An Investigation of the Performance of the 3M™ Capital™ Hip System

July 2001

The Royal College *of* Surgeons *of* England

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Chair's introduction to the report

This report is the result of a long and painstaking investigation into the 3M Capital Cemented Hip System. It is by its very nature a scientific document and I am pleased that a simpler leaflet for patients has also been produced as a companion paper. As lay Chair, it has been a privilege to be part of the steering group that managed this investigation, drew conclusions and produced this report.

Although we were a wide-ranging group with representatives from several organisations, we have worked well together. Several factors were important in accomplishing our task. First, the patients who had received a 3M Cemented Capital Hip and who were affected by the Hazard Notice and subsequently the investigation. The interest of these patients was at the forefront of our thinking and our deliberations throughout our work. Next, team-working and constructive challenge; during our work it was essential that a robust framework was developed and that all voices be heard and respected and considered. For this, I thank my fellow steering group members.

Then the diligent research, which was provided under the leadership of Dr Barnaby Reeves from the Clinical Effectiveness Unit, The Royal College of Surgeons of England, who worked tirelessly and for many, many months beyond our anticipated time. Lastly, our external helpers, Dr Richard Morris and Professor Ray Fitzpatrick, who read our report and its conclusions and provided an external perspective on our work.

As will be seen from this report, there were many elements which played a part in the performance of Capital Hips and there are lessons for the future for many different groups. One thing is particularly clear to me, however, and it is this: If a national hip registry had been in place to collect appropriate information then poorly performing hip replacements could have been detected at a much earlier stage. This would have reduced the pain, anxiety and potential immobility of patients. It is my hope that this report will play its part in helping to bring such a registry into being.

Dame Rennie Fritchie DBE

July 2001

Executive summary

INTRODUCTION

This report describes an investigation of the performance of the femoral components of the 3M Capital Cemented Hip System, manufactured by 3M Health Care Limited. There were two main types of Capital Hip, modular and monobloc, and both types were available in either a 'flanged' or 'round back' design. The Capital Cemented Hip System was marketed in the UK from 1991 until 1997, during which time a total of 4,688 were supplied to 79 clinical centres in the UK. Almost all Capital Hips were sold in the UK.

The question of the performance of the Capital Hip was first raised in 1995. The Medical Devices Agency opened an investigation into the performance of the femoral component of the Capital Hip in the summer of 1996 and continued to monitor the performance until January 1998. At this time, cumulative unsatisfactory experiences with the Capital Hip at five implanting centres in the UK led the Agency to issue a Hazard Notice advising that all patients who had received a Capital Hip should be recalled for clinical review.

Within 24 hours, 3M Health Care announced that, if at the clinical review the femoral component of the Capital Hip system was found to have exhibited poor short-term performance, 3M Health Care would cover the cost of a revision operation. 3M Health Care arranged with the British United Provident Association to provide a dedicated team, called the Capital Hip Care Centre, to manage the situation. The Capital Hip Care Centre is continuing to manage all aspects of this programme in the patients' best interests.

This investigation was commissioned in 1998 by 3M Health Care and the Department of Health with the aim of determining the extent and causes of the reported poor short-term performance of the Capital prosthesis. The investigation had three objectives:

- To describe the 'survival' curve for the femoral component of the Capital Hip System in the entire cohort of patients in the UK who received this prosthesis.
- To describe survival separately for modular and monobloc femoral prostheses.
- To identify 'risk factors' associated with failure.

METHODS

The study collected relevant information from four main sources, namely patients' case notes, patients' X-rays, questionnaires to surgeons and questionnaires to patients. The characteristics of patients, the type of Capital Hip implanted and details of the surgical technique used were extracted from case notes. Further information about surgical technique was obtained from surgeons' responses to the questionnaire and from assessing X-rays taken shortly after the operation. Information about the performance of Capital Hips included details of Capital Hips that had been replaced, assessment of loosening of the hip from X-rays taken when patients were recalled and responses to the questionnaire sent to patients, which included the

Oxford Hip Score, a standardised set of questions about current pain and disability. X-rays were assessed by two research fellows, who were not radiologists but who received extensive training. The quality of cementing was assessed from X-rays taken shortly after the operation.

In this report, performance of the Capital Hip is described in two ways:

- as a 'revision' rate, equivalent to the number of Capital Hips replaced per 100 years of observation, irrespective of the number of patients in whom observations were made; and
- as the probability that a Capital Hip would not have needed replacing at a certain time after implantation (usually five years).

Comparisons between the performance of total hip replacement operations with different characteristics (of patients, Capital Hip or surgical practice) are expressed as relative risks. These describe how much more or less likely was the need for a replacement if a particular characteristic was present. Performance is described separately for the time periods before and after the Hazard Notice, but the report concentrates on the period before the Hazard Notice.

RESULTS

Analyses are based on observations for 3,688 Capital Hips that were implanted in 3,494 patients. Of these patients, 84% were understood to be alive on 1 February 2000 and 70% were alive with a Capital Hip still in place. The mean age of patients at the time of operation was 71, ranging from 20 to 94 years. Twice as many women as men received a Capital Hip.

About 75% of the 3,688 hips were implanted because of primary osteoarthritis, 9% for hip fracture, and 7% to replace an existing Capital or other type of hip. About 70% of Capital Hips implanted were of the modular type and 30% of the monobloc type, and about 70% had a flanged design and 30% a round back design. About two-thirds of the operations were carried out by a consultant. Peri-operative complications were recorded in about 4% of the operations.

The majority of Capital Hips (87%) had not been revised when follow-up for the investigation ceased on 1 February 2000 and most of these hips were functioning satisfactorily. Six per cent of all Capital Hips had been revised before the Hazard Notice (19 February 1998) and 13% had been revised by 1 February 2000. The revision rate before the Hazard Notice was 1.8 revisions per 100 hip-years (211 revisions observed in 11,891 hip-years). In the first year after the Hazard Notice, the revision rate was 8.3 revisions per 100 hip-years (213 per 2,567 hip-years), 3.78 times higher than before the Hazard Notice. During the second year after the Hazard Notice, the revision rate was 1.0 revisions per 100 hip-years (22 per 2,283 hip-years) and 0.50 times lower than before the Hazard Notice. The investigation did not identify any patients who had received Capital Hips after the Medical Devices Agency issued the Hazard Notice, indicating that the Hazard Notice was effective in preventing implantation of stocks of Capital Hips that hospitals held.

For the period before the Hazard Notice, the rate of revision depended strongly on the type and design of Capital Hip. A significant difference was found between the modular flanged and the monobloc round back Capital Hips. Five years after implantation for a primary replacement, 97.1% of the monobloc round back hips were still in place compared to 89.2% of the modular flanged hips. The revision rate was higher in younger people and higher in men. There were also tendencies for some surgical factors to have an effect on the revision rate, despite problems in collecting the data on these factors.

The quality of the cement around the Capital Hip as assessed from X-rays was associated with the risk of revision, with deteriorating quality increasing the risk by up to 1.9 times. However, this association did not explain the observed effects of type and design of Capital Hip.

It was difficult to disentangle on statistical grounds the effects of type of Capital Hip on the one hand, and factors relating to the surgeon or hospital where the operation took place, on the other. Analyses that took account of the hospital or surgeon in which a Capital Hip was implanted nevertheless still suggested that the risk of revision was lower for the monobloc round back compared to the modular flanged Capital Hip.

There was an excellent response rate from patients on the questionnaire about their current symptoms and disability (70%), demonstrating patients' willingness to contribute to the investigation. The average Oxford Hip Score for patients with Capital Hips were slightly worse than the average score for patients one year after their operations in a previous English study.

Patients were also asked how anxious they were when they first heard that there may have been a problem with some of the Capital Hips and how satisfied they were with the way in which their own situation had been handled. With respect to anxiety, 36% had been extremely anxious, 25% fairly anxious, 25% slightly anxious and 14% not at all anxious. With respect to patients' satisfaction with the way in which their clinical review had been handled, 51% were very satisfied, 32% satisfied, 10% neither satisfied nor dissatisfied and 6% dissatisfied or very dissatisfied.

CONCLUSIONS

Using data from before the Hazard Notice, 91% of all Capital Hips were estimated to be still in place five years after they were implanted. The monobloc round back Capital Hip performed best and the modular flanged Capital Hip performed worst. Younger patients and men had a higher risk of revision. Use of cement antibiotics and better cementing quality were associated with a decrease in the revision rate. None of the other items collected for the investigation, including the seniority of surgeon, was significantly associated with the revision rate.

Indirect comparisons with data from hip registries and the 'benchmark' recently set by the National Institute for Clinical Excellence suggested that, if data on implantation and revision had been collected systematically and analysed using the method chosen for this investigation, the poorer performance overall of the Capital Hip System would have become apparent during

1995. The poorer performance of the modular flanged Capital Hip, had it been analysed separately, would have been apparent by the end of 1993. These comparisons also showed that one type of Capital hip, the monobloc round back, performed as well as most other commonly used femoral hip prostheses when measured against registry data. The monobloc round back Capital Hip also performed at least as well as the benchmark set by the National Institute for Clinical Excellence and the performance of the monobloc flanged Capital Hip could not be distinguished from this standard.

Given that the Capital Hip was intended to be very similar to the Charnley, differences in design between the Capital and the Charnley Hips were considered by the manufacturer to represent a 'small' change in design. However, the importance of each of the individual small changes and their combined effect could not be established. The findings of the investigation nevertheless suggest that one or more of these changes resulted in the modular flanged Capital Hip having comparatively poor short term performance compared with the standards. The implication must be that there is no such thing as a small change in design; *any* design modification could potentially have a deleterious effect on the performance of a prosthesis.

KEY RECOMMENDATIONS

All new femoral stems and design modifications of existing femoral stems need to be evaluated fully. Manufacturers should be required to collect data that allow the performance of a hip to be assessed when introducing a new hip or whenever a design modification is made.

High quality data are required for an evaluation of a new or modified design of hip, and an effective data collection system should be established. Some members of the steering group had reservations about the quality of data likely to be available from post-market clinical trials and ad hoc analysis of adverse incidents and user experience. It is therefore recommended that a national hip registry should be established.

Aspects of 'best practice' for total hip replacement were not observed, or were not adequately documented, for a significant minority of operations. A minimum dataset for total hip replacement should be established and surgeons should be required to collect these data. The details of any implanted prosthesis should always be recorded, ideally in a way that allows the information to be retrieved easily, e.g. in an electronic database. X-rays of adequate quality should be taken and reviewed, both in the immediate post-operative period and for the assessment of loosening, at least after five years. These recommendations already exist in guidance on best practice for total hip replacement recently published by the British Orthopaedic Association. A detailed national hip registry of hip replacement would provide a means of auditing compliance with some of these recommendations.

1 Introduction

1.1 CIRCUMSTANCES LEADING TO THE STUDY

In this report, the femoral component of the 3M™ Capital™ Modular/Monobloc Cemented Hip System is referred to by the general term of 'the Capital Hip', and 'hip' also refers to the femoral component of a prosthesis, unless otherwise specified.

In 1995, at the British Orthopaedic Association annual conference, Massoud *et al*. presented their experience with the Capital Hip, noting a higher than expected rate of revision of the femoral component. These findings were subsequently published in July 1997[1].

Prior to this, following consultations with orthopaedic surgeons and in order to improve the implantation technique for Capital Hips, the clinical protocol for preparation of the femoral cavity for implantation was changed. It was recommended that rasping was followed by curettage in the proximal region, where the rasp is less efficient as a result of the tapered profile of both stem and rasp. Curettage of the medullary canal was also recommended. Surgeons who used Capital Hips were notified of this change by 3M Health Care Ltd in a guidance note sent out on 31 July 1995.

In 1995, in response to the initial findings reported by Massoud *et al*[1], 3M Health Care undertook an extensive survey of consultant orthopaedic surgeons who had used Capital Hips. The results of this survey, which reported a revision rate of femoral components of approximately five per cent as at January 1996, were considered by 3M Health Care to be within 'industry standards'.

The Medical Devices Agency opened an investigation into the performance of the femoral component of the Capital Hip in the summer of 1996 and continued to monitor the performance until January 1998. At this time, the Medical Devices Agency learnt of unsatisfactory experience with the Capital Hip at five implanting centres in the UK and, in the light of this information, they advised that all patients implanted with the device should be recalled for review (Medical Devices Agency Hazard Notice HN 9801 - 19 February 1998; see Appendix A).

In response, and to ensure that patients were treated expeditiously, 3M Health Care made a public commitment to finance the clinical review of all patients who had received the Capital Hip in the UK and also to support the costs of any revision surgery that was required owing to poor short-term performance of the prosthesis. As well as ensuring that the clinical needs of patients were met, there was a desire to investigate the performance of the Capital Hip System as thoroughly as possible. The Clinical Effectiveness Unit of the Royal College of Surgeons of England was commissioned by 3M Health Care and the Department of Health to carry out this independent investigation which had the aim of determining the extent and causes of the reported poor short-term performance of the Capital Hip in the UK.

1.2 BACKGROUND TO THE DEVELOPMENT OF THE 3M CAPITAL HIP SYSTEM

1.2.1 The Capital Hip and the Charnley Hip

The Capital Modular/Monobloc Cemented Hip System was a range of cemented hip prostheses intended for total hip replacement, both for primary and revision surgery where indicated. The femoral component range consisted of round back and flanged geometries, modular and monobloc stems in standard and long sizes. The Capital Modular/Monobloc Cemented Hip System range was believed by 3M Health Care to be based on the best aspects of hip prosthesis technology then available.

The consensus at the inception of the 3M Capital Hip System was that the 'standard' for cemented hip prosthesis was the Charnley Hip. With a clinical history of more than 30 years, the clinical performance of the Charnley Hip was well understood and known to be effective.

In developing the Capital Modular/Monobloc Cemented Hip System, 3M Health Care intended to participate in the hip replacement market with a prosthesis that could be recognised as following the design principles of the Charnley. The Capital Hip was conceived with the intention of enhancing the design features of the Charnley with improvements offered by modern prosthetic design developments. These developments included:

- both modular (titanium alloy Ti6Al4V stems with either cobalt chrome heads or titanium alloy heads with a titanium nitride coating) and monobloc (stainless steel stems and heads) prostheses;
- an optional distal spacer for prosthesis centralisation; and
- a modified proximal flanged geometry compared with the flanged Charnley Hip.

1.2.2 Design criteria and testing

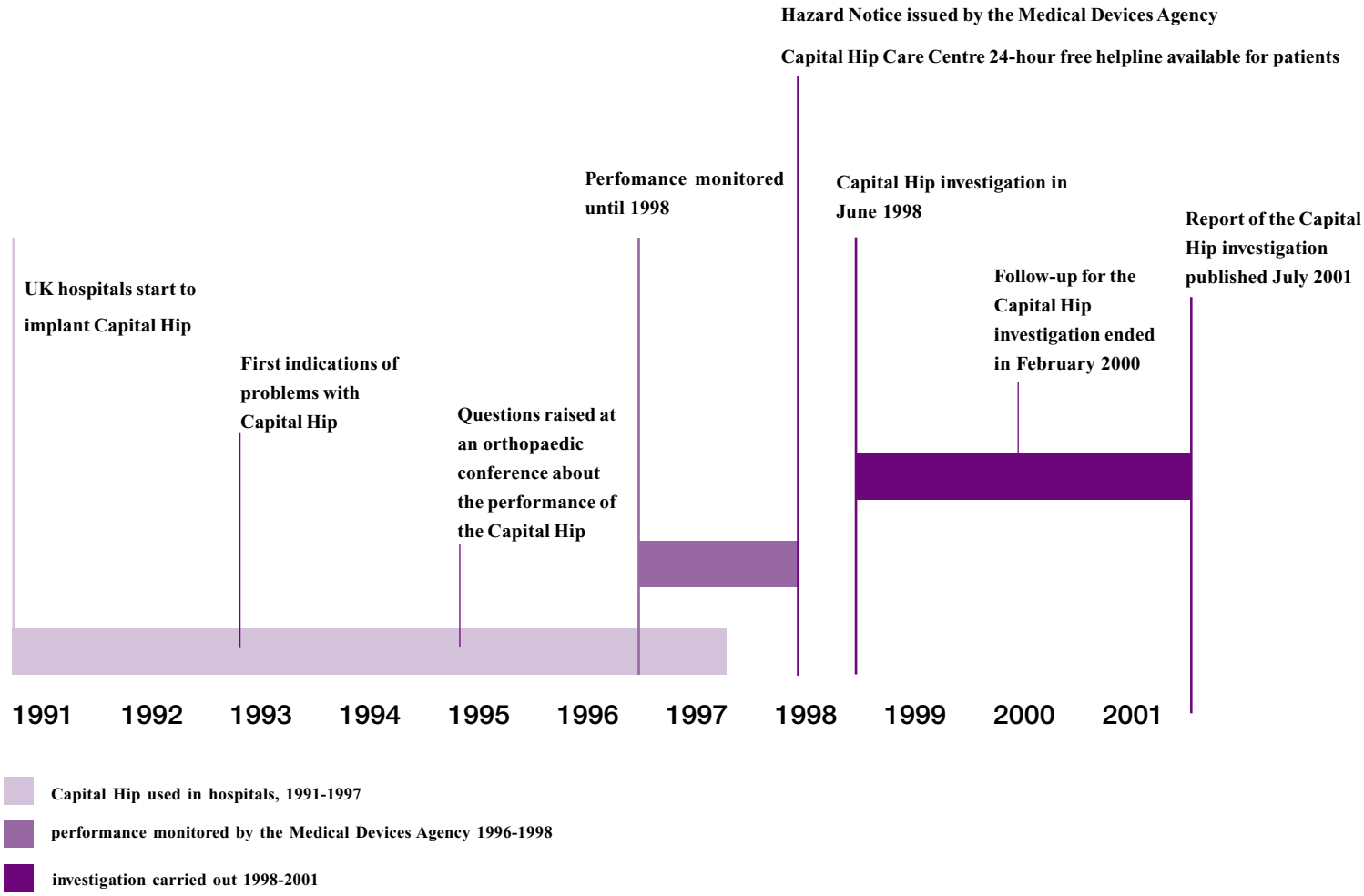
There were no specific regulations about the introduction of new hip prostheses at the time that the Capital Hip was introduced. Regulation in the form of 'CE' marking was introduced in January 1995 and the Capital Hip received a 'CE' mark early in 1995.

1.2.3 The history of the Capital Hip System

Key milestones during the history of the Capital and this investigation are summarised in Figure 1.

The Capital Hip was designed in 1990 and introduced into the market in 1991. The Capital Modular/Monobloc Cemented Hip System was marketed in the UK from 1991 until 1997, during which time 4,688 prostheses were supplied to 79 clinical centres. Almost all Capital Hips were sold in the UK. In March 1997, 3M Health Care stopped marketing the Capital Hip for commercial reasons.

Figure 1. A timeline showing significant events in the history of the Capital Hip.



1.3 MANAGEMENT FRAMEWORK

Following the issuing of the Hazard Notice HN 9801, 3M Health Care provided written information and a 24-hour helpline to address patients' concerns and subsequently established a management framework to support the process of assessing, scheduling and managing a care programme to address the needs of patients in the UK who had received a Capital Hip. The management framework was developed in collaboration with British United Provident Association and the Department of Health. It addressed the identification of patients, communication with patients, patient assessment, the health and social care of patients and management of the financial aspects of the care of patients with a Capital Hip. A full description of the management framework is included as Appendix B. A separate group, funded by 3M Health Care, was established to oversee the management of the care programme, which was implemented by the British United Provident Association through the establishment of the Capital Hip Care Centre.

The investigation, conducted for the purposes of this report, was designed to make use of the communication channels established by the management framework and some data collected in providing the care programme. The success of the investigation depended on the co-operation of several groups, each of which had different roles. These groups and their respective roles are summarised in Table 1.

Table 1. Groups and roles in the management framework.

Organisation	Role
3M Health Care	Developing the management framework; overall responsibility for care programme; payment for implementing the management framework, including the costs of care for patients with Capital Hips.
Department of Health and regional offices of the NHS Executive	Liaison with chief executives of NHS Trusts, regional directors of public health, etc.
Capital Hip Care Centre	Managing the care programme, including recording details of patients and their clinical review, need for revision and subsequent revision surgery, and financial transactions associated with any care provided.
NHS Trusts, private hospitals and contacts in these hospitals	Identification of patients who received a Capital Hip; liaison with the Capital Hip Care Centre and the Clinical Effectiveness Unit; arranging for case notes to be available for review by research staff.
Orthopaedic surgeons	Review of patients with a Capital Hip; completion of questionnaire of usual surgical practice.

The Hazard Notice recommended the recall of all patients who had received such prostheses for clinical review. Clinical care was the responsibility of the surgeon and centre that reviewed the patient, which may or may not have been the surgeon and centre that implanted the index Capital Hip. The management framework was administered by the Capital Hip Care Centre, which kept a record of all reviews and revision operations carried out under the framework.

1.4 PERSONNEL CARRYING OUT THE INVESTIGATION

1.4.1 Steering group

A steering group was set up to oversee the investigation. It included representatives of the four main interested parties (the Medical Devices Agency and the Health Services Directorate of the Department of Health, the British Orthopaedic Association and 3M Health Care Limited):

Dame Rennie Fritchie	Chairperson
Mr Hugh Phillips	British Orthopaedic Association
Professor Robin Ling	British Orthopaedic Association
Professor Paul Gregg	British Orthopaedic Association
Mr Andy Crosbie	Medical Devices Agency, Department of Health
Dr Jon Hopper	Medical Devices Agency, Department of Health
Dr Richard Spiers	3M Health Care Limited
Mr Stephan Dudman-Millbank	3M Health Care Limited
Mr David Gilbert	Health Services Directorate, Department of Health (replaced by Dr John Shaw)
Dr Valerie Day	Health Services Directorate, Department of Health (replaced by Dr Mike McGovern)
Dr Barnaby Reeves	Director, Clinical Effectiveness Unit, RCS (as an independent epidemiologist and principal investigator)

The steering group was chaired by Dame Rennie Fritchie, who was independent of all of the interested professional parties and who helped to ensure that the interests of patients were considered by the steering group.

Mr Hugh Phillips was President-elect of the British Orthopaedic Association at the time the steering group was established. Professor Ling has an international reputation in the design and development of hip prostheses. Professor Gregg led the establishment of the Trent Registry for hip replacement and is the chair of the National Total Hip Replacement Outcomes Study, which has described surgical practice, operative complications and functional outcomes up to one year in a large, representative group of patients undergoing hip replacement.

Mr Andy Crosbie and Dr Jon Hopper contributed their experience in monitoring orthopaedic devices and regulatory practices during the period when the Capital Hip was marketed.

Dr Richard Spiers represented 3M Health Care in his capacity as medical director. Mr Stephan Dudman-Millbank, who also represented 3M Health Care, had detailed knowledge of the history and features of the Capital Hip System and of the marketing of the Capital Hip.

Dr Reeves, a non-clinical epidemiologist, contributed independent scientific expertise on study design and statistical analysis to the steering group and represented the research team. Members of the research team were regularly present at steering group meetings to report on progress with the investigation.

The first meeting of the steering committee took place on 8 June 1998.

1.4.2 Research team

The research was carried out by staff of the Clinical Effectiveness Unit of the RCS who were commissioned jointly by the Department of Health and 3M Health Care. The costs of the research were funded primarily by 3M Health Care and also by the Department of Health. The research team was appointed in June 1998 and comprised a Research Fellow (Louise Klinger), to act as the study co-ordinator and who was based at the RCS, and two Research Associates (Bethan Bennett-Lloyd and David Balthazor). The personnel appointed were selected with the intention that they would be responsible for a particular geographical area of the UK. The research fellow commenced work in August 1998 and the other research associates started in September. A Research Nurse (Paul Dickinson) was seconded to cover the North and North-West parts of England and commenced work at the end of September 1999. Two members of the research team had previous medical research experience, one member was a doctor (senior house officer) with some orthopaedic experience and the research nurse was an orthopaedic nurse. Statistical analyses were carried out by Dr Jan van der Meulen, a clinical epidemiologist and member of staff in the Clinical Effectiveness Unit, and by Dr Reeves.

2 Aims and objectives

The aim of the investigation was to determine the extent and causes of the reported poor short-term performance of the Capital prosthesis. If the performance of the Capital Hip was found to be poor, there was a desire to better understand the circumstances contributing to the performance so that recommendations could be put in place to avoid a similar situation developing in the future.

The steering group agreed that the investigation had three specific objectives:

- To describe the 'survival' curve for the femoral component of the Capital Hip System in the entire cohort of patients in the UK who received this prosthesis.
- To describe survival separately for modular and monobloc femoral prostheses.
- To identify 'risk factors' associated with failure.

3 Methods

3.1 DESIGN OF THE INVESTIGATION

The study used a retrospective case series design. The intention was that, following identification of patients with a Capital Hip, review of their clinical status and obtaining of their consent, their case notes would be reviewed and relevant data extracted. Historical X-rays were also reviewed; these were assessed specifically for the project by research staff, rather than by extracting information retrospectively from radiological reports. Information about patients' current pain and disability was also sought prospectively by a self-completion questionnaire that was sent to all living patients who had not had a revision.

The success of the investigation depended on co-operation between several different groups. These included: patients who had had the Capital Hip implanted, regional offices of the NHS Executive; chief executive officers of NHS Trusts and private hospitals; surgeons who had implanted Capital Hips or who had reviewed patients; radiologists; administrative and clerical staff in hospitals; the Capital Hip Care Centre; and the research team.

3.2 STUDY POPULATION

The reference population to be studied was defined as the entire cohort of patients in the UK who had received a Capital Hip.

3.2.1 Inclusion criteria

Patients were included in the study if they had received a Capital Hip and they, or a relative or carer, had agreed to the review process. Patients who had received a Capital Hip and were deceased were included in the study.

3.2.2 Exclusion criteria

Patients who refused consent were excluded from the study. There were no other exclusions.

3.2.3 Identification of patients who received a Capital Hip

On 20 February 1998, the Department of Health issued a Health Service Circular (Health Services Circular 1998/020; see Appendix C) asking NHS Trusts in England to identify and contact patients who had received a Capital Hip. A similar circular was sent to hospitals in Scotland and Wales, as well as to private hospitals where Capital Hips were supplied. No Capital Hips were sold to hospitals in Northern Ireland.

Having identified patients with a Capital Hip, Trusts were requested to arrange a review of the clinical status of the patients and revision surgery where necessary. The costs of the review of all recipients of a Capital Hip and subsequent care, where necessary, were recovered through the Capital Hip Care Centre, which maintained a confidential

register of all patients who were identified, reviewed and cared for. The consent of patients for review of their case notes by the researchers carrying out this investigation was sought at the time of the review of their clinical status (see Review Form, Appendix B).

The management framework was implemented on 16 April 1998. In some instances, review forms were completed from information documented at clinical reviews of the status of patients carried out before this date (sometimes even before the Hazard Notice was issued). There was no requirement for hospitals to arrange for the clinical status of these patients to be reviewed again; the costs of clinical reviews carried out before the establishment of the management framework could be claimed by Trusts by completing a review form retrospectively. For such patients, hospitals were asked to contact patients separately to seek their consent for the case note review.

The protocol for this investigation assumed that the Capital Hip Care Centre would provide the Clinical Effectiveness Unit with a copy of key fields from the database held by the Capital Hip Care Centre, including all of the data collected using the review form, basic socio-demographic, prosthesis and surgeon details, and the names of other hospitals attended since the original hip replacement. The intention was that the Capital Hip Care Centre would send this information monthly, until all of the patients had been identified and had had their clinical status reviewed. The timetable for the investigation also assumed that the processes of identification and review of clinical status would be carried out promptly, ie by December 1998, in order that members of the research team could visit hospitals to extract the data required from patients' notes in an efficient manner.

It quickly became apparent that it was not practicable for the research team to wait until patients were included in the database provided by the Capital Hip Care Centre because of a considerable delay in the Capital Hip Care Centre receiving the required information from hospitals and surgeons carrying out the clinical reviews. Patients could only be included in the database when a review form had been received by the Capital Hip Care Centre. Thus, the delay arose (a) if hospitals were slow to arrange for the clinical status of patients to be reviewed or if patients were slow to respond, (b) if hospitals were slow to send separate letters to patients who had already had their clinical status reviewed to seek consent for the case note review, (c) or if hospitals were slow to submit the review form to the Capital Hip Care Centre.

A further problem arose from the fact that some patients received more than one Capital Hip, either because they received a Capital Hip in both hips, or because a Capital Hip was used to revise a hip replacement in which a Capital Hip had previously been implanted. The failure to distinguish multiple Capital Hips in the same patients initially created difficulties in reconciling the databases of the Clinical Effectiveness Unit and the Capital Hip Care Centre. This report focuses on first total hip replacement operations in which Capital Hips were implanted. Patients who received Capital Hips in both right and left hips therefore contributed two hips for the analysis. The number of revision operations in which a Capital Hip was implanted are described but these hips are not

considered further, since (a) it is known that hips implanted for revision have, on average, a poorer outcome and (b) the number of operations in which the Capital was used for revision was too small for meaningful analyses.

3.3 CHARACTERISTICS OF PROSTHESES, PATIENTS AND SURGICAL PRACTICE

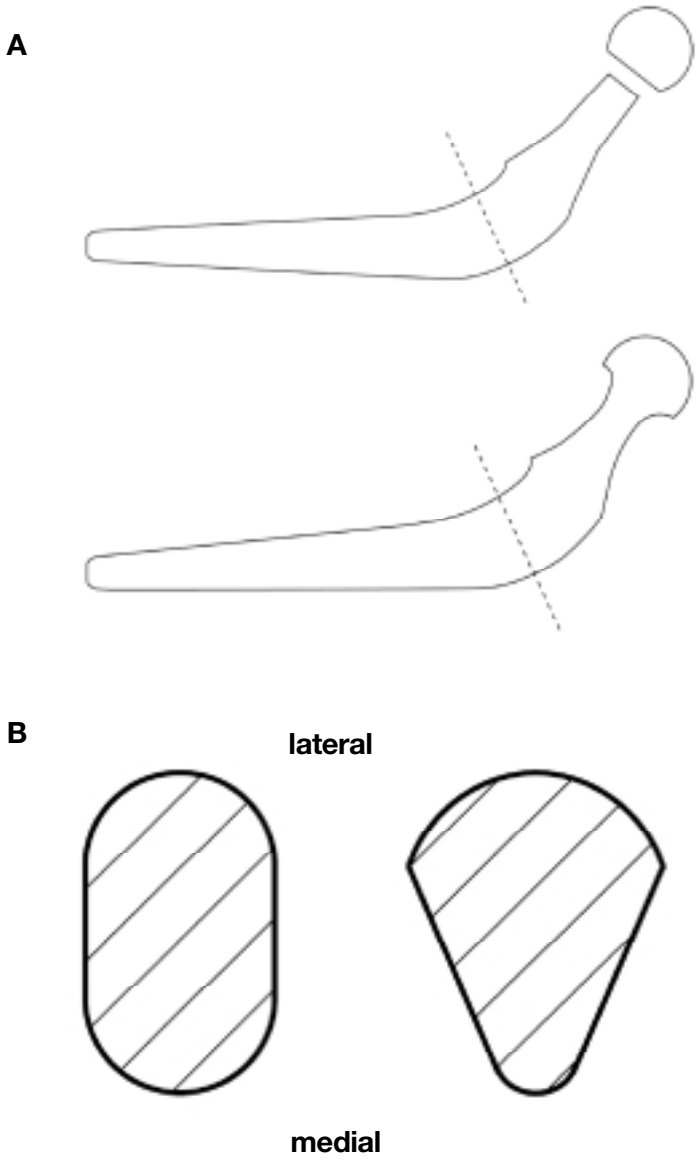
3.3.1 Prostheses

There were two main types of femoral component in the Capital Hip System, modular and monobloc. The modular stems were made from titanium alloy and were matt finished. They were designed to be used with heads manufactured from polished cobalt chrome alloy, or titanium alloy with a titanium nitride coating, or zirconia ceramic. In addition, there was a choice of head diameters and neck lengths. However, no zirconia ceramic heads were implanted. The one-piece monobloc stems were made from stainless steel with a matt finished stem surface and a polished head. Both types of femoral component were available in 'flanged' or 'round back' geometries, with a range of stem lengths and stem sizes.

The characteristics of each prosthesis were identifiable from the catalogue number, which was collected during the case note review from the case notes or theatre log book whenever it was available. Capital Hips were recorded by type, ie modular/ monobloc, and geometry, ie flanged/round back, for the purposes of analysis. Prostheses clearly identified as being Capital Hips from case notes or theatre log books, but where no catalogue number could be found, were coded as 'unclassified'. A small number of patients identified by hospitals as having received a Capital Hip were found not to have received a Capital Hip during the case note review; these patients were excluded.

The type of prosthesis, ie modular or monobloc, was identified at the outset as a factor of key interest. During steering group meetings, the Medical Devices Agency also expressed an interest in analyses of other characteristics of Capital Hips. Following discussion and consideration of the numbers of hips that had been implanted of different geometries, surface finishes and size, 'flanged' versus 'round back' geometry was also included as a factor of interest in the analyses carried out (see **3.8.3**).

Figure 2. (A) modular (upper) and monobloc (lower) Capital Hip stems; (B) cross section through round back (left) and flanged (right) Capital Hip stems at the dotted line in (A).



Researchers were responsible for recording both the catalogue number, if available, and information about revision surgery or the need for revision from case notes, ie the assessment of outcome (revision) was not, strictly speaking, 'blinded' to the catalogue number of the implanted hip. However, the classification of prosthesis by catalogue number was not known to the researchers at the time of case note review, so that the assessment of outcome could not have been influenced by this factor. Information about revision was also obtained from other sources, ie the Capital Hip Care Centre and by means of copies of the post revision patient discharge form (see Appendix B) that were sent directly to the Clinical Effectiveness Unit.

3.3.2 Details of the index operation

A clinical data questionnaire was developed on to which research staff extracted relevant and available clinical data from patients' case notes. Items included on the questionnaire were selected by members of the steering committee, including the three members of the British Orthopaedic Association who provided specialist input. The questionnaire (see Appendix D) covered the following areas:

- Patient demographic details that could be accurately and consistently retrieved from the patient's notes.
- Details of the hospital in which the Capital Hip was implanted and in which the recent review of clinical status was carried out.
- Reason for original hip replacement and past history of surgery on the same hip.
- Details of the consultant with whom a patient was registered, the surgeon and assistant who carried out the implantation, including his/her grade and whether or not he/she was a locum.
- Operative procedures, including bone preparation and cementing technique.
- Intra-operative complications.
- Batch and catalogue numbers of the implanted femoral stem, modular head (if applicable) and acetabular cup.
- Findings at the review of clinical status, if available, ie joint performing satisfactorily, completed revision of joint, joint due to be revised, and the reason for any revision that had taken place or that was planned.

The steering committee recognised that it would also have been desirable to record the weight, body mass index and activity level of patients but concluded that this information would not be consistently available.

3.3.3 Details of usual surgical practice

Surgical practice may vary considerably, both between surgeons and for each surgeon depending on clinical indications. If some detail of technique is 'habitual', it is unlikely to be documented in each patient's case notes. The failure to document relevant information in case notes was evidenced during piloting of the clinical data questionnaire, when it was found that surgical details considered important by orthopaedic members of the steering group were not always recorded. For this reason, a more detailed surgeon's questionnaire was developed for surgeons to record details of their habitual practice when implanting total hip replacements. Because a substantial amount of time had passed since most surgeons had been implanting Capital Hips, surgeons were asked to record both their current practice and how their usual practice may have changed compared with the time when they implanted Capital Hips.

The surgeon's questionnaire included details of operative technique for total hip replacement surgery and covered the following areas (see Appendix E):

- surgical approach;
- method of bone preparation;
- cementing technique (brand of cement, methods of mixing and introducing cement, cement viscosity, use of pressurisation); and
- use of prophylactic antibiotics.

The questionnaire also contained questions that pertained to aspects of the surgeon's professional experience such as caseload and details of continuing medical education (eg teaching, conferences attended and research involvement).

3.3.4 Assessment of X-rays taken shortly after the index operation (Index X-rays)

It was considered important to try to take account of the quality of cementing in analyses of performance of the Capital Hip. Because quality of cementation is known to affect the outcome of total hip replacement,[2,3,4] it was an important potential confounding factor. Therefore, hospitals were requested to provide copies of anterior-posterior and lateral X-rays taken shortly after the index operation (referred to subsequently as index X-rays).

Index X-rays were assessed by two of the research fellows, who were not radiologists. These two fellows received extensive training in interpreting the relevant aspects of index X-rays (see Appendix F, and 3.6).

The X-rays were assessed for evidence of quality of cementing technique on the following features (see Appendix G):

- Quality of film; classification of this feature included an 'unacceptable' option indicating that it was not possible to assess cementing technique owing to the poor quality of the film. When the quality of a film was classified as unacceptable, the reason for grading as unacceptable was also recorded. Films graded as 'unacceptable' were not considered to be able to contribute evidence about the quality of cementing.
- Whether a film was a 'true' anterior-posterior (or lateral) view.
- Coronal alignment of the stem in the femoral canal, ie degree of valgus/varus.
- Adequacy of cement mantle; features considered on the basis of current expert orthopaedic opinion to be indicative of inadequate cementing were (i) contact between stem and bone cortex at any point, (ii) inability to see cement in relation to any particular part of the stem, (iii) cement thickness < 2mm anywhere, on either X-ray view (see 3.8.1, X-ray assessment).

- Other features (cement/cortex gap, bone lysis, detached greater trochanter, other).

- Overall cementing technique from index X-rays, recorded as a global judgement. A 'yes' answer to an individual feature indicating poor cementing did not automatically confer an 'unacceptable' tag as this question required the assessor to take an overall view of the hip replacement. This was particularly important when a Capital Hip was used for a revision operation, because evidence of lysis or femoral perforation is not always a reflection on the surgeon carrying out the revision. If the research fellow had any reservations at all, the technique was classed as 'doubtful'. (See also 3.8.1, X-ray assessment.)

3.4 MEASURES OF PERFORMANCE

3.4.1 Revision

In routine clinical practice, revision of a hip replacement is considered to be the most objective measure of the performance of a prosthesis. However, it is clear that some hip replacements fail in a functional sense but nevertheless are not revised,[5,6] for example if the patient is not fit for further surgery. It is also the case that hip replacements are sometimes revised for reasons that are not related to the prosthesis itself, for example because of an infection or recurrent dislocation, which may or may not be the result of surgical technique.

3.4.2 Assessment of X-rays taken at clinical review (Review X-rays)

It was decided to assess X-rays taken when the clinical status of patients was reviewed (subsequently referred to as review X-rays) for signs of loosening in order to try to quantify the extent of any underestimation of the failure rate of Capital Hips by using revision only. Hospitals were requested to supply copies of these X-rays as part of the management framework. Where patients had already had the Capital Hip replacement revised, the management framework asked hospitals to supply copies of X-rays taken just prior to revision for assessment. As for index X-rays, copies of both anterior-posterior and lateral X-rays were requested.

Review X-rays were also assessed by two of the research fellows, who received extensive training in interpreting the relevant aspects of review X-rays (see Appendix F and 3.6).

The following features of X-rays were assessed for evidence of loosening of the femoral component (see Appendix H):

- Quality of film; classification of this feature included an 'unacceptable' option indicating that it was not possible to assess cementing technique owing to the poor quality of the film. When the quality of a film was classified as unacceptable, the reason for grading as unacceptable was also recorded. Films graded as unacceptable were not considered to be able to contribute evidence about loosening.

- Whether the films were a 'true' anterior-posterior (or lateral) view.

- Alignment of the stem in the femoral canal, ie degree of valgus/varus.
- Adequacy of cement mantle.
- Other features (cement/cortex gap, bone lysis, detached greater trochanter, other).
- Presence of a radiolucent line at the stem cement interface in zone 1 as evidence of stem subsidence within the cement mantle.
- Overall assessment for evidence of loosening (a global response).

3.4.3 Patients' self-report about the performance of their Capital Hips

The protocol for the investigation specified that the perspective of patients on the performance of their Capital Hips should be sought. Specifically, it was considered important to try to obtain information about patients' symptoms and level of functioning since, in normal practice, these factors primarily influence the decision to revise a prosthesis. The same factors also cause patients to seek a clinical review. As discussed above, patients with the same level of pain or loss of mobility will not necessarily all undergo revision, since the patient's choice, comorbidity, or other circumstances, may influence the decision to revise or not.

A questionnaire for patients was therefore developed (see Appendix I). It included the 12 items of the Oxford Hip Score, a validated self-completion questionnaire for assessing pain, mobility, and activities of daily living following total hip replacement surgery.[7] The Oxford Hip Score takes a value between 12 (no disability) and 60 (maximum disability). Other items concerned the location of any ongoing pain and concurrent health problems. Questions were also included that related to patients' knowledge and anxiety about the problems with the Capital Hip that had been reported in the media, and their satisfaction with the way in which their own case had been managed.

Three separate versions of the questionnaire were devised; one for patients who had a Capital Hip on the right side, one for patients who had a Capital Hip on the left side and one for patients who had Capital Hips on both sides. The left and right questionnaires were identical apart from references to the right or left hip. The questionnaire for the bilateral patients used the term hips without specifying which side and Oxford Hip Score items (items 4-15 in the patient questionnaire, see Appendix I) were asked without specific reference to the right or left hip; other questions were almost identical to the questionnaires for patients who had only one Capital Hip.

3.4.4 Combined outcome

The intention was to use (a) evidence of loosening from assessment of review X-rays and (b) an appropriate cut-off on the Oxford Hip Score as proxy measures of failure. These outcomes could then be combined with revision to produce a secondary and less conservative measure of failure than revision alone.[5]

3.5 DATA COLLECTION PROCEDURES

3.5.1 Review of case notes

Each of the four members of the research team was responsible for data collection in the geographical area in which they resided, corresponding roughly to (a) Scotland and the North of England, (b) Wales and the Midlands, (c) the South and South West, and (d) London and the South East. The size of the areas covered differed considerably and there was some flexibility and cross-over between areas so that, if a person was having to travel long distances, another member of the team would agree to cover a particular hospital in the former person's area. A list of hospital contacts, nominated by their respective hospitals, was provided by the Capital Hip Care Centre to the Clinical Effectiveness Unit. These people acted as the first point of contact at a particular hospital for the research team. Hospital contacts were responsible for arranging for hospitals notes of patients to be available for the researcher.

For a small number of hospitals that were in distant parts of the country and which had implanted only a few Capital Hips, hospital contacts arranged for copies of notes to be sent to the research co-ordinator in London. The research co-ordinator also frequently contacted hospital contacts to resolve uncertain data or inadvertent missing data on the clinical data questionnaire.

3.5.2 Interviews with orthopaedic surgeons

A decision was made to administer the surgeon questionnaire in an interview with the consultant orthopaedic surgeon of each team that had implanted a Capital Hip. While it was recognised that in many cases surgery was performed by someone other than the consultant, it was not considered feasible to trace all the trainees or non-consultant career grade surgeons who had performed the surgery. Trainees have short-term contracts of 6-12 months and move regularly between hospitals within a region during the course of their training. Non-consultant career grade surgeons also sometimes have short-term contracts and may move between hospitals. Therefore, for the purposes of the investigation, it was assumed that the practice of the consultant would be broadly reflected in the practice of the trainee members of his or her team. A standardised interview technique was adopted and face-to-face interviews were used whenever possible. Where this was not possible the questionnaire was administered by telephone or sent by post for self-completion by the surgeon.

3.5.3 Collection of X-rays

Instructions to hospitals about supplying copies of X-rays taken for the reviews of patients' clinical status were contained in the management framework document circulated to hospitals by the Capital Hip Care Centre. The cost of making copies of these X-rays was covered by the fee paid to hospitals for reviewing the clinical status of patients. Letters requesting index X-rays were sent to named contacts at hospitals at a later date by the Clinical Effectiveness Unit. This letter specified that hospitals would be reimbursed for copies of these X-rays. Copies of X-rays were usually sent by courier

to the Clinical Effectiveness Unit for assessment although in some cases the research team collected the X-rays from hospitals.

3.5.4 Mailing of questionnaires to patients

Questionnaires were sent to all living patients whose case notes had been reviewed and who had not had their Capital Hip revised, according to the information available to the Clinical Effectiveness Unit at the time. (The first item in the questionnaire asked whether the Capital Hip had been revised, in case a revision had taken place recently). Questionnaires were not sent to patients who had undergone revision because they would have been required to rate their pain and mobility retrospectively, ie recalling the severity of their symptoms immediately prior to the revision. It was felt that retrospective ratings would not be directly comparable to prospective ratings and that they would have dubious validity.

Patients known to have had bilateral total hip replacements but where a Capital Hip had been implanted in one side only were sent a questionnaire that pertained to the side of the Capital Hip. Patients known to have had bilateral Capital Hips and where one side had already been revised were sent the questionnaire for the side where the Capital Hip was still *in situ*. A covering letter explaining the reasons for the study was sent with the questionnaire, which also gave a contact telephone number for any queries (see Appendix I).

3.6 DATA QUALITY ASSURANCE

3.6.1 Measurement of inter-rater agreement for the clinical data questionnaire

It was suspected that extraction of data from case notes would involve, to some extent, interpretation of the notes by the researcher, leading to possible differences in interpretation between researchers. Therefore, a sample of notes were obtained prior to starting data collection, firstly in order to determine the likely quality of available data, secondly to discuss possible conflicting interpretations of data items on the clinical data questionnaire and, thirdly, to carry out a formal assessment of inter-rater reliability. Five raters completed the clinical data questionnaire on 24 sets of notes; three sets of notes described the care of patients who had had bilateral Capital Hip replacements.

Cohen's Kappa statistic for multiple raters was calculated for the 22 items on the clinical data questionnaire that lent themselves to such analysis, ie excluding items requiring open text, dates, serial numbers, patient identity numbers (see Appendix J). When responses are uniform across the sample, ie some response categories are never or rarely used, Kappa values will tend to be low, despite good overall agreement, because Kappa is a chance-corrected statistic. This was apparent especially for Kappa values for items 44, 45, 46 and 48, because very few complications were noted; the scarcity of complications also prevented calculation of Kappa values for pairs of raters. Therefore, overall per cent agreement for each item was also calculated. Some response categories were collapsed for the purposes of scoring, both for this assessment of inter-rater reliability and subsequently during the main investigation (see Appendix J).

The proportion of missing data for each observer, and the proportion of items on which an observer was the 'odd-one-out' (ie when all four other raters agreed) were also calculated (see Appendix J). The performance of rater 1 was influenced by the fact that this person missed all three bilateral operations.

3.6.2 Measurement of inter-rater agreement in assessing index and review X-rays

A new method of assessment was developed specifically for the investigation, partly because of the decision to use research fellows to assess the X-rays and partly because of the limited time available to make the assessments. The method was relatively simple compared to previous methods for assessing X-rays of total hip replacements and hence could be applied more quickly. Given that the method was new and was being applied by people without clinical or radiological professional qualifications, it was very important to assess the inter-rater agreement between the research fellows and the trainer at the outset, and between fellows during the period of assessment.

It was originally intended to carry out assessments of agreement between research fellows and the trainer, and between each of the fellows immediately after training. It was also planned to carry out 'checks' on agreement between the research fellows during the early, middle and late phases of assessment to check the stability of their assessments. Assessments of agreement after training between the fellows and the trainer, and between each of the research fellows, were carried out as planned. A further assessment of agreement between the research fellows was only carried out at the end of the investigation (see 3.8.1).

Cohen's Kappa statistic for two raters was calculated for the key features describing cementing quality and loosening (see Appendix K). Unweighted or weighted Kappas were calculated, depending on whether or not the response category represented at least an ordinal scale, for all X-rays rated by both raters.

3.6.3 Data quality assurance routines and linking outcome data from different sources

Before undertaking the statistical analyses, the data were checked for inconsistencies and implausible ranges. Special care was taken in checking the date of implantation, whether or not a revision had occurred and, if so, the date of revision. Errors found were re-checked against the original questionnaires, since a clinical data questionnaire was available for each Capital Hip that was included in the database. Approximately 5% of patients received more than one prosthesis, either because a Capital Hip was used for revision of a Capital Hip or because a Capital Hip was used to replace both the right and left hips of a patient. We identified patients with multiple implantations in the database using information from hospital notes on surname, date of birth and gender; where such patients were identified, unique patient identifiers were generated.

The database containing the results of the assessments of index X-rays was linked to the clinical database on the basis of the unique implantation code.

The database containing information on the practice of the orthopaedic consultant teams (surgeon's questionnaire) was linked to the database containing information from the clinical data questionnaires using a unique code assigned to each consultant team. In the analysis, data contained in the surgeon's questionnaire were combined with the data from the clinical data questionnaire for all patients operated on by a particular consultant team. The data were analysed at the level of the implanted hip prostheses to adjust for differences in surgical procedures not recorded in the clinical data questionnaire.

3.6.4 Resolution of data queries with hospital contacts and by reference to the original questionnaires

Data on questionnaires were optically scanned into a database and quality assured by carrying out range checks and a variety of cross-tabulations. Certain data items that were collected both on the clinical data questionnaire and the review form were compared and contradictions were checked, both by reference to the original questionnaires and by contacting the appropriate hospital contacts.

3.7 STATISTICAL ANALYSES

Most descriptive variables were categorical, and their relative frequencies are presented using percentages. The mean, standard deviation and range were used to describe patients' ages, and a frequency distribution for the date of surgery. For each variable, the number of Capital Hips with missing observations is also presented. For several variables describing aspects of surgical practice, 'other', unknown and missing responses were pooled, providing a binary comparison with responses that positively identified the variable as applying or having been used (in the case of some surgical instrument or material).

Survival analysis was used to describe the 'survival time' of the Capital Hips, ie the time from implantation of the prosthesis until the end of follow up or until revision, if revision happened earlier. Survival curves describe the conditional probability of a Capital Hip not having been revised as a function of time after implantation. Survival curves were calculated separately for (a) survival time prior to the Hazard Notice and (b) survival time after the Hazard Notice up to 1 February 2000 when data collection was suspended. For the pre-Hazard Notice analysis, survival time was censored (ie subsequent survival time was not included in the analysis) on the date of the Hazard Notice, or when a patient had died, if death had occurred before the Hazard Notice. For the post-Hazard Notice analysis, survival time was censored on the date when data collection was suspended (1 February 2000) or when a patient died. Kaplan-Meier survival curves were used to produce a graphical representation of the survival of the different Capital Hip prostheses.

Incidence rates of revision, subsequently referred to simply as 'revision rates', were also calculated. These rates are expressed in terms of the number of revisions carried out per 100 hip-years. The total number of hip years consists of the sum of the survival time of Capital Hips, ie one Capital Hip surviving one year contributed one hip year.

Incidence rates are an alternative method of presenting performance estimates. They were used for comparing performance data for the Capital Hip with two possible 'standard' rates derived from the Trent and Swedish Hip registries and from guidance issued by the National Institute for Clinical Excellence.

The conditional probability of survival of the different types and geometries of Capital Hip was compared before and after the issuing of the Hazard Notice by constructing survival curves as described above. For the curve describing the rate before the Hazard Notice, survival time for hips implanted up to 19 February 1998 was censored on the date of the Hazard Notice, as described above. From this date onwards, additional survival time for the same hips started to contribute to the curve describing the revision rate after the Hazard Notice, a form of censoring called left censoring or late entry. This method of constructing the survival curves allows an evaluation of the change in revision rate after the Hazard Notice that is not distorted by comparing prostheses that have been *in situ* for different lengths of time.

The effects of different prosthesis types and geometry, the characteristics of the patients and surgical factors on the revision rate were explored with Cox proportional hazards regression. Cox regression describes the effects of potential risk factors as hazard ratios,[a] ie ratio of the conditional probability of survival at a particular time when the factor is present to the conditional probability of survival when the factor is absent. The hazard ratio is assumed to be constant over time. Hazard ratios can be considered as relative risks, ie the risk of revision when a factor is present compared to the risk of revision when the factor is absent.

A stratified Cox proportional hazards regression model was used to compare the effects of potential risk factors on the revision rate before and after the Hazard Notice, allowing the baseline revision rate to be different for hips observed before and after the Hazard Notice while assuming that the relative risks were constant within each time period. The effects of potential risk factors were compared before and after the Hazard Notice by entering interaction terms in the model.

Confidence intervals were computed on the basis of robust variance estimates to take account of the fact that observations were 'clustered' within hospitals. Robust variance estimates allow for the potential influence of clustering within hospitals, ie for the possibility that two units of investigation picked at random from the same hospital might on average be more similar than two picked at random from different hospitals.[8,9]

Cox proportional hazards regression models were also used to compare the effects of potential risk factors on the revision rate after taking account of varying revision rates between hospitals and consultant teams.

Multivariate Cox proportional hazards regression analyses were carried out, including potential risk factors that were significant at a level of 0.05 as well as those not significant at this level but which were considered to be of particular interest for clinical reasons.

a The use of the statistical term 'hazard ratio' should not be confused with the Hazard Notice issued by the Medical Devices Agency on 19 February 1998.

To retain all observations in the multivariate analyses, an extra category was created for missing data for all categorical variables where missing data had not been combined with other or unknown response categories. For age (the only continuous variable used in this context), the value of missing observations was set to the mean of the non-missing observations and an extra categorical variable was created with a value of one for observations with missing values and a value of zero for all other observations.

All analyses were carried out using STATA version 6 statistical software. Robust confidence intervals were calculated where appropriate, using this software.

3.8 CRITIQUE OF THE STUDY DESIGN AND DEVIATIONS FROM THE STUDY PROTOCOL

3.8.1 Data collection

Clinical data questionnaire

Some variables previously reported to influence the outcome of total hip replacement,[10,11,12] namely weight, body mass index and mobility/level of everyday activity, were not recorded on the clinical data questionnaire. These variables could also potentially have been associated with the choice of prosthesis by a surgeon, giving rise to confounding. For example, large body size or weight is sometimes regarded by surgeons as an indication to use a flanged rather than a round back prosthesis. While a small round back type prosthesis is more appropriate for a small patient with a small femur, a larger, flanged device is more appropriate for a large patient or patient with a large femoral medullary cavity. However, the steering committee concluded that weight and body mass index would not be consistently available in the case notes and operation notes available to the research fellows. The extent of confounding between weight or body mass index and the Capital Hip type is therefore not known.

Higher levels of activity, which are more common in younger patients, have also been suggested to be a risk factor for revision and could therefore also be a confounding factor if surgeons tended to choose one type of Capital Hip rather than another for more active patients. However, the steering committee again concluded that this information would not be available and the extent of confounding between activity level and the Capital Hip type remains unknown.

Surgeon's questionnaire

The surgeon's questionnaire was designed for face-to-face administration, not administration by telephone nor for self-completion by a surgeon. Face-to-face administration allowed the research fellow to establish a rapport with the surgeon being interviewed, to clarify questions and to explain the relevance of items. Telephone administration also allowed clarification to be given but may have limited the extent to which rapport was established. Self-completion did not allow any of these advantages, and surgeons who completed the questionnaire themselves may have answered some of the questions in a different way. The extent of these differential epidemiological biases[b] are unknown, but one might expect more missing data if some items were unclear and

could not be clarified. Biases leading to an overestimation of the number of operations carried out, or other aspects of their work that surgeons might perceive would reflect well on them, might also be more pronounced with self-completion. However, since the method of administration was simply the result of logistical problems in arranging a meeting or telephone conversation at a time convenient to both the consultant and research fellow, there is no reason to suspect that surgeons who were more likely to implant one type of Capital Hip were more likely to complete the questionnaire themselves. Therefore, the variation in method of administration of the questionnaire between surgeons is likely only to have introduced measurement error, not a systematic epidemiological bias; error of this kind may reduce the strength of associations between variables on the questionnaire and revision but cannot give rise to spurious associations.

X-ray assessment

At the outset, assessment of X-rays was considered to be a very important aspect of the project, although the steering committee members who represented the British Orthopaedic Association pointed out that previous research has shown that inter-rater agreement for such assessments is poor.[13,14,15]

Research fellows, without previous experience of assessing X-rays, carried out the assessments of index and review X-rays. This decision was taken because the steering committee thought it unlikely that a radiologist or senior orthopaedic surgeon would be prepared to carry out the task, even if the cost of their time was remunerated. Research fellows were carefully trained to assess the X-rays, as described in Appendix F, and inter-rater agreement was assessed between the fellows and an expert consultant orthopaedic surgeon at the outset, and between the two fellows at the end of the assessment (see Appendix K).

One of the quality criteria for cementing adopted for this investigation was that the cement mantle should have a thickness, as assessed from index X-rays, of greater than or equal to 2mm at all points. The criterion was intended to represent a proxy measure of the risk of revision arising from a sub-optimal cement mantle, not in order to make a judgement about specific hips; that is, members of the steering group appreciated that the criterion would give rise to many misclassifications when applied to individual hips. The choice of this criterion influenced the discussion of the appropriateness of the labels used to describe different grades of quality of cementing (see below).

It should be pointed out that the criterion for cement mantle thickness represented expert opinion in 1998 (when the steering group designed the X-ray assessment criteria), not in 1993 (when 3M Health Care issued the surgical protocol for the Capital Hip), and that it was influenced by a combination of literature, discussions between orthopaedic surgeons at conferences and elsewhere, and personal experience. Some literature, both clinical[16,17] and theoretical,[18] suggests that the risk of revision increases with thin cement mantles, but other literature[19] suggests that perfectly satisfactory performance is possible with thin cement mantles. Ebramzadeh *et al* [16] also suggested that cement mantles can be too thick. It should be noted that the majority of the literature originates from

b The term 'bias' is used through the report in an epidemiological sense. Epidemiological biases can be differential or non-differential and are of two main types, selection biases and information biases. Non-differential biases (eg data missing at random, or measurement/classification errors that occur uniformly) almost always reduce the strength of findings, making it more difficult to demonstrate statistical significance. Differential biases (eg data more likely to be missing for patients with certain characteristics, or measurement error greater or less for patients with certain characteristics) can have unpredictable effects and may generate spurious findings.

specialist centres, and that the surface finish and material of the prostheses studied varied between studies.

The criterion was intended to reflect the professional view of consultant orthopaedic surgeons that, towards the end of the last decade, there has been a tendency to prefer thicker cement mantles as part of the development of 'modern cementing techniques'.[20,21] Steering group members who represented the British Orthopaedic Association felt strongly that, as a general principle, hip replacements with cement mantles less than 2mm thick at any point are more likely to require revision because of early loosening than hip replacements with cement mantles which have a radiological thickness of 2mm or greater in all locations. It is suspected that this criterion is associated with revision because the detection of a thin cement mantle on an X-ray is itself correlated with the presence of an incomplete cement mantle. It is certainly not the case that cement mantles which are less than 2mm thick at some point will inevitably loosen earlier than would otherwise have been the case.

The assessment of the thickness of the cement mantle was inevitably subject to measurement error, which was not quantified. The assessment was made with a ruler directly from X-rays viewed using a light box. It can also be difficult to determine from where the measurement should be taken because the edge of a cement mantle may be ill-defined owing to interdigitation arising from insertion of the cement under pressure. Cement mantle thickness often had to be assessed only from anterior-posterior X-rays because lateral films were not available. However, the lack of lateral X-rays could only have reduced the sensitivity of the 2mm criterion in detecting sub-optimal cement mantles, ie some mantles that would have been judged to have a thickness less than 2mm on a lateral film (if it had been available), may have appeared to have a cement mantle of 2mm or greater thickness on the anterior-posterior X-ray.

It should be noted that cement mantle thickness is not yet a standard part of assessment within the Swedish and Trent Registries that will be discussed later, nor is it part of the recent National Institute for Clinical Excellence report on total hip replacement.[22] The recent consultation document for a National Joint Replacement Registry for the UK, published by the Department of Health in October 2000,[23] does not include cement mantle thickness nor any other radiographic measurement in its proposed core data fields.

The validity of the assessments made by the research fellows is supported by better-than-chance agreement for most features between their assessments and those of the expert consultant orthopaedic surgeon who trained them. The extent of agreement was comparable to the agreement between the consultant surgeon and his assistant who carried out similar assessments routinely as part of her job. However, the relatively poor agreement (although better-than-chance) means that measurement error is likely to have been high for the features assessed, reducing the power of the investigation to detect an association between poor cementing and revision.

With hindsight, the labels 'acceptable', 'doubtful' and 'unacceptable' which were used on the data collection form (Appendix G) to grade overall cementing technique from index X-rays were inappropriate. There are several reasons why the steering committee now considers these labels to be inappropriate:

- Features indicative of an inadequate cement mantle do not necessarily lead to poor performance, although they may confer an increased risk of early failure for certain types of stem.

- An inadequate cement mantle may arise for many reasons and, for technical and anatomical reasons, imperfect cement mantles are common. Notwithstanding the frequency of imperfect cement mantles, which occur with all types of cemented hip prosthesis, the outcome of total hip replacement is excellent for the majority of patients.

- As indicated by the research fellow's account of her training, she tended to assess X-rays against an 'ideal' rather than a representative standard.

- The concept of unacceptable is based on current general thinking, not on the manufacturer's instructions in the surgical protocol for the Capital Hip, nor on established practices during much of the period when Capital Hips were being implanted.

- Quality criteria assessed by the research fellow were based on published recommendations by experts. However, there is no evidence about the extent to which these standards can be achieved in everyday practice.

The steering committee therefore interpreted the three categories simply as ordinal grades of adequacy of cementing.

It was intended that research fellows should each assess about half of the X-rays, with both research fellows assessing X-rays for 50 hips at the beginning, middle and end of the period during which assessments were made, in order to document the stability of inter-rater agreement over time as the fellows gained more experience. However, one research fellow assessed all of the X-rays, with the second research fellow re-assessing a sample of 117 sets of X-rays from three hospitals, because the second research fellow was unexpectedly not available for a considerable period of time. All analyses in this report, except those evaluating the inter-rater agreement, use the assessments made by the research fellow who assessed all of the X-rays.

Both anterior-posterior and lateral index and review X-rays were requested from hospitals but they were not always available. Where only one X-ray view was available, the research fellows still reported on all of the features on the assessment forms. This method of reporting meant that assessments were made for hips with X-rays from one view only. Important features, that might have been visible had the X-rays from the other view been available, could have been missed, ie false negative misclassifications

of poorly cemented or loose hips as satisfactory could have arisen. The observed frequencies of poorly cemented or loose hips may therefore be underestimates.

3.8.2 Study design

At the meeting to discuss the protocol for the investigation and prior to the formation of the steering group, the issue of whether or not to include a control group was discussed in detail. The meeting included representatives of the Department of Health, 3M Health Care, British United Provident Association, an external NHS advisor and Dr Reeves. Specifically, Dr Reeves pointed out that the use of a retrospective case series design for the investigation would preclude making definitive comparisons between the performance of the Capital Hip and other established prostheses. Such comparisons would have required the inclusion of a control group of hips implanted with other established prostheses during the same time period.

Participants at the meeting pointed out that including a control group would require (a) the identification of a group of suitable control patients, either by hospitals or by the research team (which might be considered to breach patient confidentiality), and (b) consent to be obtained from control patients to review their case notes. The meeting concluded that the investigation should not include a control group because of the methodological and logistical difficulties.

3.8.3 Changes to the plan of analysis

The representatives of the Medical Devices Agency expressed an interest in the risk of revision conferred by aspects of the design of Capital Hips other than simply their 'type', ie modular or monobloc. The feasibility of such analyses was considered by examining the number of Capital Hips with different combinations of design features, prior to carrying out any analyses. As a result, additional *a priori* analyses were included with the aim of investigating the effect of stem geometry, ie flanged versus round back design.

No analysis of combined outcome was carried out because of the inadequate numbers of review X-rays and patient questionnaires received by the Clinical Effectiveness Unit. The large amount of missing data for these latter outcomes meant that any analysis of a combined outcome would have been highly susceptible to selection biases, ie hips for which secondary outcome data were missing were likely to be selectively different from hips for which the data were available. Although this report subsequently describes an excellent response rate from patients (over 70%), the amount of missing data meant that it was not possible to rule out important epidemiological biases.

The steering group acknowledged that the public would expect the report to make some statement about the relative performance of the Capital Hip compared to other prostheses implanted during the same time period. Therefore, although the analyses were not part of the objectives of the study, two indirect comparisons were carried out.

First, revision rates over time were compared against a standard of 0.7 revisions per 100 hip-years (equivalent to about 96.6% survival at five years). This standard was derived from representative data collected by the Swedish Registry and, for Charnley Hips, by the Trent Registry. The method of derivation of this standard from each of these datasets is described in detail in Appendix L.

Second, revision rates over time were compared against a standard of 1.0 revisions per 100 hip-years (equivalent to about 95% survival at five years). This standard is approximately the same as set by the National Institute of Clinical Excellence in its recent technology appraisal of prostheses for total hip replacement[22] (see Appendix L).

It is important to note that both of these comparisons are indirect, in the sense that many factors, eg characteristics of patients and surgical practice, the reasons for carrying out a total hip replacement and the indications for revision, may vary between the population of patients implanted with Capital Hips in the UK, the population of patients implanted with Charnley Hips in the Trent Region and the population of patients implanted with a variety of hips in Sweden.

Furthermore, within the Trent Registry no distinction is made between the various geometries of the Charnley Hip implanted, i.e the proportions of Charnley Hips that had flanged and round back geometries. The effect of different geometries of modern Charnley Hips on the risk of revision has not been carefully investigated. However, if there had been an effect (ie a flanged geometry had poorer performance than a round back geometry or vice versa), failing to distinguish between different Charnley Hips in the Trent Registry could only have made it more difficult to demonstrate that one or more of the Capital Hips performed relatively poorly.

Equivalent Charnley Hips are included within the Swedish Registry and it should be recognised that the reported performance of the Charnley Hip is less good (approximately 1% revisions per hip year[c]) than the overall Swedish revision rate of 0.7% revisions per hip year. The lower overall revision rate in Sweden might be accounted for by the widespread[d] use of the Lubinus SP prosthesis, which has been reported to have a high survival rate (96.7% at 10 years). However, trends over time in the relative proportions of Charnley and Lubinus prostheses implanted (not described by the Swedish Registry), combined with a general improvement in cementing quality[10] or other confounding factors, might also explain the difference in performance between Charnley and Lubinus prostheses. The Lubinus SP prosthesis is not used in the UK in appreciable numbers.

Despite the indirect nature of any comparison, both the hip registry data and the NICE benchmark have the advantage that they represent ‘everyday’ rather than ‘specialist’ practice.

c 7.2% failure rate at 10 years for osteoarthrosis and aseptic loosening. Assuming this group comprises 75% of the total reasons for revision, as specified in the report from the Swedish Registry, then this leads to 90.4% total survival at 10 years or 1.01% revisions per hip year.

d Lubinus SP 18,824 implants cf. Charnley 21,729 implants.

4 Results

4.1 CHARACTERISTICS OF THE PATIENTS

In total, 3,947 implanted 3M Capital Hips were identified; 35 unused Capital Hips were returned to 3M after the Hazard Notice, so this total represents 85% of all of the Capital Hips that were supplied and not otherwise accounted for when follow-up for the investigation ceased on 1 February 2000. Consent for the case note review was refused by 60 patients, and no response was received from 199 other patients. Data from a further 633 patients who had died were included in the analysis. As a result, we included observations on 3,688 Capital Hips that were implanted in 3,494 patients; 20 patients had had bilateral implantations, 170 had had a Capital Hip revised with another Capital Hip, and two had had a Capital Hip revised twice with another Capital Hip (see Table 2).

The mean age of the patients was 71, and their ages ranged from 20 to 94 years. About 25% of the patients were younger than 65 years old and about 20% older than 80 years old. Two-thirds of those who received a Capital Hip were female. The first Capital Hip was implanted on 19 January 1990 and the last one on 6 November 1997. Of the 3,494 patients included in the study, 83% were understood to be alive on 1 February 2000, and 70% were alive with a Capital Hip *in situ*.

4.2 CHARACTERISTICS OF THE HIP REPLACEMENTS

About 75% of the 3,688 hips were implanted because of primary osteoarthritis, 9% for hip fracture, and 7% to replace an existing Capital or other type of hip (see Table 3). All other clinical indications for hip replacement were rare (3% or less). About 25% of all implanted hips were of unknown type of Capital Hip. Of the hips where the type was known, about 70% of the Capital Hips were of modular type and 30% of monobloc type, and about 70% were flanged and 30% round back. Type and geometry of the prostheses varied independently; about 50% of the Capital Hips were modular and flanged and only about 10% were monobloc and round back (see Figure 2).

About two-thirds of the operations were carried out by a consultant. The most frequently used surgical approach was posterior. Prophylactic antibiotics were almost always used. A cement restrictor, which was most often a plastic one, was used in 46% of the cases. Cement was recorded as having been used in 89% of the replacements (but was presumed to have been used in all operations) and cement antibiotics in 16% of replacements for which this information was available. Peri-operative complications occurred in about 4% of the operations.

Table 2. Characteristics of 3,494 patients at the time of first implantation of a Capital Hip.*

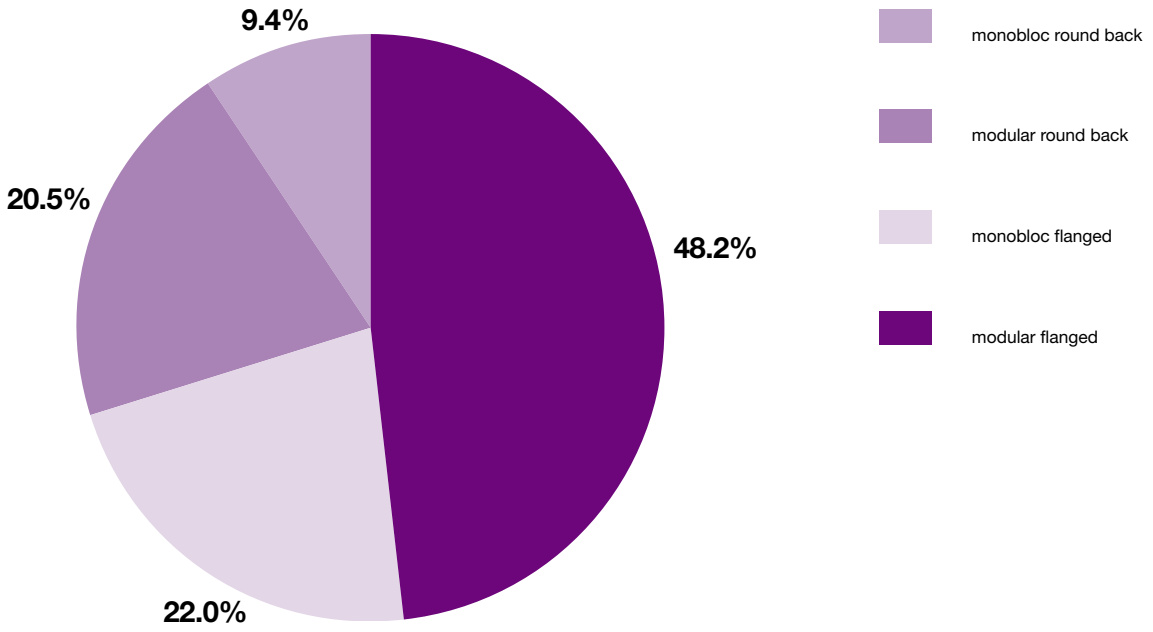
Characteristic	Value	Number of missing observations
Age at implantation (years)		n=44
mean (sd)	71.9 (10.0)	
median (range)	71.9 (20.2 to 94.0)	
< 60	12.8%	
60 – 65	13.0%	
65 – 70	15.7%	
70 – 75	22.0%	
75 – 80	17.3%	
> 80	19.4%	
Gender		n=82
men	34.4%	
women	65.6%	
Date of index operation		n=34
median (range)	31-3-94 (19-1-90 to 06-11-97)	
1990 – 1992	24.4%	
1993	19.2%	
1994	26.5%	
1995	21.3%	
1996 – 1997	8.6%	
Known to be deceased at end of follow-up	17.5%	
Known previous hip operations	10.6%	
Bilateral implantations	0.6%	n=6
Patients understood to be alive at 1 February 2000 with a 3M Capital Hip *in situ*.	70.4%	

Values are proportions, except where described as means or medians

Note:

* The database contained 3,688 hip records: one record for 3,302 patients, two records for 190 patients (20 patients with bilateral implants and 170 with successive Capital implants for the same hip), and three records for two patients.

Figure 3. Distribution of 2,801 Capital Hips by different types, where type was known*.



* The type of a further 887/3,688 Capital Hips (24% of all Capital Hips) was unknown. The percentages in the figure nevertheless represent the most likely estimates of the proportion of each type of Capital Hip implanted, since there was no evidence to suggest that information about the type of hip was more likely to be missing for one type than another.

Information about bone preparation was very often missing. The use of a 3M Modular/ Monobloc Cemented Hip System rasp was reported in 1% of operations, the use of a Charnley rasp in 0.2%, and in 51% it was stated that a rasp was used without naming the type; there was no record of whether or not a rasp had been used in the remainder. Additional use of a gouge and curette was reported in 2%. The percentages of observations in which a 3M Modular/Monobloc Cemented Hip System or Charnley rasp was used, or a gouge and curette was used, were considered to be too low to be a meaningful representation of actual practice and these variables were therefore not used in the subsequent analyses of potential risk factors for revision.

4.3 ASSESSMENTS OF INDEX X-RAYS

Index X-rays were obtained for 2,036 implanted hips; 1,806 had only anterior-posterior views, 12 only lateral views, and 218 had both. After excluding 154 sets of X-rays which could not be assessed because of their quality, there were 1,654 hips which had only anterior-posterior views, 11 which had only lateral views, and 217 which had both.

Table 3. Characteristics of 3,688 implanted Capital Hips.

	All	n(X)	MdF	MnF	MdR	MnR	Unknown
Primary indication for hip replacement*		n=96					
Primary osteoarthritis	74.6%		77.2%	76.3%	84.0%	67.3%	65.6%
Secondary osteoarthritis	2.7%		2.8%	3.5%	2.3%	1.5%	2.4%
Rheumatoid arthritis	3.2%		3.0%	3.3%	4.6%	5.4%	2.0%
Arthritis unspecified	1.3%		1.4%	0.7%	1.8%	1.2%	1.3%
Avascular necrosis	3.2%		4.1%	2.2%	3.6%	2.7%	2.2%
Fracture	9.2%		2.0%	11.4%	1.3%	20.8%	20.1%
Revision total replacement	6.9%		10.7%	5.0%	3.9%	1.5%	6.1%
Other	8.8%		9.8%	7.3%	9.8%	8.5%	7.8%
Side of implantation		n=6					
Right	56.3%		56.7%	55.1%	59.9%	56.1%	54.3%
Left	43.7%		43.3%	44.9%	40.1%	43.9%	45.8%
Type or prosthesis		n=887					
Modular, flanged	48.2%						
Monobloc, flanged	22.0%			see figure 1			
Modular, round	20.5%						
Monobloc, round	9.4%						
Grade of lead operator		n=357					
Consultant	67.4%		70.9%	67.6%	58.1%	67.6%	67.9%
Career grade/trainee with consultant	8.9%		9.5%	6.3%	11.5%	10.7%	7.3%
Career grade/trainee without consultant	9.4%		10.9%	4.9%	18.7%	8.4%	4.1%
Career grade/trainee, with unknown assistant	14.3%		8.7%	21.2%	11.7%	13.3%	20.7%
Surgical approach		n=465					
Posterior	82.4%		77.1%	92.8%	72.1%	79.4%	92.0%
Trans-trochanteric	9.2%		12.9%	1.5%	20.4%	2.4%	2.9%
Direct lateral (Hardinge)	7.0%		8.7%	3.0%	7.3%	17.3%	3.3%
Antero-lateral (Watson-Jones)	1.0%		0.3%	2.7%	0.0%	0.8%	1.8%
Anterior	0.4%		1.0%	0.0%	0.2%	0.0%	0.1%
Reported use of prophylactic antibiotics	95.0%		96.5%	95.5%	97.2%	96.6%	90.8%
Reported use of restrictor							
Bone	5.9%		3.0%	17.4%	1.9%	3.1%	5.9%
Plastic	26.3%		32.4%	21.0%	27.6%	29.0%	19.1%
Unknown type	13.8%		20.0%	5.0%	22.2%	13.7%	5.0%
Reported use of cement for femur	89.1%		91.0%	89.6%	90.1%	95.4%	83.2%
Reported use of cement antibiotics	15.8%		15.5%	21.6%	17.5%	15.7%	11.3%
Reported peri-operative complications							
Femoral fracture	1.1%		1.1%	1.0%	0.9%	1.2%	1.0%
Cement curing problem	0.2%		0.2%	0.5%	0.4%	0.0%	0.1%
Femoral perforation	1.3%		1.8%	0.5%	1.9%	1.5%	0.6%
Deep wound infection	1.2%		1.6%	1.4%	0.7%	1.2%	1.0%
At least one of the above	3.6%		4.4%	2.8%	3.7%	3.4%	2.7%
3M Capital Hips assumed to be *in situ* at 1-2-2000	70.2%		68.4%	77.9%	74.0%	71.0%	64.8%

Note:

* For 309 replacements two primary indications were given, for 20 replacements three, and for one replacement four.

Values are proportions. All – all types of Capital Hip; n(X) – number of hips for which data were missing; MdF – modular flanged, MnF – monobloc flanged, MdR – modular round back, MnR – monobloc round back, Unknown – unknown type.

Many X-rays were judged to have features that were considered to indicate poor quality of cementing. However, because the research fellows were often unsure about whether or not a feature was present, or because the scores were very unequally distributed across possible assessment categories, analyses including individual features were difficult to interpret or had low power to detect an association.

A total of 1,899 sets of X-rays were assessed for overall cementing technique and these scores were distributed more equally across the possible response categories; 13% were assessed as having 'satisfactory' cementing technique, 54% as having 'doubtful' cementing technique, and 33% as having 'unacceptable' cementing technique. In view of the relatively poor agreement between the research fellow and the consultant orthopaedic surgeon, and between the two research fellows, these proportions must be regarded with caution. Nevertheless, the fact that agreement was better than expected by chance means that it is legitimate to regard the distribution of assessments across the three categories as an ordinal scale of quality of cementing. The strength of association between overall cementing technique and the risk of revision, and the extent to which including overall cementing technique in the analysis changed the estimates of the relative risk for different types of Capital Hip, were therefore investigated by including this variable in a multivariate Cox proportional hazards model.

4.4 REVISIONS OF CAPITAL HIPS

Of the total of 3,688 Capital Hips that were included in this study, 6.3% were found to have been revised before the date of the Hazard Notice (19 February 1998) and 13.4% at the end of study follow up (1 February 2000). Similar proportions were observed if the analyses were confined to those prostheses used for primary replacement (see Table 4). Of the 3,440 patients who received a Capital Hip as a primary replacement, 3,276 could be included in survival analyses. (Reasons for exclusion of the remaining 164 patients are as follows: the date of death of 124 patients was unknown, the date of implantation was missing for 34 patients, the revision date was unknown for five patients and the last known follow-up date was missing for one patient).

The revision rate before the Hazard Notice was 1.8 revisions per 100 hip-years (211 revisions observed in 11,900 hip-years). In the first year after the Hazard Notice, the revision rate was 8.3 revisions per 100 hip-years (213 per 2,568 hip-years). Based on a stratified Cox regression model that takes account of the differences in the time after implantation, the 'relative risk'[e] of revision after Hazard Notice was 3.78 (95% confidence interval, 2.51 to 5.69), ie the 'hazard' after the Hazard Notice was 3.78 times the hazard before the Hazard Notice. During the second year after the Hazard Notice, the revision rate was 1.0 revisions per 100 hip-years (22 per 2,284 hip-years) and 0.49 times (95% confidence interval, 0.29 to 0.86; Cox regression model) the rate before the Hazard Notice.

The total number of revisions, and revision frequencies, of the different types and geometries of Capital Hip are shown in Table 4. Given the large change in the rate of revision after the Hazard Notice, it is not meaningful to combine data across both time

e Strictly speaking, here and below the term 'relative risk' should be described as a hazard ratio (see 3.7).

periods to produce a single Kaplan Meier plot for each type of Capital Hip. It is also difficult to interpret data just for the period after the Hazard Notice, because the Hazard Notice occurred at varying times after implantation for different patients.

The survival estimates for the period up to 19 February 1998, which are reported in Table 5, are almost certainly optimistic, since it is clear that additional hip replacements which had already 'failed' were identified by the clinical review process. However, the data reported in Table 4 implies that the survival estimates in Table 5 are not greatly optimistic, since there is the same rank order of performance across different types of Capital Hip, and the revision frequencies are similar to the survival estimates, eg about one in five modular flanged Capital Hips had been revised after five years.

Table 4. Frequency of revision of Capital Hips.

	Number implanted	Number revised	Revision frequency
Until end of follow-up (1 February 2000)			
All prostheses	3,688	495	13.4%
Modular flanged	1,351	275	20.4%
Monobloc flanged	615	45	7.3%
Modular round	573	82	14.3%
Monobloc round	262	7	2.7%
Unknown type	887	86	9.7%
Prostheses used for primary replacement	3,440	456	13.3%
Modular flanged	1,211	247	20.4%
Monobloc flanged	585	44	7.5%
Modular round	551	80	14.5%
Monobloc round	258	7	2.7%
Unknown type	835	78	9.3%
Until Hazard Notice (19 February 1998)			
All prostheses	3,688	234 or 239*†	6.3% or 6.5%*
Modular flanged	1,351	119 or 123*†	8.8% or 9.1%*
Monobloc flanged	615	27	4.4%
Modular round	573	35	6.1%
Monobloc round	262	4	1.5%
Unknown type	887	49	5.5%
Prostheses for primary replacement	3,440	211 or 216*†	6.1% or 6.3%*
Modular flanged	1,211	102 or 106*†	8.4% or 8.8%*
Monobloc flanged	585	26	4.4%
Modular round	551	35	6.4%
Monobloc round	258	4	1.6%
Unknown type	835	44 or 45*†	5.3% or 5.4%*

Note:

* Note that the percentage revised does not take account of differences in the pattern of implantation of different types of prosthesis, eg a tendency for one type of hip to be implanted more often than another earlier during the period in which the Capital Hip was marketed, and that the number implanted includes hips which have been implanted for varying lengths of time.

† Date of revision was missing for five revised prostheses.

Table 5. 'Survival' of 3,276 3M Capital Hips according to type used for primary replacement as a function of time after implantation from implantation to Hazard Notice (19 February 1998).*

Type	Modular flanged	Monobloc flanged	Modular round	Monobloc round	Type and geometry unknown
Number implanted†	n=1,184	n=552	n=546	n=238	n=756
Time after implantation					
6 months	99.06% (98 32 to 99.48)	99.27% (98 07 to 99.73)	99.45% (98 30 to 99.82)	100%	99.46% (98 56 to 99.80)
1 year	98.89% (98.10 to 99.35)	98.90% (97.57 to 99.51)	99.26% (98.05 to 99.72)	100%	99.18% (98.17 to 99.63)
2 years	96.15% (94.84 to 97.13)	98.15% (96.58 to 99.00)	96.75% (94.82 to 97.97)	100%	98.46% (97.24 to 99.15)
3 years	93.01% (91.26 to 94.42)	97.00% (95.06 to 98.19)	94.69% (92.27 to 96.36)	98.10% (94.16 to 99.39)	97.23% (95.68 to 98.22)
4 years	91.11% (89.03 to 92.81)	95.05% (92.51 to 96.74)	93.63% (90.86 to 95.58)	97.11% (92.30 to 98.94)	95.10% (93.02 to 96.56)
5 years	89.16% (86.56 to 91.28)	94.17% (91.24 to 96.13)	90.74% (85.91 to 93.97)	97.11% (92.30 to 98.94)	93.36% (90.78 to 95.24)
6 years	83.94% (79.43 to 87.53)	92.17% (87.65 to 95.08)	83.01% (70.82 to 90.43)	97.11% (92.30 to 98.94)	90.75% (87.04 to 93.44)

Note:

* Estimates are the percentage of prosthesis still *in situ* after varying periods of follow-up with 95% confidence intervals in parentheses. Estimates do not take account of differences in patient characteristics or aspects of surgical practice between groups of different types of Capital Hip.

† Number implanted is equal to the number of patients implanted with each type of Capital Hip. Because Capital Hips were implanted over the period 1990 to 1997, the number of each type of Capital Hip contributing to the estimates of survival decreased with increasing time after implantation, which is reflected in widening confidence intervals.

Figure 4. 'Survival' of 3,276 3M Capital Hips as function of time after implantation (year) before and after the Hazard Notice (19 February 1998).

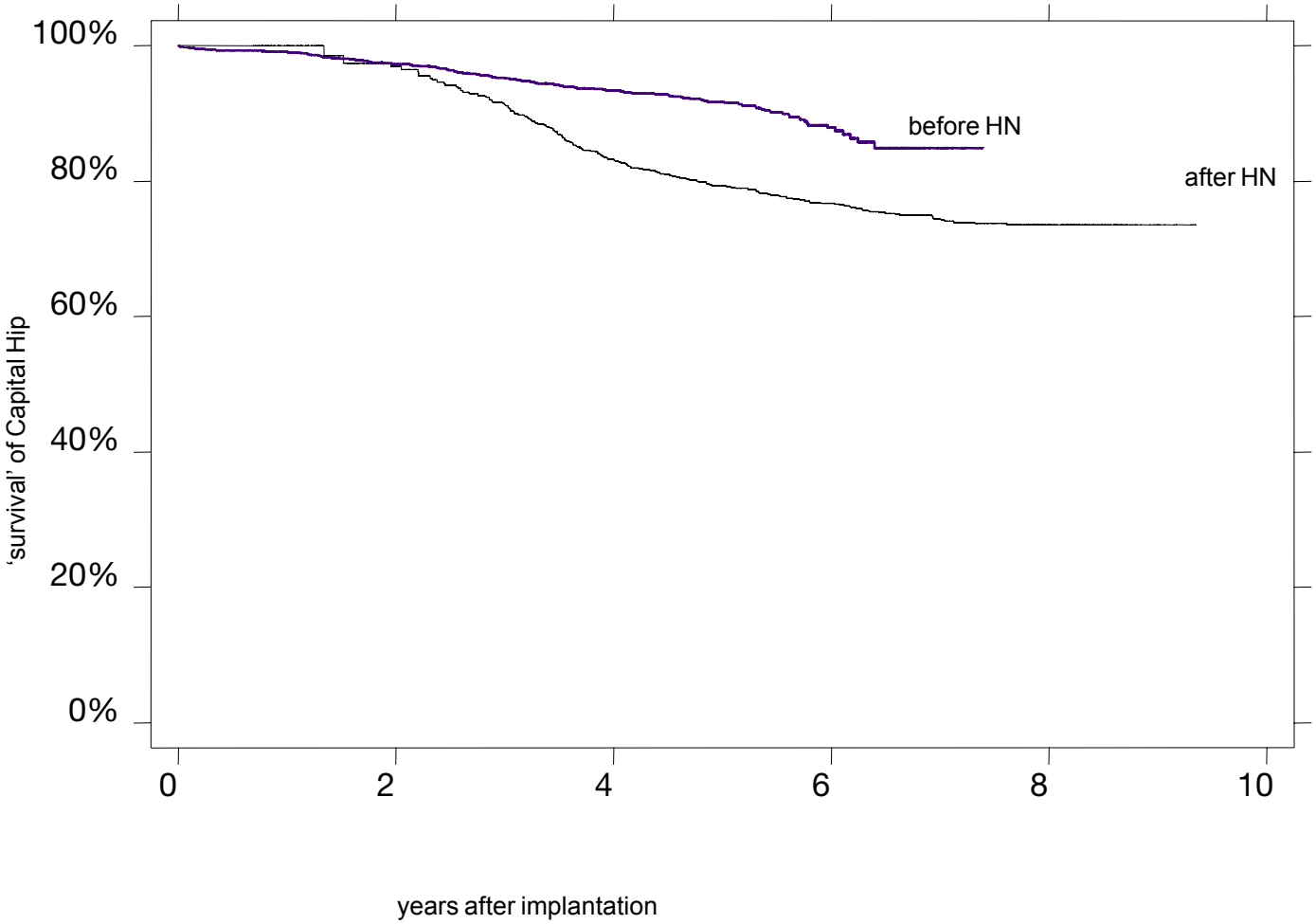
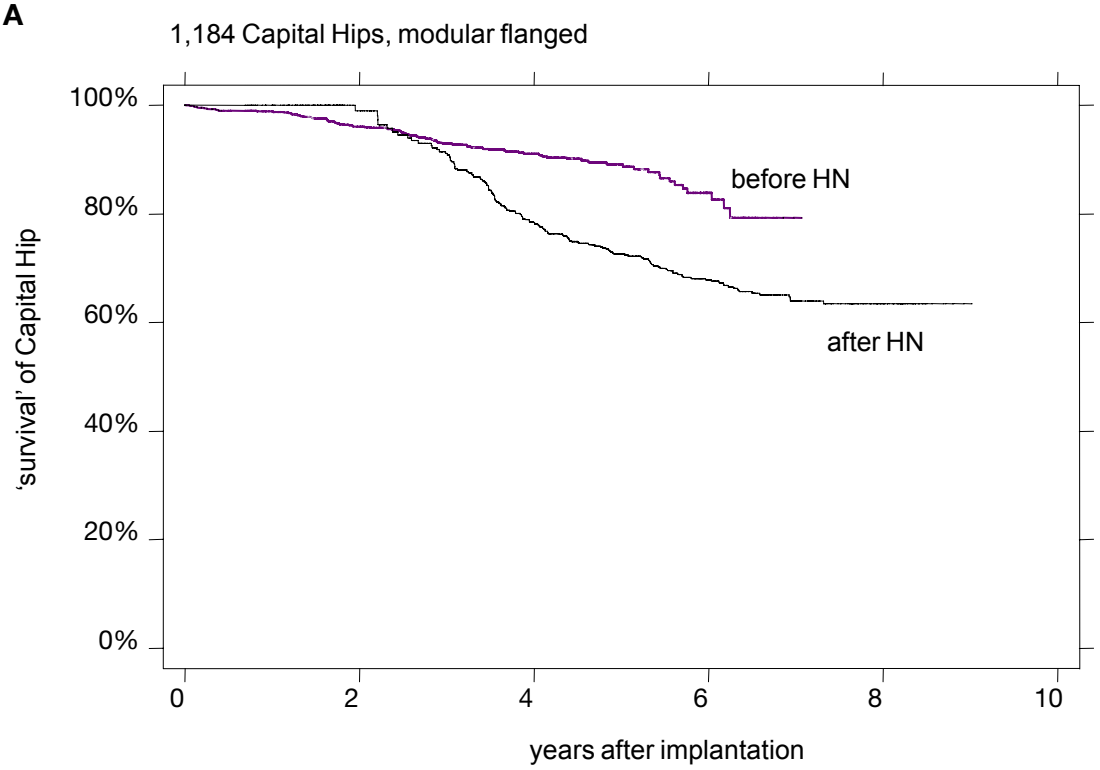


Figure 5. 'Survival' of 3,276 Capital Hips as function of time after implantation (year) to Hazard Notice (19 February 1998) according to type; (a) modular flanged, (b) monobloc flanged, (c) modular round back, (d) monobloc round back, (e) unknown type and geometry.

A



B

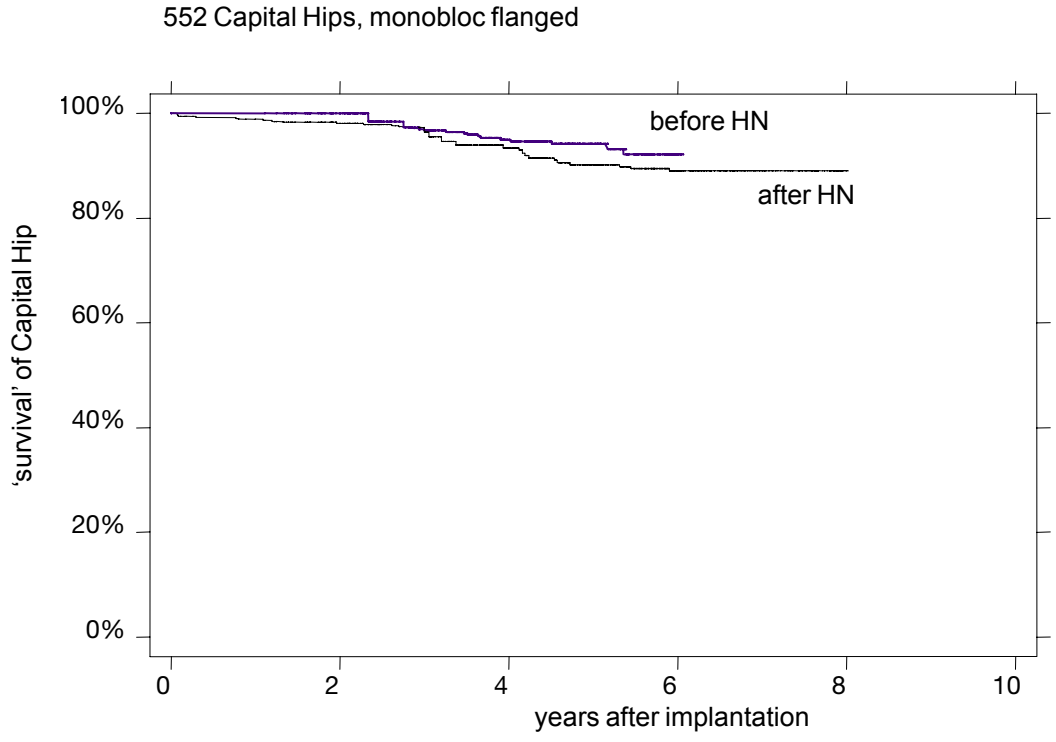
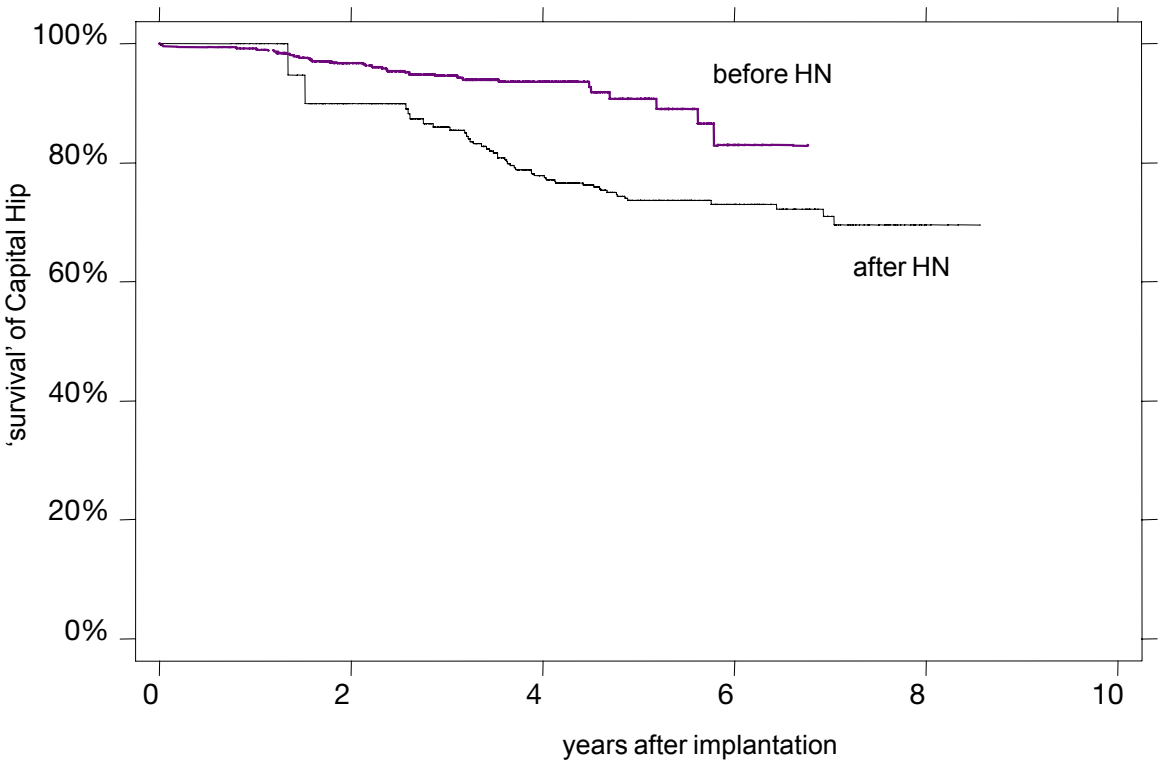
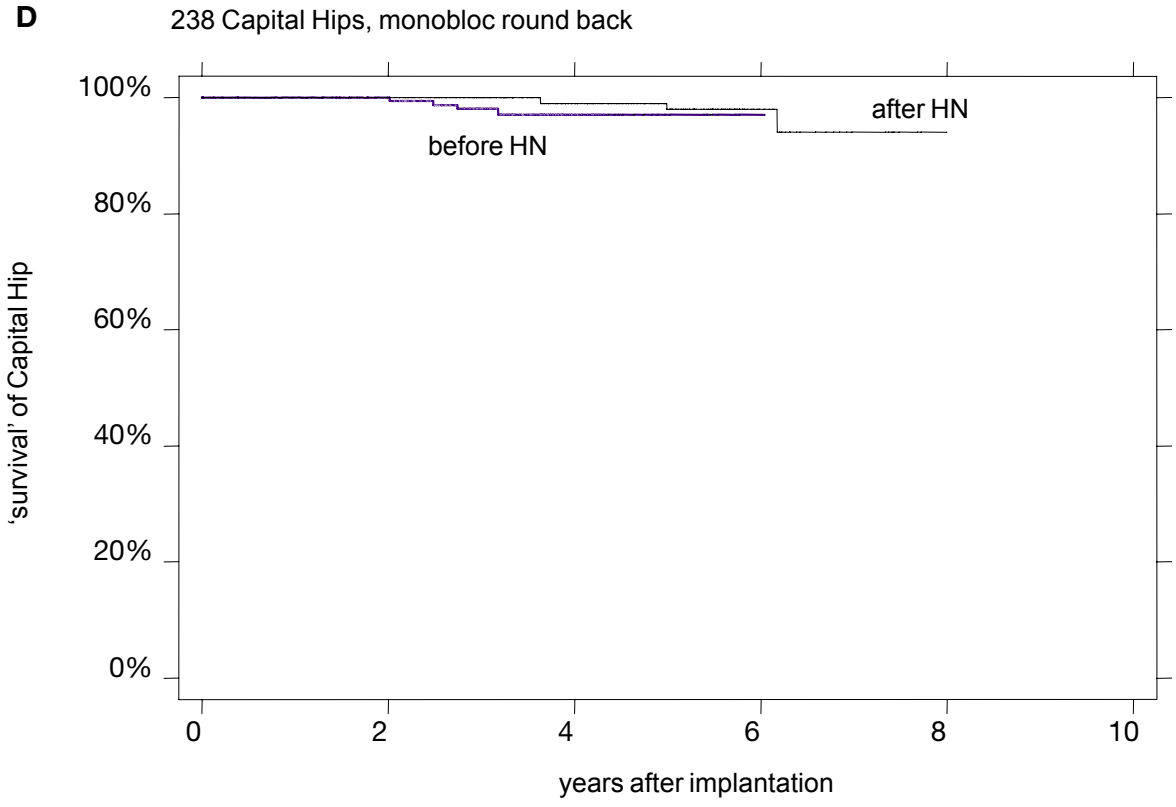


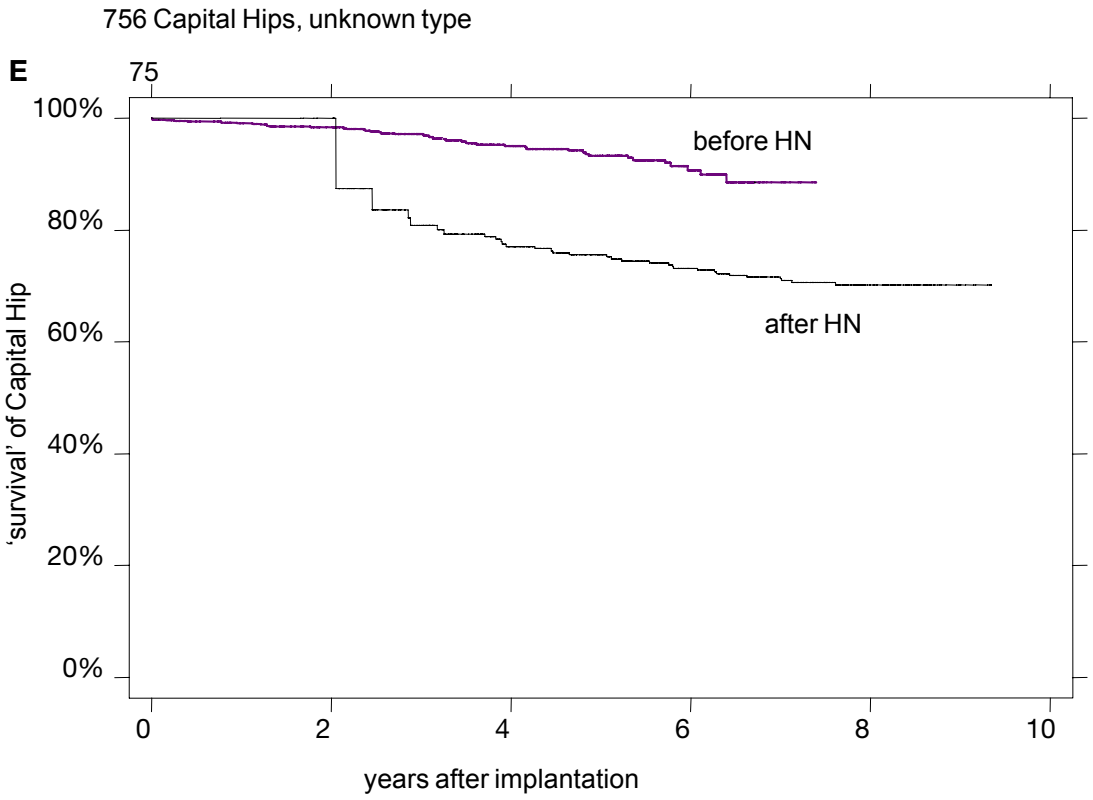
Figure 5 (continued)

C



D





Before the Hazard Notice, the rate of revision depended strongly on the type and the geometry of the prosthesis (see Figures 4 and 5 and Table 5). The most extreme differences were found between the modular flanged (the most frequently implanted hip) and the monobloc round back hip (the least frequently implanted hip). Five years after implantation for a primary replacement, 97.1% (95% confidence interval, 92.3 to 98.9) of the monobloc round back hips were estimated to be still *in situ* compared to 89.2 (95% confidence interval, 86.6 to 91.3) of the modular flanged ones.

Confidence intervals describe the extent of uncertainty about the estimate, ie the range within which the 'true' survival rate is likely to lie. The narrower the confidence interval, the greater confidence one has in the reported estimate. For the modular flanged hip, the confidence interval is quite narrow (about ±3%), reflecting the large number of this type of hip that were implanted. In contrast, the confidence interval for the monobloc round back is relatively wide (the confidence interval is asymmetric because of the high rate of survival, but the lower limit is 5% less than the estimate itself). Nevertheless, the two confidence intervals do not overlap; this observation is consistent with the monobloc round back hip having a significantly better survival than the modular flanged hip (see below).

The effect of type seemed to be particularly important (see Table 6). Compared to the modular flanged prosthesis, the relative risk of revision for the monobloc flanged prosthesis was 0.50 (95% confidence interval, 0.24 to 1.04), whereas the relative risk of revision for the modular round back prosthesis compared to the modular flanged prosthesis was 0.81 (95% confidence interval, 0.56 to 1.17). The observed relative risk for the monobloc round back prosthesis was 0.26 (95% confidence interval, 0.07 to 0.97), which is even lower than the expected relative risk based simply on the combined

Table 6. Incidence rate ratios (95% confidence interval) for revision in 3,276 Capital Hips used for a primary replacement from implantation to Hazard Notice (19 February 1998).

Characteristic	Univariate results	Multivariate results
Patient characteristics		
Age (per increase of 10 years)	0.86 (0.76 to 0.99)	0.87 (0.76 to 1.00)
Male	1.84 (1.31 to 2.58)	1.73 (1.26 to 2.39
Known previous hip surgery	1.00 (0.48 to 2.14)	1.07 (0.53 to 2.15)
Replacement characteristics		
Primary indication for hip replacement*,†		
Primary osteoarthritis	0.78 (0.57 to 1.08)	
Secondary osteoarthritis	1.00 (0.53 to 1.91)	
Rheumatoid arthritis	1.50 (0.78 to 2.91)	
Arthritis unspecified	0.85 (0.34 to 2.15)	
Avascular necrosis	1.21 (0.65 to 2.26)	
Fracture	1.16 (0.65 to 2.05)	
Other	1.22 (0.78 to 1.92)	
Right hip	0.89 (0.72 to 1.10)	
Type or prosthesis		
Modular, flanged	=†	=†
Monobloc, flanged	0.50 (0.24 to 1.04)	0.53 (0.25 to 1.13)
Modular, round back	0.81 (0.56 to 1.17)	1.02 (0.71 to 1.48)
Monobloc, round back	0.26 (0.07 to 0.97)	0.28 (0.06 to 1.32)
Grade of operator		
Consultant	=†	=†
Career grade trainee with consultant	1.04 (0.62 to 1.75)	0.99 (0.58 to 1.69)
Career grade trainee without consultant	0.86 (0.50 to 1.47)	0.75 (0.45 to1.26)
Career grade trainee with unknown assistant	1.04 (0.76 to 2.98)	1.10 (0.78 to 1.54)
Surgical approach		
Posterior	=†	=†
Trans-trochanteric	0.56 (0.30 to 1.05)	0.47 (0.24 to 0.92)
Direct lateral (Hardinge)	1.16 (0.41 to 3.29)	0.93 (0.35 to 2.47)
Antero-lateral (Watson-Jones)	n.a‡	n.a‡
Anterior	1.25 (0.14 to 10.91)	1.07 (0.14 to 8.15)
Reported use of prophylactic antibiotics	0.84 (0.49 to 1.42)	
Reported use of restrictor		
None	=†	=†
Bone	0.77 (0.40 to 1.47)	0.90 (0.50 to 1.61)
Plastic	1.62 (0.96 to 2.72)	1.63 (0.98 to 2.71)
Unknown type	1.18 (0.73 to 1.92)	1.07 (0.65 to 1.76)
Reported use of cement for femur	1.28 (0.79 to 2.08)	
Reported use of cement antibiotics	0.62 (0.39 to 0.99)	0.56 (0.34 to 0.91)

Notes:

* Primary indication for hip replacement was not considered in the multivariate analyses.

† Reference category.

‡ Not available.

effects of type and geometry (ie 0.50 x 0.81 = 0.40). The difference between the observed and expected relative risk, based on the assumption that geometry has the same effect for both types, suggests the presence of an interaction between type and geometry but the significance level of the interaction was not significant (p=0.4).

The effects of type and geometry as independent effects, ie ignoring the possibility of an interaction, were also estimated. These effects represent comparisons between modular and monobloc types, assuming the effect of geometry to be constant for both types, and between flanged and round back geometries, assuming the effect of type to be constant for both geometries. The relative risk of the monobloc compared to the modular prosthesis was estimated to be 0.47 (0.23 to 0.97) in the univariate model and 0.47 (0.21 to 1.03) in the multivariate model. The relative risk of the round back compared to the flanged geometry was estimated to be 0.80 (0.56 to 1.15) in the univariate model and 0.93 (0.64 to 1.35) in the multivariate model.

The fact that the estimate of the relative risk of revision for the monobloc compared to the modular type was the same for univariate and multivariate models suggests that the estimate is unlikely to be confounded by other variables included in the model. In contrast, the change in the relative risk of the round back compared to the flanged geometry in the univariate and multivariate models suggests that the geometry of the hip used for implantation was associated with other variables included in the model.

The revision rate was found to be higher in younger people and higher in men (see Table 6). Surgical factors seemed to have had some effect on the revision rate. There were tendencies for a transtrochanteric approach to decrease the revision rate compared to a posterior approach, for a plastic restrictor to increase the revision rate compared to no use of a restrictor at all, and for the use of cement antibiotics to decrease the revision rate.

Multivariate analysis of risk factors for revision hardly changed the results (see Tables 5 and 6). The most noticeable change was that the effect of geometry in modular prostheses disappeared, whereas it remained unchanged in monobloc prostheses.

The increase in the revision rate after the Hazard Notice was much more pronounced in patients who had a modular Capital Hip compared to those who had a monobloc Capital Hip (see Figure 5; compare, for example, the increase in the revision rate after the Hazard Notice for the modular flanged Capital Hip of 2.86 times with the increase for the monobloc flanged of 1.97 times, p for interaction = 0.02). The effect of the Hazard Notice was also larger for male patients (relative increase in the period after the Hazard Notice of 5.36 in men and 2.63 in women, p for interaction = 0.02) and in people aged less than or equal to 70 years (relative increase of 5.05 in people aged less than or equal to 70 years and 2.35 in people older than 70, p for interaction = 0.004).

The effect of the quality of cementing (see 4.3) was investigated in univariate and multivariate models, including cases with missing data as a separate category. ‘Doubtful’

(relative risk = 1.40, 95% confidence interval, 0.81 to 2.41) and 'unacceptable' quality of cementing (relative risk 1.90, 95% confidence interval, 1.19 to 3.04) were associated with an increase in the revision rate. These relative risks were reduced in the multivariate model; relative risks for 'doubtful' and 'unacceptable' cementing were 1.18 (95% confidence interval, 0.70 to 2.00) and 1.50 (95% confidence interval, 0.88 to 2.55) respectively. On the assumption that this variable was ordinal, the increase in risk across the three categories of quality of cementing was significant in the univariate model (test for trend: relative risk 1.37, 95% confidence interval, 1.11 to 1.70, p=0.003) but not in the multivariate model (test for trend: relative risk 1.24, 95% confidence interval, 0.95 to 1.61, p=0.11).

Although this analysis demonstrated that the quality of cementing, as judged from the index X-rays, was associated with an increased risk of revision, this association did not explain the observed effects of type and geometry. Adjustment for cementing technique by adding it into the multivariate model did not affect the observed relative risks for type and geometry appreciably. Compared to the modular flanged prosthesis, estimates of relative risks were:

- monobloc flanged Capital Hip, 0.55 (95% confidence interval, 0.26 to 1.17);
- modular round back Capital Hip, 1.05 (95% confidence interval, 0.72 to 1.53); and
- monobloc round back Capital Hip, 0.29 (95% confidence interval, 0.06 to 1.38).

It appeared that the 66 hospitals included in the study had implanted preferentially prostheses of a certain type and geometry (Appendix M). This fact makes it difficult to disentangle on strictly statistical grounds the effects of prosthesis type and geometry on the one hand, and factors relating to the hospital where the operation took place on the other. Similar preferential use of prostheses of a certain type and geometry was observed across consultant teams (Appendix N). There was only one hospital that had a distribution of type and geometry that more or less matched the overall distribution. With a total of 508 replacements this hospital also contributed the largest number of hips to the study.

Adjustment for variation in revision rate by hospital was carried out by stratifying the multivariate Cox proportional hazards model by hospital. For hospital, adjustment shifted the relative risks for all types of Capital Hips closer to unity (ie no difference in risk compared to modular flanged Capital Hip). Estimates of relative risks were:

- monobloc flanged Capital Hip, 0.95 (95% confidence interval, 0.39 to 1.88);
- modular round back Capital Hip, 0.85 (95% confidence interval, 0.65 to 1.38); and
- monobloc round back Capital Hip, 0.47 (95% confidence interval, 0.15 to 1.47).

The changes in the estimates of relative risk were expected because of the tendency for hospitals to implant preferentially Capital Hips of a certain type and geometry. Nevertheless, the estimate for the monobloc round back prosthesis still suggests a clinically important reduction in the risk of revision compared to the modular flanged Capital Hip.

Adjustment for variation in revision rate by consultant team was carried out in the same way, ie by stratifying by consultant team. Adjustment again shifted the relative risks for all types of Capital Hips closer to unity (ie no difference in risk compared to modular flanged Capital Hip). Estimates of relative risks were:

- monobloc flanged Capital Hip, 0.90 (95% confidence interval, 0.46 to 1.79);
- modular round back Capital Hip, 1.05 (95% confidence interval, 0.70 to 1.59); and
- monobloc round back Capital Hip, 0.54 (95% confidence interval, 0.19 to 1.49).

The changes in the estimates of relative risk were again expected because of the tendency for consultant teams to implant preferentially Capital Hips of a certain type and geometry. As in the case of the analysis stratified by hospital, the estimate for the monobloc round back prosthesis still suggests a clinically important reduction in the risk of revision compared to the modular flanged Capital Hip.

The very wide range in the estimates of the rate of revision per 100 hip-years across hospitals (Appendix M) demonstrates the problems in interpreting variation in revision rates by hospital and consultant team. After excluding hospitals that had implanted only one or two hips, the rate of revision still varied by more than five-fold across hospitals (95% of rates lay between 0 and 5.4 revisions per 100 hip-years). However, there were data for less than 10 hips for over 40% of implanting hospitals so that a substantial proportion of the variation represents sampling error, which cannot be distinguished from 'true' variations in performance. Moreover, as already described, it is also impossible to disentangle by statistical methods variation attributable to poor performance and variation attributable to different types of Capital Hip.

To investigate further whether the associations between type and geometry of the prosthesis and the revision rate could be explained by differences in the surgical practices used among the hospitals, we used additional information from the surgeon questionnaire. These data showed that there were associations between reported 'usual surgical practice' and type of Capital Hip, which probably arose because of the tendency for consultant teams to implant preferentially Capital Hips of a certain type and geometry (Appendix O). The effect of type and geometry of the Capital Hip on the revision rate was not affected by adjustment for this additional information about surgical practice (ie use of cement centraliser, use of prosthesis specific rasp/reamer system, curettage of cancellous bone from greater or from lesser trochanter, cement viscosity, method of cement mixing, method of introducing cement, use of a proximal seal to pressure cement). After additional adjustment for these characteristics of the surgical procedure,

the relative risks of revision compared to the modular flanged Capital Hip according to the multivariate model were:

- monobloc flanged Capital Hip, 0.55 (95% confidence interval, 0.29 to 1.04);
- modular round back Capital Hip, 1.01 (95% confidence interval, 0.70 to 1.47); and
- monobloc round back Capital Hip, 0.33 (95% confidence interval, 0.12 to 0.87).

4.5 ASSESSMENT OF REVIEW X-RAYS

One or more review X-rays were obtained for 1,391 implanted hips that had not been revised by 1 February 2000, ie 44% (1,391/3,193) of all hips that had not been revised; 803 had only anterior-posterior views, five only lateral views, and 583 had both. Nine sets of X-rays, which could not be assessed because of their quality, were excluded. After excluding these X-rays, there were 796 hips which had only anterior-posterior views, five which had only lateral views, and 581 which had both.

One or more review X-rays were obtained for 251 implanted hips that had been revised by 1 February 2000, ie 51% (251/495) of all hips that had been revised; 225 had only anterior-posterior views, four only lateral views, and 22 had both. Twelve sets of X-rays, which could not be assessed because of their quality, were excluded. After excluding these X-rays, there were 213 hips which had only anterior-posterior views, four which had only lateral views, and 22 which had both.

Many X-rays were judged to have features that were suggestive of loosening, eg presence of a black line at the stem/cement interface in Gruen zone 1. However, the research fellow was unsure about the overall assessment of loosening in about one-third of cases. Given the number of hips for which X-rays were not available, and the number of aspects of the assessment which the research fellow was unsure about or could not assess, it was decided not to analyse the data from review X-rays further. There were two main reasons for this decision. First, the amount of missing data (that is, patients for whom no review X-rays were available) would have made any analysis susceptible to selection bias since one cannot assume that X-ray data were missing at random. For example, X-rays may have been more likely to be available for hips which were suspected of being loose on the basis of clinical examination. Second, the relatively small number of hips for which X-rays were available would have meant that any analysis of a combined outcome, ie revision and evidence of loosening, would have had limited power.

4.6 PATIENTS' SELF-REPORTS ABOUT THE PERFORMANCE OF THEIR CAPITAL HIPS

The responses from patients who had right or left Capital Hips *in situ* were combined into one database, but the responses from patients who had bilateral Capital Hips were kept separate because the questions in the patient questionnaire were not exactly the same. The interpretation of the Oxford Hips Scores for bilateral patients was also potentially different, since the questionnaire has not previously been used in this situation.

All data for the Oxford Hip Score are therefore described separately for patients with unilateral and bilateral Capital Hips.

Overall, there was an excellent response rate of 70% (1,715 of 2,456 patients understood to be alive on 1 February 2000 with a Capital Hip *in situ*), demonstrating patients' willingness to contribute to the investigation. Some patients volunteered very detailed comments, in addition to completing the questionnaire, and often commented in a positive way about the opportunity to give their perspective about the situation and their current symptoms.

The majority of patients completed all Oxford Hip Score items, although the percentage of questionnaires with missing data for one or more items was greater for patients with unilateral Capital Hips (24%, 1,231/1,625) than for patients with bilateral Capital Hips (13%, 79/90). Less than 10% of patients failed to complete two or more items. The graphs showing the distributions of Oxford Hip Scores only include the responses of patients who completed all 12 items (see Figure 6). The distributions were essentially unchanged when the total Oxford Hip Scores for patients who had not responded to one or more items were 'averaged up' on the basis of the items to which they had responded.

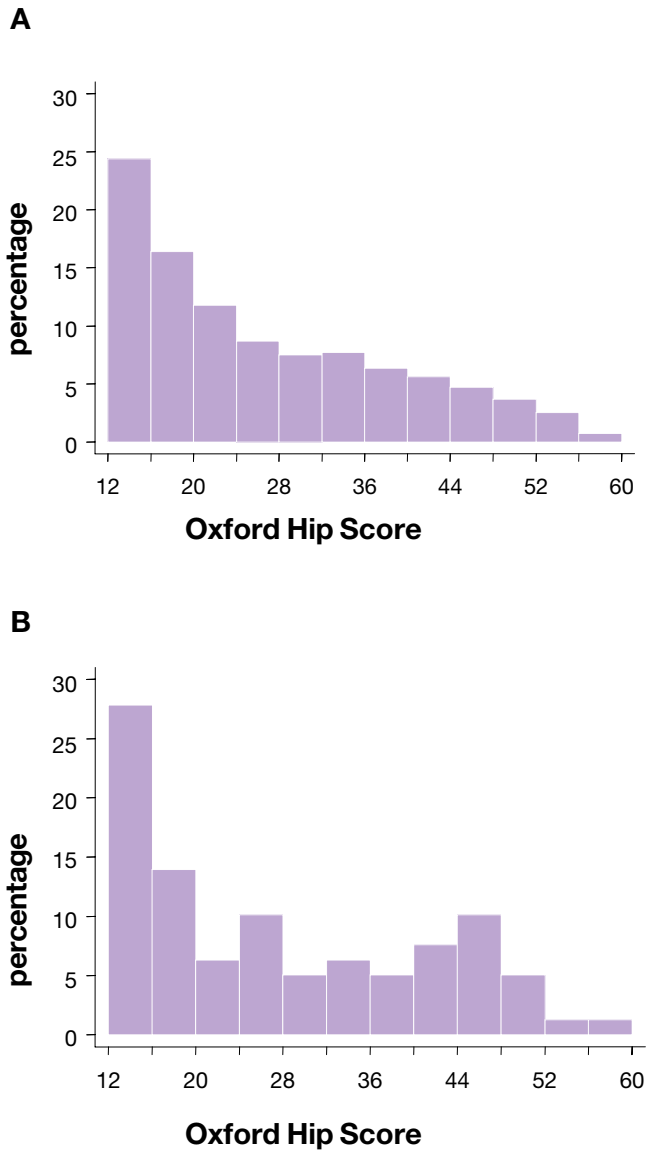
The mean Oxford Hip Scores (25.2 for patients with a unilateral Capital Hip and 26.6 for patients with bilateral Capital Hips) were slightly worse than the mean score for patients in the National Total Hip Replacement Outcomes Study one year after their operations (21.9). However, the standard deviations of the Oxford Hip Scores were substantially larger (13.4 and 15.4 for patients with unilateral and bilateral Capital Hips compared to 9.3 for patients in the National Total Hip Replacement Outcomes Study) suggesting that the means may have been increased by a relatively small number of patients with substantial pain and poor mobility. This interpretation is supported by Figure 6, from which it can be seen that the distributions are highly positively skewed, with about 4% of patients having Oxford Hip Scores greater than 50.

It should also be noted that the patients in this study completed the Oxford Hip Score at varying times after their Capital Hips had been implanted, and that the time since implantation was greater than one year for all patients. There was consensus between orthopaedic surgeons on the steering committee that the symptomatic outcome of total hip replacement is likely to continue to improve for at least a year after the operation. The difference between the average Oxford Hip Score for patients with Capital Hips and the average Oxford Hip Score of patients who took part in the National Total Hip Replacement Outcomes Study may to some extent be attributable to a difference in the average length of time since implantation. However, there was no evidence from the responses of patients that total hip score was related to the length of time since the Capital Hip had been implanted.

Patients were also asked how anxious they were when they first heard that there may have been a problem with some of the Capital Hips and how satisfied they were with the way in which their own situation had been dealt with. With respect to anxiety, 36%

of 1,656 patients who answered this question were extremely anxious, 25% fairly anxious, 25% slightly anxious and 14% not at all anxious. Only 3% of all patients (59 of 1,715) did not answer this question. With respect to patients' satisfaction with the way in which their clinical review had been dealt with, 51% of 1,659 patients who answered this question were very satisfied, 32% satisfied, 10% neither satisfied nor dissatisfied and 6% dissatisfied or very dissatisfied. Three per cent of all patients (56 of 1,715) did not answer this question.

Figure 6. Histograms of Oxford Hip Scores for (A) 1,231 patients with a unilateral Capital Hip and (B) 79 patients with bilateral Capital Hips. Low scores represent patients with less pain and better mobility (minimum 12, maximum 60).



5 Discussion

5.1 SUMMARY OF FINDINGS

When follow-up for the investigation ceased on 1 February 2000, a total of 3,947 Capital Hip implants had been identified. Given that 4,688 Capital Hips were sold to hospitals and 35 were returned unused to 3M, this total represents at least 85% of all Capital Hips that were implanted in the UK. None of the patients identified by this study were implanted with a Capital hip after the Hazard Notice was issued. This observation indicates that the Hazard Notice was effective in preventing stocks of Capital Hips held by hospitals from being implanted.

As at 1 April 2001, 4,214 Capital Hip implants had been identified and reviewed by the Capital Hip Care Centre. A further 83 patients were identified by hospitals but could not be traced. A further 106 patients were traced and may have been reviewed by their surgeon but did not register for care with the Capital Hip Care Centre. Thus 4,403 of the 4,688 Capital Hips sold have now been identified.

The revision rates for some types of Capital Hip were found to be higher than for others, and higher than for other commonly used prostheses. However, it is important to point out that, without considering the duration since implantation, 87% of all Capital Hips implanted had not been revised at 1 February 2000. Furthermore, from the distributions of Oxford Hip Scores, it appears that the majority of patients with Capital Hips *in situ* have a similar level of pain and mobility to patients with some other widely used prostheses at one year after hip replacement. Patients who have required revision or who currently have painful hips that impair mobility have, unfortunately, experienced a disappointing result. The care of patients who have had a successful revision continues through the NHS or the private sector. The care of patients who currently have painful hips, either because of an unsuccessful revision or because their Capital Hip is symptomatic, continues through the Capital Hip Care Centre. The majority of patients still have the Capital Hip and appear to have a satisfactory result; their follow up and review is also ongoing through the Capital Hip Care Centre.

More detailed consideration of the performance of the Capital Hip requires findings for the periods before and after the Hazard Notice to be considered separately. Findings concern:

- the relative performance of different types of Capital Hip;
- variation in revision rates by hospitals and consultant teams; and
- the risk of revision conferred by patients' demographic characteristics and aspects of surgical practice.

BEFORE THE HAZARD NOTICE

The performance of the Capital Hip system as a whole before the Hazard Notice is similar to the performance estimates obtained from the survey carried out by 3M Health Care Limited in January 1996. However, there were important differences in the estimates of survival rates at five years for different types of Capital Hip:

- modular flanged, 89%;
- monobloc flanged, 94%;
- modular round back, 91%; and
- monobloc round back, 97%.

There was also wide variation in the revision rates by hospital and consultant team (see Appendices M and N). It was impossible to separate by statistical methods the influences on revision rates of:

- varying performance between hospitals and consultant teams;
- different types of Capital Hip; or
- sampling error arising from the varying number of hips implanted by different hospitals.

The difficulty in separating the influences of these different factors on revision rates arose because the hospitals and surgeons included in the study were observed to have implanted preferentially prostheses of a certain type and geometry (Appendices M and N).

Interpretation of the possible effects of different types and designs of prostheses are discussed in more detail in section 5.2. Survival estimates were relatively imprecise for different types of Capital Hip, and comparisons between types of hip other than monobloc round back versus modular flanged Capital Hips were not statistically significant, because of the relatively small numbers of hips in all but the modular flanged sub-group. In other words, although there was a rank order of survival across different types of Capital Hip, ie monobloc round back best, monobloc flanged second, modular round back third and modular flanged worst, it was only possible to conclude with confidence that the monobloc round back and the modular flanged Capital Hips had significantly different performance. Nevertheless, some of the differences in survival for other types of Capital Hip are still likely to be important, as indicated by indirect comparisons against two possible performance 'standards' (see 5.4).

A comparison of the performance of all modular hips *versus* all monobloc Capital Hips also showed that the latter were significantly less likely to require revision. There was no strong evidence that round back Capital Hips were less likely to fail than flanged

hips. This was observed to be the case in all analyses carried out but the difference in the risk of revision never reached statistical significance.

The ability of the investigation to identify patient and surgical practice risk factors for revision was limited by the available information. Some important information about patients was not collected, ie weight, body mass index and activity level, because it was considered at the outset that the information was unlikely to be available. The quality of information about surgical practice was limited because the information was often not documented in patients' case notes and because one could not be certain that information from the surgeon questionnaire was applicable to the other surgeons in a consultant's team and that the information was recalled accurately.

Nevertheless, some risk factors emerged from the analyses. With respect to patient characteristics, younger age and male gender were observed to be associated with an increased risk of revision, as found previously.[10,11,12] With respect to surgical factors, use of cement antibiotics was associated with a decrease in the revision rate. None of the other items recorded from case notes, including grade of surgeon and whether or not a trainee was supervised, were significantly associated with the revision rate.

Differences in surgical practice, as reported in the surgeon questionnaire, were observed between consultant teams. These differences might, potentially, have confounded the observed associations between different types of Capital Hip and the revision rate, because of the tendency for some surgeons preferentially to implant one or other type of Capital Hip. In multivariate analyses these surgical factors did not in fact appear to alter the results for different types and designs of prosthesis. However, as described above, the quality of the data available to characterise surgical technique for analysis was limited (clinical data questionnaire; see 4.2) and potentially biased or inaccurate (surgeon questionnaire). The multivariate analyses may therefore have failed adequately to control for confounding factors.

It should be noted that the grade of the surgeon who carried out the operation and whether or not a trainee was supervised were not significantly associated with the revision rate. This finding is robust, since there was no evidence at all of a trend towards a higher risk of revision for less experienced or unsupervised surgeons and information about the grade of operator and supervision of trainees was available for more than 90% of operations. The public should be reassured by this finding.

The overall assessment of cementing quality, judged from X-rays, was found to be significantly associated with the risk of revision in the univariate analysis. Notwithstanding the reservations about the labels (see 3.8.1), 'unacceptable' cementing quality was associated with approximately twice the risk of revision, and 'doubtful' cementing quality with one and half times the risk of revision, compared to 'satisfactory' cementing quality. The stepped increase in the risk of revision across the three possible response categories was highly significant. This trend for an increased risk of revision with deteriorating cementing quality was reduced and became non-significant in the

multivariate analysis, suggesting that poor cementing was itself associated with some of the surgical practices or patient characteristics assessed in this investigation. The statistical interpretation of the change in effect of cementing quality in the multivariate analysis is that cementing quality is associated with other variables measured in this investigation, ie patient characteristics and aspects of surgical practice. Such an association may mean that cementing quality depends on these other factors.

Although the cementing quality could not be assessed for a large number of operations, because X-rays were not available or were of poor quality, there was no evidence to suggest that the operations for which the information was available were unrepresentative. If anything, the measurement error arising from relatively poor reliability of the assessment of cementing quality is likely to have caused the risk of poor cementing quality to have been underestimated.

The overall assessment of cementing quality did not take account of the recommendation in the surgical protocol written by 3M Health Care Ltd, namely that the cement mantle should have a thickness of at least 1mm. Expert advice given by the orthopaedic members of the steering group, based on current thinking in 1998, was that the cement mantle should have a radiological minimum thickness of 2mm as assessed from anterior-posterior and lateral view X-rays. Thus, the assessment of overall cementing quality took account of the advice from the orthopaedic members of the steering group, in conjunction with other factors, rather than the surgical protocol. Among the index X-rays assessed, only a minority of hips met the criterion adopted in this study, ie that the cement mantle should have a minimum thickness of 2mm. It is not clear how this finding arose but it is consistent with data from a study on cement mantle thickness for Charnley hips implanted during 1990 and recorded in the Trent Registry; in this study, only 50% of surviving implants had cement mantles that met the criterion of a mantle width of greater than 2mm in all Gruen zones on an anterior-posterior radiograph.[17]

The lack of a control group of non-3M prostheses implanted by the same consultant teams in this investigation, and the absence of other cohorts of patients for whom X-rays have been assessed in a similar way, means that the investigation cannot address the question of whether cementing quality was different in patients who received a Capital Hip compared with patients who received other commonly used types of hip. The extent to which less-than-satisfactory cementing quality arises for reasons outside the control of the surgeon is also unknown.

AFTER THE HAZARD NOTICE

In the first year after the Hazard Notice, the rate of revision of Capital Hips increased by 3.78 times. The size of this increase varied for different types of Capital Hip, but the overall pattern remained the same. The increase in the revision rate after the Hazard Notice was also more pronounced in:

- patients who had either type of modular Capital Hip;

- male patients; and
- people aged 70 years or less.

The differential increase in the rate of revision of modular Capital Hips after the Hazard Notice provides some evidence that the review process functioned as intended, ie it brought to the attention of orthopaedic surgeons hips that required revision earlier than would otherwise have been the case. If the review process had led surgeons or patients to elect for a revision independently of the clinical status of the hip, the differential increase in the revision rate between the groups identified above would not have been observed. However, the threshold of surgeons and patients for the decision to revise may have been lowered by the Hazard Notice, irrespective of the differential increase, since it is likely that more modular than monobloc hips would have been judged to have failed against a lower threshold. As an additional point, it is noted that none of the patients identified by this study were implanted with a Capital Hip after the Hazard Notice was issued. This is evidence that the Hazard Notice was effective in preventing further Capital Hip implant operations.

In the second year after the Hazard Notice, the rate of revision dropped to a level lower than the rate of revision before the Hazard Notice. This observation suggests that hips identified by the review process as requiring revision were promptly reviewed and revised.

5.2 INTERPRETATION OF PERFORMANCE OF THE CAPITAL HIP BEFORE THE HAZARD NOTICE

The observation that modular flanged Capital Hips were more likely to be revised than monobloc round back hips could have arisen in different ways:

- The association might be caused by confounding factors that were not adequately taken into account by the multivariate analysis, eg weight/body mass index, pre-operative activity level.
- The operative practices of individual surgeons or groups of surgeons and hospitals that preferentially implanted modular flanged prostheses resulted in earlier loosening.
- Consultant teams and hospitals which implanted modular flanged prostheses had poorer quality results for other reasons that were not measured in this investigation.
- Design features of the modular flanged Capital Hip, eg geometry, material, or surface finish, instrumentation used with Capital Hips or the recommended method of implantation resulted in earlier loosening.

Confounding factors

The investigation cannot rule out the possibility that observed associations between type of Capital Hip and the risk of revision arose from confounding factors. Potential

confounding factors that were not measured, such as patients' weight, body mass index and pre-operative activity level, would be most likely to cause confounding that was not accounted for. For example, there may have been an important difference in the average weight of patients implanted with flanged and round back Capital Hips, if surgeons selected the most appropriate hip depending on weight. No conclusion can be drawn about the importance of these factors in this investigation. Factors that were measured (see Table 6) did not appear to be important confounding factors, since the relative risk of revision for different types of Capital Hip were not substantially altered in the multivariate compared to the univariate analyses.

Operative practices

Information about surgical factors from case notes was sparse and was supplemented by information obtained from consultant orthopaedic surgeons about their 'usual' practice. It was observed that some of the surgical practices of consultant teams who implanted one type of Capital Hip tended to be different from those of consultant teams who implanted another type of Capital Hip. This observation provides a possible explanation for the differences in revision rates for different types and designs. Statistical analyses that took account of these differences did not alter the results for different types of Capital Hip.

Consultant teams and hospitals

The third possible explanation for poor performance of the modular flanged compared with the monobloc round back Capital Hip arises because of the tendency for some hospitals and consultant teams preferentially to implant one or other type of Capital Hip. Wide variation in revision rate between hospitals and consultant teams was expected purely on the basis of sampling error. Wide variation in revision rate could also have arisen from unmeasured aspects of the surgical practices of individual surgeons or hospitals. The latter view gains some credence since the majority of Capital Hips, including modular flanged hips, appeared to be functioning satisfactorily at review. There may have been no increased risk of revision when a modular flanged hip was implanted perfectly in an appropriate patient but a substantially increased risk of revision with small deficiencies in technique or instrumentation, ie the modular flanged hip may not have been as 'forgiving' of imperfect technique as other hips.

Design features of the modular flanged Capital Hip

There are three reasons for favouring the fourth possibility, which was the prior hypothesis, despite not being able to exclude the possibility that differences in performance between Capital Hips might have arisen from confounding factors, differences in operative practices or the practices of implanting centres or surgeons. (A more detailed discussion of the possible effects of design features of Capital Hips follows in 5.5).

- The first is plausibility, not withstanding the limitations of the data. If the observed effects were to be attributed to consultant teams or centres rather than to prosthesis

type, it would be necessary to conclude that consultant teams and hospitals with poorer results (for whatever reason) were more likely to choose to implant modular flanged hips. This conclusion seems intrinsically less plausible than attributing the differences in survival to design features of the prostheses, since design features have been implicated in early failure for other prostheses.[24,25,26,27,28,29,30,31] Although the relative risks for different types of Capital Hip were attenuated in analyses that stratified by hospital for consultant team, this attenuation was inevitable given the tendency for some hospitals and consultant teams preferentially to implant one or other type of hip. Moreover, the variation in revision rate between hospitals and consultant teams was consistent with sampling error arising from the wide variation in the number and duration of follow-up of implanted hips.

- The second reason is that the increased risk of revision associated with the modular flanged prosthesis persisted *after* taking account of the information available from the clinical data questionnaire, which included some surgical factors (described in Table 3). Taking account of aspects of 'usual surgical practice' reported by surgeons, which were associated with the use of different types of Capital Hip, slightly reduced this increased risk but did not remove it.

- The third reason is the similarity of the revision rate for monobloc round back Capital Hips to the revision rate for the prosthesis on which the Capital Hip was modelled, ie the Charnley Hip System (which could include round back or flanged designs, of varying length). No comparative data on modular or flanged devices, of the type generated in this study, are available as a benchmark. Hence only indirect comparisons of the performance of the Capital Hip and published performance estimates for other cohorts are discussed in detail in section 5.4.

5.3 INTERPRETATION OF PERFORMANCE OF THE CAPITAL HIP AFTER THE HAZARD NOTICE

The increase in the rate of revision immediately after the Hazard Notice is difficult to interpret. In the UK, the clinical status of patients who have had a total hip replacement is not always routinely reviewed in the long term. Therefore, the process of notifying patients who had received a Capital Hip and carrying out a clinical review is likely to have detected some patients with total hip replacements that were failing or had failed, which might not otherwise have been detected by that time. An effect of this kind was observed by Fender *et al,*[6] when they reviewed a cohort of patients in the Trent Hip Registry five years after the operations had been carried out. These researchers found that the rate of failure of the 'index' replacement, ie revised or judged to have failed, was more than double the rate of revision.

An alternative, or additional, explanation is that the Hazard Notice, the associated adverse publicity and the opportunity to have a revision funded by the manufacturers may have reduced the threshold of patients and consultant orthopaedic surgeons in making a decision to revise the index replacement. It should also be noted that the

adverse publicity may have created a presumption of widespread failure of Capital Hips and public anxiety among those who had received a Capital Hip.

These difficulties were anticipated at an early stage in the investigation and quantifying the effect of the Hazard Notice on the rate of revision was therefore an important aspect of the statistical analyses (see 3.7). Having established that there was a large increase in the rate of revision after the Hazard Notice, the comparison of data from the post Hazard Notice period of this study with data for other commonly used prostheses is problematic. The uncertainty in interpreting the changes in revision rate after the Hazard Notice led us to focus on the period before it was issued.

5.4 INDIRECT COMPARISONS OF THE PERFORMANCE OF THE CAPITAL HIP BEFORE THE HAZARD NOTICE WITH THE PERFORMANCE OF HIPS DOCUMENTED IN REGISTRIES

As already described, the decision not to include a control group in the investigation precludes making any direct comparison between the performance of different types of Capital Hip and the prosthesis on which it was modelled, ie the Charnley Hip, or other 'standards' for the performance of prostheses. However, given the importance of the relative performance of Capital Hips, the likelihood of indirect comparisons with other data available in the literature being attempted by readers of this report and the difficulty of interpreting indirect comparisons, the steering group agreed that it was appropriate to carry out and interpret comparisons of this kind.

Two types of standards were agreed by the steering group. The first type of comparison was of data for the Capital Hip against a standard set by reviewing empirical data collected by existing hip registries. Data from registries were chosen for comparison because they are intended to include all patients having total hip replacement in a designated population, notwithstanding the potential for confounding by differences in the respective populations discussed in Section 3.8.3. The inclusion of all patients in a designated population means that registries represent the range of both orthopaedic practice and patients. Although the data from this investigation did not have a defined population base, the data are very likely to represent the range of orthopaedic practice and patients in the hospitals that used the Capital Hip, since there has been no suggestion that particular types of patients were selected to have a Capital Hip implanted rather than some other hip.

The second type of comparison was of data for the Capital Hip against a benchmark set by an expert panel, namely the appraisals committee of the National Institute for Clinical Excellence.[22]

The steering group, in the main, considered that it was more appropriate to compare the performance of the Capital Hip indirectly against other empirical data first, and against the benchmark set by an expert panel second, because of limitations of the evidence available to the appraisals committee of the National Institute for Clinical Excellence. Evidence available to the committee consisted primarily of two systematic

reviews.[32,33] The period of time considered by both of these reviews predated evidence available to the steering group.[11,6] Moreover, the majority of the evidence reviewed related to reports of the performance of prostheses from specialist centres.

The steering group agreed that it was appropriate to carry out and interpret comparisons against data from two existing hip registries. Data from the Trent Regional Arthroplasty Study, subsequently referred to as the Trent Registry, and the Swedish Hip Arthroplasty Registry were used for comparison with the data from this investigation. These two registries have different advantages and limitations. The Trent Registry represents practice in one part of the UK and includes data for a similar period to that during which the Capital Hip was implanted. However, although it covers a defined population, ie one NHS Region, this population is not the same as that covered by this investigation, ie the whole of the UK. Detailed data on the revision rate in the Trent Registry are also only available for the Charnley Hip.[6] This limitation restricts the amount of data available for comparison but is also advantageous since the Charnley Hip represents an appropriate standard against which to compare the Capital Hip. The Swedish Registry includes data for the whole of Sweden and data are available for the same period as studied in this investigation but, clearly, the nature of orthopaedic practice and the characteristics of Swedish patients may differ from the UK (although see Table 7). For example, the Swedish Registry is believed to have had the effect of improving and standardising surgical practice across Sweden in a way that has not occurred in the UK.[20,21] Many different kinds of prosthesis are represented in the Swedish Registry.

The current dataset for Capital Hips and data from both registries used here for indirect comparison all consider actual revision rates (see Appendix K). Because of evidence that clinical review of patients brings to the attention of orthopaedic surgeons patients who need revision earlier than would otherwise happen,[6] it is important to consider how the datasets compare in this respect. Data from the Trent Registry covers a similar period of time to the data for the Capital Hip and clinical review in the Trent Region during this period is likely to have been broadly similar to the rest of the UK. The Capital Hip data for the period before the Hazard Notice are likely to represent the revision rate without regular clinical review.[34]

In view of the suggestion from the Capital Hip data that a flanged geometry may have poorer performance than a round back geometry, it should be noted that the geometry of the Charnley has altered over time and, during the period of interest, different geometries were available. These different geometries did not exactly match those of the Capital Hip. Differences in the performance of early (flat back) and later geometries of the Charnley Hip have been reported,[35] although the implications of this finding for the performance of current Charnley Hips with different geometries is uncertain. Data were not available from the Trent Registry to distinguish different geometries of Charnley Hip. This limitation could only lead to an underestimate of the difference in performance between the Capital and the round back (2nd generation) Charnley Hip.

Both registries provide very similar estimates of the rate of revision, namely 0.7% revisions per hip-year (see Appendix K). Although the similarity of these estimates may have arisen through differences between the registries (eg standardised surgical practice but using a range of prostheses in the Swedish Registry *versus* less standardised practice in Trent Registry using only the Charnley) rather than through similarities, the similarity of the estimates makes this revision rate a credible 'standard' for total hip replacement carried out in everyday practice.

Figure 7 shows how the data for all Capital Hips, and for different types of Capital Hip, compare against the standard of 0.7% revisions per hip-year (derived from the Trent and Swedish Registries) as the total number of implanted Capital Hips increased during the period from 1993 to 1998. The vertical line, with a relative risk of '1', is equivalent to the standard of 0.7% revisions per hip-year. The horizontal axis (on a logarithmic scale) represents deviations from this standard. Points to the right of the line represent poorer performance than the standard and points to the left, better performance than the standard. For the years 1993, 1994, 1995, 1996 and 1998, the performance of all Capital Hips together, and each type separately (including unknown type), is shown with the 95% confidence interval. When the confidence interval does not cross the vertical line, the performance of the Capital Hip is significantly different from the standard. The columns to the right of the graph describe the number of each type of hip implanted and the number revised at each time point.

Figure 7 demonstrates several important points:

- As early as the end of 1993, the poor performance of the modular flanged Capital Hip would have been apparent if data on implantation and revision had been collected systematically, analysed in this way and compared against the standards derived from the Swedish and Trent Registries. Thus, for a hip with the level of performance demonstrated by the modular flanged Capital Hip, only about 500 need to be implanted and followed up carefully for 2-3 years for this difference in performance to be detected.

- By 1994, if the Capital Hip were to have been considered as a single system, the significantly higher revision rate for all Capital Hips would have been apparent. For a hip system with the level of performance demonstrated by the Capital Hip system as a whole, only about 2,000 need to be implanted and followed up carefully for 3-4 years for this difference in performance to be detected. Note that the performance estimate for the modular flanged hip remains unchanged but has a narrower confidence interval, because more of these hips had been implanted and more hip-years and more revisions had accumulated.

- By the time of the Hazard Notice in 1998, the performance of all types of Capital Hip except the monobloc round back was significantly poorer than the standard.

- The performance of the monobloc round back was similar to the standard over the entire period studied.

At the time of the Hazard Notice, there had been 2.53 (95% confidence interval, 2.20 to 2.92) times more revisions of Capital Hips than expected on the basis of the standard of 0.7% revision per hip-year. The number of revisions for modular flanged Capital Hips only was 3.52 (95% confidence interval, 2.89 to 4.30) times higher than expected on the basis of the standard. Figure 7 shows that, at the end of 1994, the observed number of revisions for all types of Capital Hips taken together clearly differed from the number that was expected on the basis of the standard; this finding was even more obvious for the modular flanged Capital Hips. These findings indicate that a nation-wide hip registry, designed to monitor the performance of different hip prostheses, would have substantiated concerns about the performance of the Capital Hips at that time, using the standards available now.

There are many factors that influence the revision rate, including the four that have been considered in greater or lesser detail in this report: (a) the performance of the prosthesis; (b) the performance of the surgeon; (c) the characteristics of patients undergoing total hip replacement; and (d) the method of review and the basis for making a decision about revision, eg the relative weights attached to clinical symptoms and X-ray appearance. Assuming that the patients are broadly similar in the two registries and in this investigation (see Table 7; there is no evidence that indications for hip replacement differ markedly in different European countries) and that the monobloc round back is unlikely to have had better performance than the Charnley (since it was the type of Capital Hip that was most similar to the Charnley), the similarity of the performance of the monobloc round back Capital prosthesis to the standard derived from the Trent and Swedish Registries suggests that:

- Either the surgeons implanting the round back monobloc Capital Hip were especially skilled and the performance of the monobloc round back was, in fact, *poorer* than the standard, ie the view that the poor performance of the modular flanged was a result of the poor skill of the implanting surgeons (surgeons of differing skill preferentially implanted different types of Capital Hip).

- Or the round back monobloc Capital Hip had similar performance to the Charnley (and other prostheses used in Sweden) and was implanted by surgeons with a broadly similar range of performance to surgeons in the Trent Region who implanted the Charnley Hip and to surgeons in Sweden implanting a range of prostheses.

Table 7. Comparison of the characteristics of patients with Capital Hips and patients in the Trent and Swedish Registries.

Characteristic	Capital Hip data	Trent Registry	Swedish Registry
Male*	34%	40%	39%
Age (years; mean and SD) *	71 (10)	69 (10)	70 (11)
Primary indication for replacement†			
Primary osteoarthritis	80%	87%	76%
Rheumatoid osteoarthritis	3%	7%	6%
Trauma	10%	3%	11%
Other	7%	3%	7%

Notes:

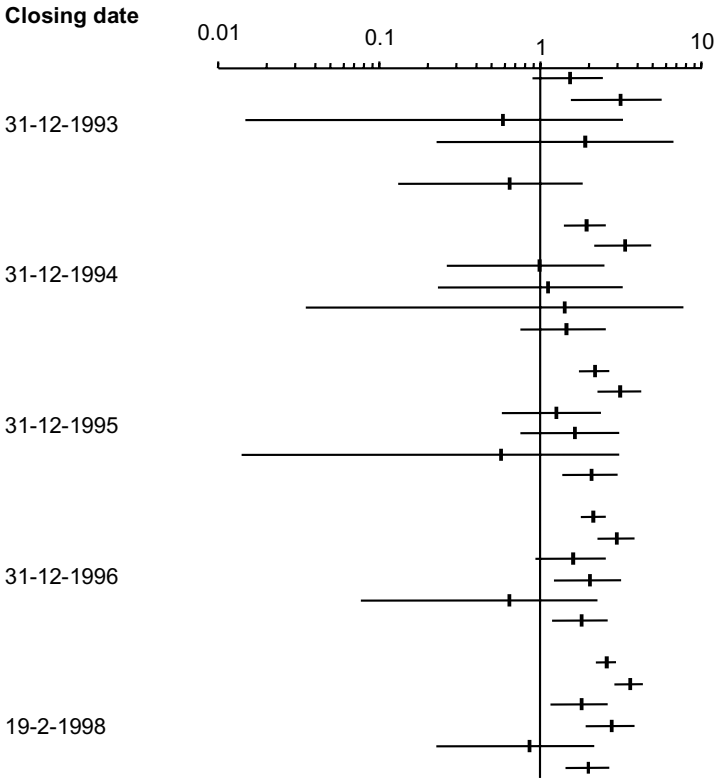
* For the Capital Hip data, percentage of patients who were male and average age were calculated from the entire database.

† For the Capital Hip data, percentage of patients with different primary indications excluded patients who underwent revision total hip replacement.

A similar comparison can be made with the 'benchmark' recently set by the National Institute for Clinical Excellence for new prostheses, ie 10% revision at 10 years.[22] This standard corresponds to 1.05% revisions per hip-year (see Appendix K and Figure 8). Figure 8 shows the same information as Figure 7, except that the vertical line corresponding to a relative risk of '1' represents the standard of 1.0% revisions per hip-year. The pattern shown in the figure is very similar, the main differences being that:

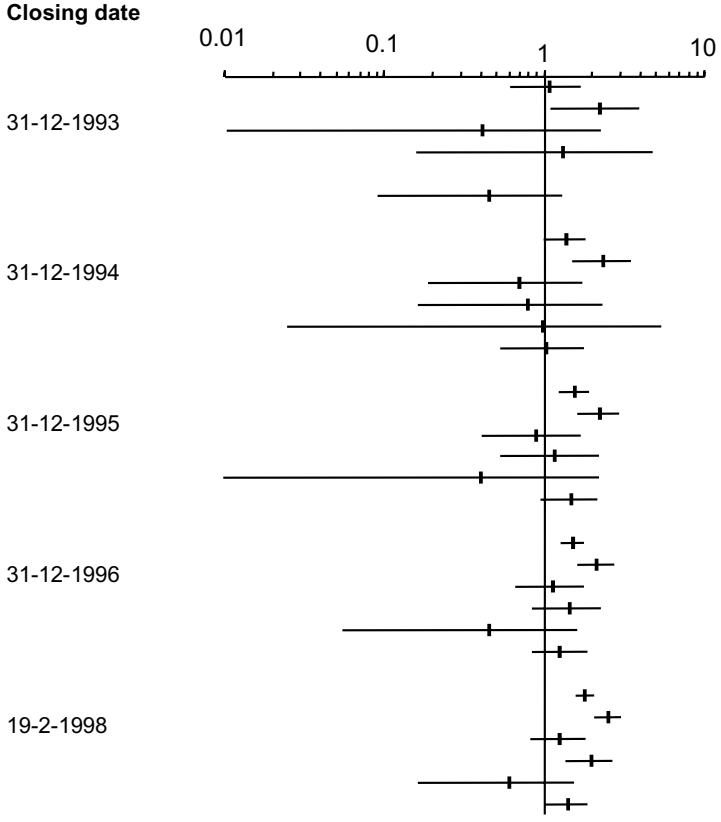
- By the end of 1993, the performance of the modular flanged Capital Hip is still significantly poorer than the standard but the lower limit of the confidence interval only just excludes the standard.
- By the end of 1994, the performance of the Capital Hip System as a whole cannot be reliably distinguished from the standard; the poorer performance of the Capital Hip System becomes apparent during 1995 and is clearly worse than the standard by the end of 1995.
- The performance of the monobloc flanged Capital Hip could not be reliably distinguished from the standard, even by the time of the Hazard Notice.

Figure 7. Relative risk of revision compared to 0.7% per hip-year (95%CI). Cumulative results according to closing date of registry.



Closing date	Type and geometry	Number implanted	Number revised
31-12-1993	All	1394	17
	Mod fl	451	11
	Mon fl	267	1
	Mod ro	166	2
	Mon ro	40	0
	?	470	3
31-12-1994	All	2260	45
	Mod fl	776	25
	Mon fl	415	4
	Mod ro	317	3
	Mon ro	125	1
	?	627	12
31-12-1995	All	2994	88
	Mod fl	1060	43
	Mon fl	507	9
	Mod ro	486	9
	Mon ro	200	1
	?	741	26
31-12-1996	All	3235	129
	Mod fl	1161	62
	Mon fl	551	17
	Mod ro	536	18
	Mon ro	232	2
	?	755	30
19-2-1998	All	3276	211
	Mod fl	1184	103
	Mon fl	552	26
	Mod ro	546	35
	Mon ro	238	4
	?	756	43

Figure 8. Relative risk of revision compared to 1.0% per hip-year (95% confidence interval). Cumulative results according to closing date of registry.



Closing date	Type and geometry	Number implanted	Number revised
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	Mon ro	232	2
	?	755	30
19-2-1998	All	3276	211
	Mod fl	1184	103
	Mon fl	552	26
	Mod ro	546	35
	Mon ro	238	4
	?	756	43

5.5 A REVIEW OF THE FINDINGS OF THE INVESTIGATION IN THE CONTEXT OF RECENT LITERATURE ON THE DESIGN OF PROSTHETIC HIPS

On the balance of the evidence, the modular flanged Capital Hip had significantly poorer performance compared to the monobloc round back Capital Hip and other commonly used cemented hips including the Charnley, on which it was modelled. A question of great importance for future patients is why the performance of the modular flanged Capital Hip was poorer than other commonly used prostheses. Consideration of this question is central to the aim of reducing the likelihood of the introduction into clinical practice in the future of a prosthetic hip with a similar level of performance. The steering group considered it necessary to review the literature about issues that they judged important in the design and introduction of new prostheses.

In the discussion that follows, the steering group has drawn on evidence from the literature, as well as information about the performance and design features of the Capital Hip, with a view to making recommendations about issues that should be considered in the design and introduction of future prostheses. It should be emphasised at the outset that orthopaedic practice for total hip replacement has changed substantially over the 10 years since the Capital Hip was introduced to the UK market. Almost all of the literature cited in this section has been published since 1990 and much of it since the Capital Hip was withdrawn in 1997. It should also be noted that this investigation was an epidemiological study and cannot provide bio-mechanical insight into what aspects of the modular flanged Capital Hip may have made it more prone to early failure than the monobloc round back Capital Hip. The nature of the study and the limitations of the data preclude such a conclusion.

The poor performance of the modular flanged Capital Hip might be attributed to one or more of the following factors (not necessarily in order of importance):

- the material from which a cemented prosthesis is manufactured;
- the surface finish of the cemented prosthesis;
- the geometry of the cemented prosthesis;
- the instrumentation supplied with the cemented prosthesis;
- the surgical protocol issued by the manufacturer for implantation of the cemented prosthesis; and
- the surgical and cementing technique used by the surgeon for implantation of a cemented prosthesis.

Before examining these factors in more detail, it should be pointed out that titanium alloy has been widely used in uncemented hip prostheses, and in some cemented hip prostheses, in the UK without giving cause for concern.

All of these factors differed between the Charnley Hip and the modular flanged Capital Hip, although the extent to which instrumentation supplied with the Capital Hip was used and the surgical protocol followed, and the extent to which differences existed in other aspects of surgical practice, eg type of cement, is unknown. The geometry (third factor) of monobloc as well as modular Capital Hips varied and the application in clinical practice of the fourth, fifth and sixth factors are also likely to have varied within monobloc Capital Hips. Nevertheless, these factors may have affected performance of the modular flanged Capital Hip adversely through an interaction with the first or second factor. The differences between the various types of Capital Hip and the Charnley Hip with respect to these factors are summarised in Table 8.

Each of the above six factors are considered in turn below. The discussion focuses on design features that differed between monobloc and modular Capital Hips, or on design features common to both types of Capital Hip but which might have interacted with a design feature which differed between the two types.

Material from which a cemented prosthesis is manufactured

The modular Capital Hip was manufactured from titanium alloy and the monobloc Capital Hip from stainless steel. These two materials differ with respect to (a) their moduli of elasticity and (b) their resistance to wear.

Titanium alloy has a lower modulus of elasticity compared to stainless steel or cobalt chrome,[36] which has been perceived to be an advantage in the past.[37] For a given stem geometry, a stem manufactured from titanium alloy will be about half as stiff as an identical stem manufactured from stainless steel, giving approximately a doubling of the deflection of the stem under a given load.

Titanium alloy also has a decreased resistance to wear, compared to other alloys commonly used for manufacturing implants.[38,39,40,41] The decreased resistance to wear of titanium alloy may be particularly important in the context of wear of a titanium alloy femoral stem against acrylic cement when the surface of the stem is roughened (see below). The decreased resistance to wear of titanium alloy can also affect the surface finish of a prosthesis, since a standard process for surface finishing, eg shot-blasting, will produce a rougher surface when applied to a softer alloy. This was the situation in the case of the Capital Hip, where the same shot-blasting process produced a rougher surface on the modular Capital Hip, which was manufactured from titanium alloy, than on the monobloc Capital Hip, which was manufactured from stainless steel.

There are several reports of poor performance of cemented femoral stems manufactured from titanium alloy,[42,43,44,45,46] but these studies could not exclude the possibility of interactions of titanium alloy with other factors, such as local tissue reaction, surface finish, geometry, offset, instrumentation and cementing technique. The hips investigated in these studies also used various designs and combinations of materials, all of which were different compared to the Capital Hip, and all of which might be implicated in

failure. However, the Ceraver-Osteal titanium alloy stem[19] and the Furlong Monoblock titanium alloy stem[47] are reported to have performed well.

The surface finish of the cemented prosthesis

Comparisons between the performance of the 'same' prosthesis with different surface finishes are most important when considering the role of surface finish. There have been two examples of femoral stems manufactured with alternative surface finishes, namely the Exeter (polished or 'matt' (roughened) surface)[48] and Iowa prostheses (different levels of roughness).[49] In both cases, the stem with the polished or less rough surface finish performed better.

Wear at the stem-cement interface, and the consequences of such wear, is one possible explanation for the poorer performance of a prosthesis with a roughened surface. Rough-surfaced cemented femoral stems are intended to function as composite beams,[29,31] ie the so-called 'shape-closed' stem design that implies perfect bonding between the stem and the cement. However, there is now considerable evidence[50,51,52,53,54,55,56,57] to support the view that 'de-bonding' at the stem-cement interface is much more common than has been suspected in the past, and may well be inevitable. Both axial migration[58] and cyclical micro-movement of the stem (the latter associated with the bending of the stem under the cyclical loads associated with activities of daily living) are known to take place within the cement and may become associated with abrasive wear at the stem-cement interface.

A titanium alloy stem with a roughened surface will move more and abrade more than a roughened stem made of a harder and stiffer alloy, given the relatively low modulus of elasticity and low resistance to wear of titanium alloy. The patterns of wear observed on retrieved modular Capital Hips[59] are consistent with the influence of torsional forces in producing the wear. As mentioned above, there have been several reports in the literature over the last 10-12 years of poor performance of cemented titanium alloy stems, some of which had a roughened surface.[42,43,44,46] In this context, it is notable that one cemented titanium alloy stem reported to have low revision due to loosening had an anodised surface finish[19] that is an order of magnitude less rough (0.08μm) than that of the modular Capital Hip.

There is also some evidence that particles of titanium alloy have a different biological effect compared to cobalt chrome alloy, eg titanium alloy particles have been shown to promote the production of the cytokine PGE2 in macrophage preparations which is associated with bone lysis.[60] Wear between the stem and the cement mantle also produces other particulate debris, eg from the cement, the radio-opacifiers and from the material used to shot-blast the stem, which may also be biologically active. There is a clear potential for interaction between the features of material and surface finish demonstrating the multifactorial nature of aseptic loosening.

Geometry

The geometry of the stem and the support provided for it by the cement mantle in any individual hip will affect the stability of the stem, especially in torsion. The highly successful early polished design of the Charnley 'flat back' stem[61] possessed an asymmetrical cross section that would contribute to torsional stability within the cement mantle. This stem had better performance than succeeding versions of the Charnley prosthesis that had more rounded cross sections and a flange,[35] as well as a matt surface (Vaquasheen surface, 0.5-0.6 micron; see Table 8). The rounded sections were introduced to reduce the chance of a cement fracture, but at the same time may have compromised the torsional stability of the stem within the cement mantle. Thus, the geometry of a femoral stem represents a compromise of features designed to reduce the incidence of fracture of the cement or the stem of the prosthesis and features designed to promote torsional stability. A stem that has less torsional stability is likely to undergo greater micro-movement with each application of load.

The geometry of the flanged Capital Hip (either modular or monobloc) had rounded medial and lateral surfaces below the shoulder. This design is likely to have been beneficial with respect to reducing the incidence of fracture of cement but to have adversely affected torsional stability. Lower torsional stability may have been more important with the modular Capital Hip, since titanium alloy is less wear resistant and more flexible, given the same application of load. The combined effects that have been discussed may enlarge the internal dimension of the cement mantle from abrasive wear, increase the effective joint space, and create a hydrostatic effect.[62]

Instrumentation

A femoral prosthesis is supported by the surrounding cement mantle and the thickness and continuity of the cement mantle may therefore influence the performance of a prosthesis. The thickness of a cement mantle is affected by the instrumentation used to prepare an intramedullary cavity for the femoral prosthesis, by the way in which the instruments are used by the surgeon and by the subsequent position of the stem.

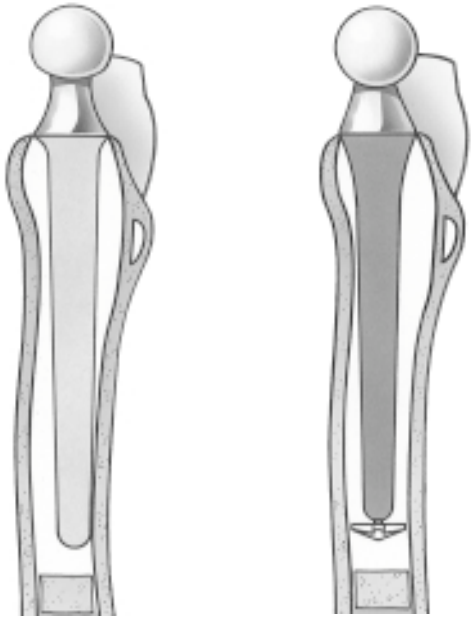
The Capital Hip instrumentation provided a rasp that was oversized by 1mm compared to the stem. In theory, this would produce an intramedullary cavity 1mm greater in radius than the implant stem. The cement mantle produced by this technique would have been at least 1mm, given symmetric stem insertion, and might have been greater depending on further bone preparation including subsequent curettage and cement pressurisation to produce interdigitation.[63f] However, it will also be influenced by the symmetry of stem insertion.

A rasp oversized by only 1mm may have been particularly important in the context of a flanged version of the modular Capital Hip. There are anatomical reasons for speculating that the combination of the wide proximal flange, which would be expected to centralise the stem at the level of the neck section, and a distal centraliser, which was designed to centralise the tip of the stem in the femoral canal, could increase the chance of a

f It should be noted that Isaac *et al*[63] only used anterior-posterior X-rays.

cement mantle defect anteriorly at or just below the level of the lesser trochanter owing to the shape of the femoral canal (see Figure 9). The effect of such a cement mantle defect[53,64] may be exacerbated by the use of a roughened titanium alloy cemented femoral prosthesis.

Figure 9. Diagram illustrating how the combination of a wide proximal flange and a distal centraliser (right) could give rise to a cement mantle defect anteriorly at or just below the level of the lesser trochanter.



Surgical protocol

3M Health Care Limited issued a surgical protocol for the Monobloc/Modular Capital Hip System in 1993, which recommended using the Capital instrumentation. As described in section 1, this protocol was modified in 1995, after consultation with orthopaedic surgeons most of whom had experience of using the Capital Hip, to include the recommendation that rasping was followed by curettage in the proximal region, where the rasp is less efficient as a result of the tapered profile of both stem and rasp. Curettage of the medullary canal was also recommended.

The effects of following or deviating from the surgical protocol cannot be separated from those of the instrumentation (see 4, above).

Surgical technique and instrumentation used

The extent to which surgeons used Capital Hip instrumentation and followed the recommended surgical protocol is unknown. If surgeons used other instrumentation or did not follow the Capital Hip surgical protocol, these factors could have influenced performance of the Capital Hip. Factors not specified in the surgical protocol might

also have been important. For example, the choice of cement type and the methods used for mixing and introducing cement into the prepared cavity in the femur may have affected the continuity of the cement mantle.

If the surgeons who preferred the modular flanged Capital Hip adopted surgical practices that were associated with revision, the observed tendency for surgeons preferentially to implant one or other type of Capital Hip could have explained the poorer performance of the modular flanged Capital Hip. Despite the limited data about surgical technique that were obtained in this investigation, there was no evidence that surgical factors associated with revision, eg a trans-trochanteric approach, explained the difference in revision rate between different types of Capital Hip.

Summary of review of recent literature on the design of prosthetic hips

The preceding discussion demonstrates the range of factors, singly or in combination, that can be implicated in the early loosening of a cemented prosthesis. The steering group concluded from the review that:

- It is not possible to identify one factor, or a combination of factors, that led to the poor performance of the flanged modular Capital Hip.
- It is likely that a particular combination of factors led to the comparatively poor short term performance of Capital Hips[65] other than the monobloc round back (when compared with registry data) and the monobloc flanged Capital Hip (when compared with the standard set by the National Institute for Clinical Excellence).
- These conclusions imply that it is not possible to generalise from the findings with respect to the design characteristics of future prostheses.
- Nevertheless, the design features, instrumentation and surgical protocol reviewed here should be considered very carefully by any designer when designing new or modified hips.
- This investigation suggests that there is no such thing as a small modification; it appears that any modification has the potential to have "unintended consequences that may lead to early failure".[65]
- From the evidence available, it is not possible to conclude whether or not surgical technique could be implicated in the poorer performance of the modular Capital Hip.

Table 8. Differences in design features, instrumentation supplied and surgical protocol between different Capital Hips and the Charnley Hip

Type of hip prosthesis	Material	Surface finish	Geometry	Instrumentation
Modular flanged Capital	Titanium alloy Ti6Al4V (ISO 5832-3)	Ra = 1.1 μm*	Flanged	Specific to Capital Hip System
Monobloc flanged Capital	Stainless steel (ISO 5832-9)	Ra < 1.1 μm*	Flanged	Specific to Capital Hip System
Modular round back Capital	Titanium alloy Ti6Al4V (ISO 5832-3)	Ra = 1.1 μm*	Round back	Specific to Capital Hip System
Monobloc round back Capital	Stainless steel (ISO 5832-9)	Ra < 1.1 μm*	Round back	Specific to Capital Hip System
Charnley	Stainless steel (ISO 5832-9)	'Vaquasheen' surface, Ra = 0.5-0.6 μm	Either flanged or round back‡	Specific to Charnley Hip System

* The same shot-blasting process was used to roughen the surface of both modular and monobloc Capital Hips. However, because the titanium alloy was a softer material, this process resulted in a rougher surface for the modular Capital Hip than the monobloc Capital Hip. The roughness of modular stems was measured from retrieved stems.[59]

‡ During the period of the investigation, Charnley Hips in the Trent Region could have had either a flanged or round back geometry, but the geometry of implanted Charnley Hips was not documented in the Trent Registry. It should be noted that, although the concept of flanged and round back geometries was the same for the Charnley Hip as for the Capital Hip, the precise characteristics of the geometries were not the same for the Charnley and Capital Hips.

6 Lessons learnt relevant to a future investigation of a similar nature

6.1 PROBLEMS EXPERIENCED IN IDENTIFYING PATIENTS WITH CAPITAL PROSTHESES

It proved impossible to determine the total number of patients who had received a Capital Hip because of the incomplete records kept by hospitals. 3M Health Care Limited supplied records of the number of Capital Hips sold to different hospitals and the number of unused Capital Hips that were returned, but some hospitals could not identify whether any remained unused. Some hospitals in which Capital Hips had been implanted had closed or merged.

The research team was not aware of any hospital that had a system in place, eg an electronic register of implanted medical devices, that allowed easy identification of patients who had Capital Hips. Identifying patients appeared to require hand searches of various non-electronic records. Some patients must have been identified from searching the medical records of patients of surgeons known to have implanted Capital Hips, since there were many instances when batch and catalogue numbers were not found in theatre records, case notes or operation notes. A small number of patients, identified by hospitals as having had a Capital Hip, were subsequently found not to have had a Capital Hip from examination of X-rays. It also seems likely that some patients with a Capital Hip were missed. If prosthesis labels had been attached to theatre records, the identification of patients would have been relatively straightforward in hospitals that had not closed or merged.

6.2 PROBLEMS EXPERIENCED IN OBTAINING DATA REQUIRED FOR THE INVESTIGATION

Various problems were experienced in collecting the data required for the investigation:

- a minority of hospitals failed to make notes available promptly for abstracting;
- a substantial minority of hospitals failed, or were unable, to supply X-rays promptly as requested (see 4.3 and 4.5); and
- a minority of surgeons failed to complete the questionnaire about their individual surgical practice.

The lack of compliance by some hospitals and surgeons with requests for information may, in part, be explained by the workload of NHS hospitals. Although hospitals and surgeons were paid for the work that they were asked to carry out for the investigation, the payment may not have facilitated the work or have been used directly to remunerate those carrying out the tasks or to employ additional staff. Staff with the skills required

to carry out the relevant tasks are in short supply and may not have been available for employment on a part-time or short-term basis.

It was also unfortunate that some threats of legal action against surgeons were made following the Hazard Notice. These may have discouraged particular surgeons from co-operating fully. Legal action by patients against 3M Health Care Limited was also being taken during the period of the investigation. This action did not in any way inhibit the participation of 3M Health Care Limited, who co-operated fully to ensure that the aims and objectives of this investigation were met.

A substantial minority of surgeons were found to keep incomplete records of their surgical practice, as evidenced by the large number of Capital Hips of unknown type. Each prosthesis was supplied with labels documenting the batch and catalogue numbers so that the numbers could be easily recorded in the patient's case notes and in the theatre records. However, for over 25% of prostheses, no record of the batch and catalogue number could be found in either location. The batch and catalogue number was missing from one or other location in additional instances. Documentation in the medical or operation notes also did not always match the labels. Research staff noted some instances when the notes stated that a Charnley Hip had been implanted yet labels for a Capital Hip were attached, or vice versa. These inconsistencies may have arisen because some surgeons viewed the Charnley and Capital Hips as interchangeable.

In designing the clinical data questionnaire, the steering group only included items of information that were expected to be recorded in the case notes. However, some items were frequently not found, especially those relating to the materials used during the operation. There were also problems with the supply of X-rays for the investigation that may have arisen from inadequate systems in place in hospitals or the practice of destroying X-rays after five years. One possible reason for the failure of hospitals to supply X-rays for the investigation (see section 4.5) is that the X-rays were not requested after the index operation or at the time of clinical review by an orthopaedic surgeon responsible for a patient's care, although the investigation was unable to differentiate reasons for not providing X-rays. About 10% of X-rays that were available could not be assessed because of their quality. Although ultimate responsibility for the quality of X-rays must lie with the radiologists, this finding indicates that some surgeons were either not reviewing the X-rays or were not re-requesting them when the quality was inadequate for making clinical decisions.

6.3 QUALITY OF THE INFORMATION THAT WAS AVAILABLE FOR THE INVESTIGATION

Given the retrospective nature of the investigation, the number of case notes identified and reviewed represents a considerable achievement. However, the quality of some of the data was poor:

- Important surgical information, as judged by the British Orthopaedic Association representatives on the steering group, was often not available in the case notes, operation notes or theatre records.

- In particular, batch and catalogue numbers were missing for a substantial proportion of prostheses.

- Contradictions were sometimes observed in information from different sources, for example from data extracted from case notes and data obtained by the Capital Hip Care Centre from review forms.

- Either post-operative or review X-rays, or both, were not available for a substantial minority of patients.

- A small minority of available X-rays were of poor quality.

- A majority of available X-rays were taken from a single view only.

The reasons for contradictions between different sources of information were not identified. However, wherever possible research staff checked the uncertain data items with hospital contacts and most contradictions were found to arise from mistakes in data obtained from review forms.

We were not able to determine why some hospitals failed to provide X-rays for some patients, or why the quality of some X-rays that were made available was so poor. Provision of X-rays may have been affected by the need to issue an amendment to the management framework with respect to index X-rays.

6.4 PROBLEMS EXPERIENCED WHILE CARRYING OUT THE INVESTIGATION

Carrying out the investigation proved more difficult than had been expected for two reasons. First, the review process progressed more slowly than anticipated (see 3.2.3). Second, there were problems in linking the databases held by the Capital Hip Care Centre and the Clinical Effectiveness Unit, which was essential for combining all of the relevant information.

Combining information collected by the research team with information collected in due course by the Capital Hip Care Centre from review forms required the two databases to be linked using an identifier assigned by the Capital Hip Care Centre. There were initial difficulties in using this identifier because, during the early part of the investigation, one identifier was sometimes used mistakenly for the same patient for both right and left hips (or for revisions of a Capital Hip to another Capital Hip). A few of the Capital Hip Care Centre identifiers also changed as patients progressed through additional episodes of care.

7 Conclusions

The overall survival estimate for all Capital Hips was 91.4% at five years, equivalent to 1.8 revisions per 100 hip-years (or 1.8% per hip-year).

Differences were seen in the rate of revision by type of Capital Hip before the Hazard Notice was issued. The difference in revision rate between the monobloc round back Capital Hip, which performed best, and the modular flanged Capital Hip, which performed worst, was statistically significant. The monobloc flanged Capital Hip had the second best performance and the modular round back Capital Hip the third best performance. The performance of these latter two types of Capital Hip could not confidently be distinguished from that of the modular flanged Capital Hip.

Younger patients and men were found to have a higher risk of revision. Use of cement antibiotics and better cementing quality were associated with a decrease in the revision rate. None of the other items collected for the investigation were significantly associated with the revision rate. The public should be reassured that there was no evidence at all that grade of surgeon, and whether or not a trainee was supervised by a consultant, were related to the revision rate.

The rate of revision increased by 3.78 times in the first year after the Hazard Notice. The increase in the revision rate was particularly pronounced for modular Capital Hips. The rate of revision decreased to half the rate before the Hazard Notice in the second year after the Hazard Notice, suggesting that patients who had a Capital Hip that had failed were promptly reviewed and revised.

Comparison of the performance of the different types of Capital Hip before the Hazard Notice with two credible standards (0.7% and 1.0% revisions per hip-year) demonstrates that all types of Capital Hip except the monobloc round back had a higher revision rate than expected compared with the more demanding standard, and that both types of modular Capital Hip had a higher revision rate than expected compared with the less demanding standard.

After reviewing design factors that might be implicated in early failure, the steering group concluded that:

- It is not possible to identify one factor, or a combination of factors, that led to the poor performance of the flanged modular Capital Hip.
- It is likely that a particular combination of factors led to the comparatively poor short term performance of Capital Hips[65] other than the monobloc round back (when compared with registry data) and the monobloc flanged Capital Hip (when compared with the standard set by the National Institute for Clinical Excellence).
- These conclusions imply that it is not possible to generalise from the findings with respect to the design characteristics of future prostheses.

- Nevertheless, the design features, instrumentation and proposed surgical protocol should be considered very carefully by any designer when designing new or modified hips.
- This investigation suggests that there is no such thing as a small modification; it appears that any modification has the potential to have "unintended consequences that may lead to early failure".[65]
- From the evidence available, it is not possible to conclude whether or not surgical technique could be implicated in the poorer performance of the modular Capital Hip.

8 Recommendations

Recommendations from the investigation relate to: (a) the design and clinical evaluation of hip prostheses; (b) aspects of orthopaedic practice; and (c) lessons learnt during the investigation that are relevant should a similar investigation be required in the future.

8.1 RECOMMENDATIONS ABOUT THE DESIGN AND CLINICAL EVALUATION OF HIP PROSTHESES

The opinion of the steering group was that, although the new regulations are intended to ensure new prostheses undergo more rigorous evaluation prior to their introduction, they cannot be relied upon to prevent a hip prosthesis with poor performance similar to the modular flanged Capital Hip coming to the market in the future. This lack of confidence in the regulations arises, in part, because of the potential for differing interpretations of the regulations in Europe. New regulations on the monitoring of the performance of medical devices, which require manufacturers to report adverse experiences, might have alerted the regulators, and through them the profession, to the fact that there was a problem sooner. However, the first report of poor performance of the Capital Hip System appeared as early as 1995 and, as demonstrated by the history of the Capital Hip, there were only sufficient data available at that time to raise the index of suspicion and not enough to warrant issuing a Hazard Notice. It is clear from the comparison of the data for the Capital Hips against credible standard rates of revision (see 5.4), that the poor performance of the Capital Hip System as a whole, and the modular flanged Capital Hip in particular, could have been demonstrated beyond reasonable doubt by 1994, depending on the standard chosen, when about half of all Capital Hips had been implanted (see Figures 7 and 8), if the performance standards used in this investigation had been available at the time.

It is therefore recommended that all new femoral stems and design modifications of existing femoral stems should be evaluated fully (see below). Manufacturers should be required to collect data that allow the performance of a hip to be assessed when introducing a new hip or whenever a design modification is made. Full evaluation requires thorough pre-clinical trials, eg by radio-stereometric analysis of stem migration, clinical trials and careful post-marketing surveillance, as described in recent guidance from the Medical Devices Agency (Appendix P).

The example of the Capital Hip System demonstrates that manufacturers and surgeons need to distinguish between different models of femoral stem marketed under the same generic trade name. Manufacturers should in future avoid creating confusion about the identity of different models through branding.

Ideally, randomised controlled trials should be carried out to evaluate the performance of prostheses used for total hip replacement. However, the steering group recognised that such studies are extremely problematic in the context of total hip replacement, for example because of the excellent performance of existing prostheses and the long

period of follow-up required before clinically important differences are likely to be apparent.

High quality post-market surveillance is an alternative method of evaluation and requires documenting a large volume of representative patients undergoing total hip replacement, ideally in non-specialist NHS centres, followed up for a minimum of three to five years. More precise quantification of the number of patients and the duration of follow-up required depends on the extent of the decrease in performance relative to a chosen standard that one wishes to be able confidently to detect. This investigation suggests that a sample of about 2,500 patients followed up for an average duration of about three years (see Figures 7 and 8) is sufficient to detect the decrease in performance shown by the Capital Hip System overall. Similarly, a sample of only about 500 patients followed up for an average duration of about two years (see Figures 7 and 8) is sufficient to detect the decrease in performance shown by the modular flanged Capital Hip.

High quality data are required if such evaluations are to be valid, implying that an effective data collection system should be established. Three alternatives currently exist: (a) a registry; (b) post-market clinical trials; and (c) ad hoc analysis of adverse incidents and user experience. The latter can only be used to raise the index of suspicion, as happened prior to this investigation. As a result, this method is not reliable and is unlikely to be able to detect a problem at an early stage. Post-market clinical trials rarely achieve the characteristics outlined above, generally because sample size may be insufficient, compliance is often patchy, patients are usually recruited from a small number of specialist centres and the duration of follow-up is inadequate. Although analyses carried out for this investigation give some indication of the sample sizes and duration of follow-up that are likely to be required, some members of the steering committee had reservations about relying on post-market clinical trials for such data.

It is therefore recommended that a national hip registry should be established. This recommendation is timely given the publication of the government's consultation document[23] and the support for a national joint register from the National Audit Office,[34] the Public Accounts Committee[66] and the National Institute for Clinical Excellence.[22] If the experience of the Swedish Registry were to be replicated in the UK, a national hip registry could:

- detect poorly performing prostheses at an early stage;
- improve the quality of surgery;
- provide a mechanism for clinical audit of joint replacement;
- identify patients, should they have a need for urgent clinical review; and
- restrict the uptake of unevaluated prostheses.

These benefits, if realised, could, in the long term, help to offset the cost of maintaining a national hip registry by reducing the number of revision operations required and constraining the cost of implanting expensive new prostheses, the performance of which may not have been established.

For the first of the indirect comparisons carried out, this investigation adopted a 'standard' that is more stringent than the one disseminated by the National Institute for Clinical Excellence.[22] It is recommended that the information available to the steering group be considered by the National Institute for Clinical Excellence when updating its appraisal of prostheses for total hip replacement in 2003.

It has been suggested that a number of factors may influence the performance of hip prostheses (see 5.5), and that these factors may interact in a multi-factorial way. However, evidence to support these views has not been systematically reviewed; such a review was considered to be outside the scope of this investigation. It is therefore recommended that a systematic review of these and other suspected factors, carried out according to established principles, be commissioned.

8.2 RECOMMENDATIONS ABOUT ASPECTS OF ORTHOPAEDIC PRACTICE

Batch and catalogue numbers of prostheses should always be recorded in patients' case notes and in theatre records. Methods of auditing compliance with this recommendation should be developed. This information should be stored in such a way that it can be easily searched and retrieved, eg in an electronic database.

A minimum dataset for total hip replacement should be established and surgeons should be required to document this dataset in patients' case notes or in their operation notes.

Surgeons should ensure that X-rays of adequate quality are taken and reviewed, both in the immediate post-operative period and for the assessment of loosening, at least after five years.

These recommendations would be satisfied if surgeons complied with the guidance on best practice for total hip replacement recently published by the British Orthopaedic Association.[67] A detailed national hip registry of hip replacement would provide a means of auditing compliance with some of these recommendations.

8.3 RECOMMENDATIONS SHOULD A SIMILAR INVESTIGATION BE NECESSARY IN THE FUTURE

Investigators and commissioners of an investigation should be aware of the length of time that is likely to be required to recall and carry out a clinical review of affected patients. When the results of an investigation are urgently required, it is important to communicate to chief executives of relevant NHS organisations that the clinical review of patients is a priority. Alternatively, the investigation should be scheduled over a

longer period of time. Reviewing patients may require additional resources, which should be dispersed to the departments carrying out the work.

Hospital managers should review their preparedness for similar investigations in the future and establish procedures for co-operating with them. This review should include consideration of what happens when hospitals merge or are closed, to ensure that all important information is safely archived or integrated into the information system of the resulting organisation.

Clinicians carrying out the review process must be made aware of the importance of supplying all information requested.

When an investigation depends on collating information obtained by different organisations or from different sources, all parties need to agree a system for maintaining a unique ID for each health care episode of interest.

The recommendation about the recording of catalogue and batch numbers should be considered for other implantable medical devices.

8.4 RECOMMENDATIONS FOR REDUCING ANXIETY AMONG PATIENTS SHOULD A SIMILAR INVESTIGATION BE NECESSARY IN THE FUTURE

The process of notifying patients, health authorities, NHS and private hospitals and primary care organisations when there are concerns about some aspect of the public or private health services has two main aims. First, it seeks to prevent further exposure of the public to the hazard or potential hazard that has been identified. Second, it aims to set in place a system for identifying members of the public who have already been exposed to the hazard and who may need to be reviewed or to undergo further treatment. In the case of the Capital hip, the Steering Group was reassured that the Hazard Notice achieved its aims as no further Capital hips were implanted after the Hazard Notice, the overwhelming majority of patients were identified by the Health Service for review, and the Hazard Notice had a striking effect on the revision rate.

The process of notification, however, inevitably causes anxiety to some patients and their carers. Despite the effectiveness of the Hazard Notice as described above, the Steering Group was keen to consider how unnecessary anxiety amongst patients and their carers could be minimised in the future since, with advancing medical technology and an increasing number of implantable devices, it is likely that there may be a need to recall patients at some date in the future. Although this was not an issue about which the Steering Group felt it appropriate to make formal recommendations, since it did not consider evidence on the subject, it was nevertheless an aspect of the investigation on which it wished to comment.

When there is a health care alert, the main sources of information are the statutory agencies (ie the government, government agencies and the NHS Executive), the manufacturer and the media. Hazard Notices and other alerts issued by the statutory

agencies are required to be placed in the public domain and are often reported in the media. The role of these two channels of communication, official and unofficial, are considered separately.

It should be recognised that managing the official alert is a complex process. In order to ensure that the process is orderly, it is important to keep the information contained in the alert secure up to the time of publication. However, it is also necessary to have a framework in place for acting on the alert within a very narrow window of time after publication, typically one week. There is often a need to inform many organisations during this period, eg NHS Executive regional offices, health authorities, hospitals, primary care teams and patients' organisations and to provide them with a clear brief for action, depending on their respective roles. Therefore, the process has to be pragmatic. The steering group felt that the following issues need to be considered and should be kept under constant review by the authorities involved in co-ordinating health care alerts:

- Information contained in an alert should be targeted as precisely as possible, in order to minimise unnecessary anxiety among patients with similar devices or conditions, but who are unaffected. Effective targeting requires good information systems so that the process of identification of 'at risk' patients is fast and effective in reaching all concerned.

- The alert itself should explain that information is being targeted (and possibly how the information is being targeted) and provide a telephone helpline for patients or their carers to contact if they are concerned.

- The statutory agency responsible for issuing an alert should ensure co-operation between interested parties to maximise the use of available information to achieve effective targeting.

Reporting in the media has both advantages and disadvantages. On the one hand, the wide distribution and high profile achieved by the national press, television and radio may reach patients or carers who might otherwise be missed or for whom notification might be delayed, eg because of a lack of up-to-date contact details. On the other hand, untargeted reporting can lead to unnecessary anxiety in related groups of patients who are completely unaffected. Clearly, sensational treatment of such issues is not justified and can only act against the interests of patients.

Two mechanisms could help to achieve effective targeting of information and to minimise unnecssary anxiety, namely NHS Direct and a national joint replacement registry:

- The establishment of NHS Direct in 1999/2000 has provided an infrastructure which is available to the NHS for effective dissemination of a prepared statement or advice to patients and their carers who may be concerned, consistently across England and Wales. It has already been used for this purpose, for example in the case of a hepatitis C 'lookback' exercise in March 2000, warnings from the Medical Devices

Agency on hydrogel filled breast implants in December 2000 and the publication of the report into the Alder Hey Inquiry earlier this year.

- A National Joint Replacement Registry would allow rapid identification of affected patients and effective targeting of information. Establishing such a registry is a separate recommendation of this report.

9 References

1 Massoud SN, Hunter JB, Holdworth BJ, Wallace WA, Juliusson-R. Early femoral loosening in one design of cemented hip replacement. *J Bone Joint Surg* (Br) 1997;**79**:603-8.

2 Roberts DW, Poss R, Kelley K. Radiographic comparison of cementing techniques in total hip arthroplasty. *J Arthroplasty* 1986;**1**:241-7.

3 Barrack RL, Mulroy RD Jr, Harris WH. Improved cementing techniques and femoral component loosening in young patients with hip arthroplasties: a 12-year radiographic review. *J Bone Joint Surg* (Br) 1992;**74-B**:385-9.

4 Ballard WT, Callaghan JJ, Sullivan PM, Johnston RC. The results of improved cementing techniques for total hip arthroplasty in patients less than fifty years old: a ten-year follow-up study. *J Bone Joint Surg* (Am) 1994;**76**:959-64.

5 Britton AR, Murray DW, Bulstrode CJ, McPherson K, Denham RA. Pain levels after total hip replacement: their use as endpoints for survival analysis. *J Bone Joint Surg* (Br) 1997;**79**:93-8.

6 Fender D, Harper WM, Gregg PJ. Outcome of Charnley total hip replacement across a single health region in England: the results at five years from a regional hip register. *J Bone Joint Surg* (Br) 1999;**81**:577-81.

7 Dawson J, Fitzpatrick R, Carr A, Murray D. Questionnaire on the perceptions of patients about total hip replacement. *J Bone Joint Surg* (Br) 1996;**78**:185-90.

8 Lin DY, Wei LJ. The robust inference for the Cox proportional hazards model. *J Am Stat Assoc* 1989;**84**:1074-1078.

9 STATA Corporation. *STATA Release 6 User's Guide*. STATA Corporation, Texas; 1999.

10 Malchau H, Herberts P. *Prognosis of total hip replacement. Surgical and cementing technique in THR: a revision-risk study of 134,056 primary operations*. Report from the Swedish National Hip Arthroplasty Register. Scientific exhibit at the 63rd meeting of the American Academy of Orthopaedic Surgeons, Atlanta, USA; 1996.

11 Malchau H, Herberts P. *Prognosis of total hip replacement. Revision and re-revision in THR: a revision study of 148,359 primary operations*. Report from the Swedish National Hip Arthroplasty Register. Scientific Exhibit at the 65th meeting of the American Academy of Orthopaedic Surgeons, New Orleans, USA; 1998.

12 Young NL, Cheah D, Waddell JP, Wright JG. Patient characteristics that affect the outcome of total hip arthroplasty: a review. *Can J Surg* 1998;**41**:188-95.

13 Kelly AJ, Lee MB, Wong NS, Smith EJ, Learmonth ID. Poor reproducibility in radiographic grading of femoral cementing technique in total hip arthroplasty. *J Arthroplasty* 1996;**11**:525-8.

14 McCaskie AW, Brown AR, Thompson JR, Gregg PJ. Radiological evaluation of the interfaces after cemented total hip replacement. Interobserver and intraobserver agreement. *J Bone Joint Surg* (Br) 1996;**78**:191-4.

15 Harvey EJ, Tanzer M, Bobyn JD. Femoral cement grading in total hip arthroplasty. *J Arthroplasty* 1998;**13**:396-401.

16 Ebramzadeh E, Sarmiento A, McKellop HA, Llinas A, Gogan W. The cement mantle in total hip arthroplasty. Analysis of long-term radiographic results. *J Bone Joint Surg* (Am) 1994;**76**:77-87.

17 Chambers IR, Fender D, McCaskie AW, Reeves BC, Gregg PJ. Radiographic features predictive of aseptic loosening of cemented Charnley femoral stems. *J Bone Joint Surg* (Br), in press.

18 Ramaniraka NA, Rakotomanana LR, Leyvraz PF. The fixation of the cemented femoral component. Effects of stem stiffness, cement thickness and roughness of the cement-bone surface. *J Bone Joint Surg* (Br) 2000;**82**:297-303.

19 Nizard RS, Sedel L, Christel P, Meunier A, Soudry M, Witvoet J. Ten-year survivorship of cemented ceramic-ceramic total hip prosthesis. *Clin Orthop* 1992;**282**:53-63.

20 Herberts P, Malchau H. How outcome studies have changed total hip arthoplasty practices in Sweden. *Clin Orthop* 1997; **344**:44-60.

21 Herberts P, Malchau H. Many years of registration have improved the quality of hip arthroplasty. *Lakartidningen* 1999;**96**:2469-73,2475-6.

22 National Institute for Clinical Excellence. *Guide on the Selection of Prostheses for Primary Total Hip Replacement*. National Institute for Clinical Excellence, London; 2000.

23 Department of Health. *National Joint Replacement Registry (NJR) A Consultation Document*. London, Department of Health; 2000.

24 Wilson LF, Nolan JF, Heywood-Waddington MB. Fracture of the femoral stem of the Ring TCH hip prosthesis. *J Bone Joint Surg* (Br) 1992;**74**:725-8.

25 Gie GA, Ling RS. Loosening and migration of Exeter THR. *J Bone Joint Surg* (Br) 1994;**76**:506-7.

26 Owen TD, Moran CG, Smith SR, Pinder IM. Results of uncemented porous-coated anatomic total hip replacement. *J Bone Joint Surg* (Br) 1994;**76**:258-62.

27 UK Medical Devices Agency. *Zimmer Ltd – fracture of the femoral component of Ring TCH hip prostheses manufactured before March 1988*. Safety Notice SN 9520; August 1995.

28 Howie DW, Middleton RG, Costi K. Loosening of matt and polished cemented femoral stems. *J Bone Joint Surg* (Br) 1998;**80**:573-6.

29 Huiskes R, Verdonschot N, Nivbrant B. Migration, stem shape, and surface finish in cemented total hip arthroplasty. *Clin Orthop* 1998;**355**:103-12.

30 Middleton RG, Howie DW, Costi K, Sharpe P. Effects of design changes on cemented tapered femoral stem fixation. *Clin Orthop* 1998;**355**:47-56.

31 Shen G. Femoral stem fixation. An engineering interpretation of the long-term outcome of Charnley and Exeter stems. *J Bone Joint Surg* (Br) 1998;**80**:754-6.

32 Faulkner A, Kennedy LG, Baxter K, Donovan J, Wilkinson M, Bevan G. Effectiveness of hip prostheses in primary total hip replacement: a critical review of evidence and an economic model. *Health Technology Assessment* 1998;**2(6)**:1-134.

33 Fitzpatrick R, Shortall E, Sculpher M, Murray D, Morris R, Lodge M, *et al*. Primary total hip replacement surgery: a systematic review of outcomes and modelling of cost effectiveness associated with different prostheses. *Health Technology Assessment* 1998;**2(20)**:1-64.

34 National Audit Office. *Hip Replacements: Getting It Right the First Time*. HC 417 Session 1999-00. London, The Stationery Office; 2000.

35 Dall DM, Learmonth ID, Solomon MI, Miles AW, Davenport JM. Fracture and loosening of Charnley femoral stems. Comparison between first-generation and subsequent designs. *J Bone Joint Surg* (Br) 1993;**75**:259-65.

36 Black J. *Orthopaedic Biomaterials in Research and Practice*. Churchill Livingstone, New York; 1988.

37 Sarmiento A, Gruen TA. Radiographic analysis of a low-modulus titanium-alloy femoral total hip component. Two to six-year follow-up. *J Bone Joint Surg* (Am) 1985;**67**:48-56.

38 McKellop H, Kirkpatric J, Markolf KL, Amstutz H. Abrasive wear of Ti-6A1-4V prostheses by acrylic cement particles. Transactions of Twenty-sixth Annual Orthopaedic Research Society Meeting. Atlanta, Georgia; 1980.

39 Bischoff UW, Freeman MA, Smith D, Tuke MA, Gregson PJ. Wear induced by motion between bone and titanium or cobalt-chrome alloys. *J Bone Joint Surg* (Br) 1994;**76**:713-6.

40 Brummitt K, Hardaker CS, McCullagh PJ, Drabu KJ, Smith RA. Effect of counterface material on the characteristics of retrieved uncemented cobalt-chromium and titanium alloy total hip replacements. *Proc Inst Mech Eng H* 1996;**210**:191-5.

41 McKellop HA, Rostlund T, Ebramzadeh E, Samiento A. Wear of titanium 6-4 alloy in laboratory tests and in retrieved human joint replacements. In *Medical Applications of Titanium and its Alloys: the Material and Biological Issues*, eds. Brown SA, Lemons JE. ASTM STP 1272. American Society for Testing & Materials, 1996.

42 Robinson RP, Lovell TP, Green TM, Bailey GA. Early femoral component loosening in DF-80 total hip arthroplasty. *J Arthroplasty* 1989;**4**:55-64.

43 Witt JD, Swann M. Metal wear and tissue response in failed titanium alloy total hip replacements. *J Bone Joint Surg* (Br) 1991;**73**:559-63.

44 Karrholm J, Frech W, Nilsson KG, Snorrason F. Increased metal release from cemented femoral components made of titanium alloy. 19 hip prostheses followed with radiostereometry (RSA). *Acta Orthop Scand* 1994;**65**:599-604.

45 Tompkins GS, Lachiewicz PF, DeMasi R. A prospective study of a titanium femoral component for cemented total hip arthroplasty. *J Arthroplasty* 1994;**9**:623-30.

46 Scholl E, Eggli S, Ganz R. Osteolysis in cemented titanium alloy hip prosthesis. *J Arthroplasty* 2000;**15**:570-5.

47 Warren PJ, O'Doherty D, Scott G, Greenough CG. The Furlong total hip: satisfactory interim results of a new cemented arthroplasty. *J Orthop Rheumatol* 1993;**6**:33-36.

48 Malchau H, Herberts P, Soderman P, Oden A. *Prognosis of total hip relacement*. Update and validation of results from the Swedish National Hip Arthroplasty Register 1979-1998. Department of Orthopaedics, Goteborg University, Sweden, 1998.

49 Collis DK, Mohler CG. Loosening rates and bone lysis with rough finished and polished stems. *Clin Orthop* 1998;**355**:113-22.

50 Fornasier VL, Cameron HU. The femoral stem/cement interface in total hip replacement. *Clinical Orthop* 1976;**116**:248-52.

51 Ahmed AM, Pak W, Burke DL, Miller J. Transient and residual stresses and displacements in self-curing bone cement - Part I: characterization of relevant volumetric behavior of bone cement. *J Biomech Eng* 1982;**104**:21-7.

52 Ahmed AM, Nair R, Burke DL, Miller J. Transient and residual stresses and displacements in self-curing bone cement - Part II: thermoelastic analysis of the stem fixation system. *J Biomech Eng* 1982;**104**:28-37.

53 Anthony PP, Gie GA, Howie CR, Ling R. Localised endosteal bone lysis in relation to the femoral components of cemented total hip arthroplasties. *J Bone Joint Surg* (Br) 1990;**72**:971-9.

54 Davies JP, Tse M. Non-destructive testing of bonding and debonding of cemented femoral components *in vitro*. *Transactions of the Orthopaedic Research Society* 1992;**16**:359.

55 Verdonschot N, Huiskes R. *Surface Roughness of Straight Tapered Stems in Cemented THA Reduces Subsidence but not Cement Damage*. PhD thesis. University of Nijmegen: The Netherlands; **1995**:47-8.

56 Wang JS, Franzen H, Lidgren L. Interface gap after implantation of a cemented femoral stem in pigs. *Acta Orthop Scand* 1999;**70**:234-9.

57 Crawford RW, Evans M, Ling RSM, Murray DW. Fluid flow around model femoral components of differing surface finishes – *in vitro* investigations. *Acta Orthop Scand* 1999;**70**:589-95.

58 Karrholm J, Nivbrant B, Thanner J, Anderberg C, Borlin N, Herberts P *et al*. *Radiostereometric evaluation of hip implant design and surface finish. Micromotion of cemented femoral stems*. Scientific exhibit at the 67th meeting of the American Academy of Orthopaedic Surgeons, Orlando, USA; 2000.

59 Fisher J, McGrath L, Shardlow D, Ingham E, Tipper JL, Andrews CM, *et al*. *An Initial Investigation of Ten Explanted Capital Hip Prostheses – a Report to the Medical Devices Agency*. University of Leeds, Leeds; 1998.

60 Haynes DR, Rogers SD, Hay S, Pearcy MJ, Howie DW. The differences in toxicity and release of bone-resorbing mediators induced by titanium and cobalt-chromium-alloy wear particles. *J Bone Joint Surg* (Am) 1993;**75**:825-34.

61 Schulte KR, Callaghan JJ, Kelley SS, Johnston RC. The outcome of Charnley total hip arthroplasty with cement after a minimum twenty-year follow-up. The results of one surgeon. *J Bone Joint Surg* (Am) 1993;**75**:961-75.

62 Schmalzreid TP, Jasty M, Harris WH. Periprosthetic bone loss in total hip arthroplasty. *J Bone Joint Surg* (Am) 1992;**74**:849-863.

63 Isaac GH, Busch CA, Shetty V, Drabu KJ: Radiographic assessment of the cement mantle thickness of the femoral stem in total hip replacement: a case study of 112 consecutive implants. *Proc Inst Mech Eng* 2000; **214**:H (471-477)

64 Anthony PP, Crawford RW, Gie GA, Ling RSM, Malcolm AJ, Murray DW, Timperley AJ. Localised endosteal bone lysis following cemented hip arthroplasty. *J Bone Joint Surg* (Br) 1999;**81** (suppl III):327.

65 Barrack RL. Early failure of cemented stems. *J Arthroplasty* 2000;**15**:1036-50.

66 Committee for Public Accounts. 43rd report. *Hip replacements: getting it right first time*. House of Commons ordered to be printed on 8 November 2000. Available from: URL: http://www.parliament.the-stationery-office.co.uk/pa/cm199900/cmselect/cmpubacc/513/51302.htm

67 British Orthopaedic Association. *Total Hip Replacement: A Guide to Best Practice*. British Orthopaedic Association; 1999.