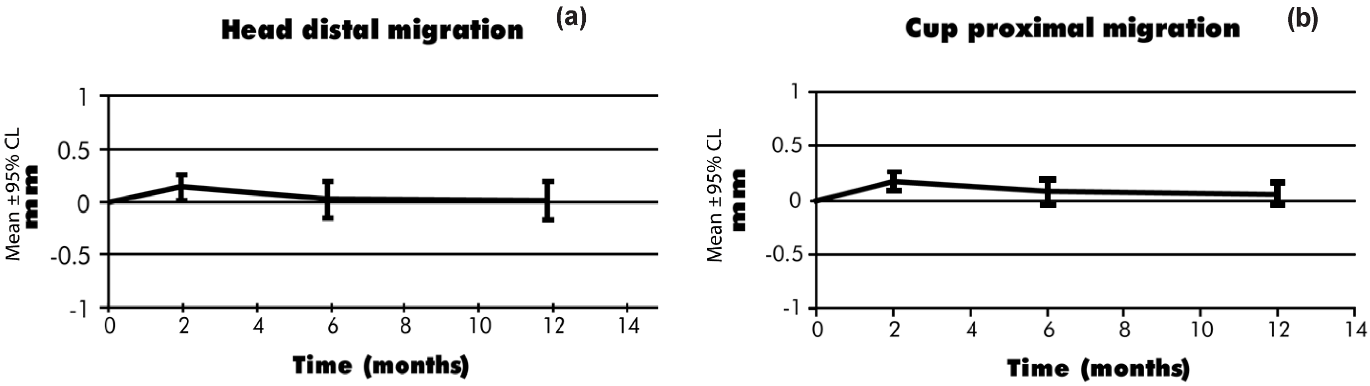

Fig. 18 - RSA migration on BHR femoral component up to 1-year **a)**. RSA migration on BHR acetabular component up to 1-year **b)**.

An RSA study has been performed on 19 patients (20 hips) with Dr Lars Nistor and Dr Arne Lundberg (Sweden) and migration measurements have been made up to 1-year with 2-year migration measurements yet to be performed. Very low migration has been observed up to the 1-year stage (Fig.18).

Retrieved components from both autopsy and revision have shown good ingrowth into the acetabular porous cup surface and solid fixation on the femoral side. Five pairs of retrieved BHR components have been available for wear analysis where the time in situ was 8mths, 12mths, 18mths, 42mths and 45mths. These were analysed in the same way as the McMinn hybrid implants and the average wear rate for the BHR cups was 0.77micrometres/year and the average wear rate for the BHR heads was 1.62micrometres/year (assuming a constant wear rate). Survivorship analysis on all the author's hybrid fixed resurfacings shows a 97% survival at 7-8yrs versus a 40% survival at the same time period in Wagner resurfacings performed in Birmingham (Fig.19) (11).

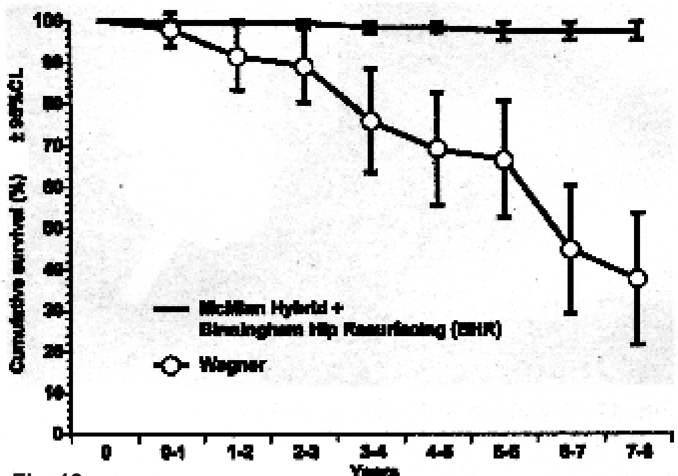

Fig. 19

DISCUSSION

Metal/Metal Hip Resurfacing is gaining popularity as a treatment method for the young active patient with hip arthritis, and the author is aware of its use in 15 different countries. At present 3 systems are available and several other systems are under development. All these implant systems are relatively new and they all rely on the satisfactory long term bearing performance of historical metal/metal total hip replacements as justification for their use. It seems to this author fundamentally unsound to implant a metal/metal bearing which has a quite different microstructure from the historical metal/metal bearings and then expect that the new bearing will behave like the bearings of 30 years ago.

Evidence has been presented to show that various heat processes change the microstructure of the historically proven material, worse still the standarised processes of hot isostatic pressing and solution heat treatment can apparently produce a range of different microstructures. These metals with altered microstructures should be considered as new materials and not regarded as the historically proven as-cast metal. Since the microstructures in the retrieved 1996 components showed marked variability it is likely that such material variability also exists in the unrevised 1996 patients' hip prostheses. This variability in microstructure would explain why some patients from 1996 are fine and others have osteolysis.

Solution heat treatment of cast cobalt chrome is an accepted process for improving tensile/fatigue properties of the metal. This improvement in the mechanical properties of cast cobalt chrome by heat treatment is of importance when considering the tensile/fatigue properties of conventional hip replacement femoral stems. Enhanced mechanical properties are of little relevance to a metal/metal articulation and for hip resurfacing bearings, wear resistance is the crucial property that will determine the implants survival. Whilst solution heat treatment improves the mechanical properties of cobalt chrome it is known that it decreases the wear resistance when used as a metal/metal articulation (12-14). Some McKee-Farrar metal/metal replacements were solution heat treated and it is suggested that this heat treatment explains the higher wear in the McKee-Farrar metal/metal articulation compared to the other as-cast articulations in use at the same time period (15).

Hot isostatic pressing post dated the historical metal/metal era and so has not been used hitherto in bearings for metal/metal articulations. Hot isostatic pressing however is a widely used process today for reducing micro-porosity and thus improving the mechanical properties of cast cobalt chrome and again this is mainly of importance in conventional stemmed implants. Porosity in the metal castings for metal/metal articulations is a major manufacturing problem, with implants having to be scrapped at a late stage in the manufacturing process. Repair welding of defects on the articular surface is regarded as unacceptable today. In order to avoid porosity in the castings and the need for tribologically damaging hot isostatic pressing, considerable care is needed in designing the feeds and implants for the investment casting process and in addition full advantage must be taken from modern advances in casting technologies.

Sintering of beads for ingrowth surfaces also post dated the historical metal/metal era and there is therefore no long-term clinical data with sintered metal/metal articulations. One hip simulator study did however show higher wear in metal/metal articulations that had been subjected to the heat of sintering (16).

Hip simulators have been advocated for pre-clinical testing of new materials, but with metal/metal bearings it is known that different simulators produce very different wear rates in the same bearings (Fig.20) (17). Results from different hip simulators must therefore be interpreted with extreme caution. Hip simulator results from different laboratories have already caused confusion in relation to the wear of different material combinations for metal/metal bearings. One study comparing low carbon cobalt chrome to high carbon cobalt chrome showed no difference in the wear of the two different materials (18). Another hip simulator study however showed fourteen times higher steady state wear in the low carbon compared to the high carbon cobalt chrome (19). In the event hip simulators were not required to settle this simple matter of the superiority of high carbon cobalt chrome as a pin on plate study (20) and a pin on disc study (15) showed unacceptably high wear of the carbide free, low carbon cobalt chrome material.

From our retrieved resurfacing components the heat processes of hot isostatic pressing and solution heat treatment increase component linear wear rates by up to 20 times compared to the as-cast microstructure components. Volumetric wear measurements, not presented in this paper, are up to 80 times higher in the heat treated components compared to the as-cast resurfacing components. This is much higher wear than one would expect from the Calowear tests with the double heat treated metal wear factor only 33% higher than the as-cast material. A possible explanation for the worse clinical performance comes from the pin on disc tests where carbide pluck out has been observed in the heat-treated metal. These hard carbides may act as a third body and cause excess wear of the

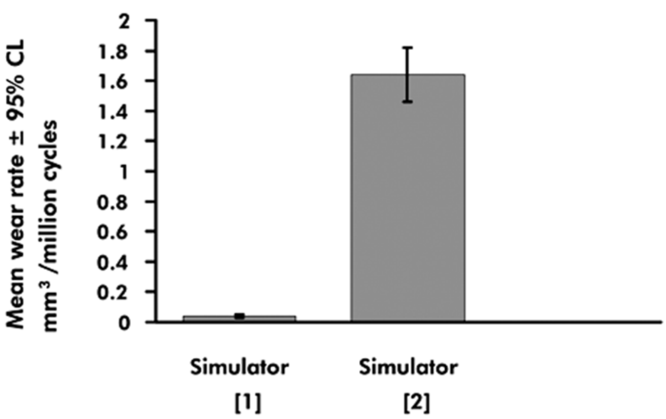

Fig. 20 - Same metal/metal bearings on two different simulators. Figure courtesy of Professor John Fisher, University of Leeds, UK.

heat-treated metal/metal bearings. This however seems unlikely since as can be seen from the retrieved implants, low wear rates of one component did accompany high wear rates of a matching component. This argues against third body debris as a cause of increased bearing wear in these retrieved components, as any third body debris would be expected to damage and wear both matching bearing surfaces. The more likely explanation is that the double heat treatment of the laboratory test pieces produced only moderate carbide depletion and not the profound carbide depletion seen in some retrieved components with very high wear.

In the Birmingham Hip Resurfacing series the single largest cause of failure was fracture of the femoral neck. The four fractures in the authors series all occurred within the first three post-operative months and all occurred in patients with poor bone stock quality. Two patients were over the age of 70 years and had osteoporosis. One younger female patient had dexa-scan proven generalised osteoporosis and another young patient was on steroids and had renal osteodystrophy. These failures serve as a reminder that hip resurfacing cannot safely be performed in patients with poor bone stock quality. Older patients particularly older female patients should be advised against having a hip resurfacing in view of the increased risk of femoral neck fracture.

Younger patients with osteoarthritis who are on long term anti-inflammatory drugs can have severe peri-articular bone destruction and may be beyond the limits of treatment with hip resurfacing (Fig.21) (21, 22). In these patients with anti-inflammatory drug induced destructive arthritis great care is required with case selection and in order to prevent this problem it is the author’s practice to counsel young patients with hip osteoarthritis against the use of anti-inflammatory or aspirin containing drugs.

Avascular necrosis and collapse of the femoral head can occur after hip resurfacing but to-date the author has had only one such failure from 1,503 resurfacings in the hybrid fixed series.Fixation of components now seems to have been solved, at least in the early years, with no loosening of components in 1,209 Birmingham Hip Resurfacing’s.

CONCLUSION

Hip resurfacing using metal/metal bearings with historically proven metallurgy and employing hybrid fixation offers a viable treatment alternative for the young and more active patient with hip arthritis. Hip resurfacing has had a troubled history and needs no further set backs due to wear of defective materials.

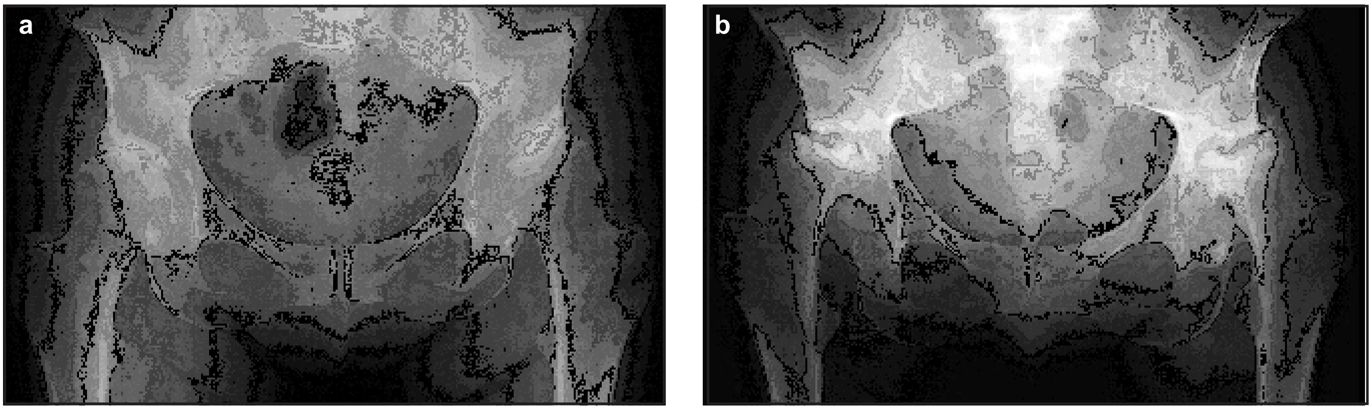

Fig 21. 61-year-old woman with osteoarthritis secondary to mild developmental dysplasia. Patient advised against hip arthroplasty in view of relative youth and prescribed anti-inflammatory drugs **a)** Severe destruction of femoral heads & acetabulae after 3-years of anti-inflammatory medication **b)**

ACKNOWLEDGEMENTS

The author would like to thank Mr Tim Band of Doncaster's Centaur Precision Castings Ltd. UK and the Materials Research Institute, Sheffield Hallam University, UK, for the metallurgical information, Finsbury Instruments Ltd. UK, for component wear measurement and Miss Claire Doyle for preparing the manuscript.

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