Dilemmas in Uncemented Total Hip Arthroplasty

Johannes H.M. Goosen

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Dilemmas in Uncemented Total Hip Arthroplasty

De dilemma's van de ongecementeerde totale heup arthroplastiek

(met een samenvatting in het Nederlands)

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Johannes Henricus Maria Goosen
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Co-promotor: Dr. C.C.P.M. Verheyen

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Introduction

Introduction

In this thesis, different aspects determining the survivorship and clinical outcome of the uncemented total hip prosthesis are analysed. The current pre-dominant dilemmas in uncemented total hip arthroplasty are:

- 1. Polyethylene wear leading to osteolysis and loosening of the components,
- 2. Stress shielding,
- 3. Early component fixation and
- 4. Minimally invasive surgery.

This introduction outlines the history and general definition of these dilemmas. At the end of the introduction, eight question's concerning these dilemma's are posed. These questions are further analysed and answered in the subsequent chapters of this thesis.

1. Polyethylene Wear and Osteolysis

Although the formal history of hip replacement dates back to the beginning of the 20th century[1] survival of total hip replacement was dramatically improved by Sir John Charnley's concept of low friction arthroplasty[2]. During the decades after this improvement, good to excellent survival rates of most cemented hip prosthesis have been reported[3]. On the other hand, an increasing number of cases was reported of radiolucent lines and/or cavitations around the implant, related to osteolysis of the adjacent bone[4]. As the presence of cement-particles was histologically observed in these osteolytic areas, the aseptic loosening of components associated with this phenomenon was erroneously called "cement disease"[5]. These reports of high rates of aseptic loosening of cemented femoral components, especially in younger and more active patients, have stimulated the development of implant fixation without cement[6,7]. However, osteolytic changes occurred around these uncemented prostheses as well, and in these cases, histology of the surrounding tissue showed polyethylene and metal particles, with extensive macrophage reaction. Thus it was realized that so-called "third body wear", rather than "cement disease" leading to bone resorption should be considered as the main problem in total hip arthroplasty[8]. Metal or polyethylene particles are phagocytosed by macrophages, which become activated and release cytokines causing bone resorption[9]. The rate of wear depends on a multitude of causes, like the age and activity of the patient, as well as the mechanical and physical-chemical features of the material[10, 11]. Different bearing surfaces such as metal on metal, or ceramic on ceramic, or combinations with ultra high molecular weight polyethylene (UHMWP) were introduced, leading to different wear characteristics. Also, production and package sterilisation techniques for

the polyethylene used in acetabular components are known to affect the rate of wear[11]. Since air sterilisation of Ultra High Molecular Weight Polyethylene acetabular liners is associated with substantial oxidation and radical formation causing early degradation of the material, sterilisation in a low oxygen environment (inert gas) became the method of choice in the late 1990s[12,13].

2. Stress shielding

Another problem in uncemented total hip arthroplasty is ***stress shielding***, which is the term used for diffuse loss of bone mass of the periprosthetic bone. This is caused by the fact that the mechanical load is partly taken over by the implant[14]. Stress shielding is a predominant cause of bone loss in patient treated with stiff (high modulus), press-fit acetabular and femoral components[15,16]. In contrast, cemented components show a significantly lower bone mineral density loss than uncemented components, due to the fundamental difference in load transfer[17]. Retrieval and animal studies have indicated that bone remodeling is related to the ratio of the stem stiffness to femoral stiffnes: The stiffer the stem in relation to the femur is, the less stress is carried by the femur, and the greater the subsequent bone loss[18]. In the early 1970s, a soft-interface coating of a composite of polytetrafluoroethylene (PTFE) reinforced with carbon fibre or aluminium oxide was introduced as Proplast. Proplast was considered to exhibit extraordinary chemical and thermal resistance, permitting fusion to metallic implants[19]. As the elasticity of Proplast matches that of the surrounding cancellous bone, it was expected to have the advantage of a more natural tranfer of stress, causing less stress shielding and aseptic loosening[20]. Despite the possible theoretical benefits, mid-term clinical results on uncemented femoral components with a Proplast coating were not favorable[20-23]. Because of these reports, the low modulus system was considered to be a failure and was abandoned in the mid-1990s.

3. Early Component Fixation

Inferior primary fixation of the components in total hip arthroplasty can lead to a higher probability of aseptic loosening on the long term[24]. As the interface between the component and the surrounding bone becomes a continuous compartment filled with synovial fluid (the “virtual joint space”), micromotion of the component can result in high fluid pressures and the distal migration of wear particles[25]. In the late 1980s, hydroxyapatite was applied on the implant surface in uncemented total hip arthroplasty in an effort to enhance prosthesis to bone fixation, and thus seal this virtual joint space. Hydroxyapatite is highly biocompatible and has an osteo-conductive potential enhancing early fixation and stability[26]. Hydroxyapatite is the

crystalline phase of natural bone mineral. Synthetic HA is biocompatible and osteo-conductive, and in contact with bone it often develops a mechanically tight bond which probably is of a chemical nature[27,28]. Human retrieval studies have shown that the formation of newly woven bone adjacent to the HA layer does not pass through an intermediate stage of fibrous tissue and therefore secondary fixation is enhanced in these types of prostheses[29]. Reports on the HA-coated, uncemented femoral stem with a minimum follow-up 5 to 13 years show revision rates of 0 to 7.6 percent with good to excellent clinical and radiological results[30-45]. In a study comparing the effect of surface coating on bone ingrowth in two otherwise identical stem designs, human retrieval specimens were investigated on the implant-bone interface around the proximally HA-coated and porous-coated Bi-Metric femoral stem. Significantly more ingrowth and attachment of bone to the HA-coated surface were observed as compared to the porous coated surface[46]. However, clinical matched pair trials[47-50] and (bilateral) randomized controlled trials[51-58] remain ambiguous about the clinical and radiographic additional advantages of the hydroxyapatite coating.

4. Minimally invasive approaches for total hip arthroplasty

In orthopaedic surgery, after an era of pure biomechanics, in recent years much more emphasis has been placed on biological and soft tissue issues. In an attempt to improve the early clinical outcome of total hip arthroplasty, different methods of minimally invasive surgery have recently been developed[59-61]. The minimally incisive posterolateral and anterolateral approach to the hip is defined by an incision length of 10 to 12 cm or less[62], using the same technique as both classical approaches, although with custom made curved reamers and distractors. After the introduction in the early 2000s a discussion started worldwide about the possible clinical benefits of this innovative approach as compared to the classical, more extensive approaches[62]. The rationale for developing MIS was a minimized need for tissue dissection, resulting in reduced blood loss, pain, improved propriosepsis, a faster rehabilitation, and shorter hospital stay[62]. Compared with the classical approach, the first retrospective studies showed a higher peri-operative complication rate[63] in the absence of clinical improvements in the THAs performed by a posterolateral mini-incision.[63-65] Non-blinded randomized trials showed conflicting results.[66-68] Dorr et al[69] compared 30 THAs with a -posterolateral- minimally invasive incision with 30 THAs with a classical incision in a double-blinded randomised trial. They observed early pain relief at the time of discharge and less use of assistive devices such as crutches in the MIS group during hospital stay, while no differences were observed at six weeks and three months between the groups.

Questions addressed in this thesis are:

1. What is the clinical and radiological outcome of proximally hydroxyapatite coated uncemented femoral stems after a short to mid-term follow-up?
2. Is there a clinical and radiological benefit of hydroxyapatite coating on porous coated stems in uncemented primary total hip arthroplasty?
3. What is the long-term clinical and radiological outcome of low modulus Proplast coated uncemented femoral stems and when is revision indicated?
4. What is the clinical and radiological outcome of porous coated cobalt chrome high modulus femoral stems, used both as an uncemented and a cemented stem in hemiarthroplasty after a short follow-up?
5. What is the way to diagnose and, if observed, how to treat and monitor silent osteolysis associated with an uncemented acetabular component?
6. Is there an association with implantation time and position of the component and the rate of wear in metal backed uncemented acetabular components?
7. Are argon-sterilised polyethylene liners less susceptible to wear than air-sterilised liners *in vivo* during a mid-term follow-up?
8. Do patients have an improved clinical outcome, when treated with a posterolateral or anterolateral mini incision, compared with both the classical incisions during a short-term follow-up?

References

1. Wiles P. The surgery of the osteoarthritic hip. Br J Surg 1958;45-193:488-97.
2. Charnley J. Arthroplasty of the hip. A new operation. Lancet 1961;1-7187:1129-32.
3. Mäkelä K, Eskelinen A, Pulkkinen P, Paavolainen P, Remes V. Cemented total hip replacement for primary osteoarthritis in patients aged 55 years or older: results of the 12 most common cemented implants followed for 25 years in the Finnish Arthroplasty Register. J Bone Joint Surg Br. 2008;90:1562-9.
4. Barrack RL, Mulroy RD, Harris WH Improved cementing techniques and femoral component loosening in young patients with hip arthroplasty. A 12-year radiographic review. J Bone Joint Surg 1992;74A:385-9.
5. Jones LC, Hungerford DS. Cement disease. Clin Orthop Relat Res 1987;225:192-206.
6. McBeath AA, Foltz RN. Femoral component loosening after total hip arthroplasty. Clin Orthop Relat Res 1996;329S:67-70.
7. Heekin RD, Callaghan JJ, Hopkinson WJ, Savory CG, Xenos JS (1993) The porous-coated anatomic total hip prosthesis, inserted without cement. Results after five to seven years in a prospective study. J Bone Joint Surg 75A:77-91.
8. Schmalzried TP, Callaghan JJ. Wear in total hip and knee replacements. J Bone Joint Surg [Am] 1999;81:115-36.
9. Athanasou NA, Quinn J, Bulstrode CJ. Resorption of bone by inflammatroy cells derived from the joint capsule of hip arthroplasties. J Bone Joint Surg [B] 1992;74:57-62.
10. Schmalzried TP, Szuszczewicz ES, Northfield MR, Akizuki KH, Frankel RE, Belcher G, Amstutz HC. Quantitative assessment of walking activity after total hip or knee replacement. J Bone Joint Surg [Am] 1998;80:54-9.
11. Kurtz SM, Muratoglu OK, Evans M, Edidin AA. Advances in the processing, sterilization , and crosslinking of ultra-high molecular weight polyethylene for total joint arthroplasty. Biomaterials 1999;20:1659-88.
12. Faris PM, Ritter MA, Pierce AL, Davis KE, Faris GW (2006). Polyethylene sterilization and production affects wear in total hip arthroplasties. Clin Orthop 453:305-308.
13. Premnath V, Harris WH, Jasty M, Merril EW (1996). Gamma sterilization of UHMWPE articular implants: an analysis of the oxidation problem. Biomaterials 17:1741-53.
14. Oh I, Harris WH, Proximal strain distribution in the loaded femur. An in vitro comparison of the distributions in the intact femur and after insertion of different hip-replacement femoral components. J Bone Joint Surg [Am] 1978;60:75-85.
15. Mueller LA, Voelk M, Kress A, Pitto RP, Schmidt R. Progressive cancelous and cortical bone remodeling after press-fit cup fixation: a 3 year follow-up. Clin Orthop Relat Res 2007;463:213-20.
16. Huiskes R, Weinans H, van Rietbergen B. The relationship between stress shielding and bone resorption around Total hip stems and the effects of flexible materials. Clin Orthop Relat Res 1992;274:124-34.
17. Mueller LA, Schmidt R, Ehrmann C, Nowak TE, Kress A, Forst R, Pfander D. Modes of periacetabular load transfer to cortical and cancellous bone after cemented versus uncemented total hip arthroplasty: a prospective study using computed tomography-assisted osteodensitometry. J Orthop Res 2009;27:176-82.

18. Homsy CA, Cain TE, Kessler FB, Anderson MS, Kessler FB Anderson MS. Porous implant systems for prosthesis stabilization. Clin Orthop 1972;89:220-35.
19. Sychterz CJ, Topoleski LD, Sacco M, Engh CA Sr. Effect of femoral stiffness on bone remodeling after uncemented arthroplasty. Clin Orthop Relat Res 2001;389:218-27.
20. Sadr B, Arden GP. A comparison of the stability of Proplast-coated and cemented Thompson prostheses in the treatment of subcapital femoral fractures. Injury 1977;8:234-7.
21. Bryan WJ, McCaskill BL, Tullos HS. Hip endoprosthesis stabulization with a porous low modulus stem coating. Factors influencing stabilization. Clin Orthop 1981;157:125-32.
22. Tullos HS, McCaskill BL, Dickey R, Davidson J: Total hip arthroplasty with a low-modulus porous-coated femoral component. J Bone Joint Surg 1984;66A:888-98.
23. Maathuis PGM, Visser JD. High failure rate of soft-interface stem coating for fixation of femoral endoprostheses. J. Arthroplasty 1996;11:548-52.
24. Karrholm J, Herberts P, Hultmark P, Malchau H, Nivbrant B, Thanner J. Radiostereometry of hip prostheses. Review of methodology and clinical results. Clin Orthop Relat Res 1997;344:94-110.
25. Van der Vis HM, Aspenberg P, Tigchelaar W, Van Noorden CJ. Mechanical compression of a fibrous membrane surrounding bone causes bone resorption. Acta Histochem 1999;101:203.12.
26. Geesink RG, De Groot K, Klein CP (1987) Chemical implant fixation using hydroxyl-apatite coatings. The development of a human total hip prosthesis for chemical fixation to bone using hydroxyl-apatite coatings on titanium substrates.Clin Orthop 225:147-70.
27. Khalily C, Lester DK. Results of a tapered cementless femoral stem implanted in varus. J Arthroplasy 2002;17:463-66.
28. Van Blitterswijk CA, van Grote JJ, Kuypers W, Blok-van Hoek CJG, Daems WT. Biointeractions at the tissue/hydroxyapatite interface. Biomaterials 1985;43:243-51.
29. Bauer TW, Geesink RC, Zimmerman R, McMahon JT. Hydroxyapatite-coated femoral stems. Histological analysis of components retrived at autopsy. J Bone Joint Surg Am 1991;73:1439-52.
30. Capello WN. Hydroxyapatite in total hip arthroplasty: Five-year clinical experience. Orthopedics 1994;17:791-2.
31. D'Antonio JA. Remodeling of bone around hydroxyapatite-coated femoral stems. J Bone Joint Surg (Am) 1996;78:1226-34.
32. Capello WN, D'Antonio JA. Hydroxyapatite-coated total hip femoral components in patients less than fifty years old. J Bone Joint Surg (Am) 1997;79:1023-9.
33. Araujo CG, Gonzalez JF, Tonino A. Rheumatoid arthritis and hydroxyapatite-coated hip prostheses. Five-year results, J Arthroplasty 1998;13:660-7.
34. Rokkum M, Reigstad A. Total hip replacement with an entirely hydroxyapatite-coated prosthesis. 5 years follow-up of 94 consecutive hips. J Arthroplasty 1999;14:689-700.
35. Tonino AJ, Rahmy AI. The hydroxyapatite-ABG hip system. 5- to 7-year results from an international multicentre study. J Arthroplasty 2000;15:274-81.
36. McNally SA, Shepperd JAN, Mann CV, Walczak JP. The results at nine to twelve years of the use of a hydroxyapatite-coated femoral stem. J Bone Joint Surg (Br) 2000;82:378-82.
37. Capello WN, D'Antonio JA, Feinberg JR, Manley MT. Hydroxyapatite coated stems in younger and older patients with hip arthritis. Clin Orthop 2002;405:92-100.

38. D'Antonio JA, Capello WN, Manley MT, Geesink R. Hydroxyapatite femoral stems for total hip arthroplasty: 10-13-year follow up. Clin Orthop 2001;393:101-11.
39. Geesink RG. Osteoconductive coatings for total joint arthroplasty. Clin Orthop 2002;395:53-65.
40. Hernandez Cortes P, Najeraa Sagastume OO, Mesa Ramos F, Pajares Lopez M, Hernandez Hernandez MA. Hydroxyapatite-coated stems with metaphyseal and diaphyseal press-fit. Eleven-year follow-up results. Acta Orthop Belg 2002;68:24-32.
41. Skinner JA, Kroon PO, Todo S, Scott G. A femoral component with proximal HA coating. An analysis of survival and fixation at up to ten years. J Bone Joint Surg (Br) 2003 Apr;85:366-70.
42. Capello WN, D'Antonio JA, Feinberg JR, Manley MT.Ten-year results with hydroxyapatite-coated total hip femoral compnents in patients less than fifty years old. A concise follow up of a previous report. J Bone Joint Surg (Am) 2003;85:885-9.
43. Theis JC, Ball C. Medium-results of cementless hydroxyapatite-coated primary total hip arthroplasty: A clinical and radiological review. J Orthop Surg 2003;11:159-65.
44. Reikerås O, Gunderson RB. Excellent results of HA coating on a grit-blasted stem: 245 patients followed for 8-12 years. Acta Orthop Scand 2003;74:140-5.
45. Oosterbos CJM, Rahmy AIA, Tonino AJ, Witpeerd W. High survival rate of hydroxyapatite-coated hip prosthesis. 100 consecutive hip followed for 10 years. Acta Orhop Scand 2004;75:127-33.
46. Coathup MJ, Blunn GW, Flynn N, Williams C, Thomas NP. A comparison of bone remodelling around hudroxyapatite-coated, porous-coated and grit-blasted hip replacements retrieved at post-mortem. J Bone Joint Surg (Br) 2001;83:118-23.
47. McPherson EJ, Dorr LD, Gruen TA, Saberi TM (1995) Hydroxyapatite-coated proximal ingrowth femoral stems. A matched pair control study. Clin Orthop 223-30.
48. Scott DF, Jaffe WL. Host-bone response to porous-coated cobalt-chrome and hydroxyapatite-coated titanium femoral components in hip arthroplasty. Dual-enery X-ray absorptiometry analysis of paired bilateral cases at 5 to 7 years (1996) J Arthroplasty 11:429-37.
49. Sanchez-Sotelo J, Lewallen DG, Harmsen WS, Harrington J, Cabanela ME (2004) Comparison of wear and osteolysis in hip replacement using two different coatings of the femoral stem. Int Orthop 28:206-10.
50. Parvizi J, Sharkey PF, Hozack WJ, Orzoco F, Bissett GA, Rothman RH (2004) Prospective matched-pair analysis of hydroxyapatite-coated and uncoated femoral stems in total hip arthroplasty. A concise follow-up of a previous report. J Bone Joint Surg [Am] 86:783-6.
51. Søballe K, Toksvig-Larsen S, Gelineck J, Frensgaard S, Hansen ES, Ryd L, Lucht R, Bünger C (1993) A roentgen stereophotogrammetric study [migration of hydroxyapatite coated femoral prostheses. J Bone Joint Surg [Br] 75:681-7.
52. Incavo SJ, Schneider R, Elting J (1998) The effect of surface coating of femoral prostheses implanted without cement: a 2- to 4-year follow-up study. Am J Orthop 27:355-61.
53. Yee AJM, Kreder HK, Bookman I, Davey JR (1999) A randomized trial of hydroxyapatite coated prostheses in total hip arthroplasty. Clin Orthop 366:120-32.
54. Hamadouche W, Witvoet J, Porcher R, Meunier A, Sedel L, Nizard R (2001) Hydroxyapatite-coated versus grit-blasted femoral stems. J Bone Joint Surg [Br] 83:979-87.
55. Rasquina VJ, Ranawat CS, Mauriello AJ (2002) Hydroxyapatite. Catalyst or conjuror? J Arthroplasty 17:113-7.

56. Kim YH, Kim JS, Oh SH, Kim JM (2003) Comparison of porous-coated titanium femoral stems with and without hydroxyapatite coating. J Bone Joint Surg [Am] 85;1882-8.
57. Tanzer M, Gollish J, Leighton R, Orrell K, Giacchinao A, Welsh P, Shea B, Wells G (2004) The effect of adjuvant calcium phosphate coating on a porous-coated femoral stem. Clin Orthop 424:153-60.
58. Yoon KS, Kim HJ, Lee JH, Kang SB, Seong NH, Koo KH (2007) A randomized clinical trial of cementless femoral stems with and without hydroxyapatite/tricalcium-phostphate coating. J Arthroplasty 22:504-8.
59. Hartzband MA. Posterolateral minimal incision for total hip replacement: technique and early resuts. Orthop Clin North Am 2004;35:119.
60. Berger RA. Total hip arthroplasty using the minimally invasive two-incision approach. Clin Orthop Relat Res 2003;417:232-41.
61. Michel MC, Witschger P. MicroHip: a minimally invasive procedure for total hip replacement surgery using a modified Smith-Peterson approach. Ortop Traumatol Rehabil 2007;9:46-51.
62. Howell JR, Garbuz DS, Duncan CP. Minimally invasive hip replacement: Rationale, applied anatomy and instrumentation. Orthop Clin North Am 2004;35:107.
63. Woolson ST, Mow CS, Syquia JF, Lannin JW, Schurman DJ. Comparison of primary total hip replacements performed with a standard incision or a mini-incision. J Bone Joint Surg Am 2004;86:1353-8.
64. Sculco TP. Minimally invasive total hip arthroplasty. In the affirmative. J Arthroplasty. 2004 Jun;19(4 Suppl 1):78-80. Review.
65. Nakamura S, Matsuda K, Arai N, Wakimoto N, Matsushita T Mini-incision posterior approach for total hip arthroplasty. Int Orthop. 2004 Aug;28(4):214-7.
66. Chimento GF, Pavone V, Sharrock N, Kahn B, Cahill J, Sculco TP. Minimally invasive total hip arthroplasty: a prospective randomized study. J Arthroplasty 2005;20:139-44.
67. Ogonda L, Wilson R, Archbold P, Lawlor M, Humphreys P, O'Brien S, Beverland D. A minimal-incision technique in total hip arthroplasty does not improve early postoperative outcomes. A prospective, randomized, controlled trial. J Bone Joint Surg Am 2005;87:701-10.
68. Kim YH. Comparison of primary total hip arthroplasties performed with a minimally invasive technique or a standard technique. A prospective and radomized study. J Arthroplasty 2006;21:1092-8.
69. Dorr LD, Maheshwari AV, Long WT, Wan Z, Sirianni LE. Early pain relief and function after posterior minimally invasive and conventional total hip arthroplasty. A prospective, randomized, blinded study. JBJS[Am] 2007;89:1153-60.

Excellent results of proximally HA-coated femoral stems after minimum 6 years follow-up

A prospective evaluation of 100 patients

J.H.M. Goosen, A.J. Swieringa, J.G.M. Keet and C.C.P.M. Verheyen

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Department of Orthopaedic Surgery and Traumatology
Isala Clinics, Weezenlanden Hospital
Zwolle, The Netherlands

Abstract

There have been few reports on the mid- and long-term follow-up results of proximally HA-coated femoral stems. We evaluated this type of stem prospectively, with 6 to 12 years follow-up.

The survival rate, Harris Hip score and radiographic features of 106 hips in 100 consecutive patients were evaluated. The mean age at operation was 51 years (SD: 8,2). The mean Harris hip score at the time of the latest follow-up was 95 points. Spot welds occurred in 95% of the patients and were first observed at a mean follow up of 1,4 years in one or more of the Gruen regions, corresponding to the coated part of the femoral stem. A higher grade of stress shielding correlated with a less favorable Harris hip score and pain subscore. According to the criteria of Eng, all stems were graded as stable and durably bone-ingrown. No femoral component was revised.

At an average follow up of 8 years, this proximally HA-coated femoral component showed favorable clinical and radiological outcome and excellent survivorship.

Introduction

To our knowledge, there have been relatively few reports on the HA-coated, uncemented femoral stem with a minimum follow-up of 5 years or more[1-16]. In 7 of these studies proximally HA-coated stems were used.
Our prospective single-center study concerns the 6 to 12 year follow-up results of an uncemented titanium-alloy femoral component. We hypothesized that there would be a clinical and radiographic advantage of the proximally HA-coated femoral stem relative to the recently published results of its porous-coated variant[17].

Patients and methods

118 primary cementless total hip arthroplasties were implanted in 112 patients between 1992 and 1998. 6 patients were operated bilaterally. During the follow-up period, 7 patients died. None of these deaths were related to the index operation. Five patients had moved and were unable to return for follow-up. Thus, 106 hips in 100 patients underwent clinical and radiographic examination (Table 1). The mean follow-up time was 8.3 (6-12) years.
From 1992 until the time of writing, we have used the Bi-Metric stem (Biomet, Warsaw, IN) as primary uncemented total hip arthroplasty at our hospital. This stem has a 3° tapered stem design, 0° anteversion, a CCD-angle of 135° and is available in 11 sizes. The diameter of the reamers used at insertion corresponds to the stem diameter. The proximal one-third of the stem is plasma-sprayed with a HA-coating of approximally 50 μm in thicknes. This coating has a crystallinity of 50-70 percent and a minimal phase purity of 95%. The distal non-coated part is grit-blasted with a roughness of approximately 5.7 μm.
A Ringloc (Biomet) acetabular component - the multi-holed variant untill 1994 and the solid thereafter - was used. Systemic prophylactic antibiotics (cefazoline 2 g intravenously) and farmacological thromboprofylaxis (initially nandroparin 7500 IU subcutaneously the first days and followed by and acenocoumarol -target INR 2-3- until 3 months postoperatively) were used. All patients received a standard dose of indometacin (100 mg per day) during the hospital stay as a prophylaxis against the formation of periarticular ossifications.
Patients with a minimum follow-up of six years were included in the study. They were evaluated preoperatively and postoperatively at 6 weeks, 3 and 6 months, 1 year and annually thereafter. We monitored the Harris Hip Score[18]. Pelvic anteroposterior and lateral hip radiographs were exposed postoperatively, after one year and annually

Table 1 Patient characteristics

Patients (n = 100)	Sex	
	Male	43
	Female	57
	Height (m)	1.73 (range 1.53 to 1.92)
	Weight (kg)	80 (range 55 to 120)
	Body Mass Index	27 (range 19 to 39)
	Age at operation (years)	51 (22 to 63)
	Follow-up average	8.3 years (SD = 1.7)
Hips (n = 93)	Diagnosis	
	Osteoarthritis	81 (76%)
	Osteonecrosis	17 (16%)
	Rheumatoid arthritis	3 (3%)
	Developmental dysplasia	3 (3%)
	Post-trauma	2 (2%)
	Side	
	Right	55 (52%)
	Left	51 (48%)
	Approach	
	Posterior	97 (92%)
	Lateral	9 (8%)

thereafter. Spot welding, a sign of endosteal condensation and osseointegration (Fig 1), the presence of radiodense or radiolucent lines in each Gruen[19] region and the time when these changes appeared for the first time was also recorded. Pedestal formation (Fig 2) (endosteal reactive radiodensity, distally from the tip of the stem), grading of heterotopic bone formation according to the classification of Brooker[20], osteolysis, grading of stress-shielding according to the criteria of Engh[21,22] and cortical hypertrophy were noted. We measured the radiographic difference in leg-length according to Woolson[23] and varus/valgus shifting of 5° or more of the stem according to Khalily[24]. Directly after the operation and at the final follow-up, subsidence was recorded if 2 mm or more was observed between the superior tip of the greater trochanter and a standard point at the prosthesis[21]. With these parameters,

Figure 1

Spotweld formation around the proximal HA-coated part of the stem

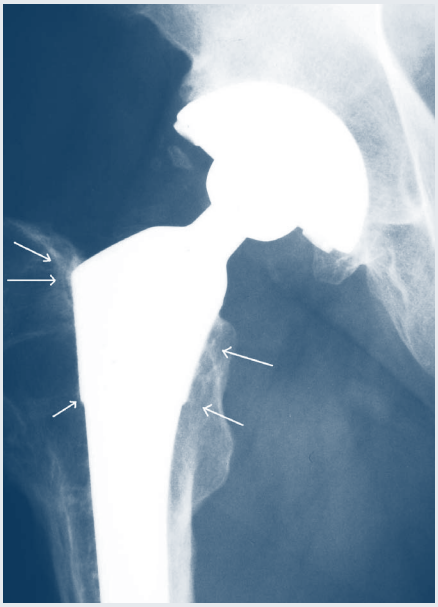
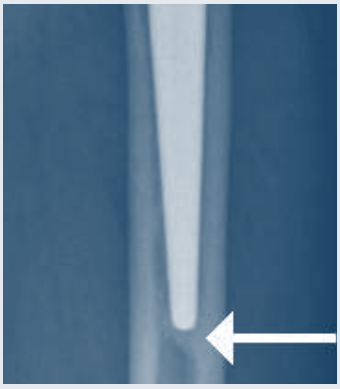


Figure 2

Endosteal bone growth distally from the tip of the stem known as pedestal formation



the state of bone-ingrowth was evaluated according to the criteria of Engh et al[21]. Kaplan-Meier analysis of the survival of the femoral component was performed for all hips from the original cohort. The best case-case scenario (in which all hips with less-than-complete follow-up were considered to have had a successful result throughout the study period), the standard-case scenario (in which all hips with less-than-complete follow-up were considered to have had a successfull result at the time of the last follow-up) and the worst-case scenario (in which all hips with less-than-complete follow-up were considered to have failed) were detemined.

Statistics

Statistical Analysis was performed with the use of SPSS statistical package (SPSS 11.0, Chicago, IL). Student's T test and linear regression were used, and significance was assumed if $p < 0.05$.

Results

Clinical

We recorded a median preoperative Harris hip score of 56 (12 - 79) and a subscore of 20 (10 - 30) points for pain. This score improved to a median of 95 (36 - 100) and 40 (10 - 44), respectively, at the final follow-up. The improvement was mainly observed in the first year after surgery (Table 2). Six patients complained of moderate, activity-related thigh pain, with an average Harris hip score and pain subscore of 92 and 37 at final follow-up.

Table 2 Average Harris Hip score and pain subscore during follow-up

Postoperative time	Average Harris Hip score (SD)	Average pain subscore (SD)
Pre-operative	56(11)	15(6)
6 weeks	78(13)	40(6)
3 months	88(11)	42(6)
6 months	93(12)	41(6)
1 year	96(11)	42(6)
5 years	95(10)	42(5)
10 years	96(6)	43(3)

Radiographic

Spotweld formation was observed in 95% of the cases in one or more of the Gruen regions 1, 7, 8 or 14 (mostly at the medial or lateral junction of the coated to uncoated part), corresponding to the HA-coated proximal one third of the stem (Table 3). All spot welds occurred within the first five years postoperatively, but predominantly (70 to 80%) during the first postoperative year.

All hips showed grade 1 stress shielding (rounding of the calcar) at 1 year. Grade 2 stress shielding (loss of medial cortical density in zone 1) occurred predominantly 2 or 3 years postoperatively. Grades 3 (loss of medial cortical density in zone 2) or 4 (loss of medial cortical density distal from zone 2) were rarely seen (Table 4). Linear regression showed that a higher grade of stress shielding was significantly correlated with a less favorable Harris hip score and pain subscore (Table 5). Typical

Table 3 Prevalence of spot weld formation per Gruen Zone (%)*

Zone	Year 1	Year 2	Year 3	Year 4	Year 5	Cumulative percentage at 5 year FU
1	**67**	**20**	**5**	**1**	**2**	**95**
2	33	7	1			41
3	17	5	1			23
4	7	1	1	1		10
5	16	5	2			23
6	20	3	2			25
7	**62**	**6**	**6**	**1**	**1**	**76**
8	**64**	**9**	**4**	**1**	**1**	**79**
9	14	2	1			17
10	7	2	1			10
11	3	1	1			5
12	6	2	2			10
13	9	1	1			11
14	**66**	**8**	**3**	**1**	**2**	**80**

* Zones representing the HA-coated part of the femoral stem are shown in bold

signs of stress transfer, such as distal cortical hypertrophy and pedestal formation, were frequently observed. Reactive lines or adverse clinical features were not observed in any of the hips showing a pedestal. Seven hips showed radio-dense lines which were located in the Gruen regions corresponding to the HA-coated part of the stem. In the uncoated, distal part, all but one of the other lines were located around the tip of the stem and continued to a pedestal (13 hips). Distal intramedullary osteolysis was identified in 1 hip in Gruen regions 1 and 7 at 6 months, and disappeared after 4 years; and spot welds occurred at 5 years postoperatively in these regions. According to the limits described by Engh[21], 35 stems subsided, of which 7 stems subsided by 5 mm or more. All cases of subsidence were observed in the first postoperative year. Preoperatively, an average difference in leg-length of 2 mm (operated side shorter) was measured. In the 7 patients with a subsidence of 5 millimeters or more, a decreased leg-length of 6 mm was observed, while the

Table 4 Prevalence of the radiologic parameters according to Eng (1990) (%)

Parameter	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Cumulative percentage at 6 years of follow-up
Fixation:							
Spot welds	67	20	5	1	2		95
Radiodense lines (HA)	4	1	1				6
Stability:							
Stress shielding							
Grade 1	100						100
Grade 2	9	46	16	1	4		76
Grade 3	1	5	2	2	0	6	16
Grade 4	1	2	1	1	1		6
Cort hypertrophy	24	31	13	6	4		78
Pedestal	12	26	21	6	2		66
Radiodense lines (Non HA)	10	1	1	1			13
Intramed osteolysis	0	0	0	1			1
Subsidence	33						33

Table 5 Relation between the mean Harris Hip score, pain-subscore and grade of stress shielding

	Grades of stress shielding (number of hips)					
	1 (36)	2 (55)	3 (8)	4 (7)	Adj. R^2	P-value*
Average Harris Hip score (SD)	98(4)	96 (9)	87 (13)	85 (24)	0.11	0.002
Average Pain score (SD)	44(1)	43 (4)	42 (5)	36 (14)	0.11	0.002

* = Linear Regression

average leg length in all hips was 0.5 mm (operated side longer) at final follow-up ($p = 0.05$, Student t-test). According to the criteria of Engh, all stems showed bone ingrowth and stability 1 year after the operation and thereafter. All but two stems were placed within 5° of alignment. One stem was placed in 6° valgus and one in 8° varus; both stems stayed in their position during follow-up. Heterotopic bone formation was observed in 28 hips, of which 24 had a posterior and 4 a lateral approach. According to Brooker, 25 hips showed grade 1, one hip showed grade 2 and 2 hips showed grade 3 heterotopic bone formation, all at the first year follow-up, without progression later. Four hips, all of which had been operated with a posterior approach, dislocated during follow-up. Three hips dislocated once: 2 in the first year and one 8 years postoperatively. One hip underwent revision of the acetabular component after 3 episodes of dislocation, with a succesful result. This revision was the only one in the study, thus none of the femoral stems were revised. Survival of the femoral component of the original cohort at final follow-up was 100% (95% CI: 99-100) in a best case scenario, 100% (95% CI: 99-100) in a standard case scenario and 90% (95% CI: 89-91) in a worst-case scenario.

Discussion

HA-coating

Hydroxyapatite is the crystalline portion of natural bone mineral. Synthetic HA is biocompatible and osteoconductive, and in contact with bone it often develops a mechanically tight bond which probably is of a chemical nature[24,25]. Human retrieval studies have shown that the formation of newly woven bone adjacent to the HA layer does not pass through an intermediate stage of fibrous tissue and therefore secondary fixation is enhanced in this prosthesis[26].

Porous- versus HA-coated implants

Coathup et al[27] investigated human retrievals on the implant-bone interface around the proximally HA-coated and porous-coated Bi-Metric femoral stem and observed significantly more ingrowth and attachment of bone to the HA-coated surface. Studies evaluating (both clinically and radiographically) proximally HA-coated stems and also a porous-coated version of the stem in the present study, all with a follow-up of 5 year or more, are listed in Table 6. As various reports were essentially based on the same cohort, we selected the study most suitable in our opinion[9,16]. Compared with a porous-coated variant with identical geometry, matched pair or bilateral studies established a clinical and radiographic[28,29] or only radiographic[30,31] advantage of HA-coating, while others

Table 6 Summary results of mimimum 5 year FU proximally HA-coated stems* and a proximally porous-coated Bi-Metric stem:

Article/author	Carcia Araujo (1998)	Theis (2003)	Oosterbos (2004)	D'Antonio (2001)	Geesink (2002)	Hernandez (2002)	Skinner (2003)	Current study	Meding (2004)
Type stem	ABG (HA)	ABG (HA)	ABG (HA)	Omnifit (HA)	Omnifit (HA)	Ti fit (HA)	Freeman (HA)	Bi-metric (HA)	Bi-Metric (PC)
Patients(hips in FU	32(33)	69(82)	62(68)	314(274)	118(99)	52(52)	100(100)	106(100)	105(95)
FU y(range)	5(NR)	7.3(5-10)	10	11.1(10-13)	12(11-13)	11(NR)	10	8.3(6-12)	10.4(10-12)
Age (range)	51.4(25-78)	57.4(31-74)	72(55-84)	51(18-81)	53(21-73)	65(45-67)	56.8 (NR)	51(22-63)	56(27-78)
Clinical results	G/E[c]	G/E[c]	G/E[c]	E[b]	E[b]	G/E[c]	NR	E[b]	E[b]
Spotwelds (%) (location; or/if Gruen-zones)	52 2,6	54 M&LJ[e]	77, 80 M&LJ 2,6	89 MJ 6,7	NR	NR	83 M&LJ 1,8	95, 76 M&LJ	62 NR
Radioactive lines	30	75	43	55	NR	30.8	50	19	10
(%HA-coated;	0	0	0	2.5			11	6	
%non coated)	30	75	43	52			39	13	NR
Cortical hypertrophy (%)	NR	NR	29	62	NR	42.3	NR	78	83
Pedestal (%)	NR	NR	NR	NR	NR	3.8	NR	66	47
Subsidence (%) (mm)	6 2-5	1 NR	1 >5	1.3 >3	NR	0	100 <7.6	7.5 >5	1 >5
Dist Intramed. Osteolysis (%)	NR	NR	2	0	0	1.9	1	1	1
%Heterotopic Bone formation (grade and %)	48 1: 33 >1: 15	41 1-2: 40 3-4: 1	46 1-2: 45 3: 1	26 1-3: 24 4: 2	NR	23 1-2: 20 3: 3	NR	26 1-2: 24 3: 2	NR

Dislocation (%)	0	6	1	NR	3.3	0	NR	3.8	2
Stems revised (%)	0	0	1	4	3	7.6	0	0	0
Cups revised (%)	0	3.6	3	12.1	4.2	9.6	3	1	9
Grades of stress shielding (%) (Gruen-zones if grade is NR)	70 zone 6, 7 30 zone 1, 2	11 zone7	1: 51 2: 73	NR	NR	NR	NR	1 : 100 2 : 76 3 : 15 4 : 6	1 : 100 2 : 100 3 : 53 4 : 17
Stable fixation (%)d	NR	NR	100	100	100	87.5	NR	100	100

[a] E Excellent, G Good

[b] Harris hip score

[c] Merle d'Aubigne score

[d] According to Engh et al. 1990

[e] MJ Medial Junction, LJ Lateral Junction

NR = Not Recorded

*(Bold) = Current study

could not demonstrate a difference[32-39]. An average increase of bone mineral density value of 48% was observed around HA-coated implants, when compared with bilaterally placed porous-coated implants of the same geometry[31]. Søballe et al[28] used X-ray stereophotogrammetric analysis to detect differences in migration in identical HA-coated and porous-coated Bi-Metric stems. HA-coated stems stop migrating at three months postoperatively, whereas porous-coated stems continued to migrate for at least 1 year. Significantly higher Harris hip and pain scores were found in the HA-coated group. This latter report and those of others (Table 6) were not in accordance with the results of our study, where vertical migration of the stem was evident in two thirds of the hips, which is rather high. According to Engh, the limits of error, measuring subsidence, are 2 mm or more. Meding et al[17] used a limit of 5 mm[37] and had only one case above that limit. In our study there were 7 cases which showed subsidence of more than 5 mm. There was no adverse relationship between subsidence of 2 mm or more and clinical or radiographic results, apart form the subsequent leg-length difference in patients with a subsidence of 5 mm or more at final follow-up.
In comparison with its porous-coated variant[17], our stems showed more spotwelds - which also developed earlier.
In conclusion, radiographically, an earlier and more stable state of bone ingrowth (according to Engh) was observed in the HA-coated stem than in the porous-coated variant, referring to the results of Meding et al[17].

Stress shielding

Morscher and Dick[38] concluded that the stress concentrations will increase with increasing rigidity of the implant. Engh et al[22] , however, found that stress-related bone loss does not influence the clinical results adversely. In our study, a less favourable Harris hip score and pain-subscore were correlated with higher grades of stress shielding. Compared to the HA-coated stem of this study, its porous-coated variant showed a higher incidence of stress-shielding for all grades, but relation to clinical findings was not recorded[17]. It can be hypothesized that there is more and earlier cancellous bone formation at the HA-coated part and therefore less distal stress concentration and bone remodelling. Allthough studies with fully HA-coated stems show favorable results[5,7,15], proximally ingrown uncemented implants can be expected to result in a more uniform stress transfer over the full length of the stem, and should therefore show less stress shielding than fully ingrown press-fit stems[39].

Cortical hypertrophy

Distal cortical hypertrophy can serve as a secondary stabilizer of the stem[9]. Adolphson[40] evaluated distal cortical hypertrophy in the same HA-coated stem as

used in the current study. In contrast to cemented hip arthroplasties, they observed an increase in the outer diameter of the distal femur and no widening of the distal medullary canal in case of cortical hypertrophy, as in the present study. It was concluded that the uncemented HA-coated device causes a different stress transfer to the cortical femoral bone, compared with the cemented device. Compared to other studies listed in Table 6, the incidence of cortical hypertrophy was rather high in our study. The incidence in our material is rather close to that of the porous-coated variant of the same implant[17], which suggests that the anatomical design of the stem is the main reason. Hernandez Cortes et al[11] suggested a relationship between cortical hypertrophy, endosteal irritation and thigh pain, a theory not supported by our findings.

Osteolysis

Similar to the stem materials in Table 6, which are all representative designs with circumferential, proximal coating, our study also shows a very low incidence of distal intramedullary osteolysis. Non-circumferential coating has been associated with a higher prevalence of osteolysis[41]. Thus, the circumferential bone ingrowth possibly has a relative sealing influence and may impede polythylene to migrate distally into the femoral canal.

To conclude: The survival rate of the evaluated proximally HA-coated femoral component is excellent. However, this stem showed no obvious advantage over the porous-coated variation of this design (historical control).

References

1. Capello WN. Hydroxyapatite in total hip arthroplasty: Five-year clinical experience. Orthopedics 1994;17:791-2.
2. D'Antonio JA. Remodeling of bone around hydroxyapatite-coated femoral stems. J Bone Joint Surg (Am) 1996;78:1226-34.
3. Capello WN, D'Antonio JA. Hydroxyapatite-coated total hip femoral components in patients less than fifty years old. J Bone Joint Surg (Am) 1997;79:1023-9.
4. Araujo CG, Gonzalez JF, Tonino A. Rheumatoid arthritis and hydroxyapatite-coated hip prostheses. Five-year results, J Arthroplasty 1998;13:660-7.
5. Rokkum M, Reigstad A. Total hip replacement with an entirely hydroxyapatite-coated prosthesis. 5 years follow-up of 94 consecutive hips. J Arthroplasty 1999;14:689-700.
6. Tonino AJ, Rahmy AI. The hydroxyapatite-ABG hip system. 5- to 7-year results from an international multicentre study. J Arthroplasty 2000;15:274-81.
7. McNally SA, Shepperd JAN, Mann CV, Walczak JP. The results at nine to twelve years of the use of a hydroxyapatite-coated femoral stem. J Bone Joint Surg (Br) 2000;82:378-82.
8. Capello WN, D'Antonio JA, Feinberg JR, Manley MT. Hydroxyapatite coated stems in younger and older patients with hip arthritis. Clin Orthop 2002;405:92-100.
9. D'Antonio JA, Capello WN, Manley MT, Geesink R. Hydroxyapatite femoral stems for total hip arthroplasty: 10-13-year follow up. Clin Orthop 2001;393:101-11.
10. Geesink RG. Osteoconductive coatings for total joint arthroplasty. Clin Orthop 2002;395:53-65.
11. Hernandez Cortes P, Najeraa Sagastume OO, Mesa Ramos F, Pajares Lopez M, Hernandez Hernandez MA. Hydroxyapatite-coated stems with metaphyseal and diaphyseal press-fit. Eleven-year follow-up results. Acta Orthop Belg 2002;68:24-32.
12. Skinner JA, Kroon PO, Todo S, Scott G. A femoral component with proximal HA coating. An analysis of survival and fixation at up to ten years. J Bone Joint Surg (Br) 2003 Apr;85:366-70.
13. Capello WN, D'Antonio JA, Feinberg JR, Manley MT.Ten-year results with hydroxyapatite-coated total hip femoral compnents in patients less than fifty years old. A concise follow up of a previous report. J Bone Joint Surg (Am) 2003;85:885-9.
14. Theis JC, Ball C. Medium-results of cementless hydroxyapatite-coated primary total hip arthroplasty: A clinical and radiological review. J Orthop Surg 2003;11:159-65.
15. Reikerås O, Gunderson RB. Excellent results of HA coating on a grit-blasted stem: 245 patients followed for 8-12 years. Acta Orthop Scand 2003;74:140-5.
16. Oosterbos CJM, Rahmy AIA, Tonino AJ, Witpeerd W. High survival rate of hydroxyapatite-coated hip prosthesis. 100 consecutive hip followed for 10 years. Acta Orhop Scand 2004;75:127-33.
17. Meding JB, Keating EM, Ritter MA, Faris PM, Berend ME. Minimum ten-year follow up of a straight-stemmed, plasma-sprayed, titanium-alloy, uncemented femoral component in primary total hip arthroplasty. J Bone Joint Surg (Am) 2004;86:92-97.
18. Harris WH. Traumatic arthritis of the hip after dislocation and acetabular fractures: Treatment by mold arthroplasty. J Bone Joint Surg (Am) 1969;51:737-55.
19. Gruen TA, McNeice GM, Amstutz HC. "Modes of failure" of cemented stem-type femoral components, a radiographic analysis of loosening. Clin Orthop 1979;141:17-27.

20. Brooker AF, Bowermann JW, Robinson RA, Riley LH. Ectopic ossification following total hip replacement. J Bone Joint Surg (Am) 1973;55;1929-32.
21. Engh CA, Massin P, Suthers KE. Roentgenographic assessment of the biologic fixation of porous-surfaced femoral components. Clin Orthop 1990;257:107-27.
22. Engh CA, Bobyn JD, Glassman AH. Porous-coated hip replacement; the factors governing bone ingrowth, stress shielding and clinical results. J Bone Joint Surg (Br) 1987;69:45-55.
23. Woolson ST, Hartford JM, Sawyer A. Results of a method of Leg-Lengt equalization for patients undergoing primary total hip replacement. J Arthroplasty 1999;14:159-64.
24. Khalily C, Lester DK. Results of a tapered cementless femoral stem implanted in varus. J Arthroplasy 2002;17:463-66.
25. Van Blitterswijk CA, van Grote JJ, Kuypers W, Blok-van Hoek CJG, Daems WT. Biointeractions at the tissue/hydroxyapatite interface. Biomaterials 1985;43:243-51.
26. Bauer TW, Geesink RC, Zimmerman R, McMahon JT. Hydroxyapatite-coated femoral stems. Histological analysis of components retrived at autopsy. J Bone Joint Surg Am 1991;73:1439-52.
27. Coathup MJ, Blunn GW, Flynn N, Williams C, Thomas NP. A comparison of bone remodelling around hudroxyapatite-coated, porous-coated and grit-blasted hip replacements retrieved at post-mortem. J Bone Joint Surg (Br) 2001;83:118-23.
28. Søballe K, Toksvig-Larsen S, Gelineck J, Fruensgaard S, Hansen ES Ryd L, Lucht U, Bünger C. Migration of hydroxyapatite-coated femoral prosteses. A roentgen-stereophotogrammatic study. J Bone Joint Surg (Am) 1993;75:681-87.
29. Donnelli WJ, Kobayashi A, Freeman MA. Radiological and survival comparison of four methods of fixation of a proximal femoral stem. J Bone Joint Surg (Am) 1997;79:351-60.
30. McPherson EJ, Dorr LD, Gruen TA, Saberi MT. Hydroxyapatite-coated proximal ingrowth femoral stems: A matched pair control study. Clin Orthop 1995;315:223-30.
31. Scott DF, Jaffe WL. Host-bone response to porous-coated cobalt-chrome and hydroxyapatite-coated titanium femoral compnents in hip arthroplasty: Dual-energy x-ray absorptiometry analysis of paired bilateral cases. J Arthroplasty 1996;11:429-37.
32. Rothman RH, Hozack WJ, Ranawat A, Moriarty L. Hydroxyapatite-coated femoral stems: A matched pair analysis of coated an uncoated implants. J Bone Joint Surg (Am) 1996;78:319-24.
33. Dorr LD, Wan Z, Song M, Ranawat A. Bilateral total hip arthroplasty comparing hydroxyapatite to porous-coated fixation. J Arthroplasty 1998;13:72-36.6
34. Yee AJ, Kreder HK, Bookman I, Davey JR. A randomized trial of hydroxyapatite-coated prostheses in total hip arthroplasty. Clin Orthop 1999;366:120-32.
35. Sharp RJ, O'Leary ST, Falworth M. Analysis of the results of the C-Fit uncemented total hip arthroplasty in young patients. J Arthroplasty 2000;15:627-34.
36. Kim YH, Kim JS, Oh SH, Kim JM. Comparison of porous-coated titanium femoral stems with and without hydroxyapatite coating. J Bone Joint Surg (Am) 2003;85:1682-88.
37. Loudon JR. Femoral prosthetic subsidence after low-friction arthroplasty. Clin Orthop 1986;211:134-39.
38. Morscher EW, Dick W. Cementless fixation of "isoelastic" hip endoprosthesis manufactured from plastic materials. Clin Orthop 1983;176:77-87.

39. Huiskes R. The various stress patterns of press-fit, ingrown, and cemented femoral stems. Clin Orthop. 1990;261:27-38.
40. Adolphson P. Femoral cortical remodeling after uncemented total hip arthroplasty. A prospective radiologic study of 26 hips followed for 2 to 4 years. J Arthroplasty 1997;12:99-105.
41. Clohisy JC, Harris WH. The Harris-Galante uncemented femoral component in primary total hip replacement at 10 years. J Arthroplasty. 1999;14:915-7.

Chapter | 3

Porous-coated femoral components with or without hydroxyapatite in primary uncemented total hip arthroplasty

A systematic review of randomized controlled trials

J.H.M. Goosen[1], A.J. Kums[1], B.J. Kollen[2] C.C.P.M. Verheyen[1]

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[1] Department of Orthopaedic Surgery and Traumatology
[2] Research Bureau, Isala Academy
Isala Clinics, Weezenlanden Hospital
Zwolle, The Netherlands

Abstract

The purpose of this systematic review was to determine the clinical and radiologic benefit of hydroxyapatite coating in uncemented primary total hip arthroplasty. A database of Medline articles published up to September 2007 was compiled and screened. Eight studies involving 857 patients were included in the review. Pooled analysis for Harris Hip Score as a clinical outcome measure demonstrated no advantage of the hydroxyapatite coating (WMD: 1.49, $p = 0.44$). Radiologically, both groups showed equal presence of endosteal bone ingrowth (RR: 1.04, $p = 0.66$) and radioactive lines (RR: 1.02, $p = 0.74$) in the surface area of the prosthesis.
This meta-analysis demonstrates no clinical nor radiologic benefits on the application of a hydroxyapatite coating on a femoral component in uncemented primary total hip arthroplasty.

Introduction

Reports of high rates of failure of cemented femoral components in younger and more active patients have stimulated the development of implant fixation without cement[1,2]. In the late 1980s, hydroxyapatite was applied on the implant surface in uncemented total hip arthroplasty because of its biocompatibility and osteo-conductive potential[3]. As opposed to the porous-coated variant with identical geometry, matched pair trials[4-7] and (bilateral) randomized controlled trials[8-15] remain ambiguous about the clinical and radiographic advantages of the hydroxyapatite coating. To determine the clinical and radiologic benefit of hydroxyapatite coating in uncemented primary total hip arthroplasty, we performed a meta-analysis of all high-quality randomized controlled trials on this subject.

Patients and Methods

We attempted to identify all relevant published and unpublished randomized trials that compared Porous-Coated femoral components with Hydroxyapatite Coating (HAC) or without an applied hydroxyapatite surface coating (Porous Coated, PC) of identical geometry. The QUOROM guidelines for reporting meta-analyses of randomized trials[16] were adhered to. We searched the MEDLINE and EMBASE electronic databases for studies published between January 1980 and September 2007, using the keywords “hydroxyapatite coating”, “primary uncemented total hip arthroplasty”, “porous coating”, “prosthesis”, “hip”, “clinical outcome”, “radiologic (or radiographic) outcome”. Only articles (or abstracts) written in the English, German and French languages were considered. Bibliographies of journal articles were hand-searched to trace additional studies. We assessed relevance using a hierarchical approach based on title, abstract and the full manuscript.

Methodological quality

Two investigators independently assessed studies for possible inclusion, and any disagreements were resolved by discussion or referred to a third investigator for arbitration. To be included, studies had to be properly randomized, be based on a total hip prosthesis (HAC and PC) with one identical geometry, and have used objective, validated clinical and radiographic outcome measurements.

To ensure high quality, we used the methodological criteria outlined by Tulder[17]. This list adheres to the following 12 mean criteria: adequate randomization procedure;

allocation concealment; baseline similarity; care provider-blinded; control for co-interventions; acceptable adherence; relevant, reliable and valid outcome measures; patient-blinded; acceptable number of withdrawals and missing values; outcome assessor-blinded; identical timing of outcome measurement; and intention-to-treat analysis.

Statistics

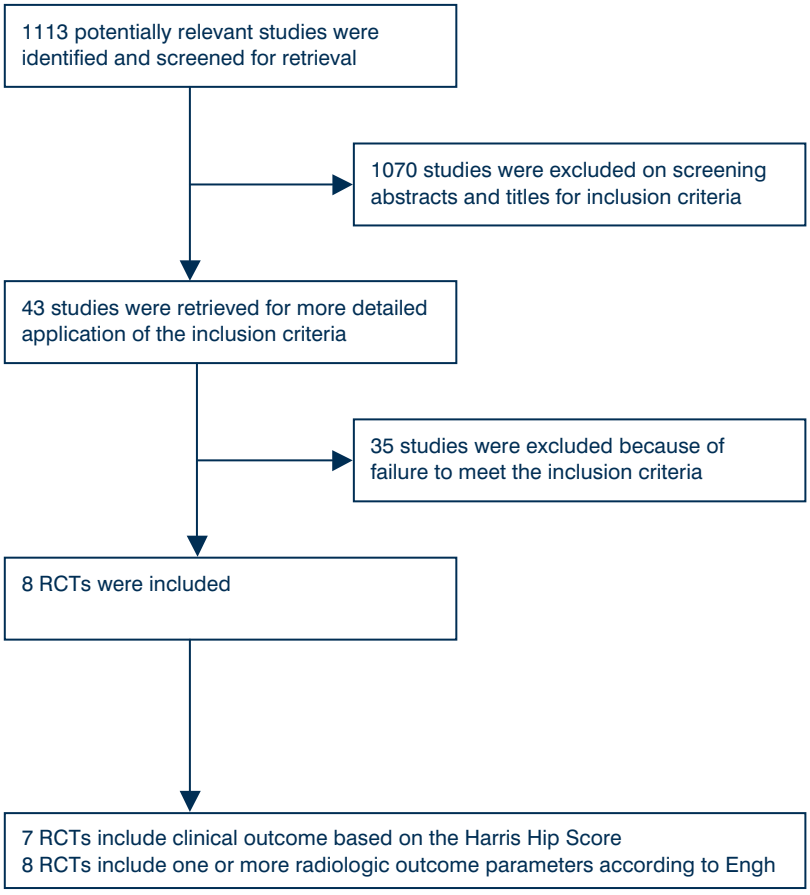
Percentage of observed agreement between reviewers was determined and interrater reliability of individual scores established using Cohen's Kappa statistics. Reviewers were blinded to author(s), institution(s) or journal. Methodological criteria scores of 9 (maximum 12) points or higher were classified as "high quality", studies with less than 5 points were classified as "low quality". We used Cochrane Collaboration software (Review manager 4.2.9) to conduct the statistical analysis and applied a fixed-effects or, if necessary, random-effects model to pool results from the individual trials. We calculated the weighted mean difference (WMD) risk ratio (RR) and 95% CI. To demonstrate statistical heterogeneity we used the I^2 statistic. An I^2>30% was considered to denote heterogeneity. The Mantel-Haenzel method was applied to pool observed study effects.

Results

Our search identified 1113 potentially eligible citations. Initially, 1070 studies were excluded on screening for inclusion criteria. After further scanning their titles and abstracts, 35 citations were excluded on the basis of language, similar data published elsewhere, use of two (or more) prostheses with a different geometry, or application of a non-validated radiographic or clinical outcome measurement. Thus a total of eight trials involving 857 patients met the inclusion criteria (Figure 1). Observer agreement was 94%, interobserver reliability K = .799 (.611–.987); P < 0.001. Table 1 shows the characteristics of the study design. There was considerable variation in number of operated hips and follow-up period. In one study, the patients received a HAC and a PC prosthesis bilaterally after randomization[13]. In all studies, proper methods were used to generate the randomized treatment allocation and had sufficient methodological criteria scores. One study showed an inadequate or uncertain concealment of treatment allocation and lack of blinding of observer because the surgeon who implanted the prosthesis also conducted the clinical evaluation at each follow-up visit[11]. The treatment and control groups were comparable at baseline in all eight studies. In three studies, patient-blinding was uncertain[8,10,13]. In four studies,

Figure 1

The QUORUM statement flow diagram



the medical personnel involved in the care of study subjects was not blinded[8-11]. Two studies provided only mean and range information for their outcome measures[13,15]. No standard deviation can be deduced from this information, so we were unable to calculate weighted effect sizes and pooled these studies for Harris Hip score[18].

Table 1 Study characteristics

Trial	Prosthesis	Number of hips (HA:PC)*	FU (y) HA:PC	Age (y) HA:PC	M:F	Clinical Outcome**	Radiographic Outcome***
Hamadouche 2001	Profile (DePuy)	50 (24:26)	8.7	65:64	41:19	HHS	A
Incavo 1998	Profile (DePuy)	50 (24: 26)	4	55	NR	HHS	A, B, C, D
Kim 2003	IPS (DePuy)	100 (50:50)	6.6	45	36:14	HHS	A, D, F
Rasquina 2002 (Biomet)	Ranawat-Burstein	174 (82:92)	4.8:4.6	55:56	114:38	Postel d'Aubigne	A, B, F
Søballe 1993	Bi-Metric (Biomet)	28 (15:13)	1	57:59	NR	HHS	A, B, C, D
Tanzer 2004	Multilock (Zimmer)	318 (159:159)	3.1	65:63	165:153	HHS	B, C, F
Yee 1999	Mallory-Head (Biomet)	62 (35:27)	4.4:4.9	48:50	40:22	HHS	A, B, C
Yoon 2007	Multilock (Zimmer)	75 (37:38)	10.5	45:46	49:14	HHS	A, B, C, D

* HA = Hydroxyapatite-Coated; PC = Porous-Coated

** HHS = Harris Hip Score

*** A = Subsidence, B = Radioactive Lines, C = Endosteal bone ingrowth (Spot Welds), D = Pedestal formation, E = Cortical hypertrophy, F = Bone ingrowth acc. to Engh

Figure 2 Weighted mean difference (WMD) estimate for Harris Hip Score

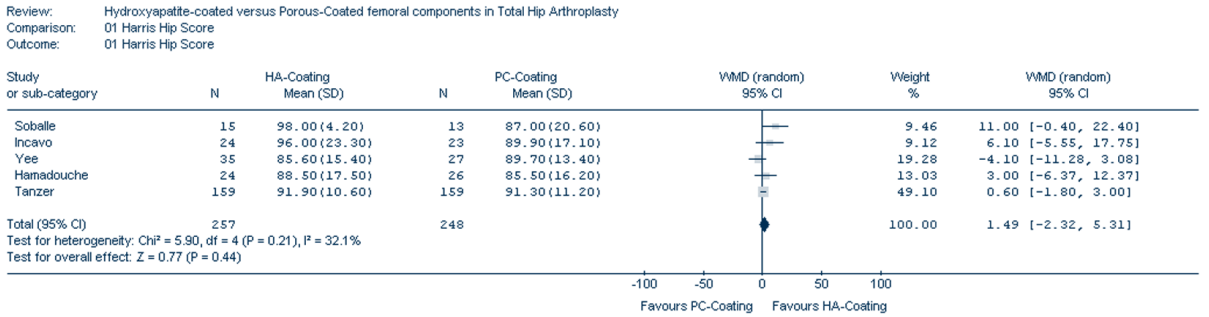


Figure 3 Relative risk (RR) estimate for Radioactive Lines (A) and Endosteal Condensation (B)

A

Study or sub-category	HA-Coating n/N	PC-Coating n/N	RR (fixed) 95% CI	Weight %	RR (fixed) 95% CI
Soballe	4/14	4/12		2.45	0.86 [0.27, 2.71]
Incavo	2/24	0/23		0.29	4.80 [0.24, 94.90]
Rasquina	57/82	61/92		32.69	1.05 [0.85, 1.29]
Tanzer	84/159	83/159		47.19	1.01 [0.82, 1.25]
Yoon	29/37	31/38		17.39	0.96 [0.77, 1.21]
Total (95% CI)	316	324		100.00	1.02 [0.90, 1.16]

Total events: 176 (HA-Coating), 179 (PC-Coating)
Test for heterogeneity: Chi² = 1.48, df = 4 (P = 0.83), I² = 0%
Test for overall effect: Z = 0.33 (P = 0.74)

B

Study or sub-category	HA-Coated n/N	PC-Coated n/N	RR (fixed) 95% CI	Weight %	RR (fixed) 95% CI
Soballe	13/14	12/12		11.81	0.94 [0.77, 1.14]
Incavo	13/24	15/23		13.51	0.83 [0.52, 1.33]
Yee	15/35	9/27		8.96	1.29 [0.67, 2.48]
Tanzer	46/159	41/159		36.15	1.12 [0.78, 1.61]
Yoon	33/37	34/38		29.58	1.00 [0.85, 1.17]
Total (95% CI)	269	259		100.00	1.04 [0.88, 1.23]

Total events: 120 (HA-Coated), 111 (PC-Coated)
Test for heterogeneity: Chi² = 2.73, df = 4 (P = 0.60), I² = 0%
Test for overall effect: Z = 0.44 (P = 0.66)

Figures 2 and 3 show the pooled analyses on HAC versus PC. Because of statistical evidence of moderate heterogeneity among the studies on the Harris Hip Score (I^2 = 32.1 %), a random-effects model was applied for analysis of the Harris Hip Score. With respect to the Harris Hip Score, we were able to pool five studies[8-11, 14]. No difference between the coatings was observed (WMD: 1.49, CI: -2.32 to 5.31, P = 0.44) (Figure 2).

Standard radiographs and one or more parameters of implant stabilization and fixation according to the criteria of Engh[19] were recorded in all studies. Five studies[8,9,12,14,15] recorded the presence of radioactive (lucent or dense) lines, which constitutes an unfavorable factor for implant stability and could be a sign of micromotion and component loosening[19]. Pooled analysis on radioactive lines could not demonstrate a difference between both coatings (RR: 1.02, CI: 0.90 to 1.16, P = 0.74) (Fig 3A). The presence of endosteal condensation (spot welds), which is considered a sign of endosteal bone ingrowth on the surface of the prosthesis, is listed as a favorable factor for implant fixation[19]. This parameter was observed in five studies[8-10,14,15]. Pooled analysis showed that spot welds were equally present in both coatings (RR: 1.04, CI: 0.88 to 1.23, P = 0.66) (Fig 3B). The studies included for pooled analysis on radioactive lines and endosteal condensation were statistically homogenous (I^2 = 0%). Stem subsidence was measured in seven studies[8-13,15], albeit with three different techniques and variable definitions. As a result, pooling on subsidence was not feasible.

Discussion

Hydroxyapatite is the crystalline portion of natural bone mineral. Synthetic HA is biocompatible and osteoconductive, and in contact with bone often develops a mechanically tight bond. These potentials were postulated as theoretical advantages of hydroxyapatite coating on femoral components in uncemented total hip arthroplasty[20]. Human retrieval studies have shown that the formation of newly woven bone adjacent to the HA layer does not pass through an intermediate stage of fibrous tissue, therefore secondary fixation is enhanced in this prosthesis[21]. Coathup[22] et al. investigated human retrievals on the implant-bone interface around the HAC and PC femoral stem, and observed significantly more ingrowth and attachment of bone to the HAC surface.

Although one study[8] showed a higher Harris Hip Score in those patients treated with a HAC compared with a PC femoral component, no difference was observed

between the two groups in our meta-analysis. Contrary to our results, which are predominantly based on RCTs performed in the early 2000s, the first (retrospective) studies after the introduction of HAC in uncemented total hip arthroplasty showed more favorable Harris Hip Scores in the HAC group, but these studies suffered from inferior methodology[23-25].

Radiologically, we could not differentiate between the HAC and PC femoral stems for presence of radioactive lines around the prosthesis or endosteal bone ingrowth. Contrary to our findings, earlier matched pair and bilateral radiologic studies report an improved bony ingrowth and fixation when using HAC[4,5]. Based on absorptiometry analysis on three bilaterally operated patients (HAC on one side and PC on the other), the bone surrounding the HAC femoral components showed a higher bone mineral density, which suggests an improved fixation[5]. McPherson[4] et al. stated that 90% of the 42 HAC femoral components achieved stable bony fixation compared with the 83% of the 42 PC stems after a 3 year follow-up, according to the criteria of Engh[19].

Unfortunately, we were unable to pool the included RCTs on marked subsidence, because these studies used different measurements. Søballe[8] et al. observed less subsidence in the HAC compared with the PC femoral components after one year follow-up, using Roentgen Stereophotogrammetric Analysis (RSA) on 28 primary total hip replacements (1.7 *vs* 3.9 mm, $p < 0.05$). In this group, the patients with an HAC femoral component also showed a better Harris Hip Score (98 *vs* 87, $p < 0.05$). Hamadouche[11] et al. also demonstrated less subsidence in 24 HAC compared with 26 PC femoral stems (1.95 *vs* 2.32 mm, $p = 0.04$) after a follow-up op approximately 5 years. They measured the femoral stem migration with 19 reference points in the femur and the stem. Magnification was corrected and distances were measured in a graphic radiologic programm; Ein Bild Roentgen Analyse Femoral Compenent Analysis (EBRA-FCA). In the other reports included in this analysis, subsidence was measured using plain radiographs, and no difference was found on subsidence between the HAC and PC femoral stems[9,10,12,13,15]. The reduction of femoral migration measured by RSA is the most sensitive, compared with EBRA-FCA and plain radiograph measurements[8,11]. Therefore, the results of Søballe et al are a very important indication of a reduction of migration in the HA-coated stems[8].
Finally, a meta-analysis remains retrospective research that is likely to suffer from publication bias, methodological deficiencies and heterogeneity. However, we kept the likelihood of bias to a minimum by developing a detailed protocol before starting this study, undertaking a meticulous search for both published and unpublished

studies, and using the appropriate methods for study selection, data extraction and data analysis.

In conclusion, this meta-analysis established no clinical or radiologic evidence of benefits of the application of hydroxyapatite coating on a femoral component in uncemented total hip arthroplasty, although this conclusion is based on only eight randomized controlled trials as a result of the stringent entry criteria. Studies reporting on the clinical and radiologic advantages of hydroxyapatite application that were based on inferior methodological designs were excluded from our meta-analyses. The randomized controlled trials included in our meta-analysis were predominantly conducted in the last 10 years.

References

1. Barrack RL, Mulroy RD, Harris WH (1992) Improved cementing techniques and femoral component loosening in young patients with hip arthroplasty. A 12-year radiographic review. J Bone Joint Surg 74A:385-9.
2. Heekin RD, Callaghan JJ, Hopkinson WJ, Savory CG, Xenos JS (1993) The porous-coated anatomic total hip prosthesis, inserted without cement. Results after five to seven years in a prospective study. J Bone Joint Surg 75A:77-91.
3. Geesink RG, De Groot K, Klein CP (1987) Chemical implant fixation using hydroxyl-apatite coatings. The development of a human total hip prosthesis for chemical fixation to bone using hydroxyl-apatite coatings on titanium substrates.Clin Orthop 225:147-70.
4. McPherson EJ, Dorr LD, Gruen TA, Saberi TM (1995) Hydroxyapatite-coated proximal ingrowth femoral stems. A matched pair control study. Clin Orthop 223-30.
5. Scott DF, Jaffe WL. Host-bone response to porous-coated cobalt-chrome and hydroxyapatite-coated titanium femoral components in hip arthroplasty. Dual-enery X-ray absorptiometry analysis of paired bilateral cases at 5 to 7 years (1996) J Arthroplasty 11:429-37.
6. Sanchez-Sotelo J, Lewallen DG, Harmsen WS, Harrington J, Cabanela ME (2004) Comparison of wear and osteolysis in hip replacement using two different coatings of the femoral stem. Int Orthop 28:206-10.
7. Parvizi J, Sharkey PF, Hozack WJ, Orzoco F, Bissett GA, Rothman RH (2004) Prospective matched-pair analysis of hydroxyapatite-coated and uncoated femoral stems in total hip arthroplasty. A concise follow-up of a previous report. J Bone Joint Surg [Am] 86:783-6.
8. Søballe K, Toksvig-Larsen S, Gelineck J, Frensgaard S, Hansen ES, Ryd L, Lucht R, Bünger C (1993) A roentgen stereophotogrammetric study [migration of hydroxyapatite coated femoral prostheses. J Bone Joint Surg [Br] 75:681-7.
9. Incavo SJ, Schneider R, Elting J (1998) The effect of surface coating of femoral prostheses implanted without cement: a 2- to 4-year follow-up study. Am J Orthop 27:355-61.
10. Yee AJM, Kreder HK, Bookman I, Davey JR (1999) A randomized trial of hydroxyapatite coated prostheses in total hip arthroplasty. Clin Orthop 366:120-32.
11. Hamadouche W, Witvoet J, Porcher R, Meunier A, Sedel L, Nizard R (2001) Hydroxyapatite-coated versus grit-blasted femoral stems. J Bone Joint Surg [Br] 83:979-87.
12. Rasquina VJ, Ranawat CS, Mauriello AJ (2002) Hydroxyapatite. Catalyst or conjuror? J Arthroplasty 17:113-7.
13. Kim YH, Kim JS, Oh SH, Kim JM (2003) Comparison of porous-coated titanium femoral stems with and without hydroxyapatite coating. J Bone Joint Surg [Am] 85;1882-8.
14. Tanzer M, Gollish J, Leighton R, Orrell K, Giacchinao A, Welsh P, Shea B, Wells G (2004) The effect of adjuvant calcium phosphate coating on a porous-coated femoral stem. Clin Orthop 424:153-60.
15. Yoon KS, Kim HJ, Lee JH, Kang SB, Seong NH, Koo KH (2007) A randomized clinical trial of cementless femoral stems with and without hydroxyapatite/tricalcium-phostphate coating. J Arthroplasty 22:504-8.
16. Moher D, Cook DJ, Eastwood S, Olkin I, Rennie D, Stroup DF (1999) Improving the quality of reports of meta-analyses of randomised controlled trials: the QUOROM statement. Quality of Reporting of Meta-analyses. Lancet 354(9193):1896-900.

17. Van Tulder MW, Assendelft WJ, Koes BW, Bouter LM (1997) Method guidelines for systematic reviews in the Cochrane Collaboration Back Review Group for Spinal Disorders. Spine 22(20):2323-30.
18. Harris WH (1969). Traumatic arthritis of the hip after dislocation and acetabular fractures: treatment by mold arthroplasty. J Bone Joint Surg [Am] 51:737-55.
19. Engh CA, Massin P, Suthers KE (1990) Roentgenographic assessment of the biologic fixation of porous-surfaced femoral components. Clin Orthop 257:107-27.
20. Geesink RG, de Groot K, Klein CPAT (1988) Bonding of bone to apatite-coated implants. J Bone Joint Surg [Br] 70:17-22.
21. Bauer TW, Geesink RC, Zimmerman R, McMahon JT (1991) Hydroxyapatite-coated femoral stems. Histological analysis of components retrived at autopsy. J Bone Joint Surg [Am] 73:1439-52.
22. Coathup MJ, Blunn GW, Flynn N, Williams C, Thomas NP (2001) A comparison of bone remodelling around hydroxyapatite-coated, porous-coated and grit-blasted hip replacements retrieved at post-mortem. J Bone Joint Surg [Br] 83:118-23.
23. Cates HE, Keating EM, Gittins M, Faris PM, Bissacotti JF, Ritter MA (1991) Early clinical results of hydroxyapatite-coated total hip arthroplasty. Semin Arthroplasty 2:317-22.
24. Vaughn BK, Lombardi AV, Mallory TH (1991) Clinical and radiographic experience with a hydrosyapatite-coated titanium plasma-sprayed porous implant. Semin Arthroplasty 2:309-16.
25. Cook SD, Enis J, Armstrong D, Lisecki E (1991) Early clinical results with the hydroxyapatite-coated porous long-term stable fixation total hip system. Sem Arthroplasty 2:302-8.

Chapter | 4

Long-term results of a soft interface-(Proplast-) coated femoral stem

J.H.M. Goosen[1], R.M. Castelein[2], W.C. Runne[3], D.A. Dartée[3] and C.C.P.M. Verheyen[1]

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[1] Department of Orthopaedic Surgery and Traumatology
Isala Clinics, Weezenlanden Hospital
Zwolle, The Netherlands
[2] Department of Orthopaedic Surgery
University Medical Hospital Utrecht
Utrecht, The Netherlands
[3] Department of Orthopaedic Surgery
Jeroen Bosch Hospital
's-Hertogenbosch, The Netherlands

Abstract

Mid-term clinical results of uncemented femoral components with a Proplast coating have been unfavourable and the low modulus system was abandoned in the mid 1990s. There is, however, still a substantial numbers of patients with a Proplast-coated prosthesis in situ. We evaluated the clinical and radiographic results in patients with 8-13 year follow-up.

We evaluated the survival rate, Harris hip score and radiographic features of 82 hips in 69 patients. Mean age at operation was 58 (35-72) years. With respect to the Harris hip score (HHS), 21% of the hips were considered to be clinical failures (HHS $<$ 70) at final follow-up, mainly because of excessive thigh pain. Osteolysis was observed in one or more Gruen zones in one-third of the hips. According to the criteria of Engh, 79/82 stems were unstable. Eleven hips were eventually revised due to aseptic loosening. Survival of the femoral component of the original cohort at final follow-up was 84% (95% CI: 75-93) in a standard-case scenario.

Extensive signs of loosening were observed in almost all hips, while not all hips were considered to be clinical failures. Thus, all patients should be thoroughly screened for radiographic progressive osteolysis or the occurrence of thigh pain. Thigh pain or progressive osteolysis warrants revision of the Proplast-coated femoral stem.

Introduction

In the early 1970s, a soft-interface coating of a composite of polytetrafluoroethylene (PTFE) reinforced with carbon fibre or aluminium oxide was introduced as Proplast. Proplast was considered to exhibit extraordinary chemical and thermal resistance, permitting fusion to metallic implants[1]. As the elasticity of Proplast matches that of the surrounding cancellous bone, it was expected to have the advantage of a more natural tranfer of stress, causing less stress shielding and aseptic loosening[2]. In animal studies, a rapid ingrowth and a ready adherence to the surrounding tissue was observed[1]. Despite the possible theoretical benefits, mid-term clinical results on uncemented femoral components with a Proplast coating were not favorable[2-5]. Because of these reports, the low modulus system was considered to be a failure and was abandoned by our clinic in the mid-1990s. Today, there is still a substantial number of patients with a Proplast-coated prosthesis *in situ*. We evaluated the long-term clinical and radiographic results in this group of patients in order to be able to issue guidelines when revision is indicated.

Patients and methods

We studied 100 consecutive primary cementless total hip arthroplasties performed between 1992 and 1997 in 83 patients with a minimum 8-year follow-up. Seventeen patients were operated bilaterally. Nine patients died before the minimum 8-year evaluation period (13 hips). None of these deaths were related to the index operation. Two patients moved and were unable to return for follow-up. Three patients underwent a revision before the minimum follow-up period, two in the first year after implantation and one after two years. All early revisions were due to aseptic loosening of the femoral stem. Thus, 18 hips in 14 patients were excluded, leaving 82 hips in 69 patients for clinical and radiographical follow-up (Table 1). The mean follow-up time was 10.2 (8-13) years.

All patients included received a Bitek femoral endoprosthesis (Biomet, Warsaw, IN). This uncemented femoral prosthesis was designed for a soft-interface coating that is a composite of polytetrafluoroethylene reinforced with aluminium oxide (Proplast II coating). A cemented (SHP Promotion, Biomet) acetabular component was used in 32 hips. In 50 hips an uncemented acetabular component (Mallory-Head/Ringloc liner, Biomet) was used. All hips were implanted using the direct lateral approach according to Hardinge[6].

Table 1 Patient characteristics

Patients (n = 69)	Sex	
	Male	31
	Female	38
	Height (m)	1.66 (1.45-1.87)
	Weight (kg)	80 (57-109)
	Body Mass Index	29 (21-35)
	Age at operation (yr)	58 (35-72)
	Follow-up average (yr)	10.2 (8-13)
Hips (n = 82)	Diagnosis	
	Osteoarthritis	76
	Osteonecrosis	1
	Developmental dysplasia	4
	Post-trauma	1
	Side	
	Right	46
	Left	36

Clinical and radiographic evaluation were performed at 3 and 6 months, at 1 year, and annually thereafter. The Harris hip score was monitored and values < 70 were considered a clinical failure. Signs of endosteal condensation and osseointegration (spot welding) and the presence of radiodense or radiolucent lines were recorded in each Gruen zone[7]. The time when these observations first occurred was noted. Pedestal formation (endosteal reactive radiodensity, distally from the tip of the stem), osteolysis, grading of stress shielding[8] and cortical hypertrophy were assessed. An increase in the distance between the superior tip of the greater trochanter and a standard point at the prosthesis of 5 mm or more was recorded as subsidence[9]. On all radiographs the magnification was based on the size of the femoral head; therefore, all measurements were corrected individually. The radiographic state of bone ingrowth was evaluated according to Engh et al[7].

Statistics

Kaplan-Meier analysis of the survival of the femoral component was performed for all hips in the original cohort. We determined the best-case scenario (in which all

hips with less-than-complete follow-up were considered to have had a successful result throughout the study period), standard-case scenario (in which all hips with less-than-complete follow-up were considered to have had a successful result at the time of the last follow-up) and worst-case scenario (in which all hips with less-than-complete follow-up were considered to have failed). The analyses were performed using SPSS software, version 11.0.

Results

The mean preoperative Harris hip Score was 56 (30-78) with a subscore of 15 (10-30) points for pain (Table 2). At the latest follow-up, these scores were 78 (25-100) and 34 (10-44), respectively. Seventeen hips (21%) were rated as poor and therefore considered clinical failures. Twenty-two patients (32%) complained of thigh pain; 14 of these had severe pain and were compromized in their daily activities.

Table 2 Clinical outcome at the latest follow-up

Clinical outcome	Hips	Harris Hip score (SD)	Pain subscore (SD)
Excellent	19	96 (3.7)	43 (1.8)
Good	36	84 (2.4)	39 (3.8)
Fair	10	73 (3.1)	35 (5.8)
Poor	17	48 (15)	17 (9.2)

Endosteal osseointegration (spotwelds) in one or more Gruen zones was observed in 47 hips (57%) (Table 3). The present spotwelds were observed in Gruen zone VII in 91% (calcar). The observed radioactive lines were dense and in all cases they were located at least in Gruen zone I (greater trochanter). In 82% of the cases, the dense lines reached to the tip of the stem (Gruen zone IV). The thickness of the lines was generally over 1 mm (70%). Subsidence was observed in 70 hips (86%), with a mean value of 12 (5-27) mm.

Stress shielding was observed in 60 hips (73%). All 60 hips showed grade-1 stress shielding (rounding of the calcar) at 1 year. Fifty hips showed progression to grade-2

Table 3 Prevalence of the radiographical parameters according to Engh (1987, 1990)

Parameter	Prevalence hips (%) (n = 82)	Time of first observation In years (SD)
Spot welds	47 (57)	1.3 (0.57)
Radio-dense lines	78 (95)	1.2 (0.91)
Stress shielding		
Grade 1	60 (73)	1.0 (0.13)
Grade 2	50 (61)	1.9 (0.14)
Grade 3	10 (12)	2.3 (0.50)
Grade 4	-	-
Cortical hypertrophy	13 (16)	2.1 (1.2)
Pedestal	13 (16)	3.3 (1.1)
Intramedullary osteolysis	25 (30)	3.2 (2.2)
Subsidence	70 (86)	0.3 (0.09)

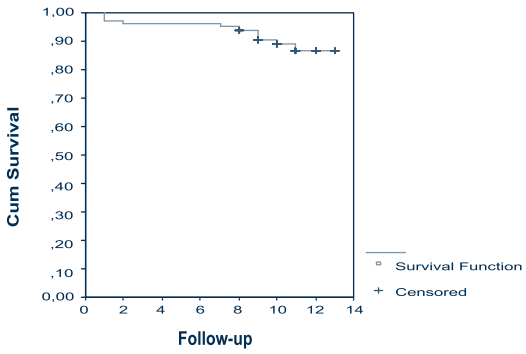
stress shielding (also loss of medial cortical density in zone 1) between the first and second years of follow-up. The progression continued to grade-3 stress shielding (loss of medial cortical density up to zone 2) in 10 hips (15%) between the second and third years of the follow-up.

Twenty-five hips (30%) showed intramedullary osteolysis of the femoral canal, mainly (21 hips) in Gruen zone VII (calcar). In the other 4 hips, the osteolysis was observed in Gruen zone IV (tip of the stem). The signs of osteolysis occurred at a mean follow-up of 3 (1-9) years. No difference in the occurence of femoral osteolysis was found when uncemented or cemented sockets were used. According to the criteria of Engh, 96% of the hips were unstable. Eleven revisions were performed because of suspected aseptic loosening. All hips were found to be loose at revision. Eight hips were revised during the 8-13 year follow-up period. Survival of the original cohort at final follow-up was 86% (95% CI: 79-93) in a best-case scenario, 84% (95% CI: 75-93) in a standard-case scenario and 67% (95% CI: 57-77) in a worst-case scenario (Figure 1).

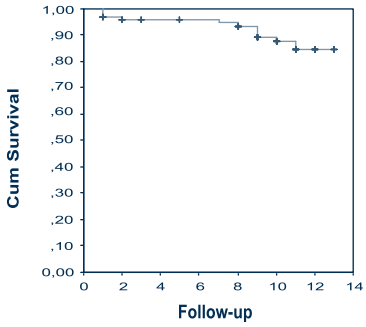
Figure 1

Survival plots for different scenario's

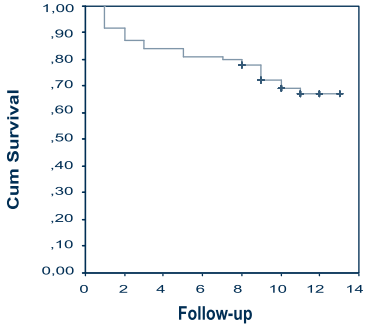
A Best-case scenario



B Standard-case scenario



C Worst-case scenario



Discussion

Reports of high rates of failure of cemented femoral components in younger and more active patients have stimulated the development of implant fixation without cement[10,11]. The transfer of load from the prosthesis to the femur alters the pattern of the natural stress transfer and varies according to the shape and stiffness of the implant[12]. In the early 1970s a rigid stem with a soft coating (low modulus system) was introduced, based on the hypothesis that a high-modulus strength implant would be incompatible with effective surface stabilization because of an unnatural stress transfer through the surrounding tissue. A low-modulus coating would rapidly become infiltrated with fibrous tissue and would then transfer stress diffusely through the coating, resulting in a physiological stimulus to the maturation of the tissue into appropriate stress-supporting structures[1]. Polytetrafluoroethylene (PTFE) with carbon or aluminium oxide (Proplast I or II, respectively) was marketed as the coating that would meet the criteria of this model. PTFE, exhibiting extraordinary chemical and thermal resistance, can be firmly fused to a high modulus substrate. Proplast was also thought to exhibit no distinct yield stress and to demonstrate massive tissue ingrowth because of the relatively high pore size of 100-500 μm[1]. In studies on dogs by the developer of Proplast, the coating was seen to be thoroughly infiltrated by dense mature collagen by 10 weeks and bone by 15 months, while no cellular inflammatory elements were found[1]. In another study, performed by independent investigators, Proplast-coated femoral prostheses were implanted in 12 goats and were clinically and radiographically observed for the first year postoperatively, with necropsy at the 1-year follow-up. Only 4 hips were found to be stable. These poor results were attributed to a lack of durable fixation after initial stabilisation, allowing movement at the interface between bone and the PTFE coating[13]. Another study reported that particles of abraded PTFE could give rise to an intense foreign-body reaction and produce collections of encapsulated caseous material, identical to the behaviour of bone and joint tuberculosis[14]. Here we have reported the outcome of the largest series to date, with the longest reported follow-up of a soft interface-coated femoral stem.

Regarding clinical outcome, 21% of the hips failed and 32% were associated with thigh pain. Similar studies with fewer patients and a shorter follow-up have reported clinical failures in 58%, 36%, 12% and 8%[4,5,15,16]. According to the criteria of Engh, 96% of the hips were rated as unstable and were considered to be loose. These findings were not associated with the clinical outcome of the patients. Other authors stated that radioactive lines are not always associated with loosening, and it is

not possible to determine whether the radiolucency on the radiograph is due to demarcation or to bone ingrowth of the coating[17]. From these statements and our findings, we conclude that the clinical performance and the presence of extensive osteolysis in a patient with a Proplast-coated femoral endoprosthesis is an indication for revision surgery rather than radiological instability of the implant.

In our study, one-third of the hips showed signs of intramedullary osteolytic lesions in one or more Gruen regions. PTFE particles from the femoral component can cause foreign-body reactions and can be slowly erosive in contact with bone[14]. The lesions can also be caused by foreign-body reactions to polyethylene particles from the acetabular component, driven into the femoral canal between the disintegrated femoral stem and the endosteal bone[18]. One of the reasons for developing a soft-interface stem was the prevention of bone resorption as a result of a different stress pattern (stress shielding)[1]. Moderate stress shielding (grade 3) was observed in one-tenth of the hips in our study; none of the hips showed severe stress shielding (grade 4). An evaluation of 106 conventional (high-modulus) femoral implants with the same configuration as the Bitek showed 16% grade-3 and 6% grade-4 stress shielding after a mean follow-up of 8.3 years. Despite a higher incidence of severe stress shielding, this high modulus variant showed an excellent clinical outcome: 100% radiographical stability and fixation at the 8-year final follow-up[19]. Kärrholm et al[20] randomized patients (68 hips) to receive either a low- or a high-modulus stem. Using a absorptiometer, they observed a statistically significant reduction in bone mineral loss around the low-modulus stem in the proximal Gruen zones at the 2-year follow-up. No difference in clinical performance were observed after this short follow-up period. Another study showed a statistically significant lower Harris hip score and a more intense bone remodeling when measuring bone mineral density using a DEXA scan in the patients with a low modulus stem compared with a high- modulus variant. The authors concluded that there was a less favorable host-bone response after long-term observation in 20 patients after 8 years[21].
In conclusion, it can be stated that although several studies have judged the Proplast-coated prosthesis to be an absolute failure, a substantial number of patients -allthough having a radiographically loose prosthesis according to the criteria of Engh- still have this prosthesis *in situ*. These patients should be thoroughly screened for the occurrence of osteolysis. Poor clinical performance and the occurrence of thigh pain justify revision surgery.

References

1. Homsy CA, Cain TE, Kessler FB, Anderson MS, Kessler FB Anderson MS. Porous implant systems for prosthesis stabilization. Clin Orthop 1972;89:220-35.
2. Sadr B, Arden GP. A comparison of the stability of Proplast-coated and cemented Thompson prostheses in the treatment of subcapital femoral fractures. Injury 1977;8:234-7.
3. Bryan WJ, McCaskill BL, Tullos HS. Hip endoprosthesis stabulization with a porous low modulus stem coating. Factors influencing stabilization. Clin Orthop 1981;157:125-32.
4. Tullos HS, McCaskill BL, Dickey R, Davidson J: Total hip arthroplasty with a low-modulus porous-coated femoral component. J Bone Joint Surg 1984;66A:888-98.
5. Maathuis PGM, Visser JD. High failure rate of soft-interface stem coating for fixation of femoral endoprostheses. J. Arthroplasty 1996;11:548-52.
6. Hardinge K. The direct lateral approach to the hip. J Bone Joint Surg 1982;64B:17-9.
7. Engh CA, Massin P, Suthers KE. Roentgenographic assessment of the biologic fixation of porous-surfaced femoral components. Clin Orthop 1990;257:107-27
8. Engh CA, Bobyn JD, Glassman AH. Porous-coated hip replacement; the factors governing bone ingrowth, stress shielding and clinical results. J Bone Joint Surg 1987;69B:45-55.
9. Malchau H, Karrholm J, Wang YX, Herberts P. Accuracy of migration analysis in hip arthroplasty. Digitized and conventional radiography, compared to radiostereometry in 51 patients. Acta Orthop Scand 1995;66:418-24.
10. Barrack RL, Mulroy RD, Harris WH. Improved cementing techniques and femoral component loosening in young patients with hip arthroplasty. A 12-year radiographic review. J Bone Joint Surg 1992;74A:385-9.
11. Heekin RD, Callaghan JJ, Hopkinson WJ, Savory CG, Xenos JS. The porous-coated anatomic total hip prosthesis, inserted without cement. Results after five to seven years in a prospective study. J Bone Joint Surg 1993;75A:77-91.
12. Huiskes R. The various stress patterns of press-fit, ingrown, and cemented femoral stems. Clin Orthop 1990;261:27-38.
13. Parvongnokul K, Lump WV. Evaluation of polytetrafuoroethylene-graphite-coated total hip prostheses in goats. Am J Vet Res 1978;39:221-8.
14. Charnley J. Tissue reactions to plyetrafluoroethylene. Lancet 1963;2:1379.
15. Keet GG, Runne WC. The Anaform endoprosthesis: a Proplast coated femoral endoprosthesis. Orthopedics 1989;12:1185-90.
16. Runne WC, Van Sambeek KJM, Stierum JL, Van Tongerloo RB. Femoral endoprosthesis fixation with a soft, flexible low modulus stem coating. Four to six year clinical results. Orthopaedics 1989;12:529-35.
17. Kwong LM Jasty M, Mulroy RD, Maloney WJ, Bragdon C, Harris WH. The histology of the radiolucent line. J Bone Joint Surg 1992;74A:67-73.
18. Willert HG, Buchhorn GH, Hess T: The significance of wear and material fatigue in loosening of hip prosthesis. Orthopäde 1989;18:350.
19. Goosen JH, Swieringa AJ, Keet JG, Verheyen CC. Excellent results from proximally HA-coated femoral stems with a minimum of 6 years follow-up. A prospective evaluation of 100 patients. Acta Orthop 2005;76:190-7.

20. Kärrholm J, Anderberg C, Snorrason, F, Thanner J, Langeland, N, Malchau H, Herberts P. Evaluation of a femoral stem wiht reduced stiffness. A randomized study with use of radiostereometry and bone densitometry. J Bone Joint Surg 2002;84A:1651-8.
21. Bodén H, Adolphson P, Öberg M. Unstable versus stable uncemented femoral stems: a radiological study of periprosthetic bone changes in two types of uncemented stems with defferent concepts of fixation. Arch Orthop Trauma Surg 2004;124:382-92.

Chapter | 5

High revision rate after treatment of femoral neck fractures with an optionally (un)cemented stem

J.H.M.Goosen,[1] M.C. Mulder,[1] K.J. Bongers,[2] C.C.P.M. Verheyen[1]

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[1] Department of Orthopaedic Surgery and Traumatology
[2] Department of General Surgery and Traumatology
Isala Clinics, Weezenlanden Hospital
Zwolle, The Netherlands

Abstract

The advantages of uncemented versus cemented components and vice versa in hip arthroplasty have been subject of debate. We have studied a hemiprosthesis, which can be optionally implanted with or without cement. Since the stem geometry and surface in cemented arthroplasty differs from the uncemented one and cannot be fused into one general design, we hypothesised that this hemiprosthesis used without cement has a considerable high revision rate, based on aseptic loosening. A hemiprosthesis, which is designed for both cemented and uncemented fixation, was used (Conquest, Smith&Nephew). Preoperatively, the choice of whether to use cement or not was based on the shape and bone quality of the femoral canal. Revision rate and indication, mortality, perioperative complications and radiographic features of 151 consecutive hips in 146 patients were evaluated. Twenty-three stems (15%) were implanted with cement and 128 (85%) without. After a mean follow-up of two years, a revision rate of 8.6% and a survival percentage of 90% (CI 85 to 95) were observed. Twelve uncemented stems warranted revision, compared with one cemented stem. Revision because of aseptic loosening was necessary in 7 (6%) stems, all uncemented. No differences in operation-related mortality and morbidity were observed. Because of the rather high revision rate, the authors advice not to use this hemiprosthesis without cement.

Introduction

The choice of whether to use cement or not in (hemiprosthetic) hip replacement surgery has been a subject of much debate for decades.[1,2] In the elderly, cemented hip arthroplasty still outperforms uncemented arthroplasty, although the latter is upcoming thanks to technical improvements on stem and surface design.[2] In a review of recent advances in the treatment of intracapsular fractures in elderly patients (60 years or older), Leighton et al.[3] concluded that such patients should be treated with a cemented hemiprosthesis, except for those patients with a high cardiovascular risk, who should be treated without cement.

Several randomised controlled trials comparing uncemented and cemented hemiprostheses demonstrate superior clinical results in the cemented hemiprosthesis.[4,5] Foster et al.[4] observed a significantly higher percentage of iatrogenic and postoperative periprosthetic fractures (7%) in 70 uncemented hemiprostheses, compared with 174 cemented hemiprostheses. Emery et al.[5] observed significantly more complaints of thigh pain and the use of walking aids in patients with an uncemented hemiprosthesis compared with patients with a cemented hemiprosthesis after 17 months.

There are a few reports which focus on a stem designed for both cemented and uncemented fixation.[6-9] These reports show a considerably higher revision rate and less favourable clinical results in the uncemented stems than the cemented stems. Several authors have stated that the surface design and geometry of an uncemented prosthesis should differ from a cemented one.[10,11] An uncemented prosthesis should have a porous coated surface to enhance secondary stability due to endosteal bone ingrowth.[10] By contrast, cemented stems with a rough surface are associated with a high aseptic loosening rate, compared with smooth-surface stems in total hip arthroplasty.[11] In uncemented arthroplasty, secondary stability by endosteal bone ingrowth can only be achieved by primary stability. Aseptic loosening of an uncemented stem is attributable to the design of the proximal part of the prosthesis, which should have a three-dimensional proximal rotational stability.[12]

Taking the above-mentioned statement into account, the authors of the present study hypothesised that it is not possible to design a hemiprosthesis which can be used both as an uncemented and a cemented stem. Therefore, a retrospective cohort analysis was conducted on a hemiprosthesis designed for both cemented and uncemented fixation.

Patients and Methods

Between 2002 and 2005, 151 consecutive hemiarthroplasties were performed on 146 patients with an acute, displaced femoral neck fracture (Garden 3 and 4) with a biological age over 65 years. A Conquest hemiprosthesis (Smith&Nephew, Memphis, TN, USA), which is designed for both cemented and uncemented fixation, was used. This is a collared stem made from a cobalt-chromium alloy. It has a fully grit-blasted surface and a 3-point fixation geometry, which should theoretically be a favourable condition for primary (high rotational) stability and secondary stability (endosteal bone ingrowth on the porous surface)[12] (Figure 1A). When fixated with cement, the 3rd-generation cementing technique was applied[13] (Figure 1B). When the patient received a hemiprosthesis, the surgeon had to decide whether to apply cement or not, based on bone quality and femoral configuration. The preoperative radiographs were scored for bone quality of the femur and acetabulum according to the classification of Bombelli.[14] The flare index of the femoral canal was measured according to the criteria of Noble,[15] dividing the width of the femoral canal at a point 20 mm distal to the centre of the lesser trochanter through the canal width of the isthmus. The shape of a femoral canal with a flare index lower than 3.0 is described as 'stove pipe', between 3.0 and 4.7 as 'normal' and above 4.7 as 'Champagne-fluted'. The stem was implanted without cement when there was good femoral and acetabular bone quality according to Bombelli,[10] in combination with normal or champagne-fluted femoral canal according to Noble.[11] Otherwise, a cemented stem was implanted.

The procedures were carried out by five consultants and three registrars (orthopaedic and general surgery). The medical records of all operated patients were retrieved and studied. Demographic data, any re-operations and mortality were recorded. Revision was considered as the primary endpoint. The preoperative radiographs were studied for bone quality of the femur and acetabulum and femoral flare index, as described earlier. The postoperative radiographs were also scored on whether the collar of the prosthesis made contact with the femoral calcar or not.

Statistics

Statistical analysis was performed using the SPSS statistical package (SPSS 15.0, Chicago). Mann-Whitney U-test, Paired T-test and Chi-square test were performed to analyse the differences between two or several groups, depending on the distribution of the variables. Kaplan-Meier analysis of the survival was performed. We determined the best-case scenario (in which all hips with less-than-complete follow-up were considered to have had a successful result throughout the study

Figure 1A

The uncemented Conquest

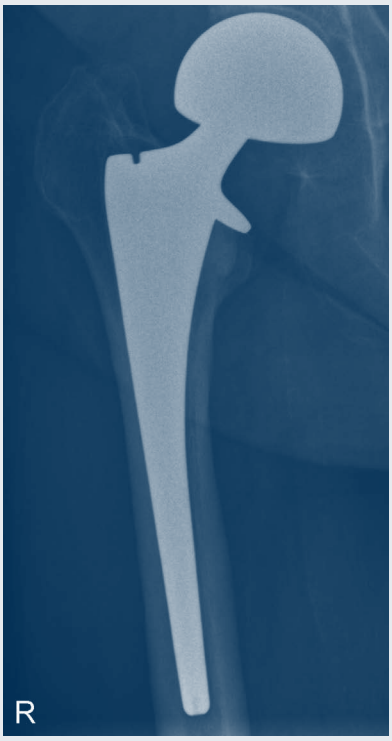
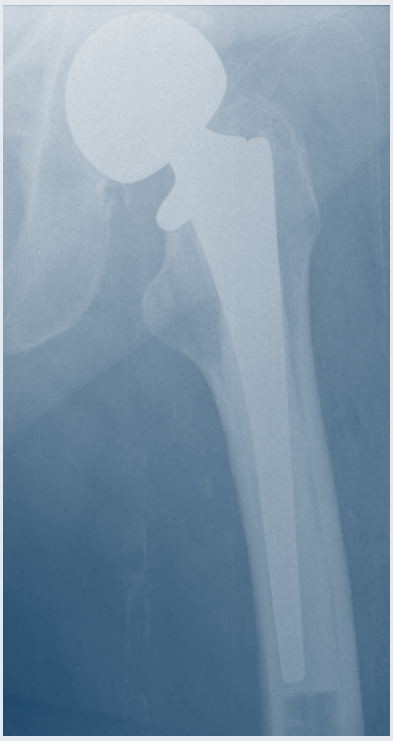


Figure 1B

The cemented Conquest



period), standard-case scenario (in which all hips with less-than-complete follow-up were considered to have had a successful result at the time of the last follow-up) and worst-case scenario (in which all hips with less-than-complete follow-up were considered to have failed).

Results

Mean follow-up was 2 (0.3 to 4) years. The demographic characteristics of the 151 consecutive hips (146 patients) are listed in Table 1. Twenty three hemiprostheses (15%) were cemented and 128 (85%) were uncemented.

Table 1 Demographic characteristics

Patients – number (%)	146 (39)
Hips – number (%)	151 (39)
Fixation	
Uncemented	128 (85)
Cemented	23 (15)
Gender – number (%)	
Male	39 (27)
Female	107 (73)
Age at operation in years (range)	82 (55 to 100)
Side – number (%)	
Right	73 (48)
Left	78 (52)
Deceased – number (%)	38 (26)
Operation-related	5 (3)

Five patients died of operation-related causes. One patient died during the operation following an unresponsive hypotensive event (cemented prosthesis), one patient with an infected prosthesis died one month postoperatively (uncemented prosthesis), and the other three suffered a cardiac event or cerebrovascular accident in the first five postoperative days (one cemented, two uncemented). The other causes of death were not related to the index operation.

Thirteen stems (8.6%) warranted revision, 7 (4.6%) of them due to aseptic loosening. One cemented stem had to be revised due to infection. Twelve uncemented (7 aseptic loosenings, 3 persisting luxations and 2 periprosthetic fractures) stems warranted revision (Table 2). The difference in revision rate between the cemented and uncemented stems was not statistically significant ($p = 0.4$).

Four patients with an uncemented stem suffered from a periprosthetic fracture. Two fractures were caused by a fall and classified as a Vancouver type-C fracture[7] (around the tip of the stem), and both were treated with a plate fixation while the prosthesis remained *in situ*. The other two fractures occurred during the index operation. One was classified as a Vancouver A_L (lesser trochanter), the other as a Vancouver A_G (greater trochanter). In both cases the uncemented prosthesis was removed and cemented in combination with cerclage wires. Radiographic analysis

Table 2 Revision procedures and causes

	Number of hips (%)
Revision – number (%)	13 (8.6)
Aseptic loosening	7 (4.6)
Septic loosening	1 (0.7)
Periprosthetic fracture	2 (1.3)
Persistent luxation	3 (2.0)

showed a flare index of 3.3 in the uncemented stems and 2.8 in the cemented stems ($p = 0.024$). Stove-piped femora were treated with a cemented stem in 62% of the cases and 75% of the normal-shaped femora were treated with an uncemented stem. Acetabular bone quality was normotrophic in 92% of the stems and inter-trochanteric cancellous bone quality was good/fair in 98%, according to the criteria of Bombelli.[10] There were no significant differences in femoral bone quality before placement of the prosthesis between the cemented and uncemented stems. In 80% of the uncemented hips, contact between the collar and the calcar was observed; this was not associated with a higher revision rate.

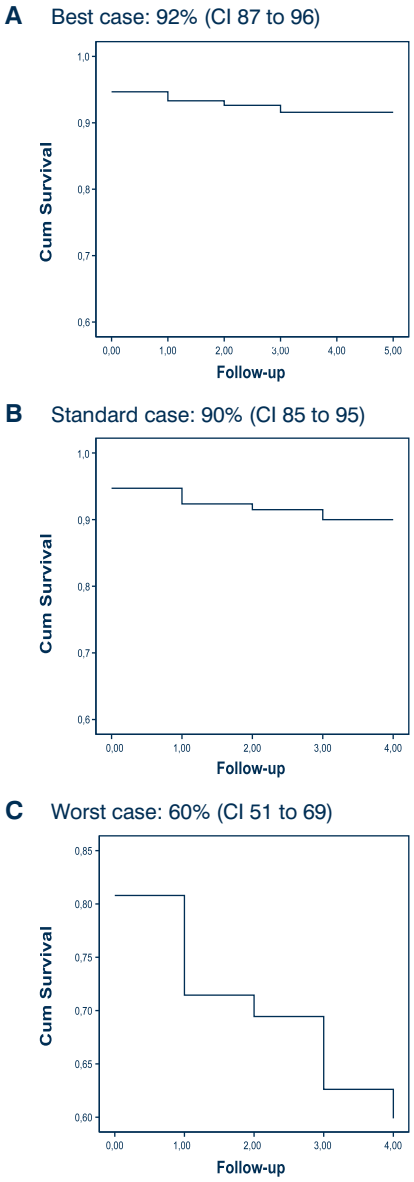
Whether cement was used or not did not affect the prevalence of morbidity and mortality of the patients ($p = 0.3$). Furthermore, the number of revisions was unrelated to the surgeon who performed the primary procedure ($P = 0.1$). Survival analysis demonstrated a 92% (CI 87 to 96) survival rate in a best-case scenario. Survival in a standard-case scenario was 90% (CI 85 to 95) and in a worst-case scenario 60% (CI 51 to 69) (Figure 2).

Discussion

Many reports have focussed on the comparison between uncemented and cemented components in hip arthroplasty.[1-4] Apart from relatively young patients (age 55 or younger), it is stated that cemented fixation still has superior survival among patients of all ages, compared with uncemented fixation.[2] This finding suggests that cemented fixation is the method of choice for hemiarthroplasty in elderly patients, who constitute the majority of the hip fracture population. On the other hand, improving survival is observed for uncemented fixation, which can be

Figure 2

Survival Scenarios



attributed to the development of uncemented technologies such as stem geometry and circumferential porous coating.[2] Several reports conclude with a preference for uncemented fixation in frail patients with significant cardiovascular risk factors.[3,12,13] Parvizi et al.[16] found a peri-operative mortality rate of 23 patients in 38,488 cemented hip arthroplasties related to the index operation, compared with none in 15,411 uncemented hip arthroplasties in a 28-year review period. Twenty-one of these patients had a history of previously diagnosed cardiovascular disease. In concordance with this statement, Lennox et al.[17] demonstrated a higher mortality rate (4%) related to the index operation in 136 patients treated with a cemented hemiprosthesis, compared with 0% in 71 patients with an uncemented stem.

There are relatively few studies on a uniform hemiprosthesis implanted with or without cement.[6-9] In these reports the cemented fixation is superior to the uncemented one, based on clinical and radiological considerations. Dorr et al.[7] reported less pain and mobility in 50 patients from the cemented group who received 37 cemented and 13 uncemented hemiarthroplasties after a two-year follow-up. Lo et al.[8] reported the results of 451 optionally cemented hemiprostheses with a 2-to-6-year follow-up. One cemented and 15 uncemented stems required revision due to aseptic loosening. Sonne-holm et al.[6] and Faraj et al.[9] observed no differences in revision rate and clinical outcome. This can be explained by their relatively short follow-up (12 and 17 months, respectively).

Min et al.[10] clearly demonstrated that an uncemented stem should have a porous surface coating. In two groups of 42 patients, 7% of grit-blasted stems had radiolucent lines in Gruen Zones 3 to 5, compared with 79% of smooth stems. Lo et al.[8] reported a higher percentage of radioactive lines and warranted revision operations in the uncemented stems. This can be explained by the fact that this hemiprosthesis had a smooth surface and was therefore not suitable for uncemented fixation.

In cemented arthroplasty, Hinrichs et al.[11] observed a rather unfavourable survival of 343 porous coated stems, compared with 220 smooth stems, mostly due to aseptic loosening (76.7 vs 95.4 percent, respectively) after a mean follow-up of 11 years. Effenberger et al.[12] emphasise the importance of rotational stability of the uncemented stem in total hip arthroplasty. They measured torsional stresses on two different stem designs using a prototype testing device, and concluded that a femoral prosthesis with a high revision rate correlated with poor rotational stability, causing a low percentage of endosteal bone ingrowth. The stem with a high rotational stability showed a significantly lower revision rate, based on aseptic loosening after a follow-up of 10 years.

The present study shows a high revision rate in the stems fixated without cement. A possible explanation is an inferior rotational stability, despite the theoretically

favourable design and surface of the stem for uncemented (hemi)arthroplasty. This statement goes beyond the scope of the present study and requires more research.

Our study showed no different revision rates in the uncemented stems with collar-calcar contact, compared with the stems in which the collar made no contact with the calcar. In the literature, no difference was observed in canal filling of the femoral component with or without collar-calcar contact in 203 hips after 4 years follow-up, suggesting that the presence of a collar in uncemented femoral components does not influence the revision rate.[18]

Compared with other studies, the revision rate in the present study at a short-term follow-up of the optional (un)cemented stem is rather high (8.6 vs 0-6%).[4-9] In the present study, preoperative radiographic flare index measurement showed that the femoral canals in the uncemented stems had a higher index than the cemented ones. This suggests that the indication of whether or not to use cement was made properly, according to the criteria of Noble.[11]

The present study shows that the stems implanted without cement (128) have an unacceptable high revision rate due to aseptic loosening (6%) after a short-term follow-up, compared with the literature, despite the attempted adaptation to the current (un)cemented prosthesiologic standards and indication. Based on the current literature and the present study, a hemiprosthesis should be implanted with cemented fixation in the majority of elderly hip fracture patients. Uncemented hemi-arthroplasty in elderly patients should only be considered in case of an eventful cardiovascular history. Because of the rather high revision rate, the authors advice not to use this hemiprosthesis without cement.

References

1. Parker M J, Gurusamy K. Arthroplasties (with or without bone cement) for proximal femoral fractures in adults (review). Cochrane database 2006 19(3):CD001706.
2. Morshed S, Bozic KJ, Ries MD, Malchau H, Colford Jr JM. Comparison of cemented and uncemented fixation in total hip replacement. Acta Orthop 2007;78(3):315-26.
3. Leighton RK, Schmidt AH, Collier P, Trask K. Advances in the treatment of intracapsular hip fractures in the elderly. Injury 2007; 38(S3);S24-34.
4. Foster AP, Thompson NW, Wong J, Charlwood AP. Periprosthetic femoral fractures-a comparison between cemented and uncemented hemiarthroplasties. Injury 2005;36(3):424-9.
5. Emery RJ, Broughton NS, Desai K, Bulstrode CJ, Thomas TL. Bipolar hemiarthroplasty for subcapital fracture of the femoral neck. A prospective randomised trial of cemented thompson and uncemented Moore stems. J Bone Joint Surg [Br] 1991;73:322-4.
6. Sonne-Holm S, Dyrbye M, Walter S, Jensen J S. Bone scintigraphy in Moore hemiarthroplasty with and without cement following femoral neck fractures. A controlled study. Acta Orthop Scand 1983;54:194-7.
7. Dorr L D, Glousman R, Sew Hoy A L S, Vanis R, Chandler R. Threatment of femoral neck fractures with total hip replacement versus cemented and noncemented hemiarthroplasty. J. Arthroplasty 1986;1:21-8.
8. Lo WH, Chen WM, Huang CK, Chen TH, Chiu FY, Chen CM. Bateman Bipolar hemiarthroplasty for displaced intracapsular femoral neck fractures. Uncemented versus cemented. Clin Orthop 1994;302:75-82.
9. Faraj A A, Branfoot T. Cemented versus uncemented Thompson's prostheses: a functional outcome study. Injury 1999;30:671-5.
10. Min B, Longjohn DB, Dorr LD, Wan Z. Radiographic comparison of diaphyseal grit blasted with smooth surface stems by matched pair analysis. Clin Orthop 2000 381:156-67.
11. Hinrichs F, Kühl M, Boudriot U, Griss P. A comparative clinical outcome evaluation of smooth (10-13 year results) versus rough surface finish (5-8 year results) in an otherwise identically designed cemented titanium alloy stem. Arch Orthop Trauma Surg 2003 123:268-272.
12. Effenberger H, Heiland A, Ramsauer T, Plitz W, Dorn U. A model for assissing the rotational stability of uncemented femoral implants. Arch Orthop Trauma Surg 2001 121:60-64.
13. Pabinger C, Kröner A, Lange A, Eyb R. Cemented titanium stems show high migration: transprosthetic drainage system has no advantage over third-generation cementation technique. Arch Orthop Trauma Surg. 2004 124:489-94.
14. Bombelli R. Osteoarthritis of the hip: classification and pathogenesis: the role of osteotomy as a consequent therapy, 2nd ed. New York: Springer, 1983:98108.
15. Noble PC, Box GG, Kamaric E, Fink MJ, Alexander JW, Tullos HS. The effect of aging on the shape of the proximal femur. Clin Orthop 1995;316:31-44.
16. Parvizi J, Holiday AD, Ereth MH, Lewallen DG. Sudden death during primary hip arthroplasty. Clin Orthop 1999;369:39-48.
17. Lennox IA, McLauchlan J. Comparing the mortality and morbidity of cemented and uncemented hemiarthroplasties. Injury 1993;24(3):185-6.

18. Meding J B, Ritter M A, Keating E M, Faris P M. Comparison of collared and collarless femoral components in primary uncemented total hip arthroplasty. J Arthroplasty 1997;12:273-80.

Chapter | 6

Silent osteolysis associated with an uncemented acetabular component

A monitoring and treatment algorithm

J.H.M. Goosen[1], R.M. Castelein[2], C.C.P.M. Verheyen[1]

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[1] Department of Orthopaedic Surgery and Traumatology
Isala Clinics, Weezenlanden Hospital
Zwolle, The Netherlands
[2] Department of Orthopaedic Surgery
University Medical Center Utrecht
Utrecht, The Netherlands

Abstract

The rate of polyethylene wear is correlated with the occurrence of osteolysis and the survival of joint prostheses. Several types of metal-backed uncemented acetabular components are associated with a rather high polyethylene wear rate. Silent, asymptomatic cavitational osteolysis can progress into segmental osteolysis that may become manifest and preclude revision procedures. Therefore close monitoring is recommended if silent osteolysis is suspected. A helical CT scan should be performed when signs of osteolysis or evident polyethylene wear are observed on conventional radiographs, or if it concerns a type of metal- backed acetabular component associated with a documented high wear rate. When a cavitational laesion is observed a helical CT scan should be performed yearly and treatment with bisphosphonates is to be considered. In case of segmental osteolysis or progression of the cavitational laesion, extensive debridement of the osteolytic cysts, bone grafting and replacement of the polyethylene liner is the treatment of choice.

Introduction

Osteolysis, causing component loosening is considered a main problem in hip arthroplasty[1]. Exposure of particulate materials, including polyethylene and metal, to bone has been cited as an underlying cause of osteolysis in hip arthroplasty[2,3]. Wear particles migrate around the prosthesis or cement mantle and cause a local macrophagic or sensitivity reaction, leading to the production of osteolytic mediators or local necrosis[4].The survival of joint prostheses depends to a large extend on factors that influence the rate of polyethylene wear[5]. Another postulated cause of osteolysis is the exposure of periprosthetic bone to joint fluid and joint fluid pressure, causing death of exposed osteocytes[4]. This can be due to early prosthesis migration and also to shape or position of the acetabular or femoral component[6]. Because metal on metal hip prostheses show significantly less wear and periprosthetic tissue reaction than metal-polyethylene hip prostheses, it is concluded that all second generation metal implants are to be considered in patients with a long life expectancy[4,7,8]. Initially termed cement disease, it is generally accepted that, in most instances, osteolysis is a manifestation of an adverse cellular response to phagocytosable particulate wear and corrosion debris, possibly facilitated by local pressure-induced effects[9]. Metal-backed acetabular components were introduced because of findings strongly suggesting a delay of cup loosening and migration by a more efficient stress transfer[10]. Clinical studies, however, observed the opposite and concluded a higher wear rate for cemented metal-backed acetabular components than non metal backed components in cemented hip arthroplasty[11]. Several authors have investigated the effect of implantation time on the wear rate with different results[11-16]. Early periprosthetic osteolysis is rarely accompanied by pain or loss of function[17]. Acetabular osteolytic defects can be classified as cavitary (a volumetric loss in the bony substance of the acetabulum but with the acetabular rim and medial wall of the hemispere remaining intact) or segmental (any loss of bone in the supporting rim or medial wall of the acetabulum)[18].
The dilemma of the way to diagnose and, if observed, how to treat and monitor silent osteolysis is a subject of further discussion[18-23].

Monitoring and treatment

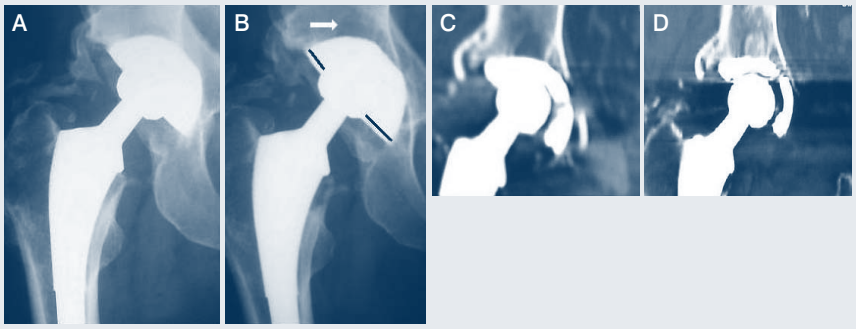
Several studies indicated that radiographs largely understate the prevalence and location of osteolysis and CT scans are superior[19,20]. Twenty-four percent of the cases of silent osteolysis were missed in 120 uncemented hip prostheses if only

radiographs were used for detection compared with CT scans[20]. Because the helical CT technique with metal-artefact minimization does not converge, it is a more sensitive method than the conventional CT scan for identifying and quantifying osteolytic lesions[20,22]. Puri et al[19] concluded that a CT scan is indicated in case of the presence of substantial polyethylene wear or the observation of osteolysis on the regular radiographs (Figure 1) and also when a certain acetabular component is associated with excessive wear in the literature.

The question if, how and when to treat in case of –silent– osteolysis has been subject of several studies[18,21-23]. Patients with cavitairy osteolysis may be considered

Figure 1

(**A**) A 74-year-old man with an uncemented total hip prosthesis. A hydroxyapatite coated metal shell with an air sterilized polyethylene liner is used. (**B**) Ten years postoperative an evident polyethylene wear (0.43 mm according to the method of Livermore[34]). And two osteolytic lesions can be observed (white arrows). (**C**) On the subsequent helical CT-scan, the lesions are seen in cross-section. (**D**) Helical CT-scan after bone grafting and liner replacement.



candidates for treatment with bisphosphonates, which inhibit the TNF-alpha release by polyethylene particles causing osteolysis[20,24]. Carlsson et al[22] determined the stability of the acetabular component in 100 revision operations and compared their findings with the preoperative radiologic obervations. Depending on the classification system, loosening of the acetabular component during the operation was demonstrated only in 6 to 31 percent of the hips with radiolucent areas. The authors concluded that the radiographic evaluation of socket stability is troublesome.

In case of treatment, the following strategies are to be considered:

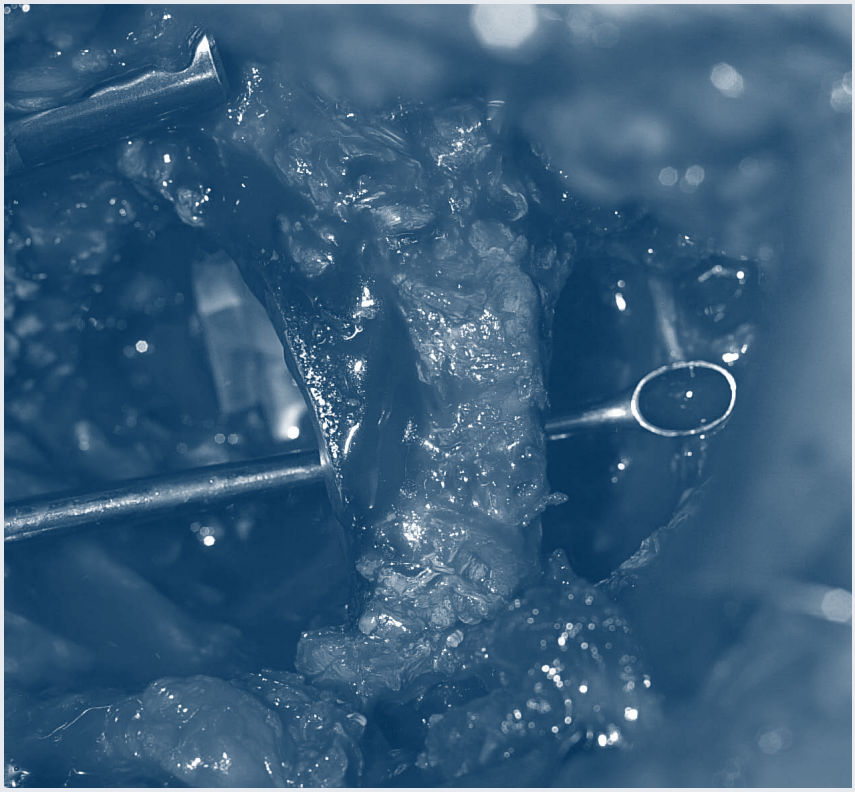
1. Retention of a well fixed shell, periacetabular bone grafting and revision of the liner: Retention of the socket with grafting of the periacetabular osteolytic lesion appears to be consistent with satisfactory socket longevity[25]. Maloney et al[27] treated 35 patients with osteolytic cysts with bone grafting and replacement of the polyethylene insert. Intraoperatively all acetabular shells where considered to be stable. After an average follow-up of three years all acetabular components seemed to be stable on conventional radiographs, 30 percent of the osteolytic cysts disappeared radiologically and the other 70 percent did not show progression. Beaulé et al[25] treated 28 acetabular periprosthetic osteolytic cysts with bone grafting and replacement of the polyethylene insert during a revision operation because of aseptic loosing of the femoral component. Five of the 28 treated acetabular shells had to be replaced at a mean of 6.8 years after the index femoral revision. The authors concluded that revision of a stable uncemented acetabular shell solely because of periacetabular osteolysis is not indicated. Debridement of the osteolytic cysts, bone grafting and replacement of a polyethylene insert of improved quality while the metal shell remains in situ, proved to be a successfull treatment (Figure 2).
2. Retention of a well fixed shell with placement of a cemented liner: Beaule et al[26] placed 17 cemented polyethylene liners into a well fixed uncemented shell and had favourable results after a follow-up of 5.1 years. This method is a good alternative for suitable candidates who have a well fixed cementless socket with an inner diameter that is larger than the outer diameter of the liner. One of the limitations of this technique is the possible relative thinness of the replaced liner, which can interfere with the wear restistance of the polyethylene[26].
3. Revision of the acetabular shell: In case of loosening of the acetabular shell because of osteolysis, the acetabulum needs to be reconstructed with bone grafting. If 50 percent or more of the surface of the acetabular shell contacts with the bone graft, a cemented acetabular component has to be placed. The placement of an uncemented acetabular component is indicated if the contact is less than 50 percent[21].

A proposed algorithm for surveillance and treatment of silent osteolysis is presented in Figure 3.

A wear rate of 0.20 millimeters per year seems to represent a critical threshold for the development of osteolysis[28]. Puolakka et al[16] reviewed 107 metal backed uncemented acetabular components on polyethylene wear after an average follow-up of 6 years. They observed an average polyethylene wear rate of 0.20 millimeters per years, which is rather high compared with studies on other polyethylene inserts

Figure 2

Major osteolytic lesions with a stable shell. The treatment included debridement, bone grafting and liner replacement

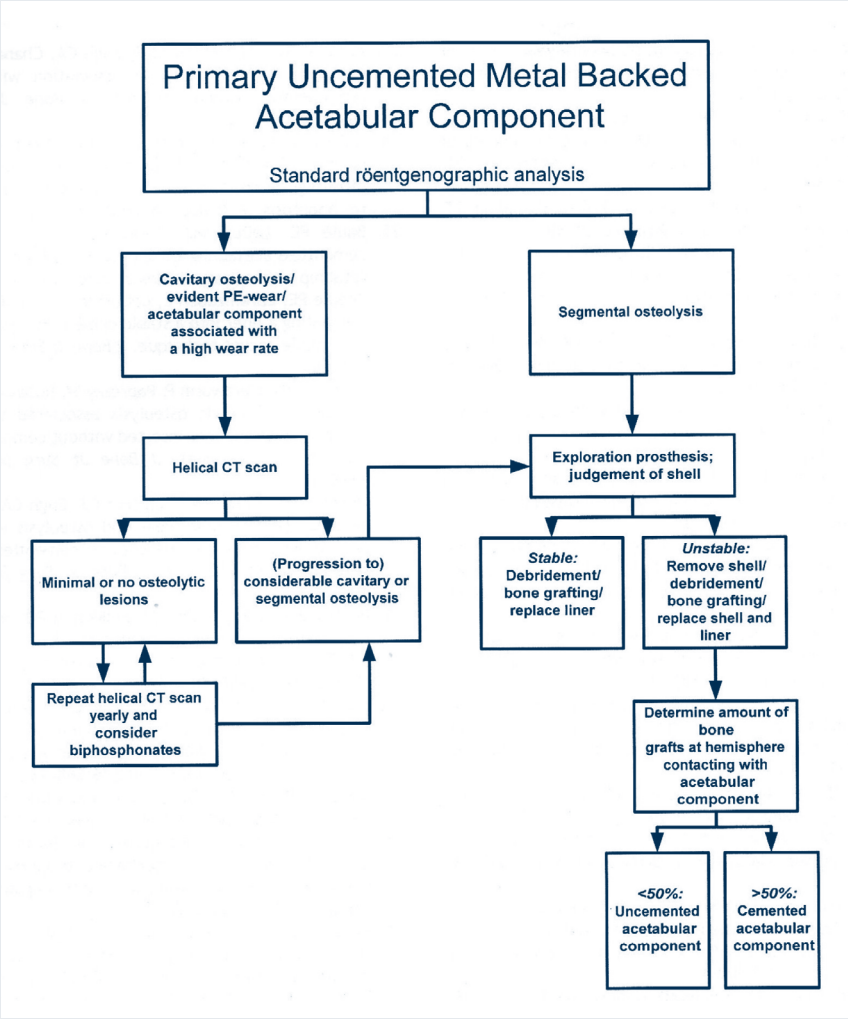


in uncemented acetabular components[11-16]. Because of an unacceptable survival percentage of 65 percent after a 9 year follow-up the studied type of insert was withdrawn from the market[29].

A metal shell containing screw holes correlates with a higher percentage of observed periacetabular osteolysis, while polyethylene particles, caused by back side wear of the polyethylene inserts, are exposed to the periacetabular bone through the screw holes[23]. Huk et al[30] observed necrosis and granolomatous tissue reactions of the bone accompanied with polyethylene particles situated at the screw holes of the metal shell after an average implantation of 22 months.

Figure 3

Monitoring and treatment algorithm of acetabular silent osteolysis



A reduction of wear rate by improving the quality of the polyethylene insert is expected to decrease the prevalence of osteolysis. Sterilization methods changed in the mid-1990s from gamma-irradiation in air to predominantly irradiation in inert

gas or vacuum packaging. Mechanical in vivo degradation, which is based on an oxidative mechanism, is higher in air than in argon gamma-sterilized UHMWPE acetabular components after implantation because of radical formation in the polyethylene during sterilization in air[31]. Kurtz et al[32] observed severe mechanical degradation caused by oxidation in 16 metal backed air sterilized polyethylene liners after an average follow-up of 11,5 years. Head et al[33] performed a randomized trial of 200 patients in which argon sterilized cups were compared with cups sterilized in air with an average follow-up of 3 years. A wear reduction of 40 percent was observed in the cups sterilized in argon. Highly cross-linked polyethylene shows an 80 to 90 percent wear reduction in hip simulator testing[35]. Digas et al[36] compared 32 patients recieved a total hip arthroplasty bilaterally with liners of highly cross-linked polyethylene on one side and conventional polyethylene on the other. After a mean follow-up of 2 years the highly cross-linked polyethylene liners showed 31 percent lower total penetration of the femoral head. The authors concluded that highly cross-linked showed a better wear performance and could increase the implant longevity. Longer follow-up is needed to establish if this new material is associated with less occurrence of osteolysis.
It is to be expected that a better polyethylene quality will decrease the wear rate and the incidence of periprosthetic osteolysis.

Conclusion

A metal-backed acetabular component, a poor rotational stability of the polyethylene insert and sterilization in air are factors that seem to correlate with a high polyethylene wear rate causing periprosthetic osteolysis. Early periprosthetic osteolysis is rarely accompanied by pain or loss of function. Timely treatment is indicated to prevent progression of the osteolytic lesions. As long as the metal shell is stable, extensive debridement of the osteolytic cysts, bone grafting and replacement of the polyethylene liner for a superior bearing material, is the treatment of choice for osteolytic lesions. In case of loosening of the acetabular shell, the acetabulum needs to be reconstructed with bone grafting, and an uncemented or cemented acetabular component has to be placed.
Future studies need to concentrate on the improvement of the quality of arthroplasty components in order to minimize the prevalence of osteolysis. Patients treated with a metal backed acetabular component associated with a high wear rate and a longterm follow-up should be monitored closely on linear wear rate, osteolysis and cup loosening.

References

1. Harris WH. The problem is osteolysis. Clin Orthop 1995;311:46-53.
2. Zicat B, Engh CA, Gokcen E. Patterns of osteolysis around total hip components inserted with and without cement. J Bone Joint Surg 1995;77:432-9.
3. Schmalzried TP, Kwong LM, Jasty M, Sedlacek RC Haire TC O'Connor DO, Bragdon CR, Kabo JM, Malcolm AJ, Harris WH: The mechanism of loosening of cemented acetabular components in total hip arthroplasty. Analysis of specimens retrieved at autopsy. Clin Orthop 1992;274:60-78.
4. P.F.Doorn. Wear and biological aspects of metal on metal total hip replacements. Thesis 2000;chapter 1:13
5. Willert HG, Buchhorn GH, Hess T. The significance of wear and material fatigue in loosening of hip prosteses. Orthopade 1989;18:350-69.
6. Aspenberg P, Van der Vis H. Fluid pressure may cause periprosthetic osteolysis. Particles are not the only thing. Acta Orhtop Scand 1998;69:1-4.
7. Jacobsson SA, Kjerf K, Wahlstrom O. Twenty-year results of McKee-Farrar versus Charnley prostheses. Clin Orthop 1996;329 Suppl:S60-8.
8. Schmalzried RP, Szuszczewicz ES, Akizuki KH, Petersen TD, Amstutz HC. Factor correlating with long term survival of McKee-Farrar to hip prostheses. Clin Orthop 1996;329 Suppl:S48-59.
9. Jacobs JJ, Roebuck KA, Archibeck M, Hallab NJ, Giant TT. Osteolysis: Basic Science. Clin Orthop 2001;393:71-7.
10. Carter DR, Vasu R, Harris WH. Stress distributions in the acetabular region—II. Effects of cement thickness and metal backing of the total hip acetabular component. J Biomech 1982;15:165-70.
11. Cates HE, Faris PM, Keating EM, Ritter MA. Polyethylene wear in cemented metal-backed acetabular cup. J Bone Joint Surg [Br] 1993;75:249-53.
12. Devane PA, Bourne RB, Rorabeck CH, MacDonald S, Robinson EJ. Measuremetn of polyetylene wear in metal-backed acetabular cups. Clin Orthop 1995;319:317-326.
13. Hozack WJ, Rothman RH, Eng K, Mesa J. Primary cementless hip arthroplasty with a titanium plasma sprayed prosthesis. Clin Orthop 1996;333:217-25.
14. Kim YH, Kim JS, Cho SH. Primarty total hip arthroplasty with a cementless porous-coated anatomic total hip prosthesis. 10- to 12-year rsults of prospective and consecutive series. J Arthroplasty 1999;14:538-48.
15. Thanner J. The acetabular component in total hip arthroplasty. Evalution of different fixation principles. Thesis. Acta Orthop Scand (Suppl) 1999;286:70.
16. Puolakka TJS, Laine HJ, Moilanen TPS, Koivisto AM, Pajamäki KJJ. Alarming wear of the first-generation polyethylene liner of the cementless porous-coated Biomet universal cup. Acta Orthop Scand 2001;72:1-7.
17. Lavernia CJ. Cost-effective3ness of early surgical intervention in silent osteolysis. J Arthroplasty 1998;13:277-9.
18. D'Antonio JA. Periprosthetic bone loss of the acetabulum. Classification and management. Orthop Clin N Am;1992;23:279-90.
19. Puri L, Wixson RL, Stern SH, Kohli H, Hendrx RW, Stulberg SD. Use of helical computed

tomography for the assessment of acetabular osteolysis after total hip arthroplasty. J Bone Joint Surg [Am] 2002;84:609-14.
20. Stulberg SD, Wixson RL, Adams AD, Hendrix RW, Bernfield JB. Monitoring pelvic osteolysis following total hip replacement surgery: an algorithm for surveillance. J Bone Joint Surg [Am] 2002;84:116-22.
21. Hozack WJ, Mesa JJ, Carey C, Rothman RH. Relationship between polyethylene wear, pelvic osteolysis and clinical symptomatology in patients with cementless acetabular components. A framework for decision making. J Arthroplasty 1996;11:769-72.
22. Carlsson AS, Gentz CF. Radiographic versus clinical loosening of the acetabular component in noninfected total hip arthroplasty. Clin Orthop 1984;185:145-50.
23. Maloney WJ, Alto P, Peters P, Engh CA, Chandler H. Severe osteolysis of the pelvis in association with acetabular replacement without cement. J Bone Joint Surg [Am] 1993;75:1627-35.
24. Huk OL, Zukor KJ, Antoniou J, Petit A. Effect of pamidronate on the stimulation of macrophage TNF-alpha release by ultra-high-molecular-weight polyethylene particles: a role for apoptosis. J Orthop Res 2003;21:81-7.
25. Baulé PE, LeDuff MJ, Dorey FJ, Amstutz HC. Fate of cementless acetabular components retained during revision total hip arthroplasty. J Bone Joint Surg [Am] 2003;85:2288-93.
26. Beaule PE, Ebramzadeh E, LeDuff M, Prasad R, Amstutz HC. Cementing a liner into a stable cementless acetabular shell: the double-socket technique. J Bone Joint Surg [Am] 2004;86:929-34.
27. Maloney WJ, Herzwurm P, Paprosky W, Rubash HE, Engh CA. Treatment of pelvic osteolysis associated with a stable acetabular component inserted without cement as part of a total hip replacement. J Bone Joint Surg (Am) 1997;79:1628-34.
28. Orishimo KF, Claus AM, Sychterz CJ, Engh CA. Relationship between polyethylene wear and osteolysis in hips with a second-generation porous-coated cementless cup after seven years of follow-up. J Bone Joint Surg [Am] 2003;85:1095-99.
29. Puolakka TJS, Pajamäki KJJ, Pulkkinen PO, Nevalainen JK. Poor survival of cementless Biomet total hip. A report on 1,047 hips from the Finnish Arthroplasty Register. Acta Orthop Scand 1999;70;425-429.
30. Huk OL, Bansal M, Betts F, Rimnac CM, Lieberman JR, Huo MH, Salvati EA. Polyethylene and metal debris generated by non-articulating surgaces of modular acetabular components. J Bone Joint Surg [Br] 1994;76:568-74.
31. Kurtz SM, Rimnac CM, Bartel DL. Degradation rate of ultra-high molecular weight polyetylene. J Orthop Res 1997;15:57-61.
32. Kurtz SM, Hozack W, Marcolongo M, Turner J, Rimnac C, Edidin A. Degradation of mechanical properties of UHMWPE acetabular liners following long-term implantation. J Arthroplasty 2003;18:68-78.
33. Head WC, Emerson RH, Millyard JM, Higgins L, Pindinson JL. Comparison of polyethylene wear in machined versus molded plyethylene liners in Ringloc acetabular cups. Texas center for joint replacement, Plano, TX, 1999.
34. Livermore J, Ilstrup D, Morrey B. Effect of femoral head size on wear of the polyetylene acetabular component. J Bone Joint Surg [Am] 1990;72:518-28.
35. Bragdon CR, Jasty M, Muratoglu OK, O'Connor DO, Harris WH. Third-body wear of highly cross-linked polyetylene in a hip simulator. J Arthroplasty 2003;18:553-61.

36. Digas G, Karrholm J, Thanner J, Malchau H, Herberts P. Highly cross-linked polyethylene in total hip arthroplasty: randomized evaluation of penetration rate in cemented and uncemented sockets using radiosteriometric analysis. Clin Orthop 2004;429:6-16.

Chapter | 7

Mid-term wear characteristics of an uncemented acetabular component

J.H.M. Goosen, C.C.P.M. Verheyen, N.J.A. Tulp

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Department of Orthopaedic Surgery and Traumatology
Isala Clinics, Weezenlanden Hospital
Zwolle, The Netherlands

Abstract

We investigated the rate of polyethylene wear of a cementless acetabular component at different periods of follow-up in order to test the hypothesis than an irrecoverable deformation process (creep) was followed by an initially low, but gradually increasing wear rate. We studied prospectively 93 uncemented total hip arthroplasties in 83 patients (mean age 50 years (22 to 63)) with a mean follow-up of 8.2 years (3 to 12). We measured the penetration of the femoral head from radiographs taken immediately after surgery at three, six and nine years, or at the latest follow-up.

The median wear rate was 0.17 mm per year in the first three years, a finding which we considered to be caused by creep. Thereafter, the rate of wear declined to 0.07 mm per year (four- to six-year period) and then increased to 0.17 mm per year (seven to nine years) and 0.27 mm per year (more than nine years), which we considered to be a reflection of genuine polyethylene wear. After the nine-year follow-up the wear rates were higher in patients with marked osteolysis. We found no relationship between the inclination angle of the acetabular component or femoral head orientation and the rate of wear. No acetabular component required revision.

Introduction

In the early years of total hip arthroplasty (THA), component loosening was considered to be the main cause of failure[1] while now, polyethylene wear leading to osteolysis is regarded as the main issue.[2] The survival of prostheses depends on factors which influence the rate of polyethylene wear.[3] The effect of implantation time on the rate of wear has been investigated by several authors, albeit with different results.[4-8] Deformation of polyethylene (creep) can occur after THA, so our aim was to test the hypothesis that polyethylene creep in the first years after implantation is followed by an initially low but increasing, genuine polyethylene wear.

Patients and Methods

Between 1992 and 1996, we implanted 122 primary uncemented THAs in 109 patients. Bilateral operations were undertaken in 13 of these patients. During the follow-up period 14 patients died from unrelated causes, and ten were lost to follow-up. In addition, one femoral stem had subsided for more than 2.5 cm because of fissuring of the calcar, and another developed early deep infection; both underwent early revision. A total of 29 THAs (26 patients) was excluded, leaving 93 THAs (83 patients) with adequate clinical and radiographic follow-up (Table 1). During this time period, a Mallory (Biomet, Warsaw, Indiana) acetabular shell was used. This was multi holed until 1994 and threeholed thereafter (44% *vs* 56% of THAs, respectively). It is hemispherical, with a titanium porous coating and has four peripheral fins providing rotational stability. A Ringloc (Biomet) compression-moulded ultra-high-molecular- weight polyethylene (UHMWPE) liner was used. In all patients, a Bi-Metric (Biomet) titanium alloy, proximally hydroxyapatitecoated femoral component, with a cobaltchrome, 28-mm femoral head (Biomet) was also used. Additional acetabular screws were used in nine hips. Systemic, prophylactic antibiotics (cefazolin 2 g intravenously) and pharmacological thromboprophylaxis were used, initially fraxiparine 2850 IU subcutaneously followed by acenocoumarol up to three months post-operatively. Patients with a minimum follow-up of three years were included in this study and were clinically evaluated pre-operatively and then postoperatively at six weeks, three and six months, at one year and annually thereafter. The Harris hip score[9] (HHS) was monitored at each visit.

Radiographic analysis

We evaluated the pelvic anteroposterior (AP) and lateral hip radiographs which

Table 1 Patient characteristics

Patients (n = 83)	Sex	
	Male	36 (39%)
	Female	46 (41%)
	Height (m)	1.73 (range 1.53 to 1.90)
	Weight (kg)	82 (range 55 to 123)
	Body Mass Index	27 (range 19 to 41)
	Age at operation (years)	50 (22 to 63)
	Follow-up average	8.2 years (3 to 12)
Hips (n = 93)	Diagnosis	
	Osteoarthritis	67 (72%)
	Osteonecrosis	14 (16%)
	Rheumatoid arthritis	5 (5%)
	Developmental dysplasia	5 (5%)
	Post-trauma	2 (2%)
	Side	
	Right	46 (49%)
	Left	47 (51%)
	Approach	
	Posterior	84 (90%)
	Lateral	19 (10%)

had been taken immediately post-operatively, and at three, six and nine years and the latest follow-up. The inclination angle of the acetabular component was measured as the angle between a horizontal line drawn through the interteardrop line and the inferior edge of the component.[10] The height of the centre of the femoral head for both operated and non-operated sides was measured perpendicular to this interteardrop line. The horizontal position of the centre of the femoral head was measured perpendicular to the interteardrop line from the inferior point of the teardrop.[11]

Linear femoral head post-penetration and direction were measured according to the method described by Livermore, Ilstrup and Morrey[12] on AP radiographs. A pair of compasses was used to establish the shortest distance from the centre of the

femoral head to the edge of the acetabular component. Distances were measured to the nearest 0.1 mm using calipers, so that a wear of ≥ 0.1 mm was measurable. A wear rate of ≥ 0.2 mm per year was considered to be excessive.[13]

Volumetric wear was calculated by the formula $v = \varpi r^2 w$, where v is the change in volume of the bearing, r the radius of the femoral head and w the linear polyethylene wear measured. On all radiographs, the magnification was based on the size of the femoral head so that all measurements were individually corrected. Osteolysis was estimated in the three regions of the acetabular interface described by DeLee and Charnley[14] and the proximal regions of the femur according to Gruen, McNiece and Amstutz.[15] The presence of osteolysis on each radiograph was recorded before any measurements were taken, eliminating any observer bias.

All radiographic evaluations were undertaken by one independent observer (JHMG). Statistical analysis was performed using the SPSS statistical package (SPSS 11.0, Chicago, Illinois). The Wilcoxon signed rank test, Mann-Whitney U test, ANOVA test and linear regression were used. Significance was assumed when $p < 0.05$.

Results

The mean length of follow-up was 8.2 years (3 to 12) and the mean age at operation was 50 years (22 to 63). The mean pre-operative HHS of 55 (12 to 79) improved to 97 (44 to 100) by the latest follow-up of which the median pain subscore improved from 15 (10 to 30) to 43 (30 to 44).

The polyethylene wear of the femoral head, centre and acetabular positions are listed in Tables 2 and 3. The median direction of penetration of the femoral head (according to Livermore et al[12]) during follow-up was 0° (from 20° laterally to 40° medially). Compared with the contralateral side, the centre of the head on the operated side was equally positioned vertically ($p = 0.110$) and horizontally ($p = 0.209$). There was no correlation between the horizontal and vertical orientation of the centre of the head and the rate and direction of the polyethylene wear. The inclination angle of the acetabular components was divided into three groups according to Sarmiento et al[16]: < 35°, 35° to 55° and > 55°. Sixty-eight (73%) of the cups were positioned between 35° and 55° and no difference in the rate and direction of polyethylene wear could be estab-lished among the three groups ($p = 0.126$ and $p = 0.863$, respectively). Neither the HHS, nor the pain subscore, were related to the rate of linear polyethylene wear. The median rates of linear and volumetric polyethylene wear, measured at different follow-up periods are listed in Table 3. The rate seen at four to six years was significantly lower ($p = 0.041$) than

Table 2 Wear rates and acetabular cup orientation

Measurable femoral head penetration	
Yes	89 (96%)
No	4 (4%)
Median linear wear rate - mm/yr (range)	0.18 (0 to 0.45)
Median volumetric wear rate – mm^3/year (range)	103 (0 to 277)
Head centre position operated hip (mm)	
Horizontal	31.0 (4.9)
Vertical	15.9 (4.7)
Head centre position contralateral hip (mm)	
Horizontal	32.0 (5.1)
Vertical	15.0 (3.7)
Inclination angle	
<35˚	21 (23%)
35˚ to 55˚	68 (74%)
>55˚	4 (3%)

Table 3 Wear rates at different periods of follow-up

	Periods of follow-up (yrs)			
	1 to 3	**4 to 6**	**7 to 9**	**>9**
Number of THAs*	93	83	71	24
Median linear wear rate	0.17	0.07	0.17	0.27
(mm/yr) - range	(0–0.67)	(0–0.63)	(0–1.40)	(0–2.11)
Median volumetric wear rate	113	41	77	141
(mm^3/year) - range	(0–412)	(0–388)	(0–862)	(0–1298)

*THA, total hip arthroplasty

after nine years of follow-up. Excessive polyethylene wear (≥ 0.20 mm per year) was seen in 45% of all THAs and in 70% of those followed up beyond nine years.

Table 4 lists the median individual differences in linear and volumetric polyethylene wear for the different follow-up periods. There was a statistically significant, higher wear rate after nine years than at the other follow-up periods. Osteolysis was seen in 18 THAs (19%) at a mean follow-up of 8.2 years. According to the zones of DeLee and Charnley[14], 11 THAs had osteolysis in zone I, three in zone II, three in zone III and one in all zones. No relationship was found with acetabular shell design or screw usage. Those THAs with a follow-up of > 9 years in which osteolysis was seen had significantly higher median wear rates after nine years than the THAs without observable osteolysis (0.66 mm per year 0 to 1.60) *vs* 0.27 mm per year (0 to 2.11) (p = 0.029). No relationship was found between the rate of polyethylene wear and the other parameters of acetabular shell diameter, design or screw usage, polyethylene thickness, body mass index, gender, or femoral head material. Four prostheses dislocated, three in the first post-operative year and one in the eighth. No component required a revision. The survival of the acetabular components was 100% (95% confidence interval (CI) 100). In a standard scenario, if all 29 THAs maintained their status before being lost to follow-up, the survival rate was 100% (95% CI 100), but in a worst case scenario (if all 29 THAs failed), this was reduced to 75% (95% CI 74 to 76).

Table 4 Differences in the rate of median linear wear at different periods of follow-up in mm per year (p-value*)

	Periods of follow-up (yrs)			
	1 to 3	**4 to 6**	**7 to 9**	**>9**
Rates of wear (mm per yr)				
1 to 3	-	0.10 (0.171)	0 (0.326)	0.10 (0.021†)
4 to 6		-	0.10 (0.068)	0.20 (0.041†)
7 to 9			-	0.10 (0.004†)
>9				-

* Wilcoxon signed ranks test

† Statistically significant

Discussion

A few studies, each with different results, have reported on the rate of polyethylene wear and its relationship with time after implantation for air-sterilised, polyethylene acetabular liners[4-8]. Kurtz et al[8] observed a progression of mechanical degradation with increasing implantation time in 16 air-sterilised polyethylene retrievals after a mean of 11.5 years. There was a statistically significant relationship with the oxidation index. The authors suggested that dissolved oxygen from body fluids diffused into the polyethylene component and reacted with residual free radicals from gamma sterilisation, a process probably comparable with shelf aging. The highest rates of mechanical degradation were recorded in the surface region of the polyethylene. In our study, the rate of wear increased significantly after nine years. Typical, although not statistically significant, was the relative reduction in wear at four to six years post-operatively in our study ($p = 0.171$). Other radiographic wear studies have suggested that the rate of wear decreases with implantation time[4-6]. Isaac et al[6] attributed their results to a rapid, irrecoverable deformation process (creep) followed by a steady, lower penetration rate associated with wear. We saw a similar transition in our study, but the rate of wear increased significantly after nine years. This creep-to-steady state transition was not supported by Gomez-Barrena et al[7] Puolakka et al[13] observed an excessive wear rate ≥ 0.20mm per year) in 42% of their cases after a six-year follow-up, similar to our study. In 70% of our THAs with a follow-up beyond nine years the rate of wear was excessive, with a wide range of up to 2.11 mm per year. Our findings suggest that the rate of wear of the acetabular components is acceptable for the first nine post-operative years and excessive after that, with an unexplained wide range. Hirakawa et al[11] reported a higher inclination angle for those acetabular components which needed revision and a high correlation with the direction of polyethylene wear. Del Schutte et al[17] failed to demonstrate any such correlation, a finding which is supported by the results of our study. Schmalzried et al[18] observed a statistically significant relationship between polyethylene wear and the centre of rotation. Hirakawa et al[11] established a significant relationship between horizontal orientation of the centre of the head and the direction of polyethylene wear. Those acetabular components which showed laterally-directed wear were more medialised than those with medially-directed wear. However, we found no relationship between the rate of wear and either the vertical or horizontal orientation of the femoral head. In support of work by Bono, Sanford and Toussaint,[19] we showed higher rates of wear in patients with osteolysis beyond nine years of follow-up. Maloney et al[20] reported acetabular osteolysis in 11 of 15 patients with a multi-holed acetabular shell, while Puolakka et al[13] showed a higher rate of wear in acetabular

components which required additional screw fixation. Meanwhile, Schmalzried et al[21] found no direct correlation between the presence of screw holes or screws and the incidence of pelvic osteolysis, a finding which is supported by our results. The acetabular components which we used have a locking mechanism which might offer better rotational stability and minimise backside polyethylene wear and osteolysis[22]. Metal-backed acetabular components were introduced because of findings which suggested that a more efficient stress transfer might delay loosening and migration[23]. However, clinical studies observed the opposite and identified a 37% higher rate of wear for cemented metal-backed acetabular components than for non-metal-backed components in cemented THA[24]. Many studies into the wear of uncemented metal-backed acetabular components and 28-mm femoral heads have been performed and have shown a polyethylene wear rate between 0.11 and 0.30 mm per year[13,24-28]. These results are comparable with our own. We also agree with Yamamoto et al[29] who found no relationship between polyethylene wear, polyethylene thickness, and age at operation after a mean follow-up of six years in 45 acetabular components with the same design of insert as used by ourselves. In the mid-1990s sterilisation methods changed from gamma irradiation in air to, predominantly, irradiation in either an inert gas or vacuum packaging. Mechanical *in vivo* degradation after implantation, which is based on an oxidative mechanism, is higher in air gamma-sterilised than in argon gamma-sterilised polyethylene acetabular components[30]. Highly cross-linked polyethylene shows an 80% to 90% wear reduction in hip simulator testing[31] and a 31% reduction in a bilateral study of 32 patients after a mean followup of two years[32]. We expect in future that better polyethylene quality will decrease the rate of wear and the prevalence of periprosthetic osteolysis in the mid to long term. Other bearing materials, such as metal-on-metal or ceramic-on-ceramic, show significantly less third-body wear and periprosthetic tissue reaction than metal-on-polyethylene designs. Some authors have, therefore, concluded that second generation all-metal implants should be considered in patients with a long life expectancy[33-35]. Ceramics are hard and strong, highly resistant to chemical and mechanical dissolution, but also brittle[36]. Hard-on-hard couples of metal-on-metal and ceramic-on-ceramic reduce wear to 0.001 mm per year[37] but can lead to high-impact loading of the acetabulum, leading to stress shielding and fractures of the periprosthetic bone.

In conclusion, penetration rates of the femoral head into the polyethylene liner of the acetabular component are variable. Typically, there is a temporary reduction four to six years after implantation which can be explained by the transition from the deformation (creep) phase to a genuine polyethylene wear thereafter. A significant, increased rate of polyethylene wear can be seen after nine years of implantation,

created by a mechanical degradation of the polyethylene surface. It is this category of patient which should be closely monitored for the rate of linear wear, osteolysis and loosening of the acetabular component.

References

1. Malchau H, Herberts P, Ahnfelt C. Prognosis of total hip replacement in Sweden. Follow-up of 92,675 operations performed 1978-1990. Acta Orthop Scand 64:497-506, 1993.
2. Harris WH. The problem is osteolysis. Clin Orthop 311:46-53, 1995.
3. Willert HG, Buchhorn GH, Hess T. The significance of wear and material fatigue in loosening of hip prostheses. Orthopade 18:350-69, 1989.
4. Charnley J, Cupec Z. The nine and ten year results of the low-friction arthroplasty of the hip. Clin Orthop 95:9-25. 1973.
5. Charnley J, Halley DK. Rate of wear in total hip replacement. Clin Orthop 112:170-9. 1975.
6. Isaac GH, Dowson D, Wroblewsky BM. An investigation into the origins of time-dependant variation in penetration rates with Charnley acetabular cups – wear, creep or degradation? Proc Inst Mech Eng (H) 210:209-16, 1996.
7. Gomez-Barrena E, Li S, Furman BS, Masri BA, Wright TM, Salvati EA. Role of polyethylene oxidation and consolidation defects in cup performance. Clin Orthop 352:105-17, 1998.
8. Kurtz SM, Hozack W, Marcolongo M, Turner J, Rimnac C, Edidin A. Degradation of mechanical properties of UHMWPE acetabular liners following long-term implantation. J Arthroplasty 18:68-78, 2003.
9. Harris WH. Traumatic arthritis of the hip after dislocation and acetabular fractures: treatment by mold arthroplasty. J Bone Joint Surg [Am] 51:737-55, 1969.
10. Sellers RG, Lyles D, Dorr LD. The effect of pelvic rotation on alpha and theta angles in total hip arthroplasty. Cont Orth 17:67-70, 1988.
11. Hirakawa K, Mitsugi N, Koshino T, Saito T, Hirasawa Y, Kubo T. Effect of acetabular cup position and orientation in cemented total hip arthroplasty. Clin Orthop 388:135-42, 2001.
12. Livermore J, Ilstrup D, Morrey B. Effect of femoral head size on wear of the polyethylene acetabular component. J Bone Joint Surg [Am] 72:518-28, 1990.
13. Puolakka TJS, Laine HJ, Moilanen TPS, Koivisto AM, Pajamäki KJJ. Alarming wear of the first-generation polyethylene liner of the cementless porous-coated Biomet universal cup. Acta Orthop Scand 72:1-7, 2001.
14. DeLee JG, Charnley J. Radiological demarcation of cemented sockets in total hip replacement. Clin Orthop 121:20-32, 1976.
15. Gruen TA, McNeice GM, Amstutz HC. 'Modes of failure' of cemented stem-type femoral components. A radiographic analysis of loosening. Clin Orthop 141:17-27, 1979.
16. Sarmiento A, Ebramzadeh E, Gogan WJ, McKellop HA. Cup containment and orientation in cemented total hip arthroplasties. J Bone Joint Surg [Am] 72:996-1002, 1990.
17. Del Schutte H, Lipman AJ, Bannar SM, Livermore JT, Ilstrup D, Morrey B. Effects of acetabular abduction on cup wear rates in total hip arthroplasty. J Arthroplasty 13:621-6, 1998.
18. Schmalzried TP, Shepher EF, Dorey FJ, Jackson WO, Rosa M, Fa'vae F, McKellop HA, McClung CD, Martell J, Moreland JR, Amstutz HC. Wear is a function of use, not time. Clin Orthop 381:36-46, 2000.
19. Bono JW, Sanford L, Toussaint JT. Severe polyethylene wear in total hip arthroplasty. J Arthroplasty 9:119-25, 1994.

20. Maloney WJ, Peters P, Engh CA, Chandler H. Severe osteolysis of the pelvic in association with acetabular replacement without cement. J Bone Joint Surg [Am] 75:1627-35, 1993.
21. Schmalzried TP, Brown IC, Amstutz HC, Engh CA, Harris WH. The role of acetabular screw holes and/or screws in the development of pelvic osteolysis. Proc Inst Mech Eng (H) 213:147-53, 1999.
22. Postak PD, Tradonsky S, Froimson AI, et al. Performance characteristics of two piece acetabular cups – series II. Orthop Transact 20:182-3, 1996.
23. Carter DR, Vasu R, Harris WH. Stress distributions in the acetabular region—II. Effects of cement thickness and metal backing of the total hip acetabular component. J Biomech 15(3):165-70, 1982.
24. Cates HE, Faris PM, Keating EM, Ritter MA. Polyethylene wear in cemented metal-backed acetabular cups. J Bone Joint Surg [Br] 75:249-53, 1993.
25. Devane PA, Bourne RB, Rorabeck CH, MacDonald S, Robinson EJ. Measurement of polyethylene wear in metal-backed acetabular cups. Clin Orthop 319:317-326, 1995.
26. Hozack WJ, Rothman RH, Eng K, Mesa J. Primary cementless hip arthroplasty with a titanium plasma sprayed prosthesis. Clin Orthop 333:217-25, 1996.
27. Kim YH, Kim JS, Cho SH. Primary total hip arthroplasty with a cementless porous-coated anatomic total hip prosthesis. 10- to 12-year results of prospective and consecutive series. J Arthroplasty 14:538-48, 1999.
28. Thanner J. The acetabular component in total hip arthroplasty. Evalution of different fixation principles. Thesis. Acta Orthop Scand (Suppl) 286:70, 1999.
29. Yamamoto K, Imakure A, Shishido T, Masaoka T, Koizumi R, Ito K, Sano K. Cementless total hip arthroplasty using porous-coated Biomet acetabular cups (Hexloc and Ringloc Types). J Orthop Sci 8:657-663, 2003.
30. Kurtz SM, Rimnac CM, Bartel DL. Degradation rate of ultra-high molecular weight polyetylene. J Orthop Res 1997;15:57-61.
31. Head WC, Emerson RH, Millyard JM, Higgins L, Pindinson JL. Comparison of polyethylene wear in machined versus molded polyethylene liners in Ringloc acetabular cups. Texas center for joint replacement, Plano, TX, 1999.
32. Bragdon CR, Jasty M, Muratoglu OK, O'Connor DO, Harris WH. Third-body wear of highly cross-linked polyetylene in a hip simulator. J Arthroplasty 2003;18:553-61.
33. Digas G, Karrholm J, Thanner J, Malchau H, Herberts P. Highly cross-linked polyethylene in total hip arthroplasty: randomized evaluation of penetration rate in cemented and uncemented sockets using radiosteriometric analysis. Clin Orthop 2004;429:6-16.
34. Doorn PF. Wear and biological aspects of metal on metal total hip replacements. Thesis 2000;chapter 1:13
35. Jacobsson SA, Kjerf K, Wahlstrom O. Twenty-year results of McKee-Farrar versus Charnley prostheses. Clin Orthop 1996;329 Suppl:S60-8.
36. Schmalzried RP, Szuszczewicz ES, Akizuki KH, Petersen TD, Amstutz HC. Factor correlating with long term survival of McKee-Farrar to hip prostheses. Clin Orthop 1996;329 Suppl:S48-59.
37. Konttinen YT, Zhao D, Beklen A, Ma G, Takagi M, Kivelä-Rajamäki M, Ashammakhi N, Santavirta S. The microenvironment around total hip replacement prostheses. Clin Orthop 2005;430:28-38.

38. Willmann G; The evolution of ceramics in total hip replacement. Hip International 2000;10:193-203.

Chapter | 8

In vivo wear reduction of argon compared to air sterilized UHMW-polyethylene liners

J.H.M. Goosen[1], C.C.P.M. Verheyen[1], B.J. Kollen[2], N.J.A. Tulp[1]

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[1] Department of Orthopaedic Surgery and Traumatology
[2] Research Bureau, Isala Academy
Isala Clinics, Weezenlanden Hospital
Zwolle, The Netherlands

Abstract

To date, no studies have been published that report on the *in vivo* advantages of sterilisation in argon (ARGON) versus air (AIR) of UHMWPE liners with respect to wear extend and pattern in uncemented total hip arthroplasty. Femoral penetration rates were measured in 93 AIR and an 79 ARGON liners, during a mean follow-up of 8 (3 to 12) years. During the first three years after implantation, both groups showed no differences in mean wear rate ($P = 0.13$). Thereafter, the ARGON liner demonstrated a decrease in wear rate of 0.04 mm/y from 4 to 6 years ($P = 0.006$), 0.14 mm/y from 7 to 9 years ($P < 0.001$), and 0.33 mm/y beyond 9-years follow-up ($P = 0.015$) compared to the AIR liner. One AIR acetabular component required revision.

Introduction

Polyethylene wear leading to osteolysis is considered to be a major contributor to the loosening process of the components in total hip arthroplasty[1,2]. Production and package sterilisation techniques for the polyethylene used in acetabular components are known to affect the rate of wear[3]. Since air sterilisation of Ultra High Molecular Weight Polyethylene (UHMWPE) acetabular liners is associated with substantial oxidation and radical formation causing early degradation of the material, sterilisation in a low oxygen environment (inert gas) became the method of choice in the late 1990s[4,5]. During mid-term follow-up, UHMWPE acetabular liners sterilised in air are likely to show a pattern of an initial deformation 'creep' phase, followed by an initially low but gradually increasing, genuine polyethylene wear[6]. The *in vivo* clinical advantages of UHMWPE liners sterilised in inert gas are still a matter of discussion[7]. Furthermore, there is no literature focussing on the *in vivo* reduction of the linear wearrates during follow-up in argon sterilised conventional UHMWPE acetabular components, compared with equally designed air sterilised components. In the present study, the mid-term wear pattern of UHMWPE-moulded acetabular liners sterilised in argon gas was compared with air-sterilised liners. In order to test the hypothesis that the argon-sterilised liners are less susceptible to wear than air-sterilised liners, the femoral head penetration was measured in both groups.

Patients and Methods

Between 1992 and 2000, we implanted 188 primary uncemented THAs in 170 patients with a biological age under 70 years. Eighteen patients were operated bilaterally. Within the first three years of follow-up, 4 patients died from unrelated causes, 10 patients were lost to follow-up and two patients underwent early revision due to fissuring of the calcar and an early infection. A total of 16 patients (16 THAs) were excluded, leaving 154 patients (172 THAs) with adequate clinical and radiographic follow-up (Table 1).

A hemispherical, titanium porous-coated Mallory acetabular shell was used (Biomet, Warsaw, IN, USA). This was multi-holed until 1994, and three-holed or solid thereafter (24% *vs* 76%). A Ringloc (Biomet) compression-moulded ultra-high-molecular-weight polyethylene (UHMWPE) liner was used. Until 1996 we used liners radiated in air (AIR), thereafter the liners were sterilised in argon (ARGON) – 46%

Table 1 Characteristics of the 154 patients with 172 total hip arthroplasties

	Air-Sterilised	Argon-Sterilised	P-value
Patients – number *(%)*	83 *(54)*	71 *(46)*	0.3
Hips – number *(%)*	93 *(54)*	79 *(46)*	0.3
Gender – number *(%)*			
Male	36 *(43)*	25 *(35)*	0.3
Female	47 *(57)*	46 *(65)*	0.3
Height in m (range)	1.73 (1.53 to 1.90)	1.72 (1.59 to 1.92)	0.7
Weight in kg (range)	82 (55 to 123)	81 (57 to 105)	0.8
Body Mass Index (range)	27 (19 to 41)	27 (21 to 38)	1.0
Age at operation in years range	50 (22 to 63)	55 (35 to 67)	0.001*
Follow-up average (range, SD)	8.2 (3 to 12, 1.9)	7.5 (3 to 12, 1.9)	0.03*
Pre-operative diagnosis in number of hips *(%)*			
Osteoarthritis	67 *(72)*	63 *(80)*	0.2
Osteonecrosis	14 *(15)*	3 *(4)*	0.01*
Developmental dysplasia	3 *(3)*	11 *(14)*	0.01*
Rheumatoid arthritis	6 *(6)*	1 *(1)*	0.1
Post-trauma	2 *(2)*	1 *(1)*	0.7
Side – number *(%)*			
Right	46 *(49)*	41 *(52)*	0.5
Left	47 *(51)*	38 *(48)*	0.5
Approach – number *(%)*			
Posterior	84 *(90)*	70 *(89)*	0.7
Lateral	9 *(10)*	9 *(11)*	0.7

** Statistically significant*

vs 54% of THAs, respectively. In all patients, a Bi-Metric (Biomet) titanium alloy, proximally hydroxyapatite-coated femoral component with a cobalt-chrome 28-mm femoral head (Biomet) was used. Additional acetabular screws were used in ten hips. Systemic, prophylactic antibiotics (cefazolin 2 g intravenously) and pharmacological thromboprophylaxis were used, initially fraxiparine 2850 IU subcutaneously followed by acenocoumarol up to three months postoperatively.

Patients with a minimum follow-up of three years were included in this study and were clinically evaluated, using the Harris Hip Score[8]. We evaluated the pelvic anteroposterior and lateral hip radiographs that had been taken immediately postoperatively, at three, six and nine years, and at the latest follow-up. The inclination angle of the acetabular component, acetabular cup position and orientation were measured as described by Sellers[9] et al. and Hirakawa[10] et al. The inclination angles of the acetabular components are divided into three groups according to Sarmiento[11]: $< 35°$, $35°$ to $55°$, and $> 55°$. Linear femoral head penetration and direction were measured according to the method described by Livermore[12] on AP radiographs. A pair of compasses was used to establish the shortest distance from the centre of the femoral head to the edge of the acetabular component. Using a caliper to an accuracy of 0.1 mm, a wear of ≥ 0.1 mm is measurable. Radiographic magnification was based on the size of the femoral head so that all measurements were individually corrected. The volumetric wear rate was calculated by the formula $v = \varpi r^2 w$, where v is the change in volume of the bearing, r the radius of the femoral head and w the linear polyethylene wear measured. Marked osteolysis was estimated in the three regions of the acetabular interface described by DeLee and Charnley[13] and the proximal regions of the femur according to Gruen[14]. All radiographic evaluations were undertaken by one independent observer (JHMG), who was blinded for sterilisation method applied to the liner.

Statistical analysis was performed using the SPSS statistical package (SPSS 15.0, Chicago). The Mann-Whitney U test and Independent T-Test were performed to analyse the differences between the two groups, depending on the distribution of the tested variables. Spearman's rho correlation test was performed to determine factors that correlate with the femoral head penetration. Kaplan-Meier analysis of the survival of both groups was conducted. In addition, MLwiN 2.02 was used to conduct multilevel analysis. The first level was defined as observations; the second level as surgeon. The iterative generalized least squares (IGLS) algorithm was used to estimate the regression coefficients. The likelihood ratio test was used to evaluate the necessity for allowing random regression coefficients into the model, while the Wald-test was used to obtain a p-value for each regression coefficient. A multilevel regression association model was developed to estimate the relationship between AIR and ARGON liners and wear rate corrected for possible confounding. A correction was applied in the event the liner regression coefficient was subject to >9% change as a result of fitting the model with a confounder[15]. Patient's age at surgery, BMI, screw application and number of screw holes in the metal shell were considered potential confounders in the relationship between liner groups

and wear rate in this study. We determined the best-case scenario (in which all hips with less-than-complete follow-up were considered to have had a successful result throughout the study period), standard-case scenario (in which all hips with less-than-complete follow-up were considered to have had a successful result at the time of the last follow-up) and worst-case scenario (in which all hips with less-than-complete follow-up were considered to have failed).

Results

The demographic features of the study-group are shown in Table 1. The mean preoperative HHS of 56 (SD = 10) improved to 96 (SD = 10) by the latest follow-up with an average of 8 (3 to 12) years. No differences between both groups were observed.

The used prosthetic material and acetabular positions are listed in Table 2. The patients with an implanted ARGON liner had a slightly higher age at surgery than the patients with an AIR liner. More patients with an ARGON liner had a preoperative diagnosis of developmental dysplasia and less osteonecrosis than patients with an AIR liner. In total, six patients (eight hips) died of unrelated causes during the follow-up period (four in the ARGON and two in the AIR group). Since 1994, only three-holed/solid shells were applied. As a consequence, more multi-holed acetabular shells were implanted in association with an air-sterilised liner, and subsequently more acetabular screws were applied in the air-sterilised group. The acetabular component was equally placed and oriented in both groups. Four AIR and five ARGON liners showed marked osteolysis in one or more acetabular regions ($P = 0.6$).

The average differences in polyethylene wear for the different sterilised liners and follow-up periods are depicted in Figure 1. Table 3 lists the polyethylene wear rates in these follow-up periods. In the ARGON liners, less femoral head penetration was measured compared with the AIR liners after a follow-up of 3 years ($P < 0.015$). In the AIR liners an increased wear rate after 9 years of follow-up ($P = 0.004$) was observed. For the ARGON liners, a rather steadily decreased wear rate was observed after 3 years of implantation ($P < 0.001$). Multi-level bivariate regression analysis revealed that the AIR liners showed an increase in longitudinal wear rate of 0.053 (0.024–0.082) mm/y, compared with the ARGON liners ($P = 0.001$). However, when considering possible confounding wear-influencing factors,

Table 2 Acetabular prosthetic features and orientation at final follow-up *(%)*

	Air-Sterilised	Argon-Sterilised	P-value
Shell – number (%)			
Multihole	37 *(40)*	6 *(8)*	0.00*
1 or 3 holes	56 *(60)*	73 *(92)*	0.00*
Screw usage – number (%)	9 *(10)*	1 *(1)*	0.02*
Marked acetabular osteolysis (%)	4 *(4)*	5 *(6)*	0.6
Head centre position operated hip (mm)			
Horizontal (SD)	31 *(4.9)*	31 *(4.9)*	0.79
Vertical (SD)	16 *(4.7)*	15 *(4.3)*	0.47
Head centre position contralateral hip (mm)			
Horizontal (SD)	32 *(5.1)*	33 *(4.1)*	0.27
Vertical (SD)	15 *(3.7)*	16 *(4.2)*	0.22
Inclination angle in number of hips (%)			
<35°	21 *(23)*	9 *(11)*	0.06
35° to 55°	68 *(73)*	66 *(86)*	0.1
>55°	4 *(4)*	4 *(3)*	0.8

** Statistically significant*

such as patient's age at surgery, screw application, number of screw holes in the metal shell (these factors were significantly different between the AIR and ARGON groups; see Tables 1 and 2) and BMI, the corrected wear rate between AIR and ARGON liner application changed little (0.048 mm/y, CI: 0.011–0.085, P = 0.011). Based on a > 9% change in regression coefficient, only the number of holes constituted a confounding factor in this relationship.

The average direction of penetration of the femoral head during follow-up was 1° and 2° medially in the ARGON and AIR liners, respectively (P = 0.460). Spearman's rho correlation test revealed no correlation between wear rate and femoral head position (p > 0.1), acetabular inclination angle (p > 0.1), HHS (p > 0.4) or direction of femoral head penetration (p > 0.2).

Figure 1

Rates of mean linear wear rate (mm/y) at different periods of follow-up (y), dark grey bars: air sterilised liners, light grey bars: argon sterilised liners

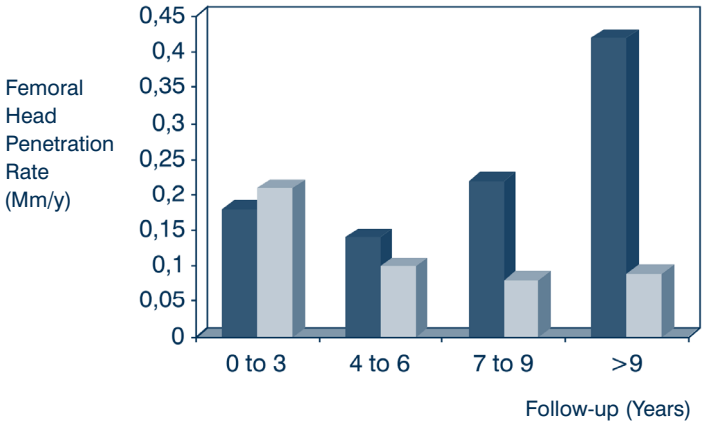

Table 3 Differences in the rates of median linear wear at different periods of follow-up. In mm per year

Follow-up	Air-Sterilised		Argon-Sterilised		P-value
(yrs)	N	Linear (SD); volumetric *(SD)* wear rate	N	Linear (SD); volumetric *(SD)* wear rate	
1 to 3	93	0.18 (0.17); *111 (105)*	79	0.21 (0.16); *129 (99)*	0.13
4 to 6	93	0.14 (0.17); *87 (102)*	79	0.10 (0.17); *59 (108)*	0.006*
7 to 9	68	0.22 (0.25); *138 (153)*	50	0.08 (0.13); *47 (82)*	<0.001*
>9	34	0.42 (0.5); *258 (206)*	20	0.09 (0.14); *53 (87)*	0.015*
Average total follow-up	93	0.18 (0.1); *110 (59)*	79	0.15 (0.12); *90 (74)*	0.009*

** Statistically significant*

One acetabular component with an AIR liner had to be revised eight years after implantation due to symptomatic periprosthetic acetabular osteolysis. Kaplan-Meier analysis revealed a 100% (CI 100) and 97% (CI 95 to 99) survival rate in a best-case scenario for the ARGON and AIR liners, respectively. The survival in both standard and best-case scenarios was 100% (CI 100) and 97% (CI 95 to 99), and in a worst-case scenario 86% (CI 70 to 100) and 90% (CI 80 to 100). No statistically significant differences in survival were found.

Discussion

In the present study, the ARGON liners showed a lower, steady wear rate after 3 years follow-up. Unlike the AIR liners, the ARGON liners did not show an increasing wear rate after 9 years, suggesting a more steady wear pattern than the AIR liners after 9 years follow-up. Both the AIR and the ARGON liners showed a similar creep phase in the first three years after implantation.

UHMWPE acetabular cups, developed by Sir John Charnley, have been used in hip replacements for the past 40 years. Sterilisation was employed with a minimum dose of gamma radiation in air-permeable packaging[16]. Sterilisation in air generates entrapped free radicals which oxidise and damage the implant before implantation, causing a brittle surface susceptible to wear. During implantation of the acetabular component, oxidation of the initially formed free radicals and damage will proceed, caused by oxygen-containing synovial fluid[16]. As a possible remedy, Premnath[4] et al. stated that sterilisation in an oxygen-depleted atmosphere, like inert gas or vacuum packaging, will reduce the degree of oxidation during sterilisation. Therefore, since the mid-1990s gamma sterilisation in an oxygen-depleted environment like inert gas (e.g. argon), gas plasma or vacuum packaging has become the method of choice[5]. The advantage of oxygen-depleted sterilised liners *in vivo* is still a matter of discussion[7]. Kurtz[16] et al. stated that *in vivo* oxidative degradation is a possible cause of long-term failure for modular polyethylene components in total hip arthroplasty. They observed the highest oxidative degradation in those regions of the liner experiencing minimal wear, such as the rim of the component. However, less polyethylene oxidation was observed at the bearing surface; this could be explained by the removal of the degraded material by the femoral head. This typical sign of degradation was observed not only in 16 air-sterilised liners (mean implantation time 11 years), but also in the 22 argon-sterilised liners (mean implantation time

4 years), which suggests that not only air-sterilised but also inert gas-sterilised components are liable to oxygen-mediated degradation *in vivo*[5,7,16]. Faris[3] et al. observed significantly less wear in inert-sterilised moulded liners than air-sterilised extruded liners after a mean follow-up of 6 years in 150 patients, although these results may be (partially) explained by the inert-sterilised components they used. These were made of moulded UHMWPE, which provides less wear than the extruded UHMWPE[17]. In our study, a lower femoral head penetration rate was observed in the ARGON liners than in the AIR liners at 3 years follow-up and thereafter. A significant link between time after implantation and rate of polyethylene wear in air-sterilised liners is observed in several studies, suggesting a rapid, irrecoverable deformation process (creep) in the first years after implantation followed by a lower, steady genuine wear rate that will increase significantly after nine years[2,6].

The AIR liners were more frequently positioned in a multi-holed shell than the ARGON liners (40% *vs* 8%). As a consequence, more shell screws were applied in the AIR group. It has been stated that the presence of screw holes in a metal backed acetabular component is correlated with the incidence of pelvic and trochanteric periprosthetic osteolytic lesions[18]. On the other hand, Schmalzried[19] et al. found no direct correlation between presence of screw holes or screws and incidence of pelvic osteolysis, suggesting that the number of holes and the use of screws in association with the acetabular shell do not affect the extent of wear. Repetitive motion between the acetabular liner and its shell, causing backside wearparticles and fluid pressure through the acetabular screw holes, contributes to the formation of retroacetabular osteolysis[20]. Tradonsky et al. performed an experimental study, in which push- and lever-out tests were performed on five different metal-backed acetabular locking mechanisms. In contrast with the other tested mechanisms, considerably high strenghts were required to separate the liner from its shell associated with a ring-wired locking mechanism, compared with the one in the present study. Consequently, components used in the current study have locking mechanisms that could provide better rotational stability and subsequently minimise backside polyethylene wear and osteolysis.[21,22] Puolakka et al.[23] observed a significantly higher wear rate in acetabular components with additional screw fixation, while others found no direct correlation between the presence of screw holes or screws and the incidence of pelvic osteolysis[19], which is supported by our results.

In our study, a difference in wear rate between the AIR and ARGON liners over the years was observed cross-sectionally and longitudinally based on multivariate

analysis. An extensive multilevel analysis clearly has demonstrated that the screw usage, BMI, age at operation, follow-up and indication did not confound the observed association between liners and wear rate and therefore did not affect the statistically significant reduction of wear of the Argon-sterilized liners.

Schmalzried[24] et al. stated that the orientation of the femoral head is strongly associated with a higher wear rate in 37 total hip arthroplasties after 1 year follow-up. In our study, the centre of rotation was similar between the THAs with the AIR and ARGON liners, which suggests that the difference of wear rate between these groups cannot be explained by the orientation of the femoral head. Contrary to the literature, we found no relation between wear rate and centre of rotation in the groups. A relation between wear rate and position of the acetabulum component was not demonstrated either.

Metal-backed acetabular components, more or less comparable with ours, have shown a polyethylene wear rate between 0.11 and 0.30 mm per year[23, 24-27]. These results are comparable with those of both our AIR and ARGON liners.

Despite the fact that our study showed that acetabular liners sterilised in argon are less sensitive to wear than air-sterilised inserts, periprosthetic osteolysis is equally present in both groups (Table 2). Following a retrieval study on 41 acetabular liners, Kurtz[7] et al. stated that the in vivo oxidation does not seem to be clinically important in the first 10 years of implantation for conventional gamma sterilized polyethylene, because the polyethylene locking mechanisms remain relatively isolated from oxidizing fluid in this period. Furthermore, it was not the primary aim of the present study to demonstrate the incidence of periprosthetic osteolytic lesions. Plain radiographs are poorly sensitive in for identifying and quantifying osteolysis compared with helical CT-scans[28], which are not performed in the present study.

Grimm[29] et al. reviewed 40 patients of which 23 had been randomly assigned to receive prostheses with conventional polyethylene and 17 to receive third-generation crosslinked polyethylene materials, sterilised in nitrogen. At eight years follow-up, wear averaged 0.088 $\pm$ 0.03 mm per year for patients in the third-generation crosslinked polyethylene group. Compared with our study, the wearrate of the crosslinked polyethylene is comparable with the wearrate of the ARGON liners after 3 years follow-up (0.08 to 0.10 mm/y), while the wearrate of the ARGON liners in the first 3 years of follow-up was relatively higher (0.21 mm/y). This suggests that “creep” is reduced by crosslinking the polyethylene.

Other bearing materials, like all-metal components, can reduce wear to a negligible rate of 0.001 mm per year[30]. Therefore, we agree with other authors who suggest that second-generation (like metal-on-metal) implants should be considered in patients with a long life expectancy[31,32].

The strenght of the present study is that it is the first study to conduct an *in vivo* comparison between air and argon sterilized UHMWPE in liners used in uncemented hip arthroplasty with an identical design. We demonstrated a reduction in the wear rate during different follow-up periods in our population. Based on multi-level analysis we were also able to demonstrate a more or less unbiased relationship between wear rate and argon group as we controlled for possible confounding factors, such as patient's age at surgery, BMI, screw application, number of screw holes in the metal shell .

Limitations of the study are the retrospective, non-randomized design, the lower number of measured liners beyond the 9 year follow-up and the use of two different metal shell-types (multi-holed and solid). Because the AIR en ARGON groups entered the study in succession, a systematic difference has occurred in the way in which study subjects were enrolled into the trial and in the way treatments were assigned to those enrolled. This introduces selection bias. Therefore, the results of this study need to be interpreted with some caution.

In conclusion, it can be stated that the *in vivo* penetration rate of the femoral head is significantly lower in argon-sterilised than air-sterilised UHMWPE liners in metal-backed uncemented components at 3 years after implantation and thereafter. Both groups showed an equally significant decreased wear rate after 3 years follow-up, suggesting an initial creep phase in the first years after implantation followed by a rather steadily decreasing genuine wear rate thereafter. After 9 years follow-up, the air-sterilised liners showed a significant increase in wear rate as opposed to the argon-sterilised liners, which remained stable. Despite their different amount and patterns of wear, no difference in marked osteolytic tissue reaction could be demonstrated.

References

1. Harris WH (1995). The problem is osteolysis. Clin Orthop 311:46-53.
2. Isaac GH, Dowson D, Wroblewsky BM (1996). An investigation into the origins of time-dependant variation in penetration rates with Charnley acetabular cups – wear, creep or degradation? Proc Inst Mech Eng (H) 210:209-16.
3. Faris PM, Ritter MA, Pierce AL, Davis KE, Faris GW (2006). Polyethylene sterilization and production affects wear in total hip arthroplasties. Clin Orthop 453:305-308.
4. Premnath V, Harris WH, Jasty M, Merril EW (1996). Gamma sterilization of UHMWPE articular implants: an analysis of the oxidation problem. Biomaterials 17:1741-53.
5. Kurtz SM, Muratoglu OK, Evans M, Edidin AA (1999). Advances in the processing, sterilization, and crosslinking of ultra-high molecular weight polyethylene for total joint arthroplasty. Biomaterials 20:1659-88.
6. Goosen JH, Verheyen CC, Tulp NJ (2005). Mid-term wear characteristics of an uncemented acetabular component. J Bone Joint Surg [B] 87:1475-9.
7. Kurtz SM, Hozack WJ, Purtill JJ, Marcolongo M, et al (2006). Significance of In Vivo degradation for polyethylene in total hip arthroplasty. Clin Orthop 453:47-57.
8. Harris WH (1969). Traumatic arthritis of the hip after dislocation and acetabular fractures: treatment by mold arthroplasty. J Bone Joint Surg [Am] 51:737-55.
9. Sellers RG, Lyles D, Dorr LD (1988). The effect of pelvic rotation on alpha and theta angles in total hip arthroplasty. Cont Orth 17:67-70.
10. Hirakawa K, Mitsugi N, Koshino T, Saito T, Hirasawa Y, Kubo T (2001). Effect of acetabular cup position and orientation in cemented total hip arthroplasty. Clin Orthop 388:135-42.
11. Sarmiento A, Ebramzadeh E, Gogan WJ, McKellop HA (1990). Cup containment and orientation in cemented total hip arthroplasties. J Bone Joint Surg [Am] 72:996-1002.
12. Livermore J, Ilstrup D, Morrey B (1990). Effect of femoral head size on wear of the polyethylene acetabular component. J Bone Joint Surg [Am] 72:518-28.
13. DeLee JG, Charnley J (1976). Radiological demarcation of cemented sockets in total hip replacement. Clin Orthop 121:20-32.
14. Gruen TA, McNeice GM, Amstutz HC (1979). 'Modes of failure' of cemented stem-type femoral components. A radiographic analysis of loosening. Clin Orthop 141:17-27.
15. Twisk JWR: Applied multilevel analysis: A practical guide. Cambridge University Press. 2006.
16. Kurtz SM, Hozack W, Marcolongo M, Turner J, et al (2003). Degradation of mechanical properties of UHMWPE acetabular liners following long-term implantation. J Arthroplasty 18:68-78.
17. Bankston AB, Cates H, Ritter MA, Keating EM, Faris PM (1995). Polyethylene wear in total hip arthroplasty.Clin Orthop. 317:7-13.
18. Schmalzried TP, Brown IC, Amstutz HC, Engh CA, Harris WH (1999). The role of acetabular screw holes and/or screws in the development of pelvic osteolysis. Proc Inst Mech Eng (H) 213:147-53.
19. Schmalzried TP, Shepher EF, Dorey FJ, Jackson WO, Rosa M, Fa'vae F, McKellop HA, McClung CD, Martell J, Moreland JR, Amstutz HC (2000). Wear is a function of use, not time. Clin Orthop 381:36-46.

20. Cates HE, Faris PM, Keating EM, Ritter MA (1993). Polyethylene wear in cemented metal-backed acetabular cups. J Bone Joint Surg [Br] 75:249-53.
21. Devane PA, Bourne RB, Rorabeck CH, MacDonald S, Robinson EJ (1995). Measurement of polyethylene wear in metal-backed acetabular cups. Clin Orthop 319:317-326.
22. Hozack WJ, Rothman RH, Eng K, Mesa J (1996). Primary cementless hip arthroplasty with a titanium plasma sprayed prosthesis. Clin Orthop 333:217-25.
23. Puolakka TJS, Laine HJ, Moilanen TPS, Koivisto AM, Pajamäki KJJ (2001). Alarming wear of the first-generation polyethylene liner of the cementless porous-coated Biomet universal cup. Acta Orthop Scand 72:1-7.
24. Schmalzried TP, Shepher EF, Dorey FJ, Jackson WO, Rosa M, Fa'vae F, McKellop HA, McClung CD, Martell J, Moreland JR, Amstutz HC. Wear is a function of use, not time. Clin Orthop 381:36-46, 2000.
25. Cates HE, Faris PM, Keating EM, Ritter MA. Polyethylene wear in cemented metal-backed acetabular cups. J Bone Joint Surg [Br] 75:249-53, 1993.
26. Devane PA, Bourne RB, Rorabeck CH, MacDonald S, Robinson EJ. Measurement of polyethylene wear in metal-backed acetabular cups. Clin Orthop 319:317-326, 1995.
27. Kim YH, Kim JS, Cho SH. Primary total hip arthroplasty with a cementless porous-coated anatomic total hip prosthesis. 10- to 12-year results of prospective and consecutive series. J Arthroplasty 14:538-48, 1999.
28. Puri L, Wixson RL, Stern SH, Kohli J, Hendrix RW, Stulberg SD. Use of helical computed tomography for the assessment of acetabular osteolysis after total hip arthroplasty. J Bone Joint Surg [A] 2002;84:609-14.
29. Grimm B, Tonino AJ, Heyligers IC (2007). Eight-year prospective randomized comparison between crosslinked and conventional polyethylene in total hip arthroplasty [abstract]. European Federation of National Associations of Orthopaedics and Traumatology Congress.
30. Konttinen YT, Zhao D, Beklen A, Ma G, et al (2005). The microenvironment around total hip replacement prostheses. Clin Orthop 430:28-38.
31. Doorn PF. Wear and biological aspects of metal on metal total hip replacements. Thesis 2000;chapter 1:13
32. Jacobsson SA, Kjerf K, Wahlstrom O (1996). Twenty-year results of McKee-Farrar versus Charnley prostheses. Clin Orthop 329 Suppl:S60-8.

Chapter | 9

Minimally Invasive versus Classical Procedures for Posterolateral and Anterolateral Approaches in Total Hip Arthroplasty

A randomized, double-blinded trial

J.H.M. Goosen[1] ,B.J. Kollen[2], R.M. Castelein[3], B,M. Kuipers[1],C.C.P.M. Verheyen[1]

SUBMITTED

[1] Department of Orthopaedic Surgery and Traumatology
Isala Clinics, Zwolle, The Netherlands
[2] Department of Epidemiology
Isala Academy, Isala Clinics
Zwolle, The Netherlands.
[3] Department of Orthopaedic Surgery
University Medical Center Utrecht, The Netherlands.

Abstract

In order to achieve a minimized need for tissue dissection resulting in a faster rehabilitation, minimally invasive surgery (MIS) in Total Hip Arthroplasty (THA) was developed. In this small incision technique the skin and musle dissection has been reduced with respect to the classical approach. Literature shows ambiguous results comparing the posterolateral minimally incisive with the classical approach. As the anterolateral approach is also a routine procedure, and to test how minimally invasive MIS is, we hypothesized that patients treated with a THA using a posterolateral or anterolateral MIS would experience superior clinical results compared with a standard incision after six weeks and no clinical differences after one year. This was tested in a double-blind randomized controlled trial with the Harris Hip Score (HHS) as a primary endpoint.

One hundred and twenty consecutive primary uncemented THAs were randomized into one of four groups of 30 patients each. Either standard posterolateral or anterolateral approaches (PL- or AL-CLASS), or minimal invasive posterolateral or anterolateral approaches (PL- or AL-MIS) were performed. CLASS incisions were 18 cm. To avoid postoperative bias, MIS incisions were extended at skin level to 18 cm at the end of the procedure. The HHS as well as patient-centered questionnaires (SF-36, WOMAC and OHS) was obtained preoperatively, at six weeks and one year after the index operation. Preoperative data, blood loss, hemoglobin, muscle damage parameters and radiological parameters were analyzed. In order to detect a minimal clinically important difference of five points or more between the MIS or CLASS groups with respect to the Harris Hip Score at the 0.05 alpha level with 80% power, 120 patients were enrolled in the study.

Mean incision length of the THAs performed by MIS was 7.8 (SD = 1.6). In the patients of the MIS group a significant increased mean HHS was observed compared with the CLASS ($p = 0.03$) after six weeks and one year. This difference was caused by the favorable results of the PL-MIS ($p = 0.009$). Of the three patient-centered questionnaires, the SF-36 results were also favourable in the PL-MIS group after six weeks ($p = 0.04$). In the MIS group operation time was longer ($p < 0.001$) and a learning curve was observed based on operation time and complication rate. Perioperative complications rates were not significantly different between the groups. Blood loss, hemoglobin, muscle damage parameters and radiological parameters also showed no difference.

This double-blind, randomized study reveals an improved clinical outcome of the PL-MIS compared with the AL-MIS, PL-CLASS and AL-CLASS after six weeks and one year follow-up with the Harris Hip Score as primary endpoint.

Introduction

After the promising introduction of minimally or mini-incisive surgery (MIS, incision length 10 to 12 cm or less[1,2]) in total hip arthroplasty (THA), a discussion started worldwide about the possible clinical benefits of this innovative approach as compared to the classical approaches (CLASS).[1,2,11] The rationale for developing MIS was a minimized need for tissue dissection, resulting in reduced blood loss, pain and hospital stay, improved propriosepsis and a faster rehabilitation.[3] Compared with the classical approach, the first retrospective studies showed a higher peri-operative complication rate[4] in the absence of clinical improvements in the THAs performed by a posterolateral MIS.[4-6] Non-blinded randomized trials showed conflicting results.[7-9] Dorr et al[2] compared 30 THAs with a posterolateral minimally invasive incision with 30 THAs with a classical incision in a double-blinded randomised trial. They observed early pain relief at the time of discharge and less use of assistive devices in the MIS group during hospital stay, while no differences were observed at six weeks and three months between the groups.

To date, no studies have compared MIS with the classical approach for both posterolateral (PL) and anterolateral (AL) incisions. To investigate these four different techniques and to contribute to a better understanding of the effects of these different THA procedures on clinical and other parameters we conducted a double-blind, randomized controlled trial. The hypothesis we set out to test was that patients treated with a THA using a PL- or AL-MIS would have improved clinical results based on Harris Hip scores (HHS), compared with a standard incision (PL- and AL-CLASS) after a six week follow-up. We also hypothesized the results would equalize between the four patient groups after one year follow-up. In addition, the procedures were studied for differences in complication and revision rates, WOMAC scores, Oxford Hip scores and SF-36 scores. Other possible predicting factors such as sex, adverse events or component position for observed HHS scores during the first postoperative year were addressed.

Materials and Methods

Patient selection and randomization process

First, approval of our institutional medical ethics committee was obtained. Between January 2005 and November 2007, patients were enrolled in the study after we obtained informed consent. Patients were excluded in case of a Body Mass Index

above 30, previous surgery of the ipsilateral hip or age older than 75 years. Based on allocation concealment, patients were included and allocated to one of the four operations. Six orthopaedic surgeons, each of whom had performed over 1000 primary THAs prior to the study, conducted the operations. All participating surgeons had attended a cadaveric course on MIS. Three of them performed the THA using the modified AL-MIS or AL-CLASS[12] and the other three the PL-MIS or PL-CLASS.[13] The applied block randomization was stratified for participating surgeons, generating 10 sealed envelopes per surgeon per time. When a patient was included two instrument sets were on standby. Ten minutes preoperatively after introduction of anaesthesia an envelope was drawn from the set of the operating orthopaedic surgeon and opened by him. Then the corresponding instrument set (MIS or standard) was selected and opened. In order to keep the patient blinded, all operation room personnel were instructed not to talk about the operative procedure perioperatively.

A Harris Hip Score (HHS) improvement of four points was shown to be the best cut-off point for optimal sensitivity and specificity to detect clinical improvement[14]. Power calculations revealed that in order to detect a clinically important difference of five points or more between the MIS or CLASS groups with respect to the Harris Hip Score at the 0.05 alpha level with 80% power, 120 patients needed to be enrolled in the study. Withdrawal of a patient for any reason or any operation (including revision) leading to a new incision of the wound area resulted in premature unblinding of the patient and exclusion from the study.

Treatment protocol

On the day of the operation the envelope was opened as described. Next, the maximal groin circumference was obtained using a tape measure. After introducing anesthesia, skin desinfection and sterile draping, a sterile curved ruler of 18 cm was placed on the greater trochanter. A 18-cm line was drawn from the edge of the ruler on the skin with a sterile pen. For MIS, the surgeon chose the length of the incision, usually the central part of the drawn line somewhere between 5 and 10 cm.

The operation took place with the designed instruments for MIS (curved acetabular and femoral reamers, skin and bone retractors, Biomet, Warsaw, Indiana). All procedures were performed using a Bi-Metric porous-coated uncemented femoral component (Biomet) and a metal-metal Magnum (Biomet) femoral head (diameter 6 mm less than the chosen cup diameter) and acetabular shell. After closure of the fascia and subcutaneous tissue, the curved ruler was placed beside the incision

and a second set of two instant pictures of the incision was taken, one in flexion and one in extension. Next, the skin incision with a thin layer of subcutaneous tissue was extended to 18 cm following the line drawn preoperatively and the skin was closed with staples. When the operation was completed, the procedure form was filled in by the surgeon. Surgical time, intraoperative blood loss, extension of the wound and any adverse events were recorded on a standardized form and placed, with the obtained pictures, in a sealed envelope. Systemic prophylactic antibiotics (preoperative cefazoline 2 gr intravenously) and pharmacological thromboprophylaxis (fondaparinux 2.5 mg/0.5ml subcutaneously up to 5 weeks postoperatively) were used. All patients received a standard dose of indometacin (100 mg per day) during the hospital stay as a prophylaxis against the formation of periarticular ossifications. Length of hospital stay was in all cases five days, as patients were enrolled in our FOR-U (Fast Orthopedic Rehabilitation Unit) program.

Data Collection, clinical and radiological analysis

All data were collected prospectively during the hospital stay, and at the six-week and one-year follow-up visits at the outpatient clinic by an investigator who had not been involved with patients' care or operation and was blinded for the applied procedure (BK). The data were analyzed by two research members that were not involved in the clinical procedures (JHG and BJK).

Venous blood was obtained on the day before the operation. Baseline hemoglobin and tissue damage parameters like myoglobin and creatinine kinase (CK) were analyzed.[15] Age, sex, operation side, diagnosis, weight, height and body mass index were recorded. Baseline preoperative functional and clinical status were obtained using the Harris Hip score (HHS).[16] The patients filled in three clinical patient-centered questionnaires (WOMAC,[17] Oxford Hip Score (OHS)[18] and SF-36[19]). On the first postoperative day, venous blood was drawn for analysis of the hemoglobin and tissue damage parameters myoglobin and CK. Radiological exams of the pelvis (pubis-centered) and hip were performed. At six weeks and one year postoperatively, the patients were clinically scored by the blinded inverstigator. The HHS, WOMAC, OHS and SF-36 forms were filled in, the latter three by the patients themselves in the waiting room. Pubic-centered pelvic and hip radiographs were obtained. We were aware of the fragility of maintaining full blinding of the patients for their treatment.

An apparent difference in appearance between the central and extended part of the MIS scar as well as information of the operation staff (despite the instructions) could easily obstruct the blinding procedure. To put the effect of the blinding to the

test, the patients and investigator were asked at the end of the one-year follow-up period which approach (MIS or CLASS) they thought had been used. The blinding was then lifted and patients were informed whether a classical or minimally invasive procedure had been used.

Radiological exams were analyzed at the one-year follow-up visit. The inclination angle of the acetabular component was measured as described by Sellers.[20] The inclination angles of the acetabular components were divided into three groups according to Sarmiento: $< 35°$, $35°$ to $55°$, and $> 55°$[21]. Grading of heterotopic bone formation,[22] position of the femoral component[23] and radiological leg length difference[24] were documented.

Statistical analysis

Statistical analysis was conducted using the SPSS statistical package (SPSS 15.0, Chicago). The Mann-Whitney U-test, Student *t*-test, Pearson Chi Square, Fisher's exact and one-way ANOVA with post-hoc tests using Bonferroni correction were used to analyze the differences between operations, depending on type and distribution of the tested variables. In addition, MLwiN 2.10 was used to conduct a multilevel analysis to determine predicting factors for longitudinal HHS scores. The first level was defined as observations, the second level as patient. The iterative generalized least squares (IGLS) algorithm was used to estimate regression coefficients, while the Wald-test was used to obtain a p-value for each regression coefficient. No imputation of missing values was implemented.

Results

One hundred and twenty patients and hips were enrolled in the study. Demographic characteristics are listed in Table 1. Missing value analysis showed that 3.3% (four of 120) of the primary endpoint data, HHS at six weeks, and 9.2% (11/120) of the HHS score at one year were missing. Four patients were unable to complete study questionnaires both at six weeks and one year follow-up. One patient was a refugee who returned to her country of origin three months after the surgery (AL-MIS). Three patients needed an early revision because of component loosening before six weeks postoperatively (two AL-MIS, one AL-CLASS).

Seven patients completed only their six-week visit but were unable to complete their one year follow-up. One patient died of an unrelated cause five months after

Table 1 Demographic Characteristics

	Approach		P-value
	MIS ***PL[1]–AL[2]***	**Classical** ***PL[1]–AL[2]***	
Hips (n)	60 *30–30*	60 *30–30*	
Gender (n)			
Male	30 *15–15*	29 *13–16*	1.0[a] *.89*[a]
Female	30 *15–15*	31 *17–14*	
Height in m (SD)	1.73 (0.07) *1.72 (0.06)–1.74 (0.08)*	1.73 (0.08) *1.73 (0.07)–1.73 (0.09)*	.94[b] .89[c]
Weight in kg (SD)	79.5 (11.0) *78 (9.8)–81 (12.1)*	79.3 (11.9) *80 (9.2)–78 (14.2)*	.93[b] *.80*[c]
Body Mass Index (SD)	26.6 (2.8) *26.4 (2.6)–26.7 (3.1)*	26.4 (2.8) *26.8 (2.7)–26.1 (2.8)*	.80[b] *.74*[c]
Age at operation in years (SD)	60 (6.8) *60 (6.3)–60 (7.4)*	62 (6.6) *62 (6.3)–62 (6.9)*	.13[b] *.51*[c]
Preoperative diagnosis (n)			
Osteoarthritis	55 *27–28*	59 *29–30*	.32[a] *.45*[a]
Osteonecrosis	1 0–1	0	
Developmental dysplasia	2 *2–0*	1 *1–0*	
Post-trauma	2 *1–1*	0	
Side (n)			
Right	39 *20 – 19*	36 *18–18*	.57[a] *.94*[a]
Left	21 *10 – 11*	24 *12 – 12*	

[1] Posterolateral; [2] Anterolateral

[a] Pearson Chi Square test; [b] Mann Whitney U test; [c] One way ANOVA test with Bonferroni Correction

surgery (AL-MIS) and two patients did not wish to visit the hospital at one year (PL-MIS; AL-CLASS). However, no adverse events or clear clinical symptoms could be established by telephone. Three patients underwent a revision procedure after the postoperative visit at six weeks (two AL-MIS, one PL-CLASS), and one patient (AL-CLASS) was re-operated (debridement) following an early infected prosthesis two months postoperatively. Because of the re-arthrotomy and the unblinding of these patients, these four cases were excluded.

After the one-year follow-up visit, 46% of the patients treated with MIS rightfully thought they were treated this way, and 45% of the CLASS patients thought they were treated with the classical approach. The investigator filled in the right answer in 57% of the cases in the MIS group and 52% in the CLASS group.

Preoperative and directly postoperative results are listed in Table 2. Mean operation time for the MIS approach was 10 minutes longer than the classical approach. A significant decrease in operating time was observed comparing the first 30 (74 minutes, SD = 21) with the last 30 MIS procedures (64 minutes, SD = 15), at $p = 0.028$. While performing the MIS, five procedures warranted extension of the incision with 1 to 5 cm distally and/or 2 to 4 cm proximally. In four cases this was necessary because of adding cerclage wires for a proximal fissure of the femur. In one patient a massive venous bleeding had to be stopped, necessitating extension of the incision. Groin circumference and BMI did not correlate with incision length, complication rates, or radiological or clinical results in the MIS group. No correlations were observed between surgeon and complication and revision rates or HHS. In two cases (both AL-MIS) the peri-operative treatment protocol had to be violated. In both cases after acetabular reaming the situation was evaluated as not fit for an uncemented cup. These patients received reversed hybrid prosthesis. However, they continued the study program and evaluation according to the intention-to-treat principle.

Table 3 lists the complications and revisions. No statistically significant differences on peri-operative complications or reoperations could be observed between the four groups. Although not significantly different from the CLASS group (two out of 60), the rate of complications in the MIS group was rather high (six out of 60). Furthermore, four of the six peroperative femoral fissures occurred in the AL-MIS group. Three of these fissures were repaired with a cerclage preoperatively and two of the hips warranted revision in the first six months postoperatively. One crack was not noticed preoperatively and resulted in subsidence, requiring stem revision.

Table 2 Preoperative and directly postoperative results

	Approach		P-value
	MIS ***PL[1]–AL[2]***	**Classical** ***PL[1]–AL[2]***	
Groin circumference (cm) (SD)	60 (7.4) *60 (6.7)–61 (8.0)*	59 (8.6) *59 (8.5)–59 (8.8)*	.15 [a] *.68* [b]
Operation time (min) (SD)	68 (18.6)	58 (13.2)	<.001 [a†]
	68 (22)–68 (15)	55 (9.1)–62 (16)	.004 [b††]
Preoperative incision length (cm)			
Hip in flexion (SD)	7.8 (1.4) *7.7 (1.4)–8.0 (1.5)*	18	<.001 [a†]
Hip in extension (SD)	7.8 (1.6) *7.8 (1.5)–7.8 (1.5)*	18	<.001 [a†]
Postoperative incision length (cm)			
Hip in flexion (SD)	8.5 (1.9) *8.6 (2.3)–8.4 (1.5)*	18	<.001 [a†]
Hip in extension (SD)	8.4 (2.0) *8.6 (2.3)–8.2 (1.6)*	18	<.001 [a†]
Peri-operative blood loss (ml) (SD)	540 (321) *579 (362)–500 (273)*	490 (228) *452 (163)–532 (279)*	.65 [a] *.36* [b]
Hemoglobin			
Preoperative	9.0 (0.8) *9.0 (0.8)–8.9 (0.7)*	8.8 (0.7) *8.8 (0.8)–8.9 (0.7)*	.62 [a] *.71* [b]
Postoperative	6.9 (0.8) *6.8 (0.8)–6.9 (0.7)*	6.7 (0.9) *6.8 (0.9)–6.7 (0.9)*	.50 [a] *.71* [b]
Creatine kinase (IU/ltr)			
Preoperative	101 (65) *98 (34)–105 (89)*	103 (45) *102 (48)–104 (43)*	.33 [a] *.97* [b]
Postoperative	485 (285) *503 (241)–464 (336)*	466 (295) *441 (343)–495 (233)*	.63 [a] *.88* [b]
Myoglobin (*μ*/ltr)			
Preoperative	37 (10) *34 (6)–39 (12)*	37 (10) *38 (13)–37 (7)*	.36 [a] *.40* [b]
Postoperative	195 (153) *170 (127)–222 (175)*	190 (107) *148 (83)–235 (113)*	.54 [a] *.09* [b]

[1] Posterolateral; [2] Anterolateral, [a] Mann Whitney U test; [b] One-way ANOVA test with Bonferroni correction,
[†] Statistically significant, [††] Statistically significant: PL-MIS and AL-MIS vs PL-CLASS and AL-CLASS

Table 3 Complications and revisions

	Approach		P-value
	MIS ***PL[1]–AL[2]***	**Classical** ***PL[1]–AL[2]***	
Preoperative complications	6 *2–4*	2 *0–2*	.08 *.24*
Proximal femoral fracture	4 *0–4*	2 *0–2*	.34 *.05*
Massive venous bleeding	1 *1–0*	0	
Ischiadic nerve neuropraxia	1 *1–0*	0	
Postoperative complications			
Infection	0	1 *0–1*	
Aseptic loosening following component revision	4 *0–4*	*2* *1–1*	.34 *.10*
Cup revision	0	1 *1–0*	
Stem revision	4 *0–4*	1 *0–1*	.36 *.11*

[1] Posterolateral; [2] Anterolateral

[a] Fisher's exact test

The other two femoral fissures occurred in the AL-CLASS group and were preoperatively repaired with cerclage wire. One other stem in the AL-MIS group had to be revised since it was radiologically and clinically loose at the revision procedure, but no infection could be established in the cultured tissue and interface. Out of the five early stem revisions, four were performed in the AL-MIS group and one in the AL-CLASS group. In the first 60 patients enrolled in the study, a significantly higher relative risk of peroperative complications of 2.00 (95CI: 1.60 to 3.45) in the MIS group with respect to the CLASS group was observed. In the next 60 patients the relative risk with respect to MIS was reduced to 1.36 (95%CI: 0.73 to 2.50), which is not significantly different. Thus in the second half of the study complication rates were not different between MIS and CLASS, compared with the first half.

The clinical results at the one-year postoperative follow-up are listed in Table 4. In total, three patients were unavailable for clinical and radiological evaluation at six weeks and one year postoperatively (one due to repatriation, two due to revisions). Six patients were not analyzed at one year follow-up postoperatively: four revisions, one death and an infected prosthesis which required a debridement.

Based on the Harris Hip score, the MIS showed more favorable clinical results at six weeks and one year follow-up. Comparing between subgroups, the Harris Hip Score in the PL-MIS group was significantly higher than the PL-, AL-CLASS and AL-MIS. At six weeks follow-up, the SF-36 showed statistically significant better results for the PL-MIS than the AL-MIS, PL-CLASS and AL-CLASS.

Table 5 lists the radiological measurements at one year follow-up. No differences were observed between the MIS and classically approached THAs. The inclination angle of the acetabular component was relatively high in the PL-CLASS and PL-MIS groups, compared with the AL-CLASS group. However, the positions of the acetabular component were equal between all groups using the grading system according to Sarmiento.

To look into the Harris Hip Score results with more detail, we performed a multilevel analysis to determine the factors that predict the HHS outcome longitudinally at six and 52 weeks. To determine which factors explain this observed outcome over time, we developed a prediction model in which we estimated the effects of a number of relevant factors individually and collectively on longitudinal HHS scores. Predictors for the HHS scores were considered those factors that demonstrated a significant association with HHS scores over time in the final linear regression model. During the first postoperative year, individuals subjected to a MIS intervention experienced higher HHS scores than those with a CLASS intervention (on average five HHS points more). Higher HHS scores were also reported by males (on average four HHS points more than females), while patients who ultimately warranted revision are responsible for a lower HHS score before they were operated (on average 12 points less than in individuals without revision). For each added degree of alignment into varus, HHS scores increased on average by ten points. In other words, varus-aligned femoral stems were associated with a higher HHS in our population. Finally, time itself is responsible for an increase in HHS, as 17 points are gained between observation at six weeks and one year in our population.

Table 4 Clinical results

	Approach		P-value [a]
	MIS ***PL[1]–AL[2]***	**Classical** ***PL[1]–AL[2]***	
Harris Hip Score (SD)			
Preoperative	58 (16) *60 (16)–56 (15)*	57 (12) *57 (13)–57 (12)*	.57 [a] *.64* [b]
6 weeks	77 (12) *80 (10) -73 (13)*	72 (13) *70 (15)–75 (15)*	.03 [a†] *.009* [b††]
1 year	94 (8) *97 (4)–91 (10)*	90 (10) *90 (10)–90 (10)*	.03 [a†] *.013* [b††]
WOMAC (SD)			
Preoperative	47 (14) *50 (12)–46 (16)*	48 (15) *48 (17)–48 (13)*	.99 [a] *.76* [b]
6 weeks	69 (16) *69 (18)–69 (12)*	72 (15) *71 (16)–73 (14)*	.32 [a] *.73* [b]
1 year	82 (18) *80 (22)–84 (13)*	81 (16) *79 (19)–82 (12)*	.36 [a] *.75* [b]
OHS (SD)			
Preoperative	40 (9) *39 (8)–42 (9)*	40 (8) *40 (9)–40 (7)*	.83 [a] *.79* [b]
6 weeks	36 (9) *34 (8)–37 (9)*	36 (12) *36 (11)–37 (13)*	.95 [a] *.62* [b]
1 year	24 (15) *26 (19)– 21 (8)*	25 (12) *27 (14)–23 (7)*	.37 [a] *.38* [b]
SF-36 (SD)			
Preoperative	56 (15) *60 (15)–53 (14)*	58 (14) *58 (15)–58 (14)*	.55 [a] *.31* [b]
6 weeks	67 (14) *71 (12)–63 (15)*	61 (16) *61 (15)–62 (17)*	.07 [a] *.04* [b††]
1 year	80 (19) *81 (15)–79 (23)*	80 (16) *75 (20)–86 (7)*	.36 [a] *.11* [b]

[1] Posterolateral; [2] Anterolateral

[a] Mann-Whitney U-test; [b] One-way ANOVA test with Bonferroni correction

[†] Statistically significant

[††] Statistically significant: PL-MIS vs AL-MIS, PL-CLASS and AL-CLASS

Table 5 Radiological results

	Approach		P-value
	MIS ***PL[1]–AL[2]***	**Classical** ***PL[1]–AL[2]***	
Stem alignment (°) (SD)	2 (2) *3 (2) - 1 (2)*	2 (2) *2 (2) - 2 (2)*	.58 [a] *.08* [b]
Cup inclination (°) (SD)	47 (9) *50 (9) - 45 (9)*	47 (7) *50 (6) - 43 (6)*	.44 [a] *<.001* [b††]
Grading of inclination (Sarmiento) (%)			
Grade 1	6 (10) *2 (7)–4 (14)*	4 (7) *0–4 (14)*	.49 [c] *.18* [c]
Grade 2	41 (68) *21 (70)–20(70)*	49 (82) *25 (83)–24 (80)*	.08 [c] *.39* [c]
Grade 3	12 (20) *7 (23)–5 (16)*	6 (10) *5 (17)–1 (6)*	.13 [c] *.17* [c]
Leg length discrepancy (mm) (SD)	0.1 (8) *1.5 (7)–1.3 (9)*	-0.5 (6) *-0.5 (6) – 0.5 (7)*	.37 [a] *.47* [b]
Periarticular ossification (Brooker) (%)			
Grade 1	11 (18) *3 (10) - 8 (27)*	8 (13) *4 (13) - 4 (13)*	.31 [c] *.27* [c]
Grade 2	3 (5) *1 (3) - 2 (6)*	2 (3) *0 - 2 (6)*	.50 [c] *.49* [c]
Grade 3	0	3 (5) *0 - 3 (10)*	.12 [c] *.02* [c†]

[1] Posterolateral; [2] Anterolateral

[a] Mann-Whitney U-Test; [b] One-way ANOVA test with Bonferroni correction; [c] Pearson Chi Square test

[†] Statistically significant: [††] PL-MIS vs AL-CLASS and PL-CLASS vs AL-CLASS

Discussion

With respect to our primary outcome measure we observed an increased Harris Hip score at six weeks and one year follow-up in favor of MIS procedures. This increase was primarily caused by the favourable results in the PL-MIS group. Of the three patient-centered scores (WOMAC, OHS and SF-36) only the SF-36 after 6 weeks follow-up was significantly higher in favor of MIS procedures. Most

Table 6 Predictors for combined HHS outcomes at six weeks and one year

	HHS			
	Bivariate analysis	Final multivariate prediction model [a]		
Predictors	***p*** [b]	***ß*** [c]	***CI***	***p*** [b]
Intervention (0=MIS, 1=CLASS)	0.03	-4.683	-7.694 -1.672	<0.01
Sex (0=male, 1=female)	0.03	-4.189	-7.207 -1.171	0.01
FU complications	0.01d			
Revision	0.01	-12.037	-22.831 -1.243	0.03
Alignment	0.02	9.943	9.224 10.662	<0.001
Observation (0=6 weeks, 1=52 weeks)	<0.001	17.200	14.789 19.611	<0.001

CI, confidence interval; FU, follow-up

[a] Only statistically significant variables from the bivariate analysis were included in the multivariate analysis; [b] significance level $p < 0.05$; [c] regression coefficient; [d] Variable failed to reach significance in the final multivariate prediction model

comparative studies have so far failed to demonstrate any clinical differences between MIS or CLASS-approaches.[5-10] With respect to 32 THAs operated using the classical approach, Chimento et al. show a statistically significant decreased blood loss and less limping at six weeks postoperatively in the group of 28 THAs treated with PL-MIS, while the other clinical and radiological parameters show no difference.[7] Other studies show no clinical or radiological differences between the two approaches.[8,9]

In a double-blind randomized controlled trial, Bennet et al.[10] attempted to blind the patient and investigator by applying a bandage over the wound. No clinical or radiological benefits were observed in 43 patients with a PL-MIS, compared with 52 classically approached patients two days postoperatively. Dorr et al.[2] performed a double-blind randomized trial on 60 THAs (30 PL-MIS vs.30 PL-CLASS). They blinded patient, examiner and investigator by extending the MIS incision to a length

of 20 cm, and observed a statistically significant shorter hospital stay and less pain on each postoperative day in the patients that were operated through a PL-MIS. However, no differences could be observed after their final follow-up at six weeks.

In the present study no statistically significant increased rates of peri-operative complications or postoperative reoperations were observed in those patients who received a THA with MIS, compared with a classical approach. On the other hand, at six out of 60 the rate of complications was rather high in the MIS group, compared with two out of 60 in the CLASS group. A possible explanation for this finding is that the surgeons who performed both the MIS and the CLASS lacked prior experience with the MIS procedure. By contrast, the procedures in other studies were performed by very experienced surgeons or even innovators of this technique, who reported to have performed more than 100 MIS procedures prior to the start of their study. All these authors point to the importance of surgical experience with respect to their results.[2, 5-10] We were able to detect a learning curve based on operating time and the relative risk of complications during the study period. Woolson et al.[4] report retrospectively the outcome of 135 THAs (50 PL-MIS and 85 PL-CLASS), performed by surgeons inexperienced with MIS. They observed a significantly higher risk of wound complications, a higher percentage of acetabular component malposition, and poor fit and fill of the uncemented femoral components with the absence of an improved clinical outcome of the MIS compared with CLASS. Contrary to our study, no improvement based on peri-operative complications was observed in time.

We observed an increased operating time in the THAs performed by MIS by approximately ten minutes (68 vs 58 minutes). In contrast to our study, Kim et al.[9] found a shorter operative time by nine minutes in a bilateral study of 70 MIS (52 minutes) and CLASS THAs (61 minutes) performed by surgeons experienced with MIS. This may be explained by the relative lack of experience with MIS of our surgeons. Other studies show no difference in operative time.[2, 4-8,10]

Radiologically, we observed no differences in the position of the acetabular and femoral components between the THAs performed by MIS and CLASS approaches. A significantly increased inclination angle was observed in the PL (CLASS & MIS) compared with the AL (CLASS & MIS). This fits with prior expectations, as the surgeons performing AL-MIS/CLASS aim for a flatter postion of the acetabular component than their collegues operating with a PL approach. In contrast to our findings, Teet et al.[25] observed a significantly increased proportion of stems more than two degrees away from neutral in varus direction (30.5%) of 73 THAs performed by PL-MIS, compared with 7.4% of 54 CLASS . The PL-MIS group showed significantly the most favorable clinical results, compared with the other three groups at six weeks and one year follow-up. Furthermore, a rather high rate of proximal femoral

fractures, of which three were detected per operatively and one postoperatively, leading to early stem revisions, was observed in the AL-MIS group. The clinical differences at the six-week and one-year postoperative visit were primarily caused by the rather favorable results of the PL-MIS-treated patients, instead of the results of the AL-MIS. Wall et al.[11] performed an analysis on the published evidence of minimally invasive total hip arthroplasty. These authors consider the AL-MIS unpopular because of the perceived direct trauma in detaching the hip abductors and the difficulty approaching the hip via this route through a small window. In concordance with the aforementioned studies, they concluded that most evidence of MIS compared with the CLASS approach had been gathered in combination with the posterior incision.[2,4-10] No RCT has been performed for the AL-MIS.[11] Lin et al[26] performed a matched study on 53 AL-MIS- and 53 AL-CLASS-approached THAs. During the first year after surgery, patients with the MIS THA had significantly better hip muscle strength, walking speed and functional score using an isokinetec dynamometer and the Harris Hip Score.

Despite the relatively increased traction on the wound in the MIS procedures with the custom retractor, no elevated muscle damage parameters (serum myoglobin and creatine kinase) could be observed two days postoperatively. A possible explanation for this finding is that the difference between the chosen minimally invasive and the classical approaches is the incision length and the use of custom retractors and reamers, while the other technical details are the same in both methods. Therefore, the authors believe that the minimally invasive technique used in the present study has to be defined as a “mini-incisive” technique. In a randomized controlled trial, a technically different minimally invasive method with respect to the classical approach, like the two-incision method, showed inferior early clinical results compared with the PL-MIS in 72 patients.[27] Although some concerns have risen concerning peri-operative wound complications in the PL-MIS,[4] we were not able to demonstrate an increased risk of wound complications.

Sculco et al[28] postulate that obese individuals (BMI $>$ 30) may not be candidates for MIS, therefore patients with a BMI $>$ 30 were not included in the study. We expected thigh cirumference to correlate more with incision length than BMI, since not all patients with a high BMI have a high thigh circumference (especially males). No influence of BMI or thigh circumference could be demonstrated on results in our MIS group though.

In this study, HHS score was the primary endpoint of the clinical outcome of the performed procedures at six weeks and one year postoperatively. However, not just THA operations but also other factors may have impacted HHS scores

in our population during the entire study period. Multivariate analyses show that type of intervention, sex, revision, alignment and observation were also significant predictors of HHS outcome during the first post-operative year in our population.

There are some limitations in this study. First, we were not able to mask posterolateral or anterolateral incisions, since the surgeons who participated in the study only performed one of the two incisions. We opted for this strategy because of the considerably higher experience and preference of the surgeon with respect to his applied approach. Although the only difference was that the PL incision was generally 2-3 cm below the AL incision, the shape of the incision was obviously identical as the same curved ruler was used. On the other hand, we do believe full blinding of MIS or CLASS procedures in our study was successful and that this is the only way to obtain unbiased results. The confirmation of this statement is that patients as well as assessors proved to have a fifty-fifty chance to guess whether an MIS or CLASS approach was originally used. Furthermore, the success of maintaining the blinding of patients has never been evaluated in previous studies. Second limitation of the study was that there was no randomization of surgeons with respect to the anterolateral or posterolateral approaches. Based on experience, this was due to the individual preference of the surgeons for one of the two approaches. The authors believe randomization of the anterolateral and posterolateral approaches could cause a higher rate of adverse events based on a lack of experience which can influence the study results. The third limitation is the relatively short final follow-up of one year after the index operation. To detect any clinical mid- or long-term follow-up differences, future studies should investigate long-term results in fully-blinded patients. Most comparable studies used similar[26] or shorter[2, 4-10] follow-up periods though. The fourth limitation constitutes our sample size which is relatively small and may explain our inability to identify any significant differences in complication and revision rates between the four groups. On the other hand, these were not our primary endpoints on which we have performed a power analysis. The fifth limitation is the exclusion of four additional patients from analysis due to reoperation as a result of infection and loosening. This may have skewed our results. Another limitation is the lost to follow up of four patients (one repatriation, one death and two no shows). However, these no show patients reported no adverse events by telephone. We believe a lost-to-follow-up rate of 3 percent (4/120) is reasonable and not unusual high and is in accordance with the rates published in the THA literature.

In conclusion, the present study reveals superior clinical results in the patients treated with posterolateral MIS technique than both the anterolateral MIS and the

PL- and AL-CLASS technique after six weeks and one year postoperatively. On the other hand, a rather high rate of peri-operative complications followed by early stem revisions and higher operative times were observed in patients subjected to a minimally invasive approach to the hip. Nonetheless, complication risks and duration of operation decreased in time. The pros and cons of minimally invasive surgery must be carefully weighted in each patient individually before deciding on which approach to elect for THA when performed by a surgeon relatively inexperienced with MIS.

References

1. Hartzband MA. Posterolateral minimal incision for total hip replacement: technique and early resuts. Orthop Clin North Am 2004;35:119.
2. Dorr LD, Maheshwari AV, Long WT, Wan Z, Sirianni LE. Early pain relief and function after posterior minimally invasive and conventional total hip arthroplasty. A prospective, randomized, blinded study. JBJS[Am] 2007;89:1153-60.
3. Howell JR, Garbuz DS, Duncan CP. Minimally invasive hip replacement: Rationale, applied anatomy and instrumentation. Orthop Clin North Am 2004;35:107.
4. Woolson ST, Mow CS, Syquia JF, Lannin JW, Schurman DJ. Comparison of primary total hip replacements performed with a standard incision or a mini-incision. J Bone Joint Surg Am 2004;86:1353-8.
5. Sculco TP. Minimally invasive total hip arthroplasty. In the affirmative. J Arthroplasty. 2004 Jun;19(4 Suppl 1):78-80. Review.
6. Nakamura S, Matsuda K, Arai N, Wakimoto N, Matsushita T Mini-incision posterior approach for total hip arthroplasty. Int Orthop. 2004 Aug;28(4):214-7.
7. Chimento GF, Pavone V, Sharrock N, Kahn B, Cahill J, Sculco TP. Minimally invasive total hip arthroplasty: a prospective randomized study. J Arthroplasty 2005;20:139-44.
8. Ogonda L, Wilson R, Archbold P, Lawlor M, Humphreys P, O'Brien S, Beverland D. A minimal-incision technique in total hip arthroplasty does not improve early postoperative outcomes. A prospective, randomized, controlled trial. J Bone Joint Surg Am 2005;87:701-10.
9. Kim YH. Comparison of primary total hip arthroplasties performed with a minimally invasive technique or a standard technique. A prospective and radomized study. J Arthroplasty 2006;21:1092-8.
10. Bennett D, Ogonda L, Elliot D, Humphreys L, Lawlor M, Beverland D. Comparison of immediate postoperative walking ability in patients receiving minimally invasive and standard-incision hip arthroplasty. A prospective blinded study. J Arthroplasty 2007;22:490-495.
11. Wall SJ, Mears SC. Analysis of published evidence on minimally invasive total hip arthroplasty. J Arthroplasty 2008;23:55-8.
12. Frndak PA, Mallory TH, Lombardi AV. Translateral surgical approach to the hip. The abductor muscle "split". Clin Orthop 1993;295:135-141.
13. Gibson A. Posterior exposure of the hip joint. J Bone Joint Surg [B] 1950;32:183.
14. Hoeksma HL, Ende CH, Ronday HK, Heering A, Breedveld FC. Comparison of the responsiveness of the Harris Hip Score with generic measures for hip function in osteoarthritis of the hip. Ann Rheum Dis 2003;62:935-8.
15. Laurence AS. Serum myoglobin and creatine kinase following surgery. British journal of anaesth 2000;84:763-6.
16. Harris WH. Traumatic arthritis of the hip after dislocation and acetabular fractures: treatment by mold arthroplasty. *J Bone Joint Surg [Am]* 1969;51:737-55.
17. Bellamy N, Buchanan WW, Goldsmith CH, Campbell J, Stitt LW. Validation study of WOMAC: a health status instrument for measuring clinically important patient relevant outcomes to antirheumatic durg therapy in patients with osteoarthritis of the hip or knee. J Rheumatol 1988;15:1833-40.

18. Dawson J, Fitzpatrick R, Carr A, Murray D. Questionnaire on the perceptions of patients about toal hip replacement. J Bone Joint Surg [Br] 1996;78:185-90.
19. Ware JE Jr, Kosinski M, Bayliss MS, et al. Comparison of methods for the scoring and statistical analysis of SF-36 health profile and summary measures: summary of results from the Medical Outcomes Study. Med Care 1995;33:264-79.
20. Sellers RG, Lyles D, Dorr LD. The effect of pelvic rotation on alpha and theta angles in total hip arthroplasty. *Cont Orth* 17:67-70, 1988.
21. Sarmiento A, Ebramzadeh E, Gogan WJ, McKellop HA. Cup containment and orientation in cemented total hip arthroplasties. *J Bone Joint Surg [Am]* 72:996-1002, 1990.
22. Brooker AF, Bowermann JW, Robinson RA, Riley LH. Ectopic ossification following total hip replacement. J Bone Joint Surg (Am) 1973;55;1929-32.
23. Callaghan JJ, Salvati EA, Pellicci PM, Wilson PD Jr, Ranawat CS. Results of revision for mechanical failure after cemented Total hip replacement, 1979 to 1982. A two to five-year follow-up. J Bone Joint Surg Am. 1985;67:1074-85.
24. Woolson ST, Hartford JM, Sawyer A. Results of a method of Leg-Lengt equalization for patients undergoing primary total hip replacement. J Arthroplasty 1999;14:159-64.
25. Teet JS, Skinner HB, Khoury L. The effect of the “mini” incision in total hip arthroplasty on component position. J Arthroplasty 2006;21:503-7.
26. Lin DH, Jan MH, Liu TK, Lin YF, Hou SM. Effects of anterolateral minimally invasive surgery in total hip arthroplasty on hip muscle strength, walking speed, and functional score. J Arthroplasty 2007;22:1187-92.
27. Pagnano MW, Trousdale RT, Meneghini RM, Hanssen AD. Slower recovery after two-incision than mini-posterior-incision total hip arthroplasty. A randomized clinical trial. J Bone Joint Surg Am. 2008;90:100-6.
28. Sculco TP, Jordan LC, Walter WL. Minimally invasive total hip arthroplasty: the Hospital for special surgery experience. Orthop Clin North Am 2004;35:137-42.

Summary, Answers to the questions and Conclusions

In this thesis, different aspects that are related to the survivorship and clinical outcome in uncemented total hip arthroplasty are analysed. The questions concerning the analysed dilemma's in this thesis are answered per chapter.

1. *What is the clinical and radiological outcome of proximally hydroxyapatite coated uncemented femoral stems after a short to mid-term follow-up?*

In **Chapter 2**, the survival rate, Harris Hip score and radiographic features of 106 hips in 100 consecutive patients were evaluated. In all cases a proximally hydroxyapatite coated titanium alloy femoral stem (Bi-Metric, Biomet) was used. The mean age at operation of 51 years (SD: 8,2).

The mean Harris hip score at the time of the latest follow-up was 95 points. Spot welds occurred in 95% of the patients and were first observed at a mean follow up of 1,4 years in one or more of the Gruen regions, corresponding to the coated part of the femoral stem. A higher grade of stress shielding correlated with a less favorable Harris hip score and pain subscore. According to the criteria of Eng, all stems were graded as stable and durable bone-ingrown. No femoral component was revised.

In conclusion, at an average follow up of 8 years, this proximally HA-coated femoral component showed favorable clinical and radiological outcome and excellent survivorship.

2. *Is there a clinical and radiological benefit of hydroxyapatite coating on porous coated stems in uncemented primary total hip arthroplasty?*

In **Chapter 3**, a systematic review was performed to determine the clinical and radiological benefit of hydroxyapatite coating compared with porous coating in uncemented primary total hip arthroplasty. A database of Medline articles published up to September 2007 was compiled and screened. Eight studies involving 857 patients were included in the review. Pooled analysis for Harris Hip Score as a clinical outcome measure demonstrated no advantage of the hydroxyapatite coating (WMD: 1.49, $p = 0.44$). Radiologically, both groups showed equal presence of endosteal bone ingrowth (RR: 1.04, $p = 0.66$) and radioactive lines (RR: 1.02, $p = 0.74$) in the surface area of the prosthesis.

In conclusion, this meta-analysis demonstrates no clinical nor radiologic benefits on the application of a hydroxyapatite coating on a femoral component in uncemented primary total hip arthroplasty.

3. *What is the long-term clinical and radiological outcome of low modulus Proplast coated uncemented femoral stems and when is revision indicated?*

In **Chapter 4**, the survival rate, Harris hip score and radiographic features of 82 hips in 69 patient were evaluated. In all cases a low modulus, PTFE (Proplast, Bitek) coated femoral stem was used. Mean age at operation was 58 (35-72) years. With respect to the Harris hip score, 21% of the hips were considered to be clinical failures (Harris Hip score < 70) at an average follow-up of 10 years, mainly because of excessive thigh pain. Osteolysis was observed in one or more Gruen zones in one-third of the hips. According to the criteria of Engh, 79/82 stems (96%) were unstable. Eleven hips were eventually revised due to aseptic loosening. Survival of the femoral component of the original cohort at final follow-up was 84% (95% CI: 75-93) in a standard-case scenario. Extensive signs of loosening were observed in almost all hips, while not all hips were considered to be clinical failures.
In conclusion, the low modulus, PTFE (Proplast coated) femoral stem is associated with a poor clinical and radiological outcome. All patients should be thoroughly screened for radiographic progressive osteolysis or the occurrence of thigh pain. Thigh pain or progressive osteolysis warrants revision of the Proplast-coated femoral stem.

4. *What is the clinical and radiological outcome of porous coated cobalt chrome high modulus femoral stems, used both as an uncemented and a cemented stem in hemiarthroplasty after a short follow-up?*

In **Chapter 5**, we hypothesised that a hemiprosthesis used without cement has a considerable high revision rate, based on aseptic loosening. A hemiprosthesis, which is designed for both cemented and uncemented fixation (Conquest, Smith&Nephew), was used. Preoperatively, the choice of whether to use cement or not was based on the shape and bone quality of the femoral canal. Revision rate and indication, mortality, perioperative complications and radiographic features of 151 consecutive hips in 146 patients were evaluated. Twenty-three stems (15%) were implanted with cement and 128 (85%) without. After a mean follow-up of two years, a revision rate of 8.6% and a survival percentage of 90% (CI 85 to 95) were observed. Twelve uncemented stems warranted revision, compared with one cemented stem. Revision because of aseptic loosening was necessary in 7 (6%) stems, all uncemented. No differences in operation-related mortality and morbidity were observed.
In conclusion, because of the rather high revision rate, the authors advice not to use this hemiprosthesis without cement.

5. *What is the way to diagnose and, if observed, how to treat and monitor silent osteolysis associated with an uncemented acetabular component?*

In **Chapter 6,** a proposed algorithm for surveillance and treatment of silent osteolysis is presented. Silent, asymptomatic cavitational osteolysis can progress into segmental osteolysis that may become manifest and preclude revision procedures. Therefore close monitoring is recommended if silent osteolysis is suspected. A helical CT scan should be performed when signs of osteolysis or evident polyethylene wear are observed on conventional radiographs, or if it concerns a type of metal-backed acetabular component associated with a documented high wear rate. When a cavitational laesion is observed, even without any clinical symptoms, a helical CT scan should be performed yearly and treatment with bisphosphonates is to be considered. In case of segmental osteolysis or progression of the cavitational laesion, extensive debridement of the osteolytic cysts, bone grafting and replacement of the polyethylene liner is the treatment of choice.

6. *Is there an association with implantation time and position of the component and the rate of wear in metal backed uncemented acetabular components?*

In **Chapter 7**, the rate of polyethylene wear of a cementless acetabular component (Mallory-Head/Ringloc, Biomet) at different periods of follow-up was investigated in order to test the hypothesis than an irrecoverable deformation process (creep) was followed by an initially low, but gradually increasing wear rate. We studied prospectively 93 uncemented total hip arthroplasties in 83 patients (mean age 50 years (22 to 63)) with a mean follow-up of 8.2 years (3 to 12). We measured the penetration of the femoral head from radiographs taken immediately after surgery at three, six and nine years, or at the latest follow-up. The median wear rate was 0.17 mm per year in the first three years, a finding which we considered to be caused by creep. Thereafter, the rate of wear declined to 0.07 mm per year (four- to six-year period) and then increased to 0.17 mm per year (seven to nine years) and 0.27 mm per year (more than nine years), which we considered to be a reflection of genuine polyethylene wear. After the nine-year follow-up the wear rates were higher in patients with marked osteolysis. We found no relationship between the inclination angle of the acetabular component or femoral head orientation and the rate of wear. No acetabular component required revision.

In conclusion, penetration rates of the femoral head into the polyethylene liner of the acetabular component are variable. A significant, increased rate of polyethylene wear can be seen after nine years of implantation, created by a mechanical degradation of the polyethylene surface. It is this category of patient which should be closely monitored for the rate of linear wear, osteolysis and loosening of the acetabular component.

7. *Are argon-sterilised polyethylene liners less susceptible to wear than air-sterilised liners in vivo during a mid-term follow-up?*

In **Chapter 8**, the femoral penetration rates were measured in 93 inserts, sterilised in oxygen containing air (AIR) (Ringloc, Biomet) and an 79 inserts, sterilised in Argon (ARGON) (Arcom Ringloc, Biomet) liners, during a mean follow-up of 8 (3 to 12) years. During the first three years after implantation, both groups showed no differences in mean wear rate ($P = 0.13$). Thereafter, the ARGON liner demonstrated a decrease in wear rate of 0.04 mm/y from 4 to 6 years ($P = 0.006$), 0.14 mm/y from 7 to 9 years ($P < 0.001$), and 0.33 mm/y beyond 9-years follow-up ($P = 0.015$) compared to the AIR liner. One AIR acetabular component required revision.

In conclusion, it can be stated that the *in vivo* penetration rate of the femoral head is significantly lower in argon-sterilised than air-sterilised UHMWPE liners in metal-backed uncemented components at 3 years after implantation and thereafter.

8. *Do patients have an improved clinical outcome, when treated with a posterolateral or anterolateral mini incision, compared with both the classical incisions during a one year follow-up?*

In **Chapter 9**, we hypothesized that patients treated with a THA using a posterolateral or anterolateral MIS would experience superior clinical results compared with a standard incision after six weeks and no clinical differences after one year. This was tested in a double-blind randomized controlled trial with the Harris Hip Score (HHS) as a primary endpoint.

One hundred and twenty consecutive primary uncemented THAs were randomized into one of four groups of 30 patients each. Either standard posterolateral or anterolateral approaches (PL- or AL-CLASS), or minimal invasive posterolateral or anterolateral approaches (PL- or AL-MIS) were performed. CLASS incisions were 18 cm. To avoid postoperative bias, MIS incisions were extended at skin level to 18 cm at the end of the procedure. The HHS as well as patient-centered questionnaires (SF-36, WOMAC and OHS) was obtained preoperatively, at six weeks and one year after the index operation. Preoperative data, blood loss, hemoglobin, muscle damage parameters and radiological parameters were analyzed. In order to detect a minimal clinically important difference of five points or more between the MIS or CLASS groups with respect to the Harris Hip Score at the 0.05 alpha level with 80% power, 120 patients were enrolled in the study. Mean incision length of the THAs performed by MIS was 7.8 ($SD = 1.6$). In the patients of the MIS group a significantly increased mean HHS was observed compared with the CLASS ($p = 0.03$) after six weeks and one year. This difference was caused by the favorable results of the

PL-MIS ($p = 0.009$). Of the three patient-centered questionnaires, the SF-36 results were also favourable in the PL-MIS group after six weeks ($p = 0.04$). In the MIS group operation time was longer ($p < 0.001$) and a learning curve was observed based on operation time and complication rate. Peri-operative complications rates were not significantly different between the groups. Blood loss, hemoglobin, muscle damage parameters and radiological parameters also showed no difference.

In conclusion, this double-blind, randomized study reveals an improved clinical outcome of the PL-MIS compared with the AL-MIS, PL-CLASS and AL-CLASS after six weeks and one year follow-up with the Harris Hip Score as primary endpoint.

Samenvatting, antwoorden op de vragen en conclusies

In dit proefschrift worden verschillen aspecten die de overleving en klinische resultaten bepalen van de ongecementeerde heupprothese geanalyseerd. De vragen die betrekking hebben op de geanalyseerde dilemma's in dit proefschrift worden per hoofdstuk beantwoord.

1. *Wat is het klinische en radiologische resultaat van proximaal hydroxyapatiet gecoate ongecementeerde femurcomponenten op de korte tot middellange termijn?*

In **Hoofstuk 2** zijn de overleving, Harris Hip score en radiologische kenmerken bestudeerd van 106 heupen in 100 opeenvolgende patiënten. In alle gevallen werd een hydroxyapatiet gecoate femurcomponent gebruikt van een titanium legering (Bi-Metric, Biomet). De gemiddelde leeftijd bij operatie was 51 jaar (SD: 8,2). De gemiddelde Harris Hip score bij de laatste follow-up was 95 punten. Tekenen van endosteale botingroei (spot welds) werden bij 95 procent van de patiënten gezien. Deze werden voor het eerst gemiddeld na 1,4 jaar in één of meerdere Gruen zones, overeenkomend met het gecoate deel van de prothese, gezien. Een ernstigere mate van stress shielding correleerde omgekeerd evenredig met de Harris Hip score en ook met de pijn subscore. Volgens de criteria van Engh werden alle femurcomponenten geclassificeerd als stabiel en ingegroeid. Geen femurcomponent werd gereviseerd.
Concluderend kan gesteld worden dat, na een gemiddelde follow-up van 8 jaar, deze femurcomponent een zeer goed klinisch en radiologisch resultaat heeft met een uitstekende overleving.

2. *Is er een klinisch en radiologisch voordeel van hydroxyapatiet coating ten opzichte van poreus gecoated femurcomponenten bij ongecementeerde totale heupartroplastieken?*

In **Hoofdstuk 3** wordt een meta-analyse gepresenteerd waarin het klinische en radiologische voordeel van hydroxyapatiet coating ten opzichte van poreuze coating bij ongecementeerde primaire totale heupprothesen tegen het licht wordt gehouden. Een database van Medline artikelen, gepubliceerd tot september 2007 werden verzameld en geanalyseerd. Acht studies met in totaal 857 patiënten werden geïncludeerd in de studie. Pooled analysis van de Harris Hip score toonde geen voordelen van de hydroxyapatiet coating (gewogen verschil 1,49, $p = 0,44$). Radiologisch toonden beide groepen evenveel voorkomen van endosteale botingroei (RR: 1.04, $p = 0,66$) en radiolucente lijnen (RR: 1,02, $p = 0,74$) ter plaatse van het oppervlak van de prothese.

3. *Wat is het klinische en radiologische resultaat op lange termijn van low modulus Proplast gecoate ongecementeerde femurcomponenten en wanneer is revisie aangewezen?*

In **Hoofstuk 4** werden de overleving, Harris Hip score en radiologische kenmerken bestudeerd van 69 patiënten. In alle gevallen werd een PTFE (Proplast, Bitek) gecoate "low modulus" femurcomponent gebruikt. De gemiddelde leeftijd bij operatie was 58 jaar (35 tot 72). Op basis van de Harris Hip score werden 21 procent van de heupen beschouwd als klinisch gefaald (Harris Hip score < 70) bij een gemiddelde follow-up van 10 jaar, grootendeels door pijnklachten. Eénderde van de heupen toonde osteolyse en één of meerdere Gruen zones. Volgens de criteria van Engh waren 79 van de 82 componenten instabiel. Elf heupen werden gereviseerd in verband met aseptische loslating. De overleving van de component van het originele cohort bij de laatste follow-up was 84 procent (95% BI: 75 tot 93) in geval van een standaard scenario. Nagenoeg alle prothesen lieten overduidelijke tekenen van loslating zien, terwijl niet alle heupen beschouwd konden worden als klinisch gefaald.

Concluderend kan gesteld worden dat patiënten die geopereerd zijn met deze prothese aandachtig gescreened moeten worden op progressieve osteolyse en pijnklachten. Bij aanwezigheid van deze twee determinanten dienst revisie overwogen te worden.

4. *Wat is het klinisch en radiologisch resultaat van poreus gecoate cobalt chromen high modulus femurcomponenten, die óf zonder óf met cement geplaast kunnen worden als kophalsprothese op korte termijn?*

In **Hoofdstuk 5** werd gehypothetiseerd dat een hemi-heupprothese, geïmplanteerd zonder cement, correleert met een hoog revisiepercentage op basis van aseptische loslating. Een hemiprothese welke ontworpen is voor zowel gecementeerd en ongecementeerd implantatie (Conquest, Smith&Nephew) werd bestudeerd. De preoperatieve keuze om cement te gebruiken of niet werd afhankelijk gesteld van de vorm en botkwaliteit van de femurschacht. Indicatie, revisiepercentage, mortaliteit, complicaties en radiologische kenmerken werden bestudeerd bij 151 opeenvolgende heupen bij 146 patiënten. Drieëntwintig componenten (15%) werden geïmplanteerd mét en 128 (85%) zónder cement. Na een gemiddelde follow-up van 2 jaar was het revisiepercentage 8,6% en de overleving 90% (95%BI: 85 tot 95). Twaalf ongecementeerde componenten ten opzichte van 1 gecementeerde werden gereviseerd. Zeven (6%) ongecementeerde stelen werden gereviseerd op basis van aseptische loslating. Er was geen verschil in operatie-gerelateerde mortaliteit en morbiditeit.

Concluderend adviseren wij dat, op basis van het relatief hoge revisiepercentage, de onderzochte femurcomponent niet ongecementeerd te implanteren.

5. *Hoe is silent osteolyse bij een ongecementeerde acetabulumcomponent te diagnostiseren en, wanneer aanwezig, hoe te behandelen?*

In **Hoofdstuk 6** wordt een algoritme ter bewaking en behandeling van "silent" osteolyse gepresenteerd. (A)symptomatische, "silent", osteolytische holtes kunnen uitbreiden tot segmentale osteolyse wat tot een revisieprocedure kan leiden. Hierdoor is het aan te bevelen de patiënten met "silent" osteolyse zorgvuldig te volgen. Een spiraal CT scan is het diagnosticum als tekenen van osteolyse of duidelijke polyethyleenslijtage worden vastgesteld op standaard röntgenopnames. Dit geldt ook voor metalen ongecementeerde acetabulaire componenten met een polyethyleen insert die geassocieerd is met een hoge slijtage snelheid. In een geval van een osteolytische holte dient jaarlijks een spiraal CT scan vervaardigd te worden en bisfosfonaten gestart te worden. Bij segmentale osteolyse of progressie van de osteolytische holte zijn bottransplantatie en vervangen van de polyethyleen insert aangewezen.

6. *Is er een associatie tussen tijd na implantatie en positie van metal backed ongecementeerde acetabulumcomponenten met de slijtagesnelheid van het polyethyleen?*

In **Hoofdstuk 7** wordt de polyethyleensnelheid van een ongecementeerde acetabulumcomponent (Mallory-Head/Ringloc, Biomet) in verschillende perioden gedurende de follow-up bestudeerd. De hypothese was dat een onomkeerbaar deformatieproces ("creep") werd gevolgd door een initieel lagere maar gradueel toenemende slijtagesnelheid. 93 ongecementeerde totale heupprothesen van 83 patiënten met een gemiddelde leeftijd van 50 jaar (22 tot 63) werden prospectief gevolgd met een gemiddelde follow-up van 8,2 jaar (3 tot 12). De penetratie van de femurkop werd gemeten met behulp van de röntgenopname juist na, en 3, 6 en 9 jaar na de implantatie of de laatste follow-up. De mediane slijtagesnelheid was 0,17 mm per jaar gedurende de eerste 3 jaar, welke door ons wordt beschouwd als "creep" van het polyethyleen. Hierna daalde de femurkoppenetratie tot 0,07 mm per jaar (4 tot 6 jaar-periode), gevolgd door een stijging tot 0,17 mm per jaar (7 tot 9 jaar-periode) en later tot 0,27 mm per jaar (9 jaar follow-up). De femurkoppenetratie vanaf 4 jaar follow-up werd beschouwd als polyethyleen slijtage. Na 9 jaar werden de componenten met een hogere slijtagesnelheid in verband gebracht met osteolytische haarden. Er werd geen relatie gevonden tussen de slijtagesnel-

heid en acetabulaire inclinatiehoek of femurkoppositie. Geen component werd gereviseerd.
Concluderend kan gesteld worden dat de penetratie snelheid van de femurkop in het polyethyleen variabel is. Een significant verhoogde snelheid van de polyethyleenslijtage wordt gezien na 9 jaar follow-up, welke wordt veroorzaakt door mechanische degradatie van het polyethyleen. Deze categorie van patiënten dienen zorgvuldig gescreend te worden op polyethyleenslijtage snelheid, osteolyse en loslating van de acetabulaire component.

7. *Zijn polyethyleeninserts, gesteriliseerd in argon in vivo minder gevoelig voor slijtage dan inserts gesteriliseerd in lucht gedurende een middellange termijn follow-up?*

In **Hoofdstuk 8** werd de femurkop penetratie gemeten van 93 in zuurstofrijke lucht (AIR) (Ringloc, Biomet) en 79 in argon (ARGON) gesteriliseerde polyethyleen inserts (Arcom Ringloc, Biomet) gedurende een gemiddelde periode van 8 (3 tot 12) jaar. Gedurende de eerste 3 jaar na implantatie lieten beide groepen een identieke femurkop penetratie snelheid zien. Hierna liet de ARGON insert een reductie van penetratie zien van 0,04 mm per jaar in de periode van 4 tot 6 jaar na implantatie ($p = 0{,}006$), 0,14 mm per jaar in de periode van 7 tot 9 jaar ($p < 0{,}001$) en 0.33 mm per jaar na 9 jaar ($p = 0.015$) vergeleken met de AIR insert. 1 acetabulum component met een AIR insert werd gereviseerd.
Concluderend kan gesteld worden dat de in vivo penetratie snelheid van de femurkop significant lager is bij de argon-gesteriliseerde UHMWPE insert vergeleken met de lucht-gesterileseerde insert bij metal-backed ongecementeerde componenten vanaf 3 jaar na implantatie.

8. *Hebben patiënten die behandeld zijn met een posterolaterale of anterolaterale mini-incisie een beter klinisch resultaat dan patiënten met een klassieke incisie gedurende een jaar na de operatie?*

In **Hoofdstuk 9** werd de hypothese getest dat patiënten die een totale heup geïmplanteerd kregen via de posterolaterale of anterolaterale minimaal invasieve benadering betere klinische resultaten zouden hebben vergeleken met de klassieke standaard benadering na 6 weken. Dit verschil zou na 1 jaar niet meer detecteerbaar zijn. Dit werd getest door middel van een dubbelblind gerandomiseerd gecontroleerde studie met de Harris Hip Score (HHS) als het primaire eindpunt. 120 opeenvolgende primaire ongecementeerde totale heuparthroplastieken werden gerandomiseerd in 1 van 4 groepen van elk 30 patiënten. Zij werden via de klassieke standaard posterolaterale of anterolaterale benadering (PL- or AL-CLASS) óf via de

minimaal invasieve PL of AL benadering (PL- or AL-MIS) geopereerd. De CLASS incisielengte was 18 cm. Postoperatieve bias werd zoveel mogelijk vermeden door de MIS incisies na de implantatie de verlengen op huidniveau tot 18 cm. De HHS en patiënt gecentreerde vragenlijsten (SF-36, WOMAC and OHS) werden preoperatief, op 6 weken en 1 jaar na de operatie afgenomen. Preoperatieve data, bloedverlies, haemoglobine, spierschade-parameters in het bloed en radiologische kenmerken werden geanalyseerd. Om een minimaal klinisch relevant verschil van 5 punten of meer tussen de MIS en CLASS groep met betrekking tot de HHS te detecteren (alpha 0,05, 80% power), moesten 120 patiënten geïncludeerd worden. De gemiddelde MIS incisie lengte was 7,8 cm (SD = 1,6). De patiënten in de MIS groep lieten een significant hogere gemiddelde HHS zien vergeleken met de CLASS groep 6 weken én 1 jaar na de operatie ($p = 0,03$). Dit verschil werd veroorzaakt door de resultaten van de PL-MIS ($p = 0.009$). De SF-36 uitkomsten waren ook het hoogste in de PL-MIS groep na 6 weken ($p = 0,04$). In de MIS groep was de operatietijd langer ($p < 0,001$). Er werd een leercurve gezien gebaseerd op operatietijd en complicatie risico. Het peroperatieve complicatie percentage, bloedverlies, haemoglobine-gehalte, spierschade-parameters en radiologische parameters waren niet statisch significant verschillend tussen beide groepen.

Concluderend kan gesteld worden dat in deze dubbelblinde, gerandomiseerde studie betere klinische resultaten worden geboekt met de PL-MIS, vergeleken met de AL-MIS, PL-CLASS en AL-CLASS op 6 weken én 1 jaar na de operatie met de HHS als primaire uitkomstmaat.

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Curriculum Vitae

Johannes Henricus Maria Goosen was born in Hilversum on October 24, 1978. He graduated from the Alberdingk Thijm College in 1997 after which he started his Medical School at the University of Utrecht. From 2004, after internships in different hospitals in the Netherlands and South Africa, he started the research on this thesis in the Isala Clinics in Zwolle under supervision of dr. C.C.P.M. Verheyen and prof. dr. R.M. Castelein from the University Medical Center Utrecht. In 2005 he started his surgical training at the department of surgery of the Isala Clinics (dr. J.E. De Vries and dr. E.J.G.M. Pierik). In 2007 he moved to Nijmegen with Emily to start his orthopedic training at the University Medical Center Nijmegen (Prof. dr. A. Van Kampen). Currently, he follows his training in the Sint Maartens-kliniek in Nijmegen (dr. A.B. Wymenga) and will be completed in 2011.

APPENDIX

**Hoeveel stappen zet een dokter in het ziekenhuis?
Geen verschil tussen internisten en algemeen chirurgen,
maar wel samenhang met leeftijd en BMI**

J.H.M.Goosen, H.B.Ettema, B.J.Kollen en C.C.P.M.Verheyen

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Department of Orthopaedic Surgery and Traumatology
Isala Clinics, Weezenlanden Hospital
Zwolle, The Netherlands

Abstract

How many steps does a doctor take in the hospital? No difference between internists and general surgeons, but a relationship with age and BMI.

To determine the number of steps taken during working days in the hospital by both internists and general surgeons and whether there is a difference between housemen, registrars and members of the staff. A validated pedometer was used to count the number of steps taken by housemen, registrars and staff members in the departments of internal medicine and general surgery. The 2 groups of doctors comprised 131 subjects from 13 training hospitals. Possible factors likely to affect the number of steps, such as age, sex, weight and height, were recorded. The average number of steps taken per day was 5325 (range: 1105-10,250) and the average number per hour was 548 (range: 143-1105), with an average working day of 9.8 hours and 8.4 measured days. When corrected for age, sex and hierarchic status, no significant difference was observed between surgeons and internists ($p = 0.097$). There were also no differences within the hierarchic structure after correction ($p = 0.936$). Age and BMI seemed to be the most important factors predicting the number of steps in this population. Each additional year of age corresponded with an average decrease of 5 steps per hour on the job ($p = 0.001$), while each point rise in BMI (+1 kg/m^2) coincided with an average decrease of 20 steps per hour ($p = 0.001$). After correcting for confounding factors, no differences were observed in the number of steps taken in the hospital by general surgeons and internists. There was also no difference between hierarchic levels. Age and BMI were the most important variables that predicted the number of steps taken per hour in this research population.

Samenvatting

Er werd vastgesteld hoeveel stappen er tijdens werkdagen in het ziekenhuis worden gezet door internisten en algemeen chirurgen en of er een verschil is tussen coassistenten, assistent-geneeskundigen en stafleden. De stappen van stafleden, assistent-geneeskundigen en coassistenten binnen de specialismen interne geneeskunde en algemene chirurgie werden geteld met behulp van een gevalideerde stappenteller. Deze 2 groepen artsen bestonden uit 131 proefpersonen uit 13 opleidingsziekenhuizen. Mogelijke factoren die het aantal stappen kunnen beïnvloeden, zoals leeftijd, geslacht, gewicht en lengte, werden genoteerd. Er werden gemiddeld 5325 (uitersten: 1105-10.250) stappen per dag en 548 (143-1105) per uur gezet, bij een gemiddelde werkdag van 9,8 uur en gemiddeld 8,4 meetdagen. Gecorrigeerd voor leeftijd, geslacht en hiërarchie bleek er geen significant verschil in gedane stappen tussen chirurgen en internisten ($p = 0,097$). Binnen de hiërarchische structuur werden na correctie ook geen verschillen aangetoond ($p = 0,936$). Leeftijd en 'body-mass index' (BMI) bleken de belangrijkste factoren in de verklaring voor het aantal genomen stappen. Stijging van 1 jaar in leeftijd kwam overeen met gemiddeld 5 stappen per uur minder op de werkvloer ($p = 0,001$); 1 punt op de BMI-schaal (+1 kg/m^2) erbij betekende een afname van gemiddeld 20 stappen per uur ($p = 0,001$). Na correctie voor verstorende factoren bleek dat de groepen artsen van algemene chirurgie en interne geneeskunde evenveel stappen zetten in het ziekenhuis. Binnen de hiërarchie werd geen verschil gemeten. De factoren leeftijd en BMI waren de belangrijkste voorspellende variabelen voor het aantal stappen per uur in deze onderzoekspopulatie.

Inleiding

Van bepaalde beroepsgroepen en patiëntenpopulaties is de mobiliteit uitgebreid onderzocht. Zo is gebleken dat vliegtuigpersoneel 842 stappen per uur zet1 en patiënten met een heupprothese 143.2 Van hun doktoren is er geen informatie over hun mobiliteit. Wij verrichtten een onderzoek naar de mobiliteit van hen die binnen de hiërarchie van de specialismen chirurgie en interne geneeskunde zoal werkzaam kunnen zijn: stafleden, assistent-geneeskundigen en coassistenten.
Wij bepaalden de mobiliteit van deze groepen tijdens werkuren in het ziekenhuis aan de hand van het aantal stappen dat door een gevalideerde pedometer werd geteld. Ook keken wij of de plaats in de hiërarchie in het ziekenhuis correleerde met de mobiliteit.

Deelnemers en methode

Het onderzoek werd verricht in 13 ziekenhuizen met de opleidingsstatus voor algemene chirurgie en interne geneeskunde.

Mobiliteitsmeting

De mobiliteit werd bepaald met behulpvan de pedometer Yamax SW-201 (Great Performance Ltd,Londen), een gevalideerd hulpmiddel, waarmee binnen een aanvaardbaar betrouwbaarheidsinterval het aantal gemaaktestappen geteld wordt. Iedere proefpersoon kreeg een casusformulier toegestuurd met instructies over hoe de meter gebruikt moest worden en het verzoek om het aantal stappen gedurende werktijd (minimaal 4 en maximaal 10 dagen) en ook het aantal gewerkte uren te noteren. Er werd gevraagd naar hiërarchische status en andere factoren die mogelijk van invloed zijn op de mobiliteit, zoals lengte, gewicht, leeftijd en geslacht. De 'body-mass index' (BMI) werd berekend in kg/m2.4 Om te kunnen differentieren tussen de twee specialismen, zonder de proefpersonen hiervan op de hoogte te stellen, maakten wij gebruik van casusformulieren met verschillende kleuren. Goedkeuring van het onderzoek door een medisch-ethische toetsingscommissie achtten wij niet nodig.

Analyse

Statistische analysen werden uitgevoerd op basis van een 'multilevel'-analyse met behulp van het softwareprogramma MLwiN 2.02 (www.cmm.bristol.ac.uk/ MLwiN/ features/index.shtml). Hierbij werd niveau 1 gedefinieerd als metingen in de tijd en vertegenwoordigde niveau 2 de verschillende ziekenhuizen. Er werden 2 modellen ontwikkeld: een associatiemodel, waarin de relatie tussen het aantal stappen per uur en specialisme of hiërarchie werd onderzocht, gecorrigeerd voor mogelijke verstorende factoren ('confounders'), en een predictiemodel, waarin de beste combinatie van factoren begrijpelijk werd gemaakt die het gemaakte aantal stappen per uur kon voorspellen in de onderzochte populatie. Bevindingen werden als significant beschouwd bij $p < 0,05$.

Resultaten

De analyse van uitschieters resulteerde in 1 internist die naar eigen zeggen 10 dagen achtereen 24 uur per dag had gewerkt. Hoewel wij ons wel konden inleven in deze perceptie van de werkelijkheid werd door het comité van toezicht voor data

en veiligheid toch besloten deze proefpersoon te excluderen. Uiteindelijk werden er 262 proefpersonen geïncludeerd in de studie. De verdeling over de subgroepen en het aantal gemaakte stappen per subgroep staan in tabel 1. Er werden gemiddeld 5325 (uitersten: 1105-10.250) stappen per dag en 548 (143-1105) stappen per uur geteld. Het gemiddelde aantal meetdagen bedroeg 8,4 (4-10).

Tabel 1 Aantal stappen (S) en *(standaard deviatie)* per groep per dag en uur (u)

	Interne geneeskunde			**Algemene chirurgie**			**Totaal**		
	N	***S/Dag***	***S/u***	***N***	***S/Dag***	***S/u***	***N***	***S/Dag***	***Sur***
Stafleden	54	4918 *(1417)*	526 *(148)*	34	4059 *(1493)*	419 *(150)*	88	4586 *(1498)*	485 *(157)*
Assistenten	43	5695 *(1400)*	602 *(155)*	53	6252 *(1471)*	629 *(140)*	96	6004 *(1459)*	617 *(146)*
Co-assistenten	34	6012 *(1352)*	576 *(98)*	44	4792 *(1580)*	504 *(54)*	78	5324 *(1120)*	536 *(84)*
Total	131	5457 *(1461)*	564 *(142)*	131	5193 *(1580)*	533 *(148)*	262	5325 *(1524)*	548 *(146)*

De gemiddelde werkdag waarop het aantal stappen werd gemeten bestond uit 9,8 (uitersten: 3-18) uren: 9,6 voor stafleden, 9,7 voor assistent-geneeskundigen en 9,9 voor coassistenten. Deze onderlinge verschillen waren niet significant en dat gold ook voor de lengte van de werkdag van de chirurgen en internisten. Wanneer geen rekening gehouden werd met mogelijke factoren die de onderzochte relatie tussen het aantal stappen van internisten en chirurgen zouden kunnen beïnvloeden, dan liepen de chirurgen gemiddeld 28 stappen per uur minder (negatieve bètacoëfficiënt) dan de internisten (tabel 2). Bij analyse van mogelijke verstorende factoren ('confounders') bleken de factoren leeftijd, geslacht en hiërarchie de bètacoëfficiënt van de centrale determinant (in dit geval het soort specialisme) met meer dan 10% te veranderen. Dit percentage werd vervolgens als ondergrens gehanteerd voor het aantonen van mogelijke confounding. Na correctie voor deze factoren in het multilevelregressiemodel werd geen statistisch significant verschil meer gevonden in het aantal stappen tussen de specialismen interne geneeskunde en algemene chirurgie

(zie tabel 2). Wanneer werd gekeken binnen de hiërarchie (specialisten, assistent-geneeskundigen dan wel coassistenten), dan liepen de assistent-geneeskundigen gemiddeld de meeste stappen per uur, namelijk 81 meer dan de coassistenten en 132 stappen meer dan hun bazen (zie tabel 1). Ook nu werd weer gecorrigeerd voor mogelijke confounders. Niet alleen bleken geslacht en leeftijd, maar ook BMI sterke confounders te zijn. Wanneer voor deze factoren werd gecorrigeerd, bleef van enig hiërarchisch verschil niets over (zie tabel 2). Hierna werd onderzocht welke factoren vooral de relatie met het aantal stappen per uur zouden kunnen verklaren. Daartoe werd een predictiemodel ontwikkeld op basis van factoren die in de bivariate modellen significant samenhingen met het aantal stappen per uur, namelijk specialisme ($p = 0{,}016$), hiërarchie ($p = 0{,}001$), geslacht ($p = 0{,}001$), leeftijd ($p = 0{,}001$), BMI ($p = 0{,}001$) en metingen in de tijd ($p = 0{,}036$). Zowel leeftijd als BMI kwamen uiteindelijk naar voren als factoren die van grote invloed waren op het aantal gelopen stappen van een dokter, zodanig dat bij elke toename van 1 jaar in leeftijd het aantal stappen per uur bij de onderzoekspersonen met gemiddeld 5 afnam (negatieve bètacoëfficiënt), terwijl een toename van 1 punt op de BMI-schaal (+1 kg/m^2) gepaard ging met een gemiddelde afname van 20 stappen per uur (zie tabel 2).

Tabel 2 Multi-level analyse

Regressie model	Stappen per uur versus	Confounding	Bèta coëfficiënt	Betrouwbaarheids-interval	P waarde
Associatie	Specialisme	voor correctie	-28,013	-50,890 - -5,136	0.016
		na correctie	-22,190	-48,448 - 4,068	0,097
	Hiërarchie	voor correctie	84,371	51,766 - 116,976	0.001
		na correctie	-1,327	-34,331 - 31,677	0,936
Predictie	Leeftijd	nvt	-5,248	-5,971 - -4,525	0,001
	BMI	nvt	-19,775	-28,911 - -10,639	0,001

Beschouwing

Vergeleken met eerdergenoemde groepen zetten de onderzochte artsen minder stappen per uur dan vliegtuigpersoneel (548 versus 842), maar veel meer dan patiënten met een heupprothese (143).1 2 Om deze gegevens in perspectief te plaatsen, vroegen wij een 7-jarige mannelijke scholier 10 dagen een stappenteller te dragen; deze kwam uit op gemiddeld 13.050 stappen per schooldag, bijna 3 maal zoveel als de gemiddelde specialist. Vooroordelen als 'hoe hoger op de hiërarchische ladder, hoe minder men moet lopen' en 'de chirurg staat toch alleen maar te opereren' lijken alleen in eerste instantie, bij oppervlakkige analyse, bevestigd te worden. Als men echter rekening houdt met confounders, in het bijzonder BMI en leeftijd, dan blijken deze conclusies niet juist te zijn. Er werd ook geen samenhang gevonden tussen het gemiddelde aantal stappen per uur en de factor 'ziekenhuis'. Bovendien bleek de factor 'ziekenhuis' geen confounder te zijn in de relatie tussen het gemiddelde aantal stappen per uur en specialisme of hiërarchie. Dat is opmerkelijk, omdat de 13 onderzochte ziekenhuizen nogal verschilden in omvang. Hiërarchie bleek wel een verstorende factor te zijn in de relatie tussen leeftijd en aantal stappen (een medisch specialist was nooit 20 jaar en een coassistent bijna nooit 55-plusser). Het aantal gemaakte stappen verminderde na correctie met 6 (in plaats van 5) per uur per extra levensjaar. Interessante onderzoeksvragen als deze vielen echter buiten het bestek van dit onderzoek, omdat de factor leeftijd nu eenmaal niet gekozen was tot centrale determinant in het ontwikkelde associatiemodel. Het belang van de leeftijd ten aanzien van het aantal stappen kwam echter duidelijk tot uiting in het predictiemodel. Door gebruik te maken van een multilevelanalyse waren wij in staat rekening te houden met verschillen in de mate van afhankelijkheid binnen en tussen metingen in de tijd enerzijds en ziekenhuizen anderzijds. Daarnaast speelde een correctie voor de invloed van factoren, zoals BMI, geslacht en leeftijd, een belangrijke rol bij het nauwkeurig vaststellen van de relatie tussen specialisme en hiërarchie en het aantal stappen in dit onderzoek. Door deze correctie verdween de in eerste instantie aantrekkelijke en aannemelijke, maar een evengoed vertekende significantie. Een mogelijke zwakte van deze studie was dat de proefpersonen hun eigen resultaten moesten invullen. Wij hadden vertrouwen in de integriteit van de proefpersonen en bovendien wisten zij niet dat hun specialisme met een ander vergeleken werd.

Concluderend was de mobiliteit van de meest ervaren stafleden het geringst. Dit hing niet samen met de status, maar met de overwegend hogere BMI en leeftijd van deze groep.

Literatuur

1. Hagihara A, Tarumi K, Nobutomo K. The number of steps taken by flight attendants during international long-haul flights. *Aviat Space Environ Med*. 2001;72:937-9.
2. Silva M, Shepherd EF, Jackson WO, Dorey FJ, Schmalzried TP. Average patient walking activity approaches 2 million cycles per year: pedometers under-record walking activity. *J Arthroplasty*. 2002;17:693-7.
3. Schneider PL, Crouter SE, Lukajic O, Bassett jr DR. Accuracy and reliability of 10 pedometers for measuring steps over a 400-m walk. *Med Sci Sports Exerc*. 2003;35:1779-84.
4. Garrow JS, Webster J. Quetelet's index (W/H2) as a measure of fatness. *Int J Obes*. 1985;9:147-53.
5. Twisk JWR. Applied multilevel analysis. Cambridge: Cambridge University Press; 2006.