Ten-year results of a double-heat-treated metal-on-metal hip resurfacing

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Second-generation metal-on-metal bearings were introduced as a response to the considerable incidence of wear-induced failures associated with conventional replacements, especially in young patients. We present the results at ten years of a consecutive series of patients treated using a metal-on-metal hip resurfacing. A distinct feature of the bearings used in our series was that they had been subjected to double-heat treatments during the post-casting phase of their manufacture. In the past these bearings had not been subjected to thermal treatments, making this a unique metal-on-metal bearing which had not been used before in clinical practice.

We report the outcome of 184 consecutive hips (160 patients) treated using a hybrid-fixed metal-on-metal hip resurfacing during 1996. Patients were invited for a clinicoradiological follow-up at a minimum of ten years. The Oxford hip score and anteroposterior and lateral radiographs were obtained. The mean age at operation was 54 years (21 to 75). A series of 107 consecutive hips (99 patients) who received the same prosthesis, but subjected to a single thermal treatment after being cast, between March 1994 and December 1995, were used as a control group for comparison.

In the 1994 to 1995 group seven patients (seven hips) died from unrelated causes and there were four revisions (4%) for osteolysis and aseptic loosening. In the 1996 group nine patients died at a mean of 6.9 years after operation because of unrelated causes. There were 30 revisions (16%) at a mean of 7.3 years (1.2 to 10.9), one for infection at 1.2 years and 29 for osteolysis and aseptic loosening. Furthermore, in the latter group there were radiological signs of failure in 27 (24%) of the 111 surviving hips.

The magnitude of the problem of osteolysis and aseptic loosening in the 1996 cohort did not become obvious until five years after the operation. Our results indicate that double-heat treatments of metal-on-metal bearings can lead to an increased incidence of wear-induced osteolysis.

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Metal-on-metal bearings are being increasingly used as a low-wear alternative to conventional bearings. The basis of their re-introduction in recent years was the satisfactory long-term survival of metal-on-metal hip replacements which had been in use since the early 1960s.[1] It was anticipated that the good results of these older metal-on-metal bearings would be replicated in the modern bearings provided that they conformed to, or improved upon, the materials and design characteristics of the original bearings.

The McKee, Ring and Stanmore replacements had been made of as-cast high-carbon (> 0.2% carbon) cobalt-chrome (CoCr) bearings. Several *in vitro* studies have shown that the high-carbon alloy has more wear resistance than the low carbon (< 0.07% C) alloy.[2-5] It is widely acknowledged[6-8] that the high-carbon alloy owes its wear resistance to the presence of a higher fraction, around 5% by volume, of metal-carbon precipitates called ‘carbides’ in the microstructure. In addition to reducing bearing wear, these precipitates also resist their own dislodgement by virtue of their size, ‘blocky’ structure and inherent stability.

However, a high-carbon alloy can be depleted of this higher carbide fraction by post-casting thermal treatments, which include solution heat treatment and hot isostatic pressing. These treatments cause some of the elemental carbon to diffuse from the precipitated carbide residues into the matrix as dissolved carbon, rendering the precipitates smaller and more easily dislodgeable.[9,10] Several *in vitro* studies have shown that this carbide depletion is detrimental to the hardness of the material and thereby to its wear resistance.[6,7] *In vitro*[8] and retrieval[10] studies have also shown an

Table I. Details of the patients

	1994 to 1995	1996	p-value
Number of hips (patients)	107 (99)	184 (161)	
Mean age in yrs (range)	49 (18 to 77)	54 (21 to 84)	< 0.01*
Mean follow-up in yrs (range)	10.9 (10 to 12.4)	10.5 (10 to 11.1)	
Gender (%)			
Male	65 (*61*)	108 (*59*)	
Female	42 (*39*)	76 (*41*)	
Mean height in metres (range)	1.71 (1.4 to 1.9)	1.70 (1.5 to 1.9)	0.5*
Mean weight in kg (range)	79.6 (45 to 144)	76.4 (51 to 152)	0.2*
Mean body mass index in kg/m^2 (range)	27.1 (19 to 56)	26.3 (18 to 41)	0.2*
Primary OA as diagnosis	82	150	0.1†
Diagnoses other than primary OA	25	34	
Median (interquartile range (IQR) femoral component diameter in mm)	48 (44 to 52)	48 (44 to 52)	0.5‡
Median (IQR acetabular component diameter in mm)	54 (50 to 58)	54 (50 to 58)	0.5‡
Radiological osteolysis/aseptic component loosening at latest follow-up	9	27	

* *t*-test
† chi-squared test
‡ Mann Whitney U test

inverse linear relationship between the carbide volume fraction in the implant and the wear factor. Furthermore, the dislodged precipitates have the potential to lead to third-body wear.[9]

Modern metal-on-metal resurfacings were first introduced into clinical usage in 1991 in Birmingham, United Kingdom, with the understanding that the beneficial features of the original replacements would be used in their manufacture. Therefore the earliest second-generation metal-on-metal resurfacing components were made of cast high-carbon CoCr alloy. Thermal treatments were later introduced into the post-casting processes to reduce porosity in the castings. Subsequent inquiry showed that different heat treatments were applied *ad libitum* initially, leading, in general, to the implants being given single heat treatments of either hot isostatic pressing or solution heat treatment between 1994 and 1995. During 1996 both processes were being routinely applied. This double heat-treatment of cast CoCr metal-on-metal bearings was unique in the history of arthroplasty and had not been used before. Thus a new bearing with no previous clinical history was introduced and implanted during 1996.

Our study is a clinicoradiological assessment and survival study after ten years of these heat-treated hip resurfacings which were implanted in 1996 to determine whether double heat-treated high-carbon CoCr-bearing hip devices affect the medium-term survival of the implant at ten years.

Patients and Methods

Between January and December 1996, 184 consecutive hips (160 patients) were treated using a second-generation metal-on-metal hip resurfacing arthroplasty (McMinn Hybrid Resurfacing; Corin Medical Ltd, Cirencester, United Kingdom). These implants reportedly underwent double-heat treatment after casting. A control series of 107 consecutive hips (99 patients) in which the same prosthetic design had been implanted between March 1994 and December 1995 was used for comparison. During this period these implants were subjected to a single thermal treatment of either hot isostatic pressing or solution heat treatment after being cast.

Details of the patients, the diagnoses and components in the two groups are shown in Table I. There were no significant differences between them except for the mean age at operation which was 49 years (18 to 77) in the 1994 to 1995 series and 54 years (21 to 84) in the 1996 series. This difference was statistically significant (*t*-test, $p < 0.01$; Table I). The different aetiologies included primary osteoarthritis (OA), inflammatory arthritis, avascular necrosis of the femoral head, acetabular dysplasia and others including Perthes' disease, slipped femoral epiphysis, protrusio acetabulae and osteopetrosis. The most common diagnosis was primary OA in both groups and the ratio of OA to non-OA was not significantly different in the two groups (chi-squared test, $p > 0.1$).

Implants. The McMinn hybrid hip resurfacing device was in clinical use from March 1994 to December 1996 (Fig. 1). It included a cemented femoral component which had a chamfered cylinder design with a short stem. This was available in four sizes, 40 mm, 44 mm, 48 mm and 52 mm. The acetabular component had a nominal thickness of 3 mm and was also available in four sizes, 46 mm, 50 mm, 54 mm and 58 mm. It was designed for cementless fixation with a complete hydroxyapatite (HA) coating on its outer surface which was smooth but had a macrotextured section above the rim to maintain bone-implant fixation after possible resorption of the HA. It had a central peg and two sets of peripheral antirotation splines for stability. It had a non-

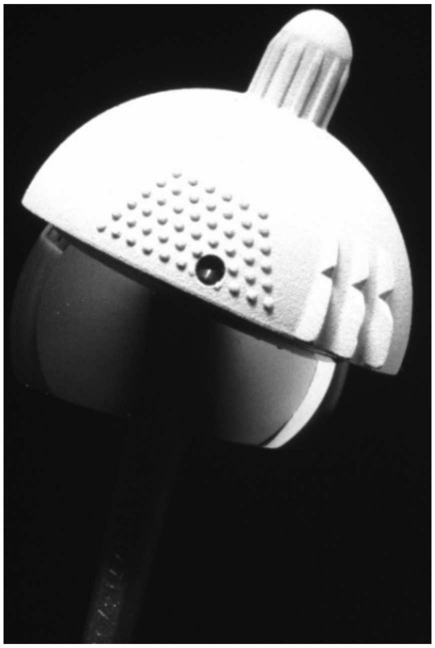

Fig. 1

Photograph of the McMinn Hybrid resurfacing device used between March 1994 and December 1996.

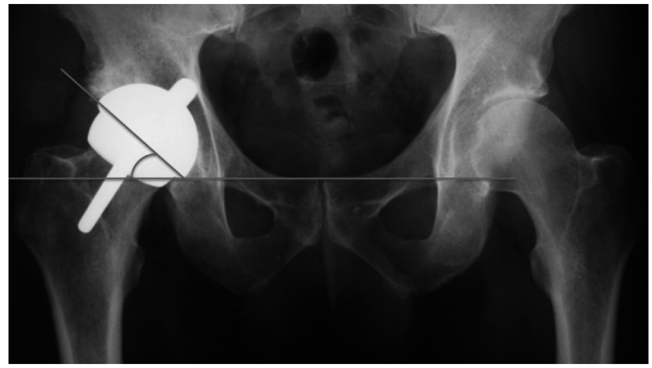

Fig. 2

Radiograph showing measurement of the inclination of the acetabular component from the angle between the base of the component and the interteardrop line.

concentric design with an outer surface of 180° for maximal fixation and an internal surface of 160° for increased range of movement. Additionally, it was expanded peripherally in order to obtain tight primary fixation. This component had an inserter which latched on through two introducer holes located in the periphery.

Operative procedure. All operations were carried out by the senior author (DJWM) or under his direct supervision through a posterior approach. The operative technique is described elsewhere.[11]

Cefuroxime (1.5 g) was given prophylactically as one pre-operative dose at induction of anaesthesia and three post-operative doses over the next 24 hours. Warfarin was given for thromboprophylaxis during in-patient stay in addition to early mobilisation and the wearing of compression stockings. On discharge from hospital after one week, the administration of low-dose aspirin was started and continued for one month.

Full weight-bearing mobilisation with a walking frame was started on the first day after operation. Patients gradually made a transition from two elbow crutches to walking sticks and on to unaided walking. At the follow-up at six weeks, the patients were reviewed by radiography, taught range of movement exercises for the hip and encouraged to gradually increase their activities which included swimming or exercising in a pool. They were advised to avoid high-impact activities during the first year after the operation.

Follow-up. All the surviving patients with unrevised hips were invited for a clinicoradiological follow-up at a minimum of ten years. Questionnaires for the Oxford hip score[12] were mailed to them a few days before the appointment and they were asked to bring the completed scores with them. The Oxford hip score ranges from 12 to 60 and measures a patients' perception of loss of hip function. An Oxford score of 12 is the best possible score and indicates no limitation of hip function and a score of 60, which is the worst possible score, indicates very poor hip function.

At the review, an anteroposterior plain radiograph of the pelvis and a horizontal-beam lateral view of the resurfaced hip were obtained and the patients were examined by one or two of the three clinicians (CP, JD or DJWM) who were experienced orthopaedic surgeons. Radiological assessment was performed by two of three authors (JD, CP or HZ). Osteolysis, periprosthetic radiolucent lines, loosening of the component and femoral fixation scores were assessed according to published definitions, zones and criteria as described by Johnston et al,[13] DeLee and Charnley[14] and Amstutz et al.[15] Hips with a femoral fixation score > grade 7, i.e., complete radiolucent lines in all three zones with or without migration, were considered to be loose. Thinning of the femoral neck was assessed using the femoral component as a reference for radiological magnification error as described by Hing et al.[16] The grading of Brooker et al[17] was used for assessing the presence of any heterotopic ossification (HO). The angle of acetabular inclination was measured as the internal angle between a line through the base of the component and the interteardrop line (Fig. 2).

Statistical analysis. When applicable, the normality of the distribution of data was assessed using the Kolmogorov-Smirnov test. Depending on this, an unpaired *t*-test or the Mann-Whitney U test was used to test null hypotheses between the groups. A p-value ≤ 0.05 was taken as the threshold for statistical significance. Kaplan-Meier survival analysis was performed with 95% confidence intervals (CI) using revision of either component for any reason and revision of either component for osteolysis or aseptic loosening as endpoints. Statistical significance was judged by non-

Table II. Implant failures and adverse radiological features at follow-up at ten years

	1994 to 1995	1996
Total number of hips (patients)	107 (99)	184 (161)
Patients deceased during follow-up (hips)	7 (7)	9 (13)
Patients lost to follow-up (hips)	2 (2)	1 (1)
Total revisions	7	30
Revision due to deep infection	1	1
Revision due to early loosening of the acetabular component	1	0
Revision due to a collapsed femoral head	1	0
Revision due to fracture of the femoral neck	0	0
Revisions with osteolysis and aseptic loosening with metallosis	4	29
Unable to attend review (lived abroad, chronic illness, logistic difficulty)	7 (8)	7 (7)
Radiological examination (hips)	83	129
Mean (range) angle of acetabular component inclination at the two-month follow-up	44.1 (28 to 58)	43.2 (34 to 57)
Femoral neck thinning	4	7
Component loosening		
Acetabular component tilt/migration	5	7
Femoral component tilt/migration	1	2

overlapping 95% CIs in the Kaplan-Meier plots. The analyses were performed using Microsoft Excel 2003 (Microsoft, Redmond, Washington) and MedCalc for Windows version 9 (MedCalc Software, Mariakerke, Belgium).

Results

The mean follow-up of the 1994 to 1995 group was 10.6 years (10.0 to 11.4) and in the 1996 group it was 10.46 years (10 to 11.1). A 45-year-old man in the 1994 to 1995 group and a 52-year-old woman in the 1996 group had a non-fatal pulmonary embolism, the former during the first post-operative week and the latter two months after operation. Both fully recovered without any sequelae after administration of anticoagulant treatment. There were no cases of wound dehiscence, neurovascular injury, fracture of the femoral neck or dislocation of the hip. In the 1994 to 1995 group, seven patients (seven hips) died from unrelated causes. Two others were lost to follow-up and a further seven (eight hips) who confirmed survival of the implant could not attend the review either because they lived abroad or had other comorbidities or logistical difficulties. In all, nine patients (13 hips) from the 1996 cohort died from unrelated causes. One patient was lost to follow-up and seven who confirmed survival of the implant could not attend the review or undergo radiological examination because of other unrelated morbidities or logistical difficulties.

Failures and survivorship. One patient from the 1994 to 1995 group with a pre-operative diagnosis of primary OA and one from the 1996 cohort with a pre-operative diagnosis of slipped femoral epiphysis with multiple previous operations were revised for deep infection (Table II). One from the 1994 to 1995 group with a pre-operative diagnosis of dysplasia had failure from early loosening of the acetabular component and was subsequently revised. Another with a pre-operative diagnosis of avascular necrosis of the femoral head was revised for further collapse of the head and failure. Neither had osteolysis or metallosis.

In addition, in the 1994 to 1995 group there were four revisions (4%) for osteolysis and aseptic loosening three to nine years after the operation, and in the 1996 cohort there were 29 revisions (16%) for osteolysis and aseptic loosening three to 11 years after the operation (Fig. 3). The cumulative survivorship at ten years with revision of either component, for any reason, as the endpoint was 93% (CI 88 to 98) in the 1994 to 1995 group and 84% (CI 78.8 to 89.2) in the 1996 group (Fig. 4). With failure from osteolysis or aseptic loosening as the endpoint, the ten-year survivorship of the 1994 to 1995 group was 96% (CI 92.2 to 99.8) and that of the 1996 group 86% (CI 80.5 to 91.5). This difference was statistically significant as seen from the non-overlapping confidence limits (Fig. 5). The mean Oxford score of the patients with surviving hips was 20 (12 to 36) in the 1994 to 1995 group and 19 (12 to 48) in the 1996 group, but the difference was not statistically significant (*t*-test $p = 0.7$).

Radiological findings. The mean angle of inclination of the acetabular component in the two-month radiographs was 44.1° (28° to 58°) in the 1994 to 1995 group and 43.2° (34° to 57°) in the 1996 group, but the difference was not significant (*t*-test, $p = 0.4$).

Radiological analysis of the surviving hips from the 1994 to 1995 group showed osteolysis in one or more zones around the acetabular component or in the femoral neck in three hips. In three other hips there were radiolucent lines in all three acetabular zones and in two the acetabular component had loosened and tilted into a more open position. Three more patients with no osteolysis showed loosening and tilt of the acetabular component and one femoral component had changed position because of collapse of the femoral head. In all, nine patients showed either osteolysis or loosening of aseptic component. One more asymptomatic patient with no evidence of osteolysis showed lucent lines in all three acetabular zones and four had non-progressive thinning of the femoral neck.

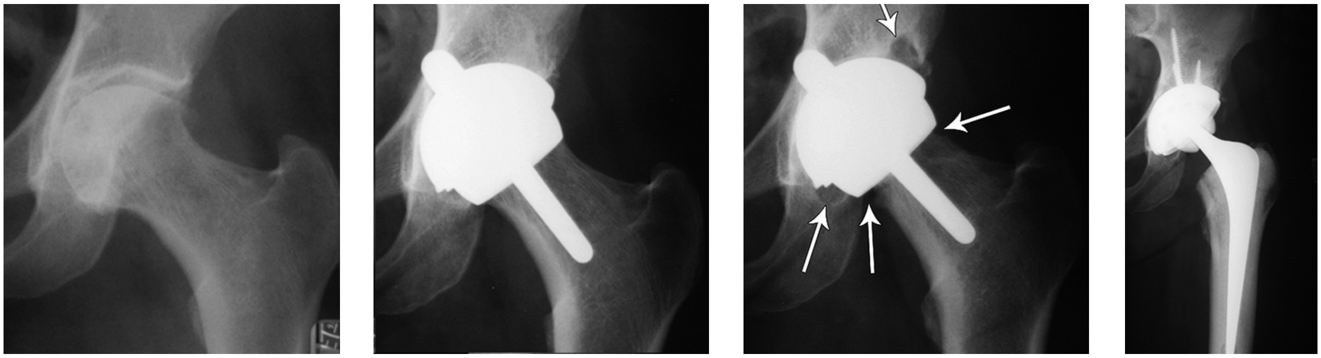

Fig. 3a Fig. 3b Fig. 3c Fig. 3d

Radiographs of the left hip of a 61-year-old woman with well-positioned and well-fixed resurfacing components implanted during 1996, showing a) a pre-operative view, b) at two months post-operatively, c) pre-revision and d) post-revision. She presented with a painful hip and was found to have osteolysis in zones 1 and 3 of the acetabulum and in the femoral neck and needed revision five years after the initial operation.

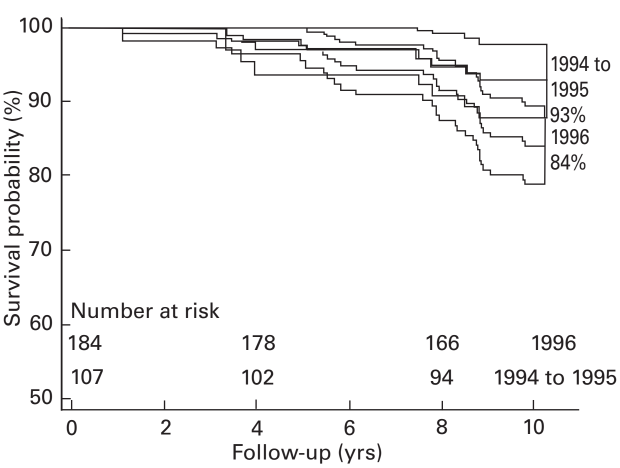

Fig. 4

Kaplan-Meier survivorship curves at ten years for 1994 to 1995 and 1996 groups of resurfacings with revision of either component for any reason as the endpoint.

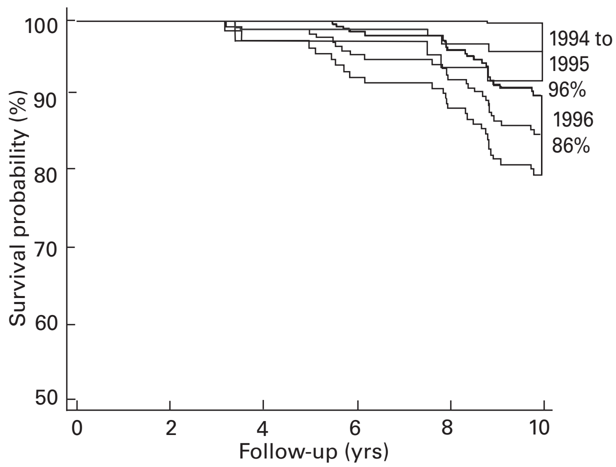

Fig. 5

Kaplan-Meier survivorship at ten years of the 1994 to 1995 and 1996 groups of resurfacings with revision of either component for osteolysis or aseptic component loosening as the endpoint.

In the 1996 group, there was evidence of osteolysis in one or more zones around the acetabular component or in the femoral neck or both in 22 hips (Fig. 6). In three of these the acetabular component had also loosened and tilted into an open position and in one both the femoral and acetabular components showed migration. An additional four patients with no osteolysis showed loosening of the acetabular component and one had migration of the femoral component. In all, 27 patients showed either osteolysis or aseptic loosening of the component. Three other asymptomatic patients with no evidence of osteolysis showed lucent lines in all three acetabular zones and two had lucent lines in all three zones around the stem. Thinning of the femoral neck exceeding 10% was found in seven hips. The mean inclination angle of the acetabular component in the radiographs at two months of the patients who were subsequently revised or developed radiological signs of osteolysis or loosening was 43.4° (95% CI, 37° to 47°). This was not significantly different ($p = 0.17$) from that of well-functioning hips with no adverse radiological signs of osteolysis or loosening with a mean inclination angle of 43.1° (95% CI 34° to 57°).

The version of the implant used in the 1996 cohort of patients was recalled and withdrawn from use at the end of 1996. The immediate reason which led to the recall was the development of a ratcheting, screeching or clicking noise in 12 patients (13 hips) during early follow-up. All of these patients reported that the noises disappeared in a short time. At follow-up at ten years none of the 12 patients who reported this noise has had revision. One of them with a

Fig. 6a

Fig. 6b

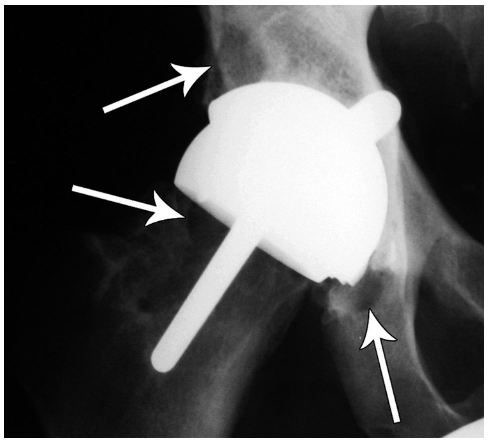

Fig. 6c

Radiographs of osteolysis in well-fixed components in a 34-year-old man from the 1996 group showing a) a pre-operative view, b) at two months post-operatively and c) at ten years post-operatively. At the ten-year follow-up he had mild pain and reduced hip function but not enough symptoms to warrant revision.

bilateral hip resurfacing died nine years post-operatively due to an unrelated cause. The other 11 patients were seen at the ten-year review. All had well-functioning hips. One patient had a non-progressive radiolucent line in acetabular zones 1 and 2 and two had non-progressive thinning of the femoral neck.

Discussion

Metal-on-metal bearings had initially fallen from favour in hip arthroplasty after the introduction of polyethylene-containing devices. However, the low incidence of osteolysis-related failures with metal-on-metal bearings in the long term[1] led to their re-introduction as alternative bearings in arthroplasty. Their resurgence has played a crucial role in the success of modern resurfacings.[18-20] It is noteworthy that the original metal-on-metal hip replacement bearings were made out of high-carbon CoCr alloy termed 'as-cast' with no post-casting heat treatments. Thermal treatments such as solution heat treatment and hot isostatic pressing were introduced into the processing of alloys in various industrial applications in order to homogenise the material and to reduce microporosity and residual casting stresses.[21] Hot isostatic pressing involves subjecting the cast alloy to high temperatures and pressures in an inert gas atmosphere in order to remove internal voids. Squeezing out the porosity improves the mechanical properties of the alloy and increases its machinability, thereby significantly reducing machining time and costs, but allows the carbide precipitates to diffuse into the surrounding matrix material. Solution heat treatment also involves heating at a similar temperature followed by rapid cooling causing the carbides to continue their diffusion into the matrix solution.

Several studies[6-8,22,23] have shown that the overall result of these thermal treatments was to reduce the carbide phase proportion resulting in reduced hardness and increased wear due to microstructural alterations. One hip-wear simulator study,[24] however, has suggested that there is no significant difference between thermally-treated CoCr alloy and the as-cast alloy with no post-casting heat treatments, although the findings in the same study showed that pin-on-plate testing of that heat-treated alloy couple revealed significantly greater wear than was found with the as-cast CoCr alloy couple. It is possible that the absence of a demonstrable difference in the simulator was due to the fact that under the unrealistic 1 Hz frequency programmed into current simulators the joint is operating in exaggerated lubrication conditions most of the time, which would artificially protect the bearing surfaces from wear. The measured *in vivo* peak frequency at which the hip operated in daily life is 0.5 Hz.[25] This low-velocity articulation, combined with the unpredictable and non-constant loads and prolonged periods of rest experienced *in vivo*, often lead to a breakdown of the fluid film in metal-on-metal bearings resulting in the implant operating in less favourable lubrication regimes such as boundary or mixed lubrication modes. It is only during these periods that the wear advantage of a harder, more favourable material, as opposed to a material with reduced hardness, is likely to be observed. Unfortunately, such periods are unlikely to be reproduced in current simulator protocols. Evidence has now emerged[26] from physiologically-relevant hip-simulator tests that under these realistic test protocols heat-treated devices have shown significantly higher wear compared with as-cast devices.

Clinical studies have shown that bearings which use low-carbon CoCr components have high rates of failure from aseptic loosening in the medium term. In 1988 the Mestasul (Sulzer, now Zimmer, Winterthur, Switzerland) bearing was introduced, which employed high-carbon on high-carbon wrought CoCr components and in 1994, the Sikomet SM21 (Plus Rotkruez Orthopedics AG, Rotkruez, Switzerland), which was made of low-carbon on low-carbon wrought CoCr alloy was also introduced. Both these bearings were total hip replacements of small diameter (28 mm or 32 mm) with a polyethylene-carbon sandwich construct for the acetabular component. Good medium-term results have been observed with the Metasul replacement from several centres[27-30] although one has observed high rates of failure from osteolysis and metallosis.[31] The Sikomet SM21 showed good early results[32] but at medium-term showed a high rate of failure from aseptic loosening.[33,34] Other series involving low-carbon-low-carbon bearings[35,36] and high-carbon-low-carbon mixed bearings[37,38] have also shown evidence of greatly elevated release of metal ions[36] or failures with osteolysis and also extensive soft-tissue necrosis in some instances.[36,38]

With regard to heat-treated high-carbon metal-on-metal bearings there are insufficient data on the medium-term clinical results. Our study is a ten-year follow-up of this unique high carbon-high carbon CoCr bearing which has been subjected to late-stage heat treatments. The high rate of failure from osteolysis and aseptic loosening in this group strongly suggests that heat treatments have the potential to affect the wear resistance of metal-on-metal bearings adversely, and that a high incidence of osteolysis-related failures occurs even in high-carbon CoCr bearings when they are subjected to dual heat treatments.

As previously stated the recall and withdrawal from use of the implants in our study at the end of 1996 was consequent on the development of a transient ratcheting, screeching or clicking noise in 12 patients in the early post-operative period. This was different from the noises previously described with metal-on-metal bearings.[39] A thorough investigation revealed that heat treatments had been introduced into the manufacturing process without the knowledge of the designer or other surgeons.

Initially, the manufacturer's investigation appeared to suggest that the most likely reason for the noises was a change in certain manufacturing practices which resulted in the introducer holes being positioned too close to the margin of the acetabular component in some cases. It has been alleged that this causes the impact load from the introducer to be transferred through the holes of the acetabular component instead of through its rim resulting in small burrs being raised at the edge of the introducer holes. While these burrs seem to be the immediate cause of the post-operative noises, it is unlikely that they are also the reason for the increased failure rate in this group. This opinion is supported by the fact that none of the 12 patients who reported the noises had required revision by the ten-year follow-up and did not show a particularly high incidence of adverse radiological features. In addition, the placement of introducer holes occurred in both the 1994 to 1995 and the 1996 groups and can therefore not explain the higher wear-related failure rate in the latter. The only difference between the groups was the double-heat treatment processes applied during 1996 as opposed to the single-heat treatment during 1994 and 1995.

Poor positioning of the acetabular component with steep inclination also does not seem to be the explanation for the increased failure in this group. The mean initial acetabular inclination angle in the 1996 group was not significantly different from that in the 1994 to 1995 group. In addition, the inclination angles of the acetabular component in the failed hips in the 1996 group were not different from those of the well-functioning hips in the same group.

The problem with the double heat-treated high-carbon bearings from 1996 was not evident initially with only two osteolysis-related failures occurring in the first five years in our series. In subsequent years, however, the rates of failure have increased and have continued up to the ten-year follow-up. A similar pattern of failure has been seen in low-carbon bearings.[29,40] The dramatic failure pattern, accompanied by periarticular necrosis,[26,40] has commenced only in later years. Thus, osteolysis-related failures in metal-on-metal bearings in general tend to occur during later follow-up and early promise does not guarantee continued success. Our study has shown that short-term results cannot be relied upon as a predictor of good long-term function in metal-on-metal bearings and that manufacturing processes involving double-heat treatment to high-carbon CoCr alloy are likely to affect the outcome adversely. Osteolysis, metallosis and aseptic loosening were the predominant modes of failure in our series suggesting that the bearings were subject to abnormal wear.

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