Documentation of hip prostheses used in Norway

A critical review of the literature from 1996–2000

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ABSTRACT We have conducted a systematic review of the scientific literature concerning outcome and clinical effectiveness of prostheses used for primary total hip replacement (THR) in Norway. The study is based on two Health Technology Assessment reports from the UK (Faulkner et al. 1998, Fitzpatrick et al. 1998), reviewing the literature from 1980 to 1995. Using a similar search strategy, we have evaluated the literature from 1996 through 2000. We included 129 scientific and medical publications which were assessed according to a specific appraisal protocol. The majority (72%) were observational studies, whereas only 9% were randomized studies. We could not retrieve any peer-reviewed documentation for one third of the implants. The Charnley prosthesis had by far the best and most comprehensive evidence base with better than 90% implant survival after about 10 years. Survival of the Charnley prosthesis declines by about 10% during each of the two following decades. Except for the Charnley and Lubinus IP, no other prosthesis on the market in Norway has given long-term results (> 15 years). 5 other cemented implants have given comparable results at about 10 years of follow-up. Some uncemented stems have shown promising medium-term outcome, but no combination of uncemented cup and stem fulfilled the benchmark criterion of ≥ 90% implant survival at 10 years, which we propose as a minimum requirement for unrestricted clinical use for prostheses used in primary THR. New or undocumented implants should be introduced through a four-step model including preclinical testing, small series evaluated by radiosterometry, randomized clinical trial involving comparison with a well-documented prosthesis, and finally, surveillance of clinical use through registers.

During the past 30 years, total hip arthroplasty has become one of the most common procedures in orthopedic surgery. The clinical results have improved steadily during this period of time and most patients have an excellent prognosis for long-term improvement of pain and physical function (Murray 1995). Although there has been an abundance of clinical and experimental papers on hip prostheses, there is a striking lack of high-quality controlled or randomized studies regarding long-term clinical performance. This may be because such studies require long follow-up (10–20 years) and a high number of patients have to be recruited to obtain sufficient statistical power in the study. In addition, most countries do not require documentation of clinical effect before the introduction of new orthopedic implants. The manufacturers are therefore under no obligation to initiate or participate in such clinical trials. Several implants have shown promising short-term results but have demonstrated high failure rates after 5 years or more. Thus, reliable evidence on the clinical effectiveness of prostheses can only be obtained by long-term follow-up. Several factors may influence the outcome of total hip replacement, and differences

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in patient characteristics and surgical practice may heavily confound comparison of the results of different clinical studies. In large register studies, however, adjustments can be made for these confounding factors and direct comparison of different variables is possible. Such studies (Havelin et al. 2000b, Furnes et al. 2001) have documented that the brand of the implant influences the survival time of the prosthesis.

The objective of this study was to carry out a systematic review of the scientific documentation and to assess the outcome and clinical effectiveness of prostheses used for primary total hip replacement in Norway. This assessment has been initiated by SMM (the Norwegian Center for Health Technology Assessment) at the request of experts in the field.

Material and methods

In 1998, two English Health Technology Assessment (HTA) reports on the effectiveness and outcome of total hip prostheses were published (Faulkner et al. 1998, Fitzpatrick et al. 1998). In these reports, the literature available from 1980 until 1995 was reviewed systematically, and we found the results and the conclusions to be highly relevant to the present Norwegian study. We therefore conducted a literature search covering 1996 through 2000. To a great extent, the methods used for this systematic review were taken from the HTA reports. In addition to electronic searches in Medline and Embase, we also identified relevant systematic reviews from other electronic databases such as the Cochrane Library, the Health Technology Assessment Database and the NHS Electronic Evaluation Database. It has, however, been shown that relevant articles may be missed by electronic searches (Dickersin et al. 1994), and we therefore conducted additional hand searches in 9 selected orthopedic journals. This was done by identifying the journals that had the highest frequency of appearance in Medline using our defined search strategy (Table 1). 1756 papers were identified, 1436 from Medline, 252 from Embase and 185 by hand searching. Two experts independently evaluated the relevance of each article on the basis of the title and the abstract. Only literature regarding prostheses used in Norway in 2000 were subjected to further analysis. Accordingly, 573 scientific papers were reviewed, but only 129 articles and 3 systematic reviews fulfilled the inclusion criteria for this study (Table 2). Each study to be

Table 1. 9 selected orthopedic journals that were hand-searched

- Clinical Orthopaedics and Related Research
- Journal of Bone and Joint Surgery (Amer.)
- Journal of Bone and Joint Surgery (Brit.)
- Acta Orthopaedica Scandinavica
- Journal of Arthroplasty
- Zeitschrift für Orthopedie und ihre Grenzgebiete
- Orthopaedics
- Archives of Orthopaedic and Trauma Surgery
- International Orthopaedics

Table 2. Criteria used to identify literature that was included into the study

Population	Primary total hip replacement
Implant	Hip prostheses used in Norway in 2000 [a]
Types of studies	Systematic reviews, Cochrane reviews
	Meta-analyses
	Randomized clinical studies
	Controlled studies
	Register studies
	Patient series
	Review articles
Follow-up	Minimum 5 years for clinical endpoints
	Minimum 2 years for other (surrogate) endpoints (RSA, DEXA, EBRA, radiological analysis) [b]
Inclusion period	1996–2000
Language of literature	English, German, French, Swedish, Danish, Norwegian

[a] Data obtained from the Norwegian Arthroplasty Register
[b] RSA = Radio Stereometric Analysis, DEXA = Dual Energy X-ray Absorptiometry, EBRA = Ein Bild Röntgen Analyse

Table 3. Grouping of scientific and medical articles according to study design and scientific quality (A = best, C = poorest)

Study design	No. of publications	Quality grading A	B	C
Patient series	93	23	21	49
Register studies	6	1	1	4
Cohort studies	18	5	5	8
Randomized studies (RCT)	12	0	5	7

included was assessed by at least two independent reviewers, then grouped according to study design (randomized studies, controlled studies, cohort or register studies and patient series) and subsequently appraised and graded within each study group with respect to scientific quality, according to three classes from A (best) to C (poorest) (Table 3). Along with the key results, these data were summarized in a data table for each of the studies (Nordsletten et al. 2002). As outcome measures we used the revision/survival rates and the reason for hip revision, clinical scoring systems, and also radiological observations of possible failures related to the survival of the prosthesis.

A questionnaire was sent to all distributors and manufacturers of hip prostheses in Norway requesting information about price, ongoing or completed clinical studies involving their prostheses, and recent changes or modifications of the implants – including documentation thereof.

Results

Literature

Three systematic reviews and 129 scientific papers fulfilled the inclusion criteria, which included publication in the period from 1996 through 2000 (Table 4). Only 2 articles not retrieved in the electronic search were retrieved in the manual search. The majority of the articles (72%) were classified as patient series without any element of comparison between different prostheses. 30 articles (23%) were reports from comparative studies; however, only 12 of these were randomized. Furthermore, 5 of the RCTs were comparisons between old and newer versions of the same type of implant. In 64% of the studies the mean follow-up time was less than 10 years. In 23% of the studies, it was between 10 and 20 years, and in 12% of studies it was more than 20 years.

Cemented prostheses

In the year 2000, 13 different brands of cemented prosthesis were used (Havelin et al. 2002). The literature review revealed 53 articles involving the Charnley prosthesis, which had an appreciable share (45%) of the implants used with cement. For 7 other implants, we found an average of 4 (range 1–8) articles, whereas we were not able to retrieve any scientific documentation for the remaining 5 implants (Table 5). Thus, among the cemented prostheses used in Norway, Charnley has been by far the most widely used and best documented hip prosthesis and the only implant, except for the Lubinus IP prosthesis (Herberts and Malchau 2000), with published clinical results beyond 15 years. Several of the cemented prostheses (Charnley, Exeter, Lubinus, Titan, Biofit, ITH, Spectron) have shown consistently good clinical survival (> 90%) after medium-term follow-up (10 years), but for 2 of the implants (Titan, Biofit) the results have been based solely on studies from the Swedish and Norwegian implant registers (Havelin et al. 2000a, Herberts and Malchau 2000). Charnley has been the only implant with good long-term documentation. However, due to substantial differences in study design, patient populations, outcome measures and several other parameters, it is difficult to compare the results from the different studies. It can be concluded, however, that most studies have shown a clinical survival for the Charnley prosthesis that is better than 90% at 10 years. Thereafter, the survival rate seems to decline by approximately 10% during each of the following two decades.

Uncemented prostheses

In 2000, the use of 10 different uncemented femoral stems and 11 cups was reported to the Norwegian Arthroplasty Register. Altogether, 743 stems and 1038 cups were implanted, indicating that approximately 300 uncemented cups were part of a so-called hybrid arthroplasty. None of the papers reporting the results of uncemented prostheses had an average follow-up of 10 years or more, although in 4 of the articles the maximum time of follow-up was more than 10 years. For 3 stem designs and 5

Table 4. Distribution of the scientific studies according to study designs and implant brand

Implant – Manufacturer	Observational study Patient series (follow-up) (n= 93)	Register study (follow-up) (n=6)	Comparative study Controlled (follow-up) (n=18)	Comparative study RCT (follow-up) (n=12)
ABG (uncemented) – SOH [a]	2 studies (5–7 yrs) (Garcia et al. 1998, Tonino and Rahmy 2000)			
Bicontact (uncemented) Bicontact – Aesculap	1 study (7 yrs) (Eingartner et al. 1997) 1 study (7–10.7 yrs) (Eingartner et al. 2000)			
Biofit – S&N [a]	1 study (11 years) (Havelin et al. 2000a)			
Bimetric (uncemented) – Biomet				Bimetric ± cement 2 studies (3.8 and 6 yrs) (Meding et al. 1997 and 1999)
Charnley – DePuy	32 studies (10–25 yrs) (Havelin et al. 1995a, Avedikian et al. 1996, Birtwistle et al. 1996, Engesæter et al. 1996, Neumann et al. 1996, Callaghan and Johnston 1997, Devitt et al. 1997, Garcia-Cimbrelo et al. 1997b, Hartofilakidis et al. 1997a,b, Kobayashi et al. 1997a, Lehtimaki et al. 1997, Madey et al. 1997, Nagano et al. 1997, Numair et al. 1997, Sochart and Porter 1997b, Soyer et al. 1997, Kobayashi et al. 1997a, Garcia-Cimbrelo et al. 1997a, Sochart and Porter 1997a, Kobayashi et al. 1997b, Berry et al. 1998, Callaghan et al. 1998, Joshi et al. 1998, Sochart and Porter 1998, Lehtimaki et al. 1999, Prakash et al. 1999, Ritter et al. 1999b, Sochart 1999, Wroblewski et al. 1999, Ritter 1999a, Callaghan et al. 2000, Garcia-Cimbrelo et al. 2000, Wroblewski et al. 2000)	Charnley 1 study (5 yrs) (Fender et al. 1999) Exeter 1 study (2.9–3.8 yrs) (Furnes et al. 1997) Lubinus IP, Exeter matte, Exeter polish 1 study (5–16 yrs) (Herberts and Malchau 1997) ITH, Exeter, Biofit, Landos, Lubinus SP 1 study (11 yrs) (Havelin et al. 2000a)	McKee-Farrar 1 study (19–20 years) (Jacobsson et al. 1996) Hi-Nek 1 study (7 yrs) (Dawson et al. 2000) Stanmore 1 study (8 yrs) (Britton et al. 1996) Hybrid: HG, Iowa 1 study (8 vs. 20 yrs) (Callaghan et al. 1997a) Omnifit 1 study (2 yrs) (Önsten et al. 1996) Lubinus SP, Lubinus IP 1 study (3–5 years) (Hedlundh et al. 1996) Exeter 1 study (2 years) (Alfaro-Adrian et al. 1999) Charnley 1 study (10–13.5 yrs) (Okamoto et al. 1997) 1 study (10–25 yrs) (Ortiguera et al. 1999)	Spectron 4 studies (10 yrs) (Garellick et al. 1998, 1999a, 1999b and 2000) HG I 1 study (5 yrs) (Önsten et al. 1998) Stanmore 1 study (5–10 yrs) (Marston et al. 1996)
Corail (uncemented) – DePuy	2 studies (5–9 yrs) (Røkkum and Reigstad 1999b, Røkkum et al. 1999a)			
Duraloc (uncemented) – DePuy	3 studies (2–6 yrs) (Sychterz et al. 1998, Fisher 1999, Stockl et al. 1999)			
Elite plus – DePuy	1 study (5 yrs) (Fisher 1999)		Exeter 1 study (2 yrs) (Alfaro-Adrian et al. 1999)	

cup designs we could not retrieve any peer-reviewed articles; this also includes the period from 1980–95 (Fitzpatrick et al. 1998). Compared with the other uncemented implants, the Omnifit prosthesis has

Table 4 continued.

Implant – Manufacturer	Observational study Patient series (follow-up) (n= 93)	Register study (follow-up) (n=6)	Comparative study Controlled (follow-up) (n=18)	Comparative study RCT (follow-up) (n=12)
Exeter – SOH [a]	1 study (3–9.8 yrs) (Chiu et al. 1997)	Charnley 1 study (2.6–3.4 yrs) (Furnes et al. 1997) Charnley, Lubinus, Exeter polished, Exeter matte 1 study (5–16 yrs) (Herberts and Malchau 1997) Charnley, Biofit, Lubinus, ITH 1 study (ca.11 years) (Havelin et al. 2000a)	Elite Charnley 1 study (2 yrs) (Alfaro-Adrian et al. 1999) Exeter polished modular vs. polished monobloc vs. matte monobloc 1 study (6–12 yrs) (Middleton et al. 1998) Exeter matte vs. polished 1 study (3–13 yrs) (Howie et al. 1998)	
Harris-Galante (HG) (uncemented) – Zimmer	27 studies (4–12.9 yrs) (Berger et al. 1996, Brinker et al. 1996, Callaghan et al. 1996, Incavo et al. 1996, Latimer and Lachiewicz 1996, Lewallen and Cabanela 1996, Woolson and Haber 1996, Berger et al. 1997, Callaghan and Johnston 1997, Devane et al. 1997, Saito et al. 1997, Tompkins et al. 1997, Bohm and Bosche 1998, Petersen et al. 1998, Sporer et al. 1998, Brown and Lachiewicz 1999, Clohisy and Harris 1999b, Lecoq et al. 1999, Lee and Han 1999, Maloney et al. 1999, Olofsson et al. 1999, Petersen et al. 1999, Clohisy and Harris 1999a, Cannestra et al. 2000, Dunkley et al. 2000, Ricci et al. 2000, Soto et al. 2000)		Hybrid: Iowa, HG, Charnley 1 study (8.2 vs. 20 yrs) (Callaghan et al. 1997a) Profile 1 study (5.4 years) (Hendrich et al. 1997) Anatomic, Biomet, Lubinus, Spectron, Tifit, HG with HA/TCP 1 study (2 yrs) (Thanner et al. 1999b)	PCA 1 study (9.4 years) (Thanner et al. 1999a) Ti-fit cement, porous, HA 1 study (5 yrs) (Kärrholm et al. 1998) Charnley 1 study (5 yrs) (Önsten et al. 1998)
ITH S&N [b]	1 study (0.3–3 yrs) (Mohr and Indrekvam 1996)	Charnley, Biofit, Lubinus, Exeter 1 study (11 yrs) (Havelin et al. 2000a)		
Lubinus – Link	2 studies (1–10 yrs) (Frøen and Lund-Larsen 1998, Stockl et al. 1999)	Charnley, Exeter matte, Exeter polished 1 study (5–16 yrs) (Herberts and Malchau 1997) Titan, Biofit, ITH, Exeter, Charnley 1 study (11 yrs) (Havelin et al. 2000a)	Lubinus IP, Lubinus SP 1 study (10 vs. 13 yrs) (Savilahti et al. 1997) Lubinus IP, Lubinus SP, Charnley 1 study (3–15 yrs) (Hedlundh et al. 1996) Lubinus IP, Lubinus SP, Furulong 1 study (1–12 yrs) (Alho et al. 2000) Anatomic, Biomet, Spectron, Ti fit 1 study (2 yrs) (Thanner et al. 1999b)	

Table 4 continued.

Implant – Manufacturer	Observational study Patient series (follow-up) (n= 93)	Register study (follow-up) (n=6)	Comparative study Controlled (follow-up) (n=18)	Comparative study RCT (follow-up) (n=12)
Omnifit (uncemented) – SOH [a]	12 studies (2–12.5 yrs) (D'Antonio et al. 1992 and 1996, Lewallen and Cabanela 1996, Capello et al. 1997, Geesink and Hoefnagels 1997, Shih et al. 1997, Capello et al. 1998, Hellman et al. 1999, Jaffe and Hawkins 1999, Lee et al. 1999, Kligman and Kirsh 2000, Lee et al. 2000)		Omnifit ± coating 2 studies (3–10 yrs) (Kitamura et al. 1999, Maruyama et al. 2000) Charnley 1 study (2 yrs) (Önsten et al. 1996) Omnifit Dual, Omnifit HA 1 study (7.9 years) (Manley et al. 1998)	
Profile (uncemented) – DePuy			Harris Galante 1 study (5.4 years) (Hendrich et al. 1997)	Profile porous, w/o coating, HA 1 study (2–4 yrs) (Incavo et al. 1998)
Spectron – S&N [b]	1 study (2–11.6 years) (Kale et al. 2000)	Charnley, Biofit, Lubinus, Exeter, ITH 1 study (11 years) (Havelin et al. 2000a)		Charnley 4 studies (8–10 yrs) (Garellick et al. 1998, 1999a, 1999b and 2000)
Ti-fit – S&N [b]			Anatomic, Biomet, Spectron, Lubinus 1 study (2 yrs) (Thanner et al. 1999b)	Ti-fit cemented, HA, porous 1 study (5 yrs) (Kärrholm et al. 1998)
Titan – DePuy		Biofit, ITH, Exeter, Charnley, Lubinus, Spectron 1 study (11 yrs) (Havelin et al. 2000a)		
Trilogy (uncemented) –Zimmer	1 study (2–8.7 yrs) (Cannestra et al. 2000)			Trilogy ± screws 1 study (min. 2 yrs) (Thanner et al. 2000)
Zweymüller (uncemented) Plus Endoprothetic	4 studies (2–12.5 yrs) (Delaunay and Kapandji 1996 and 1998, Aigner 1998, Delaunay et al. 1998)		Zweymüller 1 study (6 yrs) (Wurnig et al. 1999)	
Morscher cup –Sulzer	1 study (4.6–8.1 yrs) (Morscher et al. 1997)			
Weber cup –Sulzer	2 studies (2–7 yrs) (Weber 1996, Dorr et al. 2000)			
Articulation				
Metasul	3 studies (0.5–7 yrs) (Wagner and Wagner 1996, Weber 1996, Dorr et al. 2000)			
Zirconium ball head	1 study (1–9 years) (Allain et al. 1999)			

[a] SOH = Stryker/ Osteonics/ Howmedica
[a] S&N = Smith & Nephew

had a relatively high number of published reports, including 12 patient series and 4 comparative studies. However, 3 of the latter reports are comparisons of different coatings and surface structures of the implants (Manley et al. 1998, Kitamura et al. 1999, Maruyama et al. 2000), and one RSA study comparing migration of the Omnifit and Charnley stems and cups (Önsten et al. 1996). For the rest of the uncemented prostheses, 5 articles or less were found during the literature search.

4 of the uncemented stems have shown good and encouraging medium-term results. In a prospec-

Table 5. Components (cemented and uncemented) lacking scientific documentation regarding their use as primary hip prostheses

Prosthesis	Manufacturer
Femoral components	
CPS-plus	PLUS Endoprothetic AG
Unique	Scandinavian Customized Prosthesis
Filler	Biotechni
Fjord	DePuy
MS 30	Protek Sulzer Medica
Synergy	Smith & Nephew
Acetabular components	
Bicon PLUS	PLUS Endoprothetic
Biomex	Biomet
Contemporary	Stryker Howmedica
Endo-model Mark II	Link
Gemini [a]	DePuy
Igloo	Biotechni
Kronos	DePuy
Securfit	Stryker Howmedica
ZCA	Zimmer

[a] No longer produced; only two implants used after 1995.

tive series, Eingartner et al. (2000) reported an overall survival rate of 97% of the Bicontact stem after 11 years. In a prospective, randomized study comparing the collared and collarless Bimetric prosthesis, 6 of 437 stems were revised after 6–7 years and there was no difference between the two groups except for more femoral neck bone loss in the collarless group (Meding et al. 1999). Several reports have shown good medium-term clinical results with the Omnifit stem with HA-coating, and the survival rates in most studies were better than 95%. However, some concerns have been raised about wear problems and osteolysis related to the porous-coated Omnifit prosthesis (Shih et al. 1997, Hellman et al. 1999, Lee et al. 1999) with overall revision rates and rates for aseptic loosening of 26% and 14%, respectively, at 8 years. High revision rates have also been reported for the HA-coated Omnifit cup (Capello et al. 1998).

4 reports with a maximum follow-up of 13 years showed better than 90% survival for both the Zweymüller stem and cup; however, 3 of these reports originated from the same institution (Delaunay and Kapandji 1996, Aigner 1998, Delaunay and Kapandji 1998, Delaunay et al. 1998). The uncemented, threaded Zweymüller cup has, however, not been used in Norway. None of the uncemented cups on the market in 2000 have any documentation showing good clinical results beyond 10 years, nor has there been any combination of an uncemented cup and stem fulfilling the benchmark criterion of ≥ 90% implant survival at 10 years or more.

For several years, the Corail prosthesis has been the most widely used uncemented stem in Norway, accounting for about 50% of the uncemented market. Previously, the stem was used together with the Tropic cup, but the use of this particular prosthesis has declined markedly. This may be explained by a study showing a survival rate of only 92% for the shell and 77% for the polyethylene insert after 8 years (Røkkum et al. 1999). The Corail stem, however, has shown good results with survival rates of 98–99% after 5–8 years (Havelin et al. 1995b, Røkkum and Reigstad 1999, Røkkum et al. 1999).

We were able to find 3 reports concerning the Metasul metal-on-metal articulation (Wagner and Wagner 1996, Weber 1996, Dorr et al. 2000). In all articles the follow-up was less than 7 years, but any particular complications or reoperations related to the articulating surfaces were not reported.

15 distributors of hip prostheses received detailed questionnaires requesting information about their products. Only 5 of the companies responded to the inquiry and the majority were reluctant to disclose the prices of the implants. These prices are usually not fixed, but are subject to negotiation between the distributor and the hospital. 5 companies were involved in 9 clinical studies; 7 of these were prospective and randomized. Only 1 company gave information about design changes to their implants.

Discussion

The methodology of our review was based on two English Health Technology Assessments Reports (Faulkner et al. 1998, Fitzpatrick et al. 1998), which concluded that there was a striking paucity of clear and relevant evidence on which to make well-informed choices for primary THR based on the available literature from 1980–95. However, it was concluded that the Charnley prosthesis performed relatively well, and positive evidence was also found for the Exeter and Lubinus pros-

theses. No substantial evidence could be found for uncemented prostheses, in terms of independent observations of results from 5 or more studies. We concluded that the results and conclusions of these HTA reports, covering the literature until 1995, were relevant to the situation in Norway. Thus, we limited the literature search to the period 1996 through 2000 and only assessed studies including prostheses used for primary THR in Norway in the year 2000.

The main purpose of this review was to identify the scientific and medical documentation that was available and to assess the clinical effectiveness of different components used in total hip arthroplasty in Norway. Based on the present documentation of long-term effect and survival time, we intend to propose a system for the choice of prostheses for primary THR at Norwegian hospitals, and also a proposal for an algorithm for the introduction of new primary hip prostheses onto the market.

Quality of the literature

Prospective and randomized controlled trials (RCT) are regarded as the gold standard for comparing implants. However, very few such studies were published in the period of interest. The majority (72%) of the scientific papers relevant to our report were observational studies without any element of comparison between implants, whereas 9% of the articles represented randomized studies and 19% represented other comparative studies, including register studies from Sweden and Norway. Each of the 4 independent randomized studies on cemented prostheses included an average of only 340 patients, a number that is an order of magnitude less than recommended for such studies to have sufficient statistical power (Faulkner et al. 1998). Consequently, none of the 12 RCTs showed any statistically significant differences between any of the groups that were included in the studies. Only register studies have a sufficiently high number of patients to enable detection of significant differences in the survival of different prostheses. A fairly small number of register studies were available, and all of them originated from the Scandinavian countries (Table 3). Thus, in order to review a reasonable number of publications, observational studies were included. A further problem in evaluating the current literature is that a high number of studies are of low scientific quality; only 29 of 129 studies were graded as "good" according to the appraisal criteria outlined by Faulkner et al. (1998). Interestingly, most of the comparative studies failed to meet the key criteria for an A or B rating of quality.

Several outcome measures may be used for evaluation of the effectiveness of hip prostheses. In the present literature revision rate or implant survival, dislocation as well as radiological measurements have been used as study end-points. Very few of the studies used outcome measures such as clinical function of the replaced joint, quality of life, pain relief or patient satisfaction. It is obvious, and also well documented, that hip prostheses still in situ do not necessarily mean that a total hip replacement has been clinically successful (Söderman et al. 2001).

Interpretation of the literature

Several biases are introduced when trying to compare the effectiveness and clinical results of prostheses from different observational studies. Variables such as patient age, sex, diagnosis, criteria for implant loosening and indication for revision surgery vary between the studies, and it is usually impossible to adjust for such differences. Also, the clinical outcome after the use of one particular implant may differ considerably between studies as a result of different surgical and technical factors. However, a large number of long-term observational studies presenting similar results may give evidence towards determining the quality or effectiveness of an implant. Even for register studies, comparisons between different implants may be unjustified due to differences in methods used for recording patient data and registration of revisions. In medicine, there is a tendency to publish positive or good results rather than report studies showing inferior outcome. This may skew the literature towards prostheses that show favorable results. Another problem that arises is the fact that orthopedic surgeons who produce a high number of publications may have commercial interests in the product. Until recently, such conflicts of interest were usually not stated in journals.

It is also well known to the orthopedic community that the manufacturers regularly perform changes or modifications to the implants. The

rationale for introducing new design features may differ, but in some cases such changes are certainly motivated by commercial incentives (Bulstrode et al. 1993). Although most changes are explained as improvements that are intended to enhance the clinical performance of the implant, such changes in implant design are documented by scientific studies only sporadically.

Documentation of clinical effectiveness

In accordance with the previously published HTA reports from the UK (Faulkner et al. 1998, Fitzpatrick et al. 1998), we were unable to find any randomized studies showing that one implant is better than another. Some would argue that factors other than the brand of the implant are the major denominator for the outcome of hip surgery. In register studies, however, it is possible to adjust for confounding factors by statistical methods, and it has been shown that the type of implant clearly influences the risk for revision (Furnes et al. 2001, Malchau et al. 2002).

Our survey shows that the Charnley prosthesis still has the longest follow-up and the largest volume of documentation and, even today, is regarded as the gold standard for comparison of other implants. Several articles have shown a 20-year survival rate between 80% and 90% (Neumann et al. 1996, Hartofilakidis 1997a, Lehtimaki et al. 1999, Wroblewski et al. 1999), although the results are inferior in some cohorts of patients (Soyer et al. 1997). Between the cemented THRs, the Lubinus, Exeter, ITH, Spectron and Titan have shown similar or even better medium-term survival data, but the quality and volume of documentation has been highly variable. Some uncemented femoral stems (Bicontact, Bimetric, Omnifit and Zweymüller) have shown encouraging results at about 10 years of follow-up, but medium-term or long-term clinical results for the combination of uncemented cup and stem are not available for implants used in Norway. Murray (Murray et al. 1995) concluded that new implants and surgical techniques do not appear to have improved the results of THR substantially. Part of this conclusion still seems to be valid: based on scientific evidence, no other hip implants have outperformed the Charnley prosthesis. On the other hand, improvements in surgical and cementing techniques and perioperative treatment have led to increased survival of several implants, as shown in register studies (Espehaug et al. 1997, Malchau et al. 2002). However, we do not know whether, from the patients' own point of view, the improvements have given them a better quality of life.

The number of prosthesis brands on the market is probably too high, but an even bigger problem is that any kind of peer-reviewed documentation is unavailable for more that one third of the implants. Although the majority of the new prosthetic designs will most likely perform very well clinically, some of the new implants will undoubtedly give less satisfactory long-term results for patients in need of a total hip replacement (Murray et al. 1995, Massoud et al. 1997, Adam et al. 2002). In Norway, as within the European Community, orthopedic implants obtain the CE-marking and approval for clinical use without any kind of documentation of the clinical benefit or effectiveness of the device. The approval process for the CE-marking is basically a quality-control system regulating the different technical aspects of the implant and also issues concerning materials and manufacturing processes. Surprisingly, the legislation and directives regarding clinical introduction of pharmaceutical and of orthopedic products differ markedly from each other. Whereas pharmaceutical products must undergo an elaborate preclinical and clinical evaluation to document clinical effect and potential side effects, this is presently not required for joint prostheses. As a consequence, the orthopedic surgeons themselves have to define the standards and criteria for selecting hip prostheses to be used in clinical practice and for the introduction of new designs. We consider that our review gives a body of evidence for the practicing surgeon so that implants can be selected on the basis of good clinical results published in peer-reviewed journals. Among the THRs currently used in Norway, there is a number of prostheses that can document better than 90% survival at 10 years or more of follow-up. We believe also that this should be a minimum requirement for other implants, before they are taken into general use. From an ethical standpoint, patients are entitled to be informed about the lack of evidence for the success of particular implants and the possibilities for alternative treatment.

Surgeons should not be forced to use only established prostheses; this would delay and prevent new developments that may further improve hip replacement surgery. New prostheses should, however, only be used as part of a stepwise preclinical and clinical study, following the guidelines outlined by Malchau (1995). In addition to evaluation of radiological changes and survival data, patient-derived data such as pain, function and quality of life should also be included in the protocol for assessment of new designs or implants.

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