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Implant Use for Primary Hip and Knee Arthroplasty
Are We Getting It Right First Time?

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ABSTRACT

Implants used for hip and knee arthroplasties have recently come under increased scrutiny. In England, a large variety of prostheses are currently being used. With the need for savings within the NHS of up to £20 billion over the next five years, we should be 'getting it right first time' by using the most reliable implants with proven survivorship. The 8th Annual Report from the NJR (2011) reporting on prostheses used in 2010 was analysed to determine whether implants had published survivorship data. This study demonstrates that the majority of implants did have long-term results but a small percentage had no published data. The cost of these implants was calculated to see if the implants provided best value for money based on survivorship. Implant choice was also correlated to revision rates published in the NJR report (2011) to help determine whether their continued use was justified.

Primary total hip and knee arthroplasties are common elective orthopaedic procedures, which have been shown to be successful in terms of restoring function and relieving symptoms of end stage arthritis [1]. With the increasing average age from 38 to 40 years and a longer life expectancy, there has inevitably been an increase in demand on orthopaedic services in recent years [2]. This is highlighted by the rise in number of registered joint replacements to the National Joint Registry (NJR) of England and Wales with a 280% increase from 47,000 registered procedures in 2004 to 179,000 in 2010 [3]. Since the introduction of the modern total hip arthroplasty in 1962 and total knee arthroplasty in the early 1970s, there has been an exponential rise in the number of prostheses available [4,5]. There has been an expansion in types of prosthesis available and these include: cemented, cementless and hybrid total hip and knee replacements as well as unicondylar knee and patella-femoral joint replacements.

New implants may be introduced within the European Union once they have satisfied one of eighty-three notified bodies. When the safety of a device has been proven, a CE (Conformité Européenne) mark is awarded and the implant may be sold in any country within the European Union. The CE mark is required by law for all prostheses used in the UK. Proof of safety of the composite materials rather than clinical effectiveness qualifies the implant for use [6].

Recent implant failures such as the ASR resurfacing hip has highlighted the need for a new prosthesis to have a controlled introduction into the market as well as proven results prior to release for sales [7,8]. Further calls for better monitoring of joint replacements in the UK have led to a joint register being established for set up in 2002 by the Department of Health and Welsh Assembly Government to collect information on all types of hip and knee replacements, as well as monitor the performance of these implants [3]. An annual report is published in the public domain and the latest available report at the time of writing was the 8th Annual Report pertaining to data from 2010.

From the wide range of implants to choose from, several have substantial survivorship data whilst others have no published follow-up data. The NJR report recognises the survival of individual brands of hip prosthesis by identifying the ODEP (Orthopaedic Data Evaluation Panel) rating of hip prostheses [9]. The ODEP panel consists mainly of consultant orthopaedic surgeons who use a specific proforma to objectively assess data submitted by individual companies. A statistician, and representatives for NHS procurement are also members of the ODEP panel. This however relies heavily on the honesty of the submitting parties [9]. Each implant is given a rating according to the data submitted (Table 1). However, no such rating system exists for knee implants.

There has also been a rise in revision surgery. Between 2005 and 2010, there was an annual increase of 18.4% for revision knee arthroplasties and 9.8% for revision hip arthroplasties [10]. This revision burden will cost £1.5 billion and this is likely to rise. Although there are several indications for revision procedures, implant failure due to aseptic loosening remains common. We therefore performed a study to examine whether the implants used for hip and knee arthroplasties in 2010 had sufficient published data to support their use and also compared whether the expenditure correlates to the clinical results of each type of prosthesis and therefore appears to be best value for money. Revision rates were also examined to determine

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Table 1
Levels of ODEP Rating Given by the Panel According to Data Submitted for Evaluation.

The Four Levels That ODEP Report on are:
1. Pre-entry level, less than 3 years;
2. 3 years, clinical data available for at least 3 years
3. 7 years, clinical data available for at least 7 years
4. 10 years, clinical data available for at least 10 years

whether the most common implant choices were justified by their clinical outcomes.

Materials and Methods

The National Joint Registry 8th annual report (2011) and the NJR "prosthesis used" report were used to identify the number and type of implants used for hip and knee arthroplasties in 2010 [10,11].

The manufacturer of each implant identified in the report was contacted directly by telephone and email. The catalogue price for each individual component and information regarding survivorship data for their prostheses was requested. Information collected from the companies was entered into a database and analysed. Catalogue price of each implant identified within the 8th Annual NJR Report was used to calculate an estimate of the expenditure on each ODEP category for hip arthroplasties and length of published follow-up for knee arthroplasties. In the case of knee arthroplasty where there was no assigned ODEP rating, the literature was reviewed to obtain published implant survivorship data. A 'PubMed' and broad Internet search for each named implant was undertaken. Revision rates (excluding for infection) for the most common implant combinations as detailed in the NJR report were also examined and correlated to implant selection.

Results

Total Hip Replacements

There has been a steady increase in number of hip arthroplasties performed over the past six years with a total of 76,759 primary and revision procedures in 2010. However, there has been a decline in the proportion of cemented total hip replacements (THR) over the past 5 years, uncemented THRs now being the most prevalent form of primary hip replacement. Despite cemented total hip replacements demonstrating the lowest revision rate at seven years (3.8%), they only accounted for 36% of all THRs implanted in 2010. The percentage of hybrid primary total hip replacements has remained between 14–16% over the past 5 years.

Two hundred sixty-two brands of prosthesis were used for primary total hip arthroplasty in 2010 (Table 2). Of these, only 45 achieved an ODEP rating of 10A. Of these 10A rated products, only nine prostheses remain unchanged since their launch on the market.

A total of 7,389 procedures were performed using 116 types of implant without any ODEP classification. Twenty-two of the 'unclassified' products were used once during 2010. Sixty-six different unclassified products were used less than 10 times in the same period.

Femoral Stem Implants

Uncemented. A total of 32,292 uncemented femoral stems were implanted in 2010 (Table 3). There were 74 types of implant manufactured by 19 different companies. The most popular implant chosen by surgeons was the Corail stem, DePuy (47%) followed by the Furlong stem, JRI (12%) and Taperloc, Biomet (7%). A total of 3,763 procedures were performed using implants with an ODEP rating of 'unclassified' or 'pre-entry'. The total spent on these implants was estimated at £3,929,883. Six types of revision femoral stems were also registered with the NJR as being used in primary hip replacement procedures. It is unclear why revision stems were used in these cases.

Cemented. Sixty-eight types of cemented femoral stem implant, manufactured by 19 companies were used in 32,062 procedures (Table 4). The most popular femoral stems were the Exeter, Stryker (63%) and the CPT stem, Zimmer (11%). Ninety percent of procedures used an implant with an ODEP rating of 10 A, B, or C. Approximately 1% of procedures used implants with an ODEP rating of 'unclassified' and 'pre-entry' with an estimated cost of £554,660.

Table 2
Table of All Hip Implants Sorted by Company.

Company	Cemented Cups	Uncemented Cups	Cemented Stems	Uncemented Stems	Resurfacing	Total
Amplitude	0	2	0	0	0	2
B Braun/Aesculap	2	1	4	3	0	10
Biomet	6	9	9	7	1	32
Corin	1	2	3	5	1	12
DePuy	12	6	9	14	1	42
ESKA/TriMed	0	1	0	0	0	1
Exactech (UK) Ltd	0	2	1	1	0	4
FH Newtech Ortho Ltd	0	1	0	1	0	2
Finsbury	1	1	2	3	1	8
Implantcast GmbH	1	0	1	1	1	4
Implants International	2	1	1	0	0	4
JRI Ltd	1	5	3	2	1	12
Lima WG Healthcare	0	3	1	2	0	6
Mathys Orthopaedics Ltd	1	3	2	2	0	8
Medacta UK Ltd	0	1	0	2	0	3
Orthodynamics	1	4	1	1	0	7
Peter Brehm	0	0	1	0	0	1
Smith & Nephew	2	6	8	7	1	24
Stanmore Implants	0	0	1	0	0	1
Stryker	4	6	5	4	1	20
Surgicraft	0	1	0	0	0	1
Symbios SA	1	1	5	3	0	10
Waldemar Link	3	2	5	1	0	11
Wright Medical UK Ltd	1	2	1	3	1	8
Zimmer	2	12	8	11	1	34
TOTAL	41	72	71	73	10	267