BIOMET
MANUFACTURING CORP.

December 26, 2012

Shevon Johnson
Division of Freedom of Information
Center for Devices and Radiological Health, FDA
10903 New Hampshire Avenue, WO66 Room 5265
Silver Spring, MD 20993-0002

RE: Request for Redaction of 515(i) under Freedom of Information Act

Dear Ms. Johnson:

In response to your request of December 11, 2012, enclosed is the electronic copy of the redacted submission.

Biomet has indentified the information we believe is exempt from disclosure under the Freedom of Information Act according to 5 U.S.C. § 552(b)(4) as trade secrets and commercial or financial information. The requested deletions are completed as recommended in the information in your request.

Please contact me with any questions or concerns regarding the enclosed response. I can be reached by phone at (574) 372-1761, by e-mail at tracy.johnson@biomet.com, or by fax at (574) 371-1027.

Alternatively, you may contact Laura Williams by phone at (574) 372-6661, by e-mail at laura.williams@biomet.com, or by fax at (574) 371-1027.

Sincerely,

Kathy Fashoia for

Tracy Bickel Johnson, RAC
Global Regulatory Project Manager

Mailing Address:
P.O. Box 587
Warsaw, IN. 46581-0587
Toll Free: 800.348.9500
Office: 574.267.6639
Main Fax: 574-267-8137
www.biomet.com

Shipping Address:
56 E Bell Drive
Warsaw, IN 46582

BIOMET

MANUFACTURING CORP.

September 23, 2010

Food and Drug Administration
Center for Devices and Radiological Health
Attn: Elizabeth Frank
Document Mail Center (WO66-G609)
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

RE: Update to Biomet 515i Petition for Reclassification
Hip joint metal/metal semi-constrained, with a cemented acetabular component, prostheses (888.3320 JDL, LTO)
Hip joint metal/metal semi-constrained, with an uncemented acetabular components prostheses (888.3330 KWA)

Dear Ms. Frank:

Biomet has recently taken the initiative to update the Metal-on-Metal (MoM) 515i Reclassification Petition that was submitted to FDA on August 5, 2009, specifically as it relates to the clinical data portion of the submission. A systematic review of clinical data including what was submitted in 515i and new data sets on various Biomet M2a™ Metal-on-Metal total hip arthroplasty (Biomet MoM THA) systems was undertaken to assess Safety and Performance of these devices, confirm risks to remain acceptable in relation to clinical benefits and that Biomet MoM THAs continue to comply with regulatory requirements. This review was conducted pursuant to Biomet's post-market surveillance proceeds, Global Harmonization Task Force (GHTF) Clinical Evaluation (SGSG5/N2R8:2007) and European Commission Guidelines for Medical Devices - Clinical Evaluation: A Guide for Manufacturers and Notified Bodies (MEDDEV 2.7.1. rev 3 December 2009).

Biomet MoM THAs included in this evaluation are:

- Biomet M2a–Taper™ Metal-on-Metal Total Hip System
- Biomet M2a–Ringloc™ Metal-on-Metal Total Hip System
- Biomet M2a-38™ Metal-on-Metal Total Hip System
- M2a–Magnum™ Metal-on-Metal Total Hip System

Biomet is providing both a hard copy and an exact electronic copy of this MoM clinical update. If you have any questions regarding this submission, please contact me at 574-372-1761 or Lynnette Whitaker at 574-372-3982.

Sincerely,

Tracy Bickel Johnson

Tracy Bickel Johnson, RAC
Director, Regulatory Affairs

Mailing Address:
P.O. Box 587
Warsaw, IN 46581-0587
Toll Free: 800.348.9500
Office: 574.267.6639
Main Fax: 574.267.8137
www.biomet.com

Shipping Address:
56 E. Bell Drive
Warsaw, IN 46582

Clinical Evaluation Report on Biomet Metal on Metal THA

1. **General Details**

A systematic review of clinical data on various Biomet M2a™ Metal-on-Metal total hip arthroplasty systems (Biomet MoM THA) was undertaken to, from a clinical perspective, assess compliance with the Essential Principles of Safety and Performance of Medical Devices, confirm risks to remain acceptable in relation to clinical benefits and that Biomet MoM THAs continue to meet the Essential Principles and comply with regulatory requirements. This review was conducted pursuant to Biomet's post-market surveillance proceeds, Global Harmonization Task Force (GHTF) Clinical Evaluation (SGSG5/N2R8:2007) [1] and European Commission Guidelines for Medical Devices - Clinical evaluation: A Guide for Manufacturers and Notified Bodies (MEDDEV 2.7.1. rev 3 December 2009) [2].

Biomet MoM THAs included in this evaluation are:

- Biomet M2a–Taper™ Metal-on-Metal Total Hip System
- Biomet M2a–Ringloc™ Metal-on-Metal Total Hip System
- Biomet M2a-38™/M2a–Magnum™ Metal-on-Metal Total Hip System

It should be pointed out that other Metal-on-Metal total hip arthroplasty systems including Exceed ABT Metal-on-Metal, M2A 28mm and Stanmore Metal-on-Metal marketed outside US are excluded from this clinical evaluation. A separate clinical evaluation is being conducted on each of these three MoM systems.

2. **Device Description and Its Intended Application**

Biomet has developed three types of acetabular systems that utilize a metal-on-metal (MOM) articulating couple, as opposed to the traditional metal-on-polyethylene articulating couple, that are commercialized in the United States. The Biomet M2a–Taper™ Metal-on-Metal Total Hip System was first cleared in May 2000 (**K993438**). This Metal-on-Metal Acetabular System consists of a titanium outer shell with a cobalt chromium metallic taper insert, which articulates with a cobalt chromium modular head. The M2a-RingLoc™ Metal-on-Metal system, consisting of a polyethylene-backed cobalt liner, was cleared later that year through **K002379** (August 2000). One-piece acetabular shells (no liner) allowing larger head sizes have been cleared since 2001 (**K011110**). All these MoM acetabular systems are CE marked in Europe:

- Biomet M2a–Taper™ Metal-on-Metal Total Hip System – **CE 535523**
- Biomet M2a–Ringloc™ Metal-on-Metal Total Hip System – **CE 501174**
- Biomet M2a-38™/M2a–Magnum™ Metal-on-Metal Total Hip System – **CE 510073** and **CE 535522**

Based on mechanical testing, it has been shown that the Metal-on-Metal Acetabular System exhibits decreased wear compared to the wear observed in the traditional polyethylene and metal acetabular systems.

M2a-Taper™ System (Metallic Taper Insert Design)

Cleared 510(k)s: K993438M2a Metal-on-Metal Acetabular System (5/18/00; Product Code KWA)
K003363M2a 32mm Taper System (12/15/00; Product Code KWY)

K042841M2a/C2a Acetabular System (12/21/04; Product Code JDL, KWA)
IDE Study: G950011 Metal-on-Metal Acetabular Study

Acetabular Shell

The acetabular shells for the M2a-Taper™ System are available in two designs: the Mallory–Head® Radial and the Universal® Acetabular Component. Both designs are modular, two-piece systems consisting of a high-carbon, cobalt chromium (CoCrMo per ASTM 1537: alloy 2) taper insert and a porous coated titanium shell. The hemispherical shape of both outer shells closely matches the natural acetabulum, which leads to minimal bone removal in preparation for implantation. The two acetabular shell designs are available with holes or as a solid dome. If necessary, the shell with holes allows for the use of a 6.5mm dome screw and the 5.0mm rim screws, for optional supplemental fixation. The Mallory-Head® acetabular shell features eight peripheral fins, which aid in preventing rotation, a full hemisphere shell, three dome screw holes, and rim screws in shell sizes 58mm and larger. The Universal® Acetabular Component features a(b) (4) degree rim flare, two-hole and multi-hole options, and rim screws in multi-hole shells 58 mm and larger. Outer shell diameters for both the Mallory-Head® and Universal® shells range from 48mm to 70mm.

The outer surface of the shell is covered with a porous coating of titanium-alloy (Ti-6Al-4V) powder conforming to ASTMF-1580, which ensures immediate component fixation and maximum bone-to-implant contact. The PPS® Porous Plasma Spray surface consists of particles which are bonded together to form a random pattern with interconnecting pores. The solid shell configuration, without dome holes, increases the surface area of the porous plasma spray coating.

Acetabular Taper Insert

The high carbon, cobalt chromium bearing insert fits into the outer shell by means of a taper, similar to the taper used for the attachment of a modular head on a femoral stem. (b) (4)

Modular Femoral Head

The M2a-Taper™ System utilizes a 28mm or 32mm high carbon, cobalt chromium (CoCrMo) modular femoral head with seven neck lengths (-6mm to +12mm) designed to mate with Biomet's standard Type 1 tapers. (b) (4)

Figure 1. M2a-Taper™ Acetabular System

M2a-RingLoc™ System (Polyethylene Backed Cobalt Liner)
Cleared 510(k): K002379M2a 28mm RingLoc® Liner (8/31/00; Product Code KWA)

The Biomet M2a-RingLoc™ Metal-on-Metal Articulation is a modification of the M2a-Taper™ Metal-on-Metal System. The M2a-RingLoc™ liner articulating surface is made from the same CoCrMo per ASTM F-1537 (alloy 2) as the M2a-Taper™ Metal-on-Metal System. The M2a-RingLoc™ device maintains the same bearing geometry and dimensions as the M2a-Taper™ device, thus not affecting the wear-couple between the modular head and liner. The M2a-RingLoc™ System is designed to accept a 28mm diameter head.

Acetabular Shell
The M2a-RingLoc™ System utilizes Biomet's standard RingLoc® Acetabular shells, available for use with traditional polyethylene liners. These shells have been cleared through numerous 510(k)s with varying diameters, hole patterns and other features such as fins, spikes and rim flares.

RingLoc® Liner
The RingLoc® design represents a change to the locking mechanism of the liner within the acetabular shell, from a taper mechanism of the M2a-Taper™ to a RingLoc® mechanism in the M2a-RingLoc™ design. The RingLoc® design utilized in the M2a-RingLoc™ is the same as that used in Biomet's RingLoc® ultra-high molecular weight polyethylene (UHMWPE) liners, which was originally cleared in 510(k) number **K920640**.

The M2a-RingLoc™ design contains a high carbon, CoCrMo metal inner-inlay, compression molded into UHMWPE. The UHMWPE is then machined to standard RingLoc® geometry and size.

The M2a-RingLoc™ liner features 115 degrees range of motion, direct compression molded material, a patented impingement feature on the face of the liner, congruity between the liner and shell, (b) (4) and the lowest micromotion between liner and shell as compared with competitive modular acetabular systems[4].

Modular Femoral Head

The CoCrMo modular heads to be used with the M2a-RingLoc™ device are the same 28mm heads used with the M2a-Taper™ device. Radial clearance between the head and M2a-RingLoc™ liner is (b) (4) .

Figure 2. M2a-RingLoc™ Acetabular Liner

M2a-Magnum™ Large Metal Articulation Systems (One-Piece Acetabular Shell)

Cleared 510(k)s:
K011110M2a-38™ Acetabular System (7/2/01; Product Code KWA)
K042037M2a-Magnum™ System (10/1/04; Product Code KWA)
K061423M2a-Magnum™ 12/14 Taper Insert and One-Piece Modular Heads (7/27/06; Product Code KWA)
K062995M2a-Magnum™ Tri-Spike Acetabular Component
(10/31/06; Product Code KWA)

The M2a-Magnum™ System is a MOM articulation total hip system to be used with Biomet cleared femoral stems. They offer the stability and ROM of a big femoral head (≥38 mm) in acetabular shells as small as 44 mm.

Acetabular Shell

The M2a-Magmun™ acetabular shells consist of a one-piece, high carbon, cobalt chromium acetabular cup, with the inner surface of the cup being the bearing surface. The shells feature PPS® Porous Plasma Spray surface coating and full hemisphere geometry with four sets of paired fins. Shell outer diameters range from 44mm to 66mm (2mm increments) and head diameters range from 38 to 60mm (2mm increments).

In submission **K062995** M2a-Magnum™ Tri-Spike Acetabular Components were introduced to the M2a-Magnum™ System. The Tri-Spike component is a high carbon, CoCrMo, full hemisphere shell in outer diameters of 44mm to 66mm designed for MOM articulation. The outer surface of the shell features a porous plasma spray coating for biological fixation and three dome spikes for rotational stability.

Modular Femoral Head

One-piece, high carbon, cobalt alloy modular heads are available in six neck-length offsets from -6 to +9mm and diameters of 38 and 40mm. Larger heads, outer diameters of 42-60mm, are a two-piece design. There are two sets of taper inserts with each providing neck offsets from -6mm to +9mm. The first set has a smaller diameter and mates with modular head sizes 42 to 50mm. The second set of taper inserts has a larger outer diameter and mates with modular head sizes 52 through 60mm. The modular heads may be used in conjunction with any of Biomet's commercially available femoral components with a standard Type 1 Taper.

In **K061423,** a new set of one-piece heads and insert for the larger diameter heads were introduced to fit on Biomet femoral components with a 12/14 type taper, as opposed to Biomet's standard Type 1 tapers. The 12/14 taper inserts and one-piece modular heads are designed for use with the TaperLoc® 12/14 taper femoral components and the articulating heads and shells of the M2a-Magnum™ System for uncemented applications.

Figure 3. M2a-Magnum™ Acetabular System with two-piece femoral head

3. **Intended Therapeutic and/or Diagnostic Indications and Claims**

All above Biomet MoM THA systems are indicated for use in patients requiring total hip replacement due to the following:

- Non-inflammatory degenerative joint disease including avascular necrosis, diastrophic variant, fracture of the pelvis, fused hip, Legg Perthes, osteoarthritis, slipped capital epiphysis, subcapital fractures, and traumatic arthritis
- Rheumatoid arthritis
- Correction of functional deformity
- Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques
- Revision of previously failed total hip arthroplasty.

All Biomet MoM THAs listed previously have been cleared for non-cemented applications with the exception of M2a/C2a Acetabular System, which contained both cementless and cemented applications.

4. **Context of the Evaluation and Choice of Clinical Data Types**

Biomet MoM THAs included in this clinical evaluation have been marketed since 2000. They are the results of incremental change of metal on metal articulation technology. The developmental evolution has been described in section 2. They are all indicated for total hip replacement procedures. The clinical data used in the evaluation are for the Biomet MoM THA products in question and comparable device with the same identical MOM articulation design[1].

Essential Requirements (ERs)[2] that require support from relevant clinical data

The following specified Essential Requirements are of particular relevance to the performance and safety:
EP1 Use of medical devices not to compromise health and safety
EP2 Design and construction of medical devices to conform with safety principles
EP3 Long term safety
EP6 Benefits of medical devices to outweigh any side effects
EP9 Construction and environmental properties
EP13 Information to be provided with medical devices

Assessment on conformity with the above EPs will be conducted from a clinical perspective; The choice of clinical data is based on the following:

1. Data is generated on the approved Indications for use
2. Data used for performance assessment
3. Data used for safety assessment
4. Length of follow-ups
5. Clinical and Statistical significances of the data

Dataset searched and identified for this evaluation include:

- Literature (published reports on performance of Biomet MoM THA)
- Clinical Experience
  - Post market clinical studies
  - Registry annual reports
  - In-house vigilance databases
  - Sales Data (used for comparison to reported MDR and vigilance reports)
- Clinical Investigations
  - Regulated pre-market clinical studies

[1] *Only 3 out of 37 data sources contain data of comparable device with the same identical MoM articulation design. See Appendix A for details.*
[1] *Essential Requirements per MEDDEV 2.7.1.rev 3 and Essential Principles per GHTF are used exchangeably within this document.*

Outlines of Literature Search Process

A systematic literature search regarding published clinical data of Biomet MoM THA products was performed.
PubMed was used as the primary source for the literature search. In addition, the following sources were also utilized to identify other published data on Biomet MoM THA products

- National Joint Registers (NJR) – latest annual reports in English including:
  - Swedish Hip Arthroplasty Register (SHAR)
  - England and Wales NJR (UKNJR)
  - New Zealand NJR (NZNJR)
  - Australian NJR (AOANJR)
  - Norwegian NJR (NWNJR)
  - Danish Arthroplasty Register (DAR)
  - Finnish NJR (FNJR)
  - Canadian NJR (CNJR)

- FDA MAUDE database
- UK ODEP implant rating database (http://www.supplychain.nhs.uk/portal/page/portal/Communities/Orthopaedics/ODEP%20database)

5. Summary of Clinical Data and Appraisal

Each dataset was appraised based on suitability and contribution to the assessment of performance and safety of Biomet MoM THA products. **Table 1** illustrates the criteria of data suitability assessment

Table 1 Data Suitability Criteria

Criteria	Description	Suitability Grading
Appropriate Device	Were the data generated from the device in question?	D1 Actual device D2 Comparable device

		D3 Other device
Appropriate Indications	Was the device used for the same intended use (e.g., methods of deployment, application, etc.)?	A1 Same use A2 Minor deviation A3 Major deviation
Appropriate Patient Group	Were the data generated from a patient group that is representative of the intended treatment population (e.g., age, sex, etc.) and clinical condition (i.e., disease, including state and severity)?	P1 Applicable P2 Limited P3 Different population
Type of Data	Will the data address safety or performance of the device in question?	T1 Safety T2 Performance T3 Both T4 Neither

The above method for dataset suitability is developed based on:

1. If the dataset is on device in question.
2. If the dataset is generated from intended uses of the device in question
3. If dataset is from patient population same as intended treatment population
4. If the dataset address safety and/or performance of the device in question.

Since the data analysis will be conducted collectively not individually, sufficiency of relevant information on each individual dataset should not be a criterion to assess data suitability of the collective data. **Table 2** illustrates the criteria of data contribution assessment.

Table 2 Criteria of Data Contribution

Criteria	Description	Contribution Grading
Data source type	Type of studies from which the data is collected	T1 RCT T2 Cohort T3 Case-control T4 Case series
Outcome measures	Do the outcome measures reported reflect the intended performance of the device?	O1 Yes O2 No
Follow up	Is the duration of follow-up long enough to assess whether duration of treatment effects and	F1 Yes F2 No

	identify complications?	
Statistical significance (publication ONLY)	Has a statistical analysis of the data been provided and is it appropriate?	S1 Yes S2 No
Clinical significance	Was the magnitude of the treatment effect observed clinically significant?	C1 Yes C2 No C3 Cannot determine

Table 3 is the summary of datasets identified as clinical experience and clinical investigations and assessment on their suitability and contribution to assessing safety and performance of Biomet MoM THA products in question. The detailed description of each dataset can be found in **Appendix A.**

(b) (4)

Redacted in the following three pages - Table 3 Biomet Owned Datasets
(b)(4) EXEMPTION - Trade Secrets, Commercial or Financial Information

(b) (4)

(b) (4)

Table 4 is the summary of datasets identified via literature search and assessment on their suitability and contribution to assessing safety and performance of Biomet MoM THA products in question. The details of each dataset (only those included for this evaluation) can be found in **Appendix B.**

Table 4. Published Non-Biomet Owned Reports						
Dataset #	**Dataset Name**	**Data Type**	**Device in question**	**Included/Excluded**	**Suitability grading**	**Contribution grading**
a	Short-Term Results Of The M2a-Taper Metal-On-Metal Articulation	Publication	M2A Taper	Included/part of dataset #8	D1,P1,A1,T3	T1,O1,F1,S1,C1
b	Mid-Term Results Of A Polyethylene-Free Metal-On-Metal Articulation	Publication	M2A Taper	Included/part of dataset #8	D1,P1,A1,T3	T1,O1,F1,S1,C1
c	Large Versus Small Femoral Heads In Metal-On-Metal Total Hip Arthroplasty	Publication	M2A Taper, M2A 38mm	Included	D1,P1,A1,T1	T1,O1,F1,S1,C1
d	Metal-On-Metal Total Hip Arthroplasty With Large Heads May Prevent Early Dislocation	Publication	M2A 38mm	Included	D1,P1,A1,T1	T1,O1,F1,S2,C1
e	Reduction In Early Dislocation Rate With Large-Diameter Femoral Heads In Primary Total Hip Arthroplasty	Publication	M2A 38mm	Included	D1,P1,A1,T3	T1,O1,F1,S2,C1
f	FNJR (2007)	NJR annual report	None	Excluded (no data on Biomet MoM THA found)	D3,P1,A1,T4	
g	NZNJR (10 yr report)	NJR annual report	M2A (no specific brand name)	Included	D1,P1,A1,T1	T4,O1,F1,S1,C3

h	SHAR (2006)	NJR annual report	M2A (no specific brand name)	Excluded (usage data only)	D1,P1,A1,T4	
i	UKNJR (2009)	NJR annual report	M2A (no specific brand name)	Included	D1,P1,A1,T1	T4,O1,F1,S1,C3
j	DAR (2008)	NJR annual report	M2A (no specific brand name)	Excluded (usage data only)	D1,P1,A1,T4	
k	AOANJR (2009)	NJR annual report	Magnum, M2A 38mm	Included	D1,P1,A1,T1	T4,O1,F1,S1,C3
l	UK ODEP NHS	Rating on orthopedic implants (Hip)	Magnum, Stanmore M2A (same identical MOM articulation design as M2A Ringloc)	Included	D1&D2,P1,A1,T1	T4,O1,F1,S1,C1
m	CNJR	NJR annual report	None	Excluded (no data on Biomet MoM THA found)	D3,P1,A1,T4	
n	Metal-on-metal versus polyethylene in hip arthroplasty: a randomized clinical trial.	Publication	M2A Taper	Included	D1,P1,A1,T3	T1,O1,F1,S1,C1

(b) (4)

Following the above rationale, the performance of Biomet MoM THA is assessed by clinical outcomes, patient outcomes and implant survivorship.

Harris Hip Score

Harris Hip Score (HHS) was developed by William Harris, a prominent orthopaedist in Massachusetts. The HHS is a tool for the evaluation of how a patient is doing after their hip is replaced. Based on a total of 100 points possible, each question is awarded a certain number of points based on how it is answered. Questions are further grouped into categories. The first category is pain. For example, if you have no pain in your hip you get 44 points, slight pain 40 points, down to 0 points for disabling pain. The second category is function. If you have no limp, do not use a walking aid, and can walk more than six blocks, you get 33 points; less if you were to use a cane, or walk only two blocks, etc. The third category, functional activities, consists of questions about how you climb stairs, put on shoes, length of time you can sit in a chair, and if you can use public transportation. Finally, the physical exam results are tabulated, and based on your range of motion, up to 9 points awarded. The score is reported as 90-100 for excellent results, 80-90 being good, 70-79 fair, 60-69 poor, and below 60 a failed result. Using the HHS, results of hip replacements can be compared across the country in an objective fashion. In the clinic, the HHS allows us to rapidly get a feel for how patients are doing after surgery.

Among studies included in this clinical evaluation,21 datasets have reported Harris Hip scores on Biomet MoM THA at preoperative and various postoperative time points. A look at combined data based on Harris Hip score assessment and analysis on each dataset **(Table 5)** illustrates the majority of patients who received various Biomet's M2a™ MOM THA products have achieved good to excellent Harris Hip score, less pain and improved function postoperatively. The percentages of hips with good to excellent total HHS are 90%, 90% and 86% at 1-, 3-, and 5-years, respectively. A detailed analysis of Harris Hip Score including total, pain and function can be found in **Appendix C**

(b) (4)

(b) (4)

Redacted on the following page - Table 5 continued
(b)(4) EXEMPTION - Trade Secrets, Commercial or Financial Information

(b) (4)

Oxford Hip Score

The Oxford hip score (OHS) is a 12-item patient-based questionnaire developed and validated specifically to assess function and pain after Total Hip Replacement. When the Oxford hip score was originally devised, the scoring system was designed to be as simple as possible, in order to encourage its use.

Thus, in the original publication[5], each question was scored from 1 to 5, with 1 representing best outcome/least symptoms. Scores from each question were added so the overall score was from 12 to 60 with 12 being the best outcome. Since then, many surgeons have found this scoring unintuitive and have adapted the scoring - leading to considerable confusion. Therefore the OHS has been modified as follows: Score each question from 0 to 4 with 4 being the best outcome. This method, when summed, produces overall scores running from 0 to 48 with 48 being the best outcome (to convert from the 'old' 60–12 system to this new 0-48 system and vice versa subtract the score from 60).

Table 6 summarizes the Oxford Hip Score on patients receiving Biomet MoM THAs from the available datasets and show postoperatively patients' function and pain have improved compared to preoperatively.

(b) (4)

EQol 5D (EQ5D)

EQ5D is a generic instrument for assessing quality of life, identifies 243 possible health states. It is based on five questions about mobility, self-care, usual activity, pain/discomfort and anxiety/depression. There are three possible levels of response for each item. Each state carries a utility value, which is calculated using time trade-offs. Perfect health and death have utility values of one and zero, respectively, and states worse than death (< 0) are possible.

Clinical studies (#21) conducted in Japan and Korea collect and report EQ5D results on M2A magnum and M2A Taper. The results in **Table 7** below show that patients' general health at early postoperative (up to 6 months) have improved compared to preoperatively.

(b) (4)

(b) (4)

UCLA activity level score (UCLA)

The UCLA activity score is based on a scale of 1 to 10 with 1 being wholly inactive. Clinical studies #21 conducted in Japan and Korea collect and report UCLA results on M2A magnum and M2A Taper. The results are shown in **Table 8**.

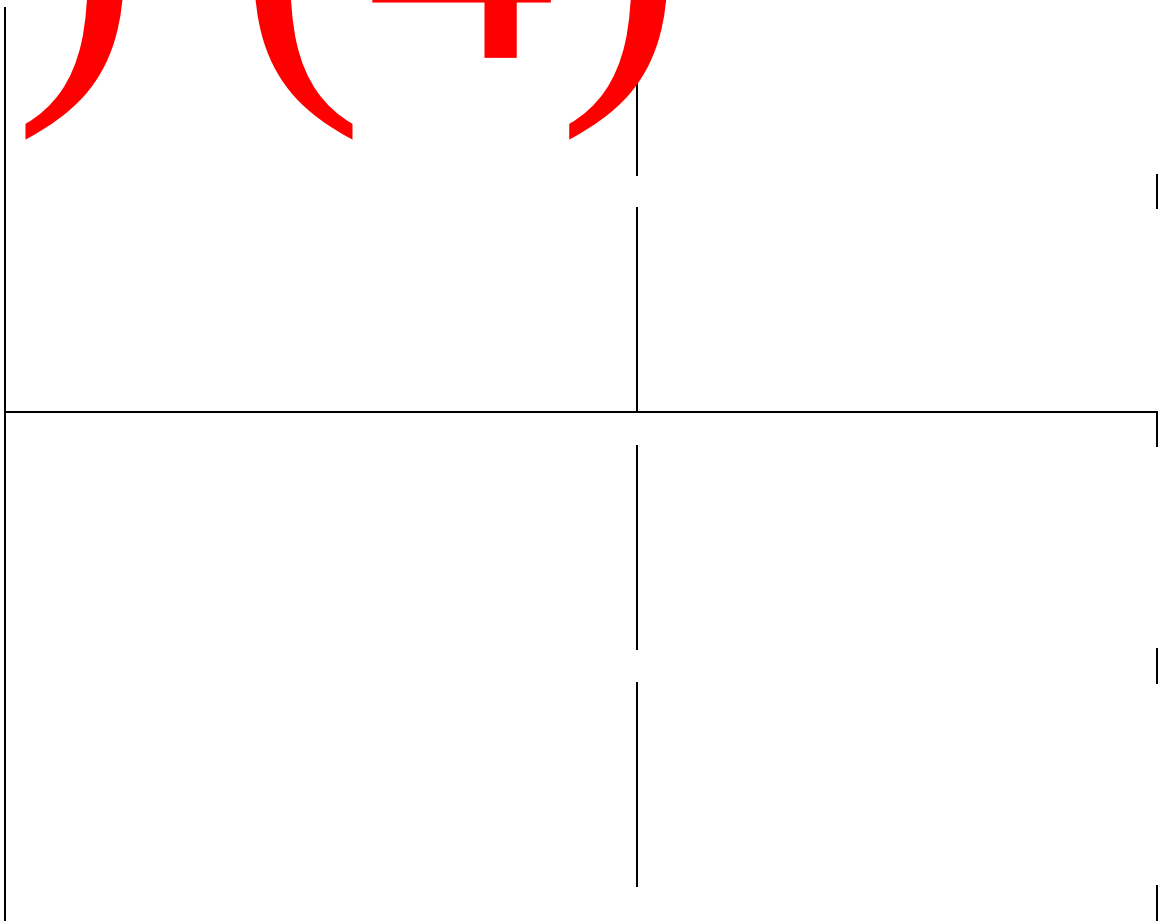
(b) (4)

The Western Ontario and McMaster Universities Index of Osteoarthritis (WOMAC)

The WOMAC was developed in the early 1980s as a disease-specific measure for hip and knee osteoarthritis[4]. It was designed to provide a standardized assessment of self-reported health status while incorporating activities relevant to patients. The instrument has since been used extensively in lower limb osteoarthritis and joint replacement research. The WOMAC consists of 24 items: 5 pain, 2 stiffness, and 17 physical function items. It produces three subscale scores (pain, stiffness, and physical function) and a total score. Patients are asked to answer each question with regard to the pain, stiffness, or difficulty experienced in the previous 48 hours. It offers 5 response options ranging from 'none' to 'extreme'. A response of 'none' is scored as 0, 'mild' as 1, 'moderate' as 2, 'severe' as 3, and 'extreme' as 4. Scores for each section are summed to produce pain, stiffness, and physical function subscale scores. The WOMAC is scored on a best to worst scale, so that lower subscale scores represent less pain, less stiffness, or better physical function. A total WOMAC score can also be produced and is commonly transformed to a 0-100 scale for ease of interpretation and comparison with other studies

Redacted on the following two pages - Table 9, Table 10 and Table 11

(b) (4)



(b) (4)

SF-12

The SF-12 is a multipurpose short form survey with 12 questions, all selected from the SF-36 Health Survey (Ware, Kosinski, and Keller, 1996). The questions were combined, scored, and weighted to create two scales that provide glimpses into mental and physical functioning and overall health-related-quality of life of patients. The SF-12 is a generic measure and does not target a specific age, disease or treatment groups.

Study #n reported mental and physical scores of SF-12 on patients who received M2A Taper compared to patients with Metal-on-Poly implants. The results **(Table 12)** show that patients received (b) (4)

(b) (4)

Survivorship/Revision Rate

Among all available datasets, (b) (4) . The following parameters, if available, are calculated on each dataset and compiled:

1. Raw revision rate - number of revisions in relation to number of cases
2. Mean survival year - number of years implants surviving in patients so far (i.e. as of last verification)
3. Revision per 100 observed component year
4. Accumulative survivorship

A detailed analysis on revision rate and survivorship of each Biomet MoM THA can be found in **Appendix D**. **Table 13** summarizes revision rates and survival time of each and overall Biomet MoM THAs. It is shown that Biomet has collected data on approximately (b) (4) cases of MoM THA with revision rate and/or survivorship information. (b) (4) .

Redacted on the following page - Table 13, Table 14 and Table 15
(b)(4) EXEMPTION - Trade Secrets, Commercial or Financial Information

(b) (4)

						Magnum & M2A 38mm)
	2.78% (2.56% - 3.0%)*	2.7% (2.57% - 2.83%)	2.79% (2.6% - 3%)	2.94% (2.8% - 3.0%)	2.51% (2.37%- 2.65%)	2.77% (2.69% - 2.85%)

***Revision Rate of Biomet MoM THA reported in Original 515(i) calculated using the same method is 3.12% (453 revisions out of 14523 THA procedures) with 95% CI of 2.84% - 3.4%. A chi-square test was conducted to compare the 2 revision rates which yielded P >0.05. Therefore chi-square test does not show statistically significant difference (95% confidence) in revision rate from what was reported in original 515i submission to this clinical evlauation.**

**NZNJR and AOANIRR are the two NJRs of which annual reports contain revision rate and revision per 100 CY.

Table 15 Accumulative Survivorship - Comparison to NJR and Peer-Reviewed Journal Article Data

Data Sources	Details	3yr - Survival rate (%)	5yr - Survival rate (%)	>5yr - Survival rate % (yr)
(b) (4)	(b) (4)			
Manley *et al*[7]	Sampling of Medicare data (1997-2004)	96.5 – 97 *(based on graphic information)*	95 -95.8 *(based on graphic information)*	
Ong *et al*[8]	Sampling of Medicare data (1997-2004)	96 – 97 *(based on graphic information)*	95 – 96 *(based on graphic information)*	
Ong *et al*[9]	Sampling of Medicare data (1997-2006)		95.9 *(based on graphic information)*	
Kurtz *et al*[10]	Nationwide Inpatient Sample (1990-2003	97 *(based on graphic information)*	95 *(based on graphic information)*	
UKNJR Annual Report 2009 (pg 89)[dataset i]	cemented	98.7		
	cementless	97.2		
	hybrid	98.1		
UKNJR Annual Report 2010[11]	cemented	98.6	98	
	cementless	97.5	96.6	
	hybrid	98.2	97.3	
Australia AOANJRR Annual Report 2009 (HG5)[dataset k]	cementless	97.1	96.2	95.4 (7), 94.9 (8)
	cemented	97.7	96.7	95.8 (7),95.0 (8)
	hybrid	97.7	96.9	96.0(7),95.6 (8)

Australia AOANJRR Data Report[dataset 19]	Other THA (excld. Magnum & m2A 38mm)	97.4	96.5	95.6 (7), 95.1 (8)
New Zealand NZNJR Annual Report[dataset g]	all	97.98	97.15	96.70 (6), 95.96 (7), 95.25 (8), 94.24 (9)

6.2 *Safety*

Safety of Biomet MoM THA products is determined by the collection of the incidence of post-operative adverse events, revisions, radiographic and metal ion concentrations in relation to overall number of patients received Biomet MoM THA products and length of implantation.

Adverse Events

I. AEs Reported from Datasets

Adverse Events reported from datasets identified in Table 3 and 4 are analyzed and summarized for each and overall Biomet MoM THAs. The detailed description can be found in **Appendix E.** A combined time distribution of AE on all Biomet MoM THAs is shown in **Table 16.** It is shown that Biomet has collected data on approximately (b) (4) of MoM THA with adverse event information. (b) (4)

(b) (4)

Redacted on the following two pages - Table 16 continued
(b)(4) EXEMPTION - Trade Secrets, Commercial or Financial Information

(b) (4)

(b) (4)

(b) (4)

II. AEs reported from MAUDE database

FDA Manufacturer and User Facility Device Experience (MAUDE) database represents reports of adverse events involving medical devices used in public, private, and nonprofit hospitals and has been used to mine adverse events related to Biomet MoM THA products. The results are summarized and included in **Appendix F.**

Metal Ion and Soft Tissue Reaction

Some patients with metal-on-metal THA have been reported to experience elevated metal ion levels (Co and Cr)[12] in serum, blood or urine. Concerns have been raised regarding the safety of and risks associated with prolonged exposure to metal ions, and whether such exposure may increase the risk of cancers or metabolic disorders. However no association between MoM prostheses and cancer or metabolic disorders has been reported.

It has also been suggested [13,14] that some patients who received Metal on Metal Hips developed an immunological response to metallic implant materials and metal debris. Histological evaluation of periprosthetic tissues suggests a cell-mediated type-IV hypersensitivity reaction (delayed-type hypersensitivity). This hypersensitivity may result in adverse reaction of tissue and bone surrounding the implant. This tissue reaction has been called pseudotumors, ALVAL (aseptic lymphocyte dominated vasculitis associated lesion). Such tissue reaction may cause groin pain, swelling, implant loosening and subsequent revision.

Metal ion Data

Among (b) (4) on Biomet MoM THA products, the following studies collected metal ion concentrations at preoperative and various postoperative time points.

(b) (4

Table 17. Mean and Median Cr, Co and Mo Metal Ion Levels

(b) (4)

(b) (4)

(b) (4)

(b) (4)

Table 18 Cobalt and Chromium Concentrations (µg/L) in MP & MM in Serum

(b) (4)

(b) (4)

Study 21-JP **(Table 19) -** In this multi-center prospective randomized trial, metal ion analysis is conducted in patients received M2A Magnum or M2A Taper. The methods used for metal Ion analysis include:

- Cobalt: ICP-MS (Inductively Coupled Plasma Mass Spectroscopy)
- Chromium: AAS (Atomic Absorption Spectrometry)

Redacted on the following four pages - Table 19, Table 20, Table 21, Table 22 and Table 23
(b)(4) EXEMPTION - Trade Secrets, Commercial or Financial Information

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

Market Analysis

As of June 2010, a Medical Device Reportable search on Biomet MoM THA products has been conducted in FDA MAUDE database. In addition European vigilance reports on Biomet MoM THA products have also been reviewed. In the mean time, sales data on MoM THA in US and internationally has been obtained. **Appendix H** shows the comparison between reported adverse events and total sales on various Biomet MoM THA products in the same period. The comparison demonstrates that the occurrence rates of adverse events on Biomet MoM THAs are very small compared to usage of these products.

6.3 Critical Review of all Clinical Data

The purpose of this evaluation is to assess performance and safety of Biomet MoM THAs from a clinical aspect. Data used to support this safety and performance assessment came from a broad range of sources from well design clinical investigations to national joint registries therefore reflect the "real-

world" applications of Biomet MoM THAs. Furthermore the data is based on the products in question and comparable product with the same identical MoM articulation design[3] from the appropriate patient population for the approved indications for use.

Performance of Biomet MoM THA products was assessed based on clinical outcomes on patients implanted with Biomet MoM THAs and implant survivorship. Harris Hip, Oxford Hip, WOMAC, EQ5D and UCLA scores all show that majority of patients implanted with Biomet MoM THAs achieve improved function, activity level and reduced pain and stiffness at various postoperative time points. Furthermore the majority of patients have demonstrated improved general health and quality of life after receiving Biomet MoM THAs. The combined and individual survivorships of Biomet MoM THAs have shown to be within those of other THA products.

Review of adverse events reported from multiple sources including clinical studies, publications, FDA MAUDE and internal vigilance databases show that:

1. All the adverse events are known risks to THA or general surgical procedures
2. The occurrence rates of reported Adverse Events are similar to that of other THA products.
3. There are no new risks identified.

7. Conclusions

Based on the clinical evidence on Biomet MoM THA presented, we conclude that

a. Biomet MoM THAs are safe and perform as intended
b. Biomet MoM THAs still conform with Essential Principles specifically:
    - Use of Biomet MoM THAs do not compromise health and safety of the patients
    - Design and construction of Biomet MoM THAs to conform with safety principles
    - Biomet MoM THAs offer long term safety
    - Benefits of Biomet MoM THAs outweigh the risks
c. Risks identified in the risk management documentation have been addressed by the clinical data.

(b) (4)

Redacted on the following page - References
(b)(4) EXEMPTION - Trade Secrets, Commercial or Financial Information

(b) (4)

Appendix A - Detailed Description of Datasets

Dataset (Study) #	Dataset Name	Was it Included in Original 515i?	Does It Have Updates since 515i?
1	NJR UK	Yes	Yes
2	(b) (4)	Yes	Yes
3	(b) (4)	Yes	No
4	NJR Finnish	Yes	No
5	(b) (4)	Yes	No
6	(b) (4)	Yes	No
7	(b) (4)	Yes	No
8	(b) (4)	Yes	No
9	(b) (4)	Yes	No
10	(b) (4)	Yes	Yes
11	(b) (4)	Yes	No
12	Stanmore MoM publication	Yes	No
12 Update	Stanmore MoM publication	No	Yes
13	(b) (4)	Yes	No
14	(b) (4)	Yes	No
15	(b) (4)	Yes	No
16	(b) (4)	Yes	No
17	(b) (4)	Yes	Yes
18	Nygaard publication	Yes	No
19	NJR AUS	No	
20	(b) (4)	No	
21-JP	(b) (4)	No	
21-KR	(b) (4)	No	
22	(b) (4)	No	
24	(b) (4) (b) (4)	No	
25	(b) (4)	No	
26	Virolainen , P.; Kostensalo I.; Seppänen M.; Mäkelä K.; Mokka J.; Virolainen P. Finnish NOF presentation	No	
28	(b) (4)	No	
29	(b) (4)	No	
30	UK NJR	No	
31	UK NJR	No	

Study #1
United Kingdom Magnum™ Survivorship Data
National Joint Registry in UK ReCap/Magnum™

This dataset contains updates since 515i submission. Items in Green are from original 515i

Data from National Joint Registry in UK was gathered on the various designs of the M2a Magnum™. The data found in the registry consisted of patient demographic, revision information, survivorship and deaths.

Objective of Data Collection

The purpose of this data collection was to document the survivorship of the Biomet M2a Magnum™ hip System. The survivorship analysis included details in the number of revisions and deaths and the reason for each revision.

Design

The data collection effort was conducted from 2005 to 2010 (dates of primary operations and revisions).

Study Population

Table 1-1: Patient Demographics

Number of Patients	2594 (1936)
Men/Women	1371/1223 (1047/889)
Mean Age, Year (range)	64.05 (13-95) 62.8 (13-95)

A total of 2594 patients were registered. The study consisted of patients receiving hip replacements to either side, left or right. There were more males than females 1371/2594, 52.8% vs. 1223/2594, 47.2%, respectively. The mean age of the patient population was 64.05 years, with a range of 13 years to 95 years. Indications included AVN, osteoarthritis, other inflammatory arthropathy, ankylosing spondylitis, osteoarthritis linked with other diseases, and much more. The number of patients presenting with each indication and a more detailed account is shown below.

Table 1-2: Indications for THA

	# of Cases *
Ankylosing Spondylitis	4
Avascular Necrosis	100 (43)
Dislocation/Dysplasia	18
Failed Hemi	4
Failed Internal Fixation	15
Slipped Upper Femoral Epiphysis	12
Other Hip Trauma	1
Fractured Neck of Femur	20
Osteoarthritis	2363 (1777)
Dislocation/Dysplasia	21

Fractured Acetabulum	8
Infection	1
Other Inflammatory Arthropathy	26
Perthes	5
Previous Arthrodesis	5
Psoriatic Arthropathy	1
Seropositive Rheumatoid Arthritis	4
Not Reported	88

**The number represented in this table is greater than the number of patients due to multiple diagnoses reported on some patients.*

Revisions

Table 1-3: Revision Summary on M2a Magnum™

Postoperative Time Points	< =1 month	<= 3 months	< 6m	<= 1 Yr	<= 2 Yr	<=5 Yr	>5yr	Not specified
Occurrence*								
Aseptic Loosening Stem		1			5	3		
Aseptic Loosening Socket			1	3	4	4		
Lysis Stem					2	2		
Lysis Socket						2		
Infection	1	1			1	3		
Pain				2	2	4		
Periprosthetic Fracture Stem	2	1			1	1		
Dislocation/Subluxation		1	1	1		1		
Dissociation of Liner						1		
Malalignment Socket	1	1	1		2	1		

Wear of Acetabular Component						1		
Implant Fracture Stem		1						
Not Specified	1					1		

**The total number of occurrence in this table is greater than the number of revisions due to multiple indications for revision reported on some patients.*

A total of 35 (25) revisions were reported for the M2a-ReCap Magnum™ population, an occurrence rate of 1.3% (1.3%)

Deaths

A total of 36 (22) deaths were reported for the M2a-Recap™ Magnum population. The Registry does not elaborate on events surrounding patient deaths.

Survivorship

Table 1-4: Survivorship in Years for M2A Magnum

	Mean (Range) in Years
Unrevised	2.06 (.04-5.59)
Revised	1.34 (.01-4.55)
Total	2.04 (.04-5.59)

Table 1-5: Revision Rate for M2A Magnum

# of Hips	# of Revision reported for all causes	Revision Rate (%)	Total Component Yr	Mean Survival in years	Revision per 100 CY
2594	35	1.35	5288.388	2.04	0.66

Redacted one page - Study #2 description details

(b)(4) EXEMPTION - Trade Secrets, Commercial or Financial Information

(b) (4)

Table 2-1. (b) (4)

(b) (4)

Note: * the specific MoM hip used was not listed.

Table 2-2 (b) (4)

(b) (4)

Side: Right/Left	(b) (4)
Body Mass Index (kg/m^2) Mean (Range)	
Follow-up: Mean (range) (years)	

Redacted one page - Title: Safety with Table 2-3 Summary of Revisions
(b)(4) EXEMPTION - Trade Secrets, Commercial or Financial Information

(b) (4)

TCJR*	**33**	**M2a-38**	**3.28**	**Acetab**	**N/A**
	34	**M2a-38**	**5.36**	**Acet Cup/Line**	**Loosening**
	35	**Magnum**	**3.33**	**Acetabulum**	**Loose prosthesis**
	36	**Magnum**	**3.32**	**Head/Femur**	**Mech comp**
	37	**Magnum**	**2.43**	**M2aMag Mod**	**Loose prosthesis**
	38	**M2a-38**	**5.03**	**Cup/Poly/Head****	**Loosening**
Cuckler	**1**	**Magnum**	**0.21**	**Femur**	**Peri-prosthetic fracture**
	2	**M2a-38**	**0.5**	**Cup**	**Dislocation**
	3	**M2a-38**	**0.63**	**Cup**	**Aseptic loosening**

Note: * If date of revision not given, date of last follow-up was used in survivorship analysis

** Unclear why "pos listed in revised components.

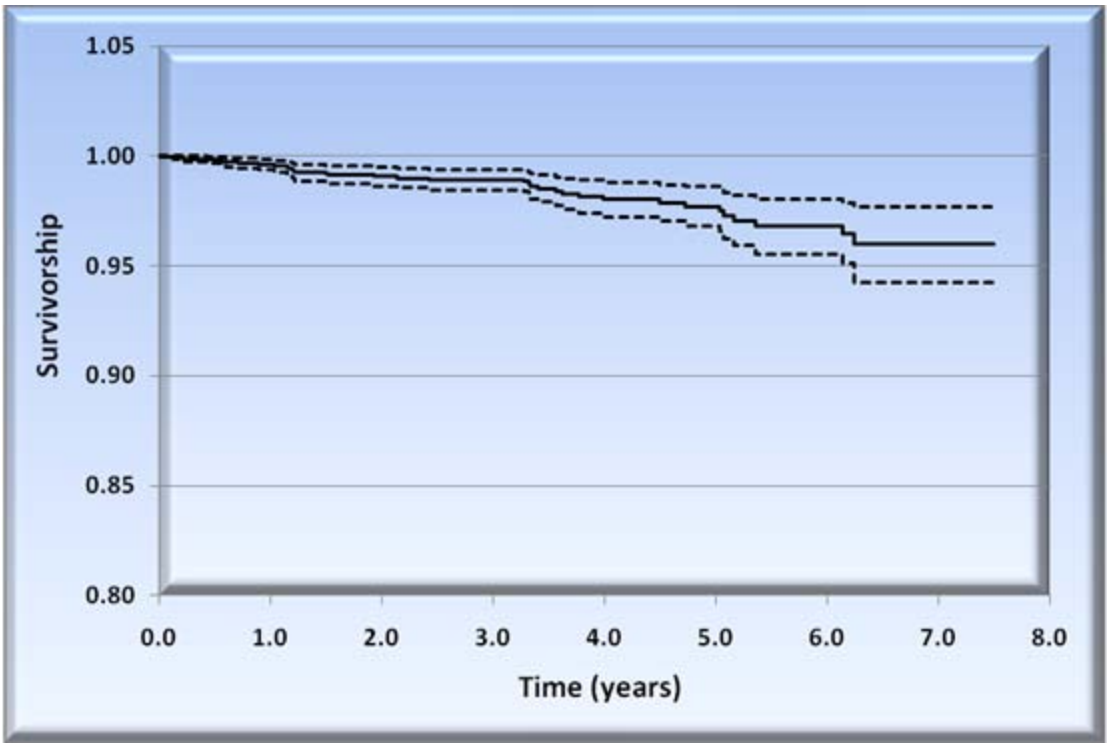


Figure 1. Kaplan-Meier survivorship analysis showing 95% confidence limits.

Conclusions

The overall revision rate was 1.2% (41 revisions out of 3,427 hips). Formal Kaplan-Meier survivorship analysis yielded 96.0% survivorship at 7.5 years for the 3 sites with updates (a revision rate of approximately 0.5% per year) and 99% survivorship at 5 yr for Cuckler's. The analysis on 3427 cases indicates a low revision rate for Biomet MoM hips.

Redacted 43 pages - Study #3, #4, #5, #6, #7, #8, #9, #10, and #11 with description details and Tables
(b)(4) EXEMPTION - Trade Secrets, Commercial or Financial Information

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

Study #12

The Stanmore Total Hip Arthroplasty: MOM versus Metal-on-PE

Clinical and radiological outcome of a prospective randomized controlled trial after 5 years follow-up

Published: Zijlistra, WP, Cheung J., Sietsma MS, van Raay, JJ, Deutman, R. No Superiority of cemented metal-on-metal vs metal-on polyethylene THA at 5-year follow-up. Orthopedics. 32(7) July 2009. 479.

No updates since 515i

Objective of Study

The purpose of this study is to compare clinical and radiological outcomes, as well as survival, of MOM hip devices versus metal-on-polyethylene hip devices.

Design

This study was designed as a prospective, randomized study in the Netherlands, comparing 102 cemented MOM Stanmore THA and 98 conventional cemented metal-on- polyethylene Stanmore THA in the period of January 1998 to February 1999. The Stanmore THA has the same identical MOM articulation as the M2a-Ringloc™ currently marketed in the US. The average follow-up intervals are 6 weeks, 3, 6, 12 months, and then annually. Outcome tools used include: Harris Hip Score, Oxford Hip Score, radiographs and cobalt serum analysis. The Stanmore device is a cemented all-poly liner with CoCr insert. However, the diametrical clearances and articulating surface is identical to the M2a-Ringloc™ MOM implant.

Data Collection

Clinical, radiograph, and patient-rated data was collected. Basic descriptive analyses were performed. Data on 88 patients treated with MOM THA is reported at the five-year timepoint.

Study Population

Table 12-1 Demographic Information – Stanmore, Zijlistra *et al*.

	MP†	MOM‡	Total
Male/Female* - Implants	20/78	21/81	41/159
Mean Age (SD)**	69 (8)	72 (7)	71 (8)
Side (R/L)* - Implants	57/41	56/46	113/87

†*Metal-on-polyethylene articulation, n=98*

‡*MOM articulation, n=102*

**Chi-square (Fisher's Exact) test, p>0.05*

***Mann-Whitney test, p=0.18*

A total of 195 patients (200 implants), aged 50 years and older, were enrolled in the study. Bilateral hip replacements were performed in five patients: three patients received a combination of MOM and MP implants, one received two MOM implants, and one received two MP implants. The primary diagnosis for each patient was idiopathic osteoarthritis. Patients with marked bone loss by rapid destructive osteoarthritis, avascular necrosis, rheumatoid arthritis, Perthes disease, and congenital dysplasia were excluded.

Patient accountability at 5-years has been exceptional, **Table 12-2** shows that in both study groups over 96% follow-up was reported.

Table 12-2. Patient Accountability at 5-years – Stanmore, Zijlistra *et al*.

	MP	MOM
Theoretical	98	102

Deaths (Cumulative)	11	8
Failures (Cumulative)	1	3
Expected	86	91
Actual[A]	71	76
% Follow Up[A]	82.6%	83.5%
Actual[B]	84	88
% Follow Up[B]	97.7%	96.7%

Actual[A] patients have complete follow up data
Actual[B] patients have incomplete follow up data (12 patients did not attend clinic but had Oxford scores, 1 patient had incomplete X-Rays)

Safety

There were no major adverse events reported other than one femoral shaft perforation. Local postoperative complications included six hematomas, five superficial would infections (none requiring revision), and one posterior dislocation. Cardiovascular and urogenital problems occurred in twelve patients. Two patients (one metal-on-polyethylene and on MOM) were treated without revision for periprosthetic fractures and were not excluded from the study.

Table 12-3. Survivorship rates for MOM and MP THA – Stanmore, Zijlistra *et al*.

	Revisions	Total Patients	Survival Rate
MM THA	3	88	97% (95% CI 93% - 100%)
MP THA	1	84	99% (95% CI 97% - 100%)

The survival rate was 97 % and 99 % for the MM and MP THA, respectively, with all revisions performed due to aseptic loosening (3 MM and 1 MP). Two of the patients with MM hips were revised after two years, and one was revised after four years. The femoral component of all MM implants was well fixed. There was no radiological evidence of loosening in the remaining hips. Metal ion analysis was performed. Increased serum cobalt levels were measured in the MM patients (0.83 µg/L) in comparison with the MP patients (0.29 µg/L).

Efficacy

A total of 148 Harris Hip Scores and 172 Oxford questionnaires were available for analysis. The average Harris Hip Score for the MM group (75 HHS scores) was 90, and the average HHS was 87 for the MP group (73 HHS scores). The average Oxford scores were 19 and 18 for the MM and MP groups, respectively. The increase in Harris Hip score and decrease in Oxford score from preoperatively to 5 years postoperatively were statistically significant in both groups (p=0.000, resp. p=0.000). There was no significant difference between the Harris Hip and Oxford Scores at 5 years (p=0.515).

Table 12-4. Mean HHS and Oxford Scores in MOM and MP Groups – Stanmore, Zijlistra *et al*.

	MP		MOM		P-value	
	HHS	Oxford	HHS	Oxford	HHS	Oxford
Preoperative	45.8	40.0	47.8	39.8	0.746	0.661
1 year	84.8	17.8	85.5	19.0	0.446	0.461
3 year	88.1	17.7	84.6	19.4	0.025	0.619
5 year	87.4	17.7	89.7	18.7	0.791	0.515

Conclusion

Based on the results reported, MOM hips are safe and effective implants for patients needing hip arthroplasty, compared to metal-on-polyethylene. While the Stanmore MOM system is not sold in the US, it has the same diametrical clearances and articulating geometry as the M2a-Ringloc™ MOM device; therefore, the clinical results are applicable to the M2a™ devices sold in the US. One major adverse event (femoral shaft perforation) occurred in the study along with 24 more postoperative, cardiovascular and urogenital complications. In addition two patients, one from each study group, were treated without revision for periprosthetic fractures and remained in the study. The survival rates at the five-year time point were very high at 97% and 99% for the MOM and MP groups, respectively. Further there was statistically no difference between the two populations at any timepoint. Revisions were reported in only three of the patients with MOM hips (2.9%), and there was an improvement in clinical outcome for both groups from preoperatively to postoperatively.

Study #12 – Update (New Addition since 515i)

No Superiority of Cemented Metal-on-Metal Over Metal-on-Polyethylene THA in a Randomized Controlled Trial at 10-Year Follow-up.

Zijlistra, WP, van Raay, JJ, Bulstra, SK, Deutman, R. No Superiority of cemented metal-on-metal vs metal-on polyethylene THA at 10-year follow-up. Orthopedics. 2010 Mar 10:154-161.

This is an update of Study #12 of which results at 5-year follow-up has been published.
Zijlistra, WP, Cheung J., Sietsma MS, van Raay, JJ, Deutman, R. No Superiority of cemented metal-on-metal vs metal-on polyethylene THA at 5-year follow-up. Orthopedics. 32(7) July 2009. 479.

Objective of Study

The purpose of this study is to compare clinical and radiological outcomes, as well as survival, of MOM hip devices versus metal-on-polyethylene hip devices.

Design

This study was designed as a prospective, randomized study in the Netherlands, comparing 102 cemented MOM Stanmore THA and 98 conventional cemented metals-on- polyethylene Stanmore THA in the period of January 1998 to February 1999. The Stanmore THA has the same identical MOM articulation as the M2a-Ringloc™ currently marketed in the US. The average follow-up intervals are 6 weeks, 3, 6, 12 months, and then annually. Outcome tools used include: Harris Hip Score, Oxford Hip Score, radiographs and cobalt serum analysis. The Stanmore device is a cemented all-poly liner with CoCr insert. However, the diametrical clearances and articulating surface is identical to the M2a-Ringloc™ MOM implant.

Data Collection

Clinical, radiograph, and patient-rated data were collected. Basic descriptive analyses were performed. Data on 47 patients treated with MOM THA is reported at a mean follow-up of 121 +/- 4 months).

Study Population

Table 12u-1. Demographic Information – Stanmore,

	MP[†]	MOM[‡]	Total
Male/Female* - Implants	20/78	21/81	41/159
Side (R/L)* - Implants	57/41	56/46	113/87
Mean Age (SD)**	69 (8)	72 (7)	71 (8)

[†] *Metal-on-polyethylene articulation, n=98*
[‡] *MOM articulation, n=102*
**Chi-square (Fisher's Exact) test, p>0.05*
***Mann-Whitney test, p=0.18*

A total of 195 patients (200 implants), aged 50 years and older, were enrolled in the study. Bilateral hip replacements were performed in five patients: three patients received a combination of MOM and MP implants, one received two MOM implants, and one received two MP implants. The primary diagnosis for each patient was idiopathic osteoarthritis. Patients with marked bone loss by rapid destructive osteoarthritis, avascular necrosis, rheumatoid arthritis, Perthes disease, and congenital dysplasia were excluded.

Table 12u-2. Patient Accountability

	MP	MOM
Theoretical	98	102
Deaths (Cumulative)	25	30
Lost to follow up	4	7
Refused cooperation	4	4
Unable due to co-morbidity (no revisions reported)	8	10
Revised	2	4
Remaining for Follow-up	55	47

Safety

Since publication of 5 yr results, no additional adverse events were reported. The 2 patients (one metal-on-polyethylene and one MOM) who were treated without revision for periprosthetic fractures and were not excluded from the study show long terms clinical improvement.

Table 12u-3. Survival rates for MOM and MP THA at 10 year follow-up.

	# of cases at risk	Survival Rate
MM THA	37	95.5% (95%-CI 91.2-99.8%)
MP THA	46	96.8% (95%-CI 92.3-100%)

Table 12u-4. Revision rates for MOM and MP THA at a mean of 10 year follow-up.

	Revisions	Total Patients	Revision Rate
MM THA	4	102	3.9%
MP THA	2	98	2.1%

The revision rate was 3.9 % and 2.1 % for the MM and MP THA, respectively, with all revisions performed due to aseptic loosening (4 MM and 2 MP). In all revision cases infection was ruled out by culture and/or histology. The authors pointed out that in one of the four revised MM patients
lymphocyte, eosinophile and macrophage infiltration was described, suggesting possible
ALVAL. In the other cases these characteristics were not mentioned, but ALVAL was not
that well recognized at the time.

Serum Cobalt and Chromium Analysis

Table 12u-5 shows the median and range of the serum cobalt and chromium concentrations (µg/L) in the metal on polyethylene (MP) and metal on metal (MM) groups, at pre-op and during follow ups. The population sizes were MP at 13 and MM at 17. Cobalt ion concentrations were measured pre-op, 5 year, and 10 year post-op. Chromium ion levels were only measured at 10 year post-op. During post-op evaluation it was determined that Cobalt and Chromium concentrations were significantly higher in the MM group.

Table 12u-5. Cobalt and Chromium Concentrations (µg/L) in MP & MM

	MP	MM	P value
Preoperatively (cobalt)	.24 (.18-.65)	.18 (.18-1.77)	.185
5 year (cobalt)	.30 (.29-1.65)	.88 (.29-7.02)	.001
10 year (cobalt)	.50 (.40-1.30)	1.10 (.50-11.0)	0.00
10 year (chromium)	.50 (.50-.90)	1.00 (.50-9.5)	0.00
P - value	0.037	0.042	

Radiographic Evaluation

Table 12u-6: Number of hips showing radiolucent lines on standard anteroposterior pelvic hip radiographs on average 10 years postoperatively.

Zone	MP	MM	P value
Stem			
1	5	6	.532
2	0	1	.447
3	0	1	.447

4	1	0	1.00
5	0	0	-
6	0	0	-
7	4	0	0.125
Cup			
1	17	13	1.00
2	16	9	.495
3	9	8	1.00
# of hips with radiolucency	27 (52%)	24 (57%)	.680

At the 10 year follow up radiographs were taken and assessed for radiolucent lines and scored according to Gruen el al and De Lee & Charnley. If any radiological loosening and migration were present, results were documented. After 10 years no focal osteolysis was seen; and there is no significant difference between the two groups.

Efficacy

Both MoM and MoP groups improved significantly postoperatively in terms of Clinical outcomes measured by Harris hip and Oxford hip scores. Furthermore Harris Hip Score and oxford Hip score at 10-year follow-up did not differ between the two groups. Eleven out of the eighteen patients with severe medical morbidity were reviewed by Oxford scores alone since they were unable to attend the clinic.

Table 12u-7. Mean HHS and Oxford Scores in MOM and MP Groups **–** Stanmore, Zijlistra *et al*.

	MP		MOM		P-value	
	HHS	Oxford	HHS	Oxford	HHS	Oxford
Preoperative	45.8	40.0	47.8	39.8	0.746	0.661
1 year	84.8	17.8	85.5	19.0	0.446	0.461
3 year	88.1	17.7	84.6	19.4	0.025	0.619
5 year	87	18	90	19	.791	0.515
10 year	87	24	86	27	.441	.494

Conclusion

This dataset is an update from results previously published. Based on the results reported, MOM hips continue to show safe and effective implants for patients needing hip arthroplasty, compared to metal-on-polyethylene. Compared to 5 yr reported in the previous publication, there are no more adverse events reported. The survival rates at the ten-year time point were very high at 95.5% and 96.8% for the MOM and MP groups, respectively. Further there was no statistically significant difference in terms of 10-year survival rate between the two populations (P=0.402). Revisions were reported in only 4 of the patients with MOM hips (2.9%), and there was an improvement in clinical outcome for both groups from preoperatively to postoperatively.

Study #13
Netherlands Stanmore Clinical Summary
This study is same as study #12 of which results were summarized here based on the raw data provided to Biomet

No updates since 515i

Objective of Study

The purpose of this study is to evaluate the medium term performance of the Stanmore MOM and metal-on-polyethylene implants.

Design

The study was designed as a randomized controlled trial conducted in the Netherlands, approved by the local Ethics committee, and meeting Good Clinical Practice (GCP) and ISO 14144 guidelines. Participating surgeons included Drs Vanraay, Gerritsma, Eikelaar, and Deutman. The follow up intervals included: 6 wks, 3m, 6m, 12 m, and annually thereafter until the 10-year timepoint. Outcome scores collected include the Harris Hip Score (HHS) and Oxford Hip Score (OHS). Radiographs were taken and adverse events were tracked. The study is ongoing. Only the MOM information is being summarized in this section. The Stanmore device is a cemented all-poly liner with CoCr insert. However, the diametrical clearances and articulating surface is identical to the M2a-Ringloc™ MOM implant.

Data collection

Data on the MOM patients only is presented here. Demographic, complication events, radiograph evidence, HHS, and OHS have been collected to the 5-year timepoint for the MOM implants only.

Study population

Table 13-1. Demographic Information- Stanmore (Netherlands)

Number of Patients/Implants		102
Men/Women		19/83
Mean Age, Year (range)		72, (51 to 88)
Diagnosis	Osteoarthritis	102

A total of 102 patients (102 implants) were enrolled in the study. The average age of the study population was 72 years old (51 – 88 years). There was a higher concentration of females versus males, 83/102, 81.4% versus 19/102, 18.6%. All patients were diagnosed with primary osteoarthritis.

Table 13-2. Patient Accountability - Stanmore (Netherlands)

	6 weeks	6 months	1 Year	3 Year	5 Year	6 Year
Theoretical	102	102	102	102	102	102

Redacted 21 pages - Study #13 continued, #14, #15, #16 and #17 with description details and Tables
(b)(4) EXEMPTION - Trade Secrets, Commercial or Financial Information

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

Study #18

Nygaard, M. *et al*. – Early Periprosthetic Femoral Bone Remodeling Using Different Bearing Material Combination in Total Hip Arthroplasties: A Prospective Randomised Study

(Nygaard M. et al. European Cells and Materials., Vol 8. 2004)

No updates since 515i

Objective

To test the hypothesis that changes in bone mass, cellular response, particle localization, and concentration of cytokines in the pseudosynovial membrane are influenced by differences in bearing materials within 1-year follow-up after hip arthroplasty. This data was collected for use to support a doctoral thesis.

Materials

After applying a series of exclusion criteria (e.g., under 18 years old, dementia, infections, etc) to gather data on the proper population, a subset of patients diagnosed with either OA or AVN that were instrumented with a hybrid total hip replacement at the Orthopedic Clinic, Frederiksberg University Hospital, Denmark. The same type of stem, Biomet's Bi-Metric® (collarless, plasma-sprayed, bi-taper) and shell was used in all patients. Patients were randomized to receive one of the bearing material combinations:

Articulation	*RingLoc insert*	*Modular Head*
I	Polyethelene	Zirconia (ZrO_2)
II	$CoCrMo^3$	CoCrMo
III	Alumina (Al_2O_3)*	Alumina (Al_2O_3)*

**Alumina/ Alumina not available in the U.S.*

Bone mineral density was determined by DEXA with patients lying in the supine position with extended knee and hip during the scanning procedure. The BMD (bone mineral density) of the operated hip was measured within 1-week postoperatively and again after 1-year follow-up. X-rays were also taken at the same timepoints as the BMD post-operation. They were analyzed for changes in position and radiolucent lines in the 7 Gruen zones, regions marking the neck and tip of the femoral component.

Results

A total of 225 patients participated in the study. A total of 188 patients (123 F, 65M) were successfully scanned immediately post op and after 1-year. The BMD (g/cm^2) measurements showed no significant difference in the periprosthetic BMD between the groups 1-year after surgery. The periprosthetic BMD level decreased significantly in all Gruen zones during the 1^{st} Year post-operation independently of the bearing materials used. Furthermore, there was no correlation between changes in BMD in body mass index, gender, or age. **Figure 11** depicts the mean BMD difference between the immediate post operative period and the 1-year. The mean BMD decrease ranged from 0.04 g/cm^2 (zone 4 and 5 in the MOM group) to 0.22 g/cm^2 (zone 7 in the MOM group). After 1-year, the relative bone loss was highest in the proximal part of the femur, -6.2% in zone 1, greater trochanter area; -12.7% in zone 7, lesser trochanter region. In the distal zones, the mean BMD decrease: -5.3, 4.2, -2.1, -2.3, and -5.6%, respectively.

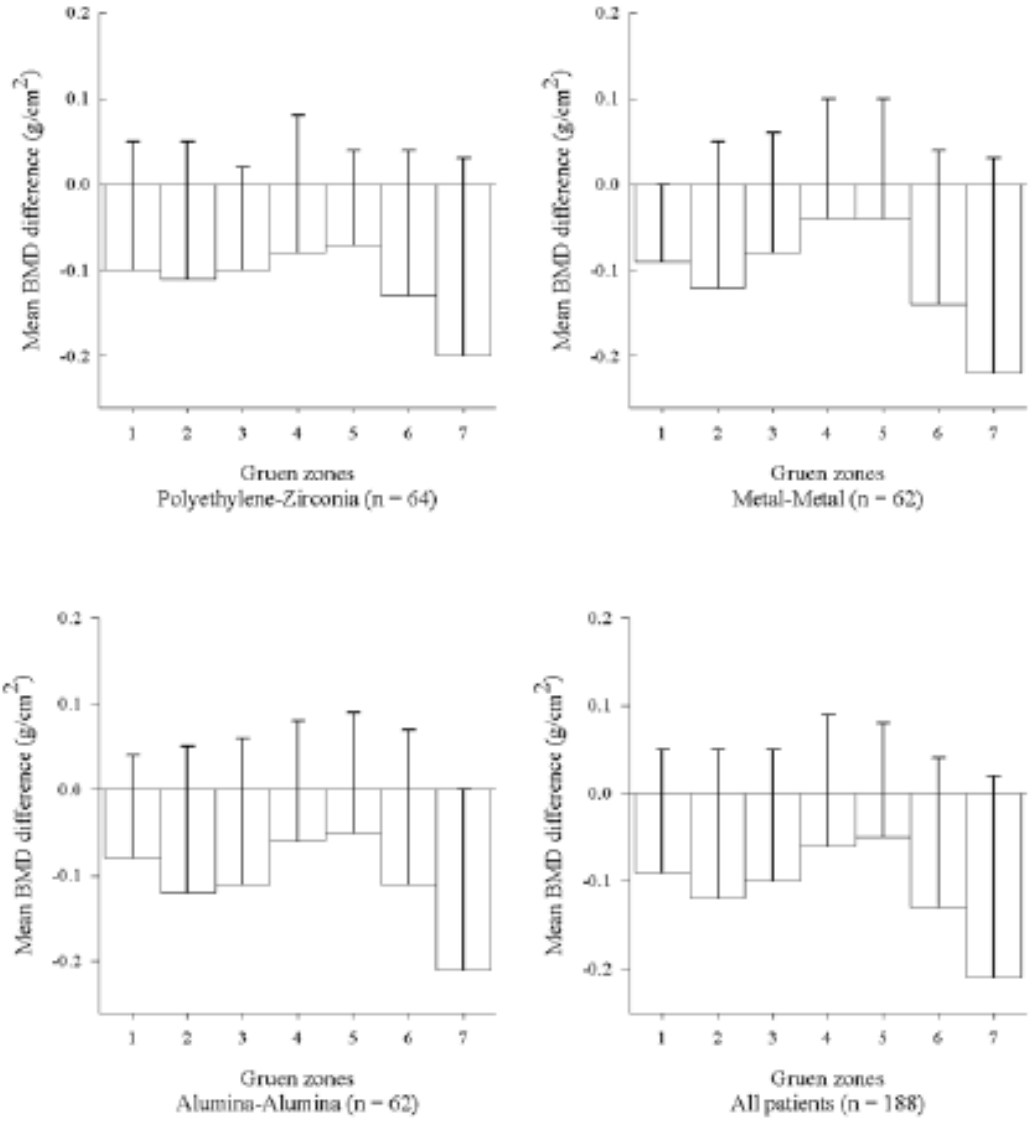


Figure 11. BMD difference in g/cm^2 between the postoperative level and after one year.

In addition, x-ray evaluations showed no patient demonstrating radiolucent zones exceeding 2mm with the exception of 1 patient in the Articulation I group. Following a revision, it was determined the area tested positive for deep infection with Staphylococcus epidermidis.

The study included biopsies of the pseudosynoival membranes of 37 patients. Granulomas were demonstrated in 33 of the 37 (35) biopsies. Two biopsies from the polyethylene-zirconia group were excluded because of failed preparation. The mean macrophages volume fractions for the Co-Cr-Co-Cr was 0.04, medium granuloma volume fractions for Co-Cr-Co-Cr was 0.04, and lastly, then median endothelial cell volume fractions for Co-Cr-Co-Cr was 0.02.

There were no differences between Co-Cr-Co-Cr group and the other articulation groups.

A high number of particles were found in the pseudosynovial membrane of the three articulation couples. Particles were located in both the extracellular matrix and intracellular in the cytoplasm of macrophages, fibroblasts, and endothelial cells in all groups. In the Co-Cr group, the extracellular particles were also seen as flake-like structure in the necrotic tissue from one patient. Most importantly, there were no inflammatory cells in relation to the extracellular particles.

Conclusions

Thus the authors have not been able to demonstrate any significant changes in bone remodeling after hip arthroplasty related to bearing materials. Since identical stems and shells were used for all 3 groups, this study supports the claim that bone remodeling is mainly due to stress shielding. The CoCr and alumina are both hard materials compared to polyethylene. The capability of absorbing impact load is reduced in hard materials compared to soft materials. The bearings used in this study had a layer of polyethylene integrated between the metal and the acetabular shell. The present study does not indicate that different types of bearings have significant impact on femoral bone remodeling adjacent to a cemented femoral stem within the first year after surgery. In addition, this study explores the reaction to particulate debris generated from the various articulation couples. Each group demonstrated a high-fraction-volume of granulomas. However, there was no connection found between the high-fraction of granulomas and bone remodeling.

The Following Datasets Are New Additions Since 515i

Study #19
Australia M2a 38mm and M2a Magnum™ Registry Data

Registry data from Australia was gathered on the designs of the M2A 38™ and M2a Magnum™ MoM hips. The data found in the registry consisted of devices usages, revision information, and survivorship.

Objective of Data Collection

The purpose of this data collection was to document the survivorship of the Biomet M2a–38™ and M2a Magnum™ Acetabular Systems among other Total Hip Replacement systems. The survivorship analysis included details in the number of revisions and the reason for each revision.

Design

The data collection effort was conducted from 2004-2008 for M2a Magnum™ and 2002-2008 for M2a 38™ (dates of primary operations and revisions).

Study Population

Table 19-1 Patient Demographics

M2a Magnum	
Number of Patients	761
Male/Female (total)	393/368
Male/Female (revision)	6/8
M2a 38mm	
Number of Patients	787
Male/Female (total)	408/379
Male/Female (revision)	17/18

A total of 761 and 787 patients were registered for the M2a Magnum and M2a 38mm. There were slightly more males than females 393/761, 51.6% vs. 368/761, 48.3%, respectively for M2a Magnum. There were also slightly more males than females for the M2a 38 mm study: 408/787, 51.8% vs. 379/787, 48.2%. Primary indications mainly included Osteoarthritis, rheumatoid arthritis, AVN and fractured femoral neck. The number of patients presenting with each indication is shown below.

Table 19-2: Primary Indications for THA

M2a Magnum	
Osteoarthritis	683
Avascular Neccrosis (AVN)	34
Fractured Neck of Femur	21
Developmental Dysplasia	8
Tumor	6
Rheumatoid Arthritis	3

Failed Internal Fixation	2
Arthrodesis Takedown	1
Other	1
Fracture/Dislocation	1
Other inflammatory Arthritis	1
Total	**761**
M2a 38mm	
Osteoarthritis	724
AVN	25
Fractured Neck of Femur	17
Developmental Dysplasia	10
Other inflammatory Arthritis	3
Rheumatoid Arthritis	3
Tumor	2
Arthrodesis Takedown	2
Other	1
Total	**787**

Revisions

Table 19-3: Revision Data

Indication for Revision-M2a Magnum	**# of Revisions**
Loosening/Lysis	5
Fracture	3
Incorrect Sizing	2
Infection	2
Leg Length Discrepancy	1
Dislocation	1
Total	**14**
Indication for Revision-M2a 38mm	**# of Revisions**
Loosening/Lysis	12
Dislocation	8
Infection	5
Fracture	6
Metal Sensitivity	2
Malposition	1
Other	1
Total	**35**

A total of 14 and 35 revisions were reported for the M2a-Magnum™ and M2a 38mm respectively. The M2a Magnum population had an occurrence rate of 1.8%, and M2a 38mm had 4.4% occurrence rate.

Table 19-4: Revisions Rates of M2a Magnum and M2a-38mm Primary Conventional Total Hip Replacement by Age

M2a Magnum	# of revisions	# of total
<55	3	201
55-64	5	279
65-74	2	184
>=75	4	97
Total:	14	761
M2a 38mm	**# of revisions**	**# of total**
<55	9	190
55-64	15	283
65-74	6	228
>=75	5	86
Total	35	787

Table 19-5: Revisions Rates of M2a Magnum and M2a-38mm Primary Conventional Total Hip Replacement by Femoral Component Head Size

M2a Magnum	# of revisions	# of total
<50mm	10	482
>=50mm	4	279
Total:	14	761
M2a 38mm	**# of revisions**	**# of total**
All M2a 38mm prostheses are the same size	35	787

(b) (4)

(b) (4)

Redacted 31 pages - Study #20 continued, #21-JP, #21-KR, #22, #24 and #25 with description details and Tables
(b)(4) EXEMPTION - Trade Secrets, Commercial or Financial Information

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

Study #26

Early results of large head metal-on-metal hip arthroplasties

Oral Presentation at 55th NOF (Nordic Othorpaedic Federation) Congress in May 2010. Abstract is available at: http://www.centraloffice-europe.com/nof2010/detail.asp?id=27

The study data from Finland was gathered on M2a Magnum with BiMetric femoral stem total hip arthroplasty. The data found in the study consisted of patient demographic, complications, clinical outcomes such as Harris Hip Score.

Objective of Data Collection

The purpose of this data collection was to document clinical outcomes of the Biomet M2A Magnum hip system and to analyze all short term complications related to metal on metal articulation. The femoral stem used was BiMetric stem.

Design

Between 9/2005 and 6/2009 the site operated 691 hips in 635 patients with M2A Magnum with Bimetric stem.

Study Population

Table 26-1: Patient Demographics

Number of Patients/Implants	635/691
Men/Women	266/369
Mean Age, Year	64.9

A total of 635 patients and 691 hip implants were operated and studied. The surgical approach is anterolateral for all cases. Six hundred and thirty-five patients received hip replacements on either side. There were slightly more females than males 369/635, 58.1% vs. 266/635, 41.9%, respectively. The mean age of the patient population was 64.9 years. The most common primary indications listed by the authors include arthrosis, secondary arthrosis due to dysplasia or chd and osteonecrosis. The number of patients presenting with each indication is shown below.

Table 26-2: The Most Common Primary indications

	# of cases(not patients)
Arthrosis	529
Secondary Arthrosis due to dysplasia or chd	80
Osteonecrosis	36
Total Cases	645

- *In this study there are 645 cases noted for the primary diagnosis and there are 635 patients, one can conclude that a few patents were diagnosed with more than one condition or that these are the 'most common' diagnoses.*

HHS

Table 26-3: HHS Data for M2a Magnum™

	Points
Pre operative	59.84
2-3 months post operation	86.38
1 year post operation	93.93

Adverse Event

Table 26-4: Adverse Events for M2a Magnum™

Event Description	# of occurrence	Subsequent Surgical Intervention (debridment, reoperation, revision)
Deep infection	9	9
Periprosthetic Femoral Fracture	9	9
Acetabular component malposition, fracture, or loosening	11	11
Nervous Glutealis Superior Lesion	1	
Rupture of Glutealis Medius Muscle	3	
Squeaking, complications to high metal ion release, ALVAL reaction or pseudotumor	0	
Nervous ischiadicus or luxation	0	
Total	33	29

There were 33 total complications for this study for M2a Magnum that is an occurrence rate of 4.8%.

The total number of revisions is unclear due to the unknown number of single open debridement procedures.

Redacted 4 pages - Study #28 description details and Tables
(b)(4) EXEMPTION - Trade Secrets, Commercial or Financial Information

(b) (4)

(b) (4)

(b) (4)

(b) (4)

Study #29
Swedish Hip Registry Data

Registry data from Sweden was gathered on the various designs of the Biomet MOM hips. The data found in the registry consisted of device usages, revision information.

Objective of Data Collection

The purpose of this data collection was to document the survivorship of the Biomet M2a hip systems. The survivorship analysis included the number of revisions and number of usage. Time points of revisions are not available.

Design

The data collection effort was conducted from 1999 to 2010 (dates of primary operations and revisions).

Data is collected on Biomet M2A Magnum, M2A 38mm and Stanmore M2A Acetabular system which is similar to M2A Ringloc.

Implant Usage and Revisions

Table 29-2 Implant Usage vs. Revisions

Type	Number of Cases	Revision	Raw Revision Rate (%)
M2A 38mm	318	7	2.2
M2A Magnum	234	4	1.71
Stanmore M2A Acetabular	7	0	0
TOTAL	559	11	1.97

Study #30
UK M2a Ringloc Liners™ Registry Data

Registry data from UK was gathered on the various designs of the M2A Ringloc Liners™ MOM hips. The data found in the registry consisted of patients demographics, devices usage, revision information, surviorships and deaths.

Objective of Data Collection

The purpose of this data collection was to document the survivorship of the Biomet M2a–Ringloc Liners™ Acetabular System. The survivorship analysis included details in the number of revisions and deaths and the reason for each revision.

Design

The data collection effort was conducted from 2004-2010 (dates of primary operations and revisions).

Study Population

Table 30-1: Patient Demographics

Number of Patients	59
Men/Women	19/40
Mean Age, Year (range)	66.23 (32-89)

A total of 59 patients were registered. The study consisted of 59 patients receiving replacement hips on either side. There were slightly more females than males 40/59, 67.8% vs. 19/59, 32.2%, respectively. The mean age of the patient population was 66.23 years, with a range of 32 years to 89 years. Indications included AVN, osteoarthritis, fractured femoral neck, failed internal fixation and FIN; fracture. The number of patients presenting with each indication is shown below.

Table 30-2: Primary indications for THA

AVN	1
Failed internal fixation	1
FIN; fractured	1
Fractured femor neck	3
Osteoarthritis	50
Reason Not Specified	3
Total	59

Revisions

Table 30-3: Revision Data for M2a–Ringloc Liner™

Indication for Revision	# of Revisions
Dislocation/Subluxation	1 (at 1 month postop)

A total of 1 revision was reported for the M2a-Ringloc Liners™ population, an occurrence rate of 1.7%.

Deaths

A total of 1 death were reported for the M2a–Ringloc liner™ population. The Registry does not elaborate on events surrounding patient deaths.

Survivorship

Table 30-4: Survivorship in Years for M2a–Ringloc Liner™

	Mean	(Range)
Unrevised	2.50	(.03-6.4)
Revised	.09	(.09)
Total	2.43	(.09-6.4)

Data is represented in years.

Table 30-5: Revision Rate for M2a–Ringloc Liner™

# of Hips	# of Revision	Revision Rate	Total Component Yr	Mean Survival in years	Revision per 100 CY
59	1	1.69%	143.15	2.43	0.7

Study #31
UK M2a 38™ Registry Data

Registry data from UK was gathered on the various designs of the M2A 38™ MOM hips. The data found in the registry consisted of patient demographic, device usages, revision information, survivorships and deaths.

Objective of Data Collection

The purpose of this data collection was to document the survivorship of the Biomet M2a–38mm Hip System. The survivorship analysis included details in the number of revisions and deaths and the reason for each revision.

Design

The data collection effort was conducted from 2005 to 2010 (dates of primary operations and revisions).

Study Population

Table 31-1. Patient Demographics

Number of Patients	1238
Men/Women	477/761
Mean Age, Year (range)	66.92 (31-92)

A total of 1238 patients were registered. The study consisted of patients receiving hip replacements to either side, left or right. There were more females than males 761/1238, 61.5% vs. 477/1243, 38.5%, respectively. The mean age of the patient population was 66.92 years, with a range of 31 years to 92 years. Indications included AVN, osteoarthritis, other inflammatory arthropathy, and osteoarthritis linked with other diseases. The number of patients presenting with each indication is shown below.

Table 31-2: Indications for THA

	# of Cases*
Ankylosing Spondylitis	2
AVN	12
AVN with fractured femor neck	1
Dislocation/Dysplasia	1
Failed Internal Fixation	1
Fractured Femor neck	3
Osteoarthritis	1221
Dislocation/Dysplasia	3
Perthes	1
Other Inflammatory Arthropathy	2
Seropositive Pheumatoid Arthritis	1
Reason not specified	9

**The number represented in this table is greater than the number of patients due to multiple diagnoses reported on some patients.*

Revisions

Table 31-3: Revision Data for M2a–38mm

Postoperative Time Points	< =1 month	<= 3 months	< 6m	<= 1 Yr	<= 2 Yr	<=5 Yr	>5yr	Not specified
Occurrence*								
Aspectic Loosening Socket	1			1	4	7		
Aspectic Loosening Stem				1	1			
Lysis				1	1			
Infection					3	3		
Pain	1			3	4	6		
Dislocation/Subluxation				3				
Malalignment Stem		1		1				
Implant fracture Head						1		
Periprosthetic Fracture Stem		1						
Not Specified						1		

**The total number of occurrence in this table is greater than the number of revisions due to multiple indications for revision reported on some patients.*

A total of 28 revisions were reported for the M2a-38mm™ population, an occurrence rate of 2.26%.

Deaths

A total of 28 deaths were reported for the M2a-38™ population. The Registry does not elaborate on events surrounding patient deaths.

Survivorship

Table 31-4: Survivorship in Years for M2a-38

	Mean (Range)
Unrevised	3.11 (.01-5.38)
Revised	1.87 (.05-4.89)
Total	3.06 (.01-5.37)

Table 31-5 Revision Rate for M2a-38

# of Hips	# of Revision of all causes	Revision Rate	Total Component Yr	Mean Survival in years	Revision per 100 CY
1238	28	2.3%	3789.34	3.06	0.74

The Journal of Arthroplasty Vol. 16 No. 8 Suppl. 1 2001

Short-Term Results of the M^2a-Taper Metal-on-Metal Articulation

Adolph V. Lombardi, Jr., MD* Thomas H. Mallory, MD,* Michael M. Alexiades, MD,† John M. Cuckler, MD,‡ Philip M. Faris, MD,§ Kenneth A. Jaffe, MD,‡ E. Michael Keating, MD,§ Carl L. Nelson, Jr., MD,‖ Chitranjan S. Ranawat, MD,†† Joseph Williams, MD,¶ Richard Wixson, MD,# Jodi F. Hartman, MS,* Susan G. Capps, PhD,** and Cheryl A. Kefauver, RN*

Abstract: A polyethylene-free, metal-on-metal acetabular system (M^2a-taper [Biomet, Inc., Warsaw, IN]) was designed in an effort to improve total hip arthroplasty (THA) longevity. Minimum 2-year follow-up results involving 72 polyethylene liner THAs and 78 metal liner THAs from a multicenter, randomized, controlled, investigational device exemption study are reported. Mean Harris hip scores of 95.54 (polyethylene liner group) and 95.23 (metal liner group) were reported at mean follow-up intervals of 3.29 and 3.23 years. Radiographic evaluation revealed no evidence of early failure. No acetabular components have been revised or are pending revision. No statistically significant differences in the data were calculated between liner types except for the immediate postoperative (P=.0415) and minimum 2-year follow-up (P=.0341) angles of inclination. The M^2a-taper metal-on-metal articulation may represent a viable alternative for THA in younger, higher demand patients. **Key words:** metal-on-metal, total hip arthroplasty, cementless, young patient, alternate bearing.

Historically a small percentage of the early metal-on-metal articulations in total hip arthroplasty (THA) functioned with great success [1–6]. These devices were studied closely to identify the characteristics of successful metal-on-metal articulations. The information gleaned from these investigations, combined with improved manufacturing techniques, has led to the resurgence of consideration of metal-on-metal articulations in THA. In response to this renewed interest, the M^2a-taper metal-on-metal articulation (Biomet, Inc., Warsaw, IN) was designed.

During initial research and development, hip simulator testing revealed extremely low volumetric wear for the M^2a-taper metal-on-metal articulation at a steady state of 2.20 mm^3 per 3 million cycles compared with 83.66 mm^3 per 3 million cycles in a metal-ArCom (Biomet, Inc., Warsaw, IN) polyethylene articulation. Fatigue testing involving cyclic loading of ≤1000 lb. for 10 million cycles revealed no evidence of fretting in the M^2a-taper articulation. The M^2a-taper metal-on-metal articulation had 97.4% less volumetric wear than the

*From the *Joint Implant Surgeons, Inc., The Ohio State University, The Ohio Orthopaedic Institute, Grant Medical Center, Columbus, Ohio; †Lennox Hill Hospital, The Hospital for Special Surgery, New York, New York; ‡University of Alabama at Birmingham, Birmingham, Alabama; §Kendrick Memorial Hospital, Mooresville, Indiana; ‖University of Arkansas for Medical Sciences, Arkansas Rehabilitation Hospital, John L. McClellan Memorial VA Medical Center, Arkansas Children's Hospital, Doctor's Hospital, Little Rock, Arkansas; ¶St. John's Mercy Hospital, St. Louis, Missouri; #Northwestern Memorial Hospital, Chicago, Illinois; **BENSOL–Biological Engineering Solutions, Warsaw, Indiana; and ††Lennox Hill Hospital, Ranawat Orthopaedic Center, Inc., New York, New York.*

Funds were received in support of the research material described in this article from Biomet, Inc.

Reprint requests: Adolph V. Lombardi, Jr., MD, FACS, Joint Implant Surgeons, Inc., 720 East Broad Street, Columbus, OH 43215. E-mail: LombardiAV@Ortholink.net

0883-5403/01/1608-1022$35.00/0
doi:10.1054/arth.2001.29307

metal-ArCom polyethylene articulation ($P<.00003$) (product brochure, Biomet, Inc., Warsaw, IN, 2000). These promising *in vitro* results led to the submission of an investigational device exemption study to the U.S. Food and Drug Administration. This multicenter prospective study was performed to evaluate the safety and efficacy of the M²a-taper metal-on-metal articulation at a 2-year minimum follow-up.

Materials and Methods

Design Description

The M²a-taper metal-on-metal articulation (Fig. 1) consists of specific acetabular metal shells, tapered inserts, and modular femoral heads. The substrate material of the tapered inserts and modular femoral heads is cobalt-chromium-molybdenum (ASTM F1537). The liner and shell have a taper angle of 18°. The tapered insert is impacted into either of 2 specifically designed titanium shells, the Mallory-Head Radial Solid Shell with Apical Hole (Biomet, Inc., Warsaw, IN) or the Universal 2-Hole Acetabular Shell (Biomet, Inc.). The outer tapered surface of the liner is roughened (Ra 150) to increase the locking strength. The average push-out strength is 612 lb. The modular femoral heads used have a diameter of 28 mm, which provides a range of motion of 126°, and are available with neck length options of −6, −3, standard, +3, +6, +9, and +12 mm. The radial clearance of the head and liner ranges from 25 to 75 μ. The surface finish is <0.05 μ, and the sphericity is <5 μ. The minimal thickness of the shell is 2.5 mm and the liner is 4.5 mm. There is no polyethylene within the articulation. All of the devices undergo quality control. Air gauge methods are used to determine the accuracy of taper angles, a coordinate measuring machine is used to check the radius, and the sphericity and surface finish are determined by laser interferometry.

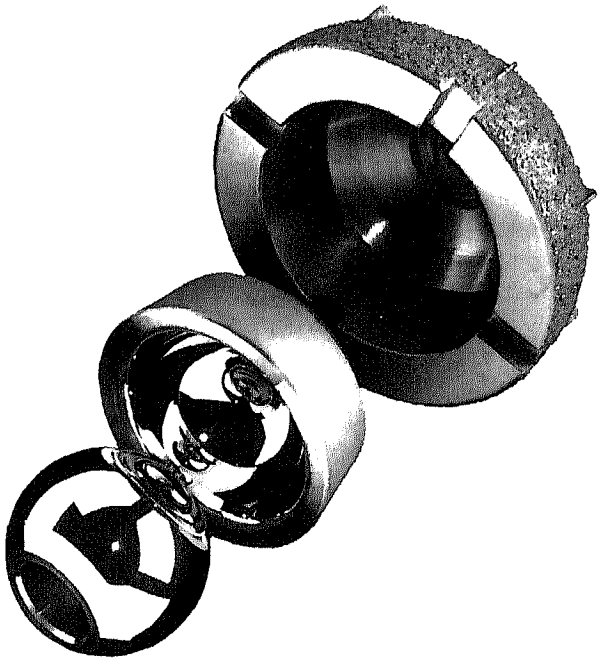


Fig. 1. The M²a-taper metal-on-metal articulation (Biomet, Inc., Warsaw, IN) is polyethylene-free, featuring specific titanium acetabular shells, cobalt-chrome-molybdenum inserts and modular femoral heads, and an 18° taper angle of the liner and shell.

Original Investigational Device Exemption Study Design

The 11 investigators who participated in the original investigational device exemption study, which began December 1995 and enrolled through November 1999, elected to participate in this present prospective study. The original study enrolled 192 patients (194 THAs) in a randomized controlled fashion. Ninety-five patients (95 THAs) randomized into a control group that received ArCom polyethylene liners were compared with 95 patients (95 THAs) randomized into the investigational group that received the metal liner. Additionally, 2 patients who underwent bilateral THA received a polyethylene liner on one side and a metal liner on the contralateral side. Candidates for conventional THA were included in the study; patients with rheumatoid arthritis, severe preoperative deformity, infection, marked osteopenia, Parkinson's disease, vascular insufficiency, and muscular atrophy or neuromuscular disease in the affected limb were excluded from the study.

Patient Selection

Of the 192 patients (194 THAs) enrolled in the randomized controlled study, 149 patients (150 THAs) have a minimum 2-year follow-up with a corresponding Harris hip score assessment. Of THAs, 72 were performed with polyethylene liners, and 78 were performed with metal liners. Four patients (5 THAs) died before the 2-year follow-up. Ten patients (10 THAs) were not yet due for 2-year follow-up, 21 patients (21 THAs) had a most recent follow-up of 1 year, and 5 patients (5 THAs) had a most recent follow-up of 6 months. Three patients (3 THAs) had only perioperative follow-up. Patient

Table 1. Demographics and Preoperative Harris Hip Scores, Polyethylene Liner Versus Metal Liner Groups

	Polyethylene Liner (n = 72)	Metal Liner (n = 78)
Age (y)	48.92 ± 1.43 (18–77)	49.33 ± 1.06 (26–73)
Body mass index*	28.71 ± 0.59 (18.55–40.93)	29.10 ± 0.61 (19.87–53.70)
Gender		
Males	55 (76.4%)	58 (74.4%)
Females	17 (23.6%)	20 (25.6%)
Side		
Left	41 (56.9%)	34 (43.6%)
Right	31 (43.1%)	44 (56.4%)
Charnley classification		
A	51 (70.8%)	60 (76.9%)
B	17 (23.6%)	13 (16.7%)
C	4 (5.6%)	5 (6.4%)
Primary diagnosis		
Avascular necrosis	13 (18.0%)	10 (12.8%)
Diastrophic variant	0 (0.0%)	1 (1.3%)
Legg-Calvé-Perthes disease	0 (0.0%)	2 (2.6%)
Osteoarthritis	52 (72.2%)	58 (74.4%)
Slipped capital epiphysis	2 (2.8%)	1 (1.3%)
Traumatic arthritis	5 (6.9%)	6 (7.7%)
Preoperative Harris hip scores		
Total	53.37 ± 1.39 (20–81)	52.82 ± 1.52 (20–81)
Pain	16.53 ± 0.89 (0–40)	16.47 ± 0.90 (0–44)
Function	29.38 ± 0.78 (12–41)	29.17 ± 0.96 (4–47)

NOTE. Values are mean ± SE (range). SE uses a pooled estimate of error variance.
*(Weight/height^2) × 703.

demographics, including age, body mass index, gender, operative side, Charnley classification, primary diagnosis, and preoperative Harris hip scores are presented in Table 1.

Clinical Assessment

The Harris hip score [7] was used as a means of clinical assessment for preoperative and postoperative follow-up evaluations. The Harris hip total score, pain component, and function component were analyzed independently. As a requirement for the investigational device exemption study, non–device-related orthopaedic complications were recorded. Failure, defined as aseptic loosening or revision of the acetabular component, also was monitored.

Radiographic Evaluation

Radiographic assessment of the femoral and acetabular components was performed independently by each investigational site. Charnley classification [8] was determined preoperatively. With respect to the femoral component, postoperative radiographs were evaluated for stem position change, stem subsidence, stress shielding, cortical hypertrophy, anteroposterior and lateral radiolucencies, and endosteal osteolysis [9,10]. Acetabular radiolucencies were noted in each of the 3 zones of DeLee and Charnley [8]. Acetabular migration was assessed in the medial and superior direction, using the technique described by Kennedy et al [11].

Statistical Analysis

An independent statistician analyzed all data using the JMP Statistical Discovery Software (SAS Institute, Cary, NC). Pearson's chi-square analysis was used to compare categorical variables. One-way analysis of variance was used to compare categorical and continuous variables using the Student's *t*-test. The Tukey-Kramer test was used to determine significance between means. Ninety-five percent confidence intervals were used throughout the analysis.

Results

Demographics and Preoperative Evaluation

There were no statistically significant differences between the polyethylene and metal liner groups in terms of demographics and preoperative Harris hip scores, supporting the randomization process of the original study and suggesting that the comparison of outcomes between the groups is appropriate and accurate.

Clinical Assessment

At a mean follow-up of 3.29 ± 0.13 years (range, 1.64–5.40 years), a mean total Harris hip score of 95.54 ± 1.41 points (range, 39–100 points) was calculated for the polyethylene liner group. A mean total Harris hip score of 95.23 ± 1.11 points (range, 65–100 points) was calculated for the metal liner group at a mean follow-up of 3.23 ± 0.12 years (range, 1.88–5.20 years). The mean follow-up Harris hip pain score was 41.08 ± 0.77 points (range, 10–44 points) for the polyethylene liner group and 40.99 ± 0.65 points (range, 20– 44points) for the metal liner group. The mean Harris hip function score at follow-up was 44.13 ± 0.64 points (range, 21–47 points) for the polyethylene group and 44.60 ± 0.51 points (range, 28–47 points) for the metal liner group. No statistically significant differences in minimum 2-year follow-up total Harris hip scores, pain components, and function components were calculated between the polyethylene and metal liner groups.

Radiographic Evaluation

No statistically significant differences between the polyethylene and metal liner groups were observed at the minimum 2-year follow-up for any of the femoral radiographic variables evaluated, including femoral component position change, subsidence, endosteal osteolysis, radiolucencies, cortical hypertrophy, and bone resorption. With respect to the acetabular component, the mean angle of inclination was 43.96 ± 0.71° (range, 27.00–60.00°) at the immediate postoperative evaluation and 43.98 ± 0.95° (range, 22.00–55.00°) at the minimum 2-year follow-up evaluation for the polyethylene liner group. In the metal liner group, the mean angle of inclination was 41.69 ± 0.83° (range, 12.00–58.00°) at the immediate postoperative evaluation and 41.14 ± 0.90° (range, 12.00–60.00°) at the minimum 2-year follow-up evaluation. Statistically significant differences for the immediate postoperative (P=.0415) and minimum 2-year follow-up (P=.0341) angles of inclination were calculated between the liner groups. There was no statistically significant difference between the liner groups, however, in terms of the change in angle of inclination from the immediate postoperative to the minimum 2-year follow-up evaluations. The acetabular zonal radiolucency incidence for the polyethylene liner group was 0 (0.0%) in zone 1, 1 (2.2%) in zone 2, and 0 (0.0%) in zone 3. The acetabular zonal radiolucency incidence for metal liner group was 0 (0.0%) in zone 1, 0 (0.0%) in zone 2, and 1 (1.7%) in zone 3. The 2 THAs in which radiolucencies were observed both had measurements of <1 mm. Superior migration was not observed in either the polyethylene or the metal liner groups. No medial migration was observed in either liner group except for 1 metal liner THA with a medial migration of 1 mm. No statistically significant differences were observed for either acetabular migration or radiolucency incidence between the metal and polyethylene liner groups at the minimum 2-year follow-up. Fig. 2 illustrates midterm stable fixation of the polyethylene and the metal liners in a bilateral THA patient at 5-year postoperative follow-up.

Complications

Non–device-related orthopaedic complications were recorded in the original investigational device exemption study population of 194 THAs (97 metal liners, 97 polyethylene liners). The following non–device-related orthopaedic complications were recorded for the polyethylene liner group: 1 (1.0%) hematoma and 1 (1.0%) revision of a femoral component owing to persistent thigh pain and minimal bone integration. Non–device-related orthopaedic complications included the following for the metal liner group: 3 (3.1%) dislocations, 1 (1.0%) iliopsoas bursitis, 1 (1.0%) periprosthetic femoral fracture, 2 (2.2%) motor vehicle accidents/soft tissue contusions, 1 (1.0%) superficial wound infection, 1 (1.0%) persistent thigh pain secondary to Paget's disease, and 1 (1.0%) wound dehiscence. Of the 3 dislocations in the metal liner group, 2 were considered early dislocations, occurring at 2 weeks and 3 months after surgery. At the time of dislocation, component position was judged satisfactory; both dislocations were treated with closed reduction. No recurrent dislocations have been reported at 3-year and 1-year follow-up evaluations. The remaining dislocation involving a metal liner occurred at 5 months after surgery and recurred at 1 year postoperatively. Because component position was considered satisfactory, both episodes were treated with closed reduction. No additional dislocations have been reported at a follow-up of 2 years.

Discussion

Metal-on-metal devices originally were available at the time of the introduction of the Charnley prosthesis. According to Amstutz and Grigoris [12], however, the use of these articulations was dismissed because of the combination of high frictional torque of some metal-on-metal bearings secondary

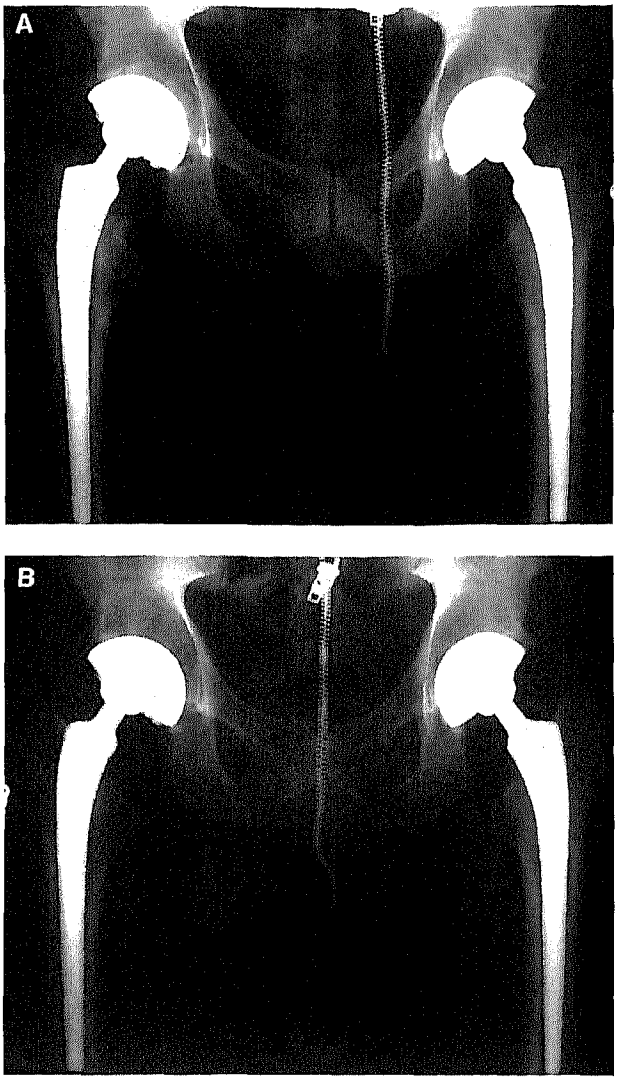


Fig. 2. (A) Immediate postoperative radiograph of a 51-year-old male patient who presented with bilateral osteoarthritis of both hips and status post left total knee arthroplasty performed 5 years previously. The radiograph reveals treatment consisting of bilateral cementless total hip arthroplasty using a Mallory-Head Porous femoral component (Biomet, Inc., Warsaw, IN) in both hips, a Mallory-Head Radial acetabular component (Biomet, Inc.) with the M^2a-taper metal-on-metal articulation on the left side, and a Mallory-Head Solid Porous acetabular component (Biomet, Inc.) with an ArCom polyethylene liner (Biomet, Inc.) on the right side. (B) Radiograph at 5-year postoperative follow-up reveals similar features of excellent fixation and components in satisfactory position and alignment, with identical Harris hip scores of 96 points for each side.

to inferior manufacturing techniques and the concerns regarding metal sensitivity and possible carcinogenesis at a time when the Charnley technique was experiencing impressive early success. The retrieval analysis performed on implants that had been *in situ* after a mean of 21.3 years by Schmalzried et al [13] reported a worst-case estimate of combined femoral and acetabular linear wear of 4.2 μ/y, which is approximately 25 times less than that seen with polyethylene. Additional retrieval analyses have reported average linear wear of rates of 2.0 to 6.60 μ [14–17]. These authors documented a relatively small inflammatory component in the pseudocapsular tissue.

In a review of the effects of the metal versus polyethylene wear particles in THA, Doorn et al [18] stated that no immunologic, toxic, or carcinogenic effects resulting from metallic particles or ions in patients with cobalt-based metal-on-metal THAs have been documented in the literature. Several studies have raised concerns, however, regarding the long-term potential effects of increased metallic particles and associated ionic metal concentrations [19–24]. Jacobs et al [25,26] identified elevated chromium concentrations in the serum and the urine of patients with metal-on-metal THAs, in addition to increased cobalt concentrations in the serum. These authors stressed that the toxicologic importance of these trace metal elevations has not been documented clearly and suggested further careful clinical evaluation. Gillespie et al [27] and Visuri et al [28] evaluated potential carcinogenicity and were unable to determine any statistical correlation of tumor formation with metal-on-metal articulations.

In the absence of concrete data to suggest harmful sequelae from metal-on-metal articulations, a reintroduction of this concept was initiated by Weber and Muller with the development of the Metasul (Sulzer Medica Technology, Winthur, Switzerland) THA bearing [29]. More than 100,000 Metasul bearings have been implanted with a variety of Sulzer femoral components [29]. Wagner and Wagner [30] reported on 78 uncemented THAs performed with the Metasul metal-on-metal articulation with a mean follow-up of 60 months. Fifty patients received an acetabular component in which polyethylene was placed between the actual metal liner and the metallic shell, whereas 28 patients received a polyethylene-free, nonmodular, cementless component. No revision for aseptic loosening was performed, but 3 hips were revised. One revision was due to dislocation, and the other 2 revisions were due to heterotopic ossification, with no metallosis identified at any revision. No differences were reported between the polyethylene and polyethylene-free prostheses. In another study, Dorr et al [31] reported the results from 56 patients

(56 THAs) performed with the Metasul metal-on-metal articulation and a cemented Weber (Sulzer Medica Technology, Winthur, Switzerland) shell. Three patients required revision THA; 1 hip was revised because of aseptic loosening and 2 were revised to treat recurrent dislocation. The Harris hip score for the remaining 53 patients at an average follow-up of 5.2 years was 89.9 points. Histologic evaluation revealed the presence of polyethylene particulate debris.

The M^2a-taper metal-on-metal articulation is modular and polyethylene-free. According to Streicher [32], the incorporation of polyethylene into the metal-on-metal articulation construct introduces the risk of polyethylene debris production and aging and degradation of the polymer. Streicher [32] and Wagner and Wagner [30] did not believe that the presence of polyethylene in the Metasul design is necessary to serve as a shock absorber or dampening effect.

Although not statistically significant, 3 dislocations occurred in the metal liner group compared with no dislocations in the polyethylene liner group. Dislocation also was reported in the study by Dorr et al [31], requiring component revision for treatment. These findings stress the importance of careful component positioning when performing metal-on-metal THA. Another consideration is the use of larger head diameters, which increase the effective range of motion, decreasing dislocations secondary to neck impingement.

The short-term results reported on the M^2a-taper metal-on-metal articulation are encouraging. No significant differences were observed in the clinical or radiographic minimum 2-year follow-up between patients with metal-on-polyethylene versus metal-on-metal articulations. The Food and Drug Administration has approved the device for general use, and it is currently available in 28-mm and 32-mm head sizes. In light of our concerns regarding the longevity of THA with conventional metal-on-polyethylene or ceramic-on-polyethylene articulations, the results of this study have encouraged us to proceed cautiously with this metal-on-metal articulation in younger, higher demand patients.

References

1. Bentley G, Duthie RB: Comparative review of the McKee-Farrar and Charnley total hip prostheses. Clin Orthop 95:127, 1973
2. Freeman PA: McKee-Farrar total replacement of the hip joint in rheumatoid arthritis and allied conditions. Clin Orthop 70:106, 1970
3. Patterson FP, Brown CS: The McKee-Farrar total hip replacement: Preliminary results and complication of 368 operations performed in five general hospitals. J Bone Joint Surg Am 54:257, 1972
4. Postel M, Kerboull M: Total prosthetic replacement in rapidly destructive arthrosis of the hip. Clin Orthop 72:138, 1970
5. Wilson PD, Amstutz HC, Czerniecki A, et al: Total hip replacement with fixation by acrylic cement: A preliminary study of 100 consecutive McKee-Farrar prosthetic replacement. J Bone Joint Surg Am 54:207, 1972
6. Zahiri CA, Schmalzried TP, Ebramzadeh E, et al: Lessons learned from loosening of the McKee-Farrar metal-on-metal total hip replacement. J Arthroplasty 14:326, 1999
7. Harris WH: Traumatic arthritis of the hip after dislocation and acetabular fractures: Treatment by mold arthroplasty. J Bone Joint Surg Am 51:737, 1969
8. DeLee JG, Charnley J: Radiological demarcation of cemented sockets in total hip replacement. Clin Orthop 121:20, 1976
9. Gruen TA, McNiece GM, Amstutz HC: "Modes of failure" of cemented stem-type femoral components: A radiographic analysis of loosening. Clin Orthop 141:17, 1979
10. Johnston RC, Fitzgerald RH, Harris WH, et al: Clinical and radiographic evaluation of total hip replacement: A standard system of terminology for reported results. J Bone Joint Surg Am 72:161, 1990
11. Kennedy JF, Rogers WB, Soffe KE, et al: Effect of acetabular component orientation on recurrent dislocation, pelvic osteolysis, polyethylene wear, and component migration. J Arthroplasty 13:530, 1998
12. Amstutz HC, Grigoris P: Metal-on-metal bearings in hip arthroplasty. Clin Orthop 329(suppl):S11, 1996
13. Schmalzried TP, Peters PC, Maurer BT, et al: Long-duration metal-on-metal total hip arthroplasties with low wear of the articulating surfaces. J Arthroplasty 11:322, 1996
14. Kothari M, Bartel DL, Booker JF: Surface geometry of retrieved McKee-Farrar total hip replacements. Clin Orthop 329(suppl):S141, 1996
15. McKellop H, Park SH, Chiesa R, et al: In vivo wear of three types of metal on metal hip prostheses during two decades of use. Clin Orthop 329(suppl):S128, 1996
16. Schmidt M, Weber H, Schon R: Cobalt chromium molybdenum metal combination for modular hip prostheses. Clin Orthop 329(suppl):S35, 1996
17. Willert HG, Buchhorn GH, Gobel D, et al: Wear behavior and histopathology of classic cemented metal on metal hip endoprotheses. Clin Orthop 329(suppl):S160, 1996
18. Doorn PF, Campbell PA, Worrall J, et al: Metal wear particle characterization from metal on metal total hip replacements: Transmission electron microscopy study of periprosthetic tissues and isolated particles. J Biomed Mater Res 42:103, 1998
19. Black J, Jacobs JJ: Materials for alternative bearings: Biological considerations. Semin Arthroplasty 9:157, 1998
20. Brodner W, Bitzan P, Meisinger V, et al: Elevated

serum cobalt with metal-on-metal articulating surfaces. J Bone Joint Surg Br 79:316, 1997
21. Case CP, Langkamer VG, Howell RT, et al: Preliminary observations on possible premalignant changes in bone marrow adjacent to worn total hip arthroplasty implants. Clin Orthop 329(suppl):S269, 1996
22. Doorn PF, Mirra JM, Cambell PA: Tissue reaction to metal on metal total hip prostheses. Clin Orthop 329(suppl):S187, 1996
23. Jacobs JJ, Gilbert JL, Urban RM: Corrosion of metal orthopaedic implants. J Bone Joint Surg Am 80:268, 1998
24. Urban RM, Jacobs JJ, Tomlinson MJ, et al: Dissemination of wear particle to the liver, spleen, and abdominal lymph nodes of patients with hip or knee replacement. J Bone Joint Surg Am 82:457, 2000
25. Jacobs JJ, Skipor AK, Doorn PF, et al: Cobalt and chromium concentrations in patients with metal on metal total hip replacements. Clin Orthop 329 (suppl):S256, 1996
26. Jacobs JJ, Skipor AK, Patterson LM, et al: Metal release in patients who have had a primary total hip arthroplasty: A prospective, controlled, longitudinal study. J Bone Joint Surg Am 80:1447, 1998
27. Gillespie WJ, Henry DA, O'Connell DL, et al: Development of hematopoietic cancers after implantation of total joint replacement. Clin Orthop 329(suppl): S290, 1996
28. Visuri T, Pukkala E, Paavolainen P, Pulkkinen P, Riska EB: Cancer risk after metal on metal and polyethylene on metal total hip arthroplasty. Clin Orthop 329(suppl):S280, 1996
29. Schmalzried TP: Metal-on-metal: Historical perspectives and lessons learned through retrieval studies. Semin Arthroplasty 9:135, 1998
30. Wagner M, Wagner H: Medium-term results of a modern metal-on metal system in total hip replacement. Clin Orthop 379:123, 2000
31. Dorr LD, Wan Z, Longjohn DB, et al: Total hip arthroplasty with use of the Metasul metal-on-metal articulation: Four- to seven-year results. J Bone Joint Surg Am 82:789, 2000
32. Streicher RM: The case for using metal-on-metal. J Arthroplasty 13:343, 1998

Mid-Term Results of a Polyethylene-Free Metal-on-Metal Articulation

Adolph V. Lombardi, Jr., MD, FACS,* Thomas H. Mallory, MD,* John M. Cuckler, MD,† Joseph Williams, MD,‡ Keith R. Berend, MD,* and Thomas M. Smith, DO*

Abstract: Beginning in December 1995, 193 patients (195 hips) were enrolled into this prospective, randomized, controlled multicenter investigational device exemption study. Ninety-eight patients (99 hips) with 46 polyethylene liners and 53 metal liners had minimum 5-year follow-up (mean, 5.7 years). Average follow-up, Harris hip score improvement, and radiographic analysis were not statistically different between groups. No stress shielding or osteolysis was observed in either group. Three polyethylene liners and no metal liners had acetabular radiolucencies <1 mm in 1 or more zones. There have been no device-related complications, no acetabular revisions performed, and none pending in either group. Based on these mid-term results, the authors conclude that a metal-on-metal articulation represents a viable alternative in young, high-demand, active patients. **Key words:** total hip arthroplasty, metal-on-metal, articulation, outcomes, survivorship, polyethylene-free.

The nature of the articulating surfaces in total hip arthroplasty (THA) has been the subject of current major debate. Despite the fact that metal-on-metal articulating surfaces have been used for well over 40 years in THA, controversy over their efficacy continues to exist. Multiple manuscripts have documented the short- and long-term success of both the first- and second-generation metal-on-metal articulations [1–15]. We have previously reported the short-term results of a polyethylene-free metal-on-metal articulation for use in THA [1]. The purpose of the current manuscript is to present the mid-term, minimum 5-year follow-up, results of this articulation.

*From *Joint Implant Surgeons, Inc., New Albany Surgical Hospital, The Ohio State University, Columbus, Ohio, †University of Alabama at Birmingham, Birmingham, Alabama, and ‡St. John's Mercy Medical Center, St. Louis, Missouri.*

Benefits or funds were received in partial or total support of the research material described in this article. These benefits or support were received from Biomet Orthopedics, Warsaw, Indiana.

Reprint requests: Adolph V. Lombardi, Jr., MD, FACS, Joint Implant Surgeons, Inc., 720 East Broad Street, Columbus, OH 43215.

0883-5403/04/1907-2008$30.00/0
doi:10.1016/j.arth.2004.06.016

Materials and Methods

Device Description

The device used is the M^2a Taper Metal-on-Metal Articulation (Biomet Orthopedics, Warsaw, IN), the design and attributes of which have been previously described [1]. The articulation diameter used in the current study is 28 mm, which provides a range of motion of 126° prior to prosthetic impingement (Fig. 1).

Original Investigational Device Exemption Study Design

Eleven investigators participated in the original investigational device exemption study, which began December 1995 and enrolled through Novem-

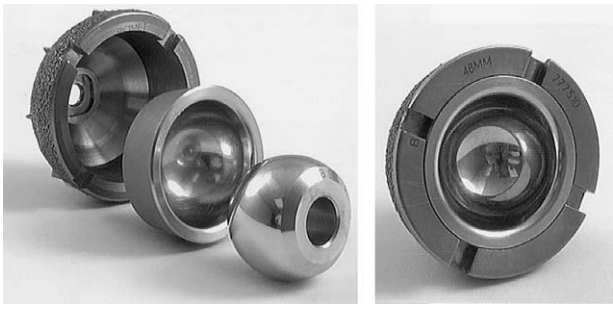


Fig. 1. Photograph showing the M^2a Taper Metal-on-Metal Articulation (Biomet Orthopedics), a porous-coated titanium acetabular shell with modular taper cobalt-chrome-molybdenum insert.

ber 1999. This study enrolled 192 patients (194 total hips) in a randomized controlled fashion and 1 patient (1 hip) was added under IDE verification for 195 hips in 193 patients. Ninety-five patients (95 total hip arthroplasties) were randomized into a control group that received ArCom polyethylene liners (Biomet). These were compared with 96 patients (96 total hips) randomized into the investigational group that received the polyethylene-free articulation with the metal liner. Additionally, 2 patients who underwent bilateral THA received a polyethylene liner on 1 side and a metal liner on the contralateral side. Of the 193 patients (195 total hips) enrolled in the study, 98 patients (99 total hips) have a minimum 5-year follow-up (average, 5.7 years, range, 5–8 years). Of these total hip arthroplasties, 53 were performed with metal liners and 46 were performed with polyethylene liners. Eleven patients (12 total hip arthroplasties) expired before the 5-year follow-up. Twenty-five patients (25 total hip arthroplasties) have a minimum 4-year follow-up. Twenty-seven patients (27 total hip arthroplasties) have a minimum 3-year follow-up. Twenty-one patients (21 total hip arthroplasties) have a minimum 2-year follow-up and 11 patients (11 total hip arthroplasties) have less than the minimum 2-year follow-up. Patient demographics, including age, body mass index, gender, and operative side; primary diagnosis; and preoperative Harris hip scores for the minimum 5-year follow-up study group are presented in Table 1.

Clinical Assessment

The Harris hip score was used as a means of clinical assessment for preoperative and postoperative follow-up evaluations [16]. As a requirement for the investigational device exemption study, non-device-related orthopedic complications were recorded. Failure, defined as aseptic loosening, revision, or pending revision of an acetabular or femoral component was also monitored and is reported.

Radiographic Evaluation

Radiographic assessment of the femoral and acetabular components was performed independently

Table 1. Demographics and Preoperative Harris Hip Scores, Polyethylene Liner Versus Metal Liner Groups

	Polyethylene Liner (n = 46)	Metal Liner (n = 53)
Age (ys)	50.90 ± 10.87 (18–75)	50.31 ± 9.94 (31–78)
Body mass index [(wt/ht^2)×703]	28.85 ± 4.87 (18.55–40.93)	29.35 ± 4.32 (21.82–41.19)
Sex		
Males	33 (71.7%)	41 (77.4%)
Females	13 (28.3%)	12 (22.6%)
Side		
Left	25 (54.3%)	20 (37.7%)
Right	21 (45.7%)	33 (62.3%)
Primary diagnosis		
Avascular necrosis	9 (19.6%)	6 (11.3%)
Diastrophic variant	0 (0.0%)	1 (1.9%)
Legg-Calvé-Perthes	0 (0.0%)	2 (3.8%)
Osteoarthritis	32 (69.6%)	40 (75.5%)
Slipped capital epiphysis	0 (0.0%)	1 (1.9%)
Traumatic arthritis	5 (10.9%)	3 (5.7%)
Preoperative Harris hip scores		
Total	53.82 ± 11.25 (30–82)	54.72 ± 12.69 (21–82)
Pain	16.74 ± 7.01 (10–40)	17.58 ± 7.63 (10–44)
Function	29.43 ± 6.93 (12–41)	29.56 ± 8.60 (4–45)

NOTE. Values are mean ± standard deviation (range).

by each investigational site. Complete radiographic evaluation in the subset of patients with minimum 5-year follow-up was available and reviewed for 44 hips in 43 patients, with 22 control polyethylene liner hips and 22 study metal-on-metal hips. With respect to the femoral component, postoperative radiographs were evaluated for stem position change, stem subsidence, stress shielding, cortical hypertrophy, anterior posterior and lateral radiolucencies, and osteolysis according to the zones of Gruen et al. [17]. Acetabular radiolucencies in the presence or absence of osteolysis were noted in each of the 3 zones of DeLee and Charnley [18]. Acetabular migration was assessed in the medial superior direction using the technique described by Kennedy et al. [19].

Statistical Evaluation

Routine analysis of frequencies, percentages, averages, and standard deviations on the available data was performed using StatsDirect (StatsDirect, Ashwell, England). The Students' t-test was performed for comparisons of means between groups and chi-squared was used for analysis of categorical variables.

Results

Demographics and Preoperative Evaluation

No statistically significant differences between the polyethylene and metal liner groups in terms of demographics and preoperative Harris hip score were noted. These data support the accuracy of the randomization process and validate comparison of outcomes between the groups.

Clinical Assessment

At a mean follow-up of 5.7 years (range, 5–8), a mean total Harris hip score of 94.31 ± 7.39 points (range, 62.5–100.0) was calculated for the polyethylene liner group. A mean total Harris hip score of 93.1 ± 8.32 points (range, 68.9–100.0) was calculated for the metal liner group at a mean follow-up of 5.7 years (range, 5–8). No statistically significant differences in follow-up intervals or total Harris hip scores were calculated between the polyethylene and metal liner groups.

Radiographic Evaluation

No statistical significance between the polyethylene and metal liner groups was observed at a minimum 5-year follow-up for any of the femoral radiographic variables evaluated. All components were observed to be well fixed and stable without change of position or progressive radiolucencies. One hip in each group showed 1 mm of nonprogressive subsidence. Two hips in the study metal liner group and none in the control group showed distal stem pedestal formation consisting of streaming trabeculae from the tip to the endosteal cortex. Both stems appeared well fixed. One metal study hip demonstrated femoral resorption in AP zone 7, which was nonprogressive. No hips showed endosteal erosion or osteolysis. There were 3 femoral components in the control polyethylene liner group with nonprogressive, limited radiolucencies and 1 femoral stem in the study metal liner group. With the limited number of femoral stems available for review, no statistical significance was found between femoral radiographic outcome measures.

With respect to the acetabular component, the mean angle of inclination was 42.1° (SD 4.3) at immediate postoperative evaluation and 42.1 (SD 6.0) at the minimum 5-year follow-up evaluation for the polyethylene liner group. In the metal liner group, the mean angle of inclination was 42.0 degrees (SD 10.6) at the immediate postoperative evaluation and 40.8° (SD 10.0) at the minimum 5-year follow-up evaluation. There were no acetabular radiolucencies noted on any minimum 5-year radiographs in either the study or the control group. Acetabular superior migration was not observed in either the polyethylene or metal liner groups. One metal liner total hip arthroplasty, with a medial migration of 1 mm at the 2-year follow-up, demonstrated no further migration. No other acetabular components in either the study metal liner group or the polyethylene control hips demonstrated any migration or change of position. No acetabular osteolysis was noted in either the metal or polyethylene liner groups. With the limited numbers available, no differences were noted statistically in any of the acetabular radiographic parameters. Figure 2 illustrates the immediate postoperative and 7-year follow-up radiographs of a bilateral total hip arthroplasty patient.

Complications

The non–device-related orthopedic complications have been previously presented [1]. Dislocation occurred and was reported in the original manuscript in 3 patients. These patients were man-

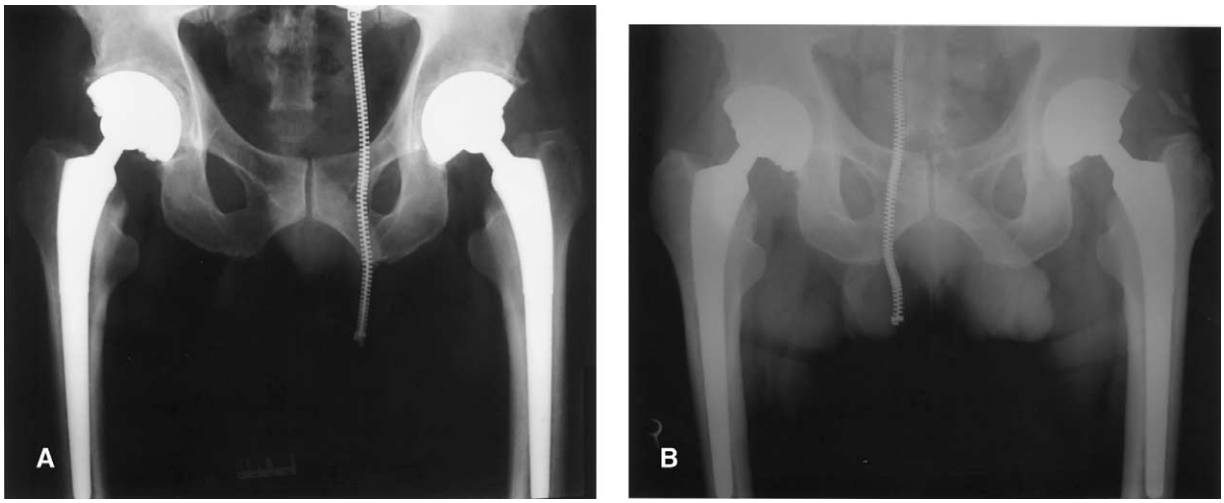


Fig. 2. (A) Immediate postoperative x-ray of a 51-year-old male patient who presented with bilateral osteoarthritis of both hips and status post left total knee arthroplasty performed 5 years previously. He underwent bilateral cementless total hip arthroplasty utilizing a Mallory-Head Porous femoral component (Biomet Orthopedics) in both hips, a Mallory-Head Radial acetabular component (Biomet Orthopedics) with the M^2a Taper Metal-on-Metal Articulation (Biomet Orthopedics) on the left side, and a Mallory-Head Solid Porous acetabular component (Biomet Orthopedics) with an ArCom polyethylene line (Biomet Orthopedics) on the right side. (B) The x-ray at 7-year postoperative follow-up reveals excellent fixation, components in satisfactory position, and alignment on both sides. There is a slight penetration of the femoral head into the polyethylene liner, but this penetration has been a stable finding and does not appear to be progressive wear.

aged without surgery, and no recurrent dislocations have occurred since the original report. No additional dislocations or device-related complications have been identified.

Discussion

The durability and efficacy of metal-on-metal articulations in total hip arthroplasty remains a matter of heated debate. Long-term survivorship of the McKee Farrar total hip prosthesis has been reported to be 84% at 20 years and 74% at 28 years [13]. This certainly compares favorably with the 65% to 84% survivorship of Charnley low-friction arthroplasties at 20 to 30 years [20–22]. In a 20-year survivorship analysis, Jacobson et al. reported a survivorship of 77% in 170 consecutive McKee Farrar arthroplasties and 73% for a similar population of Charnley arthroplasties [14]. Reporting on second-generation metal-on-metal articulations, Dorr et al. initially reported excellent 4- to 7-year survivorship and lack of significant wear [12]. The same group is now reporting a 98.8% ± 1.1% survivorship at 11 years for revision for loosening as the end point and a 96.1% ± 1.9% survivorship at 11 years for revision for any reason as the end point [23]. The current study reveals a 100% survivorship at mid-term follow-up of 5 years for a second-generation polyethylene-free metal-on-metal articulation.

The recent resurgence of enthusiasm in metal-on-metal articulation stems from the desire to avoid failure secondary to osteolysis as a result of severe polyethylene particulate debris. Numerous publications reporting short- to long-term follow-up of both first- and second-generation metal-on-metal articulations document that significant osteolysis does not occur with these articulations [1–12, 13, 14, 24]. The wear rates of metal-on-metal articulations have been shown to be significantly less than those of metal-on-polyethylene as a result of the tribiological behavior of metal-on-metal articulations [8, 10, 15, 24–27].

The Achilles' heel of metal-on-metal articulations has been the documentation of significantly elevated serum erythrocyte and urine metal ion concentrations [28–34]. Despite clear evidence of elevated metal ion concentrations, there are currently no known or reported immunologic, toxic or carcinogenic effects [35–38]. We have noted no adverse events related to this metal-on-metal articulation,

although this study does not specifically measure ion levels.

The limitations of this study include the lack of available radiographic follow-up on all patients. Radiographs from the principal author's institution and a limited number of additional radiographs were available for review. No evidence of radiographic failure or wear of the M^2a articulation was noted on these films.

The current study has reported encouraging results at a mid-term follow-up with the M^2a Tapered Metal-on-Metal Articulation. In the absence of any conclusive data regarding harmful biological effects of metal-on-metal articulations, we continue to offer the M^2a to our younger, high-demand patients. Based on the available long-term data with the first-generation designs and the burgeoning mid-term data on the second-generation designs, the authors believe that a polyethylene-free metal-on-metal articulation can provide long-term service and durable improvements in quality of life for our patients.

Acknowledgment

The authors gratefully acknowledge the contributions of the following other surgeons who were investigators in this multicenter investigational device exemption study and contributed patients and data to this manuscript: Philip M. Faris, MD and E. Michael Keating, MD from Kendrick Memorial Hospital, Mooresville, IN; Michael M. Alexiades, MD and Chitranjan S. Ranawat, MD from Lennox Hill Hospital, New York, NY; Carl L. Nelson, Jr., MD from University of Arkansas Center for Medical Sciences, Arkansas Rehabilitation Hospital, John L. McClellan Memorial VA Medical Center; Arkansas Children's Hospital, and Doctor's Hospital, Little Rock, AR; Richard Wixson, MD from Northwestern Memorial Hospital, Chicago, IL; and Kenneth A. Jaffe, MD from University of Alabama at Birmingham, Birmingham, AL.

References

1. Lombardi AV Jr, Mallory TH, Alexiades MM, et al: Short-term results of the M^2a-Taper Metal-on-Metal Articulation. J Arthroplasty 16(Suppl 1):122, 2001
2. Bentley G, Duthie RB: Comparative review of the McKee-Farrar and Charnley total hip prostheses. Clin Orthop 95:127, 1973
3. Freeman PA: McKee-Farrar total replacement of the hip joint in rheumatoid arthritis and allied conditions. Clin Orthop 70:106, 1970
4. Patterson FP, Brown CS: The McKee-Farrar total hip replacement: preliminary results and complication of 368 operations performed in five general hospitals. J Bone Joint Surg Am 54:257, 1972
5. Postel M, Kerboull M: Total prosthetic replacement in rapidly destructive arthrosis of the hip. Clin Orthop 72:138, 1970
6. Wilson PD, Amstutz HC, Czerniecki A, et al: Total hip replacement with fixation by acrylic cement: a preliminary study of 100 consecutive McKee-Farrar prosthetic replacements. J Bone Joint Surg Am 54: 207, 1972
7. Amstutz HC, Grigoris P: Metal-on-metal bearings in hip arthroplasty. Clin Orthop 329(Suppl):S11, 1996
8. Schmalzried TP, Peters PC, Maurer BT, et al: Long-duration metal-on-metal total hip arthroplasties with low wear of the articulating surfaces. J Arthroplasty 11:322, 1996
9. Zahiri CA, Schmalzried TP, Ebramzadeh E, et al: Lessons learned from loosening of the McKee-Farrar metal-on-metal total hip replacement. J Arthroplasty 14:326, 1999
10. McKellop H, Park SH, Chiesa R, et al: In vivo wear of three types of metal-on-metal hip prostheses during two decades of use. Clin Orthop 329(Suppl):S128, 1996
11. Wagner M, Wagner H: Medium-term results of a modern metal-on metal system in total hip replacement. Clin Orthop 379:123, 2000
12. Dorr LD, Wan Z, Longjohn DB, et al: Total hip arthroplasty with use of the Metasul metal-on-metal articulation: four- to seven-year results. J Bone Joint Surg Am 82:789, 2000
13. Brown SR, Davies WA, DeHeer DH, Swanson AB: Long-term survival of McKee-Farrar total hip prostheses. Clin Orthop 402:157, 2002
14. Jacobsson SA, Djerf K, Wahlstrom O: Twenty-year results of McKee-Farrar versus Charnley prostheses. Clin Orthop 329 (Suppl):S60, 1996
15. Schmidt M, Weber H, Schon R: Cobalt chromium molybdenum metal combination for modular hip prostheses. Clin Orthop 329(Suppl):S35, 1996
16. Harris WH: Traumatic arthritis of the hip after dislocation and acetabular fractures: treatment by mold arthroplasty. J Bone Joint Surg Am 51:737, 1969
17. Gruen TA, McNiece GM, Amstutz HC: "Modes of failure" of cemented stem-type femoral components: a radiographic analysis of loosening. Clin Orthop 141:17, 1979
18. DeLee JG, Charnley J: Radiological demarcation of cemented sockets in total hip replacement. Clin Orthop 121:20, 1976
19. Kennedy JF, Rogers WB, Soffe KE, et al: Effect of acetabular component orientation on recurrent dislocation, pelvic osteolysis, polyethylene wear, and component migration. J Arthroplasty 13:530, 1998

20. Older J: Charnley low-friction arthroplasty: a worldwide retrospective review at 15 to 20 years. J Arthroplasty 17:675, 2002
21. Callaghan JJ, Albright JC, Goetz DD, et al: Charnley total hip arthroplasty with cement: minimum 20-year follow-up. J Bone Joint Surg Am 82:487, 2000
22. Berry DJ, Harmsen WS, Cabanela ME, Morrey BF: Twenty-five-year survivorship of two thousand consecutive primary Charnley total hip replacements. J Bone Joint Surg Am 84:171, 2002
23. Dorr LD: Alternative bearing surfaces in total hip replacement: what we know in 2003. Symposium (I), 70th Annual Meeting of the American Academy of Orthopaedic Surgeons, New Orleans, LA, February 5–9, 2003
24. Kothari M, Bartel DL, Booker JF: Surface geometry of retrieved McKee-Farrar total hip replacements. Clin Orthop 329(Suppl):S141, 1996
25. Willert HG, Buchhorn GH, Gobel D, et al: Wear behavior and histopathology of classic cemented metal-on-metal hip endoprotheses. Clin Orthop 329(Suppl):S160, 1996
26. Doorn PF, Campbell PA, Worrall J, et al: Metal wear particle characterization from metal on metal total hip replacements: transmission electron microscopy study of periprosthetic tissues and isolated particles. J Biomed Mater Res 42:103, 1998
27. Black J, Jacobs JJ: Materials for alternative bearings: biological considerations. Semin in Arthroplasty 9:157, 1998
28. Brodner W, Bitzan P, Meisinger V, et al: Elevated serum cobalt with metal-on-metal articulating surfaces. J Bone Joint Surg Br 79:316, 1997
29. Case CP, Langkamer VG, Howell RT, et al: Preliminary observations on possible premalignant changes in bone marrow adjacent to worn total hip arthroplasty implants. Clin Orthop 329(Suppl):S269, 1996
30. Doorn PF, Mirra JM, Campbell PA, Amstutz HC: Tissue reaction to metal-on-metal total hip prostheses. Clin Orthop 329(Suppl):S187, 1996
31. Jacobs JJ, Gilbert JL, Urban RM: Corrosion of metal orthopedic implants. J Bone Joint Surg Am 80:268, 1998
32. Urban RM, Jacobs JJ, Tomlinson MJ, et al: Dissemination of wear particle to the liver, spleen, and abdominal lymph nodes of patients with hip or knee replacement. J Bone Joint Surg Am 82:457, 2000
33. Jacobs JJ, Skipor AK, Doorn PF, et al: Cobalt and chromium concentrations in patients with metal-on-metal total hip replacements. Clin Orthop 329(Suppl):S256, 1996
34. Jacobs JJ, Skipor AK, Patterson LM, et al: Metal release in patients who have had a primary total hip arthroplasty: a prospective, controlled, longitudinal study. J Bone Joint Surg Am 80:1447, 1998
35. Gillespie WJ, Henry DA, O'Connell DL, et al: Development of hematopoietic cancers after implantation of total joint replacement. Clin Orthop 329(Suppl): S290, 1996
36. Visuri T, Pukkala E, Paavolainen P, et al: Cancer risk after metal on metal and polyethylene on metal total hip arthroplasty. Clin Orthop 329(Suppl):S280, 1996.
37. Schmalzried TP: Metal-on-metal: historical perspectives and lessons learned through retrieval studies. Semin in Arthroplasty 9:135, 1998
38. Schmidt M, Weber H, Schon R: Cobalt chromium molybdenum metal combination for modular hip prostheses. Clin Orthop 329 (Suppl):S35, 1996

Large Versus Small Femoral Heads in Metal-on-Metal Total Hip Arthroplasty

John M. Cuckler, MD,* K. David Moore, MD,* Adolph V. Lombardi, Jr., MD,† Edward McPherson, MD,‡ and Roger Emerson, MD§

Abstract: The recent resurgence of metal-on-metal total hip arthroplasty has afforded the surgeon new options in femoral head diameters that were not previously available. Reduction in the risk for dislocation and potential improvements in articular wear are the obvious advantages of large-diameter femoral heads. Total hips with larger-diameter femoral heads are more resistant to dislocation. The clinical experience with 616 38 mm diameter femoral heads showed no dislocations within the first 3 months after surgery, compared with 2.5% of 78 patients receiving 28 mm diameter femoral heads with otherwise identical components. Use of larger-diameter femoral heads appears to have the potential to substantially reduce the early risk of dislocation of the prosthetic hip arthroplasty. **Key words:** total hip arthroplasty, femoral head diameter, dislocation, metal-on-metal.

Dislocation in primary total hip arthroplasty (THA) has been reported to occur in 2–4% of clinical series with conventional articular couples [1,2]. Unfortunately, the prevalence of dislocation increases with wear of the polyethylene component in conventional hip arthroplasty. This phenomenon typically occurs as the patient ages and may ultimately require revision in those patients least able to medically tolerate revision hip surgery. However, the highest risk for dislocation occurs during the first 3 months after surgery [3].

*From the *Division of Orthopaedics, University of Alabama at Birmingham, Birmingham, Alabama USA, †Joint Implant Surgeons, Columbus, Ohio USA, the ‡USC Department of Orthopaedic Surgery, Los Angeles, California USA, and the §Texas Center for Joint Replacement, Plano, Texas USA.*

Benefits or funds were received in partial or total support of the research material described in this article. These benefits or support were received from Biomet, Inc., Warsaw, Indiana.

Reprint requests: John M. Cuckler, MD, Division of Orthopaedics, University of Alabama at Birmingham, FOT 930, 1530 3rd Ave S, Birmingham, AL 35294-3409.

0883-5403/04/1908-3009$30.00/0
doi:10.1016/j.arth.2004.09.006

Factors that may influence the risk of dislocation are component position, soft tissue tension, and patient noncompliance [4–8]. The first 2 factors are controlled by the operating surgeon, while the third factor (patient noncompliance) can only partially be addressed by careful patient selection for prosthetic hip arthroplasty.

Dislocation potential of a total hip arthroplasty is also related to the diameter of the femoral head, which affects the range of motion of a femoral prosthesis without impingement of the prosthetic femoral neck against the acetabular prosthesis [9–12]. Metal-on-metal (MOM) total hip arthroplasties allow the use of large-diameter femoral heads, thus offering the prospect for reduction in the risk of dislocation, while providing reduced wear and hopefully prolonged function of the prosthetic arthroplasty [13–15]. The purpose of this study was to compare the incidence of dislocation in a series of 28 mm femoral heads with a series of 38 mm femoral heads in the first 3 months after surgery, using otherwise similar implants.

Table 1. Demographics of 28 vs. 38 mm Groups

	# Hips	# Males	# Females	Approach	
				Anterolateral	Posterolateral
28 mm	78	58	20	36	42
38 mm	616	309	246	354	262

Materials and Methods

The authors' experience with MOM THA includes 28 and 38 mm diameter femoral heads using the Bimetric® or Mallory-Head® femoral stems (Biomet, Warsaw, IN). Initial experience with the 28 mm diameter femoral head was obtained as part of the FDA IDE study on the implant [16]. This study used modular cobalt-chrome-molybdenum (CoCr) inserts in modular titanium alloy hemispheric shells with titanium plasma spray coating (Biomet). Subsequent experience with a 38 mm, nonmodular acetabular implant (M2Ar, Biomet) was obtained in a nonrandomized clinical series, using identical femoral stems. Demographics of the 2 groups of patients are presented in Table 1. Sixty-one cases among the 616 arthroplasties were bilateral.

Among the 38 mm THAs, 42.5% of the 616 cases underwent a posterolateral approach, while the remainder underwent anterolateral approaches. Within the 28 mm group, 55% underwent a posterolateral approach. Among those patients undergoing a posterolateral approach, partial repair (suture of the pyriformis tendon and posterior capsule to the posterior border of the insertion of the gluteus medius tendon) of the posterior capsule was performed at the time of closure. All patients were allowed to advance to full weight bearing as tolerated. Hip precautions such as avoiding adduction or hyperflexion of the hip were advised for the first 6 weeks postoperatively.

The binomial distribution was used to assess the probability that the incidence of dislocation between the 2 groups was significantly different from the expected dislocation rate based on an assumed risk of early dislocation of 2%. $P \leq .05$ was considered statistically significant. Power analysis was conducted to calculate the probability of type II statistical error.

Results

The range of motion without impingement of the 2 designs is 126°, and 154°, respectively, for the 28 and 38 mm components used in this series (data on file, Biomet). Seventy-eight patients received 28 mm diameter femoral heads, while 616 patients received 38 mm diameter heads. The demographics and type of surgical approach are shown in Table 1. Dislocation incidence was recorded for both groups during the first 3 months after surgery; all patients in both groups have been followed more than 3 months (28 mm group mean follow-up 5.3 years, range 3–7 years; 38 mm group mean follow-up 1.1 years, range 4 months–2 years).

There were 2 early dislocations among the 78 patients receiving 28 mm femoral heads, while no dislocations occurred among the 616 patients receiving 38 mm femoral heads. The incidence of expected dislocation, assuming 2% dislocation rate, was not statistically significant for the 28 mm group, but did achieve significance for the 38 mm group ($P = .26$ vs. $P = .00000039$, respectively). When data was stratified according to type of approach (anterolateral vs. posterior), there were 53 posterolateral approaches among those receiving 28 mm heads, versus 252 posterolateral approaches with the 38 mm femoral heads. Both dislocations among those receiving 28 mm femoral heads occurred in the posterolateral group. Again assuming a 2% risk of early dislocation, the binomial distribution achieves significance for the 38 mm group ($P = .006$) but not for the 28 mm group ($P = .15$) (Table 2).

Discussion

Larger diameter MOM femoral heads present the possibility of reduced risk of dislocation, with reduced wear of the articular couple. Whereas alternate articular couples such as ceramic-on-ceramic offer reduction in wear, the mechanical characteristics of existing ceramic materials and requirement for bone-implant fixation with modular porous coated metal shells will not allow the use of large-diameter femoral heads. The use of large-diameter femoral heads with modular highly cross-linked polyethylene inserts requires substantial reduction

Table 2. Results of Dislocation Incidence at 3 Months After Surgery

	All Surgical Approaches			Posterolateral Only		
	Dislocations	# Cases	*P* Value	Dislocations	# Cases	*P* Value
28-mm	2	78	*P* = .25 (NS)	2	42	*P* = .15 (NS)
38-mm	0	616	*P* = .00000039 (SS)	0	252	*P* = .006 (SS)

NS = not significant; SS = statistically significant.

in the thickness of the polyethylene insert, which at this time is an unproven design.

Larger femoral heads provide a reduced risk for dislocation because of the increased arc of motion without impingement of the prosthetic femoral neck against the prosthetic acetabular rim, which has been demonstrated in radiographic studies to be an important component in implant dislocation [17]. Long-term follow-up of large-diameter femoral heads used in the McKee-Farrar prosthesis has not shown evidence of metallosis or wear in retrieval study [18]. Osteolysis associated with the large-diameter femoral head in the McKee-Farrar prosthesis has been less frequent than that associated with the Charnley prosthesis in a 25-year follow-up study [19]. Larger-diameter MOM articular couples appear to wear less than smaller-diameter MOM THAs in retrieval studies [20]. In addition, a MOM articular couple may provide a secondary advantage due to the inherent nature of the thin film lubrication mechanism present in the MOM articular couples [21,22]. The boundary lubrication film provides some resistance to distraction of the femoral head from the acetabular component. This is unique to the MOM articular couple. It is not clear at this time, however, that this provides a significant clinical advantage with regard to resistance to dislocation.

Larger-diameter femoral heads are possible with MOM articular couples because of the relative absence of concerns over tensile and fatigue strength associated with other low-wear couples. Ceramic-on-ceramic designs are limited with regard to the femoral head diameter by the strength of the acetabular component [23]. When modular ceramic-on-ceramic components are used, femoral head diameters are, by necessity, limited due to the relative combined thickness of the ceramic acetabular liner and shell due to concerns over possible fracture of the ceramic liner [24]. Although larger femoral head diameters are currently in use with highly cross-linked polyethylene acetabular inserts, the use of larger femoral heads invariably requires thinner polyethylene inserts. The intermediate and long-term performance of the highly cross-linked polyethylenes in the setting of a modular design with a thin polyethylene insert remains unknown at this time.

In this study, the reduction in early dislocation rates (2.5% vs. 0%) can only be attributed to the advantage of the larger-diameter femoral head, as the implants were otherwise similar with regard to femoral stems and type of surgical approaches used. Long-term follow-up of the 38 mm femoral head experience will be necessary to confirm the advantage of larger femoral heads in the incidence of dislocation at any time. However, large diameter femoral heads in very early THA designs such as the McKee-Farrar and Ring devices have demonstrated the potential for wear reduction and long- term success, which will hopefully be improved with current modern designs of MOM THAs.

References

1. Malchau H, Herberts P, Ahnfelt L: Prognosis of total hip replacement in Sweden: Follow-up of 92,675 operations performed 1978-1990. Acta Orthop Scand 64:497, 1993
2. Cobb TK, Morrey BF, Ilstrup DM: The elevated-rim acetabular liner in total hip arthroplasty: relationship to postoperative dislocation. J Bone Joint Surg Am 78:80, 1996
3. von Knoch M, Berry DJ, Harmsen WS, et al: Late dislocation after total hip arthroplasty. J Bone Joint Surg Am 84:1949, 2002
4. Kummer FJ, Shah S, Iyer S, et al: The effect of acetabular cup orientations on limiting hip rotation. J Arthroplasty 14:509, 1999
5. Herrlin K, Pettersson H, Selvik G, et al: Femoral anteversion and restricted range of motion in total hip prostheses. Acta Radiol 29:551, 1988
6. Herrlin K, Selvik G, Pettersson H, et al: Position, orientation and component interaction in dislocation of the total hip prosthesis. Acta Radiol 29:441, 1988
7. Dorr LD, Wolf AW, Chandler R: Classification and treatment of dislocations of total hip arthroplasty. Clin Orthop 173:151, 1983
8. Amstutz HC, Lodwig RM, Schurman DJ: Range of

motion studies for total hip replacements: A comparative study with a new experimental apparatus. Clin Orthop 111:124, 1975
9. Bartz RL, Nobel PC, Kadakia NR, et al: The effect of femoral component head size on posterior dislocation of the artificial hip joint. J Bone Joint Surg Am 82:1300, 2000
10. Kelley SS, Lachiewicz PF, Hickman JM, et al: Relationship of femoral head and acetabular size to the prevalence of dislocation. Clin Orthop 355:163, 1998
11. Yuan L, Shih C: Dislocation after total hip arthroplasty. Arch Orthop Traum Surg 119:263, 1999
12. Hedlundh U, Ahnfelt L, Hybbinette CH, et al: Dislocations and the femoral head size in primary total hip arthroplasty. Clin Orthop 333:226, 1996
13. Goldsmith AA, Dowson D, Isaac GH, et al: A comparative joint simulator study of the wear of metal-on-metal and alternative material combinations in hip replacements: Proceedings of the Institution of Mechanical Engineers. J Eng Med 214:39, 2000
14. Anissian HL, Stark A, Gustafson A, et al: Metal-on-metal bearing in hip prosthesis generates 100-fold less wear debris than metal-on-polyethylene. Acta Orthop Scand 70:578, 1999
15. Sieber HP, Rieker CB, Kottig P: Analysis of 118 second-generation metal-on-metal retrieved hip implants. J Bone Joint Surg Br 81:46, 1999
16. Lombardi AV Jr, Mallory TH, Alexiades MM, et al: Short-term results of the M2a-taper: metal-on-metal articulation. J Arthroplasty 16:122, 2001
17. Herrlin K, Selvik G, Pettersson H: Range of motion caused by design of the total hip prosthesis. Acta Radiol 29:701, 1988
18. Jantsch S, Schwagerl W, Zenz P, et al: Long-term results after implantation of McKee-Farrar total hip prostheses. Arch Orthop Trauma Surg 110:230, 1991
19. Jacobsson SA, Djerf K, Wahlstrom O: Twenty-year results of McKee-Farrar versus Charnley prosthesis. Clin Orthop 329(Suppl):S60, 1996
20. McKellop H, Park SH, Chiesa R, et al: In vivo wear of three types of metal on metal hip prostheses during two decades of use. Clin Orthop 329(Suppl):S128, 1996
21. Chan FW, Bobyn JD, Medley JB, et al: Wear and lubrication of metal-on-metal hip implants. Clin Orthop 369:10, 1999
22. Dowson D, Fisher J: Analysis of fluid film lubrication in artificial hip joint replacements with surfaces of high elastic modulus: Proceedings of the Institution of Mechanical Engineers. J Eng Med 211:247, 1997
23. Nizard RS, Sedel L, Christel P, et al: Ten-year survivorship of cemented ceramic-ceramic total hip prosthesis. Clin Orthop 282:53, 1992
24. Clarke IC: Role of ceramic implants: Design and clinical success with total hip prosthetic ceramic-to-ceramic bearings. Clin Orthop 282:19, 1992

CLINICAL ORTHOPAEDICS AND RELATED RESEARCH
Number 441, pp. 137–142

Metal-on-Metal Total Hip Arthroplasty with Large Heads May Prevent Early Dislocation

Thomas M. Smith, DO; Keith R. Berend, MD*; Adolph V. Lombardi, Jr., MD*; Roger H. Emerson, Jr., MD†; and Thomas H. Mallory, MD**

Postoperative dislocation is one of the major causes of morbidity and failure of total hip arthroplasty. We reviewed 327 patients (377 hips) retrospectively with varying diagnoses and indications but all of whom received large-diameter metal-on-metal prostheses. Two surgical approaches were used: the anterolateral abductor splitting (342 procedures) and a mini-incision poste rior approach (35 procedures). Average age at time of surgery was 55.9 years and average followup was 4.0 months. There were 346 (91.8%) primary procedures, 15 (4.0%) conversion procedures, and 16 (4.2%) revisions or reimplantations. The most common preoperative diagnoses included osteoarthritis (250 hips; 66.3%) and avascular necrosis (46 hips; 12.2%). There were 62 (16.4%) patients with high-risk diagnoses for dislocation. The status in terms of postoperative dislocation was known for all patients. During the short followup period, there were no dislocations. Use of large-diameter femoral heads and metal-on-metal articulations decreases the risk of dislocations, making their use a viable choice for primary and revision procedures.

Level of Evidence: Therapeutic study, Level IV-1 (case series). See the Guidelines for Authors for a complete description of levels of evidence.

Postoperative dislocation continues to rank among the top causes of morbidity and failure of total hip arthroplasty (THA). Several authors cite a prevalence of dislocation to in primary THA ranging between 0.5% and 4%.[6,9,28,30,31] Patient factors such as previous surgery on the hip, age, gender, cognitive function, and underlying diagnosis all have been proposed as contributing factors to dislocation rates.[6,26,31,43] Additionally, surgical approach has been implicated in increasing or reducing the rate of postoperative dislocations, with the lateral and anterolateral approaches having lower rates reported in the literature.[6,7,15,26,28,43]

The contribution of the femoral head size (diameter) to the prevention of dislocation long has been debated and investigated in the laboratory; however, little clinical information exists on the actual effect of increased head diameter on postoperative stability.[1,3,4,8,10,13,27,35] Furthermore, with conventional polyethylene (PE) bearing surfaces, concern exists as to the possible increased volumetric wear associated with larger femoral heads.[4,8] With the advent of alternative bearings, such as a metal-on-metal articulation, the use of larger femoral head sizes may provide increased stability while not compromising the wear properties.[1,13,32,34]

Our purpose is to report the short-term dislocation rates with the use of a large-diameter metal-on-metal articulation in THA.

MATERIALS AND METHODS

We retrospectively reviewed all THA procedures (primary and revision) done by three surgeons (AVL, RHE, KRB) between October 2001 and October 2003, encompassing the time in which this particular component had been approved by the Food and Drug Administration (FDA) and was available. Of 1,485 consecutive primary, revision and reimplantation THAs done at two centers by these surgeons, we identified all THAs in which the M^{2}a-38™, large-sized, metal-on-metal articulation was used (Biomet, Warsaw, IN). The M^{2}a-38™ is a 38-mm diameter modular femoral head available in various neck lengths that articulates with a monolithic PE-free one-piece acetabular component. The acetabular component is constructed of Co-Cr with a titanium plasma-spray porous ingrowth coating applied to the outer surface (Fig 1). During the review period, 377 large-diameter metal-on-metal articulation components were im-

From the *Joint Implant Surgeons, Inc., Columbus, OH; and the †Texas Center for Joint Replacement, Plano, TX.
One or more of the authors (KRB, AVL, THM, RHE) own stock in and have consultancy agreements with Biomet Orthopaedics, Inc., Warsaw, IN.
Each author certifies that his institution has approved or waived approval for the human protocol for this investigation and that all investigations were conducted in conformity with ethical principles of research.
Correspondence to: Adolph V. Lombardi, Jr., MD, FACS, Joint Implant Surgeons, Inc., 7277 Smith's Mill Rd., Suite 200, New Albany, OH 43054. Phone: 614-221-6331; Fax: 614-221-4744; E-mail: LombardiAV@jointsurgeons.com.
DOI: 10.1097/01.blo.0000193810.23706.73

Fig 1. The M^{2}a-38 acetabular system features a 38-mm diameter modular Co-Cr femoral head available in various neck lengths, which articulates with a monolithic PE-free one-piece acetabular component. The acetabular component is constructed of Co-Cr with a titanium plasma-spray porous ingrowth coating applied to the outer surface.

planted in 327 patients. The primary indications to proceed with this device were in individuals who were high demand and would benefit from an alternative bearing and individuals who were considered to be at a higher risk for perioperative dislocation. Contraindications included patients with renal disease. Relative contraindications included women of childbearing age. One of the surgeons (RWE) used this device preferentially in cases done with the posterior approach. Other factors that affected the use of this device included availability, instances where dome-screw fixation was required, liner-exchange revisions, stem-only revisions, revisions requiring constrained liners such as proximal femoral replacements, surgeons' involvement in other prospective clinical studies, and cost considerations.

The average age of the patients at the time of surgery was 55.9 years (± 11.5 years; range, 25.0–93.1 years). The average height and weight of the patients were 172.11 cm (± 11.1 cm; range, 136–203 cm) and 91.2 kg (± 21.5 kg; range, 46.7–154.2 kg), respectively. Bilateral THA was done in 50 patients: 31 (8%) procedures were simultaneous and 19 (5%) procedures were staged. There were 147 (45%) women in the study. The left hip was operated on in 197 (52%) instances.

The large-diameter metal-on-metal articulation was used for a primary THA in 346 hips (92%), conversion of failed fracture surgery in 15 hips (4%), and revision/reimplantation THA in 16 hips (4%). Preoperative diagnoses were osteoarthritis in 250 hips (66%), avascular necrosis in 46 hips (12%), congenital dysplasia in 21 hips (6%), posttraumatic arthritis in 10 hips (3%), rheumatoid arthritis in seven hips (2%), slipped capital femoral epiphysis in six hips (2%), Legg-Calvé-Perthes disease in five hips (1%), osteopetrosis in one hip, conversion from failed fixation of fracture in 15 hips (4%), reimplantation after two-stage treatment of sepsis in five hips (1%), and revision THA in 11 hips (3%). The 11 revision surgeries included eight acetabular revisions for PE wear, osteolysis, and aseptic loosening (2%); two acetabular revisions for recurrent dislocation; and one femoral and acetabular revision for periprosthetic fracture of the femur. Patients having 62 of 377 procedures (16%) had "at-risk" diagnoses for postoperative dislocation, identified in an earlier study[26] as congenital dysplasia and posttraumatic arthritis in primary arthroplasty (Fig 2) and conversion, revision, and reimplantation surgeries (Fig 3).

Three hundred forty-two operative procedures were done through the anterolateral abductor split approach as described by Frndak et al,[15] and 35 operative procedures were done through a mini-incision posterior approach including formal posterior capsular and short external rotator repair.[33,38] All patients were placed on a routine postoperative protocol that included immediate weightbearing as tolerated and progression off of assistive walking devices by 6 weeks postoperatively. The status of the hip in terms of perioperative complications and postoperative dislocation was known for all patients, and no patients were lost to followup.

RESULTS

During the short followup period, there were no dislocations. The average time of clinical followup and examination was 4.0 months (± 4.1 months; range, 0.23–23.7 months).

DISCUSSION

The published rate of dislocation after THA ranges from 0.3% in primary cases to as high as 21% in revision situations. The majority of THA dislocations occur within several weeks of surgery.[6,9,30,44] In fact, it has been shown that the risk is the highest immediately after the surgery, but remains high for at least the first 3 months.[30] Many factors have been implicated in the etiology of the unstable THA, including patient factors such as gender, age, diagnosis, and cognitive function, and neurologic abnormalities.[6,26,31,43] Surgical approach also has been discussed in

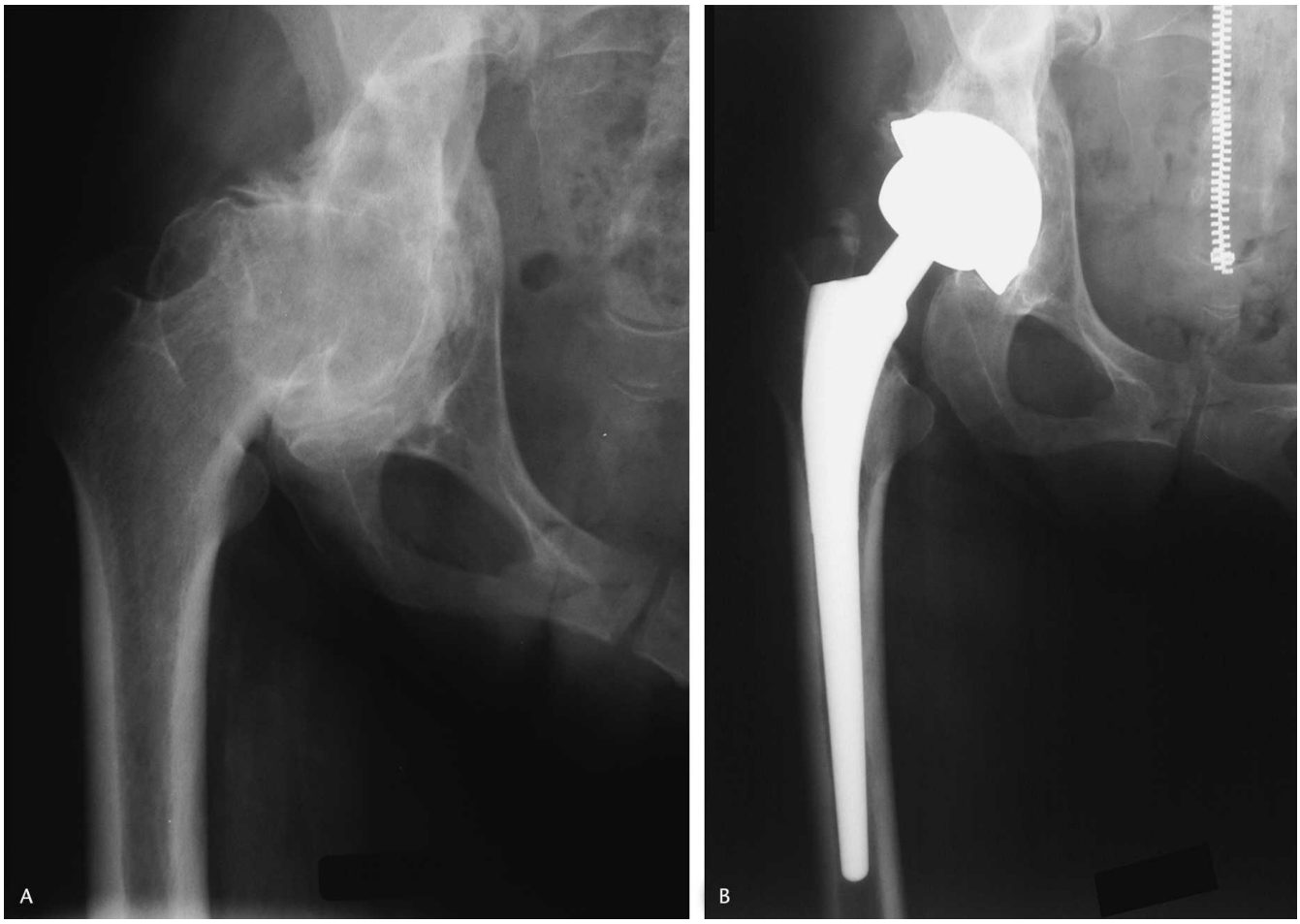


Fig 2A–B. (A) An AP radiograph of the right hip of a 44-year-old woman who presented with severe pain and difficulty walking related to posttraumatic arthritis after pelvic fracture treated without fixation is shown. Her right limb was shorter than the left by 8 cm. (B) A radiograph of the same hip 1 year after the patient had cementless primary THA on the right hip using the anterolateral approach with an Mallory-Head Porous femoral component (Biomet) and M^2a-38 acetabular component shows satisfactory position and alignment. Her leg-length discrepancy has been reduced and she is pain free with excellent functional capability.

great detail in the literature in terms of the incidence of postoperative dislocation.[6,7,15,26,28,43] The current series of 377 hips replaced in 329 patients represents a cross-section of patients with at-risk diagnoses (congenital dysplasia, posttraumatic arthritis, revision THA, conversion THA, and reimplantation THA), patient demographics (gender, age, cognitive function), primary and revision surgeries (including revision for recurrent dislocation), anterior and posterior surgical approaches, and conventional and minimally invasive surgeries. These at-risk diagnoses and revision surgeries have been reported to be associated with dislocation rates as high as 14.4% in the first 6 months.[30] However, the constant variable is the use of a large (38-mm) metal-on-metal femoral head and acetabular component. This resulted in no early dislocations in this group of selected, consecutive patients in whom this device was used.

The posterior approach decreases the incidence of early postoperative limp by leaving the hip abductors intact but has been associated with an increased dislocation rate. Negative aspects of some posterior approach techniques include the loss of the check rein of internal rotation by the capsule and the short external rotators, inadequate acetabular anteversion because of interference by the femur, the illusion of increased acetabular anteversion when a patient is in the lateral position because the pelvis tends to roll forward, and injury to the sciatic nerve.[6,26,43] Historically the posterior approach has been associated with up to 5.9 times (3.23%) higher dislocation rates than the lateral approach.[28] In the same study, Masonis and Bourne[28] compared dislocation rates for the posterior approach with and without a formal posterior repair and showed that the dislocation rate was 3.95% without a repair and 2.03% with a repair. Some authors have reported a decrease in dislo-

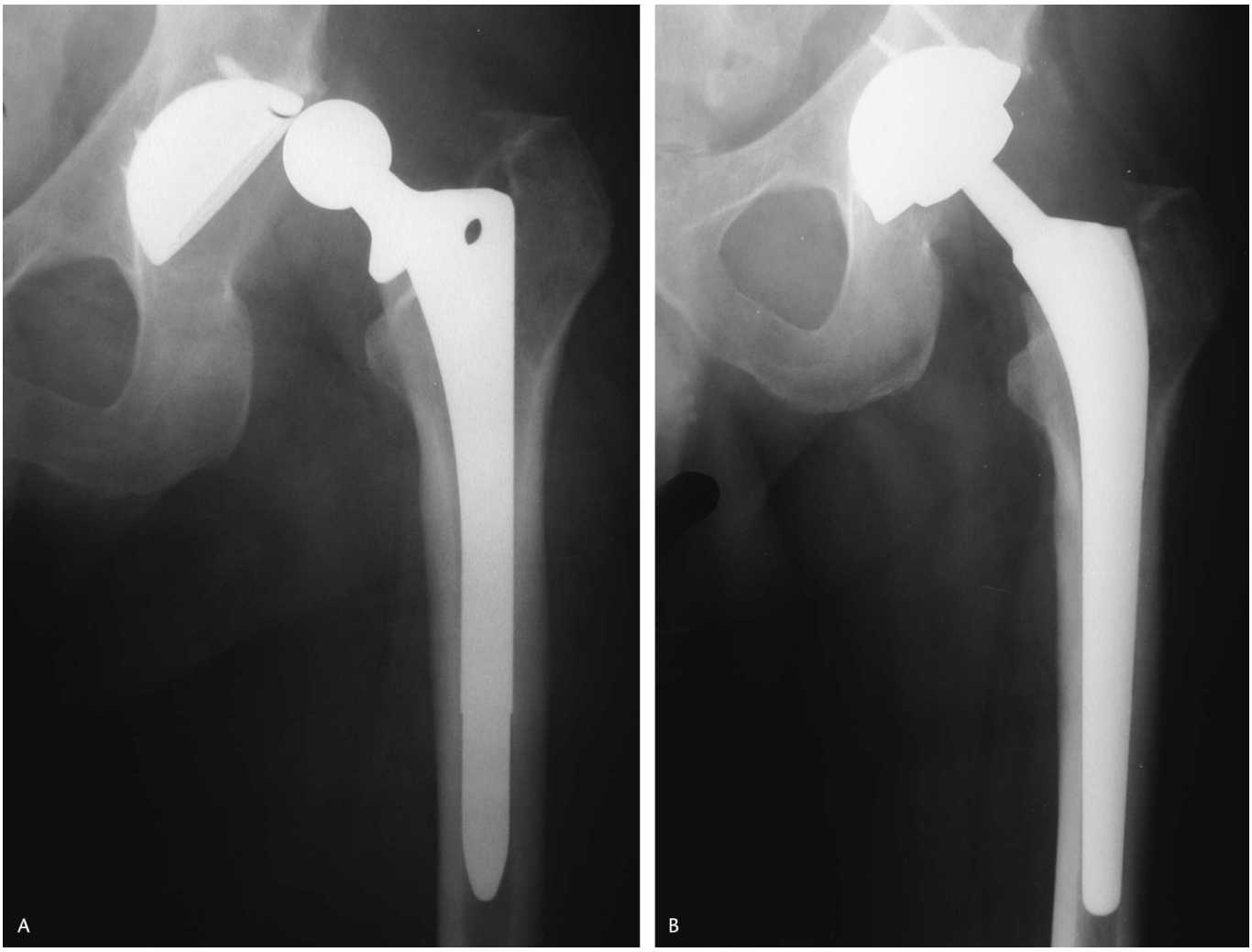


Fig 3A–B. (A) An AP radiograph of the left hip of a 46-year-old man who presented emergently with recurrent dislocation 3 months after having uncemented primary THA at another institution is shown. (B) A radiograph of the same patient after treatment with revision THA done using the anterolateral approach using an Mallory-Head Porous offset femoral component and M^{2}a-38 acetabular component shows satisfactory position and alignment. The patient has had no further dislocation.

cation rates with formal repair of the capsule and short external rotators, with early dislocation rates varying from 0% to 0.85%.[11,17,29,39,41] It seems that newer capsular repair techniques may obviate the increased risk of dislocation seen in previous reports on the posterior approach. As noted, a formal repair was done in the patients treated with the posterior approach in the current study, and no dislocations occurred.

Importantly, dislocation rates for the posterior approach in revision surgery have been significantly higher. This likely is multifactorial but includes difficulty with formal repair, abductor injury or damage, and laxity resulting from excision of scarred capsule and other surrounding structures to gain extensile exposure.[9,30,31,43] We noted no dislocations in the revision or reimplantation cases.

One might expect some dislocations during the learning curve of a relatively new mini-incision posterior or anterior approach. Wenz et al[40] reported one dislocation of 124 (0.81%) mini-incision arthroplasties using the posterior approach. With the formal repair of the capsule and short external rotators, the dislocation rate with the minimally invasive posterior approach has been low.[33,38] Although only 32 THAs (32 patients) were done with a mini-incision posterior approach in the current series, no dislocations have been observed in followup.

We have been involved with two previous studies outlining the use of and the low dislocation rate associated with the anterolateral approach. In the first study, one dislocation occurred in 65 hips for a rate of 1.54%.[15] In the second significantly larger series by Mallory et al[26] there

were 12 dislocations in 1518 primary THA cases (0.79%), defining the incidence of dislocation with this approach in primary THA. The current series includes all hip arthroplasty procedures in which the M^2a-38 component was used, including revision surgery and at-risk primary surgeries; therefore the rate of dislocation should be expected to be higher than 0.8%. In the series by Mallory et al[26] the rate of dislocation was higher in patients with posttraumatic arthritis (6.0%) and in patients with congenital hip dysplasia (8.3%). Sixty-two hips in the current series would fall into one of these higher-risk diagnostic categories including revision surgery, but again, no dislocations were seen. Followup for patients with at-risk diagnoses averaged more than 3 months.

Many authors cite a mechanical advantage in vitro and possibly a reduced rate of dislocation in vivo with the use of a larger-diameter femoral head in THA.[1,3,5–8,10,13,21,27,31,35,43] Some of these same authors report that the advantage of increasing the head-to-neck ratio reaches a maximum at a 32 mm diameter, noting that joint motion becomes limited by osseous impingement with larger head sizes.[4,8] However, neither of these two sets of authors describes the substantial increase in stability afforded by the increased jump distance with a larger-diameter femoral head. In these biomechanical studies, joint range of motion to impingement was measured, not longitudinal displacement of the femoral head required to jump the ball out of the socket. It is the cumulative protective effects of an increased head-to-neck ratio and an increased jump distance that likely make the larger femoral heads more stable in vivo.

A potential negative aspect of increased head diameters that has been published in multiple studies is the increased volumetric wear associated with larger heads and conventional PE.[4,8,21] Recent interest in highly cross-linked PE has arisen because of better wear characteristics in vitro, but evidence points toward increased wear with the use of large-diameter femoral heads, as it does in using conventional PE.[20] With an increase in head size, PE thickness decreases, which changes the mechanical properties and may negatively affect fracture toughness and fatigue crack propagation.[2,12,16,18,19] By using a PE-free, metal-on-metal articulation in concert with the enlarged femoral head, these issues of wear potentially are lessened. The results of early biomechanical testing have shown that a metal-on-metal articulation using larger diameter heads has less wear than smaller femoral diameter metal-on-metal heads likely secondary to earlier achievement of a thicker fluid–film interface.[34]

Several authors of studies done on varied implant designs have described excellent short-term and mid-term results using metal-on-metal articulations in THA.[22,23,37] However, concern remains about the effects of elevated serum levels and urine levels of metal ions produced during the lifespan of a metal-on-metal hip implant.[24,25,32,36] To date, no untoward effects have been related conclusively to the use of metal-on-metal articulations. In a large review of the available information on the subject, Tharani et al[36] concluded that the data do not support a causal relationship between THA and cancer, even in the first-generation metal-on-metal designs. Authors of two other reports have cited metal hypersensitivity or lymphocytic perivascular infiltration as a possible complication of metal-on-metal bearings.[14,42] This condition appears to be extremely rare and the incidence and clinical implications have not been reported to date. We have not, during the short followup period, observed this phenomenon in our patients.

The early results and lack of longer followup represent a drawback to this study. Most patients who have recurrent dislocations have their first dislocation within 90 days of surgery. Furthermore, most dislocations occur within this early postoperative time frame.[6,9,30,44] We therefore are encouraged by these early data. A second limitation is that, although these cases represent a consecutive series of hips in which this device was used, they do not represent a consecutive series of unselected patients.

In the current preliminary series, we report no early postoperative dislocations in a heterogeneous population of patients at varied levels of risk who had THAs. We continue to use large-diameter femoral heads and metal-on-metal articulations in primary and revision THA procedures based on this information and encouraging early-term and mid-term results with modern metal-on-metal designs and a lack of evidence of an increased risk of disease from elevated metal ions. We do, however, weigh the potential unknown effects of metal ions against the potential benefit of improved wear characteristics and lower dislocation rates during our preoperative discussions with our patients and as a standard part of the operative consent.

Acknowledgments

The authors thank Joanne Adams and Carter Mitchell for their assistance in preparing this manuscript.

References

1. Amstutz HC, Le Duff MJ, Beaule PE: Prevention and treatment of dislocation after total hip replacement using large diameter balls. Clin Orthop Relat Res 429:108–116, 2004.
2. Baker DA, Hastings RS, Pruitt L: Study of fatigue resistance of chemical and radiation crosslinked medical grade ultrahigh molecular weight polyethylene. J Biomed Mater Res 46:573–581, 1999.
3. Barrack RL: Dislocation after total hip arthroplasty: Implant design and orientation. J Am Acad Orthop Surg 11:89–99, 2003.
4. Bartz RL, Nobel PC, Kadakia NR, Tullos HS: The effect of femoral component head size on posterior dislocation of the artificial hip joint. J Bone Joint Surg 82A:1300–1307, 2000.

5. Beaulé PE, Schmalzried TP, Udomkiat P, Amstutz HC: Jumbo femoral head for the treatment of recurrent dislocation following total hip replacement. J Bone Joint Surg 84A:256–263, 2002.
6. Berry DJ: Unstable total hip arthroplasty: detailed overview. Instr Course Lect 50:265–274, 2001.
7. Bystrom S, Espehaug B, Furnes O, Havelin LI: Norwegian Arthroplasty Register: Femoral head size is a risk factor for total hip luxation: A study of 42,987 primary hip arthroplasties from the Norwegian Arthroplasty Register. Acta Orthop Scand 74:514–524, 2003.
8. Callaghan JJ, Brown TD, Pedersen DR, Johnston RC: Choices and compromises in the use of small head sizes in total hip arthroplasty. Clin Orthop Relat Res 405:144–149, 2002.
9. Callaghan JJ, Heitoff BE, Goetz DD, et al: Prevention of dislocation after hip arthroplasty: Lessons from long-term followup. Clin Orthop Relat Res 393:157–162, 2001.
10. Chandler DR, Gousman R, Hull D, et al: Prosthetic hip range of motion and impingement: The effects of head and neck geometry. Clin Orthop Relat Res 166:284–291, 1982.
11. Chiu FY, Chen CM, Chung TY, Lo WH, Chen TH: The effect of posterior capsulorrhaphy in primary total hip arthroplasty: A prospective randomized study. J Arthroplasty 15:194–199, 2000.
12. Cole JC, Lemons JE, Eberhardt AW: Gamma irradiation alters fatigue-crack behavior and fracture toughness in 1900H and GUR 1050 UHMWPE. J Biomed Mater Res 63:559–566, 2002.
13. Crowninshield RD, Maloney WJ, Wentz DH, Humphrey SM, Blanchard CR: Biomechanics of large heads: What they do and don't do. Clin Orthop Relat Res 429:102–107, 2004.
14. Davies AP, Willert HG, Campbell PA, Learmonth ID, Case SP: An unusual lymphocytic perivascular infiltration in tissues around contemporary metal-on-metal joint replacements. J Bone Joint Surg 87A:18–27, 2005.
15. Frndak PA, Mallory TH, Lombardi Jr AV: Translateral surgical approach to the hip: The abductor muscle ′split. Clin Orthop Relat Res 295:135–141, 1993.
16. Gencur SJ, Rimnac CM, Kurtz SM: Failure micromechanisms during uniaxial tensile fracture of conventional and highly crosslinked ultra-high molecular weight polyethylenes used in total joint replacements. Biomaterials 24:3947–3954, 2003.
17. Goldstein WM, Gleason TF, Kopplin M, Branson JJ: Prevalence of dislocation after total hip arthroplasty through a posterolateral approach with partial capsulotomy and capsulorrhaphy. J Bone Joint Surg 83A(Suppl 2):2–7, 2001.
18. Gomoll A, Wanich T, Bellare A: J-integral fracture toughness and tearing modulus measurement of radiation cross-linked UHMWPE. J Orthop Res 20:1152–1156, 2002.
19. Greenwald AS, Bauer TW, Ries MD: New polys for old: contribution or caveat? J Bone Joint Surg 83A(Suppl 2):27–31, 2001.
20. Hermida JC, Bergula A, Chen P, Colwell Jr CW, D'Lima DD: Comparison of the wear rates of twenty-eight and thirty-two-millimeter femoral heads on cross-linked polyethylene acetabular cups in a wear simulator. J Bone Joint Surg 85A:2325–2331, 2003.
21. Kelley SS, Lachiewicz PF, Hickman JM, Paterno SM: Relationship of femoral head and acetabular size to the prevalence of dislocation. Clin Orthop Relat Res 355:163–170, 1998.
22. Lombardi Jr AV, Mallory TH, Cuckler JM, et al: Mid-term results of a polyethylene-free metal-on-metal articulation. J Arthroplasty 19:42–47, 2004.
23. Long WT, Dorr LD, Gendelman V: An American experience with metal-on-metal total hip arthroplasties: A 7-year follow-up study. J Arthroplasty 19:29–34, 2004.
24. MacDonald SJ, Brodner W, Jacobs JJ: A consensus paper on metal ions in metal-on-metal hip arthroplasties. J Arthroplasty 19:12–16, 2004.
25. MacDonald SJ, McCalden RW, Chess DG, et al: Metal-on-metal versus polyethylene in hip arthroplasty: A randomized clinical trial. Clin Orthop Relat Res 406:282–296, 2003.
26. Mallory TH, Lombardi Jr AV, Fada RA, Herrington SM, Eberle RW: Dislocation after total hip arthroplasty using the anterolateral abductor split approach. Clin Orthop Relat Res 358:166–172, 1999.
27. Maloney WJ: Orthopaedic crossfire—Larger femoral heads: A triumph of hope over reason! In opposition. J Arthroplasty 18(Suppl 1):85–87, 2003.
28. Masonis JL, Bourne RB: Surgical approach, abductor function, and total hip arthroplasty dislocation. Clin Orthop Relat Res 405:46–53, 2002.
29. Pellicci PM, Bostrom M, Poss R: Posterior approach to total hip replacement using enhanced posterior soft tissue repair. Clin Orthop Relat Res 355:224–228, 1998.
30. Phillips CB, Barrett JA, Losina E, et al: Incidence rates of dislocation, pulmonary embolism, and deep infection during the first six months after elective total hip replacement. J Bone Joint Surg 85A:20–26, 2003.
31. Robbins GM, Masri BA, Garbuz DS, Greidanus N, Duncan CP: Treatment of hip instability. Orthop Clin North Am 32:593–610, 2001.
32. Schmalzried TP: How I choose a bearing surface for my patients. J Arthroplasty 19:50–53, 2004.
33. Sculco TP, Jordan LC, Walter WL: Minimally invasive total hip arthroplasty: The Hospital for Special Surgery experience. Orthop Clin North Am 35:137–142, 2004.
34. Smith SL, Dowson D, Goldsmith AA: The effect of femoral head diameter upon lubrication and wear of metal-on-metal total hip replacements. Proc Inst Mech Eng 215:161–170, 2001.
35. Sultan PG, Tan V, Lai M, Garino JP: Independent contribution of elevated-rim acetabular liner and femoral head size to the stability of total hip implants. J Arthroplasty 17:289–292, 2002.
36. Tharani R, Dorey FJ, Schmalzried TP: The risk of cancer following total hip or knee arthroplasty. J Bone Joint Surg 83A:774–780, 2001.
37. Wagner M, Heinz W: Medium-term results of a modern metal-on-metal system in total hip replacement. Clin Orthop Relat Res 379:123–133, 2000.
38. Waldman BJ: Advancements in minimally invasive total hip arthroplasty. Orthopedics 26(8 Suppl):s833–s836, 2003.
39. Weeden SH, Paprosky WG, Bowling J: The early dislocation rate in primary total hip arthroplasty following the posterior approach with posterior soft-tissue repair. J Arthroplasty 18:709–713, 2003.
40. Wenz JF, Gurkan I, Jibodh SR: Mini-incision total hip arthroplasty: A comparative assessment of perioperative outcomes. Orthopedics 25:1031–1043, 2002.
41. White Jr RE, Forness TJ, Allman JK, Junick DW: Effect of posterior capsular repair on early dislocation in primary total hip replacement. Clin Orthop Relat Res 393:163–167, 2001.
42. Willert HG, Buchhorn GH, Fayyazi A, et al: Metal-on-metal bearings and hypersensitivity in patients with artificial joints: A clinical and histomorphological study. J Bone Joint Surg 87A:28–36, 2005.
43. Woo RY, Morrey BF: Dislocations after total hip arthroplasty. J Bone Joint Surg 64A:1295–1306, 1982.
44. Yuan L, Shih C: Dislocation after total hip arthroplasty. Arch Orthop Trauma Surg 119:263–266, 1999.

independent sources validated matching results between abstract and publication. Any discrepancy was deferred to the senior author for a final decision.

Results: From 1996 to 2001, 168 of 292 (58%) podium abstracts presented at AAHKS meetings were published. The average time to publication was 21.7 months (±14.7). The most common journals in which the presented abstracts were published included *Clinical Orthopaedics and Related Research* (32%), *Journal of Bone and Joint Surgery* (29%), and *Journal of Arthroplasty* (28%). Together, these 3 journals constituted 89% of the sources in which AAHKS abstracts were published.

Discussion: The 58% publication rate for AAHKS ranks as one of the highest for all orthopedic specialty meetings. This rate validates the selection process, which includes passing numerous review boards, and represents the high quality of research presented at AAHKS. In conclusion, AAHKS meetings are an excellent source for scientific information as reflected by the exceptional publication rate in peer reviewed reference journals.

No institutional review board code because it does not involve patient information.

doi:10.1016/j.arth.2006.12.078

POSTER # 21

A RANDOMIZED CLINICAL TRIAL OF MOBILE-BEARING AND FIXED-BEARING (ALL-POLY TIBIA) CRUCIATE SUBSTITUTING TOTAL KNEE ARTHROPLASTY DESIGNS

Terence Gioe, MD, Neil Johnson, MD

Introduction: Mobile bearing total knee arthroplasty (TKA) proponents cite potential advantages of diminished backside wear and improved range of motion and/or function, but these advantages have not been demonstrated in prospective comparison. We conducted a randomized prospective clinical trial to compare a mobile bearing and fixed bearing cruciate substituting TKA of the same design.

Materials and Methods: Patients 60 years or older were prospectively randomized to receive either a cruciate substituting DePuy Sigma rotating platform (RP) design or fixed bearing design with an all polyethylene tibia (APT). The monoblock APT was selected to test a long term hypothesis regarding nonarticular surface wear in TKA. There were no significant demographic differences between the groups (mean age, 72.7 years; mean American Society of Anesthesiologists score, 3; mean body mass index, 32.3). Routine clinical and radiographic followup included Knee Society scores (KSS), Western Ohio and Western Ohio and McMaster Universities (WOMAC) score, and Short Form 36 outcome measures.

Results: A total of 180 TKAs in 167 patients (68 AP/112 RP) had at least 2 year (mean, 39.3 months) follow up. There was no significant difference in preoperative range of motion, KSS clinical or functional scores, WOMAC scores, or radiographic measures between the groups. Although there was significant improvement for both groups, there was no significant difference ($P < .05$) in mean postoperative range of motion (111° AP/108° RP), mean KSS clinical scores (91 AP/90.5 RP), mean KSS function scores (56.5 AP/60.6 RP), or mean KSS pain scores (45.4 AP/45.4 RP) at this followup point. There were 7 revisions; 4 for infection (2 AP/2 RP), 1 for fracture (RP), 1 for instability (RP), and 1 for aseptic loosening (RP). No patient was lost to follow up.

Discussion: Both designs functioned equivalently at early follow up. There was no significant clinical advantage of the RP design over an APT design in this patient group, and the RP design was more costly ($1875).

doi:10.1016/j.arth.2006.12.079

POSTER # 22

REDUCTION IN EARLY DISLOCATION RATE WITH LARGE-DIAMETER FEMORAL HEADS IN PRIMARY TOTAL HIP ARTHROPLASTY

Christopher L. Peters, MD, Jeffrey Jackson, MD, Jill A. Erickson

Introduction: Dislocation after total hip arthroplasty (THA) remains a major problem, with an estimated rate of 1% to 10%. Large diameter femoral heads theoretically can reduce dislocation risk, but this has not been confirmed by clinical studies. We performed 2 studies to investigate the relationship between large diameter femoral heads and postoperative dislocation. In the first study, we compared dislocation rates in 296 patients who underwent primary THA using either a 28 mm or a 38 mm head. The second study examined the rate of dislocation in a large series of primary THA with 38 to 56 mm metal on metal (MOM) femoral heads.

Methods: In study 1, surgeries were performed in 1995 2004. One hundred thirty six patients underwent primary THA with a 38 mm, MOM bearing surface via a posterior approach; average follow up was 28 months (range, 18 36). One hundred sixty patients underwent primary THA with a 28 mm head and either a metal on plastic (92%) or MOM bearing (8%) via a Hardinge approach. Average follow up was 52 months (range, 32 106). In study 2, 469 large diameter MOM THAs were performed in 2001 2004. All procedures were performed via posterior approach with average 36 months of follow up (range, 24 46).

Results: In study 1, there were no postoperative dislocations (0 of 136, 0%) in the patients with 38 mm femoral heads. The Harris hip score (HHS) improved from 58 to 98 ($P < .01$) One patient had a postoperative infection and required debridement. Four patients (4 of 160, 2.5%) with 28 mm heads experienced one or more postoperative dislocations ($P .12$). The HHS improved from 48 to 90 ($P < .01$) The 4 dislocations occurred in patients who underwent Hardinge approaches with metal on plastic components; all dislocations were anterior. In study 2, 99% of femoral components and 98.7% of acetabular components remain in place. There were 3 femoral revisions for acute subsidence and 5 acetabular revisions for aseptic loosening (4) and for impingement (1). There were 2 postoperative dislocations (2 of 469, 0.004%). Average HHS improved from 48 to 96 ($P < .01$).

Discussion: There is limited information regarding the effect of larger head sizes on the rate of dislocation. From the first study, our results indicate that the rate of dislocation in primary THA with a 38 mm MOM prosthesis via a posterior approach is the same or better than the rate of dislocation with a 28 mm articulation via a Hardinge approach, with similar improvement in HHS. The results of the second study indicate that MOM THA with femoral head sizes of 38 to 56 mm is associated with an extremely low dislocation rate (0.004%) at short term follow up.

doi:10.1016/j.arth.2006.12.081

POSTER # 23

DO PREOPERATIVE ANTIBIOTICS DECREASE INTRAOPERATIVE CULTURE YIELD?

Elie Ghanem, MD, Jesse Richman, James Purtill, MD, Peter Sharkey, MD, Javad Parvizi, MD

Introduction: Intraoperative tissue culture remains the criterion standard in diagnosing periprosthetic infection. However, an organism is not always cultured; and this has been attributed to the fact that preoperative antibiotics were administered. This study intends to examine if preoperative antibiotics prevent isolation of intraoperative organisms.

Methods: Ninety one total joint arthroplasty patients diagnosed with periprosthetic infection from 1999 2005 and who had positive aspiration culture were included in the study. All intravenous antibiotics that were given to the patient within 7 days of surgery were documented. The total number of positive intraoperative fluid and tissue samples of patients who did and did not receive antibiotics was calculated. Susceptibility of the organism(s) to antibiotics was determined by antibiogram of the preoperative and intraoperative culture.

Results: Sixty of 91 patients received preoperative antibiotics within 7 days of surgery. Antibiotics prevented isolation of an intraoperative organism in 6 of the 60 (10%) cases. All of the 31 patients who did not receive any preoperative antibiotics had positive intraoperative cultures. χ^2 analysis revealed no significant difference between giving preoperative antibiotics within 7 days and isolating an intraoperative organism ($P .068$). Giving antibiotics that specifically targets the culprit organism did not significantly affect the fluid ($P .585$) or tissue culture yield ($P .152$) either.

Conclusion: Our study demonstrated that giving preoperative antibiotics can prevent isolation of intraoperative organisms in 10% of cases. This is not statistically or clinically significant in patients with positive aspiration cultures because the organism is known beforehand. However, it is clinically and medicolegally relevant to withhold antibiotics in patients with negative aspiration cultures because the postoperative treatment antibiotic is tailored according to the organism cultured.

doi:10.1016/j.arth.2006.12.081

POSTER # 24

MOBILE-BEARING VERSUS FIXED-BEARING TOTAL KNEE ARTHROPLASTY: RESULTS WITH A CRUCIATE-RETAINING KNEE SYSTEM

Thomas Bernasek, MD, Jennifer Stahl, George Haidukewich, MD

This retrospective study compared 2 to 5 year results of fixed bearing (n 115) and mobile bearing (n 147) total knee arthroplasty. Knee Society score (KSS), passive range of motion (ROM), functional ROM, and radiographs were reviewed. Fixed bearing: (50 male, 65 female), averages: age, 63 (42 71); follow up, 4 years (2 5); body mass index, 32 (26 39); postoperative KSS pain, 96 (85 100); function, 79 (60 100). Average PROM, 117° (90° 125°); average functional ROM, 98° (40° 120°). X rays: 15 (13%) with incomplete radiolucent lines (11 nonprogressive, 4 progressive). Mobile bearing: (80 female, 67 male), averages: age, 61 years (45 78); follow up, 3.2 years (2 5); body mass index, 31 (23 38); postoperative KSS pain, 93 (86 100); function, 76 (70 100). Average PROM, 120° (85° 130°); functional ROM, 100° (50° 120°). X rays: 18 (12.2%) radiolucencies, all nonprogressive. No revisions in either group. No significant difference in PROM ($P .076$), functional ROM ($P .456$), KSS ($P .581$), or nonprogressive radiolucencies ($P .495$). Fixed bearing had a higher number of progressive radiolucencies ($P .023$).

Conclusion: We saw no significant difference in functional outcomes or ROM. Fixed bearing progres sive radiolucencies warrant observation. Passive to functional ROM correlation was 0.88 fixed bearing, 0.82 mobile bearing. Both designs demonstrated satisfactory knee scores during this follow up period.

doi:10.1016/j.arth.2006.12.082

POSTER # 25

ISOLATED TIBIAL COMPONENT REVISION WITH FEMORAL COMPONENT RETENTION: DEFECT MANAGEMENT AND CLINICAL OUTCOME

Michael Berend, MD, Merrill Ritter, MD, John Meding, MD, Phil Faris, MD, Michael Keating, MD, Rob Malinzak, MD, Michael Meneghini, MD, Jeff Pierson, MD, Andrew Pierce, MD

Introduction: Isolated modular polyethylene bearing exchange has met with limited midterm results. Nonmodular implants have decreased polyethylene wear but may require complete component revision for aseptic loosening. The purpose of this study is to report the intraoperative findings and clinical outcome for a consecutive series of isolated nonmodular tibial component revisions, which have not been previously reported.

Methods: A consecutive series of 8598 total knee arthroplasties were done in 5535 patients from 1983 to 2004. Fifty six knees (0.65%) underwent isolated tibial component revision (24 metal backed [MB], 32 all polyethylene [AP]) from 1988 until 2006.

Results: The mean time to failure was 3.2 years for MB knees and 3.0 years for AP knees. After revision, the mean follow up time was 7.0 years for AP cohort and 2.7 years for MB cohort. In the AP group, 69% of the knees were revised with a standard metal backed tibial component; and for the MB group, 70% required a long stemmed prosthesis. Screws and cement were used for most defects. No all polyethylene revision required a tibial component augment. Two knees (4%) required reoperation; one for periprosthetic femoral fracture, one for posterolateral instability. None of the revised tibial components underwent revision for loosening. Pain scores improved from 19 to 42 points, and KSS improved from 62 to 87 points after revision.

Conclusions: Revision of nonmodular tibial components has acceptable component survivorship of 98% at midterm follow up, in contrast to reported failure rates of 25% to 27% for modular polyethylene exchange. Defects differ between loose all polyethylene and nonmodular metal backed tibial components, with screws and cement and long stems with augments being the most common techniques used for revision of these cohorts, respectively. The retained femoral components and

NEW ZEALAND ORTHOPAEDIC ASSOCIATION

THE NEW ZEALAND JOINT REGISTRY

TEN YEAR REPORT

JANUARY 1999 TO DECEMBER 2008

REGISTRY BOARD

Alastair Rothwell	Chairman and Registry Supervisor
James Taylor	Deputy Chairman
Mark Wright	Orthopaedic Surgeon
Peter Devane	Orthopaedic Surgeon
Helen Tobin	Secretary NZOA Orthopaedic Surgeon
Paul Denham	Orthopaedic Industry Liaison Association
Alan Henwood	Arthritis New Zealand
Kim Miles	CEO New Zealand Orthopaedic Association
Toni Hobbs	Registry Coordinator
Statistician	Dr Chris Frampton

Email: toni.hobbs@cdhb.govt.nz
Tel: 0800-274-989
Website: www.cdhb.govt.nz/njr/

Date of Publication:
October 2009

CONTENTS

EDITORIAL COMMENT

It is our pleasure to present the ten year report of the New Zealand Orthopaedic Associations New Zealand Joint Registry. Ten years is an important milestone when we can pause and reflect on those early months and years when there was quite a lot of controversy over the need of a New Zealand Joint Registry when others existed in the Northern Hemisphere. Furthermore the difficulties in securing sufficient start up and ongoing funding threatened our early survival. There were also considerable frustrations in achieving nationwide ethical approval. Now almost 11 years on, the Registry and it s contributors can feel very proud of its achievements and the quality, quantity and versatility of the stored data on over 120,000 registered joint replacements. This is borne out by the increasing use of the Registry for audit and research projects. The number of publications in peer reviewed journals is increasing (see Appendix 2) and several of these are challenging some firmly held orthopaedic beliefs and should influence national and international orthopaedic arthroplasty practice.

For the individual surgeon registry data is becoming increasingly important for personal audit, peer review and continuing professional development requirements. In addition other agencies such as the Ministry of Health and the Accident Compensation Corporation have come to recognise the uniqueness and importance of the data base in the New Zealand health service. As always the over riding condition for the release of any data is the protection of patient and surgeon privacy unless prior permission has been obtained.

In this years report the format of previous years has been followed such that each arthroplasty section is self contained. This does however, result in a certain amount of intersection repetition. Included for the first time are sections on cervical and lumbar disc replacements.

The total number of registered joint arthroplasties at 31.12.2008 was 116,625 which had been performed on 88292 individual patients of which 8953 (10.14%) became deceased during the 10 year period. The number of observed component years contained within the Registry has now reached 416615 years. The increase of 15311 registered joints for 2008 compared to the 15253 increase in 2007 represents a overall annual gain of 0.3% which is the smallest on record. Primary hip arthroplasty increased by 0.6% and primary knee arthroplasty fell by 3% but interestingly there were significant gains in the more minor joint sections with a 35% increase for primary ankle arthroplasty ,14% for shoulders and 11% for elbows. As for the previous two years analysis of revision data has been confined to primary registered arthroplasties.

The annual percentage of uncemented hip arthroplasties continues to rise and in 2008 reached almost 50%. This rise is at the expense of fully cemented hips which last year fell to 16% of total compared to 56% in 1999. Hybrid arthroplasty remains static at just under 40%. However when the 3 types of hip fixation are analysed against the four age bands: under 55 years, 55-64 years, 65-74 years, and greater than 75 years, it shows that the uncemented arthroplasty has a statistically significantly higher revision rate in all except the under 55 age band. The data also shows that overall the hybrid hip has the lowest revision rate across the 4 age bands.

Revision rates for individual hip component matchings as well as for individual components for which there are a minimum of 250 primary procedures have also been calculated. Just one combination of the 50 analysed demonstrated a statistically significantly higher revision rate compared to the overall mean of 0.65 per 100 component years (95% confidence intervals; 0.61, 0.68) but the total number of this combination only increased by one in 2008. With regard to individual components, 2 popular femoral stems and 3 popular acetabulae have been identified as having statistically significant higher revision rates This does not automatically mean that they are poorly performing prostheses or components as there are many factors apart from the prosthesis or component which can affect its performance. Furthermore and perhaps most importantly the overall revision rate noted above and the ten year failure of just 5.76% are among the lowest of similar joint registries so that a prosthesis with a statistically significant higher revision rate in the New Zealand Registry may not be identified as statistically significant in other registries. A similar situation applies to knee prostheses with the overall revision rate per 100 component years of 0.54 (95% confidence intervals; 0.50, 0.58) and the ten year failure of just 3.97% again among the lowest for Joint Registries. New Zealand surgeons can therefore be justifiably proud of these medium term trends. It is also interesting that none of the 10 year primary hip and knee arthroplasties were revised in 2008.

For the first time the revision rates of the various bearing surfaces used in primary hip arthroplasty ie metal on plastic, metal on metal, ceramic on plastic, ceramic on metal, ceramic on ceramic have been analysed and shows that the metal on plastic articulation has a significantly lower revision rate than the other combinations. The effect of

factors such as head size, cross-linked vs standard polyethylene, stainless steel vs chrome/cobolt, zirconia vs alumina etc will be discussed in next years report.

Although uncemented knee arthroplasty represents just 4.5% of all primary knee arthroplasties it has a statistically significantly higher revision rate than either fully cemented or hybrid in which the tibial component is cemented and the femoral component uncemented. Analyses have confirmed that it is loosening of the uncemented tibial component that is mainly responsible for the increased revision rate.

Image guidance continues to be increasingly used for primary knee arthroplasty and during 2008 was used in 13.7% of procedures. The same applies to the minimally invasive approach for the uni-compartmental knee arthroplasty and in 2008 was used in 37% of procedures.

Once again we have compared the deep infection revision rates within six months of the primary procedure for primary hip and knee arthroplasty against theatre environment. Six months was chosen as infection within this time period is highly likely to have been introduced at the time of surgery. This years analyses demonstrate that for primary hip arthroplasty there was four times the risk for revision for deep infection when the primary procedure is carried out in a laminar flow theatre with space suit as compared to a conventional theatre without a space suit. For primary knees the risk is 2.9 times greater. When the use of space suits versus deep infection is analysed the risk is almost 3 times greater when a space suit is used than when not used. These are very surprising results particularly as the use of laminar flow theatres and space suits is increasing year by year such that last year 49% of primary hips and 53% of primary knees were performed in laminar flow theatres and space suits were used for 42% of primary hips and 44% of primary knee arthroplasties. The numbers of revised infected arthroplasties however, are not large(46 primary hips, 50 primary knees) but an in depth investigation of these findings is already underway.

The number of primary ankle arthroplasties increased by 107 in 2008 and represented a 35% jump. This increased number was performed by the same number of surgeons(12) as in 2007. There is concern that not all revisions to an ankle arthrodesis are being captured by the Registry.

In the shoulder arthroplasty section, resurfacing has been added to the conventional total, reverse and hemi arthroplasty groups with respect to revision rates and Oxford scores. Although there is considerable variation in revision rates for the different prostheses there are no statistically significant differences either within or across the groups owing to very wide confidence intervals for several prostheses but the reverse group as a whole does have a significantly higher revision rate than the 3 other groups. Conventional total arthroplasty has a significantly better mean Oxford score than the other groups.

Oxford 12 Questionnaire

As noted in previous years the statistically significant relationship between the 6 month score and revision within 2 years for primary hips and knees including unicompartmental, has again been demonstrated. In addition the relationship between the 5 year score and revision within 2 years of that date demonstrates an apparently even more significant relationship although the numbers are not yet large enough to be certain of the statistical significance.

In terms of using the Oxford scores as a screening tool for arthroplasty follow up it is worth noting that 69% of hip, 79% of knee and 66% of unicompartmental revisions within 2 years would have been captured by monitoring the lowest 31%, 25% and 17% respectively of the Oxford scores.

The complication data collected with the Oxford questionnaires is statistically unreliable and therefore will no longer be analysed for the annual reports.

Alastair Rothwell	Toni Hobbs	Chris Frampton
Supervisor	Coordinator	Statistician

ACKNOWLEDGMENTS

The Registry is very appreciative of the support from the following

Canterbury District Health Board:
for the website and other facilities

New Zealand Health Information Service:
for audit compliance information

Mike Wall, Alumni Software:
for continued monitoring and upgrading of data base software

PARTICIPATING HOSPITALS

We wish to gratefully acknowledge the support of all participating hospitals and especially the coordinators who have taken responsibility for the data forms

Public Hospitals

Auckland Hospital
Auckland 1142
Contact: Shelley Thomas

Christchurch Hospital
Christchurch 8140
Contact: Barbara Clark

Gisborne Hospital
Gisborne 4010
Contact: Jackie Dearman

Hawkes Bay Hospital
Hastings 4120
Contact: Jane Hurford-Bell

Kenepuru Hospital
Porirua 5240
Contact: Emma Brooks

Masterton Hospital
Masterton 5840
Contact: Sarah Duckett

Nelson Hospital
Nelson 7040
Contact: Pauline Manley or Anne Fryer

Palmerston North Hospital
Palmerston North 4442
Contact: Philip Prujean or Karen Langvad-Forster

Southland Hospital
Invercargill 9812
Contact: Helen Powley

Tauranga Hospital
Tauranga 3143
Contact: Sue Clynes

Waikato Hospital
Hamilton 3204
Contact: Maria Ashurst or Helen Keen

Wanganui Hospital
Wanganui
Contact: Sue Slight

Burwood Hospital
Christchurch 8083
Contact: Diane Darley

Dunedin Hospital
Dunedin 9016
Contact: Jenni Taylor

Grey Base Hospital
Greymouth 7840
Contact: Anna Vorverk or Marg Wafer

Hutt Hospital
Lower Hutt 5040
Contact: Sonja Dowle or Ruby Boekholt

Manukau Surgery Centre
Auckland 2104
Contact: Amanda Ellis

Middlemore Hospital
Auckland 1640
Contact: Francine Gabriel

Northshore Hospital,
Waitemata DHB
Takapuna 0740
Contact: Chris Cavalier

Rotorua Hospital (Lakes DHB)
Rotorua 3046
Contact: Janice Reynolds

Taranaki Base Hospital
New Plymouth 4342
Contact: Allison Tijsen

Timaru Hospital
Timaru 7940
Contact: Carol Campbell

Wairau Hospital
Blenheim 7240
Contact: Monette Johnston

Wellington Hospital
Newtown 6242
Contact: Rebecca Kay

Whakatane Hospital
Whakatane 3158
Contact: Karen Burke

Whangarei Area Hospital
Whangarei 0140
Contact: Helen Harris

Private Hospitals

Aorangi Hospital
Palmerston North 4410
Contact: Frances Clark

Ascot Integrated Hospital
Remuera 1050
Contact: Elizabeth Hollier

Belverdale Hospital
Wanganui 4500
Contact: Jane Young

Bidwill Trust Hospital
Timaru 7910
Contact: Kay Taylor

Boulcott Hospital
Lower Hutt 5040
Contact: Karen Hall

Bowen Hospital
Wellington 6035
Contact: Pam Kohnke

Braemar Private Hospital
Hamilton 3204
Contact: Allison Vince

Chelsea Hospital
Gisborne 4010
Contact: Jenny Long

Grace Hospital (Norfolk Southern Cross)
Tauranga 3112
Contact: Anne Heke

Kensington Hospital
Whangarei 0112
Contact: Sandy Brace

Manuka Street Trust Hospital
Nelson 7010
Contact: Sabine Mueller

Mercy Integrated Hospital
Auckland 1023
Contact: Yve Rutland

Mercy Hospital
Dunedin 9054
Contact: Liz Cadman

Ormiston Hospital
Auckland 2016
Contact: Bodelle Cross

Royston Hospital
Hastings 4122
Contact: Suzette Du Plessis

St Georges Hospital
Christchurch 8014
Contact: Steph May

Southern Cross Hospital, Brightside
Epsom 1023
Contact: Theresa Lambert

Southern Cross Hospital
Christchurch Central 8013
Contact: Diane Kennedy

Southern Cross Hospital
Hamilton East 3216
Contact: Cathy Wine

Southern Cross Hospital
Invercargill Central 9810
Contact: Maree Henderson

Southern Cross Hospital
New Plymouth 4310
Contact: Lorraine Parthemore

Southern Cross North Harbour
Wairau Valley 0627
Contact: Rita Redman

Southern Cross Hospital
Newtown
Wellington 6021
Contact: Marian Lee

Southern Cross QE
Rotorua 3015
Contact: Chris Mott

Wakefield Hospital
Wellington 6021
Newtown
Contact: Jan Kereopa

Southern Cross Hospital
Palmerston North 4410
Contact: Susan Wright

PROFILE OF THE AVERAGE NEW ZEALAND ORTHOPAEDIC SURGEON *

From our analyses the average orthopaedic surgeon performs on an annual basis:

- 37 Total hip arthroplasties — with 66% using uncemented, 16% fully cemented and 38% hybrid prostheses: has a 94.24% survival at10 years and a revision rate of 0.65 per 100 component years; 0.38% have been revised for deep infection; 85% at 6 months and 88% at five years had an excellent or good Oxford score.
- 30 Total knee arthroplasties — with almost all cemented but only 10 with patellae resurfaced; has a 96.03% survival at 10 years and a revision rate of 0.54 per 100 component years; 0.52% have been revised for deep infection; 72% at 6 months and 81% at 5 years had an excellent or good Oxford score.
- 7 Unicompartmental knee arthroplasties — almost all cemented; has a 90.68% survival at 6 years and a revision rate of 1.51 per 100 component years; 0.3% have been revised for deep infection; 79% at six months and 87% at 5 years had an excellent or good Oxford score.
- 5 Shoulder arthroplasties — with a 60:40 split between total and hemi; has a 95.50% survival at 5 years and a revision rate of 0.98 per 100 component years; 0.4% have been revised for deep infection; 66% had an excellent or good Oxford score at 6 months.
- 6 Total ankle arthroplasties — mostly uncemented; 90.02% survival at 6 years and a revision rate of 1.3 per 100 component years; 0.4% revised for deep infection; 56% had excellent or good Oxford derived scores at 6 months.
- 2 Total elbow arthroplasties — most likely a cemented Coonrad/Morrey prosthesis; 93.73% survival at 4 years and a revision rate of 1.6 per 100 component years; 0.7% have been revised for deep infection; 70% had excellent or good Oxford derived scores at 6 months.

*** averages derived from the number of surgeons recorded performing the above procedures during 2008 and not from the total pool of orthopaedic surgeons**.

DEVELOPMENT AND IMPLEMENTATION OF THE NEW ZEALAND JOINT REGISTRY

The year 1997 marked 30 years since the first total hip replacement had been performed in New Zealand and as a way of recognising this milestone it was unanimously agreed by the membership of the NZOA to adopt a proposal by the then President, Alastair Rothwell to set up a National Joint Registry.

New Zealand surgeons have always been heavily dependent upon northern hemisphere teaching, training and outcome studies for developing their joint arthroplasty practice and it was felt that it was more than timely to determine the characteristics of joint arthroplasty practice in New Zealand and compare the outcomes with northern hemisphere counterparts. It was further considered that New Zealand would be ideally suited for a National Registry with its strong and co-operative NZOA membership, close relationship with the implant supply industry and its relatively small population. Advantages of a Registry were seen to be: survivorship of different types of implants and techniques; revision rates and reasons for; infection and dislocation rates, patient satisfaction outcomes, audit for individual surgeons, hospitals, and regions; opportunities for in-depth studies of certain cohorts and as a data base for fund raising for research.

Administrative Network
It was decided that the Registry should be based in the Department of Orthopaedic Surgery, Christchurch Hospital and initially run by three part time staff: a Registry Supervisor (Alastair Rothwell), the Registry Coordinator (Toni Hobbs) and the Registry secretary (Pat Manning). As all three already worked in the Orthopaedic Department it was a cost effective and efficient arrangement to get the Registry underway.

New Zealand was divided into 19 geographic regions and an orthopaedic surgeon in each region was designated as the Regional Coordinator whose task was to set up and maintain the data collection network within the hospitals for his region.

This network included a Theatre Nurse Coordinator in every hospital in New Zealand who voluntarily took responsibility for supervising the completion, collection and dispatch of the data forms to the Registry.

Data Collection Forms
The clear message from the NZOA membership was to keep the forms for data collection simple and user friendly. The Norwegian Joint Registers form was used as a starting point but a number of changes were made following early trials. The forms are largely if not completely filled out by the Operating Theatre Circulating Nurse and are meant to be checked and signed by the surgeon at the end of the operation.

Data Base
The Microsoft Access 97 data base programme was chosen because it is easy to use, has powerful query functions, can cope with one patient having several procedures on one or more joints over a lifetime and has “add on” provisions. The data base is expected to meet the projected requirements of the Registry for at least 20 years. It can accommodate software upgrades as required.

Patient Generated Outcomes
The New Zealand Registry is one of the first to collect data from Patient Generated Outcomes. The validated Oxford Hip and Knee outcomes questionnaires were chosen to which were added questions relating to dislocation, infection and any other complication that did not require further joint surgery. It was agreed that these questionnaires should be sent to all registered patients six months following surgery and then at five yearly intervals. The initial response rate was between 70 & 75% and this has remained steady over the five year period.

However because of the large numbers of registered primary hip and knee arthroplasties and on the advice of our statistician, questionnaires have been sent out on a random selection basis since July 2002 to achieve an annual response of 20% for each group.

Funding
Several sources of funding were investigated including contributions from the Ministry of Health, various funding agencies, medical insurance societies and an implant levy payable by surgeons and public hospitals to supplement a grant from the NZOA. In the early years the Registry had a “hand to mouth” existence relying on grants from the NZOA and Wishbone Trust until it received significant annual grants from the Accident Compensation Corporation. From 2002 funding became more reliable with the surgeons paying a

$10 levy, increased to $15 in 2008, for each joint registered from a private hospital, and the Ministry of Health agreeing to pay $72,000 a year as part of the Government Joint Initiative. Since 2005 the Southern Cross Hospitals have contributed $10,000 annually.

Ethical Approval

Application was made to the Canterbury Ethical Committee early in 1998; first for approval for hospital data collection without the need for patient consent and second for the patient generated outcomes using the Oxford 12 questionnaire plus the additional questions. The first part of the application was initially readily approved but the second part required several amendments to patient information and consent forms before approval was obtained.

A reapplication had to be made when the Ethics Committee of a private hospital chain refused to allow their nurses to participate in the project unless there was prior written patient consent. This view was supported by the Privacy Commissioner on the grounds that the Registry data includes patient identification details. The approval process was eventually successful but having to obtain patient consent has created some difficulties with compliance.

Surgeon and Hospital Reports

It was agreed that every six months reports were to be generated from the Registry data base for primary and revision hip and knee replacements and to consist of: the number of procedures performed by the individual surgeon or at the hospital; the total number of procedures performed in the region in which the surgeon works; the national total and cumulative totals for each of these categories. Six month and more recently 5 year Oxford 12 scores are also included. Since 2008 each surgeon also receives their individual revision rate for their registered primary arthroplasties, and the reports have become annual rather than six monthly.

Introduction of the Registry

The National Joint Registry was introduced as a planned staged procedure.

Stage I November 1997 to March 1998
The base administrative structure was established. The data forms and the data base were developed and a trial was performed at Burwood Hospital.

Stage II April 1998 to June 1998
Further trialling was performed throughout the Christchurch Hospitals and the data forms and information packages were further refined.

Stage III July 1998 to March 1999
The data collection was expanded into five selected New Zealand regions for trial and assessment.

Also during this time communication networks and the distribution of information packages into the remaining regions of New Zealand were carried out.

Stage IV April 1st 1999 the National Joint Registry became fully operational throughout New Zealand.

DEVELOPMENTS SINCE THE INTRODUCTION OF THE REGISTRY

Inclusion of other joint replacement arthroplasties

At the request of the NZOA membership the data base for the Registry was expanded to include total hip replacements for fractured neck of femur, unicompartmental replacements for knees, and total joint replacements for ankles, elbows and shoulders including hemiarthroplasty for the latter. Commencement of this data collection was in January 2000 and this information is included in the annually surgeon and hospital reports.

The validated-Oxford questionnaire was available for the shoulder and was adapted but not validated for the elbow and ankle joints. All those receiving total arthroplasty of the above joints as well as unicompartmental knee arthroplasty are sent questionnaires with a reply rate of between 70 and 75%. As for hips and knees the questionnaires are sent out 6 months post surgery and then at five yearly intervals.

Monitoring of Data Collection

The aim of the Registry is to achieve a minimum of 90% compliance for all hospitals undertaking joint replacement surgery in New Zealand.

It is quite easy to check the compliance for public hospitals as they are required to make regular returns with details of all joint replacement surgery to the NZ Health Information Service. For a small fee the registered joints from the Registry can be compared against the hospital returns for the same period and the compliance calculated. Any obvious discrepancies are checked out with the hospitals concerned and the situation remedied. It is more difficult with private hospital surgery as they are not required to file electronic returns. However by enlisting the aid of prosthesis supply companies it is possible to check the use of prostheses region by region and any significant discrepancy is further investigated.

Another method is to check data entry for each hospital against the previous corresponding months and if there is an obvious trend change then again this is investigated.

The most recent compliance audit in March 2009 again demonstrated a New Zealand wide public hospital compliance of 98% when compared to NZHIS data

Registered patient deaths are also obtained from the NZHIS.

DATA ENTRY BY SCANNING

Barcoding of the labels containing all the prosthesis identification data has now become widespread throughout the implant industry and currently staff are able to scan in 84% of hip and 90% of knee prosthesis data directly into the Registry.

All manually entered data is at least double checked for accuracy.

Staffing

Staff has expanded to four part time data entry and secretarial personnel. This is in order to maintain a lag time between receipt and entry of data forms of no more than two months. It has also been necessary to employ extra staff in order to free up the Coordinator to cope with the ever increasing numbers of requests for Registry data.

The 2008 Registry staff are Alastair Rothwell, Supervisor, Toni Hobbs, Coordinator, Pat Manning Secretary, Lynley Diggs, Anne McHugh and Jane Tope-Cobb data processors.

Use of Registry Data

There have been increasing numbers of requests for information from the Registry from a wide variety of sources. Great care is taken to protect patient confidentiality at all times and patient details are only released to appropriately accredited personnel and it is emphasised that Ethics Committee approval is required for any research projects involving patient contact.

Registry Board

This Board has now been formalised and the membership consists of: 5 Orthopaedic Surgeons; Registry Coordinator; OILA Representative; Arthritis New Zealand Representative; Chief Executive NZOA. The main tasks of the Committee are to monitor the organisational structure and functions of the Registry, rule on difficult requests for information from the Registry, advise appropriate authorities regarding data from the Registry that could effect the health status of implant patients, encourage and support research and work with the International Registry Association.

NUMBER OF JOINTS ANALYSED
1ST JANUARY 1999 – 31ST DECEMBER 2008

Numbers of procedures registered

	10 years	9 years	8 years	7 Years	6 Years	5 Years
Hips, primary	56383	49374	42421	35998	29680	23457
Hips, revision	8405	7360	6383	5487	4570	3641
Knees, primary	40068	34458	28705	23565	18537	14371
Knees, revision	3293	2883	2499	2149	1736	1419
Knees, unicompartmental	4826	4284	3709	3122	2565	1926
Shoulders, primary	2498	2044	1641	1275	982	693
Shoulders, revision	180	139	105	80	57	45
Elbows, primary	267	227	191	160	130	101
Elbows, revision	41	36	31	26	20	15
Ankles, primary	484	377	298	216	146	99
Ankles, revision	29	26	19	12	8	6
Lumbar Disc, primary	94	75	59	38	22	
Cervical Disc, primary	57	31				
TOTAL	**116625**	**101314**	**86061**	**72128**	**58,453**	**45,776**

BILATERAL JOINT REPLACEMENTS CARRIED OUT UNDER THE SAME ANAESTHETIC

Bilateral hips	1164 patients	(2328 hips)	4.0%	of primary hips
Bilateral knees	1792 patients	(3584 knees)	9.0 %	of primary knees
Bilateral Unicompartmental knees	390 patients	(780 knees)	16.0%	of primary uni knees
Bilateral ankles	2 patients	(4 ankles)		
Bilateral shoulders	2 patients	(4 shoulders)		

The percentages have remained essentially unchanged from the previous reports.

During the 10 year period 88292 individual patients were registered with a mortality rate of 10.14%.

Registrar Surgeons In the following analyses consultants took responsibility for their registrar surgeon procedures.

HIP ARTHROPLASTY

PRIMARY HIP ARTHROPLASTY

The ten year report analyses data for the period January 1999 – December 2008. There were 56,383 primary hip procedures registered including 708 resurfacing arthroplasties. This is an additional 6,996 compared to last year's report.

1999	4117
2000	4721
2001	4934
2002	4830
2003	5059
2004	6029
2005	6317
2006	6427
2007	6953
2008	6996

There was a 0.6% increase in hip registrations for 2008, which is the smallest annual increase excepting the 2.1% decrease in 2002.
Overall there has been a 70% increase in annual registrations since 1999.

DATA ANALYSIS

Age and sex distribution

The average age for all patients with primary hip arthroplasty was 66.84 years, with a range of 15.43 – 100.13 years.

All hip arthroplasty

	Female	Male
Number	29670	26713
Percentage	52.62	47.38
Mean age	68.36	65.16
Maximum age	100.13	96.97
Minimum age	15.43	15.87
Standard dev.	11.73	11.52

Conventional hip arthroplasty

	Female	Male
Number	29501	26174
Percentage	52.99	47.01
Mean age	68.47	65.43
Maximum age	100.13	96.97
Minimum age	15.43	15.87
Standard dev.	11.66	11.41

Resurfacing hip arthroplasty

	Female	Male
Number	169	539
Percentage	23.87	76.13
Mean age	49.26	52.03
Maximum age	65.88	75.69
Minimum age	25.72	20.55
Standard dev.	7.55	8.62

A further 191 resurfacing hips were registered during 2008, which were just 3 more than for 2007. The male to female ratio is 3.2:1.

Previous operation

None	53504
Internal fixation	1230
Osteotomy	369
Internal fixation for SUFE	99
Arthroscopy/arthrotomy	57
Arthrodesis	54
Core decompression	42
Open reduction	36
Other	96

Diagnosis

Osteoarthritis	48364
Acute fracture NOF	2004
Avascular necrosis	1817
Developmental dysplasia	1558
Rheumatoid arthritis	931
Old fracture NOF	774
Other inflammatory	553
Tumour	259
Post acute dislocation	201
Fracture acetabulum	105
Other	155

Approach

Posterior	34767
Lateral	16134
Anterior	2929
Minimally invasive	1008
Trochanteric osteotomy	111
Image guided surgery	50

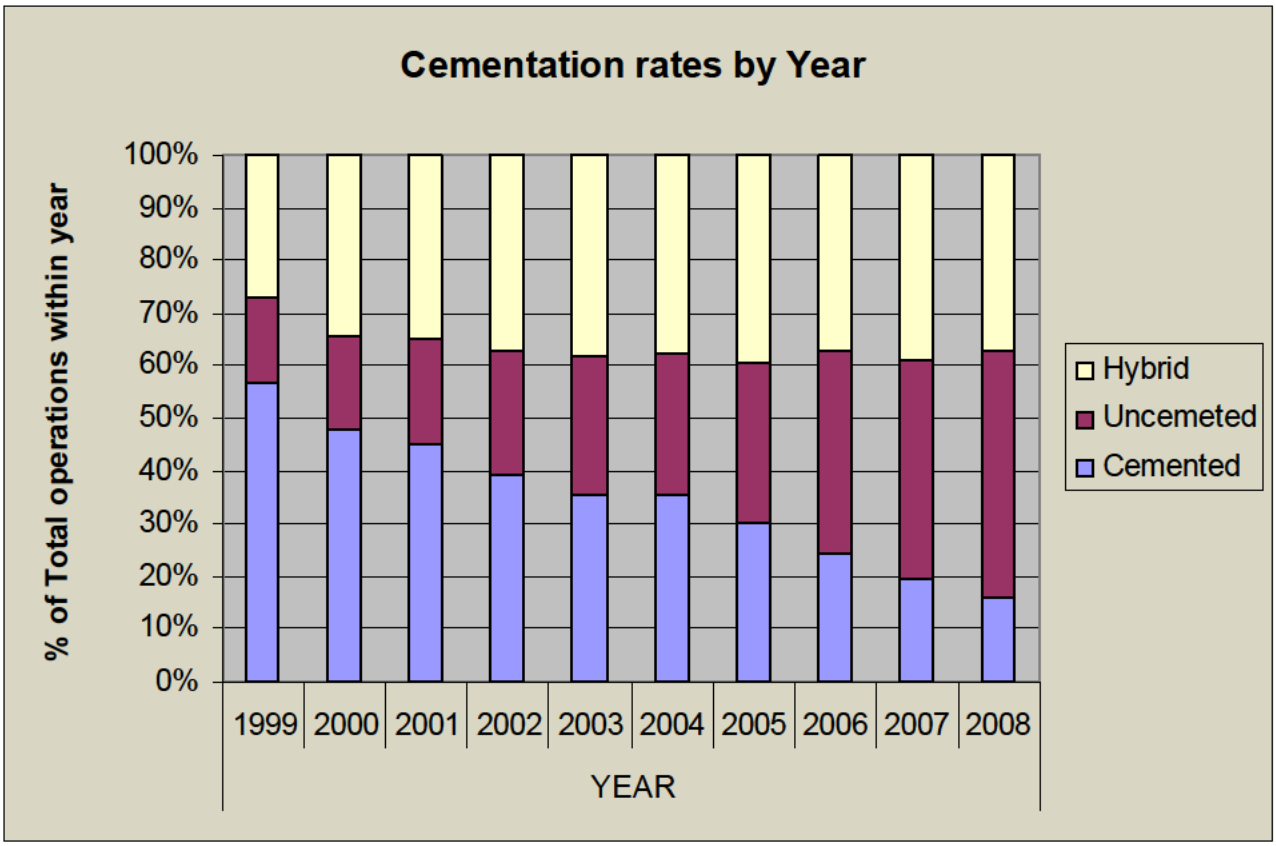
Image guided surgery was added to the updated forms at the beginning of 2005, but there has been little interest in the technique. In contrast the minimally invasive approach continues to gain in popularity and in 2008 accounted for 4.0% of approaches, up from 2.6% in 2007.

Bone graft

Femoral autograft	148
Femoral allograft	30
Femoral synthetic	2
Acetabular autograft	428
Acetabular allograft	70
Acetabular synthetic	2

Cement

Femur cemented	38958	(69%)
Antibiotic in cement	21827	(56%)
Acetabulum cemented	18956	(34%)
Antibiotic in cement	10565	(56%)



The proportion of uncemented hips continues to increase to almost 50% in 2008 at the expense of fully cemented hips which were just 16% of total compared to 56% in 1999.The hybrid remain static at just under 40%.

Systemic antibiotic prophylaxis

Patient number receiving at least one systemic antibiotic 53890 (96%)

A cephalosporin was used in 90% of patients.

Operating theatre

Conventional	36505
Laminar flow	18958
Space suits	13046

The number of hip arthroplasties being performed in laminar flow theatres continues to increase and in 2008 accounted for 49% of the total.
Space suits were used in 42% of arthroplasties.

ASA Class

This was introduced with the updated forms at the beginning of 2005.

Definitions

ASA class 1: A healthy patient
ASA class 2: A patient with mild systemic disease
ASA class 3: A patient with severe systemic disease that limits activity but is not incapacitating
ASA class 4: A patient with an incapacitating systemic disease that is a constant threat to life

For the four-year period 2005 -2008, there were 23,235 (87%) primary hip procedures with the ASA class recorded

ASA	Number	Percentage
1	4147	18
2	13619	59
3	5276	22
4	193	1

Operative time – skin to skin

Mean	81	minutes
Standard deviation	28	minutes
Minimum	24	minutes
Maximum	459	minutes

Surgeon grade

The updated forms introduced in 2005 have separated advanced trainee into supervised and unsupervised. The following figures are for the four-year period 2005 – 2008.

Consultant	23076
Advanced trainee supervised	2018
Basic trainee	734
Advanced trainee unsupervised	690

There was no change in the number of supervised/unsupervised advanced trainee numbers for 2008.

Prosthesis usage

Resurfacing hips

	2004	2005	2006	2007	2008
BHR	7	101	132	156	173
ASR	10	38	37	29	14
Durom	4				
Adept				2	
Mitch				1	4
Total	21	139	169	188	191

The BHR is the most common resurfacing prosthesis used at 80% of the total.

Conventional primary hips

Top 10 femoral components used in 2008

Exeter V40	1922
TwinSys uncemented	822
Corail	757
CLS	590
Spectron	410
Muller	304
Accolade	288
MS 30	226
CPT	216
Summit	197

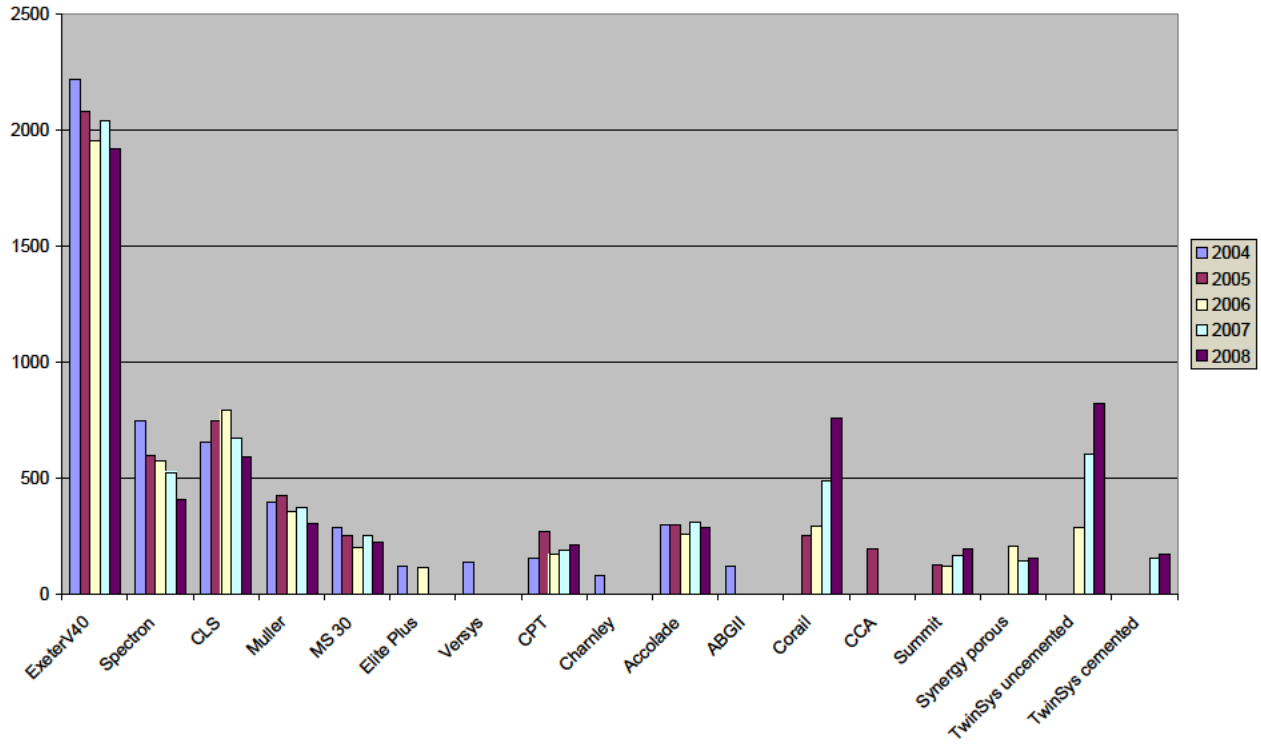
There was no change in the top 10, but the TwinSys and Corail move up although still well behind the Exeter V40.

Top 10 acetabular components used in 2008

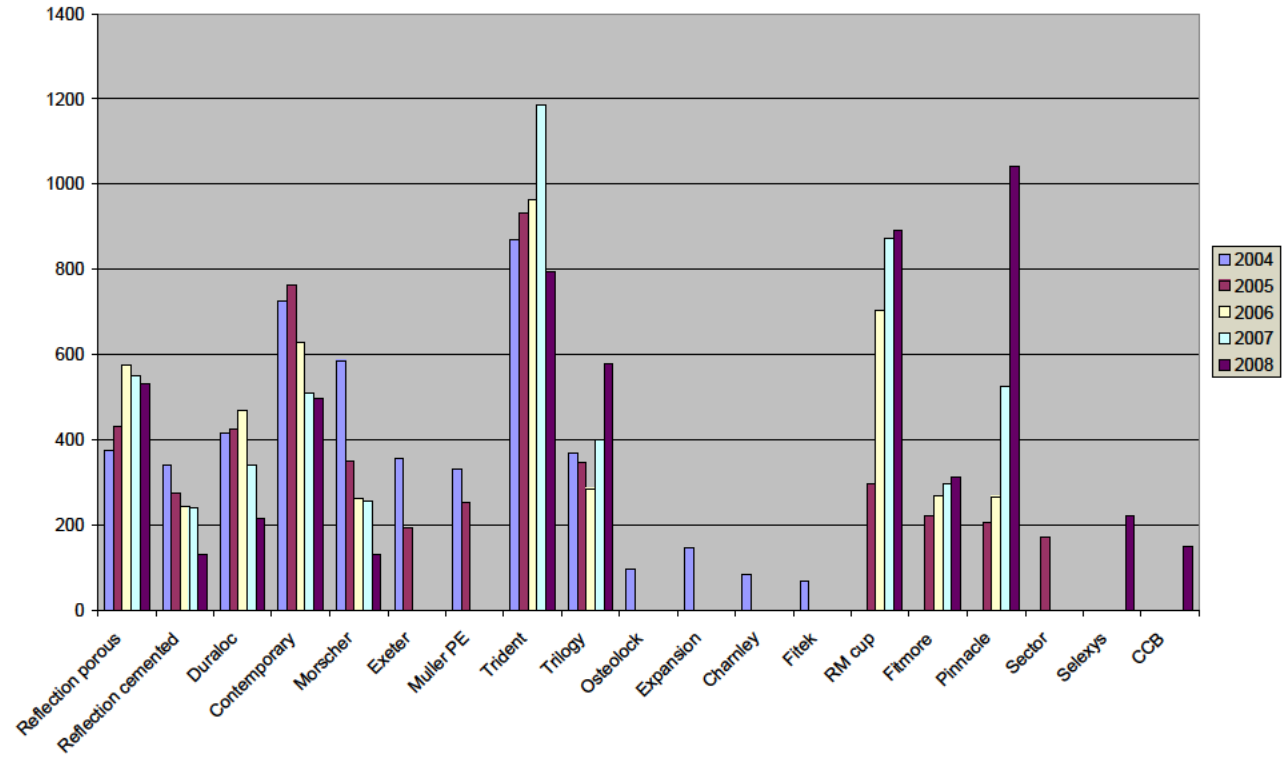
Pinnacle	1042
RM cup	891
Trident	794
Trilogy	578
Reflection porous	531
Contemporary	498
Fitmore	311
Selexys	221
Duraloc	214
CCB	132

The Pinnacle has continued its surge to the top with twice the number registered in 2008 than for 2007. Selexys and CCB have replaced Morscher and Reflection cemented.

MOST USED FEMORAL COMPONENTS 5 YEARS 2004- 2008



MOST USED ACETABULAR COMPONENTS 5 YEARS 2004 -2008



Surgeon and hospital workload

Surgeons
In 2008, 188 surgeons performed 6996 total hip replacements, an average of 37 procedures per surgeon.

29 surgeons performed less than 10 procedures and 45 performed more than 50.

Hospitals
In 2008 primary hip replacement was performed in 50 hospitals, 26 public and 24 private.

The average number of total hip replacements per hospital was 140.

REVISION HIP ARTHROPLASTY
Revision is defined by the Registry as a new operation in a previously replaced hip joint during which one of the components are exchanged, removed, manipulated or added. It includes excision arthroplasty and amputation, but not soft tissue procedures. A two-stage procedure is registered as one revision.

Data analysis
For the ten year period January 1999 – December 2008, there were 8,405 revision hip procedures registered. This is an additional 1,043 compared to last year's report.

The average age for a revision hip replacement was 69.77 years, with a range of 17.52 – 97.72 years.

Revision hips

	Female	Male
Number	4100	4305
Percentage	48.78	51.22
Mean age	69.92	69.63
Maximum age	97.72	95.78
Minimum age	17.52	25.68
Standard dev.	12.28	10.82

The ratio of revision hips to primary hips remains at 1:7.7(13%.)

REVISION OF REGISTERED PRIMARY HIP ARTHROPLASTIES
This section analyses data for revisions of primary hip procedures for the ten year period.

There were 1,504 revisions of the 55,675 primary conventional hip replacements (2.7%) and 12 revisions of the 708 resurfacing hip replacements (1.7%), a total of 1516.

Time to revision for conventional hips

Mean	972	days
Maximum	3529	days
Minimum	0	days
Standard deviation	942	days

Reason for revision

Dislocation	528
Loosening acetabular comp.	321
Loosening femoral component	244
Deep infection	214
Pain	139
Fracture femur	135
Wear polyethylene	25
Implant breakage	29
Osteolysis	21
Wear acetabulum	10
Malposition of components	5
Tumour	4
Subsidence of prostheses	4
Other	29

There was often more than one reason listed on the data form and all were entered.

The percentages for the 4 main reasons for revision are;

Dislocation	35%
Loosening acetabular comp.	21%
Deep infection	16%
Loosening femoral component	14%

Analysis by time of the 4 main reasons for revision
Dislocation n = 528

< 6 months	231
6 months – 1 year	56
2 years	85
3 years	49
4 years	36
5 years	21
6 years	20
7 years	12
8 years	7
9 years	10
10 years	1

Loosening acetabular component n = 321

< 6 months	45
6 months – 1 year	23
2 years	38
3 years	31
4 years	32
5 years	29
6 years	21
7 years	42
8 years	27
9 years	22
10 years	11

Loosening femoral component n = 244

< 6 months	19
6 months – 1 year	15
2 years	35
3 years	31
4 years	29
5 years	23
6 years	29
7 years	30
8 years	19
9 years	10
10 years	4

Revision for loosening of either component seems to have reached a peak at seven years and then dropped away. It will be interesting to see if this trend continues.

Deep infection n = 214

< 6 months	46
6 months – 1 year	27
2 years	46
3 years	37
4 years	19
5 years	16
6 years	4
7 years	8
8 years	6
9 years	5
10 years	-

Time to revision for resurfacing hips

N = 708 and revised n = 12

Mean	403 days
Maximum	796 days
Minimum	28 days
Standard deviation	278 days

Reason for revision

Fracture femur/neck of femur	6
Loosening acetabular comp.	1
Loosening femoral component	1
Deep infection	1
Pain	1
Subluxation	2
Avascular necrosis	1
Metal allergy	1

Statistical note

In the tables below there are two statistical terms readers may not be familiar with.

Observed component years

This is the number of registered primary procedures multiplied by the number of years each component has been in place.

Rate/100 component years

This is equivalent to the yearly revision rate expressed as a percent and is derived by dividing the number of prostheses revised by the observed component years multiplied by 100. It therefore allows for the number of years of post operative follow up in calculating the revision rate. These rates are usually very low, hence it is expressed per 100 component years rather than per component year. Statisticians consider that this is a more accurate way of deriving a revision rate for comparison when analysing data with widely varying follow up times. It is also important to note the confidence intervals. The closer they are to the estimated revision rate/100 component years, the more precise the estimate is.

Statistical Significance

Where it is stated that a difference is significant the p value is 0.05 or less.

All Primary Hip Arthroplasties

	No. Ops.	Observed comp. Yrs	Number Revised	Rate/100-component-years	Exact 95% confidence interval	
All patients	55675	232292.68	1504	0.65	0.62	0.68

Resurfacing Arthroplasty

	No Ops	Observed comp. Yrs	Number Revised	Rate/100-component-years	Exact 95% confidence levels	
All patients	708	1326.07	12	0.90	0.47	1.59

There is no significant difference compared to total hip arthroplasty.

Revision versus hip Prosthesis Matchings sorted on revision rate/ 100 component years

Femoral Component	Acetabular component	Total	Observed Component Years	Number Revised	Rate/100-component-years	Exact 95% Confidence Interval	
Exeter V40	Contemporary	3689	11377.17	62	0.55	0.42	0.70
Exeter V40	Trident	3080	8105.29	47	0.58	0.43	0.77
Spectron	Reflection cemented	2786	15145.99	97	0.64	0.52	0.78
Spectron	Reflection porous	2035	7568.88	48	0.63	0.47	0.84
CLS	Morscher	1627	8272.31	53	0.64	0.48	0.84
Exeter	Contemporary	1550	11147.68	74	0.66	0.52	0.83
Accolade	Trident	1485	4585.97	41	0.89	0.64	1.21
Exeter V40	Exeter	1342	5216.94	22	0.42	0.26	0.64
Exeter	Exeter	1326	9141.43	53	0.58	0.43	0.76
Muller	Muller PE cup	1278	6222.67	21	0.34	0.21	0.52
Spectron	Duraloc	1155	6835.35	61	0.89	0.69	1.15
CLS	CLS Expansion	1123	5890.84	43	0.73	0.53	0.98
TwinSys stem uncemented	RM cup	1098	1371.79	13	0.95	0.50	1.62
Corail	Pinnacle	1039	1475.74	15	1.02	0.57	1.68
Exeter V40	Trilogy	1039	3012.51	13	0.43	0.23	0.74
Exeter V40	Duraloc	935	3330.21	20	0.60	0.37	0.93
Exeter	Osteolock	836	5977.94	35	0.59	0.41	0.81
Muller	RM cup	772	2109.50	13	0.61	0.33	1.05
MS 30	Morscher	770	4145.45	29	0.70	0.47	1.00
CLS	Fitmore	757	2004.15	20	0.99	0.61	1.54
Charnley	Charnley	757	4511.71	17	0.38	0.22	0.60
CLS	Duraloc	672	3815.75	33	0.86	0.60	1.21
Synergy Porous	Reflection porous	669	1903.93	13	0.68	0.36	1.17
CLS	Fitek	657	4061.39	9	0.22	0.10	0.42
Elite plus	Duraloc	608	2892.92	27	0.93	0.62	1.36
Exeter V40	Morscher	586	2170.30	15	0.69	0.39	1.14
Exeter	Duraloc	552	4155.93	32	0.77	0.53	1.09
Exeter	Morscher	551	4166.88	20	0.48	0.29	0.74

CCA	CCB	519	1872.25	7	0.37	0.15	0.77
CPT	ZCA	495	2587.05	15	0.58	0.32	0.96
Summit	Pinnacle	490	1084.58	9	0.83	0.38	1.58
SL monoblock	Muller PE cup	488	3080.05	8	0.26	0.11	0.51
MS 30	Fitmore	468	999.36	3	0.30	0.06	0.88
CPT	Trilogy	459	1131.11	12	1.06	0.55	1.85
MS 30	Muller PE cup	459	2324.84	11	0.47	0.24	0.85
TwinSys stem uncemented	Selexys TPS	447	494.93	7	1.41	0.57	2.91
Corail	Duraloc	440	1347.84	5	0.37	0.12	0.87
Muller	Weber	421	1678.86	7	0.42	0.17	0.88
Versys cemented	ZCA	359	1835.26	11	0.60	0.30	1.07
ABGII	Trident	341	1047.29	11	1.05	0.52	1.88
TwinSys stem cemented	RM cup	335	508.29	0	0	0	0.73
Elite plus	Charnley	332	2361.2	15	0.64	0.36	1.05
SL modular stem	RM cup	323	2412.05	18	0.75	0.44	1.18
Exeter V40	RM cup	314	560.68	5	0.89	0.29	2.08
Exeter V40	Reflection cemented	293	643.15	1	0.16	0.00	0.87
Elite plus	Elite Plus LPW	282	1542.88	7	0.45	0.18	0.93
Versys	Trilogy	272	1727.35	9	0.52	0.24	0.99
Exeter V40	Pinnacle	270	271.09	2	0.74	0.09	2.67
Exeter V40	Osteolock	269	1354.52	7	0.52	0.20	1.06
CLS	RM cup	252	593.22	7	1.18	0.47	2.43

There are 456 hip prosthesis matchings in the Registry. The table above contains the analysis of the 50 that have a minimum of 250 primary registered procedures. As stated above it is important to note the confidence intervals and observed component years in conjunction with the revision rates.
The Spectron/ Duraloc has a revision rate significantly higher than the overall rate of 0.65/100 ocys @ the 95% confidence interval.

Femoral Components sorted on revision rate/ 100 component years

Minimum of 50 implantations

Femur Prosthesis	No. Ops.	Observed comp. Yrs	Number Revised	Rate/100-component-years	Exact 95% confidence interval	
Exeter V40	12826	39208.09	201	0.51	0.44	0.59
Spectron	6831	33849.63	227	0.67	0.59	0.77
CLS	6361	28597.11	212	0.74	0.64	0.85
Exeter	5748	41133.61	239	0.58	0.51	0.66
Muller	2862	11233.31	51	0.45	0.34	0.60
MS 30	2328	10367.50	56	0.54	0.41	0.70
Corail	2072	3971.55	28	0.71	0.47	1.02
Accolade	1787	5286.86	44	0.83	0.60	1.11
TwinSys stem uncemented	1738	2018.08	25	1.24	0.80	1.83
CPT	1541	5897.95	41	0.70	0.50	0.94
Elite plus	1353	7529.78	53	0.70	0.53	0.92
CCA	886	3593.75	26	0.72	0.47	1.06
Synergy Porous	850	2374.10	14	0.59	0.32	0.99

Charnley	815	4859.20	18	0.37	0.22	0.59
Summit	778	1746.64	17	0.97	0.57	1.56
ABGII	729	2735.48	26	0.95	0.62	1.39
Versys cemented	620	3125.15	18	0.58	0.34	0.91
SL monoblock	558	3594.13	11	0.31	0.15	0.55
S-Rom	487	1917.71	19	0.99	0.60	1.55
TwinSys stem cemented	459	625.95	0	0	0	0.59
SL modular stem	449	3391.58	22	0.65	0.41	0.98
CBC Stem	385	903.26	16	1.77	1.01	2.88
C-Stem	338	1229.38	14	1.14	0.62	1.91
Versys	313	1885.46	13	0.69	0.37	1.18
Mallory-Head	240	974.89	8	0.82	0.35	1.62
Omnifit	202	963.84	6	0.62	0.23	1.35
ABG	189	1632.80	13	0.80	0.42	1.36
Wagner cone stem	150	785.16	11	1.40	0.70	2.51
Prodigy	149	960.59	9	0.94	0.43	1.78
Friendly	116	219.83	1	0.45	0.01	2.53
Trabecular Metal Stem	110	160.26	4	2.50	0.68	6.39
DSP Thrust Plate	104	885.77	12	1.35	0.70	2.37
Charnley Modular	88	116.11	0	0	0	3.18
Femoral Stem Press Fit	84	107.49	1	0.93	0.02	5.18
AML MMA	75	456.32	2	0.44	0.05	1.58
Basis	75	153.79	1	0.65	0.02	3.62
Contemporary	71	528.32	5	0.95	0.31	2.20
C-Stem AMT	66	62.37	2	3.21	0.39	11.59
Furlong	66	229.16	4	1.75	0.48	4.47
Anthology Porous	64	33.11	1	3.02	0.08	16.83
CPCS	61	245.32	2	0.82	0.10	2.94
Modular Taperloc	59	139.76	1	0.72	0.02	3.99
AML	55	385.99	2	0.52	0.06	1.872

The CBC and Twinsys uncemented have significantly higher revision rates than the overall rate of 0.65/100 ocys @ the 95% confidence interval

Acetabular Components sorted on revision rate/ 100 component years

Minimum of 50 implantations

Acetabular Prosthesis	No. Ops.	Observed comp. Yrs	Number Revised	Rate/100-component-years	Exact 95% confidence levels	
Trident	5673	16713.73	119	0.71	0.59	0.85
Duraloc	5652	29911.53	236	0.79	0.69	0.90
Contemporary	5590	24389.77	153	0.63	0.53	0.73
Morscher	4025	21690.23	131	0.60	0.50	0.71
RM cup	3609	9189.44	69	0.75	0.58	0.95
Reflection porous	3319	11098.55	72	0.65	0.51	0.81
Reflection cemented	3226	16458.81	102	0.62	0.51	0.75
Trilogy	2849	9823.91	63	0.64	0.49	0.82
Muller PE cup	2786	14731.76	49	0.33	0.24	0.44
Exeter	2693	14479.12	76	0.52	0.41	0.66
Pinnacle	2350	4079.31	40	0.98	0.70	1.34
CLS Expansion	1501	7860.73	60	0.76	0.58	0.98
Fitmore	1394	3574.84	28	0.78	0.52	1.13

Charnley	1177	7263.75	38	0.52	0.37	0.72
Fitek	1166	7206.59	29	0.40	0.27	0.58
Osteolock	1130	7489.09	47	0.63	0.46	0.83
ZCA	1003	4875.07	29	0.59	0.40	0.85
CCB	744	2153.35	7	0.33	0.13	0.67
Weber	555	2339.52	9	0.38	0.18	0.73
Monoblock Acetabular Cup	499	1408.74	10	0.71	0.34	1.31
Delta-PF Cup	489	1058.68	6	0.57	0.21	1.23
Selexys TPS	462	507.95	7	1.38	0.55	2.84
Elite Plus LPW	341	1667.75	10	0.60	0.29	1.10
ASR	339	456.18	9	1.97	0.90	3.74
Ultima	246	1093.39	6	0.55	0.20	1.19
Elite Plus Ogee	242	1036.68	5	0.48	0.16	1.13
Durom	222	431.10	5	1.16	0.38	2.71
Mallory-Head	197	835.57	3	0.36	0.07	1.05
Allofit	190	371.10	4	1.08	0.29	2.76
Bio-clad poly	190	1055.13	5	0.47	0.15	1.11
ABGII	175	1328.41	11	0.83	0.41	1.48
M2A	170	540.65	3	0.55	0.11	1.62
BHR Acetabular Cup	147	204.65	2	0.98	0.12	3.53
Trabecular Metal Shell	131	152.04	3	1.97	0.41	5.77
Expansion Shell	116	250.09	4	1.60	0.44	4.10
Biomex acet shell porous	112	748.66	3	0.40	0.08	1.17
Weill ring	108	714.01	5	0.70	0.23	1.63
Recap Resurfacing Acetabular S	87	186.23	0	0	0	1.99
R3 porous	80	30.69	1	3.26	0.08	18.16
Artek	72	461.19	17	3.69	2.15	5.90
Furlong cup	62	227.00	3	1.32	0.27	3.86
Expansion shell	59	124.20	3	2.42	0.50	7.06

The Artek, ASR, Duraloc and Pinnacle cups have significantly higher revision rates than the overall rate of 0.65/100 ocys @ the95% confidence interval.

Revision vs Bearing Surfaces

Femoral head	Acetab/liner	No Ops	Observed comp. Yrs	Number Revised	Rate/100-component-years	Exact 95% confidence levels	
Ceramic	Ceramic	2595	6835.72	57	0.83	0.63	1.08
Ceramic	Metal	60	29.82	0	0	0	12.37
Ceramic	Polyethylene	7301	27848.25	210	0.75	0.66	0.86
Metal	Metal	3484	12891.17	111	0.86	0.71	1.04
Metal	Polyethylene	37694	163416.65	974	0.60	0.56	0.63

The metal on polyethylene articulation has a significantly lower revision rate than the other articulations among which there are no significant differences.

Resurfacing Hip Prostheses sorted on revision rate/ 100 component years

Prosthesis	No Ops	Observed comp. Yrs	Number Revised	Rate/100-component-years	Exact 95% confidence levels	
ASR	128	309.59	5	1.62	0.52	3.77
Adept	2	3.56	0	0	0	103.48
BHR	569	990.86	6	0.61	0.22	1.318
Durom	4	18.27	0	0	0	20.19
Mitch TRH Resurfacing Head	5	3.78	1	26.43	0.67	147.25

Although the ASR has a higher revision rate than the BHR it does not reach statistical significance.

Revision vs Age Bands

Age Bands	No Ops	Observed comp. Yrs	Number Revised	Rate/100-component-years	Exact 95% confidence levels	
LT55	8417	37456.04	321	0.86	0.77	0.96
55_64	13835	59383.22	424	0.71	0.65	0.79
65_74	18443	78002.43	475	0.61	0.56	0.67
GE75	14980	57450.98	284	0.49	0.44	0.56

The < 55 age band have significantly higher revision rates those 65 or older.

Revision vs Gender

Revision vs Gender	No Ops	Observed comp. Yrs	Number Revised	Rate/100-component-years	Exact 95% confidence levels	
F	29501	123002.95	712	0.58	0.54	0.62
M	26174	109289.73	792	0.72	0.68	0.78

Males have a significantly higher revision rate than females

Revision vs Arthroplasty Fixation

Cementation	No Ops	Observed comp. Yrs	Number Revised	Rate/100-component-years	Exact 95% confidence levels	
Cemented	18432	90311.15	480	0.53	0.49	0.58
Uncemented	16888	58630.43	496	0.85	0.77	0.92
Hybrid	20355	83351.09	528	0.63	0.58	0.70

Uncemented hips have a significantly higher revision rate than either fully cemented or hybrid hips

Revision by Age Bands vs Arthroplasty Fixation

Cemented	No Ops	Observed comp. Yrs	Number Revised	Rate/100-component-years	Exact 95% confidence levels	
LT55	545	3294.69	48	1.46	1.07	1.93
55_64	1968	11346.35	94	0.83	0.67	1.01
65_74	6853	35717.04	180	0.50	0.43	0.58
GE75	9066	39953.08	158	0.40	0.34	0.46

Uncemented	No Ops	Observed comp. Yrs	Number Revised	Rate/100-component-years	Exact 95% confidence levels	
LT55	5636	22671.44	173	0.76	0.65	0.89
55_64	6522	23274.07	195	0.83	0.72	0.96
65_74	3593	10234.32	99	0.97	0.79	1.18
GE75	1137	2450.60	29	1.18	0.79	1.70

Hybrid	No Ops	Observed comp. Yrs	Number Revised	Rate/100-component-years	Exact 95% confidence levels	
LT55	2236	11489.91	100	0.87	0.71	1.06
55_64	5345	24762.81	135	0.55	0.46	0.65
65_74	7997	32051.07	196	0.61	0.53	0.70
GE75	4777	15047.30	97	0.64	0.52	0.79

Revision by Arthroplasty Fixation vs Age Bands

	Cementation	No Ops	Observed comp. Yrs	Number Revised	Rate/100-component-years	Exact 95% confidence levels	
LT55	**Cemented**	545	3294.69	48	1.46	1.07	1.93
	Uncemented	5636	22671.44	173	0.76	0.65	0.89
	Hybrid	2236	11489.91	100	0.87	0.71	1.06
55_64	**Cemented**	1968	11346.35	94	0.83	0.67	1.01
	Uncemented	6522	23274.07	195	0.84	0.72	0.96
	Hybrid	5345	24762.81	135	0.55	0.46	0.65
65_74	**Cemented**	6853	35717.04	180	0.50	0.43	0.58
	Uncemented	3593	10234.32	99	0.97	0.79	1.18
	Hybrid	7997	32051.07	196	0.61	0.53	0.70
GE75	**Cemented**	9066	39953.08	158	0.40	0.34	0.46
	Uncemented	1137	2450.60	29	1.18	0.79	1.70
	Hybrid	4777	15047.30	97	0.64	0.52	0.79

For the under 55 age band the revision rate for uncemented and hybrid group is significantly lower than for cemented hips; for age band 55 – 64 hybrid hips have a significantly lower revision rate than both cemented and uncemented hips, but there is no significant difference between the latter two; for the 65 – 74 age band both cemented and hybrid hips have significantly lower revision rates than uncemented and for the >74 age band cemented hips have a significantly lower revision rate than both hybrid and uncemented hips and in turn hybrid hips have a significantly lower revision rate than uncemented hips.
Overall the hybrid hip is demonstrating the lowest revision rate across all 4 age bands.

Revision vs Approach

Approach	No Ops	Observed comp. Yrs	Number Revised	Rate/100-component-years	Exact 95% confidence levels	
Anterior	2906	13291.83	83	0.624	0.50	0.77
Posterior	34156	138132.52	947	0.69	0.64	0.73
Lateral	15914	63557.69	362	0.57	0.51	0.63
Troch	114	531.86	4	0.75	0.20	1.93

There are no significant differences in the revision rates among the approaches

Revision for Dislocation vs Approach

Dislocation-free survival Approach	No Ops	Observed comp. Yrs	Number Revised	Rate/100-component-years	Exact 95% confidence levels	
Anterior	2906	13291.83	26	0.20	0.13	0.29
Posterior	34156	138132.52	391	0.28	0.64	0.73
Lateral	15914	63557.69	82	0.13	0.10	0.16
Troch	114	531.86	1	0.19	0.00	1.048

The posterior approach has a significantly higher revision rate for dislocation compared to the lateral and anterior approaches.

Revision vs Surgeon annual workload

Operations per Year	N	Sum comp. Yrs	Number Revised	Rate/100-component-years	Exact 95% confidence levels	
LT10	564	2526.39	29	1.15	0.77	1.65
10_25	5853	24061.09	185	0.77	0.66	0.89
25_50	28227	115717.05	763	0.66	0.61	0.71
50_75	10150	43646.09	270	0.62	0.55	0.70
75_100	4874	19914.911	109	0.55	0.45	0.66
GE100	5989	26349.37	147	0.56	0.47	0.66

Those surgeons performing <10 arthroplasties a year have significantly higher revision rate than those performing 25 or more per year.

Revision vs ASA status

ASA Class	No Ops	Observed comp. Yrs	Number Revised	Rate/100-component-years	Exact 95% confidence levels	
1	3916	6691.10	53	0.79	0.59	1.04
2	13253	22237.78	184	0.83	0.71	0.96
3	5238	8353.71	90	1.08	0.87	1.32
4	193	292.29	3	1.03	0.21	3.00

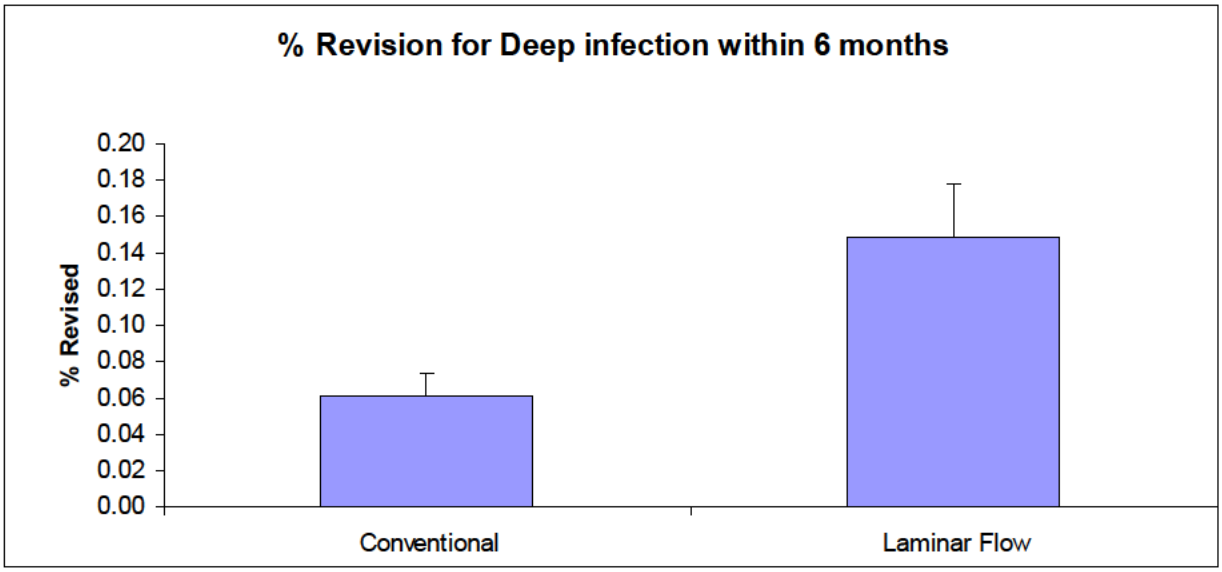
Revision vs ASA public private hospitals

	No Ops	Observed comp. Yrs	Number Revised	Rate/100-component-years	Exact 95% confidence levels	
Public	11873	19905.71	186	0.93	0.80	1.08
Private	10727	17669.16	144	0.81	0.69	0.96

There is no significant difference in revision rates among the ASA classes or between public and private hospitals.

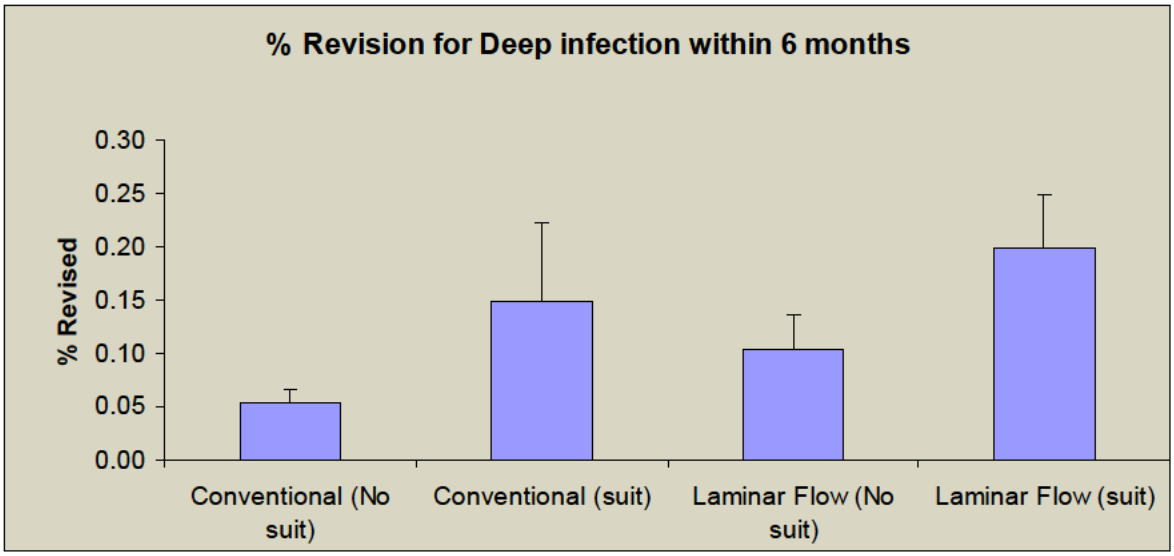
Revision for Deep Infection within 6 months vs Theatre Environment

Deep Infection Revision within 6 months of op.				
Theatre	**Total Number**	**Number Revised**	**%**	**SE**
Conventional	34635	21	0.06	0.01
Laminar	16850	25	0.16	0.03



There is a significant difference in revision rates for deep infection within 6 months of surgery between conventional and laminar flow theatres.

	Total Number	Number Revised	%	SE
Conventional (No suit)	31939	17	0.05	0.01
Conventional (suit)	2696	4	0.15	0.07
Laminar Flow (No suit)	8772	9	0.10	0.03
Laminar Flow (suit)	8078	16	0.20	0.05



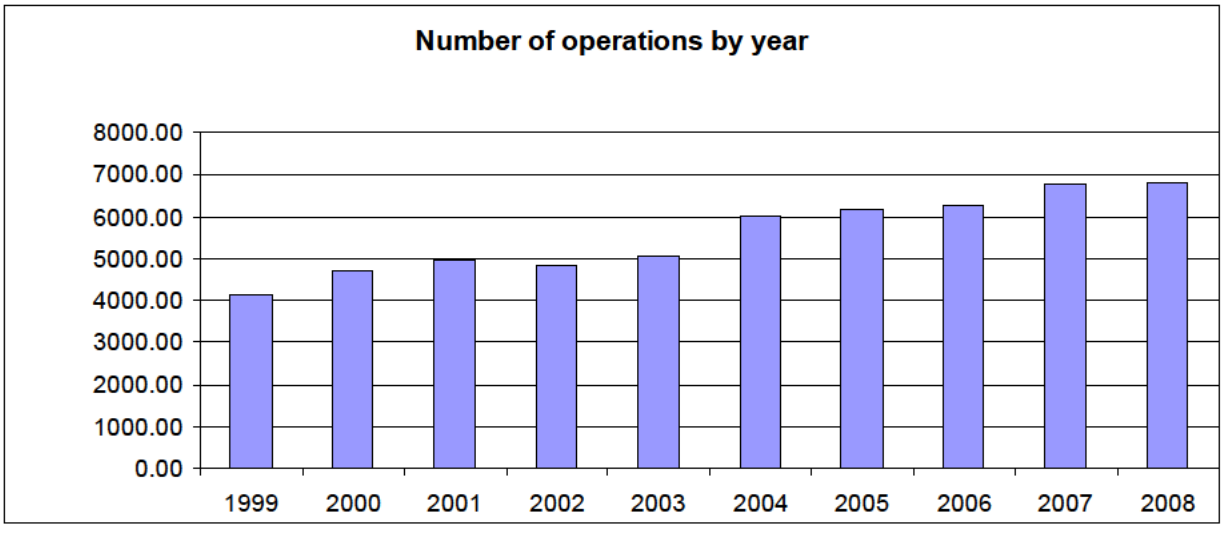
There is a significant difference in the revision rates between conventional/ no suit and laminar flow/suit environments. There is 4 times the risk for revision in the latter compared to the former environment.

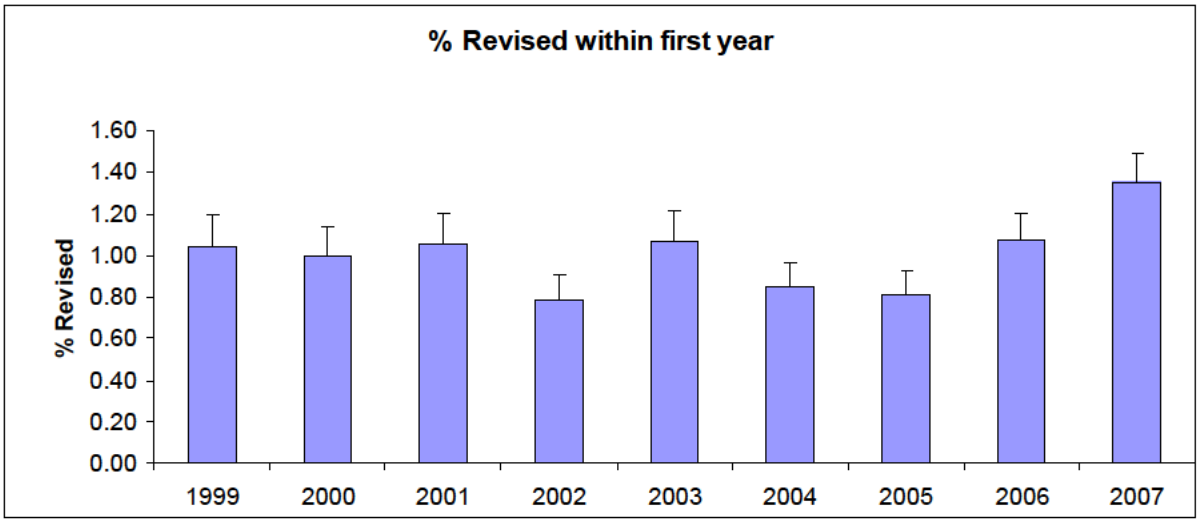
	Deep Infection Revision within 6 months of op.			
	Total Number	Number Revised	%	SE
No Suit	40711	26	0.06	0.01
Suit	10774	20	0.19	0.04

Furthermore there is a significant increase in revision rates when suits are used in either conventional or laminar flow theatres.
From the above data it would appear that the use of space suits increases the risk of deep infection threefold within the first 6 months following the arthroplasty

Percentage of hips revised in first year.

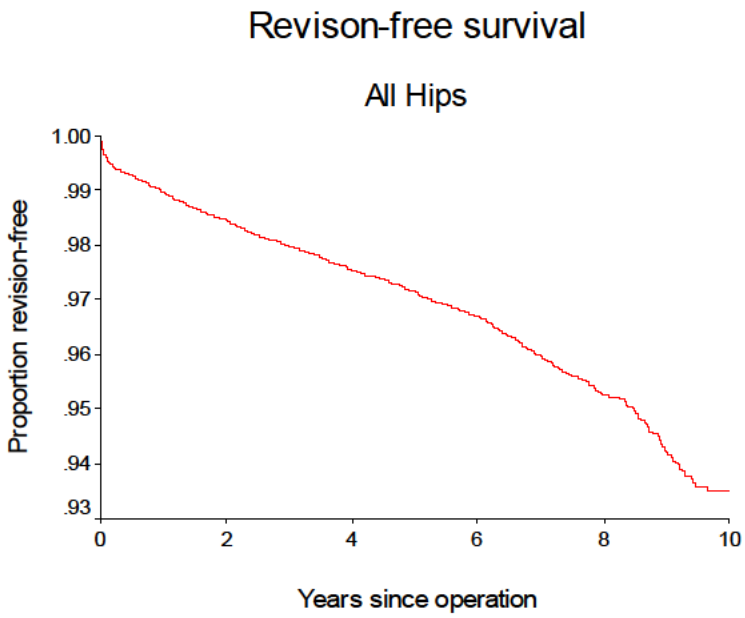
The following two bar graphs show that the % of hips revised in the first year has fluctuated over the 10 years but was the highest in 2007.




% Revised within first year
% Revised
1.60
1.40
1.20
1.00
0.80
0.60
0.40
0.20
0.00
1999
2000
2001
2002
2003
2004
2005
2006
2007

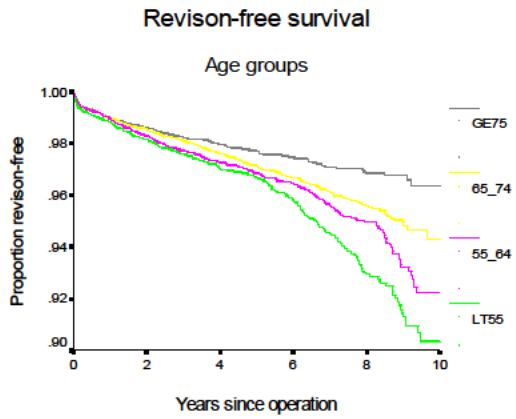
Kaplan Meier Curves

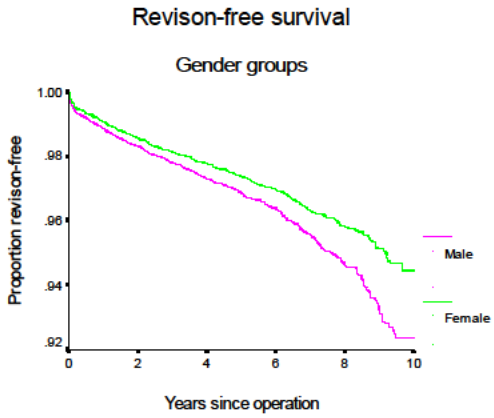
The following Kaplan Meier survival analyses are for the years 1999 – 2008 with deceased patients censored at time of death.

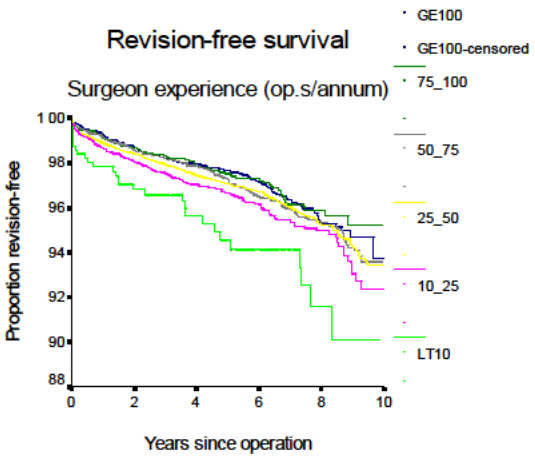


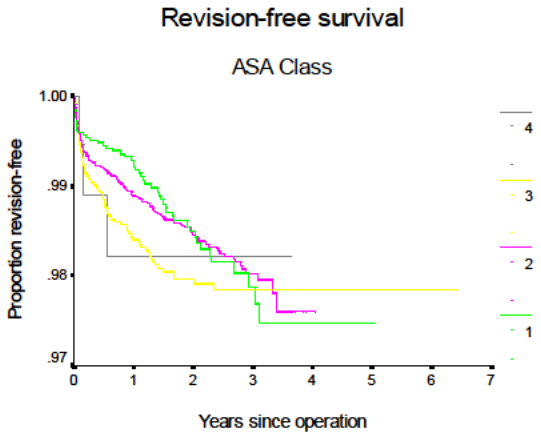
Years	% Revision-free
1	98.97
2	98.45
3	97.98
4	97.55
5	97.15
6	96.70
7	95.96
8	95.25
9	94.24

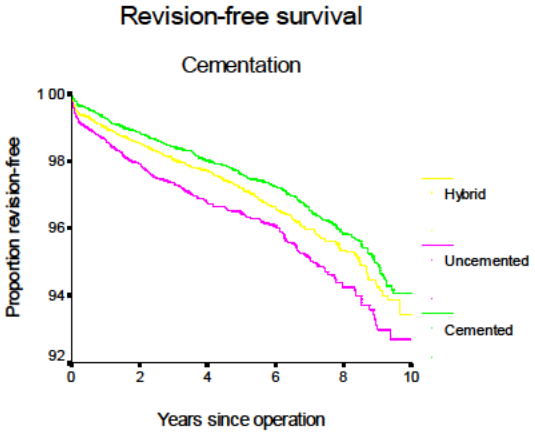
The KM analysis is to 9 yrs rather than 10 because no 10yr primary registered hips were revised in 2008

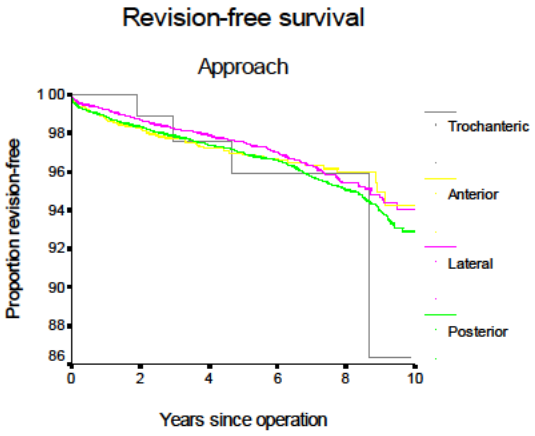












Re-revisions of conventional hips

Analysis was undertaken of 3 groups of hip re-revisions.

There were 171 registered conventional hip replacements that had been revised twice, 32 that had been revised three times and 5 that had been revised four times.

Second revision

Time between the first and second revisions averaged 485 days, with a range of 2 – 2984 and a standard deviation of 535. This compares to an average of 972 days between the primary and first revision.

Reason for revision

Dislocation	59
Deep infection	47
Loosening acetabular	25
Loosening femoral	20
Pain	18
Fracture femur	10
Implant breakage	4
Iatrogenic pelvic diss.	2
Wear acetabular component	2
Instability	2
Bone graft dissolution	1

Revision

Change of head	75
Change of acetabular	63
Change of liner	54
Change of all	46
Change of femoral	45

Third revision

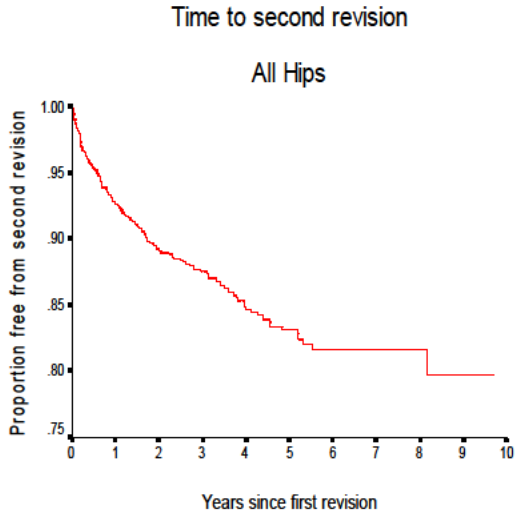
The average time between second and third revisions for the 32 arthroplasties was 460 days with a range of 13 – 1665 and a standard deviation of 427.

Fourth revision
The average time between the third and fourth revisions for the 5 arthroplasties was 322 days with a range of 40 – 679 and a standard deviation of 268.

Overall it can be noted that the time between successive revisions steadily decreases.

Re- revisions of resurfacing hip replacements

There have been 3 re-revisions.



The KM graph confirms that survival following the first revision is poorer than for primary arthroplasty.

PATIENT BASED QUESTIONNAIRE OUTCOMES AT SIX MONTHS AND FIVE YEARS POST SURGERY

Questionnaires at six months post surgery
At six months post surgery a random selection of patients are sent the Oxford 12 questionnaire in order to achieve a response rate of 20% of the total which is deemed to be ample to provide powerful statistical analysis.

The new scoring system as recommended by the original authors has been adopted. (see appendix 1)

There are 12 questions with the scores now ranging from 4 to 0. A score of 48 is the best, indicating normal function. A score of 0 is the worst, indicating the most severe disability.

In addition we have grouped the questionnaire responses according to the classification system published by Kalairajah et al, 2005. (appendix 1)

This groups the scores into one of four categories;

Category 1	>41	excellent
Category 2	34 – 41	good
Category 3	27 – 33	fair
Category 4	< 27	poor

For the ten year period, and as at August 2009, there were 19,030 primary hip questionnaire responses registered at six months post surgery.
The mean hip score was 40.73 (standard deviation 7.47, range 48 – 0)

Scoring	> 41	11107
Scoring	34 -41	5051
Scoring	27 -33	1735
Scoring	< 27	1137

At six months post surgery, 85% had an excellent or good score.

Questionnaires at five years post surgery
All patients who had a six- month registered questionnaire, and who had not had revision surgery were sent a further questionnaire 5 years post surgery.

This dataset represents sequential Oxford hip scores for 4,092 individual patients.

At six months post surgery, 88% of this cohort of patients achieved an excellent or good score and had a mean of 41.57.

At five years post surgery, 89% of these patients achieved an excellent or good score and had a mean of 42.57.

Six-month scores pre and post revision
The group of patients who had six-month primary scores and subsequent revision scores were also analysed. The number with both these scores was 398.
At six months post primary surgery, 75% of this group achieved an excellent or good score and a mean of 37.45.
The revision scores for this group had a mean of 35.99 and 65% had achieved an excellent or good score.

Analysis of the individual questions at six months and five years post surgery
Analysis of the individual questions showed that the most common problem occurred with limping (Q10).

Percentage scoring 0 or 1 (worst categories) for each question (n=19,030) at six-months, and at five-years post surgery (n = 4,092)

		% 6/12	% 5 yrs
1	Moderate or severe pain from the operated hip	7.1	7.3
2	Only able to walk around the house or unable to walk before pain becomes severe	4.2	3.0
3	Extreme difficulty or impossible to get in and out of a car or public transport	1.9	1.9
4	Extreme difficulty or impossible to put on a pair of socks	8.9	5.7
5	Extreme difficulty or impossible to do the household shopping on your own	3.6	2.8
6	Extreme difficulty or impossible to wash and dry yourself	1.9	1.2
7	Pain interfering greatly or totally with your work	3.9	3.2
8	Very painful or unbearable to stand up from a chair after a meal	1.9	1.4
9	Sudden severe pain most or all of the time	1.3	1.1
10	Limping most or every day	13.1	9.2
11	Extreme difficulty or impossible to climb a flight of stairs	3.6	3.5
12	Pain from your hip in bed most or every nights	4.6	2.7

As noted in previous years there is little significant change between the six-month and five-year scores, which means the six-month score is indicative of the medium term outcome.

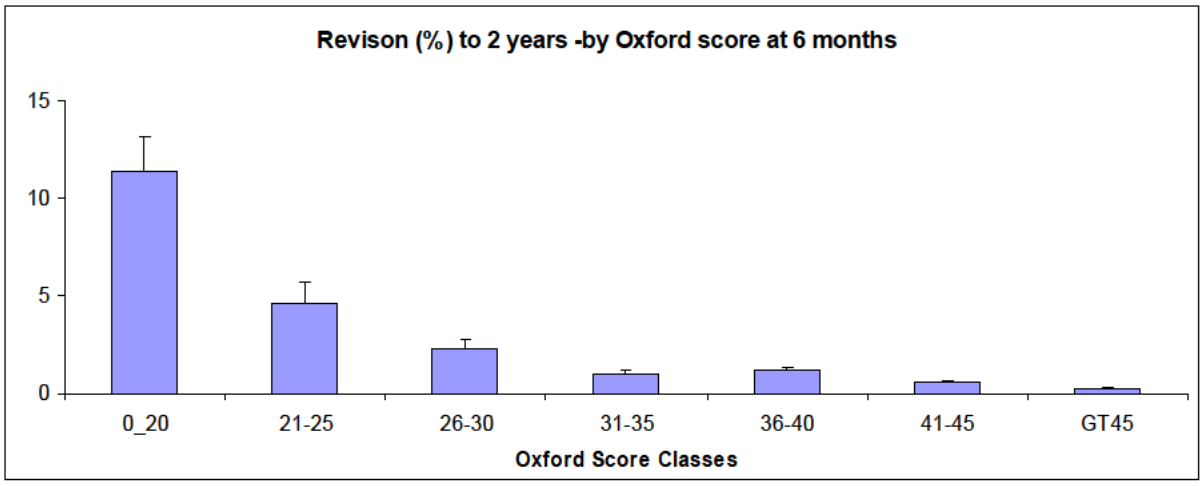
Revision hip questionnaire responses
There were 4,820 revision hip responses with 65% achieving an excellent or good score. This group includes all revision hip procedures. The mean revision hip score was 35.75 (standard deviation 9.55, range 48 – 1)

OXFORD 12 SCORE AS A PREDICTOR OF HIP ARTHROPLASTY REVISION

A statistically significant relationship has been confirmed between the Oxford scores at 6 months and 5 years post surgery and arthroplasty revision within two years of the Oxford 12 questionnaire date.

Six month score and revision arthroplasty

By plotting the patients scores in groups of 5, except at the range extremes, against the proportion of hips revised for that same group it demonstrates that there is an incremental increase in risk during the first 2 years related to the oxford score. A patient with a score below 20 has 20 times the risk of a revision within 2 years of the questionnaire data compared to a person with a score 41 to 45

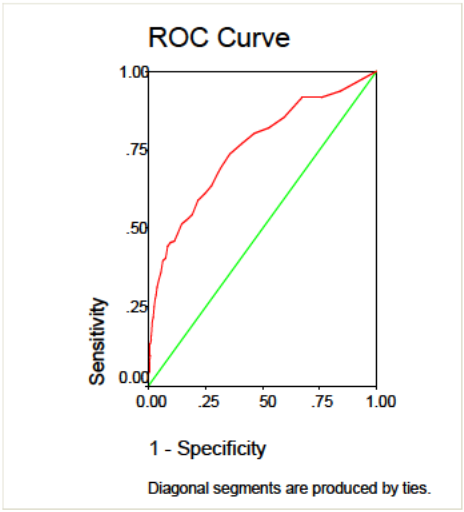


A person with an oxford score of 41-45 has a 0.57% risk of revision within 2 years compared with an 11.33% risk with a score less than 20.

A ROC analysis has demonstrated that a patient with a score less than or equal to 39.5 has 5.25 times the risk of needing a revision within 2 years compared to a person with a score greater than 31.5.

Alternatively the ROC analysis predicted 69% of the revisions within 2 years from just the lowest 31% of Oxford scores.

ROC curve at six months versus revision within two years



A receiver operating characteristic (ROC) curve is a graphical representation of the trade off between the false negative and false positive rates for every possible cut off. Equivalently, the ROC curve is the representation of the tradeoffs between sensitivity and specificity. The more the curve climbs towards the upper left corner the better the reliability of the test.

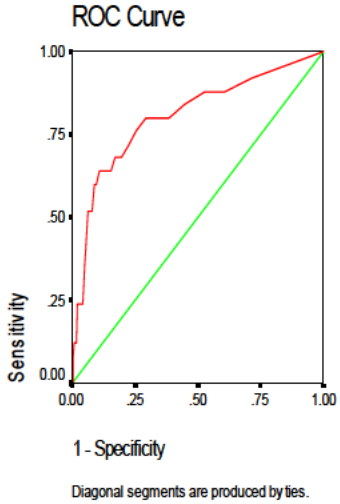
Five year score and revision arthroplasty

The ROC analysis at 5 years has demonstrated that a patient with a score less than or equal to 40.5 has11 times the risk of needing a revision within 2 years compared to a person with a score greater than 40.5.

Alternatively the ROC analysis predicted 76% of the revisions within 2 years from just the lowest 26% of Oxford scores

Although the 5 year results reinforce the relationship between the oxford score and revision within 2 years the 5 year numbers are still too small for statistical significance.

ROC curve at five years versus revision within two years



KNEE ARTHROPLASTY

PRIMARY KNEE ARTHROPLASTY

The ten year report analyses data for the period January 1999 – December 2008. There were 40,068 primary knee procedures registered, an additional 5,595 compared to last year's report.
This includes 98 patello-femoral prostheses with 8 registered in 2008.

1999	2429
2000	3015
2001	3058
2002	2893
2003	3046
2004	4098
2005	5024
2006	5152
2007	5758
2008	5595

There has been a 3% decrease in registrations during 2008 compared to 2007.

DATA ANALYSIS

Age and sex distribution

The average age for a knee replacement was 68.71 years, with a range of 8.19 – 100.49 years.

All knee arthroplasty

	Female	Male
Number	20693	19375
Percentage	51.65	48.35
Mean age	69.07	68.33
Maximum age	100.49	98.68
Minimum age	10.17	8.19
Standard dev.	9.99	9.41

Conventional knee arthroplasty

	Female	Male
Number	20620	19350
Percentage	51.59	48.41
Mean age	69.09	68.34
Maximum age	100.49	98.68
Minimum age	10.17	8.19
Standard dev.	9.98	9.41

Patello-femoral arthroplasty

	Female	Male
Number	73	25
Percentage	74.49	25.51
Mean age	63.35	61.43
Maximum age	85.78	78.62
Minimum age	32.93	34.38
Standard dev.	10.90	10.51

There was a 69% decrease in patello-femoral registrations during 2008.

Previous operation

None	33271
Menisectomy	4110
Osteotomy	792
Arthroscopy/debridement	666
Ligament reconstruction	421
Internal fixation for juxtarticular fracture	278
Patellectomy	169
Synovectomy	87
Removal of loose body	31
Other	71

Diagnosis

Osteoarthritis	37328
Rheumatoid arthritis	1252
Post fracture	440
Other inflammatory	390
Post ligament disruption /reconstruction	244
Avascular necrosis	151
Tumour	41
Other	66

Approach

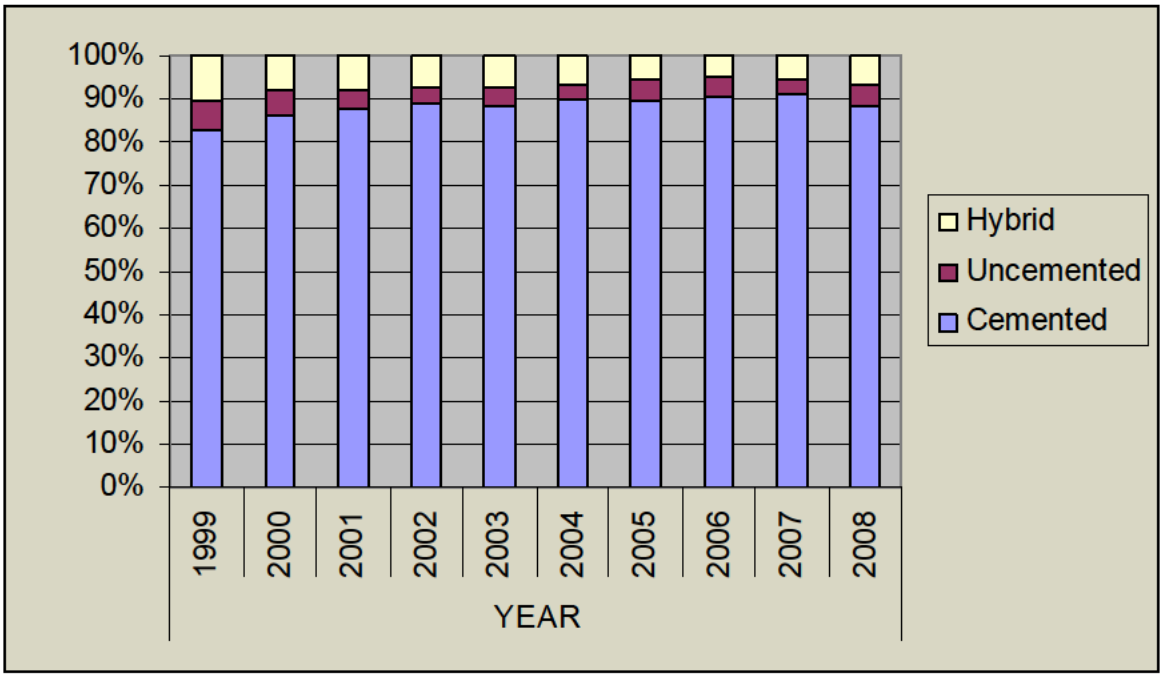
Medial parapatellar	36130
Other	1121
Lateral parapatellar	740
Image guided surgery	1957
Minimally invasive surgery	61

Image guided surgery was added to the updated forms at the beginning of 2005 and last year was used for 13.7% of arthroplasties.

Bone graft

Femoral autograft	55
Femoral allograft	8
Femoral synthetic	2
Tibial autograft	34
Tibial allograft	11

Prosthesis Fixation by Year



Cement

Femur cemented	35723	89%
Antibiotic in cement	23007	64%
Tibia cemented	38005	95%
Antibiotic in cement	24000	63%

Systemic antibiotic prophylaxis

Patient number receiving at least one systemic antibiotic37883 95%

A cephalosporin was used in 89% of arthroplasties.

Operating theatre

Conventional	24266
Laminar flow	15404
Space suits	10699

1n 2008, 53% of procedures were performed in laminar flow theatres and space suits were used in 44%.

ASA Class

This was introduced with the updated forms at the beginning of 2005.

For the four-year period 2005 – 2008 there were 18,492 (86%) primary knee procedures with the ASA class recorded.

Definitions

ASA class 1:	A healthy patient
ASA class 2:	A patient with mild systemic disease
ASA class 3:	A patient with severe systemic disease that limits activity but is not incapacitating
ASA class 4:	A patient with an incapacitating disease that is a constant threat to life

ASA	Number	Percentage
1	2055	11
2	11706	63
3	4639	25
4	92	1

Operative time (skin to skin)

Mean	84 minutes
Standard deviation	26 minutes
Minimum	24 minutes
Maximum	431 minutes

Surgeon grade

The updated forms introduced in 2005 have separated advanced trainee into supervised and unsupervised. The following figures are for the four-year period 2005 – 2008.

Consultant	18910
Advanced trainee supervised	1536
Basic trainee	541
Advanced trainee unsupervised	379

Prosthesis usage

Patello-femoral prostheses

Avon-patello	90
LCS PFJ	6
Mod 3	1
Themis	1

There are 98 patello-femoral procedures registered to 36 surgeons. Avon- patello is the most common prosthesis at 92% of the total.

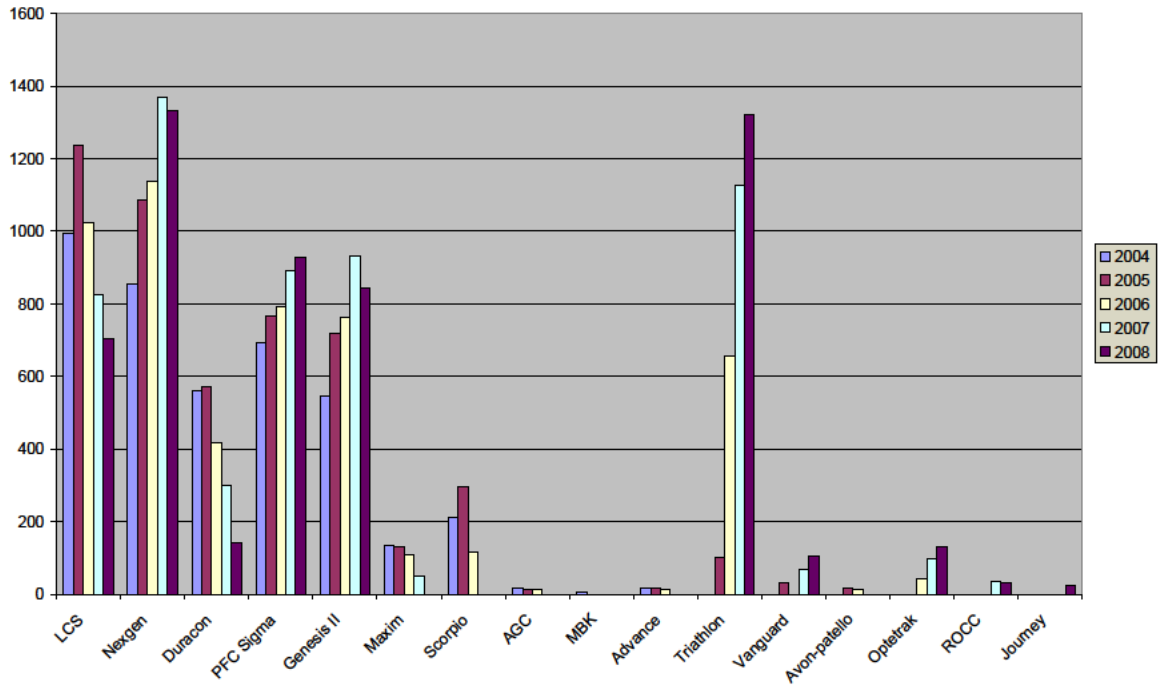
Conventional primary knees

Top 10 knee prostheses used in 2008

Nexgen	1330
Triathlon	1321
PFC Sigma	928
Genesis II	843
LCS	705
Duracon	142
Optetrak	131
Vanguard	106
ROCC	30
Journey	23

The Journey displaced the Maxim in 2008

MOST USED KNEE PROSTHESES 2004 - 2008



The triathlon continues its rapid rise in popularity

Patellar resurfacing

28,192 (71%) of the conventional knee procedures were registered with the patella not resurfaced and 11,778 (29%) resurfaced.

Surgeon and hospital workload

Surgeons

In 2008, 189 surgeons performed 5,595 total knee replacements, an average of 30 procedures per surgeon; 29 surgeons performed less than 10 procedures and 46 performed more than 40.

Hospitals
In 2008 primary knee replacement was performed in 49 hospitals. 25 were public hospitals and 24 were private.
For 2008 the average number of total knee replacements per hospital was 114.

REVISION KNEE ARTHROPLASTY
Revision is defined by the Registry as a new operation in a previously replaced knee joint during which one or more of the components are exchanged, removed, manipulated or added. It includes arthrodesis or amputation, but not soft tissue procedures. A two or more staged procedure is registered as one revision.

Data analysis
For the ten year period January 1999 – December 2008, there were 3,293 revision knee procedures registered. This is an additional 384 compared to last year's report.

The average age for a revision knee replacement was 70.07 years, with a range of 10.57 – 98.39 years.

Revision knees

	Female	Male
Number	1593	1700
Percentage	48.38	51.62
Mean age	70.35	69.81
Maximum age	95.79	98.39
Minimum age	10.57	15.49
Standard dev.	10.77	10.07

The ratio of revision knees to primary knees remains at 1:12.5 (8%).

REVISION OF REGISTERED PRIMARY KNEE ARTHROPLASTY
This section analyses data for revisions of primary knee procedures for the ten year period.

There were 835 revisions of the 39,970 primary conventional knee replacements (2.1%) and 5 revisions of the 98 patello-femoral replacements (5.1%), a total of 840.

This analysis includes the patello-femoral revisions.

Time to revision

Mean	849	days
Maximum	3473	days
Minimum	1	day
Standard deviation	719	days

Reason for revision

Pain	271
Deep infection	211
Primary patellar comp.	194
Loosening tibial component	180
Loosening femoral component	100
Instability	66
Stiffness	38
Dislocation component	27
Fracture tibia	14
Loosening patellar	14
Wear component	13
Malalignment	10
Fracture femur	10
Implant breakage	10
Osteolysis	5
Other	38

Analysis by time of the 5 main reasons for revision

Pain n = 271

< 6 months	16
6 months – 1 year	49
2 years	87
3 years	48
4 years	33
5 years	17
6 years	9
7 years	4
8 years	3
9 years	4
10 years	1

Deep infection n = 211

< 6 months	51
6 months – 1 year	46
2 years	53
3 years	21
4 years	19
5 years	7
6 years	4
7 years	6
8 years	2
9 years	2
10 years	-

Addition of patellar component n = 194

< 6 months	8
6 months – 1 year	40
2 years	70
3 years	37
4 years	21
5 years	7
6 years	5
7 years	3
8 years	1
9 years	2
10 years	-

Loosening tibial component n = 180

< 6 months	7
6 months – 1 year	16
2 years	30
3 years	36
4 years	30
5 years	22
6 years	14
7 years	10
8 years	10
9 years	2
10 years	3

Loosening femoral n = 100

< 6 months	1
6 months – 1 year	9
2 years	18
3 years	14
4 years	10
5 years	8
6 years	9
7 years	7
8 years	10
9 years	2
10 years	2

Patellar resurfacing

As noted previously, 71 %(28,192) of the 39,970 conventional primary knees registered were not resurfaced and 29% (11,778) were resurfaced. Of the group that was not resurfaced, 134(0.4%) had the patella later resurfaced as the only revision procedure and a further 60 had the patella resurfaced as part of other component revision

Statistical note

In the table below there are two statistical terms readers may not be familiar with.

Observed component years

This is the number of registered primary procedures multiplied by the number of years each component has been in place.

Rate/100 component years

This is equivalent to the yearly revision rate expressed as a percent and is derived by dividing the number of prostheses revised by the observed component years multiplied by 100. It therefore allows for the number of years of post operative follow up in calculating the revision rate. These rates are usually very low, hence it is expressed per 100 component years rather than per component year. Statisticians consider that this is a more accurate way of deriving a revision rate for comparison when analysing data with widely varying follow up times. It is also important to note the confidence intervals. The closer they are to the estimated revision rate/100 component years, the more precise the estimate is.

Statistical Significance

Where it is stated that a difference is significant the p value is 0.05 or less.

All Primary Total Knee Arthroplasties

All patients	Total	Observed component years	Number revised	Rate/100 component years	Exact 95% confidence interval	
	39970	155114.75	835	0.54	0.50	0.58

Revision rate of individual knee prostheses

Prosthesis	Total	Observed component years	Number revised	Rate/100 component years	Exact 95% confidence interval	
Triathlon uncemented	78	64.86	2	3.08	0.37	11.14
Insall/Burstein	249	1863.75	33	1.77	1.22	2.49
Optetrak cemented	183	323.24	5	1.55	0.50	3.61
LCS Complete uncemented	1598	3853.77	42	1.09	0.79	1.47
Scorpio	849	3436.47	34	0.99	0.69	1.38
LCS uncemented	1090	7360.89	67	0.91	0.71	1.16
Vanguard (TM) CR	141	128.76	1	0.78	0.02	4.33
Nexgen LPS-Flex cemented	2315	4951.16	37	0.75	0.53	1.03
MBK cemented	222	1464.10	10	0.68	0.33	1.26
PFC Sigma uncemented	180	471.82	3	0.64	0.13	1.86
Nexgen LPS cemented	2090	8237.22	49	0.59	0.44	0.79
Advance cemented	157	875.83	5	0.57	0.19	1.33
Genesis II cemented	5123	16965.23	93	0.55	0.44	0.67
Nexgen uncemented	350	1701.56	9	0.53	0.24	1.00
LCS cemented	3575	24614.89	130	0.53	0.44	0.63
LCS Complete cemented	3452	10478.41	55	0.52	0.40	0.68
Triathlon cemented	3128	4140.76	20	0.48	0.30	0.75
Cruciate Retained uncemented	75	227.07	1	0.44	0.01	2.45
PFC Sigma cemented	5404	18618.92	80	0.43	0.34	0.53
Nexgen cemented	3665	16464.92	60	0.36	0.28	0.47
Duracon uncemented	736	4031.36	14	0.35	0.19	0.58
Duracon cemented	3379	16229.43	54	0.33	0.25	0.43
AGC cemented	375	2413.84	8	0.33	0.14	0.65
Maxim	819	4045.42	11	0.27	0.14	0.49
AMK cemented	95	746.52	1	0.13	0.00	0.75
Nexgen CR-Flex Cemented	133	122.71	0	0.00	0.00	3.00
Optetrak uncemented	123	131.07	0	0.00	0.00	2.81

The 2 LCS uncemented and the Scorpio prostheses have significantly higher revision rates than the overall rate of 0.54 /100 ocys @ the 95% confidence interval.

Revision vs Age Bands

Age Bands	Total	Observed component years	Number revised	Rate/100 component years	Exact 95% confidence interval	
LT55	3254	12619.00	131	1.04	0.87	1.23
55_64	10433	39863.96	283	0.71	0.63	0.80
65_74	14908	59089.67	295	0.50	0.44	0.56
GE75	11375	43542.10	126	0.29	0.24	0.34

Each successive age band in ascending order has a significantly lower revision rate

Revision vs Gender

Sex	Total	Observed component years	Number revised	Rate/100 component years	Exact 95% confidence interval	
F	20621	81968.97	423	0.52	0.47	0.57
M	19349	73145.78	412	0.56	0.51	0.62

There is no significant difference in revision rates between males and females which is contrary to hip arthroplasty

Revision vs Arthroplasty Fixation

Cementation	Total	Observed component years	Number revised	Rate/100 component years	Exact 95% confidence interval	
Cemented	35506	136424.32	690	0.51	0.47	0.54
Uncemented	1835	7485.81	83	1.11	0.88	1.37
Hybrid	2629	11204.61	62	0.55	0.42	0.71

Uncemented knees have a significantly higher revision rate than either cemented or hybrid knees(cemented tibia, uncemented femur). Further analyses have shown that it is loosening of the uncemented tibial component that is responsible for the higher revision rate.

Revision by Age Bands vs Arthroplasty Fixation

Cemented	Total	Observed component years	Number revised	Rate/100 component years	Exact 95% confidence interval	
LT55	2573	9807.07	85	0.87	0.69	1.07
55_64	8990	33846.11	229	0.68	0.59	0.77
65_74	13468	52955.36	264	0.50	0.44	0.56
GE75	10475	39815.77	112	0.28	0.23	0.34

The higher 2 age bands have significantly lower revision rates than the lower 2 age bands

Uncemented	Total	Observed component years	Number revised	Rate/100 component years	Exact 95% confidence interval	
LT55	399	1738.98	36	2.07	1.45	2.87
55_64	667	2703.24	29	1.07	0.72	1.54
65_74	522	2036.92	14	0.69	0.38	1.15
GE75	247	1006.67	4	0.40	0.11	1.02

The lowest age band has a significantly higher revision rate than the other 3 age bands

Hybrid	Total	Observed component years	Number revised	Rate/100 component years	Exact 95% confidence interval	
LT55	282	1072.95	10	0.93	0.45	1.71
55_64	776	3314.61	25	0.75	0.49	1.11
65_74	918	4097.39	17	0.41	0.24	0.66
GE75	653	2719.66	10	0.37	0.18	0.68

There is no significant difference among the age bands

Revision vs Approach

Approach	Total	Observed component years	Number revised	Rate/100 component years	Exact 95% confidence interval	
Medial	36036	133112.97	723	0.54	0.50	0.58
Lateral	740	3296.11	18	0.55	0.32	0.86
Other	1116	5116.04	24	0.47	0.30	0.70

There is no significant difference among the 3 approaches

Revision vs Surgeon annual workload

Operations per Year	Total	Observed component years	Number revised	Rate/100 component years	Exact 95% confidence interval	
LT10	941	3531.21	23	0.65	0.41	0.98
10_25	9982	39123.37	234	0.60	0.52	0.68
25_50	20649	67830.48	407	0.60	0.54	0.66
50_75	5678	15406.66	122	0.79	0.66	0.95
75_100	2589	8380.33	48	0.57	0.42	0.76

There is no significant difference among the 5 groups

Revision vs ASA status

ASA Class	Total	Observed component years	Number revised	Rate/100 component years	Exact 95% confidence interval	
1	2042	3345.71	26	0.78	0.51	1.14
2	11669	19647.56	128	0.65	0.54	0.77
3	4631	7766.58	53	0.68	0.51	0.89
4	92	167.71	1	0.60	0.02	3.32

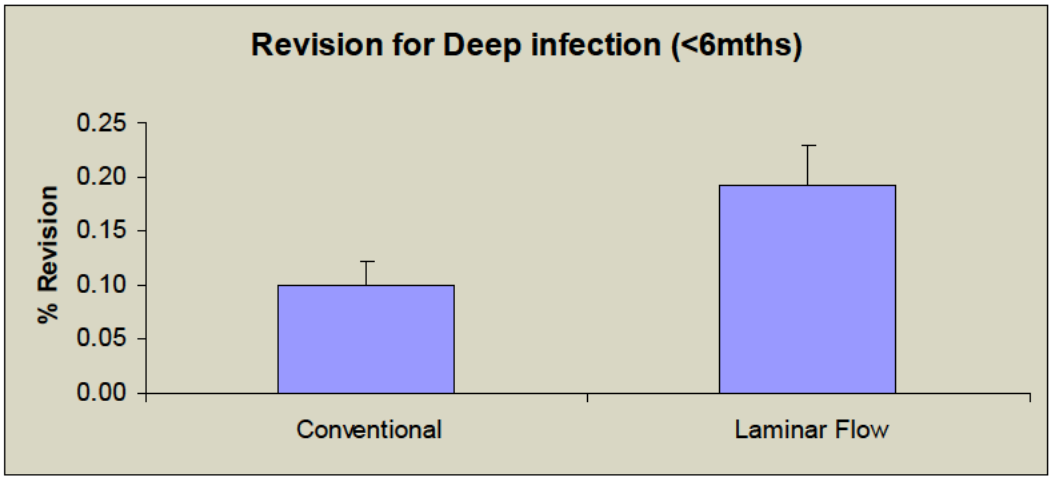
Revision vs ASA public/private hospitals

	Total	Observed component years	Number revised	Rate/100 component years	Exact 95% confidence interval	
Public	9699	16806.95	113	0.67	0.55	0.81
Private	8735	14120.62	95	0.67	0.54	0.82

There is no significant difference in revision rates among the ASA classes or between public and private hospitals.

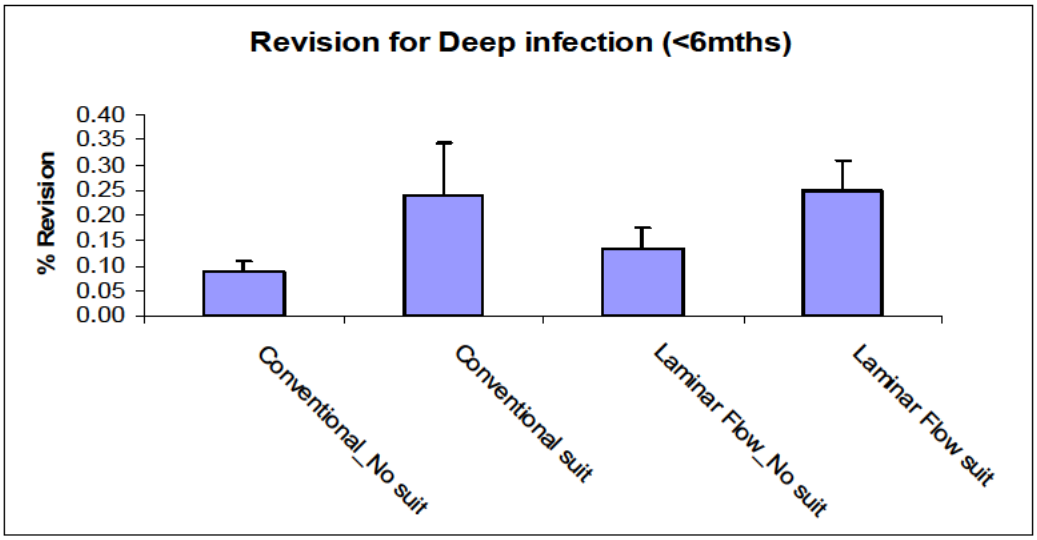
Revision for Deep infection within 6 months versus theatre environment

Theatre	Total Number	Number Revised	%	SE
Conventional	22863	23	0.10	0.02
Laminar Flow	13963	27	0.19	0.04



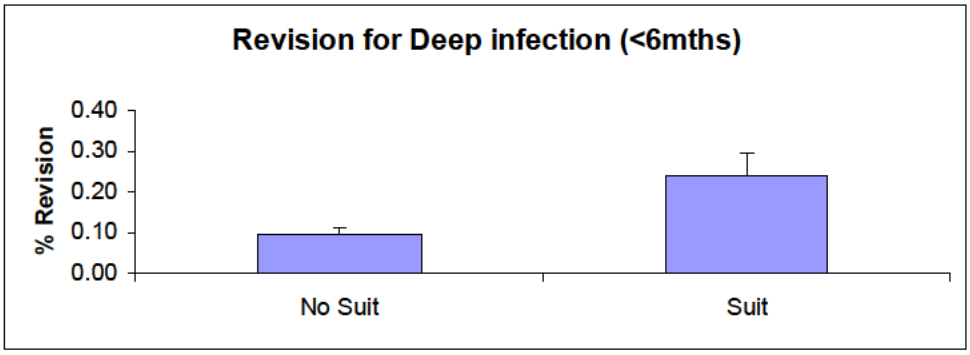
As with hip arthroplasty there is a significant difference in knee revision rates for deep infection within 6 months of surgery between conventional and laminar flow theatres.

Theatre/Suit	Total Number	Number Revised	%	SE
Conventional No suit	20753	18	0.09	0.02
Conventional suit	2110	5	0.24	0.11
Laminar Flow No suit	6786	9	0.13	0.04
Laminar Flow suit	7177	18	0.25	0.06



There is a significant difference in the revision rates between conventional/no suit and laminar flow/suit environments. There is 2.9 times the risk for revision in the latter compared to the former environment.

Theatre Suit	Total Number	Number Revised	%	SE
No Suit	27792	27	0.10	0.02
Suit	9471	23	0.24	0.05

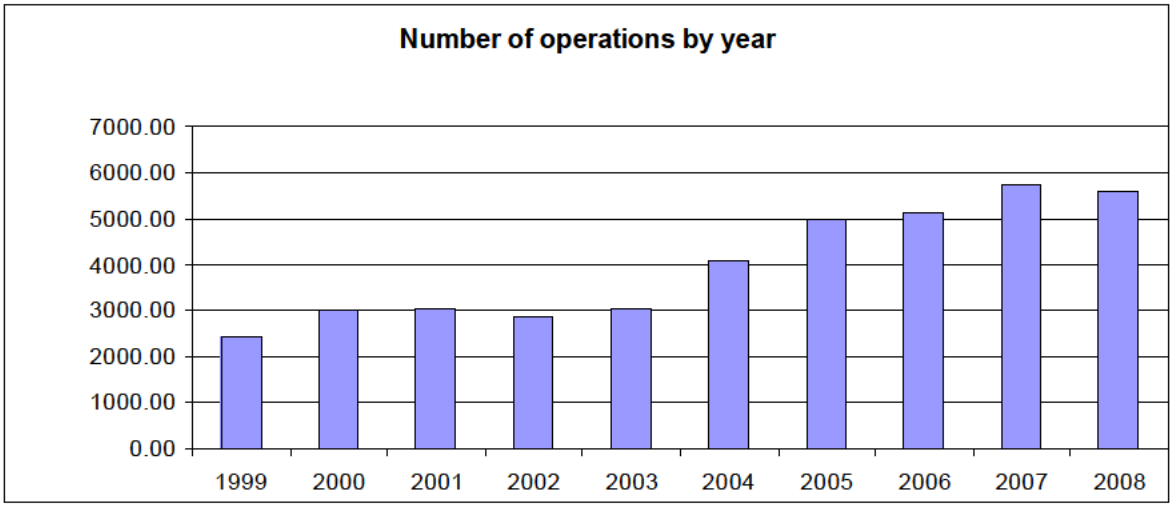


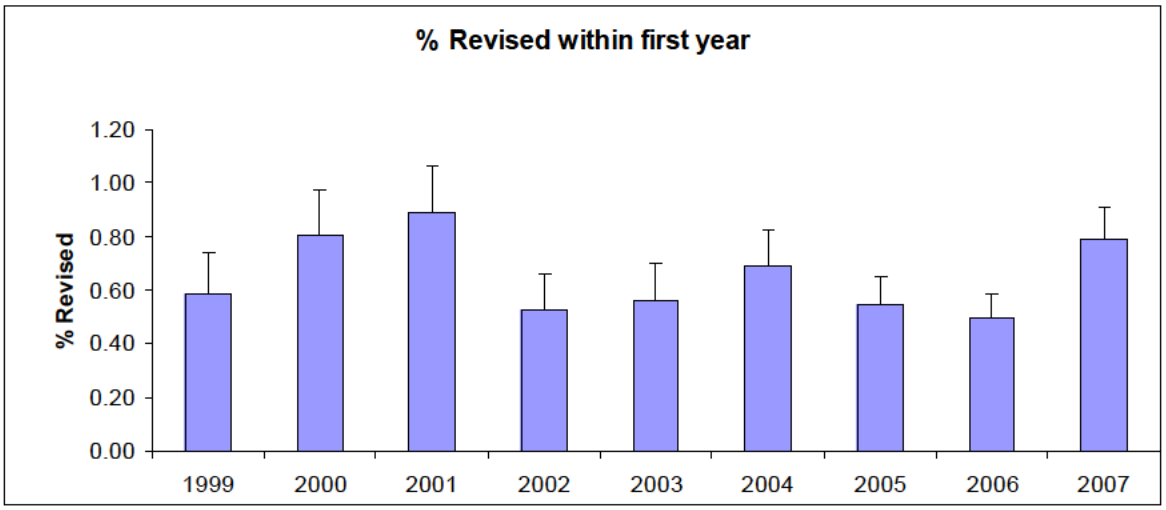
Furthermore there is a significant increase in revision rates when suits are used in either conventional or laminar flow theatres.

From the above data it would seem that, similar to hip arthroplasty, the use of space suits increases almost threefold the risk of deep infection within the first 6 months following the arthroplasty

Percentage of knees revised in first year.

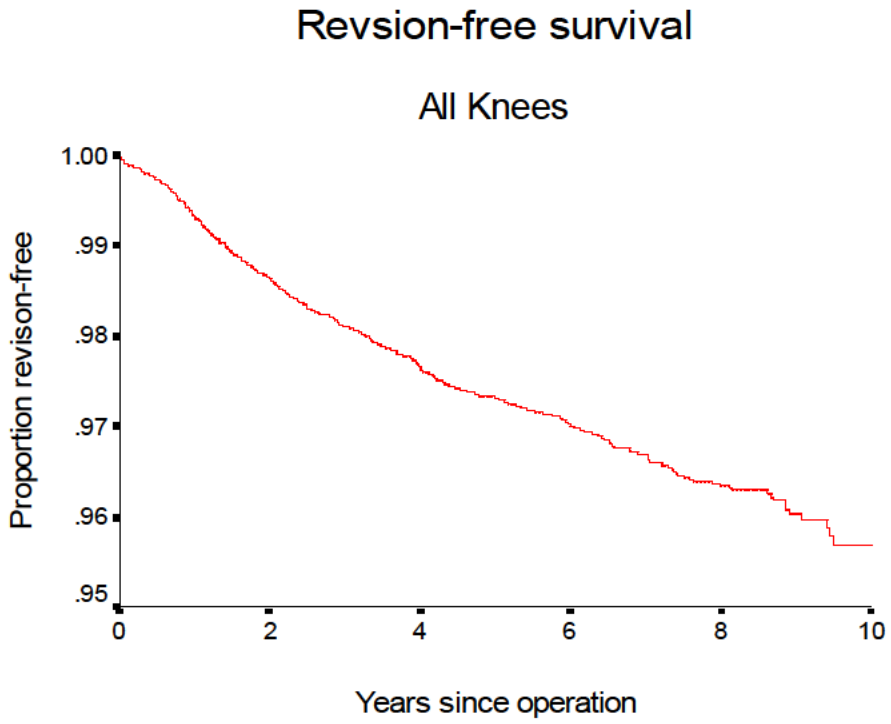
The following two bar graphs show that % of knees revised in the first year has fluctuated between 0.5% and 0.9%.





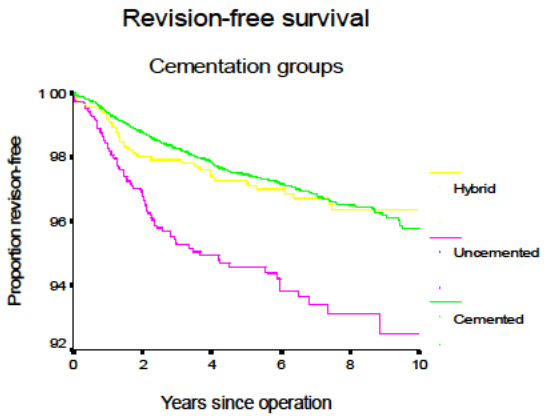
Kaplan Meier Curves

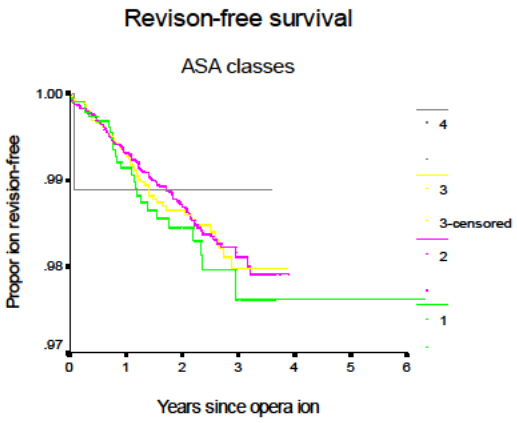
The following Kaplan Meier survival analyses are for years 1999 to 2008 with deceased patients censored at time of death.

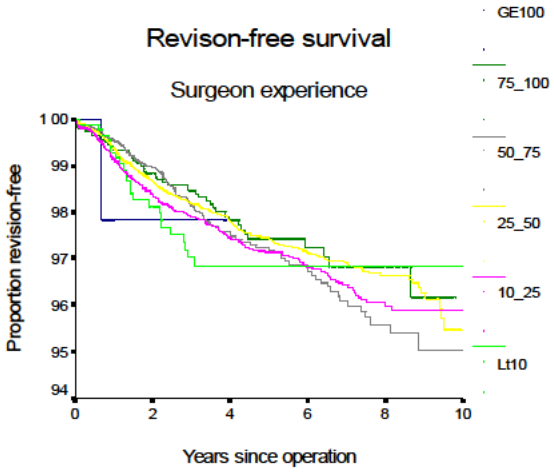


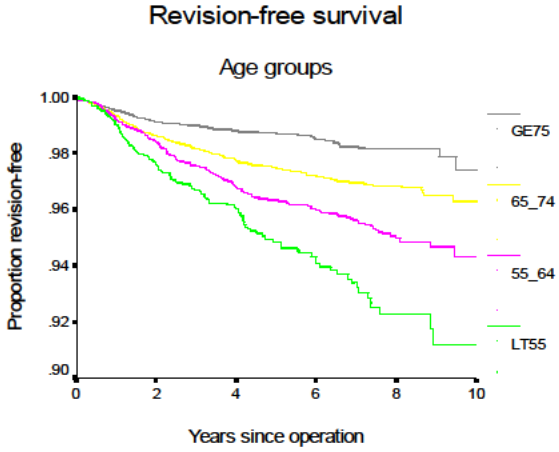
Years	% Revision-free
1	99.32
2	98.63
3	98.11
4	97.67
5	97.31
6	97.00
7	96.69
8	96.34
9	96.03

The KM analysis is to 9 yrs rather than 10 because no 10yr primary registered knees were revised in 2008









Knee re-revisions

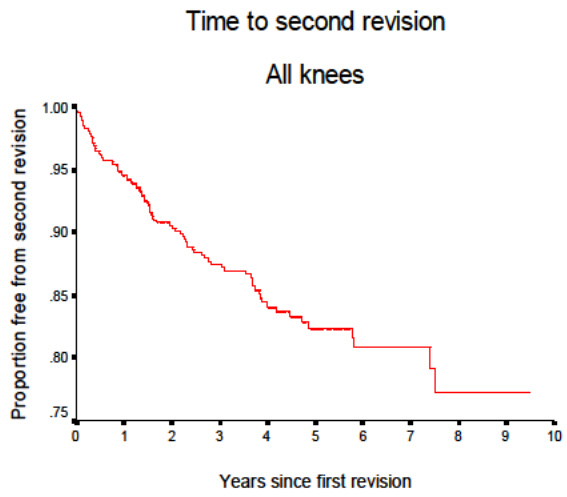
Analysis was undertaken of re-revisions.
There were 99 registered primary knee revisions that had been revised twice, 15 that had been revised 3 times and 1 had been revised 4 times.

Second revision

Time between the first and second revision for the 99 knee arthroplasties averaged 626 days, with a range of 2 – 2746 and a standard deviation of 598 days.
This compares to an average of 849 days between primary and first revision arthroplasty.

Reason for revision

Deep infection	41
Pain	24
Loosening tibial component	21
Loosening femoral component	14
Instability	12
Dislocation	5
Stiffness	2
Patellar fracture	2
Loosening patellar component	2
Fracture femur	1
Other	6



The KM graph confirms that survival following the first revision is poorer than for primary arthroplasty.

Third revision

The average time between second and third revisions for the 15 knee arthroplasties was 541 days, with a range of 70 – 1277 and a standard deviation of 358 days.

Fourth revision

The time between third and fourth revision for the 1 patient was 119 days.

PATIENT BASED QUESTIONNAIRE OUTCOMES AT SIX MONTHS AND FIVE YEARS POST SURGERY

Questionnaires at six months post surgery

At six months post surgery a random selection of patients are sent the Oxford 12 questionnaire in order to achieve a response rate of 20% of the total which is deemed to be ample to provide powerful statistical analysis.

The new scoring system as recommended by the original authors has been adopted. (appendix 1)

The scores now range from 4 to 0. A score of 48 is the best, indicating normal function. A score of 0 is the worst, indicating the most severe disability.

In addition we have grouped the questionnaire responses according to the classification system published by Kalairajah et al, 2005. (appendix1)

This groups each score into one of four categories;

Category 1	>41	excellent
Category 2	34 – 41	good
Category 3	27 – 33	fair
Category 4	< 27	poor

For the ten year period and as at August 2009, there were 14,793 primary knee questionnaire responses registered at six months post surgery.
The mean knee score was 37.01 (standard deviation 8.31, range 48 – 0)

Scoring > 41	5328
Scoring 34 – 41	5254
Scoring 27 – 33	2393
Scoring < 27	1818

At six months post surgery, 72% had an excellent or good score.

Questionnaires at five years post surgery

All patients who had a six- month registered questionnaire, and who had not had revision surgery were sent a further questionnaire at five years post surgery.

This dataset represents sequential Oxford knee scores for 3,922 individual patients.

At six months post surgery, 75% of this cohort of patients had achieved an excellent or good score and had a mean of 37.74.

At five years post surgery, 81% of patients achieved an excellent or good score and had a mean of 39.63.

Six month scores pre and post revision
The group of patients who had six-month primary scores and subsequent revision scores were also analysed. The number with both these scores was 270.

At six months post surgery, 42% of this group achieved an excellent or good score. The mean was 29.17.

The revision scores for this group had a mean of 30.64 and 42% achieved an excellent or good score.

Analysis of the individual questions at six months and five years post surgery
Analysis of the individual questions showed that the most common persistent problem occurred with kneeling (Q4).

Percentage scoring 0 or 1(worst categories) for each question out of the group of 14,793 primary knee responses at six months and 3,922 at five-years.

		% 6/12	% 5 yrs
1	Moderate or severe pain from the operated knee	13.5	8.6
2	Only able to walk around the house or unable to walk before pain becomes severe	5.6	4.3
3	Extreme difficulty or impossible to get in and out of a car or public transport	4.7	4.3
4	Extreme difficulty or impossible to kneel down and get up afterwards	43.1	41.4
5	Extreme difficulty or impossible to do the household shopping on your own	4.2	4.8
6	Extreme difficulty or impossible to wash and dry yourself	1.3	1.7
7	Pain interfering greatly or totally with your work	5.7	4.4
8	Very painful or unbearable to stand up from a chair after a meal	3.9	2.1
9	Most of the time or always feeling that the knee might suddenly “give way”	2.3	1.8
10	Limping most or every day	12.1	8.7
11	Extreme difficulty or impossible to walk down a flight of stairs	7.9	7.3
12	Pain from your knee in bed most or every nights	9.9	4.5

As noted in previous years there is little significant change between the six-month and five-year scores which means the 6 month score is indicative of the medium term outcome.

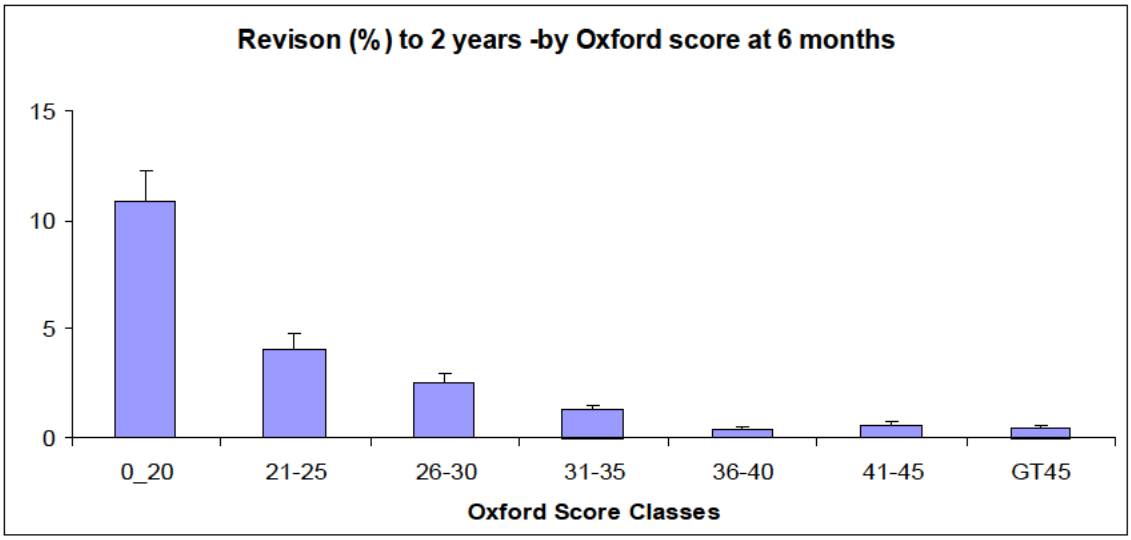
Revision knee questionnaire responses
There were 1,948 revision knee responses with 49% achieving an excellent or good score. This group includes all revision knee procedures. The mean revision knee score was 32.30 (standard deviation 10.30, range 48-3°

OXFORD 12 SCORE AS A PREDICTOR OF KNEE ARTHROPLASTY REVISION

A statistically significant relationship has been confirmed between the Oxford scores at 6 months and 5 years post surgery and arthroplasty revision within two years of the Oxford 12 questionnaire date.

Six month score and revision arthroplasty

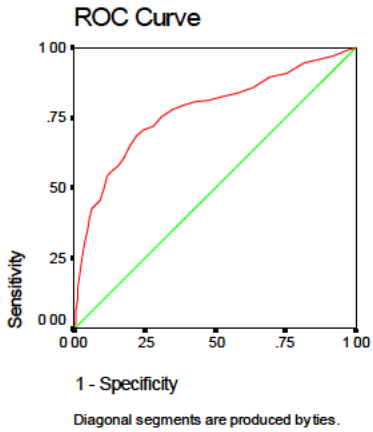
By plotting the patients scores in groups of 5, except at the range extremes, against the proportion of knees revised for that same group it demonstrates that there is an incremental increase in risk during the first 2 years related to the oxford score. A patient with a score below 20 has 30 times the risk of a revision within 2 years compared to a person with a score 36 to 40



A person with an oxford score of 36 – 40 has a 0.38% risk of revision within two years compared to a 10.90% risk with a score of 20 or less.

A ROC analysis has demonstrated that a patient with a score less than or equal to 31.5 has 7 times the risk of needing a revision within 2 years compared to a person with a score greater than 31.5. Alternatively the ROC analysis predicted 71% of the revisions within 2 years from just the lowest 25% of Oxford scores.

ROC curve at six months versus revision within two years



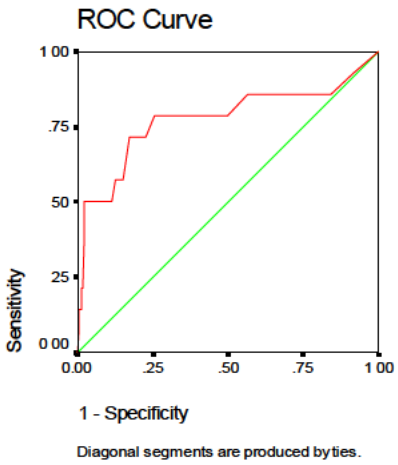
A receiver operating characteristic (ROC) curve is a graphical representation of the trade off between the false negative and false positive rates for every possible cut off. Equivalently, the ROC curve is the representation of the tradeoffs between sensitivity and specificity. The more the curve climbs towards the upper left corner the better the reliability of the test.

Five year score and revision arthroplasty

The ROC analysis at 5 years has demonstrated that a patient with a score less than or equal to 35.5 has 11 times the risk of needing a revision within 2 years compared to a person with a score greater than 35.5. Alternatively the ROC analysis predicted 78.5% of the revisions within 2 years from just the lowest 25% of Oxford scores.

Although the 5 year results reinforce the relationship between the Oxford score and revision within 2 years the 5 year numbers are still too small for statistical significance.

ROC curve at five years versus revision within two years



UNICOMPARTMENTAL KNEE ARTHROPLASTY

PRIMARY UNICOMPARTMENTAL KNEE ARTHROPLASTY

The **nine**-year report analyses data for the period January 2000 – December 2008. There were 4,826 unicompartmental knee procedures registered, an additional 539 compared to last year's report.

2000	340
2001	430
2002	533
2003	633
2004	634
2005	558
2006	584
2007	575
2008	539

The annual number of unicompartmental knees has continued to decline from the highs of 2003/4

DATA ANALYSIS

Age and sex distribution

The average age for a unicompartmental knee replacement was 66.50 years, with a range of 33.05 – 94.71 years.

	Female	Male
Number	2300	2526
Percentage	47.66	52.34
Mean age	66.39	66.60
Maximum age	94.71	93.42
Minimum age	33.05	35.24
Standard dev.	10.23	8.98

Previous operation

None	3782
Meniscectomy	757
Arthroscopy/debridement	249
Osteotomy	20
Ligament reconstruction	18
Internal fixation	21
Arthrotomy	3
Synovectomy	1
Other	11

Diagnosis

Osteoarthritis	4685
Avascular necrosis	40
Post ligament disruption	18
Other inflammatory	18
Post fracture	12
Rheumatoid arthritis	13
Tumour	1
Other	8

Approach

Medial	3867
Minimally invasive surgery	974
Other	179
Lateral	110
Image guided surgery	7

Image guided surgery was added to the updated forms at the beginning of 2005, but unlike the total knee arthroplasty, has never become popular.

The minimally invasive approach continues to be increasingly used and in 2008 was utilised in 37% of arthroplasties.

Cement

Femur cemented	4494	93%
Antibiotic in cement	2667	59%
Tibia cemented	4522	94%
Antibiotic in cement	2682	59%

Systemic antibiotic prophylaxis

Patient number receiving at least one systemic antibiotic	4630	96%

Operating theatre

Conventional	3637
Space suits	1132
Laminar flow	1112

ASA Class

This was introduced with the updated forms at the beginning of 2005.
For the four year period 2005 – 2008, there were 1,981 (88%) unicompartmental knee procedures with the ASA class recorded.

Definitions

ASA class 1:	A healthy patient
ASA class 2:	A patient with mild systemic disease
ASA class 3:	A patient with severe systemic disease that limits activity but is not incapacitating

ASA class 4: A patient with an incapacitating disease that is a constant threat to life

ASA	Number	Percentage
1	372	18
2	1303	66
3	297	15
4	9	1

Operative time (skin to skin)

Mean	81 minutes
Standard deviation	24 minutes
Minimum	24 minutes
Maximum	195 minutes

Surgeon grade

The updated forms introduced in 2005 have separated advanced trainee into supervised and unsupervised.
The following figures are for the four year period 2005 – 2008.

Consultant	2119
Advanced trainee supervised	106
Advanced trainee unsupervised	10
Basic trainee	8

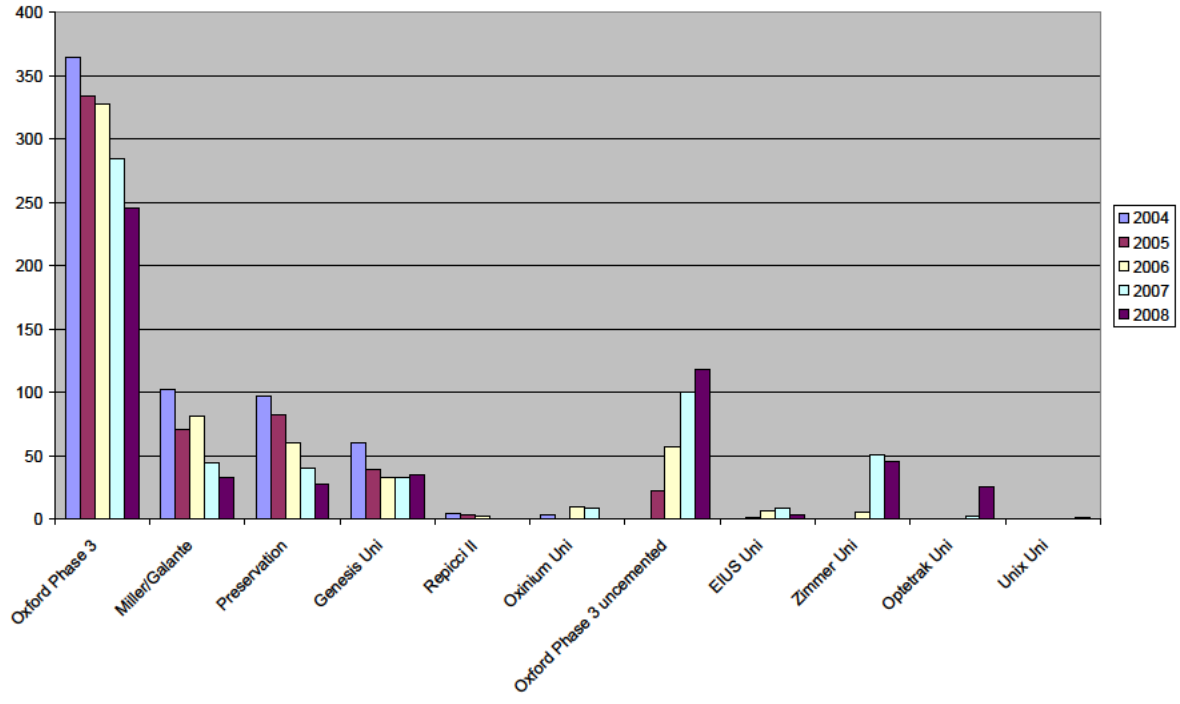
Prosthesis usage

Unicompartmental knee prostheses used in 2008

Oxford Phase 3	246
Oxford Phase 3 uncemented	118
Zimmer Uni	46
Genesis Uni	35
Miller/Galante	33
Preservation	28
Optetrak Uni	26
EIUS Uni	4
Unix Uni	2
Oxinium Uni	1

The main changes compared to 2007 have been significant increases in the Oxford uncemented and Optetrak unis at the expense of most of the others.

Most used unicompartmental prostheses 2004 – 2008



Surgeon and hospital workload

Surgeons
In 2008, 75 surgeons performed 539 unicompartmental knee replacements, an average of 7 procedures per surgeon. Over half of the surgeons (42) performed less than 5 procedures and 7 performed more than 15 procedures.

Hospitals
In 2008 unicompartmental knee replacement was performed in 36 hospitals. 18 were public and 18 were private.
For 2008 the average number of unicompartmental knee replacements per hospital was 15.

REVISION OF REGISTERED PRIMARY UNICOMPARTMENTAL ARTHROPLASTY
This section analyses the data for revision of unicompartmental knee replacement over the nine-year period.

There were 284 revisions of the 4,826 registered unicompartmental knee replacements (5.89%) with 48 having been revised in 2008

A further 20 had had a second revision and 2 a third revision.

248 of the 284 (87%) were revised to total knee replacements. 36 (13%)were revised to unicompartmental replacements

Time to revision

Mean	883 days
Maximum	3016 days
Minimum	10 days
Standard deviation	683 days

Reason for revision

Pain	121
Loosening tibial component	69
Loosening femoral component	48
Progression of disease	22
Bearing dislocation	21
Deep infection	14
Fracture tibia	10
Wear tibial	6
Impingement	4
Instability	3
Implant breakage	2
Fracture femur	1
Other	10

Deep infection was the reason for 4.9% of revisions.

Analysis by time of the 3 main reasons for revision

Pain n = 121

< 6 months	7
6 months – 1 year	20
2 years	45
3 years	19
4 years	9
5 years	11
6 years	6
7 years	2
8 years	2
9 years	0

Loosening tibial component n = 69

< 6 months	6
6 months – 1 year	14
2 years	25
3 years	5
4 years	7
5 years	5
6 years	3
7 years	3
8 years	1
9 years	0

Loosening femoral component n = 48

< 6 months	0
6 months – 1 year	9
2 years	16
3 years	5
4 years	10
5 years	1
6 years	2
7 years	2
8 years	3
9 years	0

Statistical note
In the table below there are two statistical terms readers may not be familiar with.

Observed component years
This is the number of registered primary procedures multiplied by the number of years each component has been in place.

Rate/100 component years
This is equivalent to the yearly revision rate expressed as a percent and is derived by dividing the number of prostheses revised by the observed component years multiplied by 100. It therefore allows for
the number of years of post operative follow up in calculating the revision rate. These rates are usually

very low, hence it is expressed per 100 component years rather than per component year. Statisticians consider that this is a more accurate way of deriving a revision rate for comparison when analysing data with widely varying follow up times. It is also important to note the confidence intervals. The closer they are to the estimated revision rate/100 component years, the more precise the estimate is.

Statistical Significance
Where it is stated that a difference is significant the p value is 0.05 or less.

All Primary Unicompartmental Knee Arthroplasties

	Total	Observed component years	Number revised	Rate/100 component years	Exact 95% confidence interval	
All patients	4826	18862.73	284	1.51	1.34	1.69

Revision rate of individual knee prostheses

	Total	Observed component years	Number revised	Rate/100 component years	Exact 95% confidence interval	
Prosthesis						
EIUS Uni Knee	22	39.79	0	0	0	9.27
Genesis Uni	303	1109.03	20	1.80	1.10	2.79
LCS Uni	6	38.39	2	5.21	0.63	18.82
Miller/Galante	620	2786.10	32	1.15	0.79	1.62
Optetrak Unicondylar Cemented	29	17.38	0	0	0	21.22
Oxford Phase 3	2866	12041.26	178	1.48	1.27	1.71
Oxford Phase 3 uncemented	299	415.80	2	0.48	0.06	1.74
Oxinium Uni	30	72.07	7	9.71	3.90	20.01
Preservation	450	1626.63	34	2.09	1.45	2.92
Repicci II	96	607.98	8	1.32	0.57	2.59
Zimmer Unicompartmental Knee	103	107.47	1	0.93	0.02	5.18

Apart from the no longer used LCS and Oxinium Unis there is no significant difference in the revision rates among the various prostheses.

Revision vs Arthroplasty Fixation

Age Band	Total	Observed component years	Number revised	Rate/100 component years	Exact 95% confidence interval	
Operation Type						
Cemented	4487	18273.84	278	1.52	1.35	1.711
Uncemented	297	502.75	5	0.99	0.32	2.32
Hybrid	42	86.14	1	1.16	0.03	6.47

Although the uncemented unis appear to have a significantly lower revision rate than cemented this is not statistically significant in view of the small number of ocys.

Revision vs Age Bands

	Total	Observed component years	Number revised	Rate/100 component years	Exact 95% confidence interval	
LT55	575	2216.04	44	1.99	1.44	2.67
55_64	1627	6351.34	119	1.87	1.55	2.24
65_74	1627	6531.53	80	1.22	0.97	1.52
GE75	997	3763.82	41	1.09	0.78	1.48

There is a significantly higher revision rate for the 55-64 age band when compared to the 65-74 & >75 age bands. Although the revision rate for the <55 age band is the highest it does not quite reach statistical significance.

Revision vs Gender

	Total	Observed component years	Number revised	Rate/100 component years	Exact 95% confidence interval	
M	2526	9938.10	144	1.45	1.22	1.71
F	2300	8924.63	140	1.57	1.32	1.85

There is no significant difference in revision rates between males and females

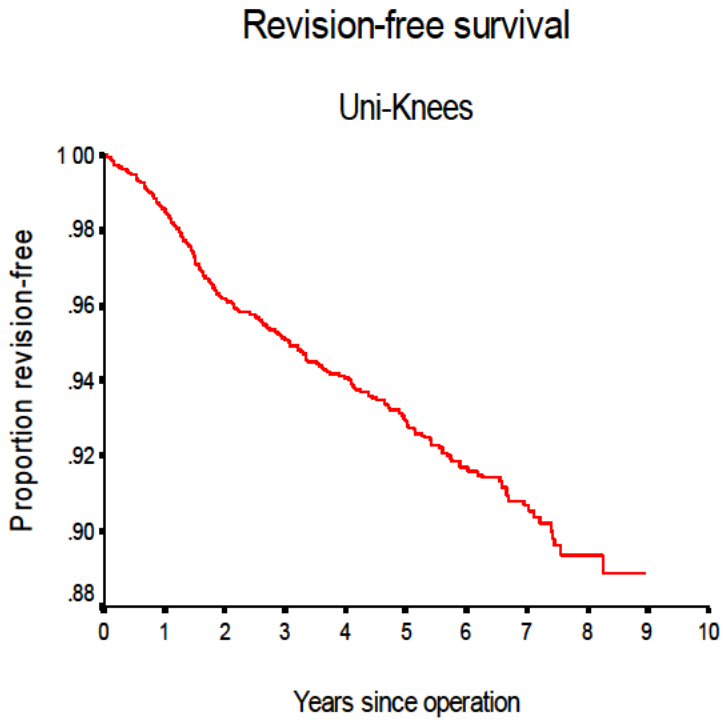
Revision vs Surgeon annual workload

	Total	Observed component years	Number revised	Rate/100 component years	Exact 95% confidence interval	
<10	2539	10268.99	180	1.75	1.51	2.03
>=10	2287	8593.74	104	1.21	0.99	1.47

Those surgeons performing <10 per year have a significantly higher revision rate.

Kaplan Meier Curves

The following Kaplan Meier survival analyses are for years 2000 to 2008 with deceased patients censored at time of death.



Numbers too few for accurate % survival beyond 7years

Years	% Revision-free
1	98.47
2	96.18
3	95.13
4	94.09
5	92.89
6	91.69
7	90.68

Revised to	Observed component years	Number re-revised	Rate/100 component years	Exact 95% confidence interval
Total Knee 205	695.2	13	1.87	0.99, 3.42
Uni Knee 31	119.3	7	5.87	2.38, 12.08

When compared to the primary total knee arthroplasty revision rate of 0.54 (C.I. 0.50, 0.58), there is a significantly increased revision rate when a unicompartmental arthroplasty is converted to a total knee arthroplasty. This statistic is even more significant following conversion of a unicompartmental to a further unicompartmental arthroplasty. Further evidence is that the average six month oxford score following conversion of a unicompartmental to total arthroplasty is similar to that for a revised primary total knee arthroplasty.

Patient based questionnaire outcomes at six-month post surgery

At six months post surgery all patients are sent the Oxford-12 questionnaire.

The new scoring system as recommended by the original authors has been adopted. (appendix one)

There are 12 questions, with the scores now ranging from 4 to 0. A score of 48 is the best, indicating normal function. A score of 0 is the worst, indicating the most severe disability.

In addition we have grouped the questionnaire responses according to the classification system published by Kalairajah et al, 2005 (appendix 1)

This groups each score into one of four categories;

Category 1	>41	excellent
Category 2	34 – 41	good
Category 3	27 – 33	fair
Category 4	< 27	poor

For the nine-year period and as at August 2008, there were 3,382 unicompartmental knee questionnaire responses registered at six months post surgery.
The mean unicompartmental knee score was 38.85 (standard deviation 7.57, range 3 – 48)

Scoring > 41	1575
Scoring 34 - 41	1105
Scoring 27 - 33	442
Scoring < 27	260

At six months post surgery, 79% had an excellent or good score.

Questionnaires at five years post surgery
Patients who had a six-month questionnaire registered, and who had not had revision surgery were sent a further questionnaire at five years post surgery.
This dataset represents sequential Oxford knee scores for individual patients.

The number of patients with six-month and five-year scores was 626.

At six months post surgery, 83% of this cohort of patients had achieved an excellent or good score and had a mean of 39.12.

At five years post surgery, 87 % of patients had achieved an excellent or good score and had a mean of 40.73.

Six-month scores pre and post revision
The group of patients who had six-month scores and subsequent revision scores was also analysed. The number with both these scores was 139.
At six months post primary surgery, 42% of this group had achieved an excellent or good score. The mean was 30.60.
The revision scores for this group had a mean of 31.78 and 42% achieved an excellent or good score.

Analysis of the individual questions at six months post surgery
Analysis of the individual questions showed that the most common problem occurred with kneeling (Q4) and pain in the operated knee (Q1).

Percentage scoring 0 or 1 for each question out of the group of 3,382 at six months post surgery and 626 at five-years.

		% 6/12	% 5 yrs
1	Moderate or severe pain from the operated knee	11.1	8.9
2	Only able to walk around the house or unable to walk before pain becomes severe	3.5	2.9
3	Extreme difficulty or impossible to get in and out of a car or public transport	1.8	0.9
4	Extreme difficulty or impossible to kneel down and get up afterwards	32.8	28.4
5	Extreme difficulty or impossible to do the household shopping on your own	1.7	1.4
6	Extreme difficulty or impossible to wash and dry yourself	0.5	0.4
7	Pain interfering greatly or totally with your work	3.3	2.7
8	Very painful or unbearable to stand up from a chair after a meal	3.6	1.6
9	Most of the time or always feeling that the	1.7	1.4

	knee might suddenly "give way"		
10	Limping most or every day	9.5	5.6
11	Extreme difficulty or impossible to walk down a flight of stairs	4.0	3.0
12	Pain from your knee in bed most or every nights	7.8	3.7

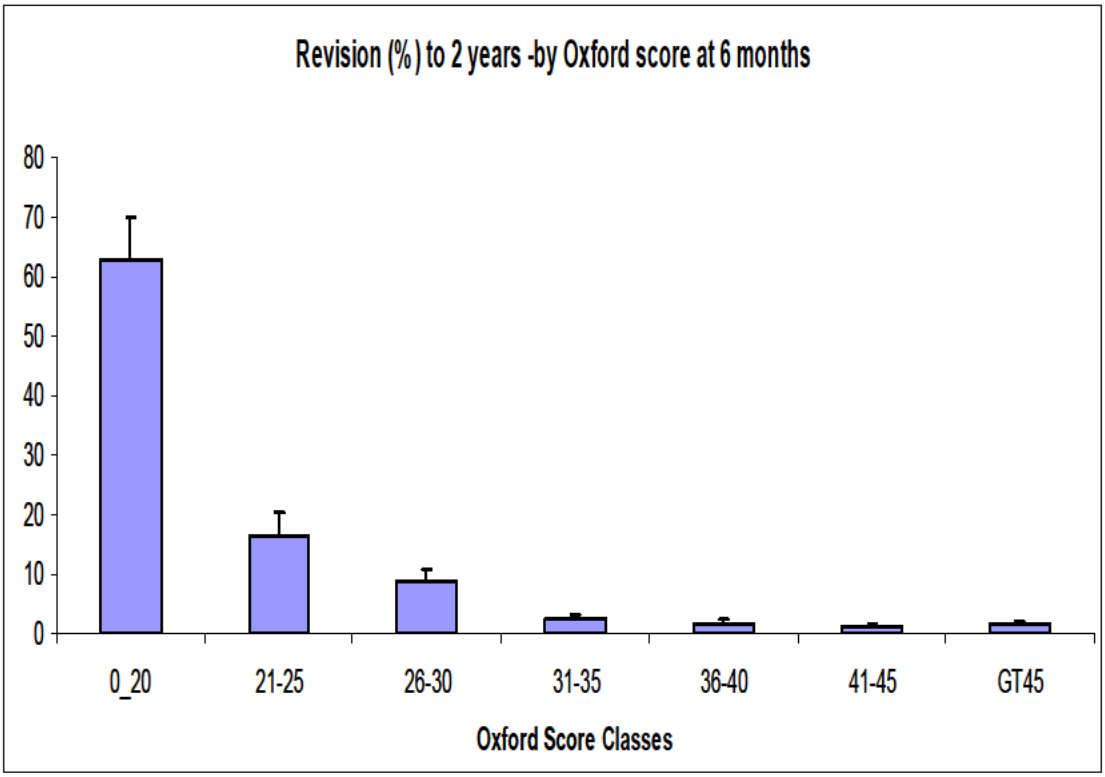
As noted in previous years there is little significant change between the six-month and five-year scores which means the six-month score is indicative of the medium term outcome.

OXFORD 12 SCORE AS A PREDICTOR OF KNEE ARTHROPLASTY REVISION

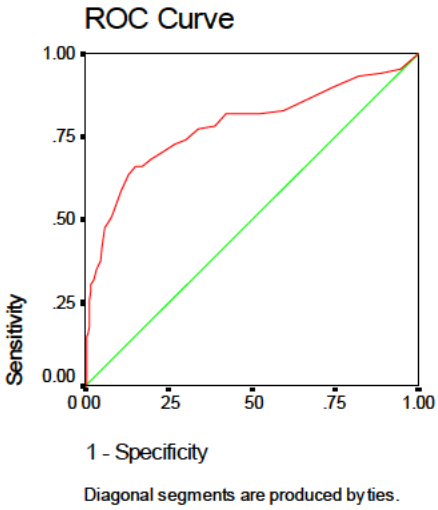
A statistically significant relationship has been confirmed between the Oxford scores at 6 months and arthroplasty revision within two years of the Oxford 12 questionnaire date.

By plotting the patients scores in groups of 5, except at the range extremes, against the proportion of unicompartmental knees revised for that same group it demonstrates that there is an incremental increase in risk during the first 2 years related to the Oxford score. A patient with a score below 20 has 50 times the risk of a revision within 2 years compared to a person with a score 41-45

A ROC analysis has demonstrated that a patient with a score less than or equal to 31.5 has 11 times the risk of needing a revision within 2 years compared to a person with a score greater than 31.5. Alternatively the ROC analysis predicted 66% of the revisions within 2 years from just the lowest 17% of Oxford scores.



A person with an oxford score of 36 – 40 has a 1.7% risk of revision within two years compared to a 62.8% risk with a score of 20 or less.



A receiver operating characteristic (ROC) curve is a graphical representation of the trade off between the false negative and false positive rates for every possible cut off. Equivalently, the ROC curve is the representation of the tradeoffs between sensitivity and specificity. The more the curve climbs towards the upper left corner the better the reliability of the test.

ANKLE ARTHROPLASTY

PRIMARY ANKLE ARTHROPLASTY

The **nine**- year report analyses data for the period January 2000 – December 2008. There were 484 primary ankle procedures registered, an additional 107 compared to last year's report and represents a 35% increase over 2007

2000	17
2001	28
2002	28
2003	26
2004	48
2005	70
2006	81
2007	79
2008	107

DATA ANALYSIS

Age and sex distribution

	Female	Male
Number	183	301
Percentage	37.81	62.19
Mean age	63.23	66.24
Maximum age	85.44	88.38
Minimum age	32.51	35.62
Standard dev.	9.24	8.56

The average age for an ankle replacement was 65.10years, with a range of 32.51 – 88.38 years.

Previous operation

None	375
Internal fixation for juxtarticular fracture	49
Arthroscopy/debridement	20
Arthrodesis	20
Osteotomy	9
Reconstruction/repair	4
Other	3

Diagnosis

Osteoarthritis	351
Post trauma	85
Rheumatoid arthritis	51
Other inflammatory	5
Other	7

Approach

Anterior	427
Anterolateral	26
Other	7

Bone graft

Tibia autograft	27
Tibia allograft	2
Talus autograft	5
Talus allograft	1

Cement

Tibia cemented	1
Antibiotic in cement	7
Talus cemented	6
Antibiotic in cement	3

Systemic antibiotic prophylaxis

Patient number receiving at least one systemic antibiotic 462 (95%)

Operating theatre

Conventional	287
Laminar flow	194
Space suits	55

ASA Class

This was introduced with the updated forms at the beginning of 2005.
For the four-year period 2005 -2008, there were 254 (75%) primary ankle procedures with the ASA class recorded.

Definitions

ASA class 1:	A healthy patient
ASA class 2:	A patient with mild systemic disease
ASA class 3:	A patient with severe systemic disease that limits activity but is not incapacitating
ASA class 4:	A patient with an incapacitating disease that is a constant threat to life

ASA	Number
1	57
2	151
3	45
4	1

Operative time (skin to skin)

Mean	127 minutes
Standard deviation	37 minutes
Minimum	30 minutes
Maximum	275 minutes

Surgeon grade

The updated forms introduced in 2005 have separated advanced trainee into supervised and unsupervised.
The following figures are for the four-year period 2005 -2008.

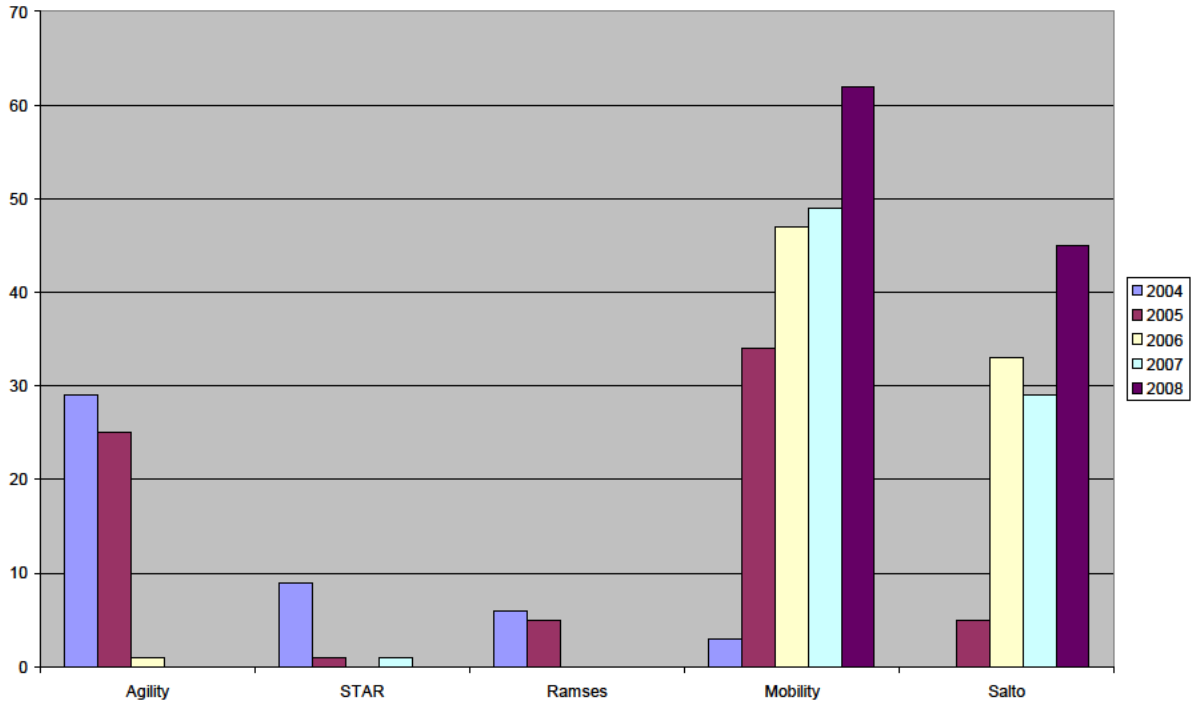
Consultant	332
Advanced trainee supervised	4

Prosthesis usage

Ankle prostheses used in 2008

Mobility	62
Salto	45

MOST USED ANKLE PROSTHESES 2004 – 2008



Surgeon and hospital workload

Surgeons

In 2008, 12 surgeons performed 107 primary ankle procedures, an average of 9 procedures per surgeon. 1 surgeon performed more than 20 procedures and 3 performed 1 procedure.

Hospitals

In 2008 primary ankle replacement was performed in 18 hospitals. 10 were private and 8 were public.

REVISION ANKLE ARTHROPLASTY

Revision is defined by the Registry as a new operation in a previously replaced ankle joint during which one or more of the components are exchanged, removed, manipulated or added. It includes arthrodesis or amputation, but not soft tissue procedures. A two or more staged procedure is registered as one revision.

Data analysis

For the nine-year period January 2000– December 2008, there were 29 revision ankle procedures registered.

The average age for an ankle revision was 64.71 years, with a range of 42.15 – 78.98.

	Female	Male
Number	8	21
Percentage	27.59	72.41
Mean	60.30	66.39
Maximum age	78.98	76.56
Minimum age	42.15	51.71
Standard dev.	13.23	6.78

REVISION OF REGISTERED PRIMARY ANKLE ARTHROPLASTY

This section analyses data for revisions of primary ankle procedures for the nine-year period.

There were 18 revisions of the primary group of 484 (3.72%) and 1 re-revision giving 19 revisions in total.

Time to revision

Mean	924 days
Maximum	1969 days
Minimum	21 days
Standard deviation	679 days

Reason for revision

Loosening talar component	7
Pain	10
Loosening tibial component	2
Deep infection	2
Other	4

Analysis by time of the 2 main reasons for revision

Loosening talar component n = 7

< 6 months	1
3 years	1
4 years	1
5 years	2
6 years	2

Pain n = 10

6 months – 1 year	1
2 years	4
3 years	2
4 years	2
6 years	1

Statistical note

In the table below there are two statistical terms readers may not be familiar with.

Observed component years

This is the number of registered primary procedures multiplied by the number of years each component has been in place.

Rate/100 component years

This is equivalent to the yearly revision rate expressed as a percent and is derived by dividing the number of prostheses revised by the observed component years multiplied by 100. It therefore allows for the number of years of post operative follow up in calculating the revision rate. These rates are usually very low, hence it is expressed per 100 component years rather than per component year.

Statisticians consider that this is a more accurate way of deriving a revision rate for comparison when analysing data with widely varying follow up times. It is also important to note the confidence intervals. The closer they are to the estimated revision rate/100 component years, the more precise the estimate is.

Statistical Significance

Where it is stated that a difference is significant the p value is 0.05 or less

All primary ankle arthroplasties

All patients	Total	Observed component years	Number revised	Rate/100 component years	Exact 95% confidence interval	
	484	1408.67	18	1.28	0.76	2.02

Revision vs prosthesis type

Prosthesis	Total	Observed component years	Number revised	Rate/100 component years	Exact 95% confidence interval	
Agility Tibial Shell	119	623.70	7	1.12	0.45	2.31
Mobility	195	337.34	5	1.48	0.48	3.46
Ramses	11	41.46	1	2.41	0.06	13.44
Salto	112	166.40	0	0	0	2.21
Scandinavian Total Ankle Repl.	47	239.77	5	2.09	0.68	4.87

There is no statistically significant difference in the revision rates among the prostheses

Revision vs gender

Gender	Total	Observed component years	Number revised	Rate/100 component years	Exact 95% confidence interval	
Females	183	548.46	4	0.73	0.20	1.87
Males	301	860.21	14	1.63	0.89	2.73

Although there appears to be a higher revision rate for males, this is not statistically significant.

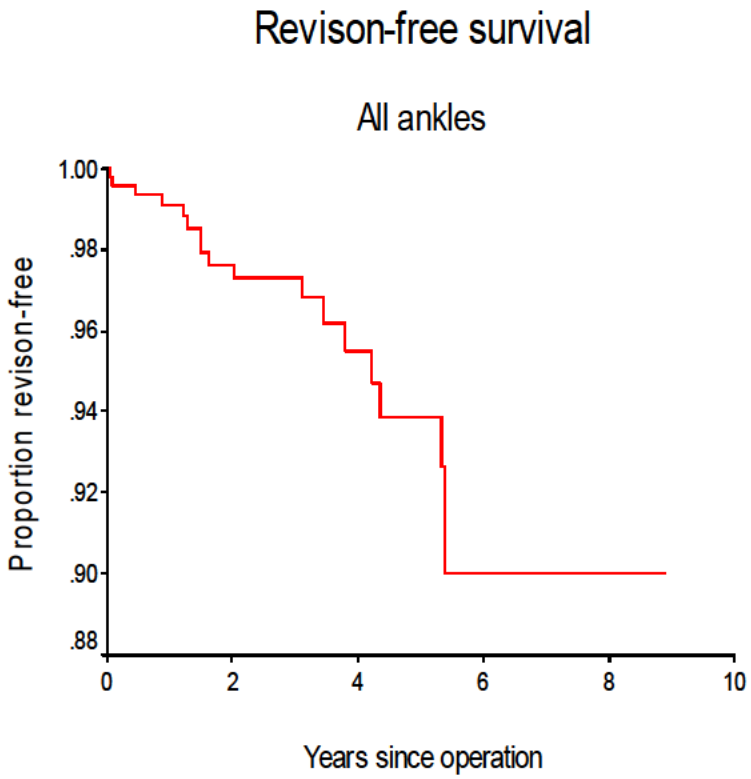
Revision vs age bands

Age Bands	Total	Observed component years	Number revised	Rate/100 component years	Exact 95% confidence interval	
LT55	60	193.49	3	1.55	0.32	4.53
55_64	174	536.11	8	1.49	0.64	2.94
65_74	182	513.60	6	1.17	0.43	2.54
GE75	68	165.46	1	0.60	0.02	3.37

There is no significant difference in the revision rates among the age groups

KAPLAN MEIER CURVES

The following Kaplan Meier survival analyses are for 9 years to 2008 with deceased patients censored at time of death.



Years	% Survival
1	99.1
2	97.65
3	97.31
4	95.53
5	93.88
6	90.02

There are insufficient numbers to give an accurate revision % beyond 6 years.

PATIENT BASED QUESTIONNAIRE OUTCOMES AT SIX-MONTH POST SURGERY

At six months post surgery patients are sent a questionnaire which is modelled on the Oxford 12, but is not validated.

The same scoring system has been adopted as recommended by the original authors of the Oxford 12 hip and knee questionnaires.

The scores now range from 4 to 0. A score of 48 is the best, indicating normal function. A score of 0 is the worst, indicating the most severe disability.

We have grouped the questionnaire responses based on the scoring system published by Kalairajah et al, 2005(appendix1)
This groups each score into one of four categories;

Category 1	>41	excellent
Category 2	34 – 41	good
Category 3	27 – 33	fair
Category 4	< 27	poor

For the nine year period and as at August 2009, there were 391 primary ankle questionnaire responses registered at six months post surgery. The mean primary ankle score was 33.42 (standard deviation 9.64, range 2 – 48)

Scoring > 41	94
Scoring 34 - 41	125
Scoring 27 - 33	79
Scoring < 27	93

At six months post surgery, 56% had an excellent or good score.

Analysis of the individual questions
Analysis of the individual questions showed that the main problems were with limping (Q6) and swelling of the foot (Q10).

Percentage scoring 0 or 1 for each question (n = 391)

1	Moderate or severe pain from the operated ankle	22.0
2	Only able to walk around the house or unable to walk before the pain becomes severe	7.4
3	Extreme difficulty or impossible to walk on uneven ground	14.1
4	Most of the time or always have to use an orthotic	23.8
5	Pain greatly or totally interferes with usual work	18.2
6	Limping most or every day	33.8
7	Extreme difficulty or impossible to climb a flight of stairs	6.4
8	Pain from your ankle in bed most or every nights	6.6
9	Pain from your ankle greatly or totally interferes with usual recreational activities	21.5
10	Have swelling of your foot most or all of the time	32.0
11	Very painful or unbearable to stand up from a chair after a meal	5.4
12	Sudden severe pain from your ankle most or every day	5.9

Revision ankle questionnaire responses
There were 14 revision ankle responses with only 5 (36%) achieving an excellent or good score. This group includes all revision ankle responses. The mean revision ankle score was 26.64 (standard deviation 13.85, range 8 – 48). There was no complication data reported.

SHOULDER ARTHROPLASTY

PRIMARY SHOULDER ARTHROPLASTY

The **nine**-year report analyses data for the period January 2000 – December 2008. There were 2498 primary shoulder procedures registered, an additional 457 compared to last year's report.

2000	122
2001	162
2002	193
2003	225
2004	280
2005	293
2006	366
2007	400
2008	457

There was a 14 % increase in registrations for 2008 and continues the steady upward trend seen every year. There has been a 275% increase since 2000.

Of the 2498 shoulder registrations, 1038 (42%) are hemi arthroplasties, 961(38%) total shoulder arthroplasties, 426(17%) reverse shoulder arthroplasties and 73 (3%) resurfacing arthroplasties.

DATA ANALYSIS

Age and sex distribution

The average age for all patients with a shoulder arthroplasty was 70.19 years, with a range of 15.63 – 97.71 years.

All shoulder arthroplasty

	Female	Male
Number	1610	888
Percentage	64.45	35.55
Mean age	71.78	67.29
Maximum age	97.71	90.48
Minimum age	15.63	21.83
Standard dev.	10.28	10.63

Hemiarthroplasty

	Female	Male
Number	697	341
Percentage	67.15	32.85
Mean age	71.23	66.09
Maximum age	97.71	90.48
Minimum age	15.63	27.81
Standard dev.	11.18	11.79

Total shoulder arthroplasty

	Female	**Male**
Number	**620**	**341**
Percentage	64.52	35.48
Mean age	71.01	67.61
Maximum age	94.62	85.26
Minimum age	26.64	29.38
Standard dev.	9.40	8.18

Reverse shoulder arthroplasty

	Female	Male
Number	273	153
Percentage	64.08	35.92
Mean age	75.94	73.32
Maximum age	91.60	88.17
Minimum age	40.70	49.41
Standard dev.	7.44	7.72

Resurfacing arthroplasty

	Female	Male
Number	20	53
Percentage	27.40	72.60
Mean age	58.45	55.62
Maximum age	78.44	79.37
Minimum age	20.70	21.83
Standard dev.	15.28	12.26

Reverse arthroplasty patients have a higher mean age.

Previous operation

None	2120
Rotator cuff repair	84
Internal fixation for juxtarticular fracture	70
Previous stabilisation	52
Arthroscopy/debridement	39
Acromioplasty	37
Subacromial decompression	6
Other	16

Diagnosis

Osteoarthritis	1346
Cuff arthropathy	313
Acute fracture prox. humerus	277
Rheumatoid arthritis	266
Post old trauma	205
Avascular necrosis	91
Other inflammatory	30
Post recurrent dislocation	29
Tumour	11
Post dysplasia	3
Other	13

Approach

Deltopectoral	2257
Deltoid split	55
Trans deltoid	5
Posterior	3

Bone graft

Humeral autograft	62
Humeral allograft	13
Humeral synthetic	3
Glenoid autograft	15
Glenoid allograft	4

Cement

Humerus cemented	950	(39%)
Antibiotic in cement	541	(57%)
Glenoid cemented	748	(54%)
Antibiotic in cement	481	(64%)

Systemic antibiotic prophylaxis

Patient number receiving at least one systemic antibiotic	2321	(93%)

Operating theatre

Conventional	1698
Laminar flow	771
Space suits	308

ASA Class

This was introduced with the updated forms at the beginning of 2005.
For the four-year period 2005 – 2008 there were 1336 (88%) shoulder procedures with the ASA class recorded.

Definitions

ASA class 1: A healthy patient
ASA class 2: A patient with mild systemic disease
ASA class 3: A patient with severe systemic disease that limits activity but is not incapacitating
ASA class 4: A patient with an incapacitating disease that is a constant threat to life

ASA	Number	Percentage
1	146	11
2	712	53
3	464	35
4	14	1

Operative time (skin to skin in minutes)

	Total	Hemi	Reverse	Resurf
Mean	133	106	118	104
Min	53	30	54	49
Max	270	360	246	285
SDev	33	36	30	43

Surgeon grade

The updated forms introduced in 2005 have separated advanced trainee into supervised and unsupervised.
The following figures are for the four-year period 2005 – 2008.

Consultant	1456
Advanced trainee supervised	56
Advanced trainee unsupervised	3
Basic trainee	1

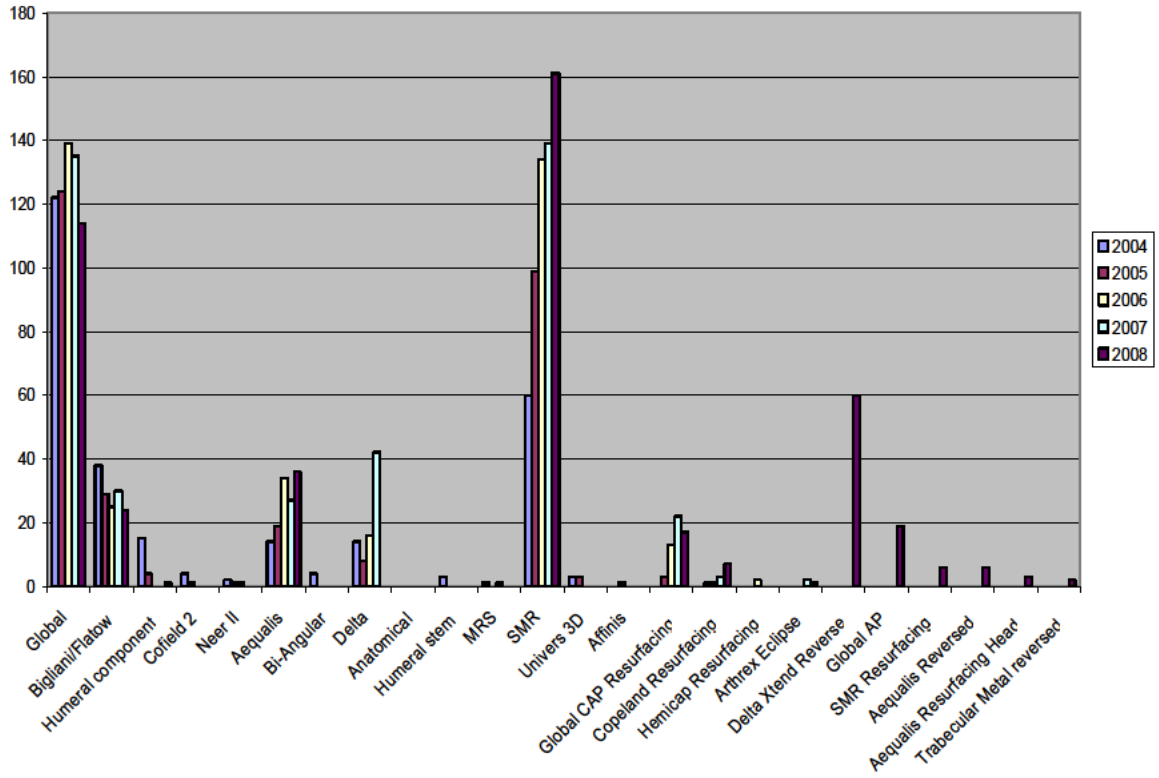
Prosthesis usage

Shoulder prostheses used in 2008.

SMR	161
Global	114
Delta Xtend Reverse	60
Aequalis	36
Bigliani/Flatow	24
Global AP	19
Global CAP Resurfacing	17
Copeland Resurfacing	7
SMR Resurfacing	6
Aequalis Reversed	6
Aequalis Resurfacing Head	3
Trabecular Metal Reverse	2
Humeral component	1
Arthrex Eclipse	1

Some of the above eg SMR, include total, hemi and reverse options.

MOST USED SHOULDER PROSTHESES 2003 -2007



The SMR continues to increase in popularity and 2008 saw the rise in prominence of resurfacing and reverse prostheses.

Surgeon and hospital workload

Surgeons
In 2008, 66 surgeons performed 457 shoulder procedures, an average of 7 procedures per surgeon. 1 surgeon performed more than 30 procedures and 20 surgeons performed 1 procedure.

Hospitals
In 2008, shoulder replacement was performed in 45 hospitals. 24 were public and 21 were private.
For 2008 the average number of shoulder replacements per hospital was 10.

REVISION SHOULDER ARTHROPLASTY

Revision is defined by the Registry as a new operation in a previously replaced shoulder joint during which one or more of the components are exchanged, removed, manipulated or added. It includes arthrodesis, excision arthroplasty or amputation, but not soft tissue procedures. A two or more staged procedure is registered as one revision.

Data analysis
For the nine-year period January 2000 – December 2008, there were 180 revision shoulder procedures registered. This is an additional 41 compared to last year's report.
The average age for a shoulder revision was 67.35 years with a range of 24.05 – 89.68 years.

	Female	Male
Number	100	80
Percentage	55.56	44.44
Mean	69.32	64.88
Maximum age	89.68	81.38
Minimum age	33.89	24.05
Standard dev.	12.05	11.23

REVISION OF PRIMARY SHOULDER ARTHROPLASTY

This section analyses data for revisions of registered primary shoulder procedures for the nine-year period.

There were 78 revisions of the primary group of 2498 (3.12%). There were 8 procedures that had been revised twice and 1 that had been revised 3 times.

Time to revision

Mean	561	days
Maximum	3097	days
Minimum	0	days
Standard deviation	594	days

Reason for revision

Pain	25
Dislocation/instability anterior	18
Deep infection	10
Loosening glenoid	8
Wear glenoid	6
Cuff failure	4
Subacromial cuff impingement	4
Instability posterior	2
Fracture humerus	1
Loosening humeral	1
Other	8

Analysis by time for the 3 main reasons for revision

Pain n = 25

< 6 months	1
6 months – 1 year	5
2 years	8
3 years	5
4 years	2
5 years	4

Dislocation n = 18

< 6 months	13
6 months – 1 year	2
2 years	3

Deep infection n = 10

< 6 months	2
6 months – 1 year	2
2 years	3
3 years	3

Statistical note

In the table below there are two statistical terms readers may not be familiar with.

Observed component years

This is the number of registered primary procedures multiplied by the number of years each component has been in place.

Rate/100 component years

This is equivalent to the yearly revision rate expressed as a percent and is derived by dividing the number of prostheses revised by the observed component years multiplied by 100. It therefore allows for the number of years of post operative follow up in calculating the revision rate. These rates are usually very low, hence it is expressed per 100 component years rather than per component year. Statisticians consider that this is a more accurate way of deriving a revision rate for comparison when analysing data with widely varying follow up times. It is also important to note the confidence intervals. The closer they are to the estimated revision rate/100 component years, the more precise the estimate is.

Statistical Significance

Where it is stated that a difference is significant the p value is 0.05 or less

All Total Shoulder Arthroplasties

All patients	Total	Observed component years	Number revised	Rate/100 component years	Exact 95% confidence interval	
	2498	7991	78	0.98	0.77	1.22

Revision vs Gender

Gender	Total	Observed component years	Number revised	Rate/100 component years	Exact 95% confidence interval	
F	1610	5321	43	0.81	0.58	1.09
M	888	2670	35	1.31	0.91	1.82

There is no significant difference between the two groups.

Revision vs Age Bands

Age Bands	Total	Observed component years	Number revised	Rate/100 component years	Exact 95% confidence interval	
LT55	197	661	12	1.82	0.94	3.17
55_64	476	1522	18	1.18	0.7	1.87
65_74	909	2943	29	0.99	0.66	1.42
GE75	916	2865	19	0.66	0.4	1.04

There is no significant difference among the 4 groups.

Revision vs Operation Category

Operation Category	Total	Observed component years	Number revised	Rate/100 component years	Exact 95% confidence interval	
Total	961	3117	19	0.61	0.37	0.95
Reverse	426	799	15	1.88	1.05	3.1
Hemis	1038	3974	43	1.08	0.78	1.46
Resurfacing	73	102	1	0.98	0.02	5.48

The Reverse shoulder procedures have a significantly higher revision rate than conventional total arthroplasty.

Revision vs Surgeon annual workload

Consultant Number of ops/yr	Total	Observed component years	Number revised	Rate/100 component years	Exact 95% confidence interval	
<10	1383	4636	49	1.06	0.78	1.4
>=10	1115	3355	29	0.86	0.58	1.24

There is no significant difference between the two groups.

Revision rate of individual shoulder prostheses

Operation Type	Prosthesis	Total	Observed component years	Number revised	Rate/100 component years	Exact 95% confidence interval	
Total	Aequalis	121	378.05	3	0.79	0.16	2.32
	Affinis	1	3.18	0	0	0	116.05
	Anatomical	8	48.59	0	0	0	7.59
	Bi-Angular	8	38.94	0	0	0	9.47
	Bigliani/Flatow	173	712.47	2	0.28	0.03	1.01
	Cofield 2	21	133.52	0	0	0	2.76
	Global	303	873.84	5	0.57	0.19	1.34
	Global AP	15	3.41	0	0	0	108.30
	Osteonics	49	257.77	1	0.39	0.01	2.16
	Sulzer Medica	27	161.56	0	0	0	2.28
	Neer 3	2	14.20	0	0	0	25.98
	Neer II	12	86.29	0	0	0	4.27
	SMR	208	381.09	8	2.10	0.91	4.14
	Univers 3D	5	17.17	0	0	0	21.49
Reverse	Aequalis Reversed	11	12.09	0	0	0	30.51

	Delta	55	199.22	1	0.50	0.01	2.80
	Delta Xtend Reverse	91	69.09	3	4.34	0.90	12.69
	SMR	267	517.77	11	2.12	1.06	3.80
	Trabecular Metal Reverse	2	0.35	0	0	0	1060.90
Hemi	Aequalis	71	285.74	5	1.75	0.57	4.08
	Anatomical	5	31.65	0	0	0	11.66
	Arthrex Eclipse	1	1.09	0	0	0	339.39
	Bi-Angular	19	126.63	2	1.58	0.19	5.71
	Bigliani/Flatow	114	526.51	5	0.95	0.31	2.22
	Bio-modular	1	7.14	1	14.00	0.35	78.03
	Cofield 2	50	309.05	0	0	0	1.19
	Delta	1	2.28	0	0	0	161.94
	Delta Xtend Reverse	4	2.14	0	0	0	172.52
	Global	560	1932.97	22	1.14	0.71	1.72
	Global AP	4	1.23	0	0	0	298.75
	Osteonics	43	236.57	1	0.42	0.01	2.36
	Sulzer Medica	14	83.39	0	0	0	4.42
	MRS Humeral	3	8.54	0	0	0	43.18
	Neer II	24	135.27	0	0	0	2.73
	Randelli	1	6.40	0	0	0	57.68
	SMR	122	273.78	7	2.56	1.03	5.27
	Univers 3D	1	3.64	0	0	0	101.30
Resurface							
	SMR Resurfacing	7	3.45	0	0	0	106.93
	Copeland Resurfacing	12	12.77	1	7.83	0.20	43.63
	Eclipse	2	2.29	0	0	0	161.36
	Global CAP Resurfacing	50	78.37	0	0	0	4.70
	Hemicap Resurfacing	2	4.79	0	0	0	77.04

Although there appear to be some prostheses with comparatively higher revision rates than the overall mean none are statistically significant owing to some wide CIs.

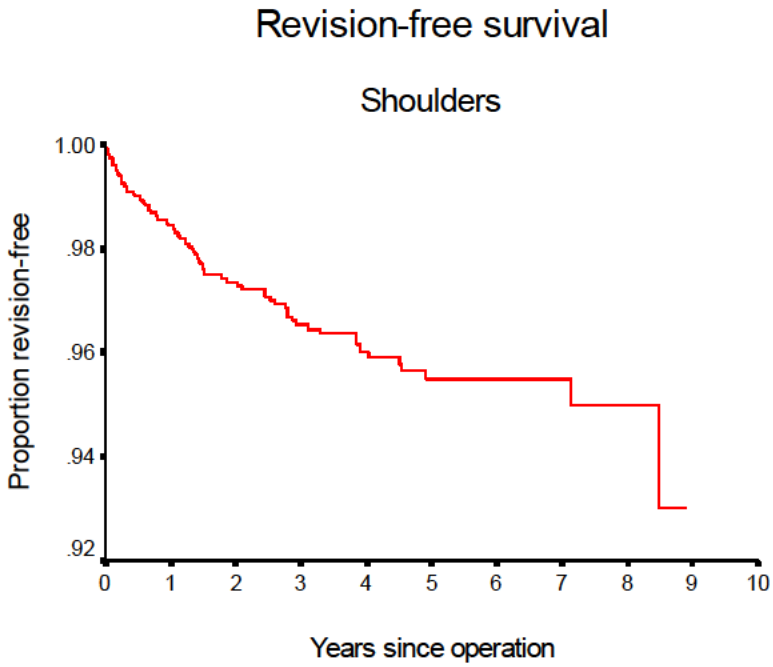
Cemented vs uncemented glenoids

	No Ops	Observed comp. Yrs	Number Revised	Rate/100-component-years	Exact 95% confidence levels	
Cemented	736	2644.67	13	0.49	0.26	0.84
Uncemented	225	471.90	6	1.27	0.47	2.77

Although the uncemented glenoid appears to have a much higher revision rate this is not statistically significant as the small number of total component years gives very wide C.I.s.

KAPLAN MEIER CURVES

The following Kaplan Meier survival analysis is for years 2001 to 2008 with decreased patients censored at time of death.



Years	% Revision-free
1	98.44
2	97.36
3	96.53
4	96.03
5	95.50

There are insufficient numbers to give an accurate revision % beyond 5 years.

PATIENT BASED QUESTIONNAIRE OUTCOMES AT SIX-MONTH POST SURGERY

At six months post surgery patients are sent the Oxford 12 questionnaire.

The new scoring system has been adopted as recommended by the original authors(appendix 1).

The scores now range from 4 to 0. A score of 48 is the best, indicating normal function. A score of 0 is the worst, indicating the most severe disability.

We have grouped the questionnaire responses based on the scoring system published by Kalairajah et al, 2005 (appendix 1)
This groups each score into one of four categories;

Category 1	>41	excellent
Category 2	34 – 41	good
Category 3	27 – 33	fair
Category 4	< 27	poor

For the nine year period and as at August 2009, there were 1,725 shoulder questionnaire responses registered at six months post surgery.
The mean shoulder score was 35.85(standard deviation 9.8, range 3 – 48)

Scoring > 41	617
Scoring 34 - 41	523
Scoring 27 - 33	271
Scoring <27	314

At six months post surgery, 66% had an excellent or good score.

Oxford score at 6 months for the 4 types of arthroplasty

Estimates Dependent Variable: Score				
Operation Type	Mean	Std. Error	Exact 95% Confidence Interval	
Hemi	31.70	.353	30.98	32.37
Resurface	36.20	1.43	33.39	39.01
Reverse	34.88	.52	33.84	35.90
Totals	39.95	.33	39.30	40.60

Hemi vs resurface p=0.002, vs reverse p<0.001, vs totals p<0.001: i.e. Hemi worse than all others.

Resurface vs Reverse p=0.385, vs totals p=0.011 : resurface and reverse similar but both have poorer scores than Total.

Reverse vs totals p=<0.001.

Overall conventional total arthroplasty has significantly better scores than all the other groups and hemi arthroplasty is significantly worse.

Analysis of the individual questions

Analysis of the individual questions showed that there were problems with pain (Q1 and Q2), brushing hair (Q7) and hanging clothes in a wardrobe (Q9).

Percentage scoring 0 or 1 for each question out of the group of 1,725 at six-months and 222 at five-years.

		% 6/12	% 5 yrs
	The worst pain from the shoulder is severe or unbearable	17.5	14.9
2	Usually have moderate or severe pain from the operated shoulder	21.6	14.9
3	Extreme difficulty or impossible to get in and out of a car or public transport	3.2	3.2
4	Extreme difficulty or impossible to use a knife and fork at the same time	4.4	3.2
5	Extreme difficulty or impossible to do the household shopping on your own	7.2	7.7
6	Extreme difficulty or impossible to carry a tray containing a plate of food across a room	8.1	7.2
7	Extreme difficulty or impossible to brush or comb hair with the operated arm	18.5	18.0
8	Extreme difficulty or impossible to dress yourself because of your operated shoulder	7.3	4.5
9	Extreme difficulty or impossible to hang clothes in a wardrobe using operated arm	16.8	16.2
10	Extreme difficulty or impossible to wash and dry under both arms	9.7	8.1
11	Pain from operated shoulder greatly or totally interfering with usual work	13.3	17.1
12	Pain from shoulder in bed most or every nights	15.0	12.6

Questionnaires at five-years post surgery
All patients who had a six-month registered questionnaire, and who had not had revision surgery were sent a further questionnaire at five years post surgery.

This dataset represents sequential Oxford shoulder scores for 222 individual patients.

At six months post surgery, 149 (67%) of this cohort of patients achieved an excellent or good score and had a mean of 36.22.

At five years post surgery, 148 (67%) of these patients achieved an excellent or good score and had a mean of 37.11.

Revision shoulder questionnaire responses
There were 116 revision shoulder responses with 39% achieving an excellent or good score. This group includes all revision shoulder responses. The mean revision shoulder score was 29.36(standard deviation 10.49, range 3 – 47).

ELBOW ARTHROPLASTY

PRIMARY ELBOW ARTHROPLASTY

The **nine**-year report analyses data for the period January 2000 – December 2008. There were 267 primary elbow procedures registered, an additional 40 compared to last year's report.

2000	18
2001	29
2002	32
2003	23
2004	28
2005	30
2006	31
2007	36
2008	40

There has again been a slight increase in elbow arthroplasty numbers and since 2000 a 122% increase.

DATA ANALYSIS

Age and sex distribution

The average age for an elbow replacement was 65.43 years, with range of 36.38 – 90.54 years.

	Female	Male
Number	210	57
Percentage	78.65	21.35
Mean age	65.70	64.43
Maximum age	90.54	87.87
Minimum age	36.38	41.62
Standard dev.	11.46	12.17

Previous operation

None	227
Internal fixation for juxtarticular fracture	11
Synovectomy	7
Debridement	5
Nerve transposition	5
Osteotomy	2
Ligament reconstruction	1
Interposition arthroplasty	1
Other	4

Diagnosis

Rheumatoid arthritis	157
Post fracture	66
Osteoarthritis	29
Other inflammatory	8
Tumour	5
Post dislocation	4
Post ligament disruption	2
Other	5

Approach

Posterior	170
Medial	53
Lateral	20

Bone graft

Humeral autograft	23
Humeral allograft	2
Humeral synthetic	1
Ulnar autograft	2

Cement

Humerus cemented	248	
Antibiotic in cement	160	(65%)
Ulna cemented	239	
Antibiotic in cement	149	(62%)
Radius cemented	16	
Antibiotic in cement	15	(94%)

Systemic antibiotic prophylaxis

Patient number receiving at least one systemic antibiotic	247	(93%)

Operating theatre

Conventional	203
Laminar flow	63
Space suits	28

ASA Class

This was introduced with the updated forms at the beginning of 2005.
For the four-year period 2005 – 2008, there were 117 (85%) primary elbow procedures with the ASA class recorded.

Definitions

ASA class 1: A healthy patient
ASA class 2: A patient with mild systemic disease
ASA class 3: A patient with severe systemic disease that limits activity but is not incapacitating
ASA class 4: A patient with an incapacitating disease that is a constant threat to life

ASA	Number
1	4
2	50
3	60
4	2

Operative time (skin to skin)

Mean	135	minutes
Maximum	255	minutes
Minimum	29	minutes
Standard dev	34	minutes

Surgeon grade

The updated forms introduced in 2005 have separated advanced trainee into supervised and unsupervised.
The following figures are for the four- year period 2005 – 2008.

Consultant	134
Advanced trainee supervised	2
Advanced trainee unsupervised	2

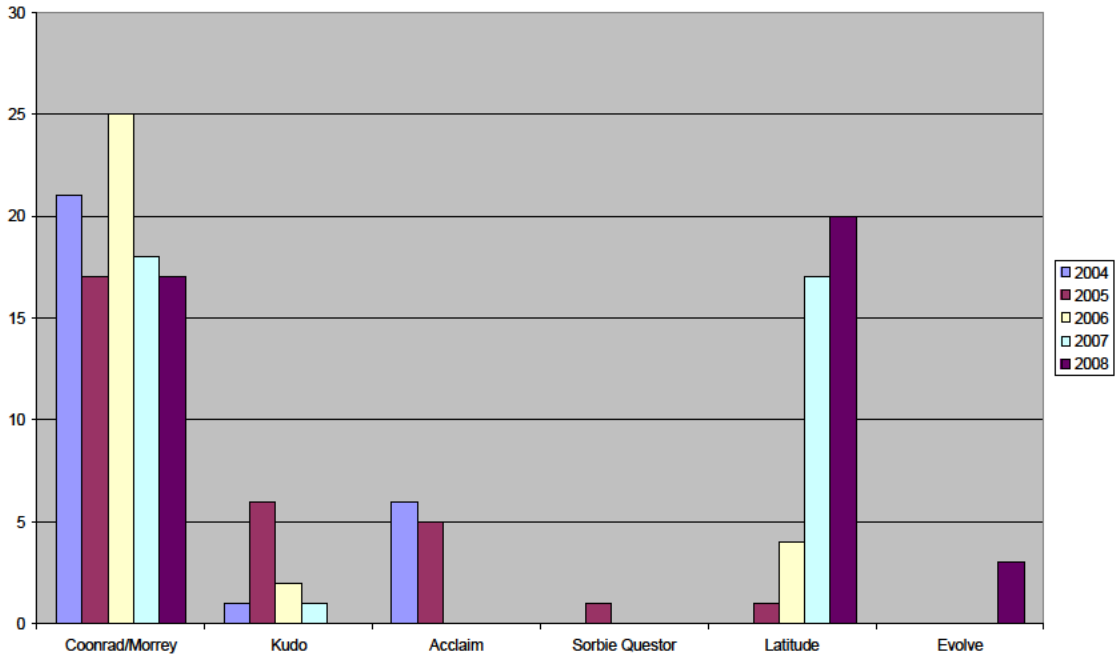
Prosthesis usage

Elbow prostheses used in 2008

Latitude	20
Coonrad/Morrey	17
Evolve	3

For the first time the Coonrad/Morrey has been pushed into second place. The Evolve makes its first appearance.

MOST USED ELBOW PROSTHESES 2004 - 2008



Surgeon and hospital workload

In 2008, 19 surgeons performed 40 primary elbow procedures, an average of 2 procedures per surgeon.

Hospitals

In 2008, primary elbow replacement was performed in 15 hospitals. 10 were public and 5 were private. For 2008 the average number of primary elbow replacements per hospital was 3.

REVISION ELBOW ARTHROPLASTY

Revision is defined by the Registry as a new operation in a previously replaced elbow joint during which one or more of the components are exchanged, removed, manipulated or added. It includes arthrodesis or amputation, but not soft tissue procedures. A two or more staged procedure is registered as one revision.

Data analysis

For the nine-year period January 2000 – December 2008, there were 41 revision elbow procedures registered. This is an additional 5 compared to last year's report.
The average age for a revision elbow replacement was 64.38 years, with a range of 42.23 – 88.95 years.

	Female	Male
Number	29	12
Percentage	70.73	29.27
Mean	64.63	63.76
Maximum age	88.95	80.37
Minimum age	42.23	50.73
Standard dev.	10.35	8.97

REVISION OF REGISTERED PRIMARY ELBOW ARTHROPLASTIES

This section analyses data for revisions of primary elbow procedures for the nine-year period.

There were 11 revisions of the primary group of 267 (4.12%).
There were 3 that had been revised twice and 1 that had been revised 3 times.

Time to revision

Mean	691 days
Maximum	1180 days
Minimum	62 days
Standard deviation	353 days

Reason for revision

Loosening ulnar component	3
Loosening humeral component	2
Pain	2
Deep infection	2
Fracture humerus	1
Dislocations	1
Dissociation of components	1
Stiffness	1
Instability	1

Statistical note

In the table below there are two statistical terms readers may not be familiar with.

Observed component years

This is the number of registered primary procedures multiplied by the number of years each component has been in place.

Rate/100 component years

This is equivalent to the yearly revision rate expressed as a percent and is derived by dividing the number of prostheses revised by the observed component years multiplied by 100. It therefore allows for the number of years of post operative follow up in calculating the revision rate. These rates are usually very low, hence it is expressed per 100 component years rather than per component year. Statisticians consider that this is a more accurate way of deriving a revision rate for comparison when analysing data with widely varying follow up times. It is also important to note the confidence intervals. The closer they are to the estimated revision rate/100 component years, the more precise the estimate is.

Statistical Significance

Where it is stated that a difference is significant the p value is 0.05 or less

All Primary Total Elbow Arthroplasties

All patients	Total	Observed component years	Number revised	Rate/100 component years	Exact 95% confidence interval	
	267	945.89	11	1.61	0.58	2.08

Revision vs Gender

Gender	Total	Observed component years	Number revised	Rate/100 component years	Exact 95% confidence interval	
Females	210	778.53	6	0.77	0.28	1.68
Males	57	167.36	5	2.99	0.97	6.97

Despite higher revision rate for males, not statistically significant.

Revision vs Age Bands

Age Groups	Total	Observed component years	Number revised	Rate/100 component years	Exact 95% confidence interval	
LT55	51	193.68	2	1.03	0.13	3.73
55_64	77	281.02	6	2.14	0.78	4.65
65_74	75	234.31	1	0.43	0.01	2.38
GE75	64	236.89	2	0.84	0.10	3.05

No significant difference among the age bands.

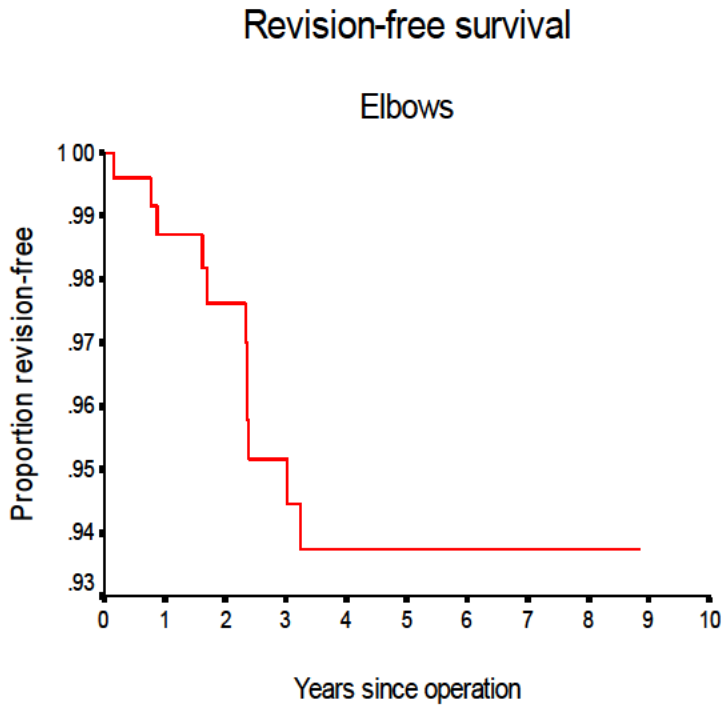
Revision rate of individual Elbow prostheses

Prosthesis	Total	Observed component years	Number revised	Rate/100 component years	Exact 95% confidence interval	
Acclaim	16	62.83	3	4.77	0.98	13.95
Coonrad/Morrey	186	749.24	6	0.80	0.29	1.74
Evolve Stem	3	1.58	0	0	0	233.10
Kudo	18	77.56	2	2.58	0.31	9.32
Latitude	42	43.34	0	0	0	8.51
Sorbie Questor	1	3.16	0	0	0	116.76

Although there are quite varying revision rates in the above tables none reach statistical significance due to the relatively small numbers and wide CIs

KAPLAN MEIER CURVES

The following Kaplan Meier survival analyses for the years 2001 to 2008 with deceased patients censored at time of death.



Years	% Revision-free
1	98.71
2	97.63
3	95.15
4	93.73

There are insufficient numbers to give an accurate revision % beyond 4 years.

PATIENT BASED QUESTIONNAIRE OUTCOMES AT SIX-MONTHS POST SURGERY

At six months post surgery patients are sent a questionnaire which is modelled on the Oxford 12, but is not validated.

The same scoring system has been adopted as recommended by the original authors of the Oxford 12 hip and knee questionnaires.

The scores now range from 4 to 0. A score of 48 is the best, indicating normal function. A score of 0 is the worst, indicating the most severe disability.

We have grouped the questionnaire responses based on the scoring system published by Kalairajah et al, 2005(appendix1)

This groups each score into one of four categories;

Category 1	>41	excellent
Category 2	34 – 41	good
Category 3	27 – 33	fair
Category 4	< 27	poor

For the nine year period and as at August 2009, there were 194 primary elbow responses registered at six months post surgery.
The mean primary elbow score was 37.15 (standard deviation 9.91, range 8 – 48)

Scoring > 41	89
Scoring 34 - 41	46
Scoring 27 - 33	26
Scoring < 27	33

At six months post surgery, 70% had an excellent or good score.

Analysis of the individual questions
Analysis of the individual questions showed that there were problems with carrying the household shopping (Q5), brushing or combing hair (Q7) and pain (Q8).

Percentage scoring 0 or 1 for each question (n = 194)

1	The worst pain from the shoulder is severe or unbearable	11.3
2	Extreme difficulty or impossible to dress yourself because of your operated elbow	6.2
3	Extreme difficulty or impossible to lift a teacup safely with your operated arm	5.2
4	Extreme difficulty or impossible to get your hand to your mouth	3.6
5	Extreme difficulty or impossible to carry the household shopping with your operated arm	16.5
6	Extreme difficulty or impossible to carry a tray containing a plate of food across a room	12.4
7	Extreme difficulty or impossible to brush or comb hair with the affected arm	13.4
8	Usually have moderate or severe pain from the operated elbow	13.4
9	Extreme difficulty or impossible to hang clothes in a wardrobe using operated arm	9.3
10	Extreme difficulty or impossible to wash and dry under both arms	12.4
11	Pain from operated elbow greatly or totally interfering with usual work or hobbies	12.9
12	Pain from elbow in bed most or every nights	7.7

Revision elbow questionnaire responses
There were 25 revision elbow responses with 48% achieving an excellent or good score. This group includes all revision elbow responses. The mean revision elbow score was 32.88 (standard deviation 10.23, range 8 – 48).

LUMBAR DISC REPLACEMENT

LUMBAR DISC REPLACEMENT

This report analyses data for the **seven**-year period January 2002 – December 2008. There were 94 primary lumbar disc replacements registered to 9 surgeons.

2002	1
2003	3
2004	18
2005	16
2006	21
2007	16
2008	19

DATA ANALYSIS

The average age for a lumbar disc replacement was 39.93 years, with a range of 25.22 – 62.19 years.

	Female	Male
Number	46	48
Percentage	48.94	51.06
Mean age	40.40	39.49
Maximum age	62.19	60.71
Minimum age	25.22	27.19
Standard dev.	8.99	7.65

Disc replacement levels

L3/4	13
L4/5	66
L5/S1	23

Fusion levels

L3/4	1
L4/5	7
L5/S1	42

Previous operation

Discectomy	22
L3/4	0
L4/5	9
L5/S1	13
Fusion	8
L3/4	0
L4/5	2
L5/S1	8

Diagnosis

Degenerative disc disease	
L3/4	5
L4/5	34
L5/S1	61
Other	1
Annular tear MRI scan	
L3/4	8
L4/5	48
L5/S1	12
Other (L2/3)	1
Discogenic pain on discography	
L3/4	14
L4/5	66
L5/S1	51
Other (L2/3)	1

Approach

Retroperitoneal midline	85
Retroperitoneal lateral	2
Transperitoneal	1

Intraoperative complications

Damage to major veins	4
Subsidence	1

Systemic antibiotic prophylaxis

Patient number receiving systemic antibiotic prophylaxis	72	(77%)

Operating theatre

Conventional	59
Laminar flow	35
Spacesuits	2

Operative time (skin to skin)

Mean	146	minutes
Standard deviation	41	minutes
Minimum	77	minutes
Maximum	276	minutes

Surgeon grade

Consultant	94

Oswestry Disability Index

There are 10 sections. For each section, the total score is 5: if the first statement is marked the score = 0; if the last statement is marked, the score = 5. Intervening statements are scored according to rank.

If more than one box is marked in each section, take the highest score.

If all 10 sections are completed, the score is calculated as follows:

Example: 16 (total scored)/50(total possible score) x 100 = 32%

If one section is missed (or not applicable) the score is calculated:

Example: 16 (total scored)/45(total possible score) x 100 = 35.5%

0 is the best score and 100 is the worst score.

Pre operative scores

Modified Roland and Morris	n = 80
Mean	14.26
Maximum	23
Minimum	1
Standard deviation	4.39

Oswestry Disability Index	n = 10
Mean	36.14
Maximum	68.00
Minimum	0.00
Standard deviation	27.73

Post operative score

Oswestry Disability Index	n = 2
Mean	4.00
Maximum	8.00
Minimum	0.00
Standard deviation	5.66

CERVICAL DISC REPLACEMENT

CERVICAL DISC REPLACEMENT

This report analyses data for the five-year period January 2004 – December 2008. There were 57 primary cervical disc replacements registered to 8 surgeons.

2004	1
2005	12
2006	9
2007	11
2008	24

DATA ANALYSIS

The average age for a cervical disc replacement was 44.29 years, with a range of 24.92 – 58.89 years.

	Female	Male
Number	24	33
Percentage	42.11	57.89
Mean age	45.21	43.63
Maximum age	56.88	58.89
Minimum age	30.14	24.92
Standard dev.	6.79	7.54

Disc replacement levels

C3/4	3
C4/5	5
C5/6	28
C6/7	30
C7T1	0

Previous operation

Foraminotomy	1
Adjacent level fusion	8
Adjacent level disc arthroplasty	0
Discectomy	3

Diagnosis

Acute disc prolapse	33
Chronic spondylosis	0
Neck pain	1
Degenerative disc disease	14
Myelopathy	2

Approach

Anterior right	28
Anterior left	0
Smith Robinson	1

Intra operative complications

There were no intra operative complications reported.

Systemic antibiotic prophylaxis

Patient number receiving systemic antibiotic prophylaxis	18 (32%)

Operating theatre

Laminar flow	36
Conventional	21
Spacesuits	0

Operative time (skin to skin)

Mean	139	minutes
Standard deviation	55	minutes
Minimum	68	minutes
Maximum	282	minutes

Surgeon grade

Consultant	57

Neck Disability Index Scoring

There are 10 sections. For each section, the total score is 5: if the first statement is marked the score = 0; if the last statement is marked, the score = 5. Intervening statements are scored according to rank.

If more than one box is marked in each section, take the highest score.

If all 10 sections are completed, the score is calculated as follows:

Example: 16 (total scored)/50(total possible score) x 100 = 32%

If one section is missed (or not applicable) the score is calculated:

Example: 16 (total scored)/45(total possible score) x 100 = 35.5%

0 is the best score and 100 is the worst score.

Pre operative score

Neck Disability Index	n = 18
Mean	44.06
Maximum	87.00
Minimum	2.00
Standard deviation	20.78

Post operative score

Neck Disability Index	n = 16
Mean	21.82
Maximum	52.00
Minimum	0.00
Standard deviation	15.01

Appendix I

Murray, D.W et al, The use of the Oxford hip and knee scores. J Bone Joint Surg (Br) 2007; 89-B: 1010-14

Questionnaire on the perceptions of patients about shoulder surgery
Jill Dawson, Ray Fitzpatrick, Andrew Carr. J Bone Joint Surg B. 1996 July;78(4) 593-600

Kalairajah, Y et al, Health outcome measures in the evaluation of total hip arthroplasties: a comparison between the Harris hip score and the Oxford hip score. J Arthroplasty 2005; 20: 1037-41

Appendix II

Publications in Peer Reviewed Journals

Development of the New Zealand Joint Register
Rothwell A G. Bull Hosp Jt Dis. 1999;58(3):148-60

A New Zealand national joint registry review of 202 total ankle replacements followed for up to 6 years
Hosman AH, Mason RB, Hobbs T, Rothwell AG.
Acta Orthop. 2007 Oct; 78(5):584-91

Functional outcomes of femoral peri prosthetic fracture and revision hip arthroplasty: a matched pair study from the New Zealand Registry.
Young SW, Walker CG, Pitto RP.
Acta Orthop. 2008 Aug: 79(4); 483-8

Bilateral total joint arthroplasty : the early results from the New Zealand National Joint Registry
Hooper GJ, Hopper NM, Rothwell AG, Hobbs T.
J Arthroplasty. 2008 Dec 2. (Pub Med)

Revision following cemented and uncemented primary total hip replacement: a seven year analysis from the New Zealand Joint Registry
Hooper GJ, Rothwell AG, Stringer M, Frampton C.
J Bone Joint Surg Br. 2009 Apr;91(4):451-8

Accepted for Publication by J Bone Joint Surg. B.
An analysis of the Oxford hip and knee scores and their relationship to early joint revision
Data from the New Zealand Joint Registry
Rothwell AG, Hooper GJ, Hobbs A, Frampton C.

The survivorship and functional outcomes of unicompartmental knee replacements converted to total knee replacements: The New Zealand National Joint Registry
Andrew J Pearse, Gary J Hooper, Alastair G Rothwell, Chris Frampton.

Submitted to JBJS B
Osteotomy and unicompartmental knee replacement converted to total knee replacement – data from the New Zealand National Joint Registry
Andrew J Pearse, Gary J Hooper, Alastair G Rothwell, Chris Frampton

Appendix III

PROSTHESIS INVENTORY HIPS		
	Femoral Components	**Acetabular Components**
DE PUY	Elite Plus	Charnley
	Summit	Duraloc
	Charnley	Pinnacle
	Corail	
	ASR	
STRYKER	Accolade	Trident
	Exeter	Exeter
		Contemporary
ZIMMER	CCA	CCB
	CLS	CLS
	CPT	Fitek
	MS30	Fitmore
	Versys	Morscher
	Muller	ZCA
	Duron	Osteolock
		Trilogy
SMITH & NEPHEW	Spectron cemented	Reflection cemented
	Basis cemented	Polar cup cemented
	CPCS cemented	
	Synergy Porous	BHR porous
	BHR resurfacing	R3 porous

	Anthology Porous	Reflection porous
	Emperion Porous	Polar Cup uncemented
	SL Plus	EP Fit uncemented
	Polar Stem	
	SL Plus MIA	
	Echelon Porous	
MATHY'S	Twinsys	RM
		Weber
BIOMET	Bi-Metric X HA	Exceed ABT Exceed Ringloc X

KNEES		
BIOMET	AGC	
	Maxim Vanguard	
De Puy	LCS	
	PFC Sigmar	
	LCS PFJ	
Global Orthopaedics	MBK	
Smith & Nephew	Genesis II	
	Genesis II Oxinium	
	Journey BCS	
	Legion	
STRYKER	Duracon	
	Scorpio	
	Triathlon	
	Avon Patello	
ZIMMER	Insall Burstein	

	Nexgen	
ORTHOTEC	Optetrak	
	Themis	
ADVANCED SURGICAL TECHNOLOGIES	Advance	

UNI COMPARTMENTAL KNEES		
BIOMET	Oxford Cemented Oxford Cementless	
	Repicci II	
Zimmer	Miller/Galante	
	Zimmer Uni	
De Puy	Preservation	
	LCS	
Smith & Nephew	Genesis	
	Oxinium	
STRYKER	EIUS Uni	

SHOULDERS		
DEPUY	Global	
	Delta	
Orthotec	SMR	
	Hemicap Resurfacing	
REM Systems	Aequalis	
Zimmer	Bigliani/Flatow	
	Neer	
Biomet	Copeland Resurfacing	
Smith & Nephew	Promos	

ANKLES		
DEPUY	Agility	
	Mobility	
Orthotec	Ramses	
REM Systems	Salto	
Link	Star	

ELBOWS		
ZIMMER	Coonrad/Morrey	
DEPUY	Acclaim	
Biomet	Kudo Discovery Elbow	
REM Systems	Latitude	

DO NOT PLACE IN PATIENT NOTES TO BE RETAINED IN THEATRE SUITE

NEW ZEALAND JOINT REGISTRY

Primary Replacement Hip

Free Phone 0800-274-989 **Total Hip Arthroplasty ❑** **Resurfacing Arthroplasty ❑** **07.04.2005**

Date: .....

Side:..... **

Tick Appropriate Boxes

Patient Name:
Address:

d.o.b. **NHI:**

Attach Patient Label

Consultant: ……
[If different from patient label]

Hospital: .....

Town/City ……

PREVIOUS OPERATION ON INDEX JOINT

- ❑ None
- ❑ Internal fixation for juxtarticular fractures
- ❑ Osteotomy ……..
- ❑ Arthrodesis
- ❑ Other: .....

DIAGNOSIS

- ❑ Osteoarthritis
- ❑ Rheumatoid arthritis
- ❑ Other inflammatory
- ❑ Acute fracture NOF
- ❑ Developmental dysplasia/dislocation
- ❑ Old fracture NOF
- ❑ Post acute dislocation
- ❑ Avascular necrosis
- ❑ Tumour
- ❑ Other: Name: .....

APPROACH ❑ Anterior ❑ Posterior ❑ Image guided surgery ❑ Minimally invasive surgery ❑ Lateral ❑ Trochanteric osteotomy

FEMUR

Please do not fold bar-coded label

ACETABULUM

Please do not fold bar-coded label

STICK EXTRA LABELS ON REVERSE SIDE

BONE GRAFT - FEMUR

- ❑ Allograft
- ❑ Autograft ❑ Synthetic

BONE GRAFT - ACETABULUM

- ❑ Allograft
- ❑ Autograft ❑ Synthetic

FEMORAL HEAD

Please do not fold bar-coded label

AUGMENTS

Please do not fold bar-coded label

STICK EXTRA LABELS ON REVERSE SIDE

CEMENT

❑ Femur ❑ Acetabulum ❑ Antibiotic brand: .....

❑SYSTEMIC ANTIBIOTIC PROPHYLAXIS

Name: ..... ASA Class: 1 2 3 4 (please circle one)

OPERATING THEATRE

❑ Conventional ❑ Laminar flow or similar ❑ Space suits

SKIN TO SKIN TIME *mins* Start skin..... Finish skin.....

PRIMARY OPERATING SURGEON

❑ Consultant ❑ Adv Trainee Unsupervised ❑ Adv Trainee Supervised Year…… ❑ Basic Trainee

*****NB*** ***If bilateral procedure two completed forms are required***

DO NOT PLACE IN PATIENT NOTES TO BE RETAINED IN THEATRE SUITE

NEW ZEALAND JOINT REGISTRY
Revision Hip Joint

Free Phone 0800-274-989 07.04.2005

Date: .....

Side:..... **

Tick Appropriate Boxes

Patient Name:
Address:

d.o.b. **NHI:**

Attach Patient Label

Consultant: ……
[If different from patient label]

Hospital: .....

Town/City: ……

REASON FOR REVISION

- ❑ Loosening acetabular component
- ❑ Loosening femoral component
- ❑ Dislocation
- ❑ Pain
- ❑ Previous hemiarthroplasty
- ❑ Deep infection
- ❑ Fracture femur
- ❑ Removal of components
- ❑ Other: Name: ……

Date Index Operation: ……

If re-revision - Date previous revision: ……..

REVISION

- ❑ Change of femoral component
- ❑ Change of acetabular component
- ❑ Change of head
- ❑ Change of liner
- ❑ Change of all components

APPROACH ❑ Image guided surgery ❑ Minimally invasive surgery

❑ Anterior ❑ Posterior ❑ Lateral ❑ Trochanteric osteotomy

FEMUR

Please do not fold bar-coded label

ACETABULUM

Please do not fold bar-coded label

STICK EXTRA LABELS ON REVERSE SIDE

BONE GRAFT - FEMUR

❑Allograft ❑ Synthetic

❑Autograft

BONE GRAFT - ACETABULUM

❑Allograft ❑ Synthetic

❑Autograft

FEMORAL HEAD

Please do not fold bar-coded label

AUGMENTS

Please do not fold bar-coded label

STICK EXTRA LABELS ON REVERSE SIDE

CEMENT

❑ Femur ❑ Acetabulum ❑ Antibiotic brand: .....

❑**SYSTEMIC ANTIBIOTIC PROPHYLAXIS**

Name ..... ASA Class: 1 2 3 4 (please circle one)

OPERATING THEATRE

❑ Conventional ❑ Laminar flow or similar ❑ Space suits

SKIN TO SKIN TIME *mins* Start skin..... Finish skin.....

PRIMARY OPERATING SURGEON

❑ Consultant ❑ Adv Trainee Supervised ❑ Adv Trainee Supervised Year…… ❑ Basic Trainee

****NB*** ***If bilateral procedure two completed forms are required***

DO NOT PLACE IN PATIENT NOTES TO BE RETAINED IN THEATRE SUITE

NEW ZEALAND JOINT REGISTRY

Primary Replacement Knee

Free Phone 0800-274-989 ❑ Total Knee Arthroplasty ❑ Unicompartmental ❑ Patellofemoral **07.04.2005**

Date: .....

Side:..... **

Tick Appropriate Boxes

Patient Name:
Address:

d.o.b. **NHI:**

Attach Patient Label

Consultant: ……
[If different from patient label]

Hospital: .....

Town/City: ……

PREVIOUS OPERATION ON INDEX JOINT

- ❑ None
- ❑ Internal fixation for juxtarticular fracture
- ❑ Ligament reconstruction
- ❑ Menisectomy
- ❑ Osteotomy
- ❑ Synovectomy
- ❑ Other: Name: .....
  ……

DIAGNOSIS

- ❑ Osteoarthritis
- ❑ Rheumatoid arthritis
- ❑ Other inflammatory
- ❑ Tumour
- ❑ Post fracture
- ❑ Post ligament disruption/reconstruction
- ❑ Avascular necrosis
- ❑ Other: Name: .....

APPROACH ❑ Image guided surgery ❑ Minimally invasive surgery

❑ Medial parapatellar ❑ Lateral parapatellar ❑ Other

FEMUR

Please do not fold bar-coded label

TIBIA

Please do not fold bar-coded label

STICK EXTRA LABELS ON REVERSE SIDE

BONE GRAFT - FEMUR

❑ Allograft
❑ Autograft ❑ Synthetic

BONE GRAFT - TIBIA

❑ Allograft
❑ Autograft ❑ Synthetic

PATELLA

Please do not fold bar-coded label

AUGMENTS

Please do not fold bar-coded label

STICK EXTRA LABELS ON REVERSE SIDE

CEMENT

❑ Femur ❑ Tibia ❑ Patella ❑ Antibiotic brand: .....

❑SYSTEMIC ANTIBIOTIC PROPHYLAXIS

Name ..... ASA Class: 1 2 3 4 (please circle one)

OPERATING THEATRE

❑ Conventional ❑ Laminar flow or similar ❑ Space suits

SKIN TO SKIN TIME *mins* Start skin..... Finish skin.....

PRIMARY OPERATING SURGEON

❑ Consultant ❑ Adv Trainee Unsupervised ❑ Adv Trainee Supervised Year…… ❑ Basic Trainee

*****NB*** ***If bilateral procedure two completed forms are required***

DO NOT PLACE IN PATIENT NOTES TO BE RETAINED IN THEATRE SUITE

NEW ZEALAND JOINT REGISTRY
Revision Knee Joint

Free Phone 0800-274-989 07.04.2005

Date: .....

Side:..... **

Patient Name:
Address:

d.o.b. NHI:

Attach Patient Label

Consultant: ……
[If different from patient label]

Hospital: .....

Town/City:……

Tick Appropriate Boxes

REASON FOR REVISION

- ❑ Loosening femoral component
- ❑ Loosening tibial component
- ❑ Loosening patellar component
- ❑ Pain
- ❑ Previous Unicompartmental
- ❑ Deep infection
- ❑ Fracture femur
- ❑ Fracture tibia
- ❑ Other details: ……..

Date Index Operation: …… If re-revision - Date previous revision: ……..

REVISION

- ❑ Change of femoral component
- ❑ Change of tibial component
- ❑ Change of patellar component
- ❑ Addition of patellar component
- ❑ Change of tibial polyethylene only
- ❑ Change of all components
- ❑ Removal of components
- ❑ Other

APPROACH ❑ Image guided surgery ❑ Minimally invasive surgery

❑ Medial parapatellar ❑ Lateral parapatellar ❑ Other

FEMUR

Please do not fold bar-coded label

TIBIA

Please do not fold bar-coded label

STICK EXTRA LABELS ON REVERSE SIDE

BONE GRAFT – FEMUR

❑ Allograft
❑ Autograft ❑ Synthetic

BONE GRAFT – TIBIA

❑ Allograft
❑ Autograft ❑ Synthetic

PATELLA

Please do not fold bar-coded label

AUGMENTS

Please do not fold bar-coded label

STICK EXTRA LABELS ON REVERSE SIDE

CEMENT

❑ Femur ❑ Tibia ❑ Patella ❑ Antibiotic brand: .....……

❑**SYSTEMIC ANTIBIOTIC PROPHYLAXIS**

Name .....…… ASA Class: 1 2 3 4 (please circle one)

OPERATING THEATRE

❑ Conventional ❑ Laminar flow or similar ❑ Space suits

SKIN TO SKIN TIME *mins* Start skin..... Finish skin.....

PRIMARY OPERATING SURGEON

❑ Adv Trainee Unsupervised

❑ Consultant ❑ Adv Trainee Supervised Year…….. ❑ Basic Trainee

***NB** *If bilateral procedure two completed forms are required*

DO NOT PLACE IN PATIENT NOTES TO BE RETAINED IN THEATRE SUITE

NEW ZEALAND JOINT REGISTRY

Primary Replacement Shoulder

0800-274-989 ❑ Total shoulder Arthroplasty ❑ Hemiarthroplasty ❑ Reverse Shoulder **06.05.2009**

Date: .....

Side:..... **

Tick Appropriate Boxes

Patient Name:
Address:

d.o.b. **NHI:**

Attach Patient Label

onsultant: ……
[If different from patient label]

Hospital: .....

Town/City ……

PREVIOUS OPERATION ON INDEX JOINT

- ❑ None
- ❑ Internal fixation for juxtarticular fracture
- ❑ Previous stabilisation
- ❑ Osteotomy
- ❑ Arthrodesis
- ❑ Other: Name: .....

DIAGNOSIS

- ❑ Rheumatoid arthritis
- ❑ Osteoarthritis
- ❑ Other inflammatory
- ❑ Acute fracture proximal humerus
- ❑ Post recurrent dislocation
- ❑ Avascular necrosis
- ❑ Cuff tear arthropathy
- ❑ Post old trauma
- ❑ Other: Name: .....

APPROACH

❑ Deltopectoral ❑ Other : specify

HUMERUS

Please do not fold bar-coded label

GLENOID

Please do not fold bar-coded label

STICK EXTRA LABELS ON REVERSE SIDE

BONE GRAFT - HUMERUS

❑ Allograft
❑ Autograft ❑ Synthetic

BONE GRAFT - GLENOID

❑ Allograft
❑ Autograft ❑ Synthetic

HUMERAL HEAD

Please do not fold bar-coded label

AUGMENTS

Please do not fold bar-coded label

STICK ALL LABELS ON REVERSE SIDE

CEMENT

❑ Humerus ❑ Glenoid ❑ Antibiotic brand: .....

❑SYSTEMIC ANTIBIOTIC PROPHYLAXIS

Name: ..... ASA Class: 1 2 3 4 (please circle one)

OPERATING THEATRE

❑ Conventional ❑ Laminar flow or similar ❑ Space suits

SKIN TO SKIN TIME *mins* Start skin..... Finish skin.....

PRIMARY OPERATING SURGEON

❑ Consultant ❑ Adv Trainee Unsupervised ❑ Adv Trainee Supervised Year…… ❑ Basic Trainee

*****NB*** ***If bilateral procedure two completed forms are required***

DO NOT PLACE IN PATIENT NOTES TO BE RETAINED IN THEATRE SUITE

NEW ZEALAND JOINT REGISTRY
Revision Shoulder

Free Phone 0800-274-989 **07.04.2005**

Date: .....

Side:..... **

Patient Name:
Address:

d.o.b. **NHI:**

Attach Patient Label

Consultant: ……
[If different from patient label]

Hospital: .....

Town/City: ……

Tick Appropriate Boxes

REASON FOR REVISION

- ❑ Loosening glenoid component
- ❑ Loosening humeral component
- ❑ Loosening both components
- ❑ Dislocation/instability anterior
- ❑ Instability posterior
- ❑ Subacromial tuberosity impingement
- ❑ Subacromial cuff impingement/tear
- ❑ Fracture humerus
- ❑ Deep infection
- ❑ Pain
- ❑ Other: Name: ……

Date Index Operation: ……

If re-revision - Date previous revision: ……

REVISION

- ❑ Change of head only
- ❑ Change of humeral component
- ❑ Change of glenoid component
- ❑ Change of liner (glenoid non cemented)
- ❑ Change of all components
- ❑ Remove glenoid
- ❑ Remove humerus
- ❑ Removal of components
- ❑ Other Specify: ……

APPROACH

- ❑ Deltopectoral
- ❑ Other: specify

HUMERUS

Please do not fold bar-coded labels

GLENOID

Please do not fold bar-coded labels

STICK EXTRA LABELS ON REVERSE SIDE

BONE GRAFT - HUMERUS

- ❑Allograft
- ❑Autograft
- ❑ Synthetic

BONE GRAFT - GLENOID

- ❑Allograft
- ❑Autograft
- ❑ Synthetic

HUMERAL HEAD

Please do not fold bar-coded labels

AUGMENTS

Please do not fold bar-coded labels

STICK EXTRA LABELS ON REVERSE SIDE

CEMENT

❑ Humerus ❑ Glenoid ❑ Antibiotic brand: .....

❑SYSTEMIC ANTIBIOTIC PROPHYLAXIS

Name …… ASA Class: 1 2 3 4 (please circle one)

OPERATING THEATRE

❑ Conventional ❑ Laminar flow or similar ❑ Space suits

SKIN TO SKIN TIME *mins* Start skin..... Finish skin.....

PRIMARY OPERATING SURGEON

❑ Consultant ❑ Adv Trainee Unsupervised ❑ Adv Trainee Supervised Year……. ❑ Basic Trainee

*****NB*** ***If bilateral procedure two completed forms are required***

DO NOT PLACE IN PATIENT NOTES TO BE RETAINED IN THEATRE SUITE

NEW ZEALAND JOINT REGISTRY
Primary Replacement Ankle

Free Phone 0800-274-989 **07.04.2005**

Date: .....

Side:..... **

Tick Appropriate Boxes

Patient Name:
Address:

d.o.b. **NHI:**

Attach Patient Label

Consultant: ……
[If different from patient label]

Hospital: .....

Town/City …….

PREVIOUS OPERATION ON INDEX JOINT

- ❑ None
- ❑ Internal fixation for juxtarticular fractures
- ❑ Osteotomy
- ❑ Arthrodesis
- ❑ Other: Name: .....

DIAGNOSIS

- ❑ Osteoarthritis
- ❑ Rheumatoid arthr tis
- ❑ Other inflammatory
- ❑ Post trauma
- ❑ Avascular necrosis talus
- ❑ Other: Name: .....

APPROACH

❑ Anterior ❑ Anterio-lateral ❑ Other

TIBIA

Please do not fold bar-coded label

TALUS

Please do not fold bar-coded label

STICK EXTRA LABELS ON REVERSE SIDE

BONE GRAFT - TIBIA

❑ Allograft
❑ Autograft ❑ Synthetic

BONE GRAFT - TALUS

❑ Allograft
❑ Autograft ❑ Synthetic

AUGMENTS

Please do not fold bar-coded label

FUSION DISTAL TFJ

STICK ALL LABELS ON REVERSE SIDE

CEMENT

❑Tibia ❑ Talus ❑ Antibiotic Brand: .....

❑SYSTEMIC ANTIBIOTIC PROPHYLAXIS

Name: ..... ASA Class: 1 2 3 4 (please circle one)

OPERATING THEATRE

❑ Conventional ❑ Laminar flow or similar ❑ Space suits

SKIN TO SKIN TIME *mins* Start skin..... Finish skin.....

PRIMARY OPERATING SURGEON

❑ Consultant ❑ Adv Trainee Unsupervised ❑ Adv Trainee Supervised Year…… ❑ Basic Trainee

*****NB*** ***If bilateral procedure two completed forms are required***

DO NOT PLACE IN PATIENT NOTES TO BE RETAINED IN THEATRE SUITE

NEW ZEALAND JOINT REGISTRY
Revision Ankle Joint

Free Phone 0800-274-989 07.04.2005

Date: .....

Side:..... **

Patient Name:
Address:

d.o.b. NHI:

Attach Patient Label

Consultant: ……
[If different from patient label]

Hospital: .....

Town/City: ……..

Tick Appropriate Boxes

REASON FOR REVISION

- ❑ Loosening talar component
- ❑ Loosening tibial component
- ❑ Dislocation
- ❑ Pain
- ❑ Deep infection
- ❑ Fracture talus
- ❑ Fracture tibia
- ❑ Dislocations
- ❑ Other details: ……

Date Index Operation: …… If re-revision - Date previous revision: ……

REVISION

- ❑ Change of talar component
- ❑ Change of tibial component
- ❑ Change of polyethylene only
- ❑ Change of all components
- ❑ Removal of components
- ❑ Other Name: ……

APPROACH

❑ Anterior ❑ Anterio-lateral ❑ Posterior

TIBIA

Please do not fold bar-coded label

TALUS

Please do not fold bar-coded label

STICK ALL LABELS ON REVERSE SIDE

BONE GRAFT - TIBIA

❑ Allograft
❑ Autograft ❑ Synthetic

BONE GRAFT - TALUS

❑ Allograft
❑ Autograft ❑ Synthetic

AUGUMENTS

Please do not fold bar-coded label

FUSION DISTAL TFJ

Yes ❑ No ❑

STICK EXTRA LABELS ON REVERSE SIDE

CEMENT

❑ Talus ❑ Tibia ❑ Antibiotic brand: ……..

❑ **SYSTEMIC ANTIBIOTIC PROPHYLAXIS**
Name ……. ASA Class: 1 2 3 4 (please circle one)

OPERATING THEATRE

❑ Conventional ❑ Laminar flow or similar ❑ Space suits

SKIN TO SKIN TIME *mins* Start skin..... Finish skin.....

PRIMARY OPERATING SURGEON

❑ Adv Trainee Unsupervised
❑ Consultant ❑ Adv Trainee Supervised Year…… ❑ Basic Trainee

***NB** *If bilateral procedure two completed forms are required*

DO NOT PLACE IN PATIENT NOTES TO BE RETAINED IN THEATRE SUITE

NEW ZEALAND JOINT REGISTRY
Primary Replacement Elbow

Free Phone 0800-274-989 07.04.2005

Date: .....

Patient Name:
Address:

d.o.b. **NHI:**
Attach Patient Label

Consultant: ……
[If different from patient label]

Side:…… **

Hospital: .....

Town/City: ……

Tick Appropriate Boxes

PREVIOUS OPERATION ON INDEX JOINT

- ❑ None
- ❑ Internal fixation for juxtarticular fracture
- ❑ Ligament reconstruction
- ❑ Interposition arthroplasty
- ❑ Debridement
- ❑ Synovectomy ± removal radial head
- ❑ Osteotomy
- ❑ Other: Name: .....

DIAGNOSIS

- ❑ Rheumatoid arthritis
- ❑ Osteoarthritis
- ❑ Other inflammatory
- ❑ Post dislocation
- ❑ Post fracture
- ❑ Post ligament disruption
- ❑ Other: Name: .....

APPROACH

❑ Medial ❑ Lateral ❑ Posterior

HUMERUS

Please do not fold bar-coded label

ULNA

Please do not fold bar-coded label

STICK EXTRA LABELS ON REVERSE SIDE

BONE GRAFT - HUMERUS

❑ Allograft ❑ Autograft ❑ Synthetic

BONE GRAFT - ULNA

❑ Allograft ❑ Autograft ❑ Synthetic

RADIAL HEAD

Please do not fold bar-coded label

AUGMENTS

Please do not fold bar-coded label

STICK EXTRA LABELS ON REVERSE SIDE

CEMENT

❑ Humerus ❑ Ulna ❑ Radius ❑ Antibiotic brand: .....

❑SYSTEMIC ANTIBIOTIC PROPHYLAXIS

Name ……. ASA Class: 1 2 3 4 (please circle one)

OPERATING THEATRE

❑ Conventional ❑ Laminar flow or similar ❑ Space suits

SKIN TO SKIN TIME *mins* Start skin..... Finish skin.....

PRIMARY OPERATING SURGEON

❑ Consultant ❑ Adv Trainee Unsupervised ❑ Adv Trainee Supervised Year…… ❑ Basic Trainee

*****NB** If bilateral procedure two completed forms are required*

DO NOT PLACE IN PATIENT NOTES TO BE RETAINED IN THEATRE SUITE

NEW ZEALAND JOINT REGISTRY
Revision Elbow Joint

Free Phone 0800-274-989 07.04.2005

Date: .....

Consultant: ……
[If different from patient label]

Side:..... **

Patient Name:
Address:

d.o.b. NHI:

Attach Patient Label

Hospital: .....

Town/City: ……

Tick Appropriate Boxes

REASON FOR REVISION

- ❑ Loosening humeral component
- ❑ Loosening ulnar component
- ❑ Loosening radial head component
- ❑ Pain
- ❑ Deep infection
- ❑ Fracture humerus
- ❑ Fracture ulna
- ❑ Dislocations
- ❑ Other Name: ……

Date Index Operation: …… If re-revision - Date previous revision: ……

REVISION

- ❑ Change of humeral component
- ❑ Change of ulnar component
- ❑ Change of radial head component
- ❑ Change of all components
- ❑ Removal of components
- ❑ Other Name: ……

APPROACH

❑ Medial ❑ Lateral ❑ Posterior

HUMERUS

Please do not fold bar-coded label

ULNA

Please do not fold bar-coded label

STICK EXTRA LABELS ON REVERSE SIDE

BONE GRAFT - HUMERUS

❑ Allograft
❑ Autograft ❑ Synthetic

BONE GRAFT - ULNA

❑ Allograft
❑ Autograft ❑ Synthetic

RADIAL HEAD

Please do not fold bar-coded label

AUGMENTS

Please do not fold bar-coded label

STICK EXTRA LABELS ON REVERSE SIDE

CEMENT

❑ Humerus ❑ Ulna ❑ Radius ❑ Antibiotic brand: .....……

❑ **SYSTEMIC ANTIBIOTIC PROPHYLAXIS**
Name .....…… ASA Class: 1 2 3 4 (please circle one)

OPERATING THEATRE

❑ Conventional ❑ Laminar flow or similar ❑ Space suits

SKIN TO SKIN TIME *mins* Start skin..... Finish skin.....

PRIMARY OPERATING SURGEON

❑ Adv Trainee Unsupervised
❑ Consultant ❑ Adv Trainee Supervised Year……..…… ❑ Basic Trainee

****NB** If bilateral procedure two completed forms are required*

DO NOT PLACE IN PATIENT NOTES **TO BE RETAINED IN THEATRE SUITE**

NEW ZEALAND JOINT REGISTRY

Primary Cervical Disc Replacement

Free Phone 0800-274-989 **14.08.2008**

Date: .....

Patient Name:
Address:

DOB: **NHI:**

Attach Patient Label

Consultant: ……
[If different from patient label]
Hospital: .....
Town/City: ……

Tick Appropriate Boxes **ACC** ☐ **ACC Claim No: ……**

LEVELS OF DISC REPLACEMENT

- ❑ C3/4
- ❑ C4/5
- ❑ C5/6
- ❑ C6/7
- ❑ C7/T1
- Other ……..

PRE OP PATIENT SCORE
(NECK DISABILITY INDEX) ……..

PREVIOUS OPERATION

- ❑ Foreminotomy
- ❑ Adjacent Level Fusion
- ❑ Adjacent Level Disc Arthroplasty
- ❑ Other ……

DIAGNOSIS

- ❑ Acute Disc Prolapse
- ❑ Chronic Spondylosis
- ❑ Neck Pain
- ❑ Other ……

APPROACH

- ❑ Anterior Right
- ❑ Anterior Left
- ❑ Other ……

IMPLANTS

Affix Supplier Label

Affix Supplier Label

STICK EXTRA LABELS ON REVERSE SIDE

Affix Supplier Label

Affix Supplier Label

STICK EXTRA LABELS ON REVERSE SIDE

INTRAOPERATIVE COMPLICATIONS

……..
……..

SYSTEMIC ANTIBIOTIC PROPHYLAXIS

- ❑ Yes
- ❑ No

OPERATIVE THEATRE

- ❑ Conventional
- ❑ Laminar flow or similar
- ❑ Space suits

SKIN TO SKIN TIME *mins* **Start skin.....** **Finish skin.....**

PRIMARY OPERATING SURGEON

- ❑ Consultant
- ❑ Adv Trainee Unsupervised
- ❑ Adv Trainee Supervised **Year ……..**
- ❑ Basic Trainee

DO NOT PLACE IN PATIENT NOTES TO BE RETAINED IN THEATRE SUITE

NEW ZEALAND JOINT REGISTRY

Primary Lumbar Disc Replacement

Free Phone 0800-274-989 14.08.2008

Date: .....

Patient Name:
Address:

d.o.b. NHI:

Attach Patient Label

Consultant: ……
[If different from patient label]
Hospital: .....
Town/City ……

Tick Appropriate Boxes ACC ACC Claim No. .....

DISC REPLACEMENT Levels	FUSION Levels	PRE OP PATIENT SCORE
		Modified Roland and Morris
❑ L3/4	❑ L3/4	Total number of "Yes" responses ……
❑ L4/5	❑ L4/5	*Oswestry Score*
❑ L5/S1	❑ L5/S1	Percentage score ……

Other ……

PREVIOUS OPERATION
❑ Discectomy ❑ L3/4 ❑ L4/5 ❑ L5/S1 ❑ Other ……
❑ Other …….. ❑ L3/4 ❑ L4/5 ❑ L5/S1

DIAGNOSIS

1. Degenerative Disc disease (plain x-ray changes present) ❑ L3/4 ❑ L4/5 ❑ L5/S1 ❑ Other ……
2. Annular tear MRI scan (normal plain x-ray) ❑ L3/4 ❑ L4/5 ❑ L5/S1 ❑ Other ……
3. Discogenic pain on discography ❑ L3/4 ❑ L4/5 ❑ L5/S1 ❑ Other ……

APPROACH
❑ Retroperitoneal midline abdominal wall incision ❑ Transperitoneal
❑ Retroper toneal lateral abdominal wall incision ❑ Other ……..

IMPLANTS

Affix Supplier Label

Affix Supplier Label

STICK EXTRA LABELS ON REVERSE SIDE

Affix Supplier Label

Affix Supplier Label

STICK EXTRA LABELS ON REVERSE SIDE

INTRAOPERATIVE COMPLICATIONS
……
……

❑SYSTEMIC ANTIBIOTIC PROPHYLAXIS
Yes ❑ No ❑

OPERATIVE THEATRE
❑Conventional ❑ Laminar flow or similar ❑ Space suits

SKIN TO SKIN TIME *mins* Start skin ..... Finish skin .....

PRIMARY OPERATING SURGEON

❑ Consultant ❑ Adv Trainee Year…… ❑ Basic Trainee

DO NOT PLACE IN PATIENT NOTES TO BE RETAINED IN THEATRE SUITE

NEW ZEALAND JOINT REGISTRY

Revision Lumbar Disc Replacement

Free Phone 0800-274-989 **14.08.2008**

Date: .....

Patient Name:
Address:

d.o.b. **NHI:**

Attach Patient Label

Consultant: ……
[If different from patient label]
Hospital: .....
Town/City: .....

Tick Appropriate Boxes

REASON FOR REVISION

- ❑ Loosening of components
- ❑ Dislocation of articulating core
- ❑ Loss of spinal alignment
- ❑ Pain
- ❑ Deep infection
- ❑ Fracture of vertebra
- ❑ Removal of components
- ❑ Other: Name: ……

Date Index Operation: …… **If re-revision - Date previous revision:** ……..

REVISION

- ❑ Change of TDR components
- ❑ Change to Anterior Fusion
- ❑ Change of articulating core
- ❑ In-situ posterior instrumented fusion

APPROACH

- ❑ Retroperitoneal midline abdominal wall incision
- ❑ Retroperitoneal lateral abdominal wall incision
- ❑ Transperitoneal
- ❑ Other ……..
- ❑ Posterior Approach for in-situ fusion

NEW DISC REPLACEMENT Levels

- ❑ L3/4
- ❑ L4/5
- ❑ L5/S1

NEW FUSION Levels

- ❑ L3/4
- ❑ L4/5
- ❑ L5/S1

PRE OP PATIENT SCORE

Modified Roland and Morris

Total number of "Yes" responses ……

Oswestry Score

Percentage score ……

Other ……

IMPLANTS

Affix Supplier Label

Affix Supplier Label

STICK EXTRA LABELS ON REVERSE SIDE

Affix Supplier Label

Affix Supplier Label

STICK EXTRA LABELS ON REVERSE SIDE

INTRAOPERATIVE COMPLICATIONS

……

❑SYSTEMIC ANTIBIOTIC PROPHYLAXIS

Yes ❑ **No** ❑

OPERATIVE THEATRE

❑Conventional ❑ **Laminar flow or similar** ❑ **Space suits**

SKIN TO SKIN TIME *mins* **Start skin** ..... **Finish skin** .....

PRIMARY OPERATING SURGEON

❑ **Consultant** ❑ **Adv Trainee** **Year**…… ❑ **Basic Trainee**

DO NOT PLACE IN PATIENT NOTES TO BE RETAINED IN THEATRE SUITE

NEW ZEALAND JOINT REGISTRY

Revision Cervical Disc Replacement

Free Phone 0800-274-989 14.08.2008

Date: .....

Patient Name:
Address:

DOB: NHI:

Attach Patient Label

Consultant: ……..
[If different from patient label]

Hospital: .....

Town/City: ……

LEVEL OF REVISION

- ❑ C3/4 ❑ C6/7
- ❑ C4/5 ❑ C7/T1
- ❑ C5/6 ❑ Other:

Tick Appropriate Boxes ACC ACC Claim No: ……..

REASON FOR REVISION

- ❑ Dislocation of component
- ❑ Failure of component
- ❑ Infection
- ❑ Pain (Neck)
- ❑ Adjacent level surgery
- ❑ Additional decompression required
- ❑ Heterotopic calcification
- ❑ Other: Name: ……

Date Index Operation: ……. If re-revision - Date previous revision: ……

REVISION

- ❑ Replace disc prosthesis (same)
- ❑ Replace disc prosthesis (different)
- ❑ Fuse
- ❑ Removal only
- ❑ Other: ……..

APPROACH ❑ Image guided surgery ❑ Minimally invasive surgery

❑ Anterior ❑ Posterior ❑ Lateral ❑ Trochanteric Osteotomy

IMPLANTS

Please do not fold bar-coded label

Please do not fold bar-coded label

STICK EXTRA LABELS ON REVERSE SIDE

Please do not fold bar-coded label

Please do not fold bar-coded label

STICK EXTRA LABELS ON REVERSE SIDE

SYSTEMIC ANTIBIOTIC PROPHYLAXIS

Name .....……

OPERATING THEATRE

❑ Conventional ❑ Laminar flow or similar ❑ Space suits

SKIN TO SKIN TIME *mins* Start skin..... Finish skin.....

PRIMARY OPERATING SURGEON

❑ Consultant ❑ Adv Trainee Supervised ❑ Adv Trainee Unsupervised Year……..... ❑ Basic Trainee

TOTAL HIP REPLACEMENT - QUESTIONNAIRE

Patient Name: …… **Date of Birth:** ……..

Patient Address:…… **Operating Surgeon:** ……

……. **Date of Surgery:** ……

We would like you to score yourself on the following 12 questions. Each question is scored from 1 to 5, from least to most difficulty or severity: 1 being the least difficult/severe and 5 being the most difficult/severe. Please circle the number which best describes yourself **OVER THE LAST 4 WEEKS**

Please circle the SIDE on which you had your surgery performed Left Right

1. How would you describe the pain you usually have from your operated on hip?
   1 None
   2 Very mild
   3 Mild
   4 Moderate
   5 Severe

2. For how long have you been able to walk before the pain from your operated on hip becomes severe? (with or without a stick)
   1. No pain up to 30 minutes
   2 16 to 30 minutes
   3 5 to 15 minutes
   4 Around the house only
   5 Unable to walk because of severe pain.

3. Have you had any trouble getting in and out of a car or using public transport because of your operated on hip?
   1 No trouble at all
   2 Very little trouble
   3 Moderate trouble
   4 Extreme difficulty
   5 Impossible to do

4. Have you been able to put on a pair of socks, stockings or tights?
   1 Yes, easily
   2 With little difficulty
   3 With moderate difficulty
   4 With extreme difficulty
   5 No, impossible

5. Could you do the household shopping on your own?
   1 Yes, easily
   2 With little difficulty
   3 With moderate difficulty
   4 With extreme difficulty
   5 No, impossible

6. Have you had any trouble with washing and drying yourself (all over) because of your operated on hip?
   1 No trouble at all
   2 Very little trouble
   3 Moderate trouble
   4 Extreme difficulty
   5 Impossible to do

7 How much has pain from your operated on hip interfered with your usual work (including housework)?
   1 Not at all
   2 A little bit
   3 Moderately
   4 Greatly
   5 Totally

8. After a meal (sat at a table), how painful has it been for you to stand up from a chair because of your operated on hip?
   1 Not at all painful
   2 Slightly painful
   3 Moderately painful
   4 Very painful
   5 Unbearable

9. Have you had any sudden, severe pain - 'shooting', 'stabbing' or 'spasms' - from the affected operated on hip?
   1 Rarely/never
   2 Sometimes or just at first
   3 Often, not just at first
   4 Most of the time
   5 All of the time

10. Have you been limping when walking, because of your operated on hip?
   1 No days
   2 Only 1 or 2 days
   3 Some days
   4 Most days
   5 Every day

11. Have you been able to climb a flight of stairs?
   1 Yes, easily
   2 With little difficulty
   3 With moderate difficulty
   4 With extreme difficulty
   5 No, impossible

12 Have you been troubled by pain from your operated on hip in bed at night?
   1 No nights
   2 Only 1 or 2 nights
   3 Some nights
   4 Most nights
   5 Every night

Additional Information

Have you at any time been hospitalised because:

	Yes	No	Approx Date
The artificial joint dislocated?	°	°	……..
The joint became infected?	◦	°	……..
or for any other reason related to the artificial joint ……..			
Hospital admitted to: ……..			

I wish to receive a progress report on the study. . **NB:** If there are reasons other than the operation which would stop you doing one of the tasks listed, try to answer the question from the joint replacement aspect alone.

REVISION HIP REPLACEMENT - QUESTIONNAIRE

Patient Name: ……. **Date of Birth: …..……..**

Patient Address:……. **Operating Surgeon: …….**

…..……. **Date of Surgery: …….**

We would like you to score yourself on the following 12 questions. Each question is scored from 1 to 5, from least to most difficulty or severity: 1 being the least difficult/severe and 5 being the most difficult/severe. Please circle the number which best describes yourself **OVER THE LAST 4 WEEKS**

Please circle the SIDE on which you had your surgery performed Left Right

1. How would you describe the pain you usually have from your operated on hip?
   1 None
   2 Very mild
   3 Mild
   4 Moderate
   5 Severe

2. For how long have you been able to walk before the pain from your operated on hip becomes severe? (with or without a stick)
   1. No pain up to 30 minutes
   2 16 to 30 minutes
   3 5 to 15 minutes
   4 Around the house only
   5 Unable to walk because of severe pain.

3. Have you had any trouble getting in and out of a car or using public transport because of your operated on hip?
   1 No trouble at all
   2 Very little trouble
   3 Moderate trouble
   4 Extreme difficulty
   5 Impossible to do

4. Have you been able to put on a pair of socks, stockings or tights?
   1 Yes, easily
   2 With little difficulty
   3 With moderate difficulty
   4 With extreme difficulty
   5 No, impossible

5. Could you do the household shopping on your own?
   1 Yes, easily
   2 With little difficulty
   3 With moderate difficulty
   4 With extreme difficulty
   5 No, impossible

6. Have you had any trouble with washing and drying yourself (all over) because of your operated on hip?
   1 No trouble at all
   2 Very little trouble
   3 Moderate trouble
   4 Extreme difficulty
   5 Impossible to do

7 How much has pain from your operated on hip interfered with your usual work (including housework)?
   1 Not at all
   2 A little bit
   3 Moderately
   4 Greatly
   5 Totally

8 After a meal (sat at a table), how painful has it been for you to stand up from a chair because of your operated on hip?
   1 Not at all painful
   2 Slightly painful
   3 Moderately painful
   4 Very painful
   5 Unbearable

9 Have you had any sudden, severe pain - 'shooting', 'stabbing' or 'spasms' - from the affected operated on hip?
   1 Rarely/never
   2 Sometimes or just at first
   3 Often, not just at first
   4 Most of the time
   5 All of the time

10 Have you been limping when walking, because of your operated on hip?
   1 No days
   2 Only 1 or 2 days
   3 Some days
   4 Most days
   5 Every day

11 Have you been able to climb a flight of stairs?
   1 Yes, easily
   2 With little difficulty
   3 With moderate difficulty
   4 With extreme difficulty
   5 No, impossible

12 Have you been troubled by pain from your operated on hip in bed at night?
   1 No nights
   2 Only 1 or 2 nights
   3 Some nights
   4 Most nights
   5 Every night

Additional Information

Have you at any time been hospitalised because:

	Yes	No	Approx Date
The artificial joint dislocated?	°	°……..	
The joint became infected?	°	°……..	

or for any other reason related to the artificial joint ……..……..

Hospital admitted to: ……..……..……..

I wish to receive a progress report on the study. **NB:** If there are reasons other than the operation which would stop you doing one of the tasks listed, try to answer the question from the joint replacement aspect alone.

TOTAL KNEE REPLACEMENT - QUESTIONNAIRE

Patient Name: …… **Date of Birth:** …..……..

Patient Address: …… **Operating Surgeon:** …….

…… **Date of Surgery:** ……

We would like you to score yourself on the following 12 questions. Each question is scored from 1 to 5, from least to most difficulty or severity: 1 being the least difficult/severe and 5 being the most difficult/severe. Please circle the number which best describes yourself **OVER THE LAST 4 WEEKS**

Please circle the SIDE on which you had your surgery performed Left Right

1. How would you describe the pain you usually have from your operated on knee?
   1 None
   2 Very mild
   3 Mild
   4 Moderate
   5 Severe

2. For how long have you been able to walk before the pain from your operated on knee becomes severe? (with or without a stick)
   1. No pain up to 30 minutes
   2 16 to 30 minutes
   3 5 to 15 minutes
   4 Around the house only
   5 Unable to walk because of severe pain.

3. Have you had any trouble getting in and out of a car or using public transport because of your operated on knee?
   1 No trouble at all
   2 Very little trouble
   3 Moderate trouble
   4 Extreme difficulty
   5 Impossible to do

4. Could you kneel down and get up again afterwards on your operated knee?
   1 Yes, easily
   2 With little difficulty
   3 With moderate difficulty
   4 With extreme difficulty
   5 No, impossible

5. Could you do the household shopping on your own?
   1 Yes, easily
   2 With little difficulty
   3 With moderate difficulty
   4 With extreme difficulty
   5 No, impossible

6. Have you had any trouble with washing and drying yourself (all over) because of your operated on knee?
   1 No trouble at all
   2 Very little trouble
   3 Moderate trouble
   4 Extreme difficulty
   5 Impossible to do

7 How much has pain from your operated on knee interfered with your usual work (including housework)?
   1 Not at all
   2 A little bit
   3 Moderately
   4 Greatly
   5 Totally

8 After a meal (sat at a table), how painful has it been for you to stand up from a chair because of your operated on knee?
   1 Not at all painful
   2 Slightly painful
   3 Moderately painful
   4 Very painful
   5 Unbearable

9 Have you felt that your operated on knee might suddenly "give way" or let you down?
   1 Rarely/never
   2 Sometimes or just at first
   3 Often, not just at first
   4 Most of the time
   5 All of the time

10 Have you been limping when walking, because of your operated on knee?
   1 No days
   2 Only 1 or 2 days
   3 Some days
   4 Most days
   5 Every day

11 Could you walk down a flight of stairs?
   1 Yes, easily
   2 With little difficulty
   3 With moderate difficulty
   4 With extreme difficulty
   5 No, impossible

12 Have you been troubled by pain from your operated on knee in bed at night?
   1 No nights
   2 Only 1 or 2 nights
   3 Some nights
   4 Most nights
   5 Every night

Additional Information

Have you at any time been hospitalised because:

	Yes	No	Approx Date
The artificial joint dislocated?	°	°	……..
The joint became infected?	°	°	……..

or for any other reason related

to the artificial joint ……..

Hospital admitted to: ……..

I wish to receive a progress report on the study. **NB:** If there are reasons other than the operation which would stop you doing one of the tasks listed, try to answer the question from the joint replacement aspect alone.

REVISION KNEE REPLACEMENT - QUESTIONNAIRE

Patient Name: …… **Date of Birth:** …..……..

Patient Address:…… **Operating Surgeon:** ……

…… **Date of Surgery:** ……

We would like you to score yourself on the following 12 questions. Each question is scored from 1 to 5, from least to most difficulty or severity: 1 being the least difficult/severe and 5 being the most difficult/severe. Please circle the number which best describes yourself **OVER THE LAST 4 WEEKS**

Please circle the SIDE on which you had your surgery performed Left Right

1. How would you describe the pain you usually have from your operated on knee?
   1 None
   2 Very mild
   3 Mild
   4 Moderate
   5 Severe

2. For how long have you been able to walk before the pain from your operated on knee becomes severe? (with or without a stick)
   1. No pain up to 30 minutes
   2 16 to 30 minutes
   3 5 to 15 minutes
   4 Around the house only
   5 Unable to walk because of severe pain.

3. Have you had any trouble getting in and out of a car or using public transport because of your operated on knee?
   1 No trouble at all
   2 Very little trouble
   3 Moderate trouble
   4 Extreme difficulty
   5 Impossible to do

4. Could you kneel down and get up again afterwards?
   1 Yes, easily
   2 With little difficulty
   3 With moderate difficulty
   4 With extreme difficulty
   5 No, impossible

5. Could you do the household shopping on your own?
   1 Yes, easily
   2 With little difficulty
   3 With moderate difficulty
   4 With extreme difficulty
   5 No, impossible

6. Have you had any trouble with washing and drying yourself (all over) because of your operated on knee?
   1 No trouble at all
   2 Very little trouble
   3 Moderate trouble
   4 Extreme difficulty
   5 Impossible to do

7 How much has pain from your operated on knee interfered with your usual work (including housework)?
   1 Not at all
   2 A little bit
   3 Moderately
   4 Greatly
   5 Totally

8 After a meal (sat at a table), how painful has it been for you to stand up from a chair because of your operated on knee?
   1 Not at all painful
   2 Slightly painful
   3 Moderately painful
   4 Very painful
   5 Unbearable

9 Have you felt that your operated on knee might suddenly "give way" or let you down?
   1 Rarely/never
   2 Sometimes or just at first
   3 Often, not just at first
   4 Most of the time
   5 All of the time

10 Have you been limping when walking, because of your operated on knee?
   1 No days
   2 Only 1 or 2 days
   3 Some days
   4 Most days
   5 Every day

11 Could you walk down a flight of stairs?
   1 Yes, easily
   2 With little difficulty
   3 With moderate difficulty
   4 With extreme difficulty
   5 No, impossible

12 Have you been troubled by pain from your operated on knee in bed at night?
   1 No nights
   2 Only 1 or 2 nights
   3 Some nights
   4 Most nights
   5 Every night

Additional Information

Have you at any time been hospitalised because:

	Yes	No	Approx Date
The artificial joint dislocated?	°	°	……..
The joint became infected?	°	°	……..

or for any other reason related to the artificial joint ……

Hospital admitted to: ……

I wish to receive a progress report on the study. **NB:** If there are reasons other than the operation which would stop you doing one of the tasks listed, try to answer the question from the joint replacement aspect alone.

TOTAL ANKLE REPLACEMENT - QUESTIONNAIRE

Patient Name: …… **Date of Birth:** …..……..

Patient Address:…… **Operating Surgeon:** ……

……..…… **Date of Surgery:** ……

We would like you to score yourself on the following 12 questions. Each question is scored from 1 to 5, from least to most difficulty or severity: 1 being the least difficult/severe and 5 being the most difficult/severe. Please **circle the number** which best describes yourself **OVER THE LAST 4 WEEKS**

Please circle the SIDE on which you had your surgery performed Left Right

1. How would you describe the pain you usually have from your operated on ankle?
   1 None
   2 Very mild
   3 Mild
   4 Moderate
   5 Severe

2. For how long have you been able to walk before the pain from your operated on ankle becomes severe?
   1. No pain up to 30 minutes
   2 16 to 30 minutes
   3 5 to 15 minutes
   4 Around the house only
   5 Unable to walk at all because of severe pain.

3. Have you been able to walk on uneven ground?
   1 Yes, easily
   2 With little difficulty
   3 With moderate difficulty
   4 Extreme difficulty
   5 No impossible.

4. Have you had to use an orthotic (shoe insert), heel lift, or special shoes.
   1 Never
   2 Occasionally
   3 Often
   4 Most of the time
   5 Always

5. How much has pain from your ankle interfered with your usual work (including housework and hobbies)?
   1 Not at all
   2 A little bit
   3 Moderately
   4 Greatly
   5 Totally

6. Have you been limping when walking because of your operated on ankle?
   1 No days
   2 Only one or two days
   3 Some days
   4 Most days
   5 Every day

7 Have you been able to climb a flight of stairs.
   1 Yes, easily
   2 With little difficulty
   3 With moderate difficulty
   4 With extreme difficulty
   5 Impossible

8. Have you been troubled by pain from your operated on ankle in bed at night?
   1 No nights
   2 Only one or two nights
   3 Some nights
   4 Most nights
   5 Every night

9. How much has pain from your operated on ankle interfered with your usual recreational activities?
   1 Not at all
   2 A little bit
   3 Moderately
   4 Greatly
   5 Totally

10 Have you had swelling of your foot
   1 None at all
   2 Occasionally
   3 Often
   4 Most of the time
   5 All the time

11 After a meal (sat at a table) how painful has it been for you to stand up from a chair because of your operated on ankle.
   1 Not at all painful
   2 Slightly painful
   3 Moderately painful
   4 Very painful
   5 Unbearable

12 Have you had any sudden severe pain – shooting, stabbing or spasms from your operated on ankle?
   1 No days
   2 Only 1 or 2 days
   3 Some days
   4 Most days
   5 Every day

Additional Information

Have you at any time been hospitalised because:

	Yes	No	Approx Date
The artificial joint dislocated?	°	°	……..
The joint became infected?	°	°	……..

or for any other reason related to the artificial joint ……..

Hospital admitted to: ……..

I wish to receive a progress report on the study. **NB:** If there are reasons other than the operation which would stop you doing one of the tasks listed, try to answer the question from the joint replacement aspect alone.

REVISION ANKLE REPLACEMENT - QUESTIONNAIRE

Patient Name: …… **Date of Birth:** …..……..

Patient Address:…… **Operating Surgeon:** …….

……..……. **Date of Surgery:** …….

We would like you to score yourself on the following 12 questions. Each question is scored from 1 to 5, from least to most difficulty or severity: 1 being the least difficult/severe and 5 being the most difficult/severe. Please **circle the number** which best describes yourself **OVER THE LAST 4 WEEKS**

Please circle the SIDE on which you had your surgery performed Left Right

1. How would you describe the pain you usually have from your operated on ankle?
   1 None
   2 Very mild
   3 Mild
   4 Moderate
   5 Severe

2. For how long have you been able to walk before the pain from your operated on ankle becomes severe?
   1. No pain up to 30 minutes
   2 16 to 30 minutes
   3 5 to 15 minutes
   4 Around the house only
   5 Unable to walk at all because of severe pain.

3. Have you been able to walk on uneven ground?
   1 Yes, easily
   2 With little difficulty
   3 With moderate difficulty
   4 Extreme difficulty
   5 No impossible.

4. Have you had to use an orthotic (shoe insert), heel lift, or special shoes.
   1 Never
   2 Occasionally
   3 Often
   4 Most of the time
   5 Always

5. How much has pain from your ankle interfered with your usual work (including housework and hobbies)?
   1 Not at all
   2 A little bit
   3 Moderately
   4 Greatly
   5 Totally

6. Have you been limping when walking because of your operated on ankle?
   1 No days
   2 Only one or two days
   3 Some days
   4 Most days
   5 Every day

7 Have you been able to climb a flight of stairs.
   1 Yes, easily
   2 With little difficulty
   3 With moderate difficulty
   4 With extreme difficulty
   5 Impossible

8. Have you been troubled by pain from your operated on ankle in bed at night?
   1 No nights
   2 Only one or two nights
   3 Some nights
   4 Most nights
   5 Every night

9. How much has pain from your operated on ankle interfered with your usual recreational activities?
   1 Not at all
   2 A little bit
   3 Moderately
   4 Greatly
   5 Totally

12 Have you had swelling of your foot
   1 None at all
   2 Occasionally
   3 Often
   4 Most of the time
   5 All the time

13 After a meal (sat at a table) how painful has it been for you to stand up from a chair because of your operated on ankle.
   1 Not at all painful
   2 Slightly painful
   3 Moderately painful
   4 Very painful
   5 Unbearable

12 Have you had any sudden severe pain – shooting, stabbing or spasms from your operated on ankle?
   1 No days
   2 Only 1 or 2 days
   3 Some days
   4 Most days
   5 Every day

Additional Information

Have you at any time been hospitalised because:

	Yes	No	Approx Date
The artificial joint dislocated?	°	°	……..
The joint became infected?	°	°	……..

or for any other reason related to the artificial joint ……..

Hospital admitted to: ……..

I wish to receive a progress report on the study. **NB:** If there are reasons other than the operation which would stop you doing one of the tasks listed, try to answer the question from the joint replacement aspect alone.

TOTAL SHOULDER REPLACEMENT - QUESTIONNAIRE

Patient Name: …… **Date of Birth:** …..……..

Patient Address:…… **Operating Surgeon:** …….

……..……. **Date of Surgery:** …….

We would like you to score yourself on the following 12 questions. Each question is scored from 1 to 5, from least to most difficulty or severity: 1 being the least difficult/severe and 5 being the most difficult/severe. Please **circle the number** which best describes yourself **OVER THE LAST 4 WEEKS Which is your dominant arm? Left Right**

Please circle the SIDE on which you had your surgery performed Left Right

1. How would you describe the ***worst*** pain you have had from your operated on shoulder?
   1 None
   2 Mild
   3 Moderate
   4 Severe
   5 Unbearable

2. How would you describe the pain you ***usually*** have from your operated on shoulder?
   1 None
   2 Very mild
   3 Mild
   4 Moderate
   5 Severe

3. Have you had any trouble getting in and out of a car or using public transport because of your operated on shoulder?
   1. No trouble at all
   2 A little bit of trouble
   3 Moderate trouble
   4 Extreme difficulty
   5 Impossible to do

4. Have you been able to use a knife and fork at the same time?
   1 Yes, easily
   2 With little difficulty
   3 With moderate difficulty
   4 With extreme difficulty
   5 No, impossible

5. Could you do the household shopping on your own?
   1 Yes, easily
   2 With little difficulty
   3 With moderate difficulty
   4 With extreme difficulty
   5 No, impossible

6. Could you carry a tray containing a plate of food across a room?
   1 Yes, easily
   2 With little difficulty
   3 With moderate difficulty
   4 With extreme difficulty
   5 No, impossible

7 Could you brush/comb your hair with the operated on arm?
   1 Yes, easily
   2 With little difficulty
   3 With moderate difficulty
   4 With extreme difficulty
   5 No, Impossible

8. Have you had any trouble dressing yourself because of your operated on shoulder?
   1. No trouble at all
   2 A little bit of trouble
   3 Moderate trouble
   4 Extreme difficulty
   5 Impossible to do

9. Could you hang your clothes up in a wardrobe – using the operated on arm?
   1 Yes, easily
   2 With little difficulty
   3 With moderate difficulty
   4 With extreme difficulty
   5 No, impossible

14 Have you been able to wash and dry yourself under both arms?
   1 Yes, easily
   2 With little difficulty
   3 With moderate difficulty
   4 With extreme difficulty
   5 No, impossible

15 How much has pain from your operated on shoulder interfered with your usual work hobbies or recreational activities (including housework)?.
   1 Not at all
   2 A little bit
   3 Moderately
   4 Greatly
   5 Totally

12 Have you been troubled by pain from your operated on shoulder in bed at night?
   1 No nights
   2 Only 1 or 2 nights
   3 Some nights
   4 Most nights
   5 Every night

Additional Information

Have you at any time been hospitalised because:

	Yes	No	Approx Date
The artificial joint dislocated?	◦	◦	……..
The joint became infected?	◦	◦	……..
or for any other reason related to the artificial joint ……..			
Hospital admitted to: ……..			

I wish to receive a progress report on the study. . **NB:** If there are reasons other than the operation which would stop you doing one of the tasks listed, try to answer the question from the joint replacement aspect alone.

REVISION SHOULDER REPLACEMENT - QUESTIONNAIRE

Patient Name: …… **Date of Birth:** …..……..

Patient Address:…… **Operating Surgeon:** …….

……..……. **Date of Surgery:** …….

We would like you to score yourself on the following 12 questions. Each question is scored from 1 to 5, from least to most difficulty or severity: 1 being the least difficult/severe and 5 being the most difficult/severe. Please **circle the number** which best describes yourself **OVER THE LAST 4 WEEKS Which is your dominant arm? Left Right**

Please circle the SIDE on which you had your surgery performed Left Right

1. How would you describe the ***worst*** pain you have had from your operated on shoulder?
   - 1 None
   - 2 Mild
   - 3 Moderate
   - 6 Severe
   - 7 Unbearable

2. How would you describe the pain you ***usually*** have from your operated on shoulder?
   - 1 None
   - 2 Very mild
   - 3 Mild
   - 4 Moderate
   - 5 Severe

3. Have you had any trouble getting in and out of a car or using public transport because of your operated on shoulder?
   - 1. No trouble at all
   - 2 A little bit of trouble
   - 3 Moderate trouble
   - 4 Extreme difficulty
   - 5 Impossible to do

4. Have you been able to use a knife and fork at the same time?
   - 1 Yes, easily
   - 2 With little difficulty
   - 3 With moderate difficulty
   - 4 With extreme difficulty
   - 5 No, impossible

5. Could you do the household shopping on your own?
   - 1 Yes, easily
   - 2 With little difficulty
   - 3 With moderate difficulty
   - 4 With extreme difficulty
   - 5 No, impossible

6. Could you carry a tray containing a plate of food across a room?
   - 1 Yes, easily
   - 2 With little difficulty
   - 3 With moderate difficulty
   - 4 With extreme difficulty
   - 5 No, impossible

7 Could you brush/comb your hair with the operated on arm?
   - 1 Yes, easily
   - 2 With little difficulty
   - 3 With moderate difficulty
   - 4 With extreme difficulty
   - 5 No, Impossible

8. Have you had any trouble dressing yourself because of your operated on shoulder?
   - 1. No trouble at all
   - 2 A little bit of trouble
   - 3 Moderate trouble
   - 4 Extreme difficulty
   - 5 Impossible to do

9. Could you hang your clothes up in a wardrobe – using the operated on arm?
   - 1 Yes, easily
   - 2 With little difficulty
   - 3 With moderate difficulty
   - 4 With extreme difficulty
   - 5 No, impossible

16 Have you been able to wash and dry yourself under both arms?
   - 1 Yes, easily
   - 2 With little difficulty
   - 3 With moderate difficulty
   - 4 With extreme difficulty
   - 5 No, impossible

17 How much has pain from your operated on shoulder interfered with your usual work hobbies or recreational activities (including housework)?.
   - 2 Not at all
   - 2 A little bit
   - 3 Moderately
   - 4 Greatly
   - 5 Totally

12 Have you been troubled by pain from your operated on shoulder in bed at night?
   - 1 No nights
   - 2 Only 1 or 2 nights
   - 3 Some nights
   - 4 Most nights
   - 5 Every night

Additional Information

Have you at any time been hospitalised because:

	Yes	No	Approx Date
The artificial joint dislocated?	°	°	……..
The joint became infected?	°	°	……..
or for any other reason related to the artificial joint ……..			
Hospital admitted to: ……..			

I wish to receive a progress report on the study. . NB: If there are reasons other than the operation which would stop you doing one of the tasks listed, try to answer the question from the joint replacement aspect alone.

TOTAL ELBOW REPLACEMENT - QUESTIONNAIRE

Patient Name: …… **Date of Birth:** …..……..

Patient Address:…… **Operating Surgeon:** …….

……..……. **Date of Surgery:** …….

We would like you to score yourself on the following 12 questions. Each question is scored from 1 to 5, from least to most difficulty or severity: 1 being the least difficult/severe and 5 being the most difficult/severe. Please **circle the number** which best describes yourself **OVER THE LAST 4 WEEKS Which is your dominant arm? Left Right**

Please circle the SIDE on which you had your surgery performed Left Right

1. How would you describe the ***worst*** pain you have had from your operated on elbow?
   - 1 None
   - 2 Mild
   - 3 Moderate
   - 8 Severe
   - 9 Unbearable

2. Have you had any trouble dressing yourself because of your operated on elbow?
   - 1. No trouble at all
   - 2 A little bit of trouble
   - 3 Moderate trouble
   - 4 Extreme difficulty
   - 5 Impossible to do

3. Can you lift a teacup safely with your operated on arm?
   - 1. No trouble at all
   - 2 A little bit of trouble
   - 3 Moderate trouble
   - 4 Extreme difficulty
   - 5 Impossible to do

4. Have you been able to get your hand to your mouth?
   - 1 Yes, easily
   - 2 With little difficulty
   - 3 With moderate difficulty
   - 4 With extreme difficulty
   - 5 No, impossible

5. Could you carry the household shopping with your operated on arm?
   - 1 Yes, easily
   - 2 With little difficulty
   - 3 With moderate difficulty
   - 4 With extreme difficulty
   - 5 No, impossible

6. Could you carry a tray containing a plate of food across a room?
   - 1 Yes, easily
   - 2 With little difficulty
   - 3 With moderate difficulty
   - 4 With extreme difficulty
   - 5 No, impossible

7 Could you brush/comb your hair with the affected arm?
   - 1 Yes, easily
   - 2 With little difficulty
   - 3 With moderate difficulty
   - 4 With extreme difficulty
   - 5 No, Impossible

8. How would you describe the pain you ***usually*** have from your operated on elbow?
   - 1 None
   - 2 Very mild
   - 3 Mild
   - 4 Moderate
   - 5 Severe

9. Could you hang your clothes up in a wardrobe – using the operated on arm?
   - 1 Yes, easily
   - 2 With little difficulty
   - 3 With moderate difficulty
   - 4 With extreme difficulty
   - 5 No, impossible

18 Have you been able to wash and dry yourself under both arms?
   - 1 Yes, easily
   - 2 With little difficulty
   - 3 With moderate difficulty
   - 4 With extreme difficulty
   - 5 No, impossible

19 How much has pain from your operated on elbow interfered with your usual work hobbies or recreational activities (including hobbies and housework)?.
   - 3 Not at all
   - 2 A little bit
   - 3 Moderately
   - 4 Greatly
   - 5 Totally

12 Have you been troubled by pain from your operated on elbow in bed at night?
   - 1 No nights
   - 2 Only 1 or 2 nights
   - 3 Some nights
   - 4 Most nights
   - 5 Every night

Additional Information

Have you at any time been hospitalised because:

	Yes	No	Approx Date
The artificial joint dislocated?	◦	◦	……..
The joint became infected?	◦	◦	……..
or for any other reason related to the artificial joint ……..			
Hospital admitted to: ……..			

I wish to receive a progress report on the study. . **NB:** If there are reasons other than the operation which would stop you doing one of the tasks listed, try to answer the question from the joint replacement aspect alone

REVISION ELBOW REPLACEMENT - QUESTIONNAIRE

Patient Name: …… **Date of Birth:** …..……..

Patient Address:…… **Operating Surgeon:** ……

……..…… **Date of Surgery:** ……

We would like you to score yourself on the following 12 questions. Each question is scored from 1 to 5, from least to most difficulty or severity: 1 being the least difficult/severe and 5 being the most difficult/severe. Please **circle the number** which best describes yourself **OVER THE LAST 4 WEEKS Which is your dominant arm? Left Right**

Please circle the SIDE on which you had your surgery performed Left Right

1. How would you describe the ***worst*** pain you have had from your operated on elbow?
   - 1 None
   - 2 Mild
   - 3 Moderate
   - 10 Severe
   - 11 Unbearable

2. Have you had any trouble dressing yourself because of your operated on elbow?
   - 1. No trouble at all
   - 2 A little bit of trouble
   - 3 Moderate trouble
   - 4 Extreme difficulty
   - 5 Impossible to do

3. Can you lift a teacup safely with your operated on arm?
   - 1. No trouble at all
   - 2 A little bit of trouble
   - 3 Moderate trouble
   - 4 Extreme difficulty
   - 5 Impossible to do

4. Have you been able to get your hand to your mouth?
   - 1 Yes, easily
   - 2 With little difficulty
   - 3 With moderate difficulty
   - 4 With extreme difficulty
   - 5 No, impossible

5. Could you carry the household shopping with your operated on arm?
   - 1 Yes, easily
   - 2 With little difficulty
   - 3 With moderate difficulty
   - 4 With extreme difficulty
   - 5 No, impossible

6. Could you carry a tray containing a plate of food across a room?
   - 1 Yes, easily
   - 2 With little difficulty
   - 3 With moderate difficulty
   - 4 With extreme difficulty
   - 5 No, impossible

7 Could you brush/comb your hair with the affected arm?
   - 1 Yes, easily
   - 2 With little difficulty
   - 3 With moderate difficulty
   - 4 With extreme difficulty
   - 5 No, Impossible

8. How would you describe the pain you ***usually*** have from your operated on elbow?
   - 1 None
   - 2 Very mild
   - 3 Mild
   - 4 Moderate
   - 5 Severe

9. Could you hang your clothes up in a wardrobe – using the operated on arm?
   - 1 Yes, easily
   - 2 With little difficulty
   - 3 With moderate difficulty
   - 4 With extreme difficulty
   - 5 No, impossible

20 Have you been able to wash and dry yourself under both arms?
   - 1 Yes, easily
   - 2 With little difficulty
   - 3 With moderate difficulty
   - 4 With extreme difficulty
   - 5 No, impossible

21 How much has pain from your operated on elbow interfered with your usual work hobbies or recreational activities (including hobbies and housework)?.
   - 4 Not at all
   - 2 A little bit
   - 3 Moderately
   - 4 Greatly
   - 5 Totally

12 Have you been troubled by pain from your operated on elbow in bed at night?
   - 1 No nights
   - 2 Only 1 or 2 nights
   - 3 Some nights
   - 4 Most nights
   - 5 Every night

Additional Information

Have you at any time been hospitalised because:

	Yes	No	Approx Date
The artificial joint dislocated?	°	°	……..
The joint became infected?	°	°	……..
or for any other reason related to the artificial joint ……..			
Hospital admitted to: ……..			

I wish to receive a progress report on the study. . **NB:** If there are reasons other than the operation which would stop you doing one of the tasks listed, try to answer the question from the joint replacement aspect alone.

National Joint Registry
www.njrcentre.org.uk

National Joint Registry
for England and Wales

6th Annual Report
2009

ISSN1753-9374

Prepared by

The NJR Centre, Hemel Hempstead

David Emsley

Claire Newell

Martin Pickford

Martin Royall

Mike Swanson

M&M Communications

Royal College of Surgeons Clinical Effectiveness Unit

Susan Charman

Lynn Copley

Jan van der Meulen

Healthcare Quality Improvement Partnership

Yvonne Tse

Elaine Young

This document is available in PDF format for download from the NJR website at **www.njrcentre.org.uk**

Contents

Part 1 tables

Part 1 figures

Part 2 tables

Part 2 figures

Part 3 tables

Part 3 figures

Chairman's introduction

Bill Darling C.B.E. D.L. F.R.Pharm.S

Last year in my introduction to the Annual Report I said that the National Joint Registry (NJR) was entering a new phase of its work. As well as continuing to maintain a compliance rate of more than 90% and improving the consent rate, the emphasis was moving on to improving the quality and use of data.

During the year, there has been a dramatic increase in the number of requests for data for research and other studies and a new protocol is being developed which will clarify and facilitate the process.

The NJR Steering Committee has approved a strategic plan that focuses on the objectives of the Register for the next two years. Its key aims include:

- continuing to work to improve the quality, availability and timeliness of information to stakeholders
- promoting and facilitating high quality research
- extending the benefits of the NJR by including other joint replacement procedures such as ankles, shoulders, elbows and wrists, and by including procedures in Northern Ireland
- improving stakeholder engagement
- raising awareness of the benefits of the NJR.

An additional development for next year will be our participation in the national Patient Reported Outcome Measures (PROMs) study. This will provide an opportunity for the NJR to analyse patient outcomes on a scale that was not previously possible. Agreement is in place with the Department of Health for the national PROMs data to be linked with the NJR data.

The Steering Committee has re-established the NJR's Editorial Board under the chairmanship of Martyn Porter. The Board will ensure the timely preparation of the Annual Report, widen the range of topics covered and make information more readily available to stakeholders.

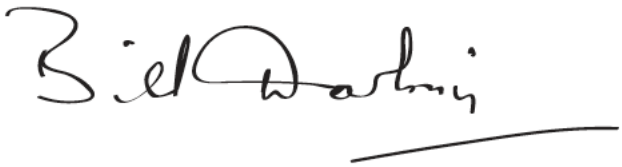
Following the Annual Meeting of the British Hip Society in February 2008 the Steering Committee approved the development of NJR Clinician Feedback. This service provides a number of reports which enable surgeons to assess their clinical practice and compare it with their colleagues at a local, sector and national level. The prototype was demonstrated at the meeting and the system went live in November 2008. The number of reports will increase as different types of data become available. Similar services for implant manufacturers and hospital and trust management are under consideration.

The Steering Committee has continued to work with the British Orthopaedic Association (BOA), Royal College of Surgeons, industry and the NJR Regional Clinical Co-ordinators' Network to develop and refine an agreed methodology and process for the identification and management of potentially outlying surgeons and prostheses. As a result of outlier analysis by the NJR, the Medicines and Healthcare products Regulatory Agency (MHRA) issued a device alert for an implant which has subsequently been withdrawn by the manufacturer. We can now quickly inform hospitals of potential problems, which significantly reduces the period between identification of an issue and patient review.

I believe we have demonstrated that the Register is a tool for excellence and that it will enable continuing improvement in best practice and patient care.

I again record my thanks to Professor Paul Gregg, Steering Committee Vice-Chairman, for his support and enthusiasm during the year. I should also like to thank Martyn Porter, in particular, for his tireless work as Chair of the Editorial Board and all other members of the Steering Committee for their generous contribution.

From 1st April 2008, the NJR has operated under the auspices of the Healthcare Quality Improvement Partnership (HQIP). I should like to record my thanks to its staff, in particular Elaine Young whose commitment to progressing the project has been enormous. I also thank the Regional Clinical Co-ordinators for their significant contribution and, last but not least, the NJR contractor, Northgate Information Solutions (UK) Ltd.



Bill Darling
Chairman, NJR Steering Committee

Vice-Chairman's foreword

Professor P J Gregg

As Vice-Chairman of the NJR Steering Committee, I am delighted to introduce our 6th Annual Report.

I am very pleased, as our Chairman has noted, that the Register's underlying compliance and consent rates have increased over the last financial year. It is now essential that our attentions are turned to checking and, where necessary, improving the quality of the data.

It is also gratifying to note the dramatic increase in the number of requests for data for research and other studies, which indicates that a significant number of health professionals believe the data we hold is of real value.

I believe the strategic plan for the next two years, as detailed in the Chairman's introduction, will lead to significant improvements and development of the NJR. It is gratifying to note that this work is fully funded.

In my foreword to last year's Annual Report, I indicated that I was particularly pleased the NJR had been able to establish a working relationship with the Department of Health's National Patient Reported Outcome Measures study. This study commenced in April 2009 and we will shortly be turning our attention to linking PROMs and NJR data with a view to assessing patient reported outcomes for different types of prosthesis, surgical technique and age group.

A significant amount of work has been carried out to refine and develop the methodology for the identification of 'potential outlier' data for prosthesis survival by prosthesis type and surgeon. It is vitally important to ensure absolute robustness and fairness in this process. Further work remains to be done, in particular, around mandating registration of joint replacements with the NJR.

As stated in the 5th Annual Report, I still believe it is important to develop a workable system for the assessment of case complexity. The contribution of the British Hip Society and the British Association for Surgery of the Knee would be much appreciated in relation to this work.

One of the particularly interesting findings in the 6th Annual Report is that three year survivorship, for all age groups including the younger age group, is highest for cemented hip prostheses. At a time when the use of cement is declining in hip replacement surgery, perhaps we should all reflect on this. It would be particularly interesting to see later survivorship data in relation to the use of cement.

I am very pleased that we have been able to re-establish the NJR's Editorial Board, as outlined by our Chairman. I would like to add my thanks to Martyn Porter for his extremely hard work as Editorial Board Chair.

Once again I wish to record my thanks to the Chair of the NJR Steering Committee for all his hard work both within and outside the Committee, and for his continued enthusiasm and determination to see the further development of a National Joint Registry during these difficult times.

I wish to reinforce Bill Darling's thanks to the HQIP staff, in particular Elaine Young, whose contribution to the NJR project has been very significant. My thanks are also extended to the NJR Steering Committee, Regional Clinical Co-ordinators and Northgate Information Solutions (UK) Ltd, in particular their Regional Co-ordinators, for all their hard work and valuable contributions.

Finally, thank you to all the orthopaedic surgeons for entering their data. Hopefully, the increasing feedback to surgeons will be found to be extremely useful and encourage them to continue entering their data.

Professor P J Gregg
Vice-Chairman, NJR Steering Committee

executive summary

Part 1: Annual progress

The 6th Annual Report of the National Joint Registry for England and Wales is the public report for the period 1st April 2008 to 31st March 2009 (Part 1). The report also includes sections on joint replacement activity for the period 1st January to 31st December 2008 (Part 2) and a survivorship analysis of hip and knee joint replacement surgery using data from 1st April 2003 to 30th November 2008 (Part 3).

Collection of data on hip and knee replacement operations for the NJR began on 1st April 2003 with the aim of providing information to all those involved in the management and delivery of joint replacement surgery and to patients. The over-riding purpose of providing this information is to improve the outcomes of care for patients and patient safety.

The NJR is managed by Northgate Information Solutions (UK) Ltd under a contract with the Healthcare Quality Improvement Partnership (HQIP) which took over responsibility for the overall management of the NJR from the Department of Health (DH) on 1st April 2008. The NJR Steering Committee, as an advisory non-departmental public body, continues to oversee the work of the NJR.

The NJR is funded through a levy raised on the sale of hip and knee replacement implants.

Part 1 of the report provides information about data quality and completeness, an overview of where operations have been undertaken and highlights of progress and plans.

The financial year 2008/09 saw:

- the highest ever number of submissions of hip and knee joint replacement operations in a single year, at 160,027. This represents 92.5% of all operations carried out in England and Wales in both the NHS and independent healthcare sector. It takes overall compliance with reporting to the NJR (from 1st April 2003 to 31st March 2009) to 78%
- the highest annual rate of records submitted with patient consent, at 87.5%; this means that of all records submitted to the NJR, 78% have patient consent
- the highest annual rate of records submitted with both patient consent and an NHS number, at 92.9%[1]; the overall rate of linkable records in the NJR is now 77.4%
- the total number of records submitted to the NJR (from 1st April 2003 to 31st March 2009) rising to 742,706, of which:
  - 64.8% took place in NHS hospitals
  - 26.6% took place in independent hospitals
  - 4.7% took place in NHS treatment centres
  - 3.9% took place in independent sector treatment centres (ISTCs).

Achievements for the year included:

- the launch in November 2008 of NJR Clinician Feedback, a secure online service that enables surgeons to assess their clinical practice and compare it to that of their colleagues at hospital, regional (strategic health authority), sector (NHS or independent) and national levels
- the first occasion on which an implant was withdrawn from sale by a supplier using information provided by the NJR's outlier analysis. Following a device alert issued by the Medicines and Healthcare products Regulatory Agency (MHRA), the NJR was able very quickly to identify patients who had received the implant and inform the relevant hospitals
- a review of the outlier methodology. Following implementation on NJR Clinician Feedback, it became clear that the method was difficult to understand and interpret. As previously agreed by the NJR Steering Committee, the statistical method used for the identification of outlying data will remain under continuous review and development

[1] This rate also includes those NHS numbers that were traced using the National Strategic Tracing Service (NSTS) after submission to the NJR.

- re-establishment of the NJR Editorial Board under the chairmanship of Martyn Porter, a consultant orthopaedic surgeon at Wrightington Hospital. The Editorial Board's role is to oversee the production of the Annual Report and, as an interim measure, to consider all research requests until a dedicated research infrastructure is established
- the planned commencement, on 1st April 2009, of a national Patient Reported Outcomes Measures study (PROMs) study which will include, among other operations, elective hip and knee joint replacement surgery. Working with the DH, the NJR Steering Committee has secured agreement that the data collected by the PROMs study will be linked to NJR data and be available for analysis by the NJR
- first steps of the strategic plan for the period 2009 to 2011, which will include:
  - a major programme to assess the quality of data held on the Register and projects to improve the quality of data submissions in the future. The NJR Steering Committee will continue to promote the case for making the NJR a mandatory data collection
  - implementation of a research protocol and infrastructure for handling the increasing requests for data, including re-establishment of the Research Committee
  - improved access to information for all stakeholders, including the development of services similar to NJR Clinician Feedback for suppliers and hospital and trust managers, as well as providing better information to patients
  - extending the NJR to include ankle, shoulder, elbow and wrist joint replacement surgery and collecting data from Northern Ireland
- agreement to undertake a number of studies throughout the year ahead, looking at data quality, re-revisions, hydroxyapatite (HA) coating, thromboprophylaxis and fractured neck of femur.

Part 2: Clinical activity 2008

Part 2 of the National Joint Registry (NJR) 6th Annual Report summarises the data and findings for hip and knee procedures carried out between 1st January 2008 and 31st December 2008 in England and Wales and entered into the NJR by 28th February 2009.

During 2008, 408 hospitals and treatment centres were active and, of these, 386 (95%) submitted at least one operative procedure to the NJR. The compliance rate for the calendar year 2008 was similar to the previous year (86%). This compares with 92.5% compliance for the financial year 2008/09.

On average, 185 hip replacements and 197 knee replacements were submitted per orthopaedic unit, although there was considerable variation around this mean.

The NJR recorded 71,367 hip procedures, which represents an increase of 3.6% compared to last year. Revision operations represented 9.2% of all hip procedures.

Of the 64,722 primary hip replacement operations undertaken in 2008, 38% were cemented total hip replacements (THRs), 33% cementless THRs and 14% hybrid THRs. Of the remainder, 8% were resurfacing and 7% were large head metal on metal procedures.

Despite the evidence of superior short term results for cemented THRs, there is an increasing trend away from fixation with cement. In 2004, 53% were cemented procedures, compared to 38% during 2008; there has been a corresponding increase in cementless operations from 21% in 2004 to 33% in 2008.

Patient demographics in terms of age and sex distribution have not changed substantially in 2008 compared to previous years. However, patients' health at the time of surgery appears to have deteriorated over the years, as indicated by the fact that 37% of patients were recorded as being fit and healthy prior to surgery in 2003 (ASA grade1)[2], compared to only 18% in 2008. Over the same time period, patients' body mass index (BMI)[3] increased from 27.8 to 28.3.

Patients' age and gender significantly influenced the fixation and type of replacement operation carried out. Male patients under 55 proportionally had more resurfacings compared with female patients over the age of 65, for whom cemented fixation predominated.

In 2008, 124 different brands of acetabular cups, 12 different brands of resurfacing cups and 137 different brands of femoral stems were recorded as being used in primary and revision procedures.

The Orthopaedic Data Evaluation Panel (ODEP)[4] ratings of prostheses used have been studied again. The full 10A benchmark rating was achieved in 76% of cemented stems, 77% of cementless stems, 49% of cemented cups, 11% of cementless cups and 19% of resurfacing cups. Some of the lower figures represent newer designs which have fewer than 10 years' clinical follow up.

Of the cemented hip stem brands, the Exeter V40 was the market leader, having approximately 60% of market share, and of cemented cups the Contemporary was the market leader.

With cementless brands, the Corail stem achieved 46% of the market, while the Pinnacle socket was market leader for uncemented fixation. For resurfacing, the Birmingham hip resurfacing maintained the market lead, albeit at a reduced level compared to previous years because of increasing competition.

Of the 6,581 hip revision procedures, 86% were carried out as a single operation; the remainder were either a single operation to remove the prosthesis or two separate operations (two stage revision).

The number of knee replacement procedures entered into the NJR during 2008 was 75,629 which represents an increase of 4.3% compared to 2007. Of these, 5% were revision operations.

[2] American Society of Anaesthesiology system for grading the overall physical condition of the patient, as follows: P1 – Fit and healthy; P2 – Mild disease, not incapacitating; P3 – Incapacitating systemic disease; P4 – Life threatening disease; P5 – Not expected to survive 24 hours.
[3] BMI: 20-25 normal, 25-30 overweight, 30-40 obese, > 40 morbidly obese.
[4] Orthopaedic Data Evaluation Panel of NHS Supply Chain. See ODEP ratings in Glossary.

Of the 71,527 primary knee replacements in 2008, 91% were of the total condylar type, 8% unicondylar and just over 1% patello-femoral replacements. Cement fixation was used in the vast majority of total knee replacements; in comparison with hips, this trend has not changed substantially over the last five years.

However, similar to hips, there was a relationship between type of replacement and fixation as a function of sex and age, with younger patients proportionally receiving more unicondylar replacements. Also similar to hip replacements were the trends in terms of patients' ASA grades and BMI.

The ODEP classification does not include knee replacements.

The PFC Sigma was the market leader for condylar type knee replacements and the Oxford for unicondylar designs.

In total 3,987 revision knee procedures were carried out in 2008, of which 74% were single stage revisions and the remainder were staged.

Part 3: Implant survivorship 2003 to 2008

Part 3 of the 6th Annual Report describes the clinical outcomes of hip and knee replacement surgery, represented by survivorship analysis up to a maximum period of five years. The results were analysed according to method of fixation, implant brand, age, gender and bearing surface. Where appropriate, regression analysis was used to estimate risk factors for revision, adjusted for case mix differences.

The analysis was carried out on a subset of all patients entered on the NJR database, which was linked to Hospital Episode Statistics (HES). As such, it describes almost exclusively NHS activity; the reasons for this are outlined further in the body of this Report.

Out of 557,661 hip and knee replacements entered on to the NJR between April 2003 and November 2008, 324,404 were linked to the HES database and identified as being primary procedures. Of these, 157,232 were primary hip replacements and 2,464 were first hip revisions. The corresponding figures for knees were 167,172 primary knee replacements and 3,061 first knee revisions.

The most important difference for this Annual Report is that the revisions were identified not only on the HES database but also as subsequent registrations on the NJR database. Out of the 2,464 first hip revisions, 944 were identified in HES and NJR, 1,188 only in HES and 332 only in the NJR. These numbers emphasise the importance of using both databases in order to pick up as many as possible of the revisions that actually occur. The linkage between the two databases facilitates the debate on data quality.

Corresponding figures for the 3,061 first knee revisions were 1,220 in HES and NJR, 1,466 only in HES and 375 only in the NJR.

Using these methods has increased the number of hip revisions identified by almost 200% and the number of knee revisions by 300%. The corresponding three year revision rates were approximately 65% higher for hips and 100% higher for knees compared to last year's report.

The overall revision rates (with 95% confidence intervals) following primary hip replacement were 1% (0.9% - 1%) at one year, 2% (1.9% - 2.1%) at three years and 2.8% (2.7% - 3%) at five years.

The three year revision rates were 1.3% with a cemented hip prosthesis (1.2% - 1.4%), 1.9% with hybrid prosthesis (1.7% - 2.1%), 2.8% with cementless prosthesis (2.6% - 3.0%) and 4.5% with hip resurfacing (4% - 5%).

With the exception of hip resurfacing, elderly patients had lower revision rates following primary hip replacement than younger patients. Women had lower revision rates than men. For resurfacings, these trends were reversed and revision rates were higher for elderly patients and women.

Revision rates following primary hip replacement were found to vary according to brand. No adjustments have been made for other 'case mix' variables in these analyses.

For cemented stems, the most commonly used cemented stem, the Exeter V40, had a revision rate of 1.3% at three years. The revision rates of the other cemented stems ranged from 1.0% to 2.2%.

For uncemented stems, the Corail, the most commonly used uncemented stem had a revision rate of 2.6% at three years. The revision rates of the other cementless stems ranged from 1.9% to 3.8%.

For cemented cups, the Contemporary, which was used most frequently, had a three year revision rate of 1.3%. The revision rates of the other cemented cups ranged from 0.4% to 2.2%.

For uncemented cups, the Pinnacle, which was used most frequently, had a three year revision rate of 2.2%. The revision rates of the other uncemented cups ranged from 1.1% to 2.8%.

A number of these prostheses were implanted in relatively small numbers and, despite the differences in revision rates and hazard ratios, the 95% confidence intervals sometimes overlapped, indicating that not all these differences were statistically significant. Therefore, care needs to be taken when interpreting this data.

In comparison, there was only weak evidence that the revision rate following primary hip replacement (excluding resurfacing procedures) varied according to the bearing surface.

The overall revision rate following primary knee replacement was 0.7% (95% confidence interval 0.6% - 0.7%) at one year, 2.5% (2.4% - 2.6%) at three years and 3.7% (3.5% - 3.9%) at five years.

The three year revision rates were 2.1% with cemented knee replacement (2.0% - 2.2%), 2.4% with cementless knee replacement (2.1% - 2.9%) and 2.9% with hybrid prosthesis (2.2% - 3.9%).

The three year revision rate for unicondylar replacement was 7.2% (6.6% - 7.9%) and 8.3% for patello-femoral replacement (6.6% - 10.5%). The three year revision rate for unicondylar replacement has significantly increased from previous NJR reports as a result of the change in methodology and greater capture of revision operations. It is possible that other data quality issues may have distorted this figure and caution should be exercised when interpreting the results at this stage of the NJR.

Revision rates following primary knee replacements were lower in elderly patients. Compared to women, men had higher revision rates for cemented and hybrid prostheses but lower revision rates for unicondylar and patello-femoral replacements. Unicondylar knee replacements or patello-femoral replacements increased the risk of revision most strongly in women.

Once again, revision rates varied according to brand. Of the total condylar brands, the most commonly used, the PFC Sigma, had a three year revision rate of 1.7%. Of the other condylar brands, the revision rates ranged from 0.4% to 8.0%.

Of the unicondylar replacements, the Oxford was used most frequently. It had a three year revision rate of 6.9%. Only two other unicondylar replacements were used in any volume. The MG Uni had a revision rate of 4.5% and the Preservation had a revision rate of 12%.

The Avon was the most frequently used patello-femoral joint. It had a three year revision rate of 6.9%.

The NJR is work in progress and methods for data management and analysis are continuously being updated. The most important change this year lies in the methods used to identify revisions.

The results describe NHS activity carried out in the NHS and independent sector. The analysis does not include privately funded surgery carried out in independent hospitals and, because of lack of availability of Patient Episode Database for Wales (PEDW) data, neither does it presently describe practice in Wales.

part 1
annual progress

1.1 introduction

1.1.1 Annual Report

This report is the 6th Annual Report of the National Joint Registry (NJR) for England and Wales. The NJR collects data on hip and knee joint replacement surgery in England and Wales from both the NHS and independent sector. The information published in this report is of use to patients, clinicians, the orthopaedic implant industry and hospital and trust management. The data is collected in order to provide a broad range of stakeholders with information that will lead to an improvement in the outcomes of joint replacement surgery and in patient safety.

The report is divided into three main parts:

- **part 1** - a general outline of the NJR's work for the financial year 1st April 2008 to 31st March 2009; providing summary statistics of the data recorded during the year, summarising major developments and outlining proposed work for the financial year 2009/10
- **part 2** - a description of joint replacement activity as reported to the NJR in the calendar year 1st January to 31st December 2008
- **part 3** - an analysis of survivorship of hip and knee replacement surgery using data submitted to the NJR from 1st April 2003 to 30th November 2008, including data from the Hospital Episodes Statistics (HES) service.

1.1.2 The National Joint Registry

The National Joint Registry (NJR) was established in October 2002 and began collecting and studying data on hip and knee replacement operations in April 2003. The aim of the Registry is to provide information to all those involved in the management and delivery of joint replacement surgery with regard to surgical and implant performance and clinical best practice. This includes the regulatory authorities such as the Medicines and Healthcare products Regulatory Agency (MHRA) and the Care Quality Commission (CQC). Central to the provision of this information is the aim of improving patient outcomes and patient safety.

In order to achieve its aims, the NJR requires a continuous supply of high quality and accurate data with maximum coverage. It is only with good quality data that the long term monitoring of the effectiveness of hip and knee joint replacement surgery can be achieved. By 31st March 2009, the NJR held information on approximately 743,000 individual operations undertaken in England and Wales. Data quality is important because it affects the level and quality of monitoring and analyses that can be undertaken.

1.1.3 Management and funding

The NJR has been managed by Northgate Information Solutions (UK) Ltd since April 2006, under a contract with the Healthcare Quality Improvement Partnership (HQIP)[5], and is funded through a levy raised on the sale of hip and knee replacement implants.

From 1st April 2008, the responsibility for the management of the NJR transferred from the Department of Health (DH) to HQIP and is now included within the National Clinical Audit and Patient Outcomes Programme. The NJR Steering Committee continues to oversee the strategic direction and running of the Registry. The NJR Steering Committee is an advisory non-departmental public body; the current list of members and their declarations of interest can be found in Appendix 1 and on the NJR website.

[5] For more information about HQIP, visit the website at **www.hqip.org.uk**

part 1

1.2 data completeness and quality

1.2.1 Key indicators

The completeness and quality of data submitted to the NJR Centre is measured using three key indicators:

- compliance - the rate, expressed as a percentage, of operation records submitted to the NJR compared with the number of operations actually carried out
- consent - the number of records submitted, for which the patient has agreed to their personal data[6] being stored on the NJR database
- linkability - the number of records submitted with consent and with the patient's NHS number. The NHS number is required to link all primary and revision operations relating to a single patient.[7]

Performance against the key indicators has continued to improve year on year, although this does require the provision of continual support to orthopaedic units to either maintain or improve performance levels. Detailed figures and trends are shown below.

1.2.2 Performance against key indicators

Progress against the three measures of compliance, consent and linkability for the financial year 2008/09 was as set out below.

Compliance

All NHS trusts and NHS foundation trusts are expected to submit details of all hip and knee joint replacement operations to the NJR; the data collection is mandatory for all independent hospitals and independent sector treatment centres (ISTCs). Compliance is measured by comparing the number of submitted records to the number of levies raised through the sale of implants. For NHS organisations, compliance can also be measured by comparing submission to the NJR with records submitted to HES and its Welsh equivalent, the Patient Episode Database Wales (PEDW).

Figure 1.1 shows the total compliance rates achieved over the last five years. The figures are derived from a comparison of the number of procedures reported to the NJR with the number of levies raised through implant sales. The compliance rate has shown a steady upwards trend since 2004, although the rate of 92.5% for 2008/09 is a slight drop from that reported in the previous year (95.6%).

This drop is most likely due to large variations in the quarterly rates recorded in 2007/08; one quarter showed 120% compliance, which may have resulted in the reporting of a slightly inflated compliance rate last year. The drop may also have been compounded by a significant increase in the number of implant purchases reported in March 2009, which was not matched by a corresponding increase in the amount of reported procedures. In 2008/09 the quarterly compliance rates have been more consistent and show a quarter on quarter increase throughout the year. The overall compliance rate from 1st April 2003 to 31st March 2009 is 78.0%.

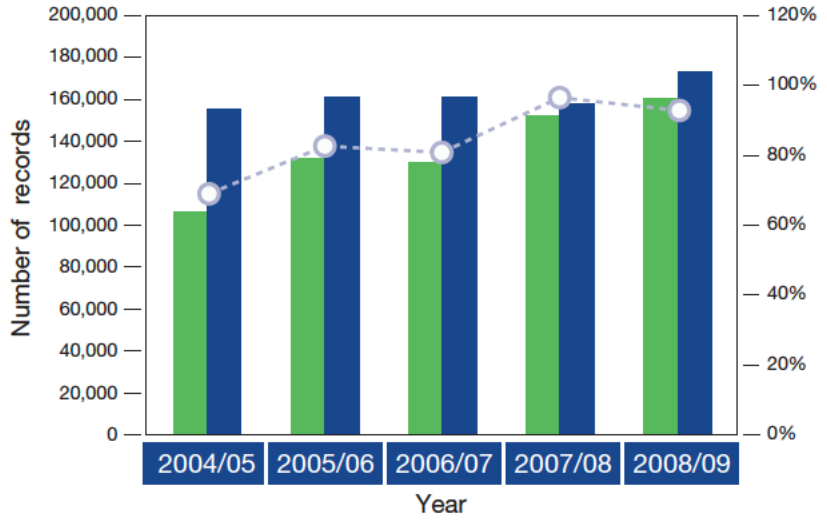


Figure 1.1

NJR Compliance: 2004 – 2009, based on levies from implant sales.

Source: Operations entered on NJR 1st April 2004 – 31st March 2009 and levy submissions to NJR by implant suppliers and manufacturers.[8]

Number of operations

Levy

Compliance (%)

[6] Personal data includes NHS number, surname, date of birth and postcode.
[7] NJR data is submitted for NHS number tracing; the linkability figure includes NHS numbers that were traced subsequent to the operation details being submitted to the NJR.
[8] The supporting data for Figures 1.1 to 1.8 are to be found on the NJR Annual Report website.

The NJR publishes figures for each hospital via its NJR StatsOnline service on its website. Patients, clinicians and managers are able to view the contribution being made by their hospital to the NJR and, ultimately, to improving patient outcomes and safety. Compliance varies widely, with some orthopaedic units failing to submit any records. Table 1.1 shows the hospitals which undertake elective hip and knee joint replacement surgery but did not submit any data to the NJR for the year 1st April 2008 to 31st March 2009.

Table 1.1 List of non-returning units, 2008/09.

Trust	Hospital
Barking, Havering and Redbridge Hospitals NHS Trust	Queens Hospital*
Bromley Hospitals NHS Trust	Orpington Treatment Centre Princess Royal University Hospital
Dartford and Gravesham NHS Trust	Darent Valley Hospital
Guy's and St Thomas' NHS Foundation Trust	Guy's Hospital* Guy's Nuffield House St Thomas' Hospital
Homerton University Hospital NHS Foundation Trust	Homerton University Hospital
Leeds Teaching Hospitals NHS Trust	Leeds General Infirmary Chapel Allerton Hospital
Mid Essex Hospital Services NHS Trust	Broomfield Hospital*
Orthopaedics and Spine Specialist Hospital	Orthopaedics and Spine Specialist Hospital
Salford Royal NHS Foundation Trust	Hope Hospital
University College London Hospitals NHS Foundation Trust	University College Hospital*
University Hospital of South Manchester NHS Foundation Trust	Wythenshawe Hospital*

**These hospitals began submitting data in May 2009*

Consent

The NJR requires consent from patients in order to be able to store their personal details including their NHS number. Without patient consent, any patient will be lost to the follow up system, which means it is not possible to link any previous or subsequent operations to the same patient. Low rates of consent would result in the NJR failing to meet its aims. Consent rates for each hospital are published via NJR StatsOnline.

The NJR has three ways of recording consent: 'Yes', 'No' and 'Not recorded'. Support has been granted under Section 251 of the NHS Act 2006 enabling the NJR to record details of patients where 'Not recorded' is indicated. It is possible that this exemption will be withdrawn in 2009, therefore it is essential to reduce the total number of submissions with consent 'Not recorded'. The total of such records was 14,400 last year alone. Patients, when asked, rarely refuse consent and the failure to record it is usually the result of inadequate processes within the hospital and the consent form not being available to the person entering the data.

Figure 1.2 shows the steady increase in the recording of patient consent over the five years of the NJR. Consent for 2008/09 was 87.5%, an increase from 2007/08 (84.4%). The consent rate for all operations submitted to the NJR from 1st April 2003 to 31st March 2009 is 78.0%.

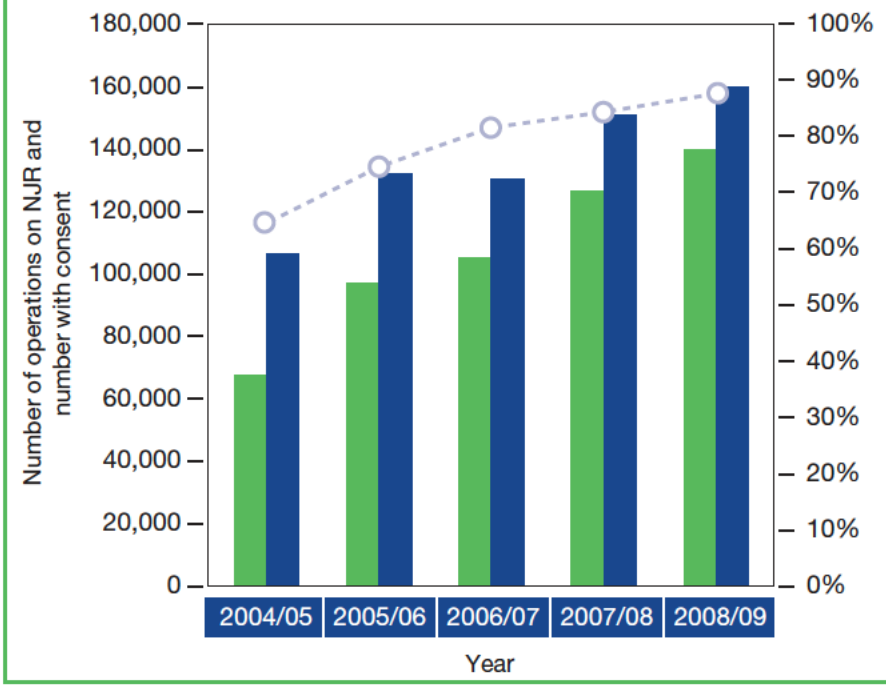


Figure 1.2

NJR Consent: annual analysis of total records received and those with patient consent, 2004 – 2009.

Source: Operations entered on NJR 1st April 2004 - 31st March 2009.[9]

Linkability

The ability to link all operations relating to an individual patient is essential to the monitoring of the performance of implants and surgery. The linkability rate refers to the percentage of operations submitted that have both positive patient consent and an NHS number recorded. Low rates of linkability adversely affect the NJR's ability to monitor surgical and implant performance.

The percentage of linkable records submitted to the NJR from 2004/05 to 2008/09 is shown in Figure 1.3. The linkability rate for 2008/09 was 92.9% compared to 90.1% for 2007/08. The overall linkability rate for the NJR database is 77.4%.

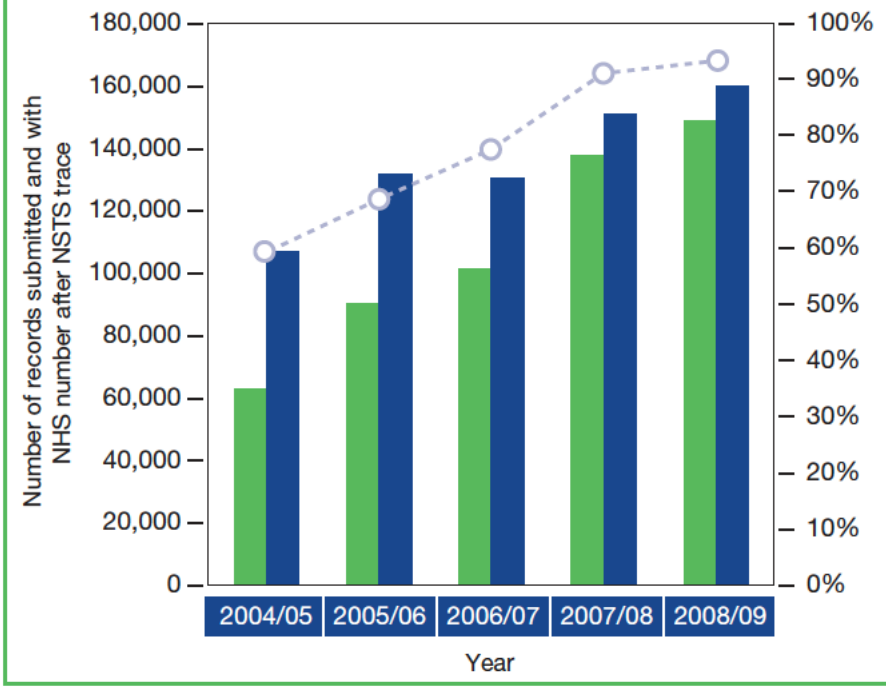


Figure 1.3

NJR Linkability: analysis of total records received and those for which NHS numbers have been traced, 2004 – 2009.

Source: Operations entered on NJR 1st April 2004 – 31st March 2009.[9]

[9] The supporting data for Figures 1.1 to 1.8 are to be found on the NJR Annual Report website.

part 1

1.3 key figures

1.3.1 Operation totals

The total number of procedures reported to the NJR between 1st April 2003 and 31st March 2009 is 742,706. The year in view saw the largest number of submissions for any year (160,027).

Figure 1.4 shows the total number of operations recorded on the NJR in England and Wales each year from 2004/05 to 2008/09. For the third year in a row, the number of knee replacement operations (82,419) exceeds the number of hip replacement operations (77,608).

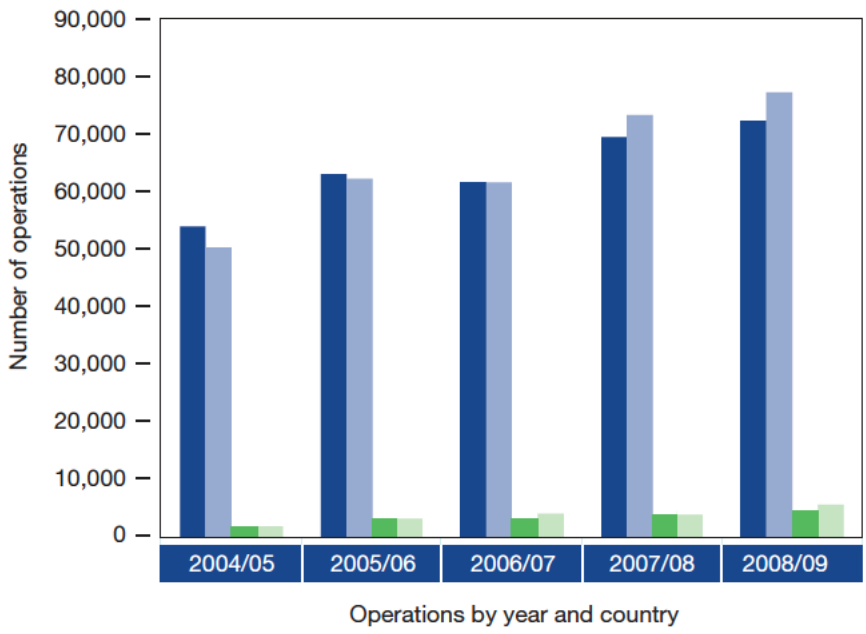


Figure 1.4

Total hip and knee joint replacement operations entered on the NJR, 2003/04 – 2007/08, recorded by country in which the operation took place.

Source: Operations entered on NJR 1st April 2004 – 31st March 2009.[10]

Operation types

The NJR has records for three different types of hip and knee joint replacement procedures:

- primary – the first time a joint is replaced
- revision – an operation that involves the removal and replacement of one or more components of a joint replacement
- re-operation other than revision – an operation following either a primary or revision operation that does not require any joint implants to be removed or replaced, for example a wound debridement (wash out)[11] .

Figure 1.5 shows the number of operations reported by type from 1st April 2004 to 31st March 2009. Primary operations continue to represent the most reported procedures (92.2%). The difference in the number of knee primary operations and hip primary operations has continued to increase in favour of the former (1.9% more as a proportion in 2005/06, compared to 4.8% in 2008/09).

[10] The supporting data for Figures 1.1 to 1.8 are to be found on the NJR Annual Report website.

[11] Re-operation information was not collected in the first version of the NJR's Minimum Dataset (MDSv1), from 1st April 2003 to 31st March 2004. It was included in MDSv2, from 1st April 2004, but removed from MDSv3 which came into use on 1st December 2007. However, some units are continuing to use MDSv2, which is why some re-operations continue to be reported. The figures are included for completeness only.

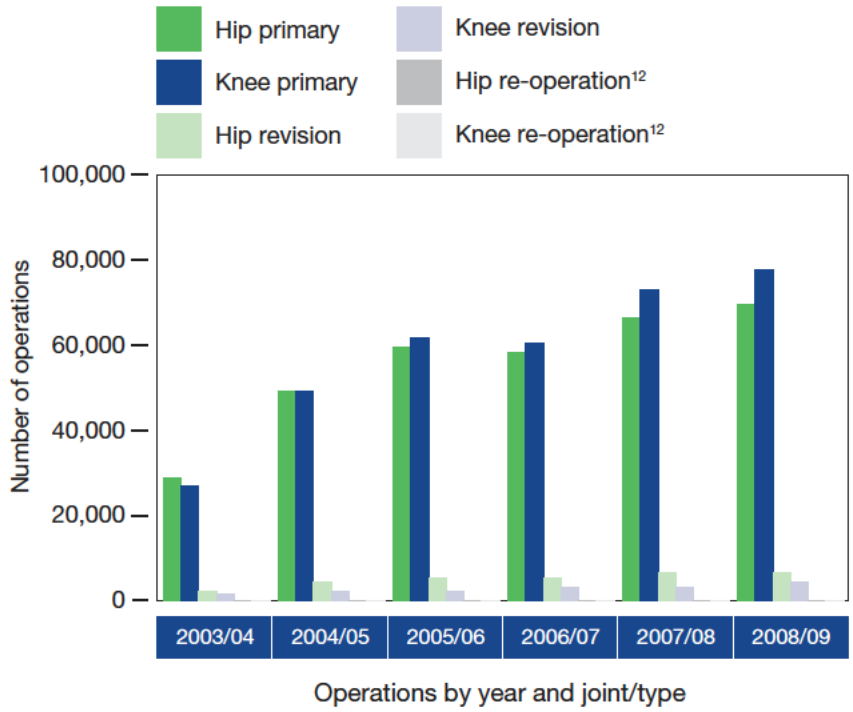


Figure 1.5

Type: hip and knee joint replacement operations entered on the NJR, 2003/04 – 2008/09, recorded by type of operation.

Source: Operations entered on NJR 1st April 2004 – 31st March 2009.[13]

Where the operations took place

Of the 742,706 operations submitted to the NJR since it started to collect data, 94.9% were carried out in England and 5.1% in Wales. In 2008/09, 149,400 (93.4%) operations were carried out in England, compared to 10,627 (6.6%) in Wales.

There are four types of organisations in England carrying out hip and knee joint replacement surgery:

- NHS hospital
- NHS treatment centre
- independent hospital
- independent sector treatment centre (ISTC).

There are no NHS treatment centres or ISTCs in Wales.

Overall, for the period 1st April 2003 to 31st March 2009, 480,743 (64.8%) of submitted operations took place in NHS hospitals in England and Wales, 197,877 (26.6%) in independent hospitals, 35,053 (4.7%) in NHS treatment centres and 29,030 (3.9%) in ISTCs. The proportion of operations by provider type is shown in Figure 1.6.

[12] NJR data is submitted for NHS number tracing; the linkability figure includes NHS numbers that were traced subsequent to the operation details being submitted to the NJR.
[13] The supporting data for Figures 1.1 to 1.8 are to be found on the NJR Annual Report website.

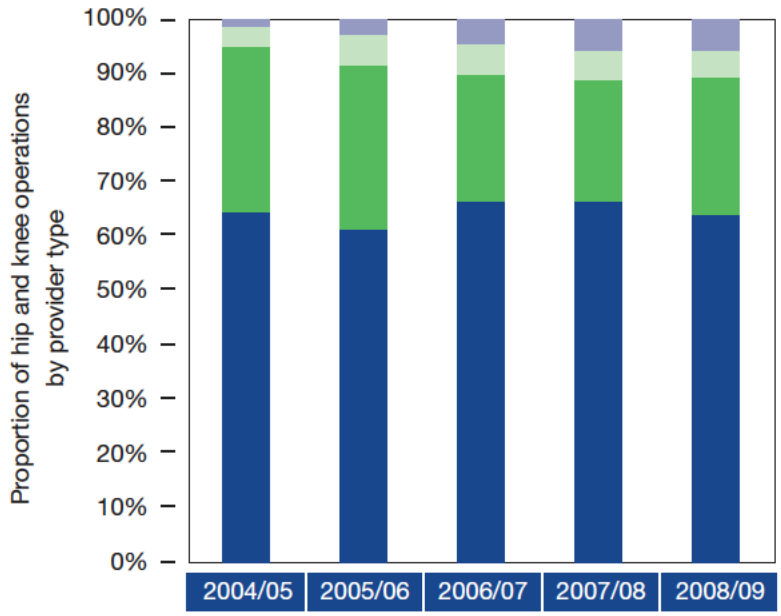


Figure 1.6

Proportion of reported operations by provider type entered on the NJR, 2004/05 – 2008/09.

Source: Operations entered on NJR 1st April 2004 – 31st March 2009.[14]

The proportion of procedures undertaken in NHS treatment centres and ISTCs has remained similar to that reported last year, while there has been an increase of 2.6% in the proportion of procedures in independent hospitals compared to a 2.4% decrease in NHS hospitals.

Figure 1.7 shows the proportion of hip replacement operations reported to the NJR by provider type.

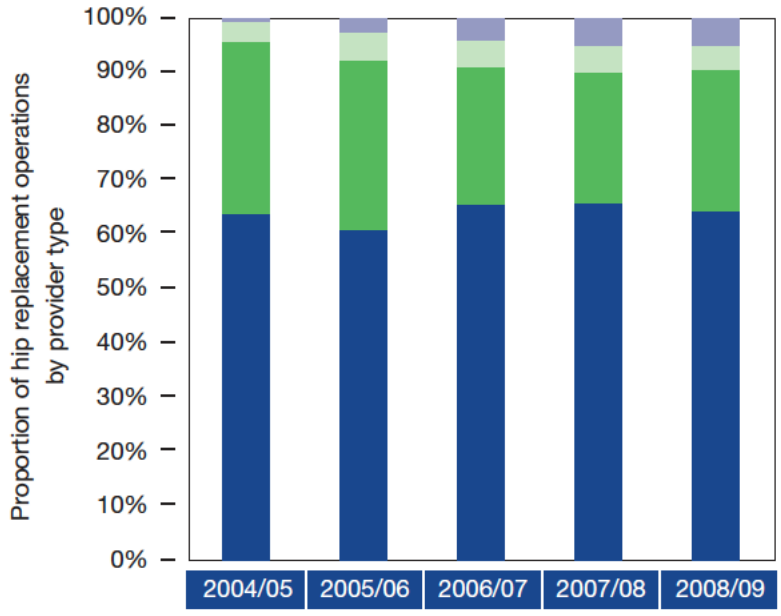


Figure 1.7

Proportion of hip replacement operations by provider type.

Source: Operations entered on NJR 1st April 2004 – 31st March 2009.[14]

[14] The supporting data for Figures 1.1 to 1.8 are to be found on the NJR Annual Report website.

The proportion of hip replacement operations undertaken in NHS treatment centres and ISTCs has remained similar to that reported last year, although there has been a slight increase in the proportion of operations carried out in independent hospitals (2.1%). The proportion of hip operations undertaken in NHS hospitals has decreased slightly from that reported last year (1.8%).

Figure 1.8 shows the proportion of knee replacement operations reported to the NJR by provider type.

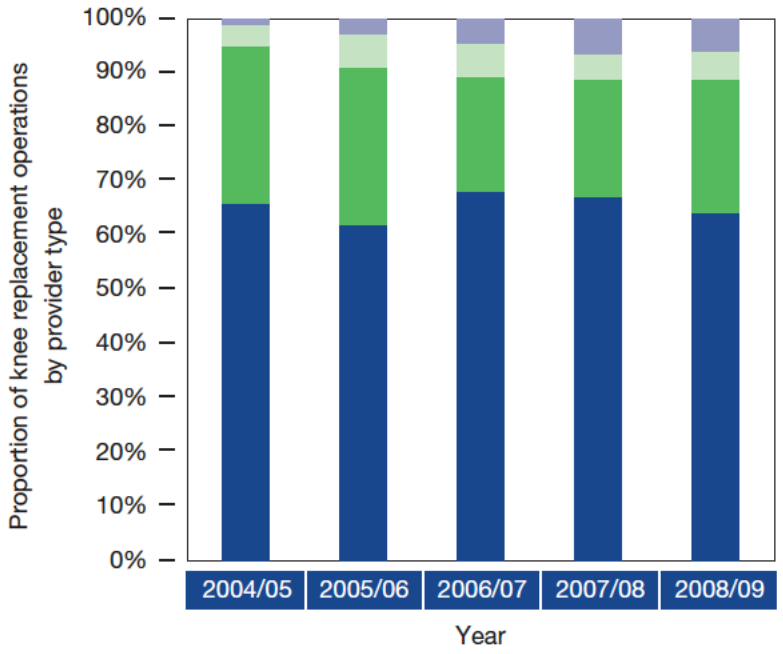


Figure 1.8

Proportion of knee replacement operations by provider type.

Source: Operations entered on NJR 1st April 2004 – 31st March 2005.[15]

The proportion of knee replacement operations undertaken by the four major provider types reported this year has seen changes similar to those reported for hip operations. The proportion of knee operations undertaken by NHS treatment centres and ISTCs has remained similar to that reported last year, with a reported increase of 3% in independent hospitals compared to a 3% decrease in NHS hospitals in England and Wales.

[15] The supporting data for Figures 1.1 to 1.8 are to be found on the NJR Annual Report website.

part 1

1.4 progress and plans

1.4.1 NJR Clinician Feedback

Following feedback from the Annual Meeting of the British Hip Society in February 2008, a set of requirements for NJR Clinician Feedback was prepared for, and approved by, the NJR Steering Committee. The service was demonstrated at the British Orthopaedic Association (BOA) Annual Congress in September 2008 and launched in November 2008. It enables surgeons to assess and compare their clinical practice at a hospital, regional, sector (NHS or independent) and national level. It is a secure, web-based service accessed via the internet.

The service is provided for surgeons only and provides them with a view of their early results. The relatively low numbers reported for each surgeon, along with inconsistent compliance rates and case mix variables, can skew the results and could lead to incorrect conclusions being drawn about a surgeon's overall practice. For this reason alone, the figures have not been made publicly available.

The service consists of a number of different reports, most of which can be filtered to adjust for case mix. Figures 1.9 and 1.10 give two sample screen shots.

Figure 1.9

NJR Clinician Feedback: primary procedure hip report.

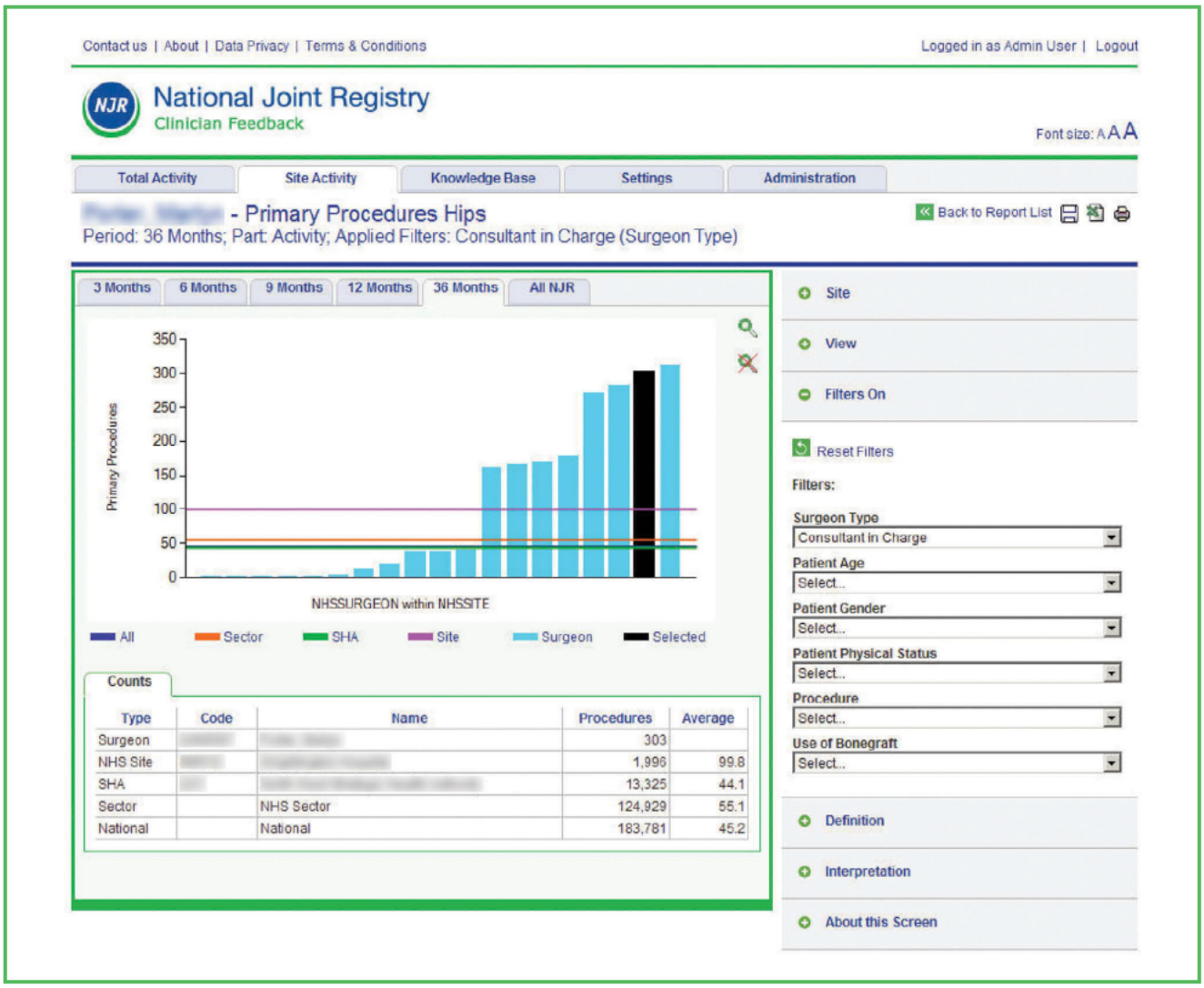


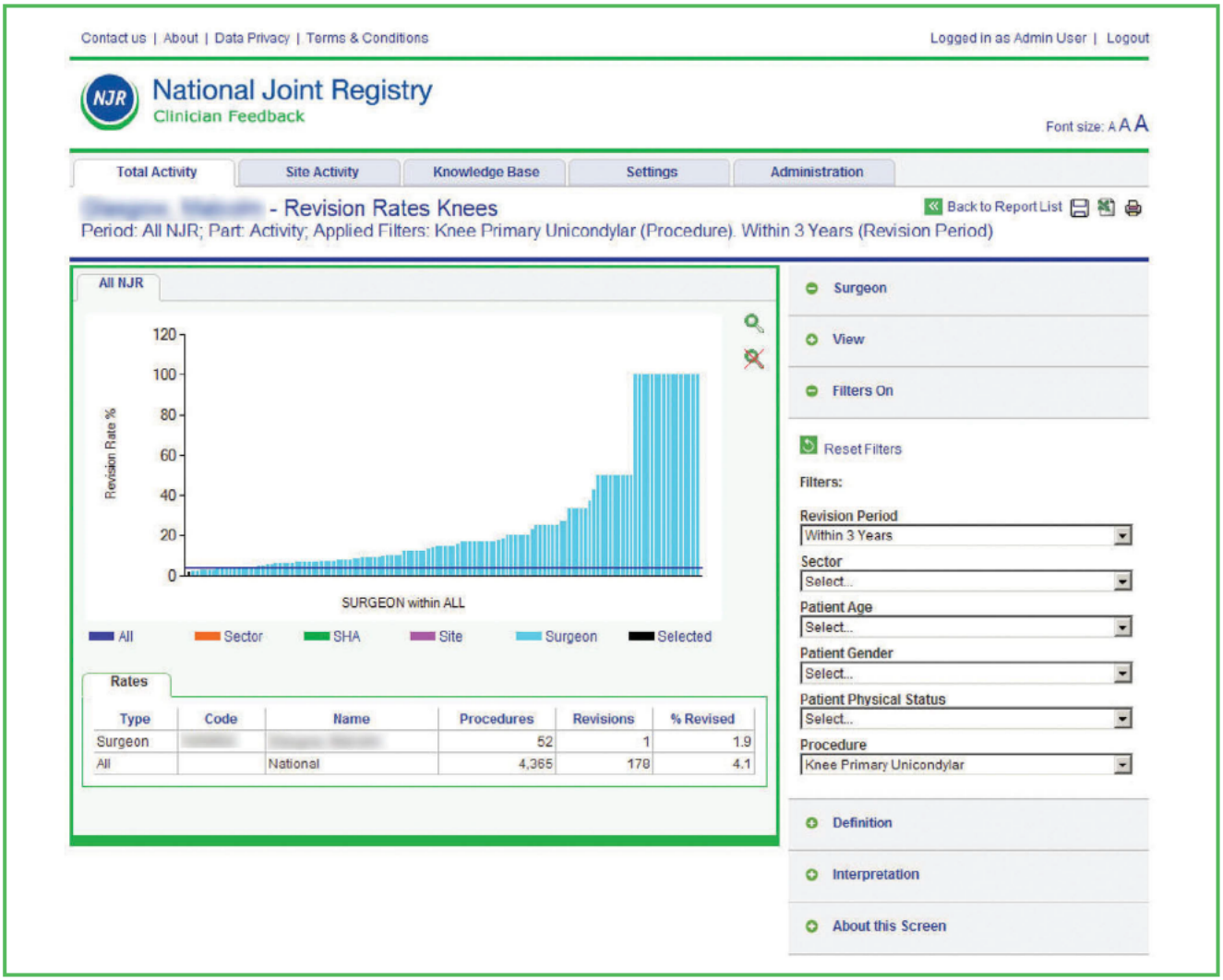
Figure 1.9 shows the number of primary hip procedures undertaken by a consultant in the last 36 months in an NHS hospital. The report shows all the surgeons registered in that hospital, with the surgeon's own figures represented by the black bar. Also shown are the averages for all surgeons at hospital, strategic health authority, NHS and national level. The reports can be filtered by case mix variables and, while the filters are shown in the screen shot, none have been applied. All reports include the actual figures.

Figure 1.10 shows the most recent report to be added to the service; the revision rate report. This example shows a three year revision rate for primary unicondylar knee. The procedures considered are those that have been in the database for a minimum of three years. The total of revisions includes those for which the revising surgeon was not the same as the primary procedure surgeon. The report accounts for where the primary procedure took place, which means it provides more accurate information than some other published sources.

This figure shows the effect of low numbers; the high revision rates shown are due to a low number of procedures being submitted. This particular report could be run at a hospital level or comparing orthopaedic units within a strategic health authority region, which may be more meaningful to patients.

Figure 1.10

NJR Clinician Feedback: three year revision rate report for primary unicondylar knee.



It is intended to continue to increase the number and type of reports available through the NJR Clinician Feedback service and to include data from HES and PEDW. This would enable additional reports to be included, such as incidences of dislocation, venous thromboembolic events, mortality and length of stay.

1.4.2 Investigating outlier data - implants

The MHRA issued a device alert on an individual implant which has subsequently been withdrawn from sale by the manufacturer. This is the first time that the withdrawal of a product has been precipitated by the use of NJR data. Having identified a potential problem, the NJR was able to provide the MHRA with the data necessary for its joint investigation with the manufacturer.

Once the decision to issue a device alert had been made, the NJR was very quickly able to identify those patients who had received the implant, where the procedure had been reported to the NJR, and inform the appropriate hospitals. This action significantly reduces the period between the identification of a problem and the clinical review of the patient.

1.4.3 Investigating outlier data - surgeons

Similar to the handling of potentially outlying implant data, there are two distinct parts to the process for surgeons: identifying outlying data in the first instance and investigating to establish whether or not there is outlying performance.

When setting up the process for identifying outlying data, the NJR Steering Committee agreed that the statistical method would be subject to continuous review. Following implementation of the agreed method through the 'patient time incidence rate report' on NJR Clinician Feedback, it quickly became clear that a detailed knowledge and understanding of statistical methods was required to interpret the report. As a result, the Steering Committee decided that the existing method should be reviewed and the report on NJR Clinician Feedback was disabled. Once the review has been completed, the revised method will be published and the report reinstated.

The process for investigating outlier data was agreed by the Steering Committee, following wide consultation, and promulgated via the BOA and other professional societies.

1.4.4 Establishment of the NJR Editorial Board

The NJR Steering Committee agreed to the re-establishment of the NJR Editorial Board to oversee the production of the Annual Report. With the amount of data now available and the limited amount of time available for analysis, it is essential that clinical and epidemiological expertise is involved as early as possible. This includes agreeing and specifying the work at the outset and reviewing the outputs as soon as they are available. The Editorial Board is chaired by Mr Martyn Porter.

1.4.5 Patient Reported Outcome Measures (PROMs)

The Department of Health has contracted for a national PROMs study for four surgical treatments: hip replacement, knee replacement, varicose veins and groin hernia. The NJR Steering Committee was involved with the Department at an early stage, offering support and developing an understanding of how the NJR might benefit from working closely with the study. As a result of that involvement, it has been agreed that the NJR will be able to access data from PROMs to link it into the NJR database.

While recognising that a single, six month follow up does not meet the NJR's wish for a longer term study, it nevertheless represents a significant step towards providing more detailed information on the outcomes of knee and hip replacement surgery from the patient's perspective. In recognising the value of patient outcomes based studies, the NJR Steering Committee has agreed to part fund the national study. One of the aims of the NJR's strategic plan (section 1.4.6) is to use the national PROMs data to undertake its own, longer term PROMs study, with patients being followed up at defined points over a number of years[16].

[16] For patients, more information about the national PROMs study can be found on the NHS Choices website at **www.nhs.uk** and, for service providers, more information is available at **www.northgate-proms.co.uk**

The contract for the national PROMs study was let in three parts. The first and second parts (data collection and data aggregation) were awarded to Northgate Information Solutions (UK) Ltd and the third part (data analysis) was awarded to Market and Opinion Research International Ltd (MORI). The data analysis will be completed by the Royal College of Surgeons Clinical Effectiveness Unit which partnered with MORI during the bidding process.

1.4.6 Strategic plan

During the year in view the NJR Steering Committee began the development and implementation of a strategic plan for the next two years (2009 to 2011), which focuses on the following broad areas outlined below.

- **Data quality and improvement**. In order to achieve its aims and objectives and meet the needs of its many stakeholders, the NJR requires good quality data. A programme to assess and monitor the quality of submitted data is under consideration. Its function would need to include providing a clear statement about data quality and regular data quality reports to orthopaedic units. Seeking agreement to make the NJR a mandatory data collection for all NHS trusts and NHS foundation trusts is a key element of this programme.
- **Research and studies**. The number of requests for information and data from the NJR has increased significantly over the last year. A protocol is being developed for handling research requests and facilitating and streamlining the process by which data is made available for studies, whether they are funded by the NJR or third parties. The strategic plan identifies the need for a supporting infrastructure to manage the research protocol. It recommends re-establishment of the NJR Research Committee to consider all requests and advise the Steering Committee on the direction and priorities for NJR research.
- **Improved information**. With six years of data now recorded, it is recognised that the NJR should make information more readily available to stakeholders on a more frequent basis, rather than relying on traditional means of communication such as the Annual Report and newsletters. Services similar to NJR Clinician Feedback, aimed at implant manufacturers and suppliers, hospital management and service commissioners, are being considered. So, too, are proposals to publish information and data currently included in the Annual Report more frequently on the NJR website. In order to provide more information to patients about joint replacement surgery in England and Wales, the NJR has begun collaboration with NHS Choices.
- **Extending the NJR**. In order to extend the scope of the NJR with regard to the types of joint replacement covered, preliminary work commenced in early February 2009 to enable the collection of data about ankle joint replacement surgery. It is hoped that elbow and shoulder joint replacement surgery will also be included in the data collection within the next 12 months. Initial meetings have taken place to pave the way for the inclusion of data from Northern Ireland.

1.4.7 Specialist studies

A number of different studies on specialist topics are planned for the year ahead, as outlined below.

- **Data quality**. Initially, three approaches are being pursued.
  - First, a 'capture-recapture analysis' to estimate the completeness of follow up. This type of analysis allows us to estimate how many revisions may have been missed in the HES and NJR databases. Initial results from this analysis indicate that the revision rates continue to be underestimated by at least 15%.
  - Secondly, a large study will examine the records held by the NJR compared to the forms filled in, and the patients' notes for primary hip and knee replacements. Similarly, the records of patients undergoing revision hip and knee replacements according to the NJR and HES will be compared for accuracy.
  - Thirdly, the patients' physical status (ASA scores 1 to 5) as reported to the NJR will be compared with HES information on co-morbid conditions, based on admissions in the year preceding the hip or knee replacement. Subsequent checks against medical records are planned, especially for patients for whom contradictory information is held by the HES and NJR.

- **Re-revisions.** An investigation to establish how many patients have a revision after the first revision of their hip or knee replacement. It will cover the re-revision rate, mortality, operative procedures and brands of implant.
- **Hydroxyapatite (HA) coating.** A study of the impact of HA coating on revision rates after hip replacement using a cementless prosthesis. It will consider patient characteristics and the procedures used during the operation.
- **Thromboprophylaxis.** This treatment is intended to prevent venous thromboembolic events (VTEs), such as deep vein thrombosis and pulmonary embolism, following joint replacement surgery. It can involve a combination of chemical and physical methods such as thrombo embolus deterrent (TED) stockings. The study will look at the methods of thromboprophylaxis and their impact on mortality, VTE and bleeding.
- **Fractured neck of femur.** An examination of the outcomes of total hip replacement in patients who have suffered a fracture to the neck of the femur. Revision rates, mortality and length of stay will be considered in relation to patient characteristics, procedures and types of implant used.

1.4.8 Governance and support

The NJR is involved with a large and diverse number of stakeholders, all of whom benefit from its work. A comprehensive list of these stakeholders can be found on the NJR website.

Steering Committee

The NJR Steering Committee met four times during 2008/09; the minutes of its meetings are published on the NJR website. Its current members were appointed by the Appointments Commission on behalf of the Secretary of State for Health following a formal recruitment process. For a current list of NJR Steering Committee members and their declarations of interest, see Appendix 1 or visit the NJR website.

Regional Clinical Co-ordinators' Network

The NJR Regional Clinical Co-ordinators' (RCCs) Network consists of 23 consultant orthopaedic surgeons who act as local 'champions' for the service and support the work of the Steering Committee and Regional Co-ordinators. The RCC Network Chair is Mr Peter Howard. Further information about the Network and its members can be found on the NJR website.

Regional Co-ordinators

The NJR Centre has six Regional Co-ordinators and it plans to recruit a further two. Their role is to provide on-site support to hospitals. Contact details for the Regional Co-ordinators and information about their areas of responsibility are available on the NJR website.

Information and communication

The NJR has continued to communicate regularly with all stakeholders. A review of its communications strategy is planned for the year ahead. While publications have included the 5th Annual Report, Joint Approach newsletters, patient information leaflets and material on the website, it is recognised that more information needs to be provided to different audiences and in formats that are appropriate and easily understood.

Representatives of the NJR Centre have attended various conferences and events, including the British Orthopaedic Association (BOA) Annual Congress and the annual meetings of the British Hip Society, British Association of Surgery of the Knee and Society of Orthopaedic and Trauma Nursing. NJR staff have continued to hold regional workshops and training in hospitals.